



## Research and Scholarly Activity Policies

Touro University Nevada (TUN) recognizes that research and scholarly activities helps students in many ways, including:

- Having access to faculty who are active in their field of study
- Being in a position to get into a first-choice residency
- Preparation to be leaders in their chosen specialty, with the tools to stay current on the best available evidence for patient treatment
- Desire to contribute as clinician partners to research activities in the future

Therefore, TUN is committed to helping students engage in high quality research or scholarly activities. The following policies and procedures guide TUN research activities.

### General Topics

1	Conflict of Interest Policy.....	2
2	Misconduct in Science.....	20
3	Academic Integrity Policy.....	29
4	Ethics in Research and Scholarly Activity from Faculty Handbook p26.....	32
5	Policy for authorship in professional venues.....	57
6	Intellectual Property Policy.....	61

### Research Safety and Oversight Policy

7	IRB Manual.....	79
8	Clinical Trials Policy.....	92
9	IACUC Guide.....	94
9a	IACUC Bylaws.....	340
10	Biosafety Manual.....	363
11	Radiation Safety Manual, DXA.....	483

### Office of Sponsored Programs Policies and Procedures

12	PI Eligibility.....	490
13	Sponsored Project Awards Management Policy.....	491
14	Other Policy for Sponsored Projects (Effort Reporting, Cost Sharing, Indirects, No Cost Extension).....	497
15	Federal Guidance- Cost Principles.....	505
16	Sponsored Project Awards Closeout Policy.....	662

# UNIFORM CONFLICT OF INTEREST POLICY

**TOURO COLLEGE  
TOURO UNIVERSITY  
TOURO UNIVERSITY NEVADA  
TOURO UNIVERSITY WORLDWIDE  
NEW YORK MEDICAL COLLEGE  
YESHIVAS OHR HACHAIM  
HEBREW THEOLOGICAL COLLEGE**

Date: December 22, 2020

Supersedes: *Code of Conduct and Policy on Conflicts of Interest 12/15/08; NYMC Code of Conduct and Policy on Conflicts of Interest and Conflict of Commitment 5/31/2012; Touro College Conflict of Interest Policy.*

Effective Date: December 22, 2020

## **1.0 PURPOSE**

The purpose of this Conflict of Interest Policy (“Policy”) is to continue to protect and enhance Touro College and University System’s (“the College”) reputation by ensuring that all trustees, officers, faculty and employees of Touro College and its affiliates, everywhere, understand how the College seeks to avoid even the appearance of impropriety. Protecting our ethical standing is not only the right thing to do -- it's good university practice. Students, the public and educational partners judge us by our conduct, as well as our courses and offerings. Potential employers of our students as well as donors want to be associated only with an institution that meets high standards for honesty, integrity, and public responsibility. Our Conflict of Interest Policy reflects the evolution of the College, as well as changes in applicable laws and regulations.

## **2.0 SCOPE**

This policy applies to all members of the College Community, including but not limited to trustees, officers and administrators, employed faculty, voluntary faculty and other full-time and part-time employees of the College (“College Community”).

## **3.0 DEFINITIONS**

“Affected Entity” means an entity other than the College that would reasonably appear to be affected by, or might in turn affect, the institutional responsibilities, including teaching, research, clinical, or service, of the faculty member or Investigator. It also includes entities that control, are controlled by or are under common control with the Affected Entity. In the context of Research and Other Sponsored Projects, an Affected Entity is an entity, such as the research sponsor, that would reasonably appear to be affected by, or might in turn affect, the Research and Other Sponsored Projects.

“Conflict of Commitment” occurs when a member of the College community’s Outside Activities compromise or may compromise his/her ability to meet the member’s obligations at the College.

"Conflict of Interest" means any circumstance in which the personal, professional, financial or other interests of an individual (including the Immediate Family of the individual) may potentially or actually diverge from, or may be reasonably perceived as potentially or actually diverging from, his or her professional obligations to the College and the interests of the College. A Conflict of Interest may exist whenever an independent observer might reasonably question whether the individual's professional actions or decisions, including the ethical and objective conduct of scholarship, research or clinical care, are determined by considerations of personal gain, financial or otherwise.

"Immediate Family" means an individual's spouse (or other significant relationship), children, parents, siblings and, for purposes of this policy, all persons dependent upon the individual or resident in the same household.

"Investigator" is defined for Research and Other Sponsored Projects as the principal investigator or program director, co-investigator, sub-investigator, and any other person who applies for or receives funds for Research and Other Sponsored Projects at the College, or who is responsible for the design, conduct or reporting of Research and Other Sponsored Projects, or who is directly involved in treatment or evaluation of research subjects, or who is responsible for making decisions related to eligibility of research subjects or for obtaining the informed consent of research subjects. Investigator also includes persons who do any of the foregoing for subgrantees, contractors, collaborators, or consultants of College Research and Other Sponsored Projects.

"Office of Research Administration" means each campus' respective Office of Research Administration or Office of Sponsored Programs.

"Outside Activities" include external professional and academic endeavors (such as public service, activities or membership in professional societies or organizations, or lecturing as a guest speaker) or any other non-College related activity. Such Outside Activities must be in compliance with all College policies, including Conflicts of Interest as set forth in this Policy and the Policy on Interactions with the Pharmaceutical, Biotechnology, Medical Device, Hospital and Research Equipment and Supplies Industries. Additional disclosures shall be required pursuant to such policies.

"Ownership Interest" means holding a financial or ownership interest in a business or entity, including stock, stock option, partnership or LLP interest, or other ownership interest. The words "property" or "benefit" mean anything of value, tangible or intangible, that may be transferred or sold or assigned for money or other consideration, including, but not limited to, cash, stock, stock options or warrants, leases, licenses, real or personal property or property rights, contract rights, rebates, vendor credits or reimbursement of personal expenses, gifts or gratuities.

"Research and Other Sponsored Projects" means any internally or externally funded research, training or professional service project conducted at or under the auspices of the College.

"Royalty Income" means any royalty income, licensing income or other proceeds (e.g., payments linked to product sales or other usage and milestone payments), or the written contractual right to receive future royalties, licensing income or other proceeds, directly or indirectly, under a pending or issued patent, license, copyright or other property right, and includes, for purpose of this policy,

all income received by the person from the College in accordance with the College's intellectual property policies.

"Remuneration" includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship, travel reimbursement).

"Significant Financial Interest" means any financial interest consisting of one of more of the following interests of an individual (which also includes those of an individual's Immediate Family Members) that reasonably appears to be related to the individual's institutional responsibilities with the College:

- A.** With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any Remuneration from Outside Activities received from the entity in the twelve months preceding the disclosure (or expected to be received from the entity in the twelve months following the disclosure) and the value of any Ownership Interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000, or (ii) the Ownership Interest as of the date of disclosure exceeds five percent (5%) in any class of the entity's securities; or
- B.** With regard to any non-publicly traded entity, a Significant Financial Interest exists if (i) the value of Remuneration from Outside Activities received from the entity in the twelve months preceding the disclosure (or expected to be received from the entity in the twelve months following the disclosure), when aggregated, exceeds \$5,000, or (ii) there is any Ownership Interest in the entity; or
- C.** Intellectual property rights (e.g., patent or copyrights), royalties from such rights, and agreements to share in royalties related to such rights.

Significant Financial Interests do not include the following types of financial interests:

1. Salary, royalties, or other Remuneration paid by the College while the recipient is currently employed or otherwise appointed by the College, including intellectual property rights assigned to the College and agreements to share in royalties related to such rights;
2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the individual does not directly control the investment decisions made in these vehicles;
3. Income from seminars, lectures, or teaching engagements sponsored by: (i) a federal, state, or local government agency; (ii) an institution of higher education as defined at 20 U.S.C. 1001(a); (iii) an academic teaching hospital; (iv) a medical center; or (v) a research institute that is affiliated with an institution of higher education; or

4. Income from service on advisory committees or review panels for: (i) a federal, state, or local government agency; (ii) an institution of higher education as defined at 20 U.S.C. 1001(a); (iii) an academic teaching hospital; (iv) a medical center; or (v) a research institute that is affiliated with an institution of higher education.

“User” means any member of the College community completing the Conflict of Interest survey.

#### **4.0 CONFLICTS OF COMMITMENT**

Members of the College community must not allow Outside Activities to detract from their obligations to the College. A Conflict of Commitment occurs when an individual’s Outside Activities compromise or may compromise his/her ability to meet his/her obligations at the College.

Outside Activities that do not constitute a Conflict of Commitment are permissible only if they also do not result in a Conflict of Interest (as discussed below) and are in accordance with all College policies, including this policy and the Policy on Interactions with the Pharmaceutical, Biotechnology, Medical Device, Hospital and Research Equipment and Supplies Industries.

##### **A. Full-Time Employees and Full-Time Faculty**

Full-time employees and full-time faculty members at the College owe their primary professional allegiance and their primary commitment of time and intellectual activities to the College. Regardless of the guidelines below, Outside Activities must not interfere with the employee’s and faculty member’s primary responsibilities to the College. Thus, full-time employees and full-time faculty must comply with the following regarding all Outside Activities prior to engaging in such activities:

1. Timely disclose in writing all Outside Activities to their supervisor or the appropriate Department Chair, with copies to the appropriate School Dean, if applicable, and the Office of Institutional Compliance.
2. Obtain the prior written approval of their supervisor or their respective Department Chair for any Outside Activities that either singularly or in the aggregate exceeds an average of one-half day (or the equivalent of 4 hours) per week.
3. All consulting relating to medical negligence or serving as an expert witness in litigation require the prior written approval of the School Dean.
4. All Outside Activities, when aggregated, must not exceed an average of one day per seven-day week (or the equivalent of an eight-hour workday).

Exceptions to the aforementioned limitation and prohibition are rare and may be made only with the prior written approval of the Office of Institutional Compliance.

## **B. Part-Time Employees and Part-Time Faculty**

Part-time employees and faculty members may accept outside employment as long as it does not result in a Conflict of Interest (see below) or otherwise interfere with any of their obligations at the College.

### **5.0 CONFLICT OF INTEREST - GENERALLY**

A Conflict of Interest means any circumstance in which the personal, professional, financial or other interests of an individual (including the Immediate Family of the individual) may potentially or actually diverge from, or may be reasonably perceived as potentially or actually diverging from, his/her professional obligations to the College and the interests of the College. A Conflict of Interest may exist whenever an independent observer might reasonably question whether the individual's professional actions or decisions, including the ethical and objective conduct of scholarship, research or clinical care, are determined by considerations of personal gain, financial or otherwise.

This definition includes any situation or relationship that permits a College employee, whether faculty or staff, or anyone else in a position of trust at the College, to gain a financial benefit at the College's expense, beyond normal compensation or as otherwise permitted by express College policy. Financial benefits are gained at the College's expense when an individual diverts or misuses the College's resources or privileges afforded by association with the College for personal gain or for the private gain of other individuals or organizations inside or outside the institution. Such benefits are also gained by diverting opportunities that should belong to the College away from the College or to some restricted College purpose when the restriction is not necessary.

The College has broad power to require disclosures of Conflicts of Interest to determine whether a Conflict of Interest exists, to manage or eliminate Conflicts of Interest, to impose appropriate sanctions on faculty and Investigators who violate this policy, to release information about Conflicts of Interest and to require faculty and Investigators to take Conflict of Interest training. Faculty or Investigators who are unclear as to whether a matter must be disclosed should err on the side of disclosure.

It is the policy of the College for faculty and employees to follow the principles outlined in this policy in relation to an actual or potential Conflict of Interest at the College:

#### **A. Financial Interests**

No individual who is an employee or faculty member in a position to influence the outcome of a transaction affecting the College should be a party to such transaction when it is with another person or organization in which the individual and/or his/her Immediate Family holds an ownership or other financial interest or holds a fiduciary position such as employee, director, officer, shareholder or consultant. For purposes of this policy, a possible Conflict of Interest includes but may not be limited to:

1. An agreement to obtain or receive an ownership or creditor's interest in another entity;

2. An agreement for compensation or consulting payments, dividends, fees, property or other thing of value from another individual or entity;
3. Any equity or other ownership or controlling interest in another entity; or
4. An interest under a royalty or similar agreement with another organization held by an individual and/or his/her Immediate Family except as permitted under the College's Intellectual Property Policy.

In determining items which require disclosure, faculty and employees should refer to existing guidelines, such as those specified in the financial disclosure requirements for sponsored research programs. In general, the materiality of a financial interest or Conflict of Interest will be judged by the College on the basis of whether or not the judgment or discretion of the individual in matters affecting the College is or may be influenced by consideration of personal gain or financial benefit.

#### **B. College's Name and College Association**

The name of the College and the privilege of association with the College as evidenced by a faculty, administrative or other title are valuable assets and attributes. They are to be used only for legitimate purposes that enhance the College's academic activities and its reputation for fair dealing in the public interest. No one may use the institution's name or one's professional title or association with the institution for advertising purposes, to identify the institution with an outside entity or to endorse the entity's product without special written approval from the Chief Compliance Officer or his/her designee.

In situations in which association of a faculty or staff member with the College is apparent from written or oral statements or from the context in which the statement(s) is made, the individual must emphasize that his comments or opinions are not to be construed as those of the College, unless that person is speaking in his capacity as a faculty member or employee and such statements are consistent with the position of the College.

The College may and does employ members of the clinical faculty and does afford them compensation in return for teaching, supervision, administration and research that are performed for the College, even though the same faculty might be engaged independently in billing for professional clinical services individually or through their employment by other organizations. The College is not a vehicle, agent or employer of its clinical faculty in their capacities as providers of clinical services billed to patients or third-party payers, except as may be the case, any University Faculty Practice Corporation under New York, California, Nevada or Illinois State law that the College may form in the future. Clinical faculty members and their practice entities are not authorized to provide clinical services under the name of any College entity, nor under the name of any College department or component forming part of the College, including divisions, centers or institutes. Clinical faculty members and their practice entities are also precluded from billing or collecting fees or corresponding as part of providing clinical services in such a context using the name of the College or any

College department or component. This policy does not preclude a faculty member from identifying oneself with the College in his academic capacity.

Clinical faculty members have a responsibility to the medical profession and to the public to become and remain informed about laws, rules and regulations applicable to third party billing for professional services, especially those relating to the Medicare and Medicaid programs.

### **C. College Property and Resources**

All College property and resources (including correspondence, records, documents, data, information (in any format), funds, personnel, intellectual property and property rights, equipment, supplies and institutional opportunities for financial gain) are to be conserved and used exclusively for the benefit and development of the College in carrying out its mission and purposes. College property and resources may not be used for personal use, including in Outside Activities, and may not be diverted away from the College to the benefit of any other organization or individual. College property includes information that would not normally be available for public disclosure without approval of the Chief Compliance Officer or his/her designee.

### **D. Confidential Information**

The College's confidential information includes information that would not normally be available for public disclosure without approval of the Chief Compliance Officer or his/her designee, a School Dean, the Chief Financial Officer, or other appropriate administrative or academic officer. Obtaining, using or disclosing College confidential information for direct or indirect personal interest, profit or advantage or, for a purpose that may be detrimental to the College creates a Conflict of Interest. Use of College confidential information for a purpose that is not authorized by the College or disclosure of College confidential information to a person who or entity that is not authorized by the College to receive it creates a Conflict of Interest. Confidential information includes, but is not limited to, medical, personnel, security, academic, background check, conflict of interest or identifiable biometric records and other information of individuals; computer system passwords and security codes, proprietary knowledge about anticipated material requirements or price actions; proprietary knowledge of information about forthcoming programs or selection of contractors or subcontractors in advance of official announcements; unpublished grant proposals, research data, or manuscripts and correspondence; non-public financial, procurement, health-safety, audit, insurance and claims information; and internal investigation, pre-litigation and non-public litigation and administrative agency charge, audit and inquiry information.

### **E. Gratuities**

No member of the College Community shall accept or permit any member of his/her Immediate Family to accept any gift (including entertainment), a loan (other than an arm's length loan made in the ordinary course of business from a banking or other



financial institution), a favor or gratuity of more than nominal value from any person or entity with a business relationship or seeking to have a business relationship with the College.

#### **F. Political Contributions and Lobbying**

By law, no contributions may be made by the College (whether directly or through reimbursement), by anyone acting on behalf of the College, or with any funds of the College from any source to, or for the benefit of, any political campaign or in support of the election of any individual for public office. No funds of the College may be used for lobbying public officials except as lawfully permitted and with written approval of the College's President.

#### **G. Outside Activities**

Employees must not allow Outside Activities or other personal activities to detract from their primary obligations to the College, as discussed in Article V above relating to Conflict of Commitment. Memberships on boards of directors, committees, advisory groups of governmental, for-profit or not-for-profit entities) distinct from the College may create potential Conflicts of Interest or the perception of a conflict. An ownership interest by the employee or by a member of the employee's family in any property or entity related to business transactions with the College may create a similar conflict. These interests and activities should be disclosed according to the procedures described in this policy and the Policy on Interactions with the Pharmaceutical, Biotechnology, Medical Device, Hospital and Research Equipment and Supplies Industries.

### **6.0 CONFLICTS OF INTEREST IN RESEARCH AND OTHER SPONSORED PROJECTS**

#### **A. Principles**

The College is committed to the principle of academic freedom and the enhancement of knowledge and health through the conduct of objective research. Investigators participating in research at the College have a primary obligation to conduct the research free of Conflicts of Interest so as to avoid the tainting or the perception of tainting of the research. Each member of the College community who engages in or seeks to engage in College Research and Other Sponsored Projects has the responsibility to disclose to the College all outside interests, as defined in this policy, which may represent a real or apparent Conflict of Interest. Based upon its review of such disclosures, the College may decide that such outside interests be severed or modified in order to remove, reduce, manage or eliminate a Conflict of Interest as a condition of accepting external research support. Alternatively, the College may structure a mechanism so that the design, conduct and reporting of research by researchers are not likely to be biased nor be perceived to be biased by any conflicting financial interests of those researchers. This policy applies to all sponsored awards, both those issued to the institution and those issued to individuals, except for Phase I SBIR/STTR applicants and recipients.

The College's primary responsibility towards its students is to educate and train them for the professions appropriate to their degree programs. In general, students' research efforts should be devoted towards projects that will enhance their training, education and ability to pursue their own next career step. For example, participation of students in projects that, because of proprietary or other justified considerations, limit the freedom of the student to discuss the results in public forums in a timely fashion may not be in the student's best interests. The participation of students in projects and contracts supported by industrial or commercial sponsors, therefore, should be carefully evaluated as to its suitability for the students' welfare.

## **B. Policy**

1. Training – Prior to engaging in research or any other academic activity at the College for which extramural support is sought, Investigators shall be required to complete training on the College's policy on conflict of interest and his/her responsibilities regarding disclosure of Significant Financial Interests and at least every four years, and immediately when any of the following apply:
  - a. The College revises its policy or procedures on conflict of interest;
  - b. An Investigator is new to the College; or
  - c. The College finds that an Investigator is not in compliance with this policy
  
2. Disclosure – Each time a faculty member or other Investigator is planning to participate in proposed Research and Other Sponsored Projects, the faculty member and each other Investigator involved with the proposed Research and Other Sponsored Project must have completed and submitted the Annual Disclosure Form and an Update Disclosure Form and/or any other form then in effect, which forms will refer the faculty member or other Investigator to this policy (including the availability and public accessibility of this policy on the College's website). Such forms require, among other matters, disclosure of the faculty member's or other Investigator's and his/her Immediate Family's:
  - a. Significant Financial Interests (specifying if any such Significant Financial Interest is in an Affected Entity relative to the Research and Other Sponsored Projects);
  - b. Employment/management roles held in any Affected Entity relative to the Research and Other Sponsored Projects;
  - c. Any rights held in intellectual property covering products or processes being used in the Research and Other Sponsored Projects (including any right to Royalty Income from intellectual property assigned to the College under the College's intellectual property policies); and

- d. The occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to his/her institutional responsibilities (provided that this requirement does not apply to travel that is reimbursed or sponsored by: (i) a federal, state, or local government agency; (ii) an institution of higher education as defined at 20 U.S.C. 1001(a);
    - e. an academic teaching hospital; (iv) a medical center; or (v) a research institute that is affiliated with an institution of higher education). The disclosure shall include, at a minimum, the following information: the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Additional information may be requested to determine whether the travel constitutes a Conflict of Interest.
3. Disclosures must be made prior to the submission of an application for the Research and Other Sponsored Projects to the sponsor, updated annually for the duration of the Research and Other Sponsored Projects, and updated within thirty days of acquiring any such new activity or interest (e.g., through gift, marriage or inheritance). The Investigator's disclosure forms must be submitted even if there is no interest, position or rights to disclose.
4. Disclosures shall be required of all individuals who are significant participants in the project, i.e., those who will be decision makers or is responsible for the design, conduct and/or reporting of the funded research, including the principal investigator, co-investigators, sub-investigators, collaborators, and consultants.
5. When a grant or contract proposal involves a subgrantee or subcontractor arrangement with investigator(s) at another institution, the written agreement with the subgrantee or subcontractor shall incorporate terms that establish whether the conflict of interest policy of the College or that of the subgrantee or subcontractor will apply to the subgrantee's or subcontractor's investigators. If it is the latter, the above referenced agreement must contain a written certification from the subgrantee or subcontractor that its policies are in full compliance with all applicable laws and the regulations of the funding agency. In addition, the above-referenced written agreement must specify time period(s) for the subgrantee or subcontractor to report all identified Conflicts of Interest to the College and any review and/or action taken with respect to such Conflicts of Interests. Such time periods must meet the College's disclosure and reporting requirements.

## **7.0 PROCEDURES: DISCLOSURES AND REVIEW**

The College is committed to ensuring an ethical and equitable environment in which to conduct teaching, in limited circumstances patient care and research while avoiding Conflicts of Commitment and Conflicts of Interest and even the appearance of such conflicts. Given the

complexity and diversity of personal and professional relationships and the fact that the perception of a Conflict of Commitment or Conflict of Interest may vary from individual to individual, the College has established a procedure according to which individuals may disclose their interests and activities so that the College may evaluate whether such interests and activities present an actual or potential Conflict of Commitment or Conflict of Interest.

**A. New Employees:**

New employees must review a copy of this policy and complete the Annual Disclosure Form prior to their first day of employment. The Annual Disclosure Form shall be distributed by and submitted to the Human Resources Department and reviewed in compliance with Section E below.

**B. Annual Notice:**

A copy of this policy shall be distributed annually to members of the College Community.

**C. Annual Disclosure Form**

With the annual distribution of a copy of this policy, an Annual Disclosure Form (which will refer to this policy, including the availability of this policy on the College's website or TouroOne portal) will be distributed. The Annual Disclosure Form is intended to solicit information so that the College can determine whether an individual has been or is currently involved in situations of conflict or potential Conflict of Commitment or Conflict of Interest with the College and its interests. Each individual to whom such a disclosure form is distributed will be expected to review his/her activities and relationships thoughtfully and thoroughly, complete and return the disclosure form each year. Consultation with one's Department, the School Dean, and/or the Office of Institutional Compliance should be sought when an individual is in doubt about whether an interest or activity creates a Conflict of Commitment or Conflict of Interest.

The Annual Disclosure Form requires, among other things:

1. Certification of compliance with this policy and related policies of the College and applicable school;
2. Disclosure of information about the employee's (and his or her Immediate Family Members) Outside Activities and other personal, professional, financial or other interests that may reasonably be perceived as giving rise to a Conflict of Interest as described in Articles 6 and 7 of this policy;
3. Disclosure of information about his or her Outside Activities as pertinent to a potential Conflict of Commitment as described in Article 5 of this policy; and
4. All of the following interests held by the employee and his or her Immediate Family in the aggregate in any Affected Entity:

- a. Each Employment/Management Role;
- b. All Ownership Interests (other than an interest in a publicly-traded corporation that does not exceed either (A) \$5,000 or (B) a five percent interest in any class of the corporation's securities);
- c. All Remuneration from an Outside Activity greater than \$5,000 in the past 12 months or expected to be greater than \$5,000 in the upcoming 12 months; and
- d. All Royalty Income greater than \$5,000 in the past 12 months or expected to be greater than \$5,000 in the upcoming 12 months.

The Annual Disclosure Form shall be submitted electronically within the time prescribed by the Human Resources Department, Office of Institutional Compliance or upon request. Failure to complete such a questionnaire responsibly and accurately or to return it as required shall be grounds for disciplinary action, which may include termination of employment or faculty appointment, or other dismissal from the College.

#### **D. Update Disclosure Form**

All members of the College Community have a continuing obligation to disclose on a timely basis current, proposed or pending situations that may raise questions of Conflict of Commitment or Conflict of Interest. Such disclosures must be made in advance of the conflict arising if possible, and otherwise within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) such situations. It is the duty of all members of the College Community to make such disclosures by submitting the Updated Disclosure Form to the Human Resources Department or Office of Research Administration. Failure to report a conflict shall be grounds for disciplinary action, which may include termination of employment or faculty appointment, or other dismissal from the College.

#### **E. Review Procedures for Annual Disclosure Forms**

Each January, the Human Resources Department of each campus will distribute the Annual and Updated Disclosure Forms to all members of their respective College Community. The Human Resources Department will collect and review all responses. Any disclosures with any actual or potential Conflicts of Interest or Conflicts of Commitment shall be sent to the Office of Institutional Compliance or, if research related, to the Office of Research Administration which shall resolve such conflicts in a timely manner. In making its determinations, the Institutional Compliance Office and/or the Office of Research Administration may consult with appropriate Department Heads, Deans, or Department Chairs. For disclosures related to Research and Other Sponsored Projects, the Office of Research Administration shall review the disclosures in accordance with the procedures in section 8. E below.

Disclosures related to all issues other than Research and Other Sponsored Projects shall be reviewed by the Office of Institutional Compliance. The Office of Institutional Compliance shall review each disclosures and evaluate any disclosed Significant Financial Interest or an actual or potential Conflict of Interest on a case by case basis, following the guidelines delineated in this policy as closely as possible. The Office of Institutional Compliance shall determine whether the Significant Financial Interest relates to the proposed research, and if so, whether a financial Conflict of Interest exists. A Significant Financial Interest is related to the User's compliance with the policy when the significant financial interest could be affected by the Outside Activity or is in an Affected Entity. A financial Conflict of Interest exists when the Significant Financial Interest could directly and significantly affect the User's obligations to the College. If the Office of Institutional Compliance reasonably determines that a financial Conflict of Interest exists, it shall develop and implement a management plan (see subsection F.3 below) to resolve or manage such financial Conflict of Interest.

## **F. Review Procedures for Disclosures Related to Research and Other Sponsored Projects**

### **1. Initial Review**

- a. Disclosures related to Research and Other Sponsored Projects shall be reviewed by the Office of Research Administration. Prior to commencement of a Research and Other Sponsored Project (including any enrollment of research subjects) or any expenditure of research funds, and consistent with the regulations of the applicable funding agency, the Office of Research Administration shall review each Investigator's disclosures and evaluate any disclosed Significant Financial Interest or an actual or potential Conflict of Interest on a case by case basis, following the guidelines delineated in this policy as closely as possible. The Office of Research Administration shall determine whether the Significant Financial Interest relates to the proposed research, and if so, whether a financial Conflict of Interest exists. A Significant Financial Interest is related to the proposed research when the significant financial interest could be affected by the proposed Research and Other Sponsored Project or is in an Affected Entity. A financial Conflict of Interest exists when the Significant Financial Interest could directly and significantly affect the design, conduct or reporting of the proposed research. If the Office of Research Administration reasonably determines that a financial Conflict of Interest exists, it shall develop and implement a management plan (see subsection E.3 below) to resolve or manage such financial Conflict of Interest.

In the case of an ongoing Research and Other Sponsored Project, when a new Investigator discloses a Significant Financial Interest or an existing Investigator discloses a new Significant Financial Interest, the disclosure will be renewed in accordance with the procedures set forth herein, with the review and evaluation completed within sixty days, including implementation on an at least an interim basis of any necessary or appropriate management and/or mitigation plan, and with timely compliance with reporting required by the sponsor or funding agency.

2. Management Plan – In the event of an actual or perceived conflict, the Office of Research Administration and/or the Office of Institutional Compliance may request that the User provide, either in writing or via a meeting, more specific information before developing a management plan. A management plan to resolve the conflict may include, without limitation, one or more of the following mechanisms:
  - a. Stipulation that the User will publicly disclose the financial Conflict of Interest (e.g., when presenting or publishing the research);
  - b. Recommendation that the support for the Research and Other Sponsored Project be accepted only if the relationship between the Investigator and the sponsor, or the financial interest of the Investigator in the product, be modified or terminated in some specified way. The Investigator may choose to continue the relationship while withdrawing the request for financial support or approval to conduct the research; Stipulation that the support for the Research and Other Sponsored Project be accepted only if the proposal is modified in some specified way – e.g., to allow for continuous or regular, independent, external review of the project and its results, or to clarify or modify the participation of students in the project;
  - c. Change of research personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
  - d. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial Conflict of Interest;
  - e. Recommendation that the funding agency be notified formally that a potential Conflict of Interest exists. This recommendation will depend largely upon the requirements of funding agencies, notably the federal and state agencies, for such disclosure;
  - f. Notification, in a timely fashion, to the Committee for the Protection of Human Subjects of the potential Conflict of Interest . This notification is necessary only when the proposal is for the support of a clinical trial or other research involving human subjects;
  - g. Recommendation that the College not accept external support for the Research and Other Sponsored Project.
  - h. Recommendation to reduce or eliminate the financial interest (e.g., sale of an equity interest.
  - i. Recommendation to sever a relationship that creates financial conflict.

3. Retrospective Review – Where a financial Conflict of Interest is present but was not disclosed or reviewed in a timely manner, the Office of Research Administration or the Office of Institutional Compliance will implement, on at least an interim basis, a conflicts mitigation plan that will include a retrospective review and determination as to whether the Research and Other Sponsored Projects, or any portion thereof, or the Outside Activity conducted prior to the identification and management of the Conflict of Interest was biased in the design, conduct, or reporting of such Research and Other Sponsored Projects or Outside Activity.
4. Compliance with Regulations – In developing, implementing and reporting any management plan, mitigation plan or retrospective review relating to Research and Other Sponsored Projects, the Office of Research Administration shall comply with all requirements of the applicable funding agency (notably, the regulations of the Department of Health and Human Services for any Public Health Service (PHS) funded research), including any and all time restrictions, due date requirements and reporting requirements.
5. Reporting to Funding Agencies – The Office of Research Administration will be responsible for submitting any notifications, periodic reports, updates, mitigation reports and/or retrospective reviews to the applicable funding agency as required by and in accordance with such agency’s regulations.
6. The disclosures made to the Office of Research Administration and the Office of Institutional Compliance and their deliberations are to be treated as highly confidential matters.
7. Enforcement – The Office of Research Administration and the Office of Institutional Compliance shall establish adequate enforcement mechanisms to ensure compliance as appropriate.
8. Records --The College shall maintain records of all financial and managerial disclosures and all actions taken with respect to each Conflict of Interest for three years beyond the date of submission of the final expenditures report to the applicable funding agency. Under special circumstances, or if required explicitly by the funding agency, records may be kept for a longer period. These records shall be maintained by the appropriate Office of Institutional Compliance and/or the Office of Research Administration.

## **8.0 STANDARDS FOR RESOLUTION OF CONFLICTS OR POTENTIAL CONFLICTS OF INTEREST**

In determining whether a relationship or situation involving a conflict or potential Conflict of Interest should or may be prohibited, modified, or managed by the College, the following considerations, among others, will be taken into account. The guidelines in this section are not meant to be either rigid or inclusive. Certain potential Conflicts of Interest, as outlined herein, may be acceptable in practice in particular cases. By the same token, one can imagine situations not



explicitly covered here that would not be appropriate or acceptable. It is our intent and hope that the mechanism set up for evaluating potential Conflicts of Interest, as outlined in other sections of this policy, will provide both for sufficient flexibility and sufficient consistency so that conflicts that may impede the College's mission are avoided, while at the same time, useful cooperation between the College and the community is fostered.

- A.** Will a requested or proposed resolution of a conflict or potential Conflict of Interest enhance, not meaningfully affect, or detract from the College's reputation, responsibility or obligation for the objective pursuit of truth in science and the education of students, or a favorable public perception of the College in the manner in which it carries out its mission, goals and objectives?
- B.** Is it possible, practically and realistically, to modify or manage a Conflict of Interest or potential Conflict of Interest so as to ensure objectivity in the work to be performed and in the results to be reported?
- C.** Have all proposed and preexisting relationships, interests and agreements, express or implied, involving the College employee or person in position of trust for the College (and members of his/her Immediate Family) and third parties involved in the Conflict of Interest been fully and adequately disclosed and inquired into?
- D.** Even if the particular conflict or potential Conflict of Interest under review is not individually likely to compromise the College's reputation, divert important opportunities from the College, or excessively benefit a College employee or person in a position of trust at the College, has serious consideration been given to the actual and potential negative effects on the College and its interests if, in the aggregate, multiple situations involving similar effects on the College were to be given approval?
- E.** Will a conflict or potential Conflict of Interest, if permitted as first presented or as subsequently modified, result in short-term benefits to the College that may, however, be outweighed by actual or potential long-term harm to the College, the morale of College faculty or staff and/or the College's reputation?
- F.** Should agreements or arrangements with other third-party entities be more beneficial to the College than the agreement or arrangement proposed by a College employee, faculty member or other person in a position of trust at the College be explored or solicited to ensure that the College will receive the benefits of the agreement or arrangement objectively most favorable to the institution as a whole?
- G.** Despite possible measures to modify or manage a Conflict of Interest at the College, might even just the apparent incentive for personal gain on the part of the College employee or other person in a position of trust at the College and the consequent challenge to his/her objectivity be sufficiently strong or questionable that the results of

the College individual's work will probably be subject to suspicion or criticism by others?

#### **H. In Cases of Research and Other Sponsored Projects**

1. Research sponsored by a company or agency in which the Investigator has a financial or managerial interest presents a Conflict of Interest. The Office of Research Administration, together with the Office of Institutional Compliance should evaluate whether the Investigator's influence within the company or agency might cause the normal review of the application for support to be short-circuited, thus bypassing an important component of science's system of checks and balances. Another issue to consider is whether the Investigator might be using the College and its resources (space, equipment, students, etc.) to support and further his or her external interests.
2. Although reasonable consultation fees, honoraria or paid travel are normally acceptable, a potential conflict may arise when an Investigator seeks research support from a company or agency from which the Investigator has accepted significant amounts of gratuities or special favors. Thus, any payment for services not otherwise identified as salary – e.g., consulting fees, honoraria, paid authorship, reimbursed travel or sponsored travel related to institutional responsibilities – must be disclosed and evaluated by the Review Committee.
3. Promises of future considerations (consultancies, ownership, royalties, etc.) in connection with or contingent upon the results of the proposed research are also problematic.
4. Research evaluating a product in which the Investigator holds a financial interest is particularly problematic. The severity of the problem increases with the magnitude of the financial interest. Early developmental research on a product by its inventor is undeniably justifiable, whatever the inventor's financial stake. However, an Investigator's financial interest in a product (e.g., through ownership in equity or intellectual property rights, such as patents or copyrights) may be significant as to constitute a financial Conflict of Interest. Thus, as a general rule, it is inappropriate for an Investigator who has a Significant Financial Interest in a product to conduct research that evaluates the suitability of that product for public consumption, particularly in the case of new drugs or other biomedical products.
5. The principle outlined in the previous guideline may be applied as well to the College itself. There may be cases in which the College has patent or licensing rights, or an equity interest in a product that is to be evaluated for efficacy or safety as a prelude to public availability. Careful consideration must be given to the propriety of such evaluative research being done by any individual associated with the College, even if the individual has no personal financial interest in the product.
6. Situations may arise in which a company offers to donate money, equipment or other resources to the College in exchange for access to specialized laboratories or professional expertise in the College. These arrangements may present valuable

opportunities for the College and a chance for fruitful collaboration between the College and industry. The College should be careful, however, that such arrangements do not clash with its primary academic, educational and service missions.


7. In all of the instances outlined above, reference to the financial or managerial interests in an external company or agency of any individual faculty member, administrator or other employee of the College is intended to include the financial and managerial interests of that individual's Immediate Family. Major financial interests of the Investigator's parents or by the parents of the Investigator's spouse may also be considered in evaluating potential Conflicts of Interest.
8. The Office of Research Administration, together with the Office of Institutional Compliance shall be guided by relevant regulations established by funding agencies, particularly those of the Public Health Service ("PHS") of the
9. U.S. Department of Health and Human Services, 42 C.F.R. §601 et seq., with regard to thresholds for external reporting of Conflicts of Interest to funding agencies.

## **9.0 REQUESTS FOR INQUIRY**

It is the College's expectation and requirement that all persons subject to this Conflicts of Interest and Conflicts of Commitment policy will endeavor faithfully to comply with its terms and requirements. In the event, however, that any person shall have reason in good faith to believe that a member(s) of the College community subject to this policy is not in compliance with the policy through ignorance, inadvertence or otherwise, that person is requested to report his/her concern in a timely manner, on an identified or an anonymous basis, in writing or by telephone, to the College's Compliance Officer or the Chief Compliance Officer. Thereafter, the Compliance Officer or Chief Compliance Officer shall conduct the appropriate inquiry into the facts and process any matters coming within this policy as provided by its terms.

## **10.0 INTERPRETATIONS**


The Chief Compliance Officer of the College or his/her designee shall have the authority to issue interpretations of the terms and provisions of this policy which shall be binding on the participants subject to review by the Board of Trustees or its Audit Committee.

 <b>Touro University Nevada</b>	<b>Page No.</b> 1 of 9	<b>Number:</b> 10.002
	<b>Effective Date:</b> July 1, 2007	
<b>POLICY AND PROCEDURE MANUAL</b>		
<b>Policy</b> <input checked="" type="checkbox"/> <b>Procedure</b> <input checked="" type="checkbox"/>		<b>Required Review:</b>
		<b>Reviewed:</b>
		<b>Revised:</b>
<b>Title: MISCONDUCT IN SCIENCE Model Policy Approved by the U.S. Office of Research Integrity, 1998</b>		<b>Responsible Position:</b>
		<b>Approval Requirements:</b>

I. Policy Statement Relating to Misconduct/Fraud in Research


- A. Touro University Nevada (TUN) strives to create a research climate that promotes faithful adherence to high ethical standards of honesty and integrity in the conduct of research without inhibiting the productivity and creativity of persons involved in research. Misconduct violates not only the relationship between a researcher and The University but also damages the reputations of those involved and to the entire research and scholarly community. Therefore, it is the responsibility of every research investigator to avoid misconduct and to assure integrity in the collection of data, storage of records and proper assignment of credit in publication. It is also the responsibility of all researchers and scholars to report instances of misconduct, as well as instances of retaliation against those who, in good faith, bring charges of misconduct in science or other scholarly research. Misconduct or fraud in research is an offense that damages not only the reputation of those involved but also that of the entire educational community. Due to the seriousness of this issue, faculty who bring allegations of misconduct that are made frivolously or not in good faith shall be subject to disciplinary action as defined in the TUN Faculty Handbook.
- B. This policy applies to all research conducted at TUN including that supported by the Public Health Service (PHS), the National Science Foundation (NSF), and other governmental entities. It also applies to research supported by private funders such as foundations and intramural funding available from the University. This policy applies to any person paid by, subject to the rules and policies of, or affiliated with TUN including scientists, trainees, technicians and other staff members, students, fellows, visiting scientists or other collaborators at or with TUN.
- C. This policy and its procedures will be followed when a University official receives an allegation of possible misconduct in scientific or other scholarly activity. Circumstances in individual cases may require variation from normal procedure to meet the best interest of TUN or the research sponsor. Change from the normal procedures must ensure fair treatment of the subject of the allegation; and any significant variation should be approved in advance by the TUN's Director of Research. The Director of Research also serves as the Research Integrity Officer for the University.

All actions undertaken pursuant to this policy will proceed promptly and with due regard for the reputation and rights of all persons involved. However, because of the inherent unfairness and the difficulties presented by any attempt to assess stale evidence, allegations of misconduct based on events that occurred six or more years ago will not be subject to review under this policy unless clear and convincing mitigating circumstances are present.

 <b>Touro University Nevada</b>	<b>Page No.</b> 2 of 9	<b>Number:</b> 10.002
	<b>Effective Date:</b> July 1, 2007	
<b>POLICY AND PROCEDURE MANUAL</b>	<b>Required Review:</b>	
<b>Policy</b> [X] <b>Procedure</b> [X]	<b>Reviewed:</b>	
	<b>Revised:</b>	
<b>Title: MISCONDUCT IN SCIENCE</b> <b>Model Policy Approved by the U.S. Office</b> <b>of Research Integrity, 1998</b>	<b>Responsible Position:</b>	
	<b>Approval Requirements:</b>	

D. Definitions

- (1). "Allegation" means any written or oral statement or other indication of possible scientific misconduct made to a University official.
- (2). "Complainant" means a person who makes an allegation of scientific misconduct.
- (3). "Conflict of Interest" means the real or apparent interference of one person's interests with the interests of another person or entity, where the potential bias may occur due to prior or existing personal or professional relationships.
- (4). "Deciding official(s)" means the University official(s) who make(s) final determination on allegations of scientific misconduct and any responsive University actions.
- (5). "Good Faith Allegation" means an allegation made with the honest belief that scientific misconduct may have occurred. An allegation is not in good faith if made with reckless disregard for or willful ignorance of facts that would disprove the allegation.
- (6). "Inquiry" means gathering information and initial fact-finding to determine whether an allegation or apparent instance of scientific misconduct warrants an investigation.
- (7). "Investigation" means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred and, if so, to determine the responsible person and the seriousness of the misconduct.
- (8). "Misconduct/fraud in research" means fabrication, falsification, plagiarism, or other practices that materially deviate from those that are commonly accepted within the academic community for proposing, conducting, or reporting research. It does not include honest errors or honest differences in interpretations or judgments of data. Misconduct/ fraud in research is a major breach of the relationship between a faculty or staff member and the institution. In order to maintain the integrity of research projects, every person engaged in research, including faculty, graduate and undergraduate students, postdoctoral fellows, and technicians, must keep a permanent auditable record of all experimental protocols, data, and findings. Co-authors on research reports of any type, including publications, must have had a bona fide role in the research and must accept responsibility for the quality of the work reported.
- (9). "ORI" means the Office of Research Integrity in the U.S. Department of Health and Human Services (DHHS). ORI is responsible for the scientific misconduct and research integrity activities of the U.S. Public Health Services (PHS).
- (10). Research Integrity Officer (RIO) means the institutional official responsible for making an inquiry into allegations of scientific misconduct and determining when such allegations warrant an investigation.
- (11). "Research Record" means any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, and/or reported research that constitutes the subject of an allegation of scientific misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or

 <b>Touro University Nevada</b>	<b>Page No.</b> 3 of 9	<b>Number:</b> 10.002
	<b>Effective Date:</b> July 1, 2007	
<b>POLICY AND PROCEDURE MANUAL</b>		
<b>Required Review:</b>		
<b>Reviewed:</b>		
<b>Revised:</b>		
<b>Policy</b> <input checked="" type="checkbox"/> <b>Procedure</b> <input checked="" type="checkbox"/>		
<b>Title: MISCONDUCT IN SCIENCE</b> <b>Model Policy Approved by the U.S. Office</b> <b>of Research Integrity, 1998</b>		
<b>Responsible Position:</b>		
<b>Approval Requirements:</b>		

contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; x-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.

- (12). “Respondent” means the person against whom an allegation of scientific misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.
- (13). “Retaliation” means any action taken by the University that adversely affects the employment or other institutional status of a complainant, who, acting in good faith, has made an allegation of scientific misconduct. Adverse actions taken against any individual who has cooperated in good faith with an investigation of alleged misconduct also constitute retaliation.
- (14). “Scientific Misconduct or Misconduct in Other Scholarly Research” means fabrication, falsification, or plagiarism. In addition, other practices that seriously deviate from ethical standards for proposing, conducting, or reporting research are unacceptable and in some cases may constitute scientific misconduct. Ordinary errors, good faith differences in interpretations or judgments of data, scholarly or political disagreements, good faith personal or professional opinions, or private moral or ethical behavior or views are not misconduct under this definition.


## II. General Procedures

### A. Reporting Misconduct or Retaliation

All employees or individuals associated with the University are encouraged to report observed, suspected, or apparent misconduct in science or other scholarly research, or retaliation for having made such allegations, to the Research Integrity Officer, or to the accused person's immediate supervisor and/or an appropriate administrative official such as a department chair, dean or other administrator. An administrative official who receives such a report must immediately contact the Vice President for Administration/CEO and/or the Research Integrity Officer.

### B. Process Options - Formal Allegations of Misconduct

1. The University's Research Integrity Officer will make an immediate inquiry into the allegations of misconduct and, in consultation with the Vice President for Administration/CEO the RIO will make an initial determination whether:
  - (a) the allegations concern subject matter and individuals that fall within the scope of this policy; and
  - (b) the allegations are sufficiently specific to allow for their evaluation and the documentation of the conclusion(s) concerning the need for an investigation.

 <b>Touro University Nevada</b>	<b>Page No.</b> 4 of 9	<b>Number:</b> 10.002
	<b>Effective Date:</b> July 1, 2007	
<b>POLICY AND PROCEDURE MANUAL</b>		<b>Required Review:</b>
<b>Policy</b> [X] <b>Procedure</b> [X]		<b>Reviewed:</b>
		<b>Revised:</b>
<b>Title: MISCONDUCT IN SCIENCE</b> <b>Model Policy Approved by the U.S. Office</b> <b>of Research Integrity, 1998</b>		<b>Responsible Position:</b>
		<b>Approval Requirements:</b>


2. If it is found that an investigation is warranted, the Research Integrity Officer, in consultation with the Vice President for Administration/CEO and/or the Executive Committee will:
  - (a) appoint the investigation committee;
  - (b) ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence;
  - (c) attempt to ensure that confidentiality is maintained;
  - (d) assist the investigation committee and all University personnel in complying with the procedures and applicable standards imposed by the government or other external funding sources;
  - (e) maintain the confidentiality and security of all documents and evidence;
  - (f) take reasonable steps to assure that the persons involved in the evaluation of allegations or evidence are fair, competent, and impartial and without a conflict of interest;
  - (g) report to ORI as required by regulation; and
  - (h) keep ORI apprised of any developments during the course of an inquiry or investigation that may affect current or potential DHHS funding for the individual under investigation; or of any developments about which the PHS needs to know in order to ensure appropriate use of federal funds and otherwise protect the public interest.

#### C. Protection of Complainant

1. The Research Integrity Officer will monitor the treatment of those individuals who bring allegations of misconduct and of those who cooperate in inquiries and investigations to ensure that they are not retaliated against in the terms or conditions of their employment or other status at the University.
2. The University, will, to the maximum extent possible, protect the privacy of those who make good faith reports of misconduct and will take diligent efforts to protect their positions and reputations.
3. In the event of an investigation, the complainant will have the opportunity to testify before the investigation committee; review portions of the investigation report pertinent to his or her allegations or testimony; be informed of the results of the investigation; and be protected from retaliation. The complainant will be given pertinent portions of draft reports for comment if the Research Integrity Officer determines that he or she may be able to provide relevant information on those portions of the draft.
4. The complainant is responsible for making allegations in good faith, maintaining confidentiality; and cooperating fully with any inquiry or investigation. Individuals who make frivolous allegations or bring them in bad faith shall be subject to disciplinary action as defined in the TUN Faculty Handbook.

#### D. Protection of Respondent

1. The respondent will be informed of the allegations when an inquiry is opened; notified in writing of the conclusion of the Research Integrity Officer; and informed of any actions that may result from that conclusion.

 <b>Touro University Nevada</b>	<b>Page No.</b> 5 of 9	<b>Number:</b> 10.002
	<b>Effective Date:</b> July 1, 2007	
<b>POLICY AND PROCEDURE MANUAL</b>	<b>Required Review:</b>	
<b>Policy</b> [X] <b>Procedure</b> [X]	<b>Reviewed:</b>	
	<b>Revised:</b>	
<b>Title: MISCONDUCT IN SCIENCE</b> <b>Model Policy Approved by the U.S. Office</b> <b>of Research Integrity, 1998</b>	<b>Responsible Position:</b>	
	<b>Approval Requirements:</b>	

2. The University will ensure fair treatment of the respondent and confidentiality to the extent possible without compromising public health and safety or the ability to thoroughly conduct an inquiry or investigation. No person involved in resolving an allegation of scientific or scholarly misconduct shall have real or apparent conflicts of interest in the matter.
3. The respondent will have the opportunity to be interviewed as a part of the initial inquiry; to present evidence to the investigation committee; and review the draft inquiry and investigation reports; and be informed of the results of the inquiry or investigation.
4. The respondent is responsible for maintaining confidentiality and cooperating with the inquiry or investigation.
5. The respondent has the right to seek University assistance in restoring his or her reputation if found not to have engaged in misconduct in science or other scholarly research.

E. Conducting the Inquiry


1. Initiation and Purpose of the Inquiry
  - (a) The Research Integrity Officer will initiate an inquiry immediately upon receipt of allegations of misconduct and will advise the relevant dean, department chair and/or center director that an inquiry is being initiated. The Research Integrity Officer will clearly identify the original allegations and any related issues that should be evaluated during the inquiry process.
  - (b) The purposes of the inquiry are: to determine if the allegations fall within the scope of this policy; to determine if the allegations are sufficiently specific to allow follow-up; to make a preliminary evaluation of the available evidence and testimony of the respondent, complainant, and essential witnesses; and to determine whether there is sufficient evidence of possible misconduct in science or other scholarly research to warrant an investigation.
2. Sequestration of the Research Records

As a part of an inquiry, the Research Integrity Officer must ensure that all original research records and materials, and all documents relevant to the allegation are immediately secured.
3. Advice

The Legal Counsel for TUN will be available throughout the inquiry to advise the Research Integrity Officer and/or Vice President for Administration/CEO, as needed.
4. Inquiry Process

The Research Integrity Officer will conduct the inquiry which will normally involve only interviews of the complainant and the respondent and an examination of key, relevant documents. If considered necessary, the Research Integrity Officer may also interview essential witnesses and other research records and materials. The Research Integrity Officer may enlist the assistance of a person or



 <b>Touro University Nevada</b>	<b>Page No.</b> 6 of 9	<b>Number:</b> 10.002
	<b>Effective Date:</b> Julv 1, 2007	
<b>POLICY AND PROCEDURE MANUAL</b>		
<b>Required Review:</b>		
<b>Reviewed:</b>		
<b>Revised:</b>		
<b>Title: MISCONDUCT IN SCIENCE</b> <b>Model Policy Approved by the U.S. Office</b> <b>of Research Integrity, 1998</b>		
<b>Responsible Position:</b>		
<b>Approval Requirements:</b>		

persons with relevant technical expertise, selected in accordance with procedures set out below for establishing an Investigative Committee, to examine relevant research records. The scope of the inquiry does not include exhaustive interviews or extensive analyses of research records. The inquiry should normally be completed within sixty (60) days after the submission of the allegations that are the subject of the inquiry. Any extension of this period will be based on good cause, as determined by the Vice President for Administration/CEO, and will be recorded in the inquiry file.

The Research Integrity Officer will determine, after consultation with the Vice President for Administration/CEO and/or the Executive Committee with Legal Council, if deemed appropriate, whether the allegations are sufficient to warrant further investigation. The purpose of the inquiry is to determine only if an investigation is warranted. This determination will be guided by the existence of clear and prevailing evidence of misconduct. No conclusion or presumption that misconduct occurred is created if the Vice President for Administration/CEO determines that there should be an investigation of the allegations.

#### 5. Inquiry Decision and Notification

The Research Integrity Officer shall prepare and transmit an inquiry report to the Vice President and CEO of TUN and the Provost for Touro University, Legal Counsel for the University, the complainant, and the respondent. This report shall state whether an investigation into the allegations is warranted.


#### F. Conducting the Investigation

##### 1. Initiation and Purpose of the Investigation

Should an investigation be determined to be warranted, the Research Integrity Officer will initiate the investigation immediately after notifying the Vice President for Administration for TUC and the Provost for Touro University. The purpose of the investigation is to: explore in detail the allegations; examine the evidence in depth; and, determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation also will determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. The findings of the investigation will be set forth in an investigation report.


##### 2. Sequestration of Research Records

The Research Integrity Officer immediately will sequester any additional pertinent research records that were not sequestered previously. The sequestration should occur before or at the time the respondent is notified that an investigation has begun.

 <b>Touro University Nevada</b>	<b>Page No.</b> 7 of 9	<b>Number:</b> 10.002
	<b>Effective Date:</b> July 1, 2007	
<b>POLICY AND PROCEDURE MANUAL</b>	<b>Required Review:</b>	
<b>Policy</b> [X] <b>Procedure</b> [X]	<b>Reviewed:</b>	
	<b>Revised:</b>	
<b>Title: MISCONDUCT IN SCIENCE</b> <b>Model Policy Approved by the U.S. Office</b> <b>of Research Integrity, 1998</b>	<b>Responsible Position:</b>	
	<b>Approval Requirements:</b>	

3. Appointment of and Charge to the Investigation Committee
  - (a) The Research Integrity Officer, in consultation with the Vice President for Administration and Legal Counsel, and the appropriate dean will appoint an investigation committee within fifteen (15) days of the notification to the respondent that an investigation is planned, or as soon thereafter as is practicable. Such committees will be composed of three (3) persons, including a committee chair. At least one (1) TUN faculty member shall be appointed to each such committee. No committee members shall have real or apparent conflicts of interest in the case. Committee members shall be unbiased and have the necessary expertise to effectively interview the principals and other witnesses and to evaluate the evidence and issues related to the allegations. Committee members may be scientists, subject matter experts, administrators, lawyers, or other qualified persons within or outside the University. Members of the investigation committee may also have assisted in the earlier inquiry concerning the allegations.
  - (b) The Research Integrity Officer will notify the respondent of the proposed committee membership. If the respondent submits a written objection to any appointed member of the inquiry committee based upon bias or conflict of interest within five (5) days, the Vice President for Administration will determine whether to replace the challenged member with a qualified substitute.
  - (c) The Research Integrity Officer will prepare a charge for the investigation committee that describes the allegations and any related issues identified during the inquiry, defines scientific misconduct, and identifies the name of the respondent. The charge will state that the committee is to evaluate the evidence and testimony of the respondent, complainant, and witnesses to determine whether, based upon a preponderance of the evidence, scientific misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.
  - (d) If during the investigation additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the committee will notify the Research Integrity Officer who will then determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.
  - (e) The Research Integrity Officer, with the assistance of the Vice President for Administration and Legal Counsel, will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of these instructions and, where PHS funding is involved, the PHS regulations.
  
- G. Investigation Process

The investigation committee will be appointed and the investigation process initiated within thirty (30) days of the completion of the inquiry. The investigation normally will involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls. The committee should, when possible, interview the complainant(s), the respondent(s), and other individuals

 <b>Touro University Nevada</b>	<b>Page No.</b> 8 of 9	<b>Number:</b> 10.002
	<b>Effective Date:</b> July 1, 2007	
<b>POLICY AND PROCEDURE MANUAL</b>	<b>Required Review:</b>	
<b>Policy</b> [X] <b>Procedure</b> [X]	<b>Reviewed:</b>	
	<b>Revised:</b>	
<b>Title: MISCONDUCT IN SCIENCE</b> <b>Model Policy Approved by the U.S. Office</b> <b>of Research Integrity, 1998</b>	<b>Responsible Position:</b>	
	<b>Approval Requirements:</b>	

who might have information regarding aspects of the allegations. Interviews of the respondent should be tape recorded or transcribed. All other interviews should be transcribed, tape recorded, or summarized. Summaries or transcripts of the interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigation file. An investigation normally should be completed within one hundred twenty (120) days of its initiation, with the initiation being defined as the first meeting of the investigation committee. This includes: conducting the investigation; preparing the report of findings; making the draft report available to the subject of the investigation for comment; and submitting the report to the Vice President for Administration, TUN, Provost for Touro University, the appropriate dean for final action.


**H. Investigation Report**

The committee shall prepare a report of its investigation for submission to the Vice President for Administration, TUN and Provost, Touro University. The report shall describe the policies and procedures under which the investigation was conducted, how and from whom information relevant to the investigation was obtained, the findings, and the basis for the findings. It shall also contain an accurate summary of the views of any person(s) found to have engaged in misconduct.

The Research Integrity Officer will provide the respondent with a copy of the report for comment and rebuttal; and will provide the complainant with those portions of the report that address the complainant's role and opinions. The complainant and respondent shall provide their comments, if any, to the committee within ten (10) days of receipt of the reports or portions of it. The Research Integrity Officer will inform the respondent and complainant, when providing them with the reports or portions of it, that the report is confidential, and may establish reasonable conditions to ensure that confidentiality. The respondent's comments will be attached to the final report and the findings of the final report should take into account the respondent's comments as well as all other evidence. The complainant's comments should be considered by the committee and the report modified as appropriate prior to its submission. The committee's report shall be submitted to the Vice President for Administration and Legal Counsel for TUN for a review of its legal sufficiency prior to its submission to the Provost, Touro University.

**I. Investigation Decision and Notification**

The Vice President for Administration, TUN and the Provost, Touro University are the deciding officials, and will make the final determination whether to accept the investigation report, its findings, and the recommended University actions. If this determination or recommendation varies from that of the investigation committee, the Vice President for Administration/CEO, TUN and the Provost, Touro University, will explain in written detail the basis for rendering a decision or recommendation different from that of the committee. This explanation shall be consistent with the definition of scientific misconduct, the University's policies and procedures, and the evidence reviewed and analyzed by the investigation committee. The Vice President for Academic Affairs/CEO, TUN, and the Provost, Touro

 <b>Touro University Nevada</b>	<b>Page No.</b> <b>9 of 9</b>	<b>Number:</b> <b>10.002</b>
	<b>Effective Date:</b> <b>July 1, 2007</b>	
<b>POLICY AND PROCEDURE MANUAL</b>	<b>Required Review:</b>	
<b>Policy</b> <input checked="" type="checkbox"/> <b>Procedure</b> <input checked="" type="checkbox"/>	<b>Reviewed:</b>	
	<b>Revised:</b>	
<b>Title: MISCONDUCT IN SCIENCE</b> <b>Model Policy Approved by the U.S. Office</b> <b>of Research Integrity, 1998</b>	<b>Responsible Position:</b>	
	<b>Approval Requirements:</b>	

University, may also return the report to the investigation committee with a request for additional fact finding and analysis. The determination of the Executive Vice President and Provost, together with the report of the investigation committee, constitutes the final report and decision.

The Research Integrity Officer will notify the respondent and the complainant in writing of the final decision of the case. The Vice President for Administration/CEO, TUN and the Provost, Touro University, will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case. The Research Integrity Officer is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies, including submissions of the final report to ORI or other appropriate agencies.

Source: Public Health Service regulations, "Responsibilities of Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science, @ 42 CFR Part 50, Subpart A, originally issue din 1989, amended in 2000 (Volume 65, Number 235).



**THE TOURO COLLEGE AND UNIVERSITY  
SYSTEM  
ACADEMIC INTEGRITY POLICY**

June 2012

## TABLE OF CONTENTS

INTRODUCTION.....	1
STATEMENT ON ACADEMIC INTEGRITY.....	2
VIOLATIONS OF ACADEMIC INTEGRITY.....	3
Plagiarism.....	3
Intentional Plagiarism.....	3
Unintentional Plagiarism.....	4
Cheating on Examinations and Other Class/Fieldwork Assignments.....	4
Research Misconduct and Other Unethical Conduct.....	5
Fabrication.....	6
Falsification.....	6
Plagiarism (As Research Misconduct).....	6
Misleading or Fraudulent Behavior.....	6
Tampering.....	7
Copyright Violations.....	8
BEST PRACTICES IN THE PROMOTION OF ACADEMIC INTEGRITY.....	7
By Faculty.....	8
Training Faculty and Staff.....	8
Training Students.....	8
Testing Procedures.....	9
Test Preparation.....	9
Test Duplication and Storage.....	10
Test Administration: Paper Examinations.....	10
Test Administration: Online Tests.....	10
Post-Test Procedures.....	10
Detecting Plagiarism.....	11
BEST PRACTICES IN THE PROMOTION OF ACADEMIC INTEGRITY IN ONLINE EDUCATION.....	11
Faculty Training and Implementation.....	11
Guidelines to Faculty.....	12
Multiple Assessment Strategies and Prevention of Plagiarism.....	12
Examinations.....	13
PROCEDURES IN RESPONSE TO VIOLATIONS OF ACADEMIC INTEGRITY.....	14
Reporting a Case of Suspected Plagiarism or Cheating.....	14
Resolution of Academic Integrity Violations.....	14
Informal Resolution.....	15
Formal Resolution.....	15
Academic Appeal Process.....	17
Sanctions.....	19
Recordkeeping.....	19
RECOMMENDATIONS ON IMPLEMENTATION OF POLICY.....	20
Oversight of Policy.....	20
Distribution of Policy.....	20
Honor Statement.....	20

Conformance of Individual School Policies .....	21
REFERENCES .....	22
APPENDIX I .....	23
Members of the Task Force .....	23
APPENDIX II .....	24
Divisions and Schools of Touro College .....	24

# THE TOURO COLLEGE AND UNIVERSITY SYSTEM POLICY ON ACADEMIC INTEGRITY

## INTRODUCTION

In November 2010, President Alan Kadish appointed a broadly representative Task Force on Academic Integrity to examine the issue of Academic Integrity throughout the Touro College and University System. The Task Force was charged with the following mission:

1. To examine the current academic culture with regard to cheating and plagiarism, and the practices and policies of the various Schools and Divisions of the Touro College and University System (TUCS) regarding the same.
2. To consider issues concerning student plagiarism at Touro and recommend appropriate ways and best practices to eliminate the phenomenon, to the extent that it exists.
3. To analyze Touro's approach to test administration and exam security—including repeating test questions, use of proctors, etc.—and recommend additional policies and actions, as appropriate.
4. To recommend a comprehensive structure and framework at Touro to ensure Academic Integrity throughout its schools, campuses, and programs.

In addressing the issues raised by the President, the Touro College and University System, under the leadership of the Task Force, joined the International Center for Academic Integrity (based in Clemson University), conducted surveys of faculty, administration, and students, and examined best practices in all areas concerning academic integrity both within the Touro College and University System and throughout academic institutions nationally and internationally. The Task Force has sought to define Policies and Procedures that are clear, uniform, and appropriate to address issues of Academic Integrity at Touro. The Touro College and University System owes a debt of gratitude to the Presidential Task Force, the members of which are listed in the Appendix.

In developing the TCUS Policy on Academic Integrity, the Task Force drew freely from exemplary policy documents that were already in place within units of the Touro College and University System, including those of the New York Medical College, the Touro College School of Health Sciences, Touro University-California and Touro University-Nevada. A college-wide survey was conducted in conjunction with Dr. Donald McCabe at Rutgers University, President of the Center for Academic Integrity. His participation and advice have been invaluable.

This document contains a Statement on Academic Integrity Policy followed by a comprehensive presentation of Violations of Academic Integrity. Additionally, this document provides Best Practices in the Promotion of Academic Integrity to be adopted by faculty, staff, and students



regarding training, test administration, and plagiarism detection. Finally, the document delineates Procedures in Response to Violations of Academic Integrity, and contains Recommendations on Implementation of this Policy.

As Dr. Kadish instructed the Task Force, “The issue of Academic Integrity is one that affects every unit and individual involved in academic life.” It is our hope that the Policies and Procedures Statement will foster Academic Integrity throughout the Touro College and University System.

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## **STATEMENT ON ACADEMIC INTEGRITY**

Touro College and University System is a community of scholars and learners committed to maintaining the highest standards of personal integrity in all aspects of our professional and academic lives. Students and faculty are expected to share a mutual respect for teaching, learning and the development of knowledge. Because intellectual integrity is a hallmark of scholarly and scientific inquiry as well as a core value of the Jewish tradition on which our university system was founded, students and faculty are expected to adhere to the highest standards of honesty, fairness, professional conduct of academic work and respect for all community members.

Academic honesty supports our shared intellectual culture and our ability to trust one another. Students must avoid all acts of dishonesty, including, but not limited to:

- cheating
- plagiarizing (presenting the work or ideas of others as your own)
- fabricating (making up information, data, or research results)
- tampering (unauthorized removal or alteration of College documents, software, equipment, or other academic-related materials, including other students’ work)
- lying
- working with others when assignments or exams require individual work
- making unauthorized copies of copyrighted material
- facilitating or tolerating the dishonesty of others

Academic dishonesty lowers scholastic quality and adversely affects those who will eventually depend on the knowledge and integrity of our graduates. Failure to uphold the principles of academic integrity negatively impacts the reputation of Touro, the value of each and every degree awarded by the institution, and the future success of our graduates.

The Touro College and University System views violation of academic integrity with the utmost gravity. Such violations will lead to appropriate sanctions, from failure in coursework up to and

including expulsion from the Touro College and University System. We commit ourselves to the shared vision of academic excellence that can only flourish in a climate of integrity.

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## **VIOLATIONS OF ACADEMIC INTEGRITY**

The following are considered to be violations of academic integrity and are prohibited by the Touro College and University System. Students, faculty, and other members of the Touro College and University System community who are in violation of one of the offenses listed below or similar such offenses or who assist in the commission of such offenses may be subject to sanctions as described below in the section “Procedures in Response to Violations of Academic Integrity.”

### **Plagiarism**

Plagiarism is defined as the unauthorized use of the writings, ideas and/or computer-generated material of others without appropriate acknowledgement and the representation of them as one’s own original work. Plagiarism encompasses acts of inadvertent failure to acknowledge sources, as well as improper attribution due to poor citation.

When using ideas/words from other sources, the student must clearly define the sources using standard methods of citation. Plagiarism can occur even when one does not use the exact words of another author. Paraphrasing written material by changing or rearranging words without the proper attribution is still considered plagiarism (even if it eludes identification by plagiarism detection software). It is therefore critically important that students understand how to cite. If students have any questions about the proper use and citation of material from other sources, they should seek help from their professors.

### **INTENTIONAL PLAGIARISM**

Plagiarism takes many forms. **Flagrant forms**, or **intentional plagiarism**, as stated in the Thesis Guidelines of the New York Medical College <sup>3</sup>, include, but are not limited to: purchasing or copying a paper from the Internet or from a fellow student or anyone else, whether or not that paper has been published; copying or cutting and pasting portions of others’ work (whether a unique phrase, sentence, paragraph, chart, picture, figure, method or approach, experimental results, statistics, etc.) without attribution; copying clinical notes/materials without personally performing the patient examination. Plagiarized sources may include not only print material but also computer programs, CD-ROM video/audio sources, emails and material from social media

sites and blogs, as well as assignments completed by other students at Touro College and University System and elsewhere. A more subtle, but equally flagrant, form is paraphrasing or attempting to put in one's own words the theories, opinions or ideas of another without proper citation.

Students may not reuse their own previous work without appropriate citation. This is a form of plagiarism called self-plagiarism, and may mislead the reader or grader into the erroneous belief that the current submission is new work to satisfy an assignment.

Students are cautioned against assuming that a fact or idea is common knowledge and are encouraged to provide citation, to deflect a charge of plagiarism.

### **UNINTENTIONAL PLAGIARISM**

Plagiarism is not only the failure to cite but the **failure to cite sources properly**. If a source is cited but in an inadequate way, the student(s) may still be guilty of unintentional plagiarism. It is therefore crucial that students understand the correct way to cite. The rules are relatively simple:

- For exact words, use quotation marks or a block indentation, with the citation.
- For a summary or paraphrase, show exactly where the source begins and exactly where it ends.

In its policies and disciplinary procedures, the Touro College and University System will seek to recognize and differentiate its penalties between **intentional plagiarism** (as defined above) and **failure to cite sources properly**. However, both forms are violations.

## **Cheating on Examinations and Other Class/Fieldwork Assignments**

The Student Code of Academic Integrity at the New York Medical College <sup>4</sup> defines cheating as improperly obtaining and/or using unauthorized information or materials to gain an advantage on work submitted for evaluation. Providing or receiving assistance unauthorized by the instructors is also cheating.

Examples of cheating include, but are not limited to:

- Giving or receiving unauthorized assistance to or from another person on quizzes, examinations, or assignments;

- Using materials or devices not specifically authorized during any form of a test or examination;
- Exceeding the restrictions put in place for “take home” examinations, such as unauthorized use of library sources, intranet or Internet sources, or unauthorized collaboration on answers;
- Sitting in for someone else or permitting someone to sit in for you on any form of test or examination;
- Working on any form of test or examination beyond the allotted time; hiding, stealing or destroying materials needed by other students;
- Altering and resubmitting for re-grading any assignment, test or examination;
- Copying from another individual’s examination or providing information to another student during an examination;
- Soliciting, obtaining, possessing or providing to another person an examination prior to the administration of the examination.

Examples of unauthorized assistance include <sup>3</sup>:

- Giving or receiving person-to-person assistance or information in any manner, including notes, text messages, or e-mails, during an examination or in the preparation of other assignments without the authorization of the instructor;
- Using crib sheets or unauthorized notes (unless the instructor provides explicit permission);
- Copying from another individual’s exam.

Failure to comply with any and all Touro College and University System test procedures will be considered a violation of the Academic Integrity Policy.

## **Research Misconduct and Other Unethical Conduct**

The integrity of the scientific enterprise requires adherence to the highest ethical standards in the conduct of research and research training. Therefore, students and other trainees conducting research are bound by the same ethical guidelines that apply to faculty investigators. These standards are described briefly in the New York Medical College **Guidelines for Ethical Practices in Research and Policies for Dealing with Instances of Alleged Violations of Ethical Standards** <sup>5</sup> and more fully in the **US Public Health Service Policies on Research Misconduct**.<sup>6</sup>

Research misconduct is defined in the USPHS Policy as “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.”<sup>6</sup> When appropriate, adjudication will be conducted according to Touro College and University System’s **Guidelines for Ethical Practices in Research** cited above.

In the Student Code of Academic Integrity, the New York Medical College uses the following as examples of research misconduct <sup>4</sup>:

### **FABRICATION**

Fabrication means making up information, data, or research results, or pretending to have performed experiments that were not, in fact, conducted.

### **FALSIFICATION**

Falsification means inappropriately altering or manipulating data, images, or information on clinical or laboratory records, practicum experiences, research results, equipment, and/or processes so that one possible conclusion or interpretation is favored over others.

### **PLAGIARISM (AS RESEARCH MISCONDUCT)**

Plagiarism, on its own a violation of academic integrity, may *additionally constitute research misconduct* if it is committed in the context of a research effort.

### **MISLEADING OR FRAUDULENT BEHAVIOR**

Misleading or fraudulent behavior, put simply, is lying, and includes acts contributing to or associated with lying. It takes on any form of fabrication, falsification or misrepresentation.

Examples include, but are not limited to:

- Reporting false information to gain an advantage;
- Omitting information or data resulting in misrepresenting or distorting findings or conclusions;
- Providing false information to explain lateness or to be excused from an assignment, class or clerkship function;
- Falsely accusing another of misbehavior, or otherwise misrepresenting information about another;
- Providing false information about oneself, such as on an application or as part of some competition;
- Taking credit for accomplishments achieved by another;
- Omitting relevant information about oneself.

## **TAMPERING**

Unauthorized removal or alteration of College documents (e.g., library books, reference materials, official institutional forms, correspondence), software, equipment, or other academic-related materials, including other students' work, for the purpose of gaining an unfair academic advantage. It should be noted that tampering as a form of cheating may also be classified as criminal activity and may be subject to criminal prosecution.

Examples include, but are not limited to:

- Tearing out the pages of an article from a library journal to prevent other students from having access to the required reading material;
- Intentionally sabotaging another student's work;
- Altering a student's academic transcript, letter of recommendation, or some other official college document;
- Electronically changing another student's or colleague's files, data, assignments, or reports.

## **Copyright Violations**

Academic integrity prohibits the making of unauthorized copies of copyrighted material, including software and any other non-print media. Individuals, under the legal doctrine of "fair use", can make a copy of an article or copy small sections of a book for personal use, or may use an image to help teach a concept. As a general rule, if you think you might be violating the copyright law, you probably are. Examples of copyright violations include:

- Making or distributing copies of a copyrighted article for a group (on paper or electronically)
- Disseminating an image or video of an artist's work without permission (such as a Netter® or Adam® anatomical drawing)
- Copying large sections of a book

The "fair use doctrine" regarding use of copyrighted materials can be found at the following link: <http://www.copyright.gov/fls/fl102.html>

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# **BEST PRACTICES IN THE PROMOTION OF ACADEMIC**

# INTEGRITY

## By Faculty

Academic integrity is the responsibility of all members of the Touro College and University System. As educators, we are obligated to demonstrate by word and action the importance of this core value. As members of the Touro College and University System, faculty members are committed to the pursuit of truth and the advancement of knowledge, tasks that can be realized only in an environment fully supportive of academic integrity. Faculty members are therefore expected to participate fully in establishing an academic environment in which the principles of integrity are understood and practiced by students.

## Training Faculty and Staff

Since promoting academic integrity is a shared responsibility, it is important that appropriate training and support be offered to both faculty and staff throughout the school year.

- Faculty development programs shall include training regarding educational resources to promote academic integrity, such as articles/case studies, websites and tutorials.
- Faculty development shall also include training in examination security and plagiarism prevention, including how to detect different types of plagiarism and awareness of proper citation.
- Orientation, Faculty Development Days, and Faculty Assembly shall include opportunities to disseminate the policies and disciplinary procedures of Academic Integrity at the Touro College and University System.

## Training Students

Factors that may influence cheating and plagiarism among students are grade pressure, time pressure, task pressure, negative personal attitude, lack of awareness, and lack of competence. It is, therefore, important to provide adequate training of students regarding all of the relevant parts of this Academic Integrity policy, as well as with as much education and as many opportunities as possible to learn about citation styles, proper writing skills, and plagiarism avoidance.

Students may find online resources, such as the self-test created by the University of Southern Mississippi, "[How much have you learned about Plagiarism](#)"<sup>7</sup> useful in clarifying-how prepared they are in this area. This test is available to TCUS students via the Touro College [Library Website](#).

Student Orientation programs shall include sessions on Touro's Academic Integrity policy, and each student shall be provided with a copy of the policy at that time. Furthermore, each student must sign an honor statement. Since many Touro schools or units are mission-based or profession-oriented, the ethical values of the school mission should be referenced in the statement. Students will also be required to complete a library-developed session or sessions that demonstrate research method, information literacy, and proper use of sources.

Faculty members are expected to promote academic integrity in the following ways in their classes:

- Describe academic integrity policies on the first day of class, and refer, in class, to the policy of the Touro College and University System, including appeal processes.
- Include a clear statement in the class syllabus with a reference to the Touro College and University System's academic integrity policy (including the website where the policy may be found).
- Create process-based or plagiarism-proof assignments (examples are abundant and available, if needed). Require up-to-date references. Assign oral reports.
- Require that all term reports be submitted electronically, preferably through Blackboard. Students must be informed that the submitted material will be checked by the instructor for plagiarism.
- Professors may choose to add an honor pledge to each written assignment and exam for students to sign.

## Testing Procedures

In order to reduce the opportunity for cheating on examinations, faculty members should employ the following best practices whenever possible:

### TEST PREPARATION

- Modify or replace a significant portion of the exam questions each time an exam is re-administered in a course or administered in a separate section.
- For courses with large numbers of students and close seating, prepare multiple versions of an exam for that section.
- Prepare different versions of multiple choice exams for use in EACH section of a course, and two separate exams for very large sections.
- Develop, to the extent possible, "cheat proof" essay or problem-solving questions.
- Prepare a different version of the exam for make-up exams.



A copy of each examination is to be filed with the Department Chairperson or Dean so that he or she can maintain a historical file on exams used in the course.

### **TEST DUPLICATION AND STORAGE**

- Type exams on a secure computer. Do not use Touro computer labs, where students, work/study students and/or lab technicians can access the files.
- Print and copy exams on secure printers and copiers.
- When duplicating examinations, do the copying yourself, or have a trustworthy administrative assistant do the copying for you. Ensure that all original copies are removed from the copiers and copy room.
- Store exams in a secure place, such as the Department office or the faculty member's paper or computer files. All exams must be stored in locked file cabinets and secured computers.

### **TEST ADMINISTRATION: PAPER EXAMINATIONS**

- Be present during examinations and actively proctor your own examinations. The Touro College and University System may supplement the proctoring by assigning extra proctors.
- Do not permit students to have any electronic devices (including cell phones, smartphones, iPADS or other tablet computers, and flash drives) or personal belongings (purses, backpacks) at their desks during the examination.
- Separate students by at least one seat, if space permits.
- Maintain control of the paper (including scrap) used during the exams.

### **TEST ADMINISTRATION: ONLINE TESTS**

- Use appropriate web-browser lock-down software, and a web-cam, as appropriate.

### **POST-TEST PROCEDURES**

- If students are permitted to review their exams, conduct the post-exam review in a secure manner, just as you administered the test.
- All exams must be collected at the end of the review period.

## Detecting Plagiarism

The Touro College and University System offers SafeAssign, a plagiarism detection system accessed through Blackboard. SafeAssign helps faculty prevent plagiarism by detecting unoriginal content in student papers. Though not 100% foolproof, particularly in instances of paraphrase or translation, SafeAssign does act as a plagiarism deterrent, and has features designed to help educate students about plagiarism and the importance of proper attribution of any “borrowed” content.

In addition to SafeAssign, faculty can avail themselves of other anti-plagiarism search engines such as Yahoo! Google, Google Scholar, Plagiarism.Org, AltaVista, Lycos and library databases.

There are many excellent sources of information on plagiarism detection. One of the best is Harris, R.A. (2001). *The Plagiarism Handbook*. Glendale, CA: Pyczak Publishing.

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## BEST PRACTICES IN THE PROMOTION OF ACADEMIC INTEGRITY IN ONLINE EDUCATION

The Touro College and University System is particularly sensitive to the challenges of academic integrity in online education because of the physical separation between faculty member and student. The online teaching environment poses specific difficulties regarding the administration of examinations and the assessment of student work. These challenges compel the College and University System to be conversant with developments and best practices in the field of online education, and to be receptive to both new opportunities and challenges associated with emerging technologies as they are being developed and implemented.

Following are a number of best practices for promoting academic integrity in online education <sup>8</sup>:

### Faculty Training and Implementation

- Admission to online educational programs should be monitored carefully to ensure the integrity of the admissions application process as well as materials submitted to support the admissions application.
- A secure student login and personalized password (meeting identity management system standards) should be required to access online courses and related resources, discussions, assignments and assessments. Information gathered as part of the identity

management system for these purposes must be safeguarded carefully to protect student privacy.

- Guidance on academic integrity issues in online education should be incorporated routinely in the training and orientation materials provided to online faculty.
- A link to the Touro College and University System Academic Integrity website should be provided to online faculty for incorporation in their course materials.
- Online faculty should be made aware of general Touro College and University System policies and procedures on academic integrity and the reporting procedure (see below) in the instance that suspected violations of academic integrity are discovered. Touro's Vice President of Online Education should also be notified of any action or decision concerning online academic integrity violations.

## Guidelines to Faculty

- Faculty members should present clearly the academic integrity policy within the online learning environment at the beginning of the course. The course outline for the online course should contain an explicit heading and section on ACADEMIC INTEGRITY in which appropriate guidelines and policies would be detailed. Faculty should offer the students the opportunity to discuss the meaning of academic integrity using the course discussion board or chat room. The URL link to the Touro College and University System Academic Integrity policy should be included in course postings.
- Students should be required to read and sign an agreement to abide by the campus academic integrity policy. An effective way of accomplishing this is through a check-off box on the home page of the online course.
- In the instance that collaborative projects are assigned, faculty should clarify to students in writing under a specific course headline the appropriate ground rules for collaboration in online education. The consequences for failure to abide by the guidelines provided should be clarified in writing.
- Rubrics, or detailed grading criteria, should be provided for every assignment at the beginning of the course, so that students understand how they will be graded.

## Multiple Assessment Strategies and Prevention of Plagiarism

- Ensuring the academic integrity of the assessment of student learning is an essential faculty responsibility. Therefore, faculty must be actively involved in structuring appropriate course assessment. Faculty may choose to **use multiple assessment techniques in place of, or to lessen reliance on, final examinations.** Indeed, most distance learning providers use multi-faceted assessment strategies rather than traditional final examinations. Assessments should be designed to be frequent, varied, and directly relevant to course learning objectives. One suggestion would be to make

assignments cumulative (students turn in parts of a project or paper throughout the semester) to minimize opportunities for fraudulent submissions. Examples of learning and assessment activities include: interactive threaded discussions, writing assignments, quizzes, capstone projects, group work, and online exams.

- Assessment activities should be modified from semester to semester.
- Instructors should become familiar with students' writing styles through multiple submissions and online discussions.
- Plagiarism detection software (such as SafeAssign or Turnitin) should always be used for written assignments.
- Both the research process and the product should be evaluated. After an assignment is due, have students post on the discussion board, describing the assignment and the research method used, a summary of conclusions, and an abstract (a meta-learning essay).

## Examinations

- Since the Touro College and University System is a multi-campus institution, it may be possible to provide physically-proctored examinations on campus for regular Touro students undertaking a course through distance learning. In these instances, faculty members are encouraged to use proctored test sites as appropriate. The primary responsibility for proctoring an examination remains with the instructor, wherever that is possible. For undergraduate courses, the assignment of any proctor other than the instructor must be at the direction of the Dean of Faculties or his/her designee. For graduate courses, the assignment of any proctor other than the instructor must be at the direction of the Dean/Director of the program.
- Students must be asked to provide a Touro ID or government-issued photo ID when they participate in a physically-proctored examination for a distance learning course. Students should be informed of this requirement when the examination is scheduled.
- In the instance that an examination is given online, faculty must be aware of academic integrity issues in the administration of these exams and consider appropriate steps to minimize these issues, such as those described below:
  - Use test banks with large numbers of questions and pull a smaller number of questions from the test bank.
  - Randomize the order of answers for multiple-choice questions, so that, for example, the correct answer for a particular question might be “a” for one student and “b” for another.
  - Require forced completion on exams, so that students cannot re-enter a test.
  - A Web browser lock-down service should be used during testing so that students cannot leave the exam once they have started.

- A variety of technological solutions to minimize the potential for cheating on online examinations are emerging, including online proctoring services and biometric measuring devices. At this point, the Touro College and University System has adopted no standard proctoring technology or approach for all online examinations. However, Touro will continue to monitor such technology, and such technology may be adopted by individual units on a pilot basis in coordination with the Touro Vice President of Online Education.
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## PROCEDURES IN RESPONSE TO VIOLATIONS OF ACADEMIC INTEGRITY

This Touro College and University System Academic Integrity Policy applies to all students in each of Touro's schools. Any act in violation of this Policy or any allegation of misconduct related to this Policy involving a student must be reported and addressed in accordance with the adjudication procedures outlined below or those of the student's school, which at no time will be less stringent than the requirements and standards set forth in this Policy Statement.

### Reporting a Case of Suspected Plagiarism or Cheating

Faculty members or other members of the Touro community who encounter cases of plagiarism or cheating should ***contact the Chair of the relevant department***, and inform the offending student of such. The Chair will report the incident, in writing, to the Dean. The Chair will provide faculty with advice specific to the individual incident. No grade may be entered onto the student's record for the course in question before the issue is resolved, either informally or formally.

### Resolution of Academic Integrity Violations

Students who are found to have violated the Touro College and University System's Standards of Academic Integrity are subject to sanctions. Each school (see Appendix II for listing of schools) shall designate the Dean responsible for adjudicating violations of Academic Integrity (herein referred to as the "**Dean**" except where otherwise noted). Depending on the school's Student Handbook or Bulletin, this may be the Dean of Students, the Dean of Faculties, or another appropriate responsible individual.

As stated above, incidents are reported to the department Chairperson, and a report by the Chair is submitted to the Dean. The method of resolution of the violation may be either informal or formal.

At the discretion of the Dean or Chair, the student may be removed from the class pending a resolution of the matter. Should a student action be of such a nature that it is felt that he or she must be relieved of his/her right to attend the Touro College and University System, the student may be temporarily suspended from the Touro College and University System upon recommendation of the Dean. In the case of suspension, an expedited formal hearing will be scheduled. Suspended students may not avail themselves of the informal resolution process.

### **INFORMAL RESOLUTION**

The student and faculty member may resolve the issue informally—with notice to the Chair of the Department and the Chair's consultation with the Dean (which must be accompanied by a written synopsis of the matter)—and the faculty member, in consultation with the Chair, may impose any range of sanctions (Class C, D, or E) short of suspension and expulsion. If the student agrees to the decision, then any disposition will be final. Once accepted by the student, the decision of the faculty member and Chair is not subject to appeal, and is binding on both the student and faculty member.

The Chair must indicate whether the violation was a minor or inadvertent violation that is not subject to reporting, or whether the violation is significant enough to warrant reporting. The outcome of the informal resolution should be reported in writing to the Dean, who will maintain the record of significant violations for the duration of the student's academic career.

The informal resolution process is not available to individuals who have been previously reported.

### **FORMAL RESOLUTION**

In the event that (1) the student denies the charge, (2) the student and faculty member do not agree to informal resolution, (3) the student is a repeat offender, or (4) for any other reason for which informal resolution is not appropriate as determined by the Chair or the Dean, then the matter shall be submitted for formal resolution.

The Touro College and University System has developed the following formal method of resolution to deal with academic integrity allegations and complaints.

To institute formal resolution, the following procedures shall be followed:

- The Dean receives a written statement from the instructor or any other complainant, as the case may be.
- The written statement must include the name of the involved student, the name and status of the reporting person, and the nature of the alleged act.
- The Dean shall arrange a hearing which, generally speaking, should take place no earlier than three (3) calendar days and no later than twenty (20) calendar days after receipt of the complaint.
- The hearing shall take place before the Standing Committee on Academic Integrity of the School. See Appendix II.
- All persons involved in a hearing shall be given adequate notice of all hearing dates, times and places. Such notice, which may be by e-mail and followed by a hard copy, will be given at least twenty-four hours prior to any hearing, unless waived by the parties involved.
- Postponements of Committee hearings may be made by the interested parties or the administration. The student may be granted a postponement if pertinent information or interested parties cannot for good cause be present at the appointed time. Any postponement may not extend beyond a three-month period.
- The student charged and the person making the charges will be afforded the following opportunities:
  - To review, but not copy, all pertinent information to be presented to the Committee. The length of time for review shall be reasonable, as determined by the Committee Chair.
  - To present fully all aspects of the issue before the Committee.

Committee Hearings will proceed under the following guidelines:

- All Committee hearings and meetings are to be closed sessions. The Committee may hear other people of its choosing who may be knowledgeable about the issue(s) under consideration, and may investigate relevant written reports, discussions with involved parties, examinations, papers, or other related documents.
- A quorum of this Committee must be present in order to conduct official business and render a decision.
- All decisions shall be made by majority vote, the mechanism to be determined by Committee membership.
- The student has the right to appear in person before the Committee in order to present his/her case, but, after proper notice of a hearing, the Committee may proceed, notwithstanding the student's absence.
- The hearing is academic in nature and non-adversarial. Representation by an attorney is not permitted.
- A recording secretary may be appointed by the Committee Chair. Transcripts of the proceedings are not mandatory or required.
- All issues in dispute shall be presented orally by the Committee Chair.

- All information supporting the charges made against a student shall be presented first. Following this presentation, the student who is under investigation will present his/her side of this issue, submitting to the Committee information that he/she chooses to submit to support the student's stance or position. The Dean, his or her designee, or other members of the Administration may also meaningfully participate in this information exchange. Pursuant to the Touro College and University System Code of Conduct, the student is expected not to obstruct the investigation or proceedings.
- At the completion of all discussions, the student and his/her accuser may each make a closing statement. The administration may also be afforded an opportunity to make a statement.
- At any time during the hearing the student, his/her accuser, the Committee, and/or the Touro College and University System's representatives may raise questions about the information under review so that all aspects of the case are clarified.

The Committee shall reach a decision using the following guidelines:

- The Committee will meet in closed session to reach a decision, including recommended sanctions, if applicable. Such meeting will generally be held within one school day following the hearing.
- If the Committee seeks additional information following commencement of its deliberations, it will notify the parties within two school days, and reconvene the hearing within five school days of the conclusion of the original hearing. The Committee's final decision must then be made.
- The Committee's decision must be based solely on the evidence presented at the hearing and will be the final disposition of the issues involved, including sanctions. The Committee's decision will be presented in writing to the Dean and the student.
- In the absence of an appeal, the Dean will transmit the Committee's decision to the Touro College and University System (TCUS) Academic Integrity Council. Solely in the event of a disparity or other irregularity in the sanction imposed, the TCUS Academic Integrity Council may remand the matter to the Dean, noting the new range of permissible sanction.

## **Academic Appeal Process**

- Following notification of the Committee decision, a student may wish to appeal the decision. He or she has three (3) working days within which to submit a formal written appeal of the decision to the Dean of the Division or School. The appeal should be accompanied by a narrative explaining the basis for the appeal. The narrative should fully explain the student's situation and substantiate the reason(s) for advocating a reversal or modification of the decision by the Committee.



- After consideration of the Appeal, the Dean may accept, reject or modify the Committee’s decision, and will notify the student in writing of the decision.
- The Dean, when notifying the student of the decision, shall inform the student of his/her right to appeal an adverse decision in the event the sanction imposed was a suspension, expulsion or revocation of the degree. In all other instances, the Dean’s decision will be FINAL.
- A copy of the Dean’s Final decision will be transmitted to the Touro College and University System (TCUS) Academic Integrity Council. Solely in the event of a disparity or other irregularity in the sanction imposed, the TCUS Academic Integrity Council may remand the matter to the Dean, noting the new range of permissible sanctions, for action consistent with overall TCUS standards.

In the event the Dean and the Committee have decided to suspend, expel or revoke a student’s degree, following notification of the Dean’s decision, a student may wish to appeal the decision. He or she has five (5) working days within which to submit a formal written appeal of the decision to the respective Chief Academic Officer (e.g., the Provost or Senior Provost) or Presidential designee. The appeal should be accompanied by a narrative explaining the basis for the appeal. The narrative should fully explain the student’s situation and substantiate the reason(s) for advocating a reversal of the prior recommendation or decision by the Committee or the Dean.

The Provost may grant an appeal only on the basis of one of the following:

- Evidence of bias of one or more of the members of the Committee or of the Dean.
- New material documenting information that was not available to the Committee or a relevant Dean at the time of the initial decision.
- Procedural error.

The Provost may interview the student, but will not conduct a hearing. The Provost will consider the merits of the appeal and may even consult the Chair of the Committee. The Provost will notify the student in writing of the appeal decision. The decision of the Provost shall be final.

#### Status of Student Pending Action

Pending resolution on charges, the status of the student will not be altered except in cases where the student has been suspended, in which case an expedited resolution procedure will be in effect. If a student is suspended for any reason, all as-yet undisbursed financial aid may be withheld unless or until the action is fully resolved and the student is reinstated. If reinstated, the financial aid funds can be released to the student. If the student is dismissed, the funds will be returned to the proper agency or lender.

## Sanctions

Sanctions may be imposed by the faculty, the Dean or the Committee.

Sanctions may include the following or combinations thereof <sup>5</sup>:

### Class A Sanctions:

- Expulsion/dismissal;
- Revocation of awarded degree in the event that the violation is identified after graduation.

### Class B Sanctions:

- Suspension (up to twenty-four months)

### Class C Sanctions:

- Indication of the disciplinary action in a letter of reprimand, in reference letters, licensure and regulatory forms, etc. ;
- Notification of the violation to the other schools within the Touro College and University System;

### Class D Sanctions:

- Placement on Probation;
- Failure in the course and requiring the student to repeat the entire course/clerkship;

### Class E Sanctions:

- Ordering student to take additional ethics tutorials intended to assist student to avoid future misconduct;
- Reduction of the grade for a particular submitted piece of work, segment of work required for a course/clerkship or the entire course/clerkship with or without the option of redoing the work;
- Requiring the student to redo the assignment;

### Other Sanctions:

- Other sanctions, as deemed just and proper. For example, repeat offenders may be subject to more stringent sanctions.

## Recordkeeping

Records of the resolution of proceedings shall be kept in accordance with the following:

- If the Committee finds no merit in the allegation under discussion, the Touro College and University System records of the proceedings shall be sealed and secured in the office of the Dean until such time as any legal statute of limitations has expired. Upon the running of the limitations period, all records shall be destroyed. Should a need arise to open the sealed records, the Provost, Dean, or Chief Compliance Officer shall issue an order to open the record. These records will not go into a student's file.
- If the Committee determines that there is merit in the allegation, all matters relative to the resolution shall be entered in the student's academic file, with a copy held by the Dean.

A student may see his/her file in accordance with Touro College and University System regulations concerning inspection of records as spelled out in *Guidelines for Access to and Disclosure of Educational Records Maintained by the Touro College and University System*.

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## **RECOMMENDATIONS ON IMPLEMENTATION OF POLICY**

### **Oversight of Policy**

A Touro College and University System (TCUS) Academic Integrity Council will be appointed by the President. The TCUS Council will receive reports on resolution of Academic Integrity issues from the various units of the TCUS (as spelled out in the above policy) and would be responsible to oversee and report to the President annually on the implementation of the Academic Integrity policy throughout the Touro College and University System. The Council would also be responsible for recommending to the President any changes to this policy.

### **Distribution of Policy**

The official Touro College and University System Policy on Academic Integrity should be distributed by the President's Office. It should be added to the Faculty Handbook, Student Handbook, etc.

### **Honor Statement**

The TCUS Academic Integrity Council will draft a template of an Honor Statement that would be adopted by Division and Schools of the TCUS for use in their individual programs.

## **Conformance of Individual School Policies**

This Touro College and University System Academic Integrity Policy applies to all students in each of Touro's schools. Any act in violation of this Policy or any allegation of misconduct related to this Policy involving a student is to be reported and addressed in accordance with the adjudication procedures outlined above or those of the student's school, which in no event will be less stringent than the requirements and standards set forth in this Policy Statement.

Within three months of the distribution of the Touro College and University System Policy on Academic Integrity, the Dean of each Touro School or Division shall inform the Touro College and University System Academic Integrity Council that the School has adopted the Touro College and University System Policy on Academic Integrity and the existence of the more stringent requirements, if any. In addition, the Dean of each Touro school or division will inform the TCUS Academic Integrity Council of the identity of the Dean designated as responsible for Academic Integrity and the composition of the Individual School Academic Integrity Committee consisting of at least three members, and preferably five. A quorum of such committee shall be three members.

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## REFERENCES

1. Center for Academic Integrity. The fundamental values of academic integrity. 1999. [http://www.academicintegrity.org/fundamental\\_values\\_project/pdf/FVProject.pdf](http://www.academicintegrity.org/fundamental_values_project/pdf/FVProject.pdf)
2. Rutgers University. Academic Integrity Policy. 2011. [http://academicintegrity.rutgers.edu/files/documents/AI\\_Policy\\_9\\_01\\_2011.pdf](http://academicintegrity.rutgers.edu/files/documents/AI_Policy_9_01_2011.pdf)
3. New York Medical College: School of Health Sciences and Practice. Thesis Guidelines of the New York Medical College. 2011. <http://library.nymc.edu/informatics/ThesisGuidelines.pdf>
4. New York Medical College. Student Code of Academic Integrity and Professionalism. 2010. <http://www.nymc.edu/universitypolicies/StudentCodeofAcademicIntegrityandProfessionalism.html>
5. Includes elements of New York Medical College. New York Medical College Guidelines for Ethical Practices in Research and Policies for Dealing with instances of Alleged Violations of Ethical Standards. 2004. [http://www.nymc.edu/Research/OfficeOfResearchAdministration/assets/Ethical\\_Practices\\_in\\_Research.pdf](http://www.nymc.edu/Research/OfficeOfResearchAdministration/assets/Ethical_Practices_in_Research.pdf)
6. U.S. Department of Health and Human Services. Public Health Services Policies on Research Misconduct; Final Rule. 2005. [http://ori.hhs.gov/documents/42\\_cfr\\_parts\\_50\\_and\\_93\\_2005.pdf](http://ori.hhs.gov/documents/42_cfr_parts_50_and_93_2005.pdf)
7. With permission from the USM Library to link the Plagiarism test on the website of Touro Libraries. University of Southern Mississippi Libraries
8. Portions of the BEST PRACTICES IN THE PROMOTION OF ACADEMIC INTEGRITY IN ONLINE EDUCATION section are based on the following sources: "[Best Practice Strategies to Promote Academic Integrity in Online Education Version 2.0, June 2009](#)" and "[Student Authentication](#)" available on the WICHE\* Cooperative for Educational Technologies Website (<http://wcet.wiche.edu/>).

\*Western Interstate Commission for Higher Education

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# APPENDIX I

## Members of the Task Force

**Dr. Stanley Boylan, Chair**, Vice President of Undergraduate Education and Dean of Faculties

**Mr. David Raab**, Chief of Staff to the President

**Rabbi Moshe Krupka**, Senior Vice President of College Affairs

### Plagiarism Subcommittee

*Professor April Schwartz, JD, Chair*, Director of Law Library and Professor of Law

Professor Laurie Bobley, Coordinator of Online Education and Special Education

Dr. Howard Feldman, Chair, Faculty Senate; Professor of Biology, Lander College for Women

Ms. Sara Tabaei, Touro Library Information Literacy Services Director

Dr. Donne Kampel, Associate Dean of Faculties for Development and Evaluation

### Examination Security Subcommittee

*Dr. Jim O'Connor, Chair*, Dean of the College of Education (COE), Touro University, California

Dr. Carole Beckford, Chair, Psychology, New York School of Career and Applied Studies (NYSCAS)

Dr. Jutta Guadagnoli, Associate Professor in Basic Sciences, Touro University, Nevada (TUN)

Dr. David Lenihan, Dean, Preclinical Medicine, Touro College of Osteopathy, NY (TouroCOM)

Dr. Anthony Polemeni, Vice President of Graduate Education and Dean, Graduate Division

Ms. Frada Harel, Chair, ESL and English, New York School of Career and Applied Studies (NYSCAS)

### Campus Culture Subcommittee

*Dr. Mark Press, Chair*, Chair, Department of Psychology, Division of Undergraduate Studies

Dr. Nadja Graff, Associate Dean, School of Health Sciences

Dr. Gordon McCarter, Assistant Dean in the College of Pharmacy (COP), Touro University, California; Chair, COP Academic Standards Committee

### Ex Officio

Mr. Michael Newman, JD, Chief Compliance Officer and General Counsel, Touro College

# **APPENDIX II**

## **Divisions and Schools of Touro College**

### **DIVISION OF UNDERGRADUATE STUDIES**

LANDER COLLEGE FOR MEN

LANDER COLLEGE FOR WOMEN – THE ANNA RUTH AND MARK HASTEN SCHOOL

LANDER COLLEGE OF ARTS AND SCIENCES IN FLATBUSH

NEW YORK SCHOOL OF CAREER AND APPLIED STUDIES

SCHOOL FOR LIFELONG EDUCATION

INSTITUTE FOR PROFESSIONAL STUDIES (IPS) – MACHON L'PARNASA

TOURO COLLEGE SOUTH

### **DIVISION OF GRADUATE STUDIES**

THE GRADUATE SCHOOL OF BUSINESS

THE GRADUATE SCHOOL OF EDUCATION

THE GRADUATE SCHOOL OF JEWISH STUDIES

THE GRADUATE SCHOOL OF PSYCHOLOGY

THE GRADUATE SCHOOL OF SOCIAL WORK

THE GRADUATE SCHOOL OF TECHNOLOGY

THE SCHOOL OF HEALTH SCIENCES

### **THE JACOB D. FUCHSBERG LAW CENTER**

### **TOURO COLLEGE OF OSTEOPATHIC MEDICINE – TouroCOM**

### **TOURO COLLEGE OF PHARMACY**

### **TOURO UNIVERSITY – CALIFORNIA**

COLLEGE OF EDUCATION AND HEALTH SCIENCES

COLLEGE OF OSTEOPATHIC MEDICINE

COLLEGE OF PHARMACY

**TOURO UNIVERSITY – NEVADA**

COLLEGE OF HEALTH AND HUMAN SERVICES

School of Education

School of Nursing

School of Occupational Therapy

School of Physical Therapy

COLLEGE OF OSTEOPATHIC MEDICINE

School of Physician Assistant Studies

**TOURO UNIVERSITY WORLDWIDE**

TOURO COLLEGE – LOS ANGELES

**INTERNATIONAL PROGRAMS**

LANDER INSTITUTE MOSCOW

TOURO COLLEGE BERLIN

TOURO COLLEGE FRANCE

TOURO COLLEGE ISRAEL





# Touro University Nevada



## FACULTY HANDBOOK

Publication date: February 11, 2021

Within three (3) months after the return to the University, the recipient of the sabbatical leave will present to the Dean a written report describing his/ her professional or academic activities during the sabbatical leave.

### *Humanitarian Leave*

This is a leave of absence for faculty members who request time away from campus to provide humanitarian services to communities who would benefit from volunteer assistance, education or gratuitous health care and require they be away from campus and involves travel, usually to remote places. The policy applies to full-time (1.0 FTE) faculty and staff who have been employed at least twelve (12) months. The Dean must approve this time away from campus and may authorize up to five (5) days of paid leave.

## **ETHICS IN RESEARCH AND SCHOLARLY ACTIVITY**

Intellectual honesty and ethical behavior while performing scholarly activities, is of paramount importance to Touro University Nevada. Therefore, the faculty members of Touro University Nevada have adopted the following statement of attitudes and preventive practices: Touro University Nevada adopts the guidelines described in the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*. Investigators are responsible for maintaining organized and legible laboratory notebooks and all data sources and maintaining them in a known and accessible location for at least 10 years past the publication date.

The information from research efforts should be made available to the general public and there should be a minimum of restrictions on publication and dissemination of the results of research efforts. The use of University resources and facilities are for academic purposes and should not be used for commercial reasons unless otherwise stipulated in an agreement between the University and the faculty member.

Touro University Nevada accepts the official DHHS definition of “scientific misconduct” as encompassing “fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research.” (42CFR Part 50.102).

### *Policy on Patents and Licensing Agreements*

#### A. Policy Statement

1. Touro University Nevada encourages and supports research relating to the advancement of knowledge and the publication and practical application of such research. Research conducted by faculty, technical staff and students may sometimes lead to inventions and discoveries by inventor(s) (hereinafter referred to as “Inventor”), which should be patented or licensed in order to comply with the requirements of sponsored research grants or fellowship awards and to protect the public interest. The Touro College and University System Intellectual Property Policy is intended to encourage invention and facilitate an appropriate reward for the Inventor and also to support facilities and the research/education programs of Touro University Nevada through its share of income from commercial licensing and royalties.
2. This Policy will also apply to the commercial licensing and the royalties for inventions which are not patented, but which have commercial value or special technology or special art.

### [TCUS Policy on Intellectual Property](#)

## **Policy for authorship in professional venues**

This policy is intended to guide decisions about authorship in venues where research is disseminated, including professional publications, gray literature, poster presentations, and oral presentations at professional conferences. Investigators are encouraged to discuss author inclusion and order prior to starting the work to avoid conflicts.

### **Authorship**

Work that is published with the name of Touro University Nevada should have authorship established according to the International Committee of Medical Journal Editors' (ICMJE) guidelines unless the entity publishing the work has authorship standards that are required to allow publication.

Each author of a manuscript must meet the four criteria identified by the ICMJE:

1. Significant involvement in study conception/design, data collection, or data analysis/interpretation;
2. Involvement in drafting or revising manuscript;
3. Approval of final version of manuscript for publication; and
4. Responsibility for accuracy and integrity of all aspects of research.

Furthermore, an author must have made an intellectual contribution to the paper that is substantive. Other contributions, which are valuable but do not make a substantive intellectual contribution (e.g., biological materials, statistical analysis code), can be cited in the acknowledgments or in citations. Honorary authorship, where individuals are included without making a substantive intellectual contribution to the work, is unethical and should be avoided.

TUN encourages the use of ORCID identifiers for each author to avoid ambiguity in citation, and also the use of Authorship Grid (example below) to verify, clarify, and report the contribution of each individual to a manuscript. Depending on the number of authors, investigators may require a certain percent contribution (e.g., at least 10% contribution for a paper with five potential co-authors) to be included.

### **Order of authors**

Conventions regarding author order in a publication vary among fields, from alphabetical to the more common practice of sorting authors by the value of their contribution to the work (first author contributed the most, second author the second-most, etc.), except for the last author, who is the most senior and possibly supervisory person in the group. First authorship can be shared. The Authorship Grid shown below can also be used to assess relative contributions and authorship.

Table 1 Example of an Authorship Grid, Each potential author should be included. For the example, the four areas of participation (defined below) are set to be equal, but they can be customized to produce a weighted average in the 'Contribution' column. Additional columns can be added as needed to reflect the major facets of the work. Based on Clement, T.P. 2014. Authorship matrix: A rational approach to quantify individual contributions and responsibilities in multi-author scientific articles. *Sci Eng Ethics* 20:345-361. PMC4033822.

	Weighting (must equal 100)				Contribution
	25	25	25	25	
Potential Author	Ideas	Work	Writing	Stewardship	
Dr. Head of Lab	50	0	10	75	33.75
Student	15	50	40	0	26.25
Collaborator	20	0	10	25	13.75
Student	15	50	40	0	26.25
Total (must =100 in each column)	100	100	100	100	100

**Definitions for Table 1**

Ideas- conception of the problem, theorizing and designing experiments, and/or interpreting data

Work- data acquisition, data analysis, coding, and/or using instruments or models

Writing- drafting the article or revising it critically for important intellectual content and approving the final version

Stewardship- Past and ongoing development of resources and guaranteeing the overall integrity of the work as a whole before and after publication"

Contribution- Weighted average of ideas, work, writing, and stewardship to estimate a potential author's contribution to the work



## TOURO COLLEGE POLICY/PROCEDURE MANUAL

### INTELLECTUAL PROPERTY

#### 1.0 PURPOSE

Touro College and University System (“Touro”) recognizes that inventions may be made and copyrightable works may be created in the course of research supported by facilities, equipment or funds of or administered by Touro. Touro desires that such inventions and works be brought into use for the public benefit at the earliest possible time. Touro understands that this objective may be best accomplished through the patenting of such inventions and the licensing of such inventions and works consistent with the public interest. Touro also desires to foster the creation and publication of scholarly works by authors at Touro. This policy seeks to reconcile these interests on behalf of the public, Touro and the inventors and authors.

#### 2.0 POLICY/PROCEDURE

All Inventions as defined in the Procedure section below, subparagraph 5.1, are owned by Touro. The copyright in Scholarly Works and Individual Works (as those terms are defined in the Procedure section, subparagraph 5.2) will be owned by the Author. All other copyrightable works that are Commercial Works (as defined in the Procedure section, subparagraph 5.2) are owned by Touro. Absent a written agreement between the Inventor and Touro College to the contrary, net cash proceeds from licensing transactions, after Touro recovers all costs and fees, will be paid as per section 5.6, which is, generally speaking, thirty-three and one-third percent (33.33%) to the inventors or authors as a group, thirty-three and

one-third percent (33.33%) to the program to which they are affiliated with and thirty-three and one-third percent (33.33%) to Touro, up to five million (\$5,000,000.00). Thereafter the proceeds shall be paid as per section 5.6, which is, generally speaking, thirty-three and one-third percent (33.33%) to the inventors or authors as a group, sixty percent (60%) to Touro, and the remainder, six and sixty-seven percent (6.67%), to the program to which the inventor is affiliated. Any equity or other class of securities derived from a license transaction will be held by Touro and managed by Touro's Office of Institutional Compliance ("OIC") or its designee. Such equity or other class of securities will be liquidated as soon as reasonably practicable, with cash proceeds distributed as described above.

### 3.0 SCOPE

This policy applies to all members of the Touro community, including faculty members, administrative staff, and students.

### 4.0 DEFINITIONS

- 4.1 Inventions – inventions, discoveries and improvements, whether patentable or not, that are conceived, reduced to practice, or generated by employees or students of Touro or by others, using the facilities, equipment or funds of or administered by Touro.
- 4.2 Unpatented Materials (including biological materials)- cell lines, organisms, proteins, plasmids, DNA/RNA, chemical compounds, transgenic animals and other materials useful for research or for commercial purposes for which patent applications are not filed or, if filed, do not issue, where such materials are developed by persons covered by this policy:

- 4.3 Inventor – an individual who is or could reasonably be determined to be an inventor under applicable Federal patent law of an Invention that is claimed or described in a patent or patent application and/or an individual who has substantially contributed to the conception, design or development of an Invention that is not claimed in a patent or patent application.
- 4.4 Author – an individual determined to be an author or joint author of a Scholarly Work, Individual Work, or Commercial Work under applicable Federal copyright law.
- 4.5 Scholarly Work – copyrightable works that are submitted and accepted for scholarly publication, such as a journal article or a text book
- 4.6 Individual Work – copyrightable works that are created outside of the scope of employment or relationship with Touro and without using the facilities, equipment or funds of or administered by Touro, such as a novel or a painting.
- 4.7 Commercial Work – all copyrightable works that (a) are neither Scholarly Works nor Individual Works; (b) all materials, information, coursework, curricula, lecture materials, artifacts used or received in furtherance of the performance of their academic and other duties for Touro, including but not limited to, materials used or provided during actual course delivery; and (c) are created by employees or students of Touro or others using the facilities, equipment or funds of or administered by Touro.
- 4.8 Net Royalties/Net Proceeds- those gross receipts that Touro is entitled to retain, less: (i) Touro’s out-of-pocket costs and fees associated with securing, maintaining and enforcing intellectual property protection such as patenting and litigation expenses, (ii) out-of-pocket costs incurred by Touro in the licensing of the intellectual property, and (iii) any out-of-pocket expenses in making, shipping or otherwise

distributing biological or other materials (including, without limitation, Unpatented Materials).

5 PROCEDURES (STEP BY STEP ANALYSIS OF THE DETAILS IN IMPLEMENTING THIS POLICY/PROCEDURE)

5.1 Ownership of Inventions. All Inventions are hereby assigned by the Inventors to, and are the sole property of, Touro. Inventions, discoveries and improvements may be, for example, data, tangible materials and know how.

5.2 Ownership of Works. Touro acknowledges Scholarly Work, will be owned by the Author. Touro further acknowledges that Individual Work will be owned by the Author. All Commercial Works are hereby assigned by the Authors to, and are the sole property of, Touro. Where applicable, Commercial Works are treated as works for hire under Federal copyright law. Examples of Commercial Works would include, but are not limited to: the text of an invention disclosure written by an Author to be used in a patent application, course materials, courseware, databases, course lectures and recordings, syllabi and the source code, all course artifacts and documentation for a new computer software program created by an Author.

5.3 Ownership of Unpatented Materials. Unpatented Materials shall consist of those materials developed under or subject to agreement between Touro and a third party; or With the use of direct or indirect financial support from Touro, including support or funding from any outside source awarded to or administered by Touro; or With use (other than incidental use) of space, facilities, materials or other resources provided by or through the university. Touro shall own all rights in Unpatented Materials and may make appropriate distribution in the public interest, including licensing or transferring



Unpatented Materials, for research and commercial purposes. Individuals named as Contributors shall be entitled to a share of licensing revenues in accordance with the royalty distribution schedule set forth below.

- 5.4 Exceptions. Touro reserves a royalty-free, non-exclusive right for itself and other profit and non-profit institutions it designates to use all Inventions, Scholarly Works, and Commercial Works for academic and research purposes. With respect to Inventions, Scholarly Works, or Commercial Works, Touro may choose to modify the disposition of its ownership under this Policy. With respect to joint invention or authorship with entities or individuals not covered by this Policy, Touro will seek to resolve any ownership questions by contract in a timely manner. All Inventors or Authors must sign an Assignment Agreement (as may be amended from time to time) giving such rights to Touro once disclosure has been made as detailed below.
- 5.5 Disclosure Process. At the commencement of his or her employment or relationship with Touro, each employee, student or other person who uses the facilities, equipment or funds of or administered by Touro is required to sign an Agreement Concerning Intellectual Property (Appendix A, as may be amended from time to time) and to be bound by this Policy. Any failure of an individual to sign such Agreement shall not affect the applicability of this Policy or relieve any individual who is subject to this Policy from the obligations imposed by it, such as prompt and full written disclosure of any Invention or Commercial Work to the OIC. An Inventor or Author must promptly disclose to OIC each Invention or Commercial Work conceived or made using funds from an entity, whether Touro or a different entity, that requires disclosure of any such Invention or Commercial Work. Additionally, an Inventor or Author must disclose an Invention or Commercial Work for which he or she wishes to seek commercialization. Each Inventor or Author will cooperate with OIC

at all times in the implementation of this Policy (including executing assignments and other documents as requested by OIC) in connection with each Invention or Commercial Work, which includes applying for, obtaining, maintaining and enforcing patents or copyrights anywhere in the world; licensing or other transactions; and cooperating in any litigation, other proceedings or any dispute resolution, such as mediation, arbitration, etc. Such cooperation is a condition of receiving a share of the Net Proceeds

5.6 Role of OIC. OIC will be the primary office at Touro responsible for managing this Policy. OIC will, for example:

- a. determine whether or not to seek patent or copyright protection for an Invention or Commercial Work and implement the selected strategy;
- b. determine whether or not releasing an Invention to the Inventor or Commercial Work to the Author is in the best interests of Touro;
- c. market Inventions and Commercial Works to potential licensees;
- d. structure, close and administer license and sponsored research transactions;
- e. facilitate the distribution of cash proceeds from license transactions consistent with the terms of Paragraph 6 of this Policy; and
- f. develop and administer procedures that are consistent with this Policy.

5.7 Allocation of Cash Proceeds.

- a. The Author will retain any cash proceeds from Scholarly Works and/or Individual Works.
- b. The use of proceeds from sponsored research transactions for Inventions and Commercial Works will be governed by applicable contracts, this Policy, and any

other applicable College and University policies.

- c. Cash proceeds (including proceeds from the liquidation of Equity as described in Paragraph 5.8 below) arising from an Invention or Commercial Work will be divided as follows: (i) first, Touro will recover all development, patenting, licensing, transactional, and other costs and fees (including e.g., fees and costs of litigation, arbitration, mediation or other proceedings) relating to the Invention or Commercial Work; and (ii) second, the remaining cash proceeds (“Net Proceeds”) will be divided as delineated in Section 2.
- d. If there is more than one Inventor of an Invention or Author of a Commercial Work, then the Inventors’ or Authors’ shares of the Net Proceeds will be divided as unanimously agreed among such Inventors or Authors according to a written share allocation agreement, a copy of which will be provided to OIC as soon as possible.
- e. Touro has no obligation to resolve disagreements among Inventors or Authors as to share allocation. However, in the event of an impasse, in the interest of fairness, OIC reserves the right to intervene, at its discretion, to facilitate a determination of the share allocation using an internal Touro process or external dispute resolution process, such as binding arbitration. The external dispute resolver may determine the shares of the individual Inventors or Authors and the share of dispute resolution fees and costs to be borne by each of them. All of the fees and costs of external dispute resolution will be borne by the Inventors or Authors. To the extent Touro incurs any fees and costs (other than internal costs) in connection with determination of share

allocation, such fees and costs will be recovered by Touro only from the Inventors' or Authors' share of Net Proceeds. This Policy will not affect any existing share allocation agreements among Inventors or Authors.

- 5.8 If an Inventor or Author who is a Head of Laboratory elects to contribute any or all of his or her share of the Net Proceeds to his or her laboratory for the purposes of supporting ongoing research at Touro, then Touro will contribute a matching sum from Touro's share of the Net Proceeds to such laboratory to support such research.
- 5.9 Distribution of Net Proceeds. Net Proceeds from licensing transactions for Inventions and Commercial Works will be distributed by Touro in its ordinary course of business to Inventors or Authors according to the share allocation agreement described in Paragraph 5.6(d). No interest will be paid on Net Proceeds. Touro will use reasonable efforts to distribute any Net Proceeds due to an Inventor or Author who is no longer associated with Touro, provided that it is the sole obligation of such Inventor or Author or his or her estate to provide current contact information to OIC. In the event of the death of an Inventor or Author, any Net Proceeds due to the Inventor or Author will be distributed to his or her estate in accordance with this Policy and applicable law. Payment of Net Proceeds to an Inventor or Author will be reported by Touro as

“royalties” and not as “salary”. Distribution of Net Proceeds to an Inventor or Author may have tax consequences for the Inventor or Author, which tax consequences will be the sole responsibility of the Inventor or Author. Each Inventor or Author should consult his or her tax advisor to determine his or her tax consequences.

5.10 Touro will distribute Net Royalties received by Touro from the licensing or other distribution of its intellectual property or technology covered by this policy, as and to the extent provided in this policy. Net Royalties are calculated based on gross receipts consisting of cash and securities or other equity shares in an enterprise received by Touro in return for use of its intellectual property minus all expense. Net Royalties do not include other non- cash benefits, sponsored research funding, or other financial benefits such as gifts.

a. Standard Distribution Method: Except as otherwise provided in this policy, the formula listed in section 2.0 will apply to the distribution of Net Royalties among Inventors and Authors, their respective research laboratories, Departments/Centers and Schools and the University, based on amounts received by Touro.

5.11 License-Derived Securities. If Touro receives any equity or other class of securities (“Equity”) of a licensee as consideration in a license transaction for Inventions or Commercial Works, then the Equity will be held by Touro and managed by its designee. It is the policy of Touro to liquidate such Equity as soon as reasonably practicable, usually in the public market, rather than seek to maximize the return on the Equity by trying to time the sale of the Equity. Touro does not act as a fiduciary for any Inventor or Author concerning such Equity, and no Inventor or Author will have any

right to vote or direct the disposition of such Equity. Touro has no obligation or duty to an Inventor or Author regarding the value realized upon liquidation of such Equity, or regarding any personal tax consequences that may arise as a result of an Inventor's or Author's receipt of Net Proceeds from the disposition of such Equity. Once the Equity is liquidated, the proceeds will be treated as New Proceeds and distributed under the terms of this Policy. For a more detailed explanation of the considerations involved in Equity transactions, see the attached Appendix B on Guidelines for License Transactions Involving Securities, which is incorporated by reference into and made a part of this Policy.

- 5.12 Inventor or Author Compensation. All Inventors and Authors are required to submit to OIC existing and proposed agreements, including proposed amendments to existing agreements, with any entity that is or becomes involved with Touro in a license transaction concerning the Inventor's or Author's Invention or Commercial Work. Should any Inventor or Author receive or have a right to receive compensation directly or indirectly (except for an Inventor's or Author's share under Paragraph 6 above) from such an entity, OIC will determine whether the existing or proposed agreement would be inconsistent with the interests of Touro. If, in its sole discretion, OIC determines that such an agreement would be inconsistent with Touro's interests, the agreement may be disclosed by OIC to the Investment Subcommittee of Touro's Board of Trustees. This Committee may then recommend to Touro President appropriate action, including adjustment of Touro's and the Inventors' or Authors' shares of Net Proceeds based on the particular circumstances of the situation. The President's decision will supersede any inconsistent provisions set forth in Paragraphs 5.6 and 5.8.

## 6.1 DISPUTE RESOLUTION

Complaints concerning this Intellectual Property policy should be sent to the Compliance Officer, 500 7th Ave, New York, New York, 10018, or, alternatively, to Compliance@touro.edu. If the complainant does not wish to resolve the complaint informally, the receiving school authority must immediately forward the complaint to the Compliance Officer who will initiate an investigation no later than twenty (20) days after receipt of a complaint.

Complaints should be filed as soon as possible after the date of the alleged misconduct, and a written complaint is preferable.

A complaint, which must be submitted within the earlier of the following two dates: (a) thirty (30) days after the alleged misconduct; or, (b) the end of the semester in which the alleged incident occurred. A complaint should include the following information:

- a. Complainant's full name, home address, email, telephone number, and Touro Student/Employee ID number.
- b. The basis for the alleged complaint including any documentation that can help substantiate the issues alleged in the complaint.
- c. A clear timeline of the activities or process giving rise to the complaint.
- d. Complainant should include the term and year of his/her most recent active employment, academic, or student status within Touro.
- e. The full name, address, and telephone number of complainant's advisor or supervisor, if any.

- f. The specific harm that resulted from the alleged act and the remedy sought.
- g. The complainant's signature and the date on which the complaint was submitted.

Should there be any controversy or claim arising out of or relating to this Intellectual Property Agreement, or the breach thereof, Touro College will confer in good faith to resolve promptly such dispute with the party involved. In the event that the party and Touro are unable to resolve the dispute, then the dispute shall be exclusively heard and settled by expedited binding arbitration before a single arbitrator who shall be an attorney. Such arbitration shall be administered by a reputable organization engaged in alternative dispute resolution ("ADR Organization"), chosen by Touro in its sole and absolute discretion. Judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. Each party shall bear the cost of arbitration equally, with each party bearing their own attorney's fees and costs of presenting their own proof. The Arbitration shall be conducted in New York, New York.

This Policy will be reviewed periodically and will be updated, as necessary. All changes to this policy will be updated on the Touro Portal where the policy can normally be found. No notice is necessary when making changes to this policy and you are responsible for keeping current on any changes to this or any other Touro policy and acting accordingly.

#### 7.0 WHO IMPLEMENTS POLICY/PROCEDURE

Michael Newman, Chief Compliance Officer

#### 8.0 WHO APPROVED THIS POLICY



9.0 HISTORY – REVISIONS

10.1 Initiated: November 17, 2013 (Board Approval)

10.2 Last Review:

10.3 Next Review:

10.1 APPENDICES

10.2 Appendix A

10.3 Appendix B

APPENDIX A AGREEMENT CONCERNING INTELLECTUAL  
PROPERTY

In consideration of my employment or engagement by Touro College ("Touro") or my use of the facilities, equipment or funds of or administered by Touro, I make this agreement with Touro:

1. I hereby agree:

- a. to be bound by Touro's Intellectual Property Policy, as it may be amended from time to time (the "Policy");
- b. to make prompt and full written disclosures in accordance with the Policy, including disclosure of certain Inventions and/or Commercial Works (as those terms are defined in the Policy) and of existing and proposed agreements that I may have with an entity that is or becomes involved with Touro in a license transaction concerning my Inventions or Commercial Works;
- c. to assign and do hereby assign to Touro all of my right, title and interest in, to and under the Inventions and/or Commercial Works of which I am an Inventor or Author; and
- d. that all right, title and interest in and to the Inventions and/or Commercial Works discovered or created by me are the property of Touro under the terms of the Policy.

2. At the request of Touro at any time and in accordance with the Policy, I will execute, without charge, all documents relating to the Inventions and/or Commercial Works, including those reflecting the

assignment herein and assist Touro in applying for, obtaining, maintaining and enforcing associated patent and copyright applications, patents and copyrights anywhere in the world.

3. At the request of Touro, I agree to assist Touro, without charge (except for reasonable compensation for extraordinary work, if I am no longer employed or engaged by Touro) in the following:

- a. Preparation, filing, prosecution of applications and maintaining patents or copyrights anywhere relating to any Invention or Commercial Work;
- b. Licensing or other transactions relating to any Invention or Commercial Work; and
- c. Any litigation, other proceedings (in courts, patent offices, copyright offices or elsewhere), or any dispute resolution process, including mediation, arbitration or negotiation, relating to any Invention or Commercial Work.

4. This Agreement will inure to the benefit of Touro and its nominees and their respective legal representatives, successors and assigns. This Agreement will be binding now and in the future on me and my heirs, legal representatives, executors, administrators and assigns. Except with the prior, written consent of an authorized official of Touro, no attempt by me to assign or transfer any rights in Inventions or Commercial Works will relieve me of any of my obligations under this Agreement or the Policy.

5. This Agreement, together with the Policy, supersedes any prior agreements or understandings I may have signed or to which I may be bound with respect to the subject matter of this Agreement. I represent and warrant that I have not entered into any agreement, understanding or obligation with any person, organization or corporation that is in conflict with my obligations under this Agreement or the Policy.

Signature: \_\_\_\_\_ Dated: \_\_\_\_\_

Printed Name: \_\_\_\_\_

## APPENDIX B GUIDELINES FOR LICENSE TRANSACTIONS INVOLVING SECURITIES

One category of potential licensees for an Invention or Commercial Work that is evaluated by OIC is a start-up company. Typically, a start-up company's survival will be tied to the development of the technology licensed to it by Touro, and the company's research and development efforts will be focused on that technology. Often, a start-up company can represent the best opportunity for the development of an early-stage technology. In some cases, a start-up company may represent the only licensing alternative available.

Most start-up companies, whether just formed or in existence for a few years, have little cash and no revenues. Under these circumstances, the heavy cash burden on the company of a traditional license transaction would divert cash needed for research and development efforts and diminish the company's ability to attract initial investors. In such a licensing transaction, equity or other class of securities ("Equity") is issued to Touro at the commencement of the license, and most of the company's cash obligations to Touro are postponed until milestones are reached and sales and sublicense fees are generated. Equity is not preferred to cash by Touro. Rather, in the absence of sufficient cash compensation available from the company and in lieu of all or part of the initiation fees, in addition to future fees and royalties, Equity may be accepted as compensation by Touro. Thus, the issuance of Equity in a license transaction is a reasonable business solution that enhances the overall potential financial return to Touro and remains acceptable to the start-up company and its investors.

OIC uses the following list, which must be read in context of the entire Policy, as a guideline in negotiating license transactions with start-up companies:

- The company should be legally formed, managed by executives experienced in the company's industry, and have the potential for credible investors.
- Touro, its officers, its employees, and the Inventors or the Authors should not hold management or fiduciary positions in the company.
- If an Inventor or Author receives or has a right to receive Equity in the company, the requirements of Touro's Policy on Conflict of Interest and Commitment in Research must be followed.
- In the event that an Inventor or Author holds or will hold Equity in a company on an individual basis, the distribution of Net Proceeds may be determined according to Paragraph 5.9 of the Policy.
- Touro should hold a minority Equity position, generally not more than fifteen percent (15%) of all outstanding Equity on a fully-diluted basis of the company post financing.
- Touro should not invest cash directly in the formation of the company or in follow-on rounds of financing. This does not preclude, for example, investments in the company by venture capital funds in which Touro has invested or the exercise of warrants or options held by Touro.
- Once Equity is received by Touro, the Equity will be held, managed and liquidated in accordance with the Intellectual Property Policy and other applicable policies and procedures of Touro.

**Institutional Review Board**

**MANUAL**

**Touro University Nevada**



Touro University Nevada  
874 American Pacific Drive  
Henderson, NV 89014

Edited November 2014



## Table of Contents

Role of the Institutional Review Board	2
Research Covered by TUN IRB Policies	3
IRB Forms	4
Application Procedures	4
Questions about Research Procedures and Application Procedures	4
Structure of the IRB	5
Review Process for Applications	5
Level of Risk	6
Informed Consent	8
Actions of the IRB	10
Requests for Reconsideration	11
Unanticipated Risks	11
Reporting Changes to an Approved Application	11
Requests for Extension	11
Records and Reporting Requirements	12



## Policies and Procedures for the Protection of Human Subjects

### **Role of the Institutional Review Board**

The Institutional Review Board (IRB) exists primarily to provide protection for human subjects who participate in research. Thus, the main focus of the IRB is to review applications to identify the risks which may exist for potential research participants. However, one of the ethical justifications for research involving human participants is the social value of advancing scientific knowledge and promoting human welfare. If a research study is so methodologically flawed that little or no reliable information will result, it is unethical to put participants at risk or even to inconvenience them through participation in such a study. To this extent, the IRB must also consider the soundness of the methodology that is proposed for a research study, so that it can determine whether “risks to subjects are reasonable in relation to . . . the importance of the knowledge that may reasonably be expected to result” [Federal Policy §46.111(a) (2)].

Touro University Nevada (TUN) has obtained a Federal-wide Assurance for the Protection of Human Subjects from the U.S. Department of Health and Human Services, by agreeing to follow the Code of Federal Regulations [see <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>]. This designates that the IRB for TUN has the responsibility to review all research which involves the use of human subjects, regardless of the source of support for that research. The IRB is required to (1) identify the risks associated with participation in a research study, (2) determine that those risks will be minimized as much as possible, (3) identify the probable benefits of the research, (4) determine that any risks are reasonable in relation to the benefits for the participants and the importance of the knowledge to be gained, (5) insure that participants will be given an accurate and fair description of any risks or discomforts and any anticipated benefits, and (6) determine how long to approve the research and the need, if any, for periodic review while the study is being conducted. The IRB must also determine that there are adequate provisions to protect the privacy of the participants, to maintain the confidentiality of the research data, and to provide additional safeguards for any participants who are likely to be members of a vulnerable population.

The IRB usually approves research for a period of one year, which is the maximum allowed [Federal Policy §46.109(e)]. Investigators who need to continue their research beyond that time may request up to two one-year extensions. This request must be submitted to the Chair of the IRB using the ***Continuing Review Form***. The investigator needs to confirm that there have been no changes in the targeted participants, the materials, or the procedures for the research and those participants have not had any

adverse experiences thus far in the research. If there is a need to continue the research beyond a third year, a new protocol must be submitted and the IRB must do a full review of the protocol. In accordance with federal policy, some research projects may not be approved for a full year. This could occur, for example, because of the overall risk of the study or because some of the relevant information could not be provided at the time the protocol was first submitted (e.g., a fieldwork or ethnographic study in which the nature of the questions to be asked is not determined until the study is underway).

The investigator is obligated to promptly inform the IRB of any unexpected risks discovered while conducting the research and to promptly report any occurrence of serious harm to participants by completing the **Adverse Event Form** [Federal Policy §46.103(b) (5)]. Although the IRB does not anticipate situations calling for the following actions, it does have the authority to observe, or to require a third party to observe, the consent process and the research itself [Federal Policy §46.109(e)] or to suspend or terminate approval of research that is not being conducted in accordance with requirements it has established or that has been associated with unexpected serious harm to participants [Federal Policy §46.113].

### **Research Covered by TUN IRB Policies**

Any human subject research that involves the use of TUN time, facilities, resources, and/or students is covered by these IRB policies. *Research* refers to a systematic investigation designed to develop or contribute to generalizable knowledge [Federal Policy §46.102(d)]. Activities sponsored by an outside agency that utilize TUN resources are considered to be under the auspices of both the TUN and the outside agency. In this case, approval must be obtained from IRBs for the protection of human subjects of both TUN and the outside agency. TUN IRB only reviews research proposals submitted by a principal investigator (PI) who is affiliated with TUN.

Research or related activities involving the use of human subjects that are conducted by TUN employees or students without the use of any University time, facilities, resources and/or students are not covered by these IRB policies. Individuals conducting such research outside the auspices of the TUN should inform themselves of their legal responsibilities. Research conducted by students within an established TUN course and in which the only participants are other students in the same course is not covered by these policies. Research in which the students in a course observe the public behavior of others but do not interact with them is also not covered by these policies. In both instances, the instructor of the course should be sure that appropriate research procedures are followed. Research in which the students in a course do interact with participants outside of the course (e.g., by conducting a survey) are covered by these IRB policies.

For any activities related to human subjects to be covered under the IRB policies, a research component must be present. In general, if one of the goals of the investigation is an expansion of scientific knowledge, a research component is inherent in the activity, and the project should be reviewed by the IRB.

Investigators affiliated with TUN have the normal legal protections provided by the TUN, if their activities have IRB approval and if they are working within the scope of their employment or TUN affiliation. If these conditions have not been met, TUN will not be in a position to protect TUN investigators performing research with human subjects.

### **IRB Forms**

All forms mentioned in the manual can be found under documents on TUN Blackboard, the TUN website under the Research Department, or by contacting the Department of Research.

### **Application Procedures**

Investigators must electronically submit all appropriate completed forms to the Chair of the IRB and to the Department of Research using the **TUN IRB Application Form**. The application must include specific references to any attachments (e.g., consent forms, tests, interview questions) that are needed, and must be included with the electronic application. Do not submit any other documents as the IRB is unable to review them.

When submitting an application to the IRB, investigators need to take into consideration the IRB's deadlines for its regularly scheduled meetings and the possibility that the IRB might request additional information and/or changes in the protocol and thus need to review the protocol again at a subsequent meeting. Applications should be submitted at least two weeks before the regularly scheduled IRB meeting for them to be reviewed before the desired starting date for the research and before any deadlines of funding agencies.

### **Questions about Research Procedures and Application Procedures**

Questions about the application procedures for human subject's approval may be directed to the Chair of the IRB, or the Department of Research. Any exceptions to the policies outlined in this manual must be approved by the IRB.

### **Structure of the IRB**

The IRB shall consist of at least five members with varying backgrounds. Members are expected to have appropriate professional expertise, maturity, and experience to thoroughly review a variety of research activities conducted at TUN. Members should also be sensitive to relevant professional standards, community attitudes and diversity, applicable laws, and institutional requirements. At least one member of the IRB must have no affiliation with TUN other than serving on the IRB. The IRB shall not consist entirely of members of the same sex or members of one profession. The IRB shall include at least one member whose primary concerns are in a nonscientific area. No member of the IRB shall be involved in the initial review or any continuing review of an activity in which the member is an investigator or a sponsor, except to provide information requested by the IRB. The IRB may invite individuals with competence in special areas to serve as non-voting reviewers when dealing with complex issues. A quorum shall consist of a majority of the IRB's membership. Members of the IRB are appointed by the TUN Faculty Senate in consultation with the Director of the Department of Research. The Chair of the IRB is appointed by the CEO/Senior Provost of Touro Western Division. Appropriate administrative assistance and support for IRB functions are to be provided by TUN through the Department of Research.

### **Review Process for Applications**

IRB applications are forwarded to members of the IRB in advance of the scheduled meeting dates to allow time for each member to individually review each application. The applications are then discussed at the scheduled meeting by the full IRB. A quorum, defined as a majority of the IRB's membership, must be present for the meeting for any vote to occur.

IRB members consist of faculty, administrators, employees, and community members who have volunteered to serve in this capacity in addition to their other obligations to TUN or the community. While the IRB attempts to be as responsive as possible to investigators, it may not be able to respond as quickly as investigators sometimes request.

For example, an "expedited review" has a particular meaning under federal regulations, and that this type of review (described in the next paragraph) may actually require a longer amount of time than the usual process, contrary to expectations about the word "expedited." For this reason, when an expedited review is requested, the IRB will usually consider that request only for an application that has a clearly stated explanation for urgency, is submitted at a time when there is more than one month between regularly scheduled meetings of the IRB, could not reasonably have been submitted in a more timely fashion, and can possibly be reviewed using the "expedited" process more quickly than if it were reviewed at the next scheduled meeting.

When an expedited review is appropriate, the Chair of the IRB will forward the application to at least two IRB members for their independent review. If those IRB members and the Chair agree that an expedited review is permitted the Chair will so inform the investigator and notify the IRB at its next meeting. If the reviewers do not agree on an action, or if any of them so request, the protocol will be considered ineligible for expedited review and will be placed on the agenda for the next meeting.

### **Level of Risk**

The IRB uses the following definitions when reviewing protocols to determine their level of risk to participants:

1. *Exempt*: Some categories of research are considered “exempt” under federal regulations. Examples include observational research on adults (but not children or minors) when the observations are recorded in a way that does not allow individual participants to be identified, reviews of pre-existing records or surveys that are completely anonymous, and studies which evaluate public service or benefit programs. Investigators of potential exempt research must complete and submit the ***Exempt Determination Form*** to IRB for review. For more specific information, see Federal Policy §46.101(b).
2. *No Risk*: Research is approved as “no risk” when no harm or discomfort is anticipated for participants.
3. *Minimal Risk*: Research is approved at “minimal risk” when the probability and magnitude of harm or discomfort anticipated for participants are no greater than what might be encountered in daily life or during the performance of routine physical or psychological examinations or tests [Federal Policy §46.102(i)]. (Note that only “minimal risk” is defined in the federal regulations.)
4. *At Risk*: Research is approved as “at risk” when the probability and/or the magnitude of possible harm (physical, psychological, social, or economic) from participation in a research study are more than minimal.

The following descriptions provide additional information about some possible kinds of risks that may occur in research studies:

1. *Physical Harm*: An example of minor physical harm would be the pain associated with taking a blood sample from a vein. Note, however, that taking a blood sample could be a significant risk to a hemophiliac; participants should be screened for this condition if the research is to be considered minimal risk. Similarly, outdoor exercises that might be considered relatively safe for healthy adults could be dangerous for persons with asthma.

2. *Psychological Harm*: An example of psychological harm would be stress or feelings of guilt or embarrassment from thinking or talking about one's own behavior or attitudes on sensitive topics such as drug use, sexual orientation, selfishness, or violence. These feelings may be aroused from being interviewed or from filling out a questionnaire. Another kind of risk would be an invasion of privacy, for example, from covert observation (even in a public place) of behavior that participants would likely consider private. Still another risk of psychological harm occurs when there is inadequate protection for the confidentiality of data that has been given voluntarily (e.g., by retaining audiotapes or videotapes longer than is necessary to analyze the relevant information).
3. *Social and Economic Harm*: Some invasions of privacy or breaches of confidentiality could result in embarrassment or harm to a participant's reputation within his or her business or social group, a loss of employment, or criminal prosecution. Areas of particular sensitivity include such topics as alcohol or drug abuse, child or partner abuse, and sexual behavior.
4. *Inadequate Protection for the Confidentiality of Research Data*: Where identifiers of individual participants are not required by the design of the research study, none should be recorded. If identifiers are recorded, they should be separated, if possible, from the data; stored securely, with linkage restored only when necessary to conduct the research; and destroyed when they are no longer needed. More elaborate procedures may be needed in some studies, either to give participants the confidence they need to answer questions truthfully (e.g., promising to submit course grades before analyzing data from one's own students) or to enable the investigator to offer honest assurances of confidentiality. Even when participants are otherwise anonymous, there may be a danger of deducing the identity of individual participants by combining specific pieces of information collected during the research about the participants. Additional precautions may be needed to deal with these circumstances.

In some studies, keeping the identity of participants confidential may be as important as or more important than keeping the research data confidential. In those instances, any written record linking participants to the study may be a threat to confidentiality. Even in studies where confidentiality is not a concern, no lists should be retained identifying those who elected not to participate.

Where data are being collected about sensitive issues (such as illegal behavior, alcohol or drug use, or sexual practices or orientation), protection of confidentiality consists of more than just preventing accidental disclosure of the data. There have been instances where the identities of participants, or research data about particular participants, have been sought by law enforcement agencies, sometimes by subpoena and with the threat of incarcerating an uncooperative researcher. Some investigators may need to obtain a federal certificate of confidentiality [Public Health Service Act §301(d)]

to protect the privacy of their participants. The certificate protects the investigator from being compelled to provide the names or other identifying characteristics of research participants in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding. (Its precedence over state law has been upheld in the New York Court of Appeals.) The certificate does not protect identifiable data that the participant may disclose about other people.

### **Informed Consent**

Informed consent assures that prospective participants understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. It is a continuing process, not just a piece of paper; especially in a lengthy study, it may be necessary to obtain consent on more than one occasion. It protects both the participant and the investigator, who otherwise faces legal hazards. Investigators may seek consent only under circumstances that provide prospective participants or their representative's sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. Furthermore, the information must be written in language that is understandable to the participants. If the prospective participants include persons who are unlikely to be familiar with specific technical terms, persons with limited verbal or cognitive skills, or persons whose primary language is not English, special care must be taken to ensure that both oral presentations and written consent forms are comprehensible to all participants. When participants may include members of a vulnerable population (such as children, elderly persons, prisoners, or economically or educationally disadvantaged persons), additional safeguards are needed to protect the rights and welfare of those subjects.

When children and/or adolescents are participants in a research study, the investigator must solicit both the assent of the children and the permission of their parents or guardians. There are limited exceptions for situations in which the parents' interests may not adequately reflect the child's interests. In certain circumstances, older adolescents may have the legal authority to give their consent even though they are not yet legally considered adults (i.e., are under the age of 18). Also, the Buckley Amendment requires parental consent for release of records or identifiable information about children in public schools, and instructional materials to be used in connection with research must be available for inspection by parents or guardians.

To minimize the possibility of coercion or undue influence, it is generally preferred that participants be recruited by open, written invitation rather than by personal solicitation. For similar reasons, it is also preferred that professors not solicit their own students as participants and that supervisors not include their own employees in research. If advertising will be used to recruit participants, the IRB needs to review that advertising to be sure that the information will not be misleading to potential participants. Similarly, if participants are to be paid for their time, either monetarily or through a gift, the IRB

needs to review the amount of the payment and provisions for full, partial, or no payment (for example, if a participant withdraws part way through the research) to assure that participants will not be unduly influenced by the payment.

In most cases, federal regulations require that participants sign a written consent form [Federal Policy §46.117], although the consent document is not a substitute for discussion of the relevant information with prospective participants. Participants must be given a clear and fair explanation of the research procedures, their risks and benefits, and provisions for confidentiality in the research. Each participant must provide informed consent prior to participation. The person who signed the consent form must be given a copy as a reference and reminder of the information conveyed.

A “short form” may sometimes be approved for the consent [Federal Policy §46.117(b)(2)]. This means that the information is presented orally to prospective participants without a written version of it in the consent document. The IRB must review and approve a written summary of what will be presented orally. The participant must sign the short consent form (stating that the information has been provided orally), and a third person must witness the oral presentation and must sign both the short consent form and a copy of the written summary of the oral presentation. The investigator obtaining the consent must also sign the written summary. A copy of the written summary must be provided to the participants even though they are not asked to sign the written summary.

A waiver of written consent or using an alternate method to document consent may only be considered if (1) the research involves no more than minimal risk, (2) the waiver or alteration will not adversely affect the rights and welfare of the participants, (3) the research could not reasonably be carried out without the waiver or alteration, and (4) whenever appropriate, participants are provided with additional pertinent information in a debriefing after their participation [Federal Policy §46.116(d)]. Furthermore, especially in studies which involve the collection of sensitive information (e.g., sexual or criminal activity), a request to waive written consent may be considered only if (1) the only record linking the participant to the research would be the consent document and the main risk in the research would be the potential harm from a breach of confidentiality (in this case, participants must be asked whether they want documentation of their consent, and they may elect to sign a consent form or not), or (2) the research is no more than minimal risk and involves no procedures for which written consent would normally be required outside of the research context [Federal Policy §46.117(c)]. The IRB may still require that a written statement of pertinent information be provided to participants who do not sign a consent form.

It may be appropriate to waive written consent (but not informed consent) for fieldwork studies where the nature of the continuing interactions with the investigator is not easily reduced to a consent form. For some observational studies of people who are not aware that they are being observed or who are unaware that their behavior is being recorded



for research purposes, it may be appropriate to completely waive the consent requirement if the knowledge to be gained is important, but such research can also raise serious ethical concerns about protecting the privacy of the unwitting participants. Similarly, it may be appropriate to waive the consent requirement for studies of pre-existing records if the information contained in the files is not particularly sensitive, the investigator has devised procedures to protect the confidentiality of the information to be collected, and the study could not practicably be carried out if consent were required.

Sometimes investigators plan to withhold information about the real purpose of the research, or even to give participants false information about some aspect of the research. This means that the participant's consent may not be fully informed. The degree to which this is acceptable depends on whether the information to be withheld would influence the decision of prospective subjects about participating in the research. When subjects have unwittingly participated in research or have knowingly participated in research that involved some form of deception, they should be debriefed afterward with pertinent information about the study whenever this can be done in a way that reduces rather than produces pain, stress, or anxiety.

Although institutions are not required to provide care or payment for research injuries, the IRB generally expects investigators to provide a way for participants to obtain at no cost any services necessitated by research injuries. This information needs to be provided in the consent form. In any case, the consent process must not involve the use of any exculpatory language through which the participant is made to waive or to appear to waive any of his or her legal rights, or releases or appears to release the investigator, sponsor, institution, or their agents from liability for negligence [Federal Policy §46.116].

### **Actions of the IRB**

When reviewing an application, the IRB may decide to approve the research, to conditionally approve the research with a request for minor modifications, to request that the protocol be resubmitted with additional information and/or more substantive modifications, or to disapprove the research (in general, disapproval would only occur if the IRB finds significant risks in the research that cannot be minimized, or when recommendations from the IRB for minimizing such risks have been declined by the investigator). The Chair of the IRB may communicate these initial decisions by e-mail to the investigator, particularly when the IRB has requested modifications to the research. A letter indicating approval of the research will be sent when the protocol is fully approved. The Chair is authorized to act on behalf of the IRB to either approve the minor modifications submitted in response to a conditional approval or refer the revised protocol to the IRB for its review.

When making these decisions, the IRB also makes its judgment of the level of risk in the proposed research. Applications may be classified as exempt or approved as

involving no risk, minimal risk, or more than minimal risk. Risks must be considered reasonable for the research, appropriate procedures must be used to minimize any risks, and the potential benefits of the research must outweigh the potential risks.

### **Requests for Reconsideration**

If an applicant believes that decisions of the IRB or changes requested by the IRB are incorrect, unfair, or improper, the applicant may submit a request for reconsideration to the IRB. The request should be made in writing to the Chair of the IRB and should include the reasons for disagreement with the IRB's action. The request for reconsideration will be considered by the full IRB, and the applicant will be invited to attend the meeting of the IRB when the request for reconsideration is discussed.

### **Unanticipated Risks**

Any unanticipated problems involving risk to participants or others must be immediately reported to the IRB in writing by completing the **Adverse Event Form**.

### **Reporting Changes to an Approved Protocol.**

Any significant changes to a previously approved protocol must be submitted to the IRB by completing the **Amendment Request Form** or the **Reporting Deviations Form**. Examples of significant changes include a different or additional principal investigator, an intention to recruit participants from a different source or via a different advertising method, changes in the consent form, and changes in any materials or equipment used in the project, changes in the research procedures, or the discovery of previously unidentified risks in the research. The IRB will respond with a letter indicating its approval of the proposed changes or, if it is unable to approve the changes, its request for additional information or for alternative changes. Investigators should not change their protocol until approved by IRB.

### **Requests for Extension**

If the research will extend past the expiration date of IRB approval for the study, the investigator will need to ask for a renewal by completing the **Continuing Review Form**. When the IRB has approved an extension for the research, a letter will be sent confirming that approval.

When requesting such an extension, the investigator should be aware of the IRB's deadlines for its regularly scheduled meetings. Requests for extension must be submitted at least two weeks before the regularly scheduled meeting for them to be considered for approval before the expiration date of the prior approval and

before any deadlines of funding agencies. The IRB is not obligated to send a reminder notice to the investigator about this requirement.

### **Records and Reporting Requirements**

Investigators are required to obtain and keep, for a period of three years after the conclusion of the research, documentary evidence of informed consent from the participants.

The IRB is required to maintain documents related to each of its activities, including applications (and attachments) received, requests for modification or extension of approval, reports of adverse reactions, correspondence with investigators, minutes of meetings (with details of IRB deliberations), and a list of IRB members. These records must be maintained for at least three years after the conclusion of the research. Records related to specific research activities are not open to persons who are not members of the IRB, other than for auditing functions by federal agencies engaged in the protection of human subjects.



# Touro University Nevada

## **FDA Regulations Relating to Good Clinical Practice and Clinical Trials**

All clinical trials at TUN must follow University and FDA policies and guidelines. A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcome.

Prior to award, institutional approvals must be received by OSP:

If the protocol involves human subjects, it must be approved by the University's Institutional Review Board (IRB). Please go to the TUN IRB website for further instructions.

These approvals must be received by OSP in form of an Approval letter. Until approval receipt, you will be unable to start your project, so please start the necessary process as soon as you have received an indication of strong potential for award by the Sponsor.

It is critical that investigators determine if their study/ancillary study meets the NIH definition of clinical trial in order to:

- Select the correct Funding Opportunity Announcement (FOA).
- Ensure the application includes all information required for Peer Review.
- Ensure that they are in compliance with appropriate policies and regulations.
- For federally sponsored Clinical trials, please go to NIH Clinical Trial Policy page for requirements.

To determine if your study meets the NIH definition of clinical trial, answer the four questions in the NIH Definition of a Clinical Trial document. For ancillary studies, take into account only the work proposed in the ancillary study, not the work being done in the parent project.

### **Common Clinical Trials Questions**

*Are all clinical trials FDA regulated?*

All such research studies must be conducted in accordance with FDA requirements for the protection of human subjects and IRBs, regardless of source of funding (21 CFR Parts 50 and 56). Such trials must comply with the FDA and the DHHS human participant regulations.

*Do all clinical trials need to be registered?*

The International committee of medical journal editors (ICMJE) requires registration of trial methodology, but does not require registration of trial results, however, the U.S. Food and Drug Administration Amendments Act of 2007 does require researchers to register results.

*What studies must be registered on clinical trials gov?*

ClinicalTrials.gov allows the registration of clinical studies with human subjects that assess biomedical and/or health outcomes and that conform to: Any applicable human subject or ethics review regulations (or equivalent). Any applicable regulations of the national or regional health authority (or equivalent).

Instructions to submit studies: <https://clinicaltrials.gov/ct2/manage-recs>

**Here are links to FDA regulations governing human subject protection and the conduct of clinical trials.**

- [Electronic Records: Electronic Signatures \(21 CFR Part 11\)](#)
- [Regulatory Hearing Before the Food and Drug Administration \(21 CFR Part 16\)](#)
- [Protection of Human Subjects \(Informed Consent\) \(21 CFR Part 50\)](#)
- [Financial Disclosure by Clinical Investigators \(21 CFR Part 54\)](#)
- [Institutional Review Boards \(21 CFR Part 56\)](#)
- [Good Laboratory Practice for Nonclinical Laboratory Studies \(21 CFR Part 58\)](#)
- [Investigational New Drug Application \(21 CFR Part 312\)](#)
- [Applications for FDA Approval to Market a New Drug \(21 CFR Part 314\)](#)
- [Bioavailability and Bioequivalence Requirements \(21 CFR Part 320\)](#)
- [New Animal Drugs for Investigational Use \(21 CFR Part 511\)](#)
- [New Animal Drug Applications \(21 CFR Part 514\)](#)
- [Applications for FDA Approval of a Biologic License \(21 CFR Part 601\)](#)
- [Investigational Device Exemptions \(21 CFR Part 812\)](#)
- [Premarket Approval of Medical Devices \(21 CFR Part 814\)](#)

# GUIDE FOR THE CARE AND USE OF LABORATORY ANIMALS

Eighth Edition

Committee for the Update of the Guide for the Care  
and Use of Laboratory Animals

Institute for Laboratory Animal Research

Division on Earth and Life Studies

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*OF THE NATIONAL ACADEMIES*

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Nutrient Requirements of Laboratory Animals, Fourth Revised Edition  
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Laboratory Animal Management: Dogs (1994)  
Recognition and Alleviation of Pain and Distress in Laboratory Animals  
(1992)  
Education and Training in the Care and Use of Laboratory Animals: A  
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Use of Laboratory Animals in Biomedical and Behavioral Research (1988)  
Animals for Research: A Directory of Sources, Tenth Edition and  
Supplement (1979)  
Amphibians: Guidelines for the Breeding, Care and Management of  
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## Reviewers

This eighth edition of the *Guide for the Care and Use of Laboratory Animals* has been reviewed in draft form by individuals chosen for their diverse perspectives and expertise, in accordance with procedures approved by the Report Review Committee of the National Research Council. The purpose of this independent review is to provide candid and critical comments that will assist the Committee in making its published report as sound as possible, and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberation process. The Committee thanks the following individuals for their review of the draft report:

Michael B. Ballinger, Amgen  
Philippe J.R. Baneux, PreLabs  
Stephen W. Barthold, University of California-Davis  
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Gemma Perretta, National Research Council, Italy  
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George E. Sanders, University of Washington  
Allen W. Singer, Battelle Memorial Institute  
William J. White, Charles River Laboratories

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations nor did they see the final draft of the report before its release. The review of this report was overseen by John Dowling, Harvard University, and John Vandenberg, North Carolina State University. Appointed by the National Research Council, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

# Preface

The purpose of the *Guide for the Care and Use of Laboratory Animals* (the *Guide*), as expressed in the charge to the Committee for the Update of the *Guide*, is to assist institutions in caring for and using animals in ways judged to be scientifically, technically, and humanely appropriate. The *Guide* is also intended to assist investigators in fulfilling their obligation to plan and conduct animal experiments in accord with the highest scientific, humane, and ethical principles. Recommendations in the *Guide* are based on published data, scientific principles, expert opinion, and experience with methods and practices that have proved to be consistent with both high-quality research and humane animal care and use. These recommendations should be used as a foundation for the development of a comprehensive animal care and use program, recognizing that the concept and application of performance standards, in accordance with goals, outcomes, and considerations defined in the *Guide*, is essential to this process.

The *Guide* is an internationally accepted primary reference on animal care and use, and its use is required in the United States by the Public Health Service Policy. It was first published in 1963, under the title *Guide for Laboratory Animal Facilities and Care*, and was revised in 1965, 1968, 1972, 1978, 1985, and 1996. More than 550,000 copies have been printed since its first publication.

In 2006 an ad hoc committee appointed by the Institute for Laboratory Animal Research recommended that the *Guide* be updated. The Committee for the Update of the *Guide for the Care and Use of Laboratory Animals* was appointed in 2008 by the National Research Council; its 13 members

included research scientists, veterinarians, and nonscientists representing biomedical ethics and the public's interest in animal welfare. The Committee widely solicited written and oral comments on the update of the *Guide* from the scientific community and the general public; comments at open meetings (on September 26, 2008, in Washington, DC; October 16, 2008, in Irvine, California; and November 14, 2008, in Chicago) as well as written comments submitted to or requested by the Committee were considered. In addition, the Committee studied the materials submitted to NIH in response to its 2005 Request for Information (NOT-OD-06-011). All comments contributed substantially to this eighth edition of the *Guide*.

In approaching its task, the Committee carried forward the balance between ethical and science-based practice that has always been the basis of the *Guide*, and fulfilled its role to provide an updated resource that enables the research community to proceed responsibly and in a self-regulatory manner with animal experimentation. The *Guide* is predicated on the understanding that the exercise of professional judgment both upholds the central notion of performance standards and obviates the need for more stringent regulations.

Laboratory animal science is a rapidly evolving field and the Committee identified a number of areas in which current available scientific information is insufficient; additional objective information and assessment are needed to provide a scientific basis for recommendations in future editions of the *Guide*. Although pursuing these concepts was beyond this Committee's charge, the following two topics merit further study: (1) space and housing needs of laboratory species and (2) the need and best methods for providing enrichment, exercise, and human contact.

The need for continual updating of the *Guide* is implicit in its objective "to provide information that will enhance animal well-being, the quality of research, and the advancement of scientific knowledge that is relevant to both humans and animals" (Chapter 1). The irregular and increasing intervals between updates, reaching a 14-year gap between the seventh edition and this eighth edition, mean that important new research findings might wait more than a decade before being reflected in recommended practice. Addressing this concern was beyond the charge of this Committee; we noted, however, that regular and more frequent updates of the information in the *Guide* will promote laboratory animal welfare and support high-quality scientific data. A formal process for revising the information in the *Guide*, including the updating of practice standards, could meet this need.

In undertaking this update, the Committee acknowledged the contributions of William I. Gay and Bennett J. Cohen in the development of the original *Guide*. In 1959, Animal Care Panel (ACP) President Cohen appointed the Committee on Ethical Considerations in the Care of Laboratory Animals to evaluate animal care and use. That Committee was chaired by Dr. Gay,

who soon recognized that the Committee could not evaluate animal care programs objectively without appropriate criteria on which to base its evaluations—that is, standards were needed. The ACP Executive Committee agreed, and the Professional Standards Committee was appointed. NIH later awarded the ACP a contract to “determine and establish a professional standard for laboratory animal care and facilities.” Dr. Cohen chaired the ACP Animal Facilities Standards Committee, which prepared the first *Guide for Laboratory Animal Facilities and Care*.

This edition of the *Guide* was financially supported by the National Institutes of Health; the Office of Research Integrity, Department of Health and Human Services; the US Department of Agriculture (USDA); the Association for Assessment and Accreditation of Laboratory Animal Care International; the American Association for Laboratory Animal Science; Abbott Fund; Pfizer, Inc.; the American College of Laboratory Animal Medicine; the American Society of Laboratory Animal Practitioners; and the Association of Primate Veterinarians.

The Committee for the Update of the *Guide for the Care and Use of Laboratory Animals* expresses its appreciation to the Animal Welfare Information Center, National Agricultural Library, USDA, for its assistance in compiling bibliographies and references. This task would have been formidable without the help of the Center’s staff. Appreciation is also extended to the reviewers of this volume, to Rhonda Haycraft for providing exemplary administrative and logistical assistance, and especially to Lida Anestidou, Study Director, who, through extraordinary patience, persistence, and scientific insight, managed the process from beginning to end.

Readers who detect errors of omission or commission are invited to send corrections and suggestions to the Institute for Laboratory Animal Research, National Research Council, 500 Fifth Street NW, Washington, DC 20001.

Janet C. Garber, *Chair*  
Committee for the Update of the *Guide for the  
Care and Use of Laboratory Animals*



# Overview

This eighth edition of the *Guide* is divided into five chapters and four appendices.

*Chapter 1* presents the goals and intended audiences of the *Guide* as well as key concepts and terminology essential to its premise and use. Incorporating some of the material from the Introduction to the last edition, the chapter highlights a commitment to the concepts of the Three Rs—Replacement, Reduction, and Refinement—and provides an enhanced discussion of the ethics of animal use and investigator/institutional obligations.

*Chapter 2* focuses on the overall institutional *animal care and use program* (Program), in addition to many of the topics previously covered in Chapter 1 of the seventh edition. It defines the evolved concept of Program and provides a framework for its intra-institutional integration, taking into account institutional policies and responsibilities, regulatory considerations, Program and personnel management (including training and occupational health and safety), and Program oversight. Discussions of the latter include institutional animal care and use committee (IACUC) functions, protocol and Program review, postapproval monitoring (a new section), and considerations such as humane endpoints and multiple survival surgical procedures. The Committee endorses the American College of Laboratory Animal Medicine's "Guidelines for Adequate Veterinary Care."

*Chapter 3* focuses on the animals themselves and, unlike previous editions, addresses terrestrial and aquatic species in separate sections, reflect-

ing the growing role of aquatic animals in biomedical research. The chapter provides recommendations for housing and environment, discusses the importance of social housing, and includes enhanced sections on environmental enrichment, animal well-being, and scientific validity.

Space recommendations were nominally expanded based on the Committee's professional and expert opinion and on current housing methods. Cage sizes have historically been interpreted as minimum space needs by users of the *Guide*, and were labeled as such ("recommended minimum space") in this edition. The use of the word "minimum" does not further restrict users of the *Guide* because, although the space requirements are numbers (i.e., engineering standards), they are used in a performance standards framework. The Committee recommends minimum space for female rodents with litter and an increase of the cage height for rabbits to 16". Further, in light of many comments submitted to the Committee requesting more information on performance goals and how to achieve them, rodent breeding recommendations are accompanied by substantial guidance.

With respect to nonhuman primates (NHPs), the Committee endorses social housing as the default and has provided some species-specific guidance. An additional group has been added for monkeys, and chimpanzees are separated in a new category. These changes were motivated by the Committee's recognition (affirmed in comments solicited from NHP experts) that these animals need more floor and vertical space, at least in some groups, to exercise their natural habits.

*Chapter 4* discusses veterinary care and the responsibilities of the attending veterinarian. It introduces the concept of *animal biosecurity* and upholds its central role in ensuring the health of laboratory animals. The chapter includes recommendations relative to animal procurement, transportation, and preventive medicine, and expands the sections on clinical care and management, surgery (with a new section on intraoperative monitoring), pain and distress, and euthanasia.

*Chapter 5* discusses physical plant-related topics and includes updated and new material on vibration control; physical security and access control; hazardous agent containment; and special facilities for imaging and whole body irradiation, barrier housing, behavioral studies, and aquatic species housing. The chapter provides detailed discussion of centralized versus decentralized animal facilities and introduces the concept of variable-volume HVAC systems with a nod toward energy conservation and efficiency.

Appendix A is the updated bibliography; Appendix B presents the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training; Appendix C presents the Statement

of Task; and Appendix D provides the biographical sketches of the Committee members.

In accordance with the Statement of Task (“In addition to the published report, the updated *Guide* will be posted on the Internet in a pdf or equivalent format such that users will be able to search the entire document at one time”), the *Guide* is available in searchable pdf format on the National Academies Press website, [www.nap.edu](http://www.nap.edu).





# Contents

<b>1</b>	<b>KEY CONCEPTS</b>	<b>1</b>
	Applicability and Goals, 2	
	Intended Audiences and Uses of the <i>Guide</i> , 3	
	Ethics and Animal Use, 4	
	The Three Rs, 4	
	Key Terms Used in the Guide, 5	
	Humane Care, 6	
	Animal Care and Use Program, 6	
	Engineering, Performance, and Practice Standards, 6	
	Policies, Principles, and Procedures, 7	
	Must, Should, and May, 8	
	References, 8	
<b>2</b>	<b>ANIMAL CARE AND USE PROGRAM</b>	<b>11</b>
	Regulations, Policies, and Principles, 12	
	Program Management, 13	
	Program Management Responsibility, 13	
	The Institutional Official, 13	
	The Attending Veterinarian, 14	
	The Institutional Animal Care and Use Committee, 14	
	Collaborations, 15	
	Personnel Management, 15	
	Training and Education, 15	
	Occupational Health and Safety of Personnel, 17	

- Personnel Security, 23
- Investigating and Reporting Animal Welfare Concerns, 23
- Program Oversight, 24
  - The Role of the IACUC, 24
    - IACUC Constitution and Function, 24
    - Protocol Review, 25
    - Special Considerations for IACUC Review, 27
  - Postapproval Monitoring, 33
- Disaster Planning and Emergency Preparedness, 35
- References, 35

### **3 ENVIRONMENT, HOUSING, AND MANAGEMENT 41**

- Terrestrial Animals, 42
  - Terrestrial Environment, 42
    - Microenvironment and Macroenvironment, 42
    - Temperature and Humidity, 43
    - Ventilation and Air Quality, 45
    - Illumination, 47
    - Noise and Vibration, 49
  - Terrestrial Housing, 50
    - Microenvironment (Primary Enclosure), 50
    - Environmental Enrichment, 52
    - Sheltered or Outdoor Housing, 54
    - Naturalistic Environments, 55
    - Space, 55
  - Terrestrial Management, 63
    - Behavioral and Social Management, 63
    - Husbandry, 65
    - Population Management, 75
- Aquatic Animals, 77
  - Aquatic Environment, 77
    - Microenvironment and Macroenvironment, 77
    - Water Quality, 78
    - Life Support System, 79
    - Temperature, Humidity, and Ventilation, 80
    - Illumination, 81
    - Noise and Vibration, 81
  - Aquatic Housing, 82
    - Microenvironment (Primary Enclosure), 82
    - Environmental Enrichment and Social Housing, 82
    - Sheltered, Outdoor, and Naturalistic Housing, 83
    - Space, 83

- Aquatic Management, 84
  - Behavior and Social Management, 84
  - Husbandry, 84
  - Population Management, 87
- References, 88

#### **4 VETERINARY CARE 105**

- Animal Procurement and Transportation, 106
  - Animal Procurement, 106
  - Transportation of Animals, 107
- Preventive Medicine, 109
  - Animal Biosecurity, 109
  - Quarantine and Stabilization, 110
  - Separation by Health Status and Species, 111
  - Surveillance, Diagnosis, Treatment, and Control of Disease, 112
- Clinical Care and Management, 113
  - Medical Management, 114
  - Emergency Care, 114
  - Recordkeeping, 115
- Surgery, 115
  - Training, 115
  - Presurgical Planning, 116
  - Surgical Facilities, 116
  - Surgical Procedures, 117
  - Aseptic Technique, 118
  - Intraoperative Monitoring, 119
  - Postoperative Care, 119
- Pain and Distress, 120
- Anesthesia and Analgesia, 121
- Euthanasia, 123
- References, 124

#### **5 PHYSICAL PLANT 133**

- General Considerations, 133
  - Location, 134
    - Centralization Versus Decentralization, 134
- Functional Areas, 135
- Construction Guidelines, 136
  - Corridors, 136
  - Animal Room Doors, 137
  - Exterior Windows, 137
  - Floors, 137

Drainage, 138	
Walls and Ceilings, 138	
Heating, Ventilation, and Air Conditioning (HVAC), 139	
Power and Lighting, 141	
Storage Areas, 141	
Noise Control, 142	
Vibration Control, 142	
Facilities for Sanitizing Materials, 143	
Environmental Monitoring, 143	
Special Facilities, 144	
Surgery, 144	
Barrier Facilities, 145	
Imaging, 146	
Whole Body Irradiation, 147	
Hazardous Agent Containment, 148	
Behavioral Studies, 149	
Aquatic Species Housing, 150	
Security and Access Control, 151	
References, 151	

<b>ADDENDUM</b>	<b>155</b>
-----------------	------------

<b>APPENDICES</b>	
-------------------	--

<b>A ADDITIONAL SELECTED REFERENCES</b>	<b>161</b>
---	------------

Subject Matter, 161	
Use of Laboratory Animals, 162	
Alternatives, 162	
Ethics and Welfare, 163	
Experimental Design and Statistics, 164	
Research and Testing Methodology, 165	
Program Management, 167	
General References, 167	
Laws, Regulations, and Policies, 168	
Education, 169	
Monitoring the Care and Use of Animals, 169	
Occupational Health and Safety, 170	
Environment, Housing, and Management, 172	
General References, 172	
Environmental Enrichment, 173	
Genetics and Genetically Modified Animals, 175	

Species-Specific References—Environment, Housing, and Management, 176	
Agricultural Animals, 176	
Amphibians, Reptiles, and Fish, 178	
Birds, 179	
Cats and Dogs, 180	
Exotic, Wild, and Zoo Animals, 181	
Nonhuman Primates, 182	
Rodents and Rabbits, 184	
Other Animals, 187	
Veterinary Care, 188	
Transportation, 188	
Anesthesia, Pain, and Surgery, 188	
Disease Surveillance, Diagnosis, and Treatment, 190	
Pathology, Clinical Pathology, and Parasitology, 190	
Species-Specific References—Veterinary Care, 191	
Agricultural Animals, 191	
Amphibians, Reptiles, and Fish, 192	
Birds, 193	
Cats and Dogs, 193	
Exotic, Wild, and Zoo Animals, 193	
Nonhuman Primates, 194	
Rodents and Rabbits, 194	
Design and Construction of Animal Facilities, 196	
<b>B U.S. GOVERNMENT PRINCIPLES FOR THE UTILIZATION AND CARE OF VERTEBRATE ANIMALS USED IN TESTING, RESEARCH, AND TRAINING</b>	<b>199</b>
<b>C STATEMENT OF TASK</b>	<b>201</b>
<b>D ABOUT THE AUTHORS</b>	<b>203</b>
<b>INDEX</b>	<b>209</b>



## Key Concepts

This edition of the *Guide for the Care and Use of Laboratory Animals* (the *Guide*) strongly affirms the principle that all who care for, use, or produce animals for research, testing, or teaching must assume responsibility for their well-being. The *Guide* is created by scientists and veterinarians for scientists and veterinarians to uphold the scientific rigor and integrity of biomedical research with laboratory animals as expected by their colleagues and society at large.

The *Guide* plays an important role in decision making regarding the use of vertebrate laboratory animals because it establishes the minimum ethical, practice, and care standards for researchers and their institutions. The use of laboratory animals in research, teaching, testing, and production is also governed or affected by various federal and local laws, regulations, and standards; for example, in the United States the Animal Welfare Act (AWA 1990) and Regulations (PL 89-544; USDA 1985) and/or Public Health Service (PHS) Policy (PHS 2002) may apply. Compliance with these laws, regulations, policies, and standards (or subsequent revised versions) in the establishment and implementation of a program of animal care and use is discussed in Chapter 2.

Taken together, the practical effect of these laws, regulations, and policies is to establish a system of self-regulation and regulatory oversight that binds researchers and institutions using animals. Both researchers and institutions have affirmative duties of humane care and use that are supported by practical, ethical, and scientific principles. This system of self-regulation establishes a rigorous program of animal care and use and provides flexibility in fulfilling the responsibility to provide humane care. The specific



scope and nature of this responsibility can vary based on the scientific discipline, nature of the animal use, and species involved, but because it affects animal care and use in every situation this responsibility requires that producers, teachers, researchers, and institutions carry out purposeful analyses of proposed uses of laboratory animals. The *Guide* is central to these analyses and to the development of a program in which humane care is incorporated into all aspects of laboratory animal care and use.

## APPLICABILITY AND GOALS

In the *Guide*, *laboratory animals* (also referred to as *animals*) are generally defined as any vertebrate animal (i.e., traditional laboratory animals, agricultural animals, wildlife, and aquatic species) produced for or used in research, testing, or teaching. *Animal use* is defined as the proper care, use, and humane treatment of laboratory animals produced for or used in research, testing, or teaching.

*Laboratory animals or animals:* Any vertebrate animal (e.g., traditional laboratory animals, agricultural animals, wildlife, and aquatic species) produced for or used in research, testing, or teaching.

but establishes general principles and ethical considerations that are also applicable to these species and situations. References provide the reader with additional resources, and supplemental information on breeding, care,

*Animal use:* The proper care, use, and humane treatment of laboratory animals produced for or used in research, testing, or teaching.

When appropriate, considerations or specific emphases for agricultural animals and nontraditional species are presented. The *Guide* does not address in detail agricultural animals used in production, agricultural research or teaching, wildlife and aquatic species studied in natural settings, or invertebrate animals (e.g., cephalopods) used in research, management, and use of selected laboratory animal species is available in other publications prepared by the Institute for Laboratory Animal Research (ILAR) and other organizations (Appendix A).

The goal of the *Guide* is to promote the humane care and use of laboratory animals by providing information that will enhance animal well-being, the quality of research, and the advancement of scientific knowledge that is relevant to both humans and animals. The Committee recognizes that the use of different species in research is expanding and that researchers and institutions will face new and unique challenges in determining how to apply the *Guide* in these situations. In making such determinations, it is

important to keep in mind that the *Guide* is intended to provide information to assist researchers, institutional animal care and use committees (IACUCs), veterinarians, and other stakeholders in ensuring the implementation of effective and appropriate animal care and use programs that are based on humane care. Throughout the *Guide*, scientists and institutions are encouraged to give careful and deliberate thought to the decision to use animals, taking into consideration the contribution that such use will make to new knowledge, ethical concerns, and the availability of alternatives to animal use (NRC 1992). A practical strategy for decision making, the “Three Rs” (Replacement, Reduction, and Refinement) approach, is discussed in more detail below. Institutions should use the recommendations in the *Guide* as a foundation for the development of a comprehensive animal care and use program and a process for continually improving this program.

### **INTENDED AUDIENCES AND USES OF THE *GUIDE***

The *Guide* is intended for a wide and diverse audience, including

- the scientific community
- administrators
- IACUCs
- veterinarians
- educators and trainers
- producers of laboratory animals
- accreditation bodies
- regulators
- the public.

The *Guide* is meant to be read by the user in its entirety, as there are many concepts throughout that may be helpful. Individual sections will be particularly relevant to certain users, and it is expected that the reader will explore in more detail the references provided (including those in Appendix A) on topics of interest.

Members of the scientific community (investigators and other animal users) will find Chapters 1 and 2 (and portions of Chapter 4) of the *Guide* useful for their interactions with the IACUC, attending veterinarian, and administrators regarding animal care as well as the preparation of animal care and use protocols. Scientific review committees and journal editors may choose to refer to multiple sections of the *Guide* to determine whether scientists contributing proposals and manuscripts have met the appropriate standards in their planned use of animals. The *Guide* can assist IACUCs and administrators in protocol review, assessment, and oversight of an animal care and use program. Veterinarians should find Chapters 3 through 5

valuable for their oversight and support of animal care and use. Educators and trainers can use the *Guide* as a document to assess both the scope and adequacy of training programs supported by the institution. Accreditation bodies will find the *Guide* useful for evaluating many areas of animal care and use programs not subject to strict engineering standards (see definition below). Finally, members of the public should feel assured that adherence to the *Guide* will ensure humane care and use of laboratory animals.

Readers are reminded that the *Guide* is used by a diverse group of national and international institutions and organizations, many of which are covered by neither the Animal Welfare Act nor the PHS Policy. The *Guide* uses some terminology that is both defined by US statute and denotes a general concept (e.g., “attending veterinarian,” “adequate veterinary care,” and “institutional official”). Even if these terms are not consistent with those used by non-US institutions, the underlying principles can still be applied. In all instances where *Guide* recommendations are different from applicable legal or policy requirements, the higher standard should apply.

## ETHICS AND ANIMAL USE

The decision to use animals in research requires critical thought, judgment, and analysis. Using animals in research is a privilege granted by society to the research community with the expectation that such use will provide either significant new knowledge or lead to improvement in human and/or animal well-being (McCarthy 1999; Perry 2007). It is a trust that mandates responsible and humane care and use of these animals. The *Guide* endorses the responsibilities of investigators as stated in the *U.S. Government Principles for Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training* (IRAC 1985; see Appendix B). These principles direct the research community to accept responsibility for the care and use of animals during all phases of the research effort. Other government agencies and professional organizations have published similar principles (NASA 2008; NCB 2005; NIH 2006, 2007; for additional references see Appendix A). Ethical considerations discussed here and in other sections of the *Guide* should serve as a starting point; readers are encouraged to go beyond these provisions. In certain situations, special considerations will arise during protocol review and planning; several of these situations are discussed in more detail in Chapter 2.

## THE THREE Rs

The Three Rs represent a practical method for implementation of the principles described above. In 1959, W.M.S. Russell and R.L. Burch published a practical strategy of replacement, refinement, and reduction—referred to as the Three Rs—for researchers to apply when considering experimental

design in laboratory animal research (Russell and Burch 1959). Over the years, the Three Rs have become an internationally accepted approach for researchers to apply when deciding to use animals in research and in designing humane animal research studies.

*Replacement* refers to methods that avoid using animals. The term includes absolute replacements (i.e., replacing animals with inanimate systems such as computer programs) as well as relative replacements (i.e., replacing animals such as vertebrates with animals that are lower on the phylogenetic scale).

*Refinement* refers to modifications of husbandry or experimental procedures to enhance animal well-being and minimize or eliminate pain and distress. While institutions and investigators should take all reasonable measures to eliminate pain and distress through refinement, IACUCs should understand that with some types of studies there may be either unforeseen or intended experimental outcomes that produce pain. These outcomes may or may not be eliminated based on the goals of the study.

*Reduction* involves strategies for obtaining comparable levels of information from the use of fewer animals or for maximizing the information obtained from a given number of animals (without increasing pain or distress) so that in the long run fewer animals are needed to acquire the same scientific information. This approach relies on an analysis of experimental design, applications of newer technologies, the use of appropriate statistical methods, and control of environmentally related variability in animal housing and study areas (see Appendix A).

Refinement and reduction goals should be balanced on a case-by-case basis. Principal investigators are strongly discouraged from advocating animal reuse as a reduction strategy, and reduction should not be a rationale for reusing an animal or animals that have already undergone experimental procedures especially if the well-being of the animals would be compromised. Studies that may result in severe or chronic pain or significant alterations in the animals' ability to maintain normal physiology, or adequately respond to stressors, should include descriptions of appropriate humane endpoints or provide science-based justification for not using a particular, commonly accepted humane endpoint. Veterinary consultation must occur when pain or distress is beyond the level anticipated in the protocol description or when interventional control is not possible.

### KEY TERMS USED IN THE GUIDE

The Committee for the Update of the *Guide* believes that the terms set out below are important for a full understanding of the *Guide*. Accordingly, we have defined these terms and concepts to provide users of the *Guide* with additional assistance in implementing their responsibilities.

## Humane Care

*Humane care* means those actions taken to ensure that laboratory animals are treated according to high ethical and scientific standards. Implementation of a humane care program, and creation of a laboratory environment in which humane care and respect for animals are valued and encouraged, underlies the core requirements of the *Guide* and the system of self-regulation it supports (Klein and Bayne 2007).

## Animal Care and Use Program

The *animal care and use program* (the Program) means the policies, procedures, standards, organizational structure, staffing, facilities, and practices put into place by an institution to achieve the humane care and use of animals in the laboratory and throughout the institution. It includes the establishment and support of an IACUC or equivalent ethical oversight committee and the maintenance of an environment in which the IACUC can function successfully to carry out its responsibilities under the *Guide* and applicable laws and policies. Chapter 2 provides a more expansive discussion of the importance of the *Guide* and its application to animal care and use programs.

## Engineering, Performance, and Practice Standards

*Engineering standard* means a standard or guideline that specifies in detail a method, technology, or technique for achieving a desired outcome; it does not provide for modification in the event that acceptable alternative methods are available or unusual circumstances arise. Engineering standards are prescriptive and provide limited flexibility for implementation. However, an engineering standard can be useful to establish a baseline and is relatively easy to use in evaluating compliance.

*Performance standard* means a standard or guideline that, while describing a desired outcome, provides flexibility in achieving this outcome by granting discretion to those responsible for managing the animal care and use program, the researcher, and the IACUC. The performance approach requires professional input, sound judgment, and a team approach to achieve specific goals. It is essential that the desired outcomes and/or goals be clearly defined and appropriate performance measures regularly monitored in order to verify the success of the process. Performance standards can be advantageous because they accommodate the consideration of many variables (such as the species and previous history of the animals, facilities, staff

expertise, and research goals) so that implementation can be best tailored to meet the recommendations in the *Guide*.

Ideally, engineering and performance standards are balanced, setting a target for optimal practices, management, and operations while encouraging flexibility and judgment, if appropriate, based on individual situations (Gonder et al. 2001).

Scientists, veterinarians, technicians, and others have extensive experience and information covering many of the topics discussed in the *Guide*. For topics on which information is insufficient or incomplete, sustained research into improved methods of laboratory animal management, care, and use is needed for the continued evaluation and improvement of performance and engineering standards.

*Practice standard* means the application of professional judgment by qualified, experienced individuals to a task or process over time, an approach that has been demonstrated to benefit or enhance animal care and use. Professional judgment comes from information in the peer-reviewed scientific literature and textbooks and, as in many other disciplines, from time-proven experiences in the field (for additional information see Chapter 2). In the absence of published scientific literature or other definitive sources, where experience has demonstrated that a particular practice improves animal care and use, practice standards have been used in determining appropriate recommendations in the *Guide*. In most situations, the *Guide* is intended to provide flexibility so that institutions can modify practices and procedures with changing conditions and new information.

## POLICIES, PRINCIPLES, AND PROCEDURES

*Policies* commonly derive from a public agency or private entity. They are generally practical statements of collective wisdom, convention, or management direction that are internal to the entity. However, policies may assume broader force when they become the means by which an implementing agency interprets existing statutes (e.g., PHS Policy). *Principles* are broader in their scope and intended application, and are accepted generalizations about a topic that are frequently endorsed by many and diverse organizations (e.g., the U.S. Government Principles). *Procedures* (often called “operating procedures” or “standard operating procedures”) are typically detailed, step-by-step processes meant to ensure the consistent application of institutional practices. Establishing standard operating procedures can assist an institution in complying with regulations, policies, and principles as well as with day-to-day operations and management.

## MUST, SHOULD, AND MAY

*Must* indicates actions that the Committee for the Update of the *Guide* considers imperative and mandatory duty or requirement for providing humane animal care and use. *Should* indicates a strong recommendation for achieving a goal; however, the Committee recognizes that individual circumstances might justify an alternative strategy. *May* indicates a suggestion to be considered.

The *Guide* is written in general terms so that its recommendations can be applied in diverse institutions and settings that produce or use animals for research, teaching, and testing. This approach requires that users, IACUCs, veterinarians, and producers apply professional judgment in making specific decisions regarding animal care and use. Because the *Guide* is written in general terms, IACUCs have a key role in interpretation, implementation, oversight, and evaluation of institutional animal care and use programs.

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## Animal Care and Use Program

The proper care and use of laboratory animals in research, testing, teaching, and production (*animal use*) require scientific and professional judgment based on the animals' needs and their intended use. An animal care and use program (hereafter referred to as the Program) comprises all activities conducted by and at an institution that have a direct impact on the well-being of animals, including animal and veterinary care, policies and procedures, personnel and program management and oversight, occupational health and safety, institutional animal care and use committee (IACUC) functions, and animal facility design and management.

*Program:* The activities conducted by and at an institution that have a direct impact on the well-being of animals, including animal and veterinary care, policies and procedures, personnel and program management and oversight, occupational health and safety, IACUC functions, and animal facility design and management.

This chapter defines the overall Program and key oversight responsibilities and provides guidelines to aid in developing an effective Program. Chapters 3, 4, and 5 cover the details of Program components: environment, housing, and management; veterinary care; and physical plant, respectively. Each institution should establish and provide sufficient resources for a Program that is managed in accord with the *Guide* and in compliance with applicable regulations, policies, and guidelines.

## REGULATIONS, POLICIES, AND PRINCIPLES

The use of laboratory animals is governed by an interrelated, dynamic system of regulations, policies, guidelines, and procedures. The *Guide* takes into consideration regulatory requirements relevant to many US-based activities, including the Animal Welfare Regulations (USDA 1985; US Code, 42 USC § 289d) and the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS 2002). The use of the *Guide* by non-US entities also presumes adherence to all regulations relevant to the humane care and use of laboratory animals applicable in those locations. The *Guide* also takes into account the U.S. Government Principles for Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (IRAC 1985; see Appendix B) and endorses the following principles:

- consideration of alternatives (in vitro systems, computer simulations, and/or mathematical models) to reduce or replace the use of animals
- design and performance of procedures on the basis of relevance to human or animal health, advancement of knowledge, or the good of society
- use of appropriate species, quality, and number of animals
- avoidance or minimization of discomfort, distress, and pain
- use of appropriate sedation, analgesia, and anesthesia
- establishment of humane endpoints
- provision of adequate veterinary care
- provision of appropriate animal transportation and husbandry directed and performed by qualified persons
- conduct of experimentation on living animals exclusively by and/or under the close supervision of qualified and experienced personnel.

Interpretation and application of these principles and the *Guide* require knowledge, expertise, experience, and professional judgment. Programs should be operated in accord with the *Guide* and relevant regulations, policies, and principles. Also, institutions are encouraged to establish and periodically review written procedures to ensure consistent application of *Guide* standards. Supplemental information on various aspects of animal care and use is available in other publications prepared by the Institute for Laboratory Animal Research (ILAR) and other organizations (Appendix A). References in the *Guide* provide the reader with additional information that supports statements made in the *Guide*. In the absence of published literature, some information in the *Guide* is derived from currently accepted practice standards in laboratory animal science (see Chapter 1). The body

of literature related to animal science and use of animals is constantly evolving, requiring Programs to remain current with the information and best practices.

## PROGRAM MANAGEMENT

An effective Program requires clearly defined roles that align responsibility with regulatory and management authority. US federal law creates a statutory basis for the *institutional official* (IO), the *attending veterinarian* (AV), and the *institutional animal care and use committee* (IACUC). The *Guide* endorses these concepts as important operating principles for all US and non-US animal care and use programs. Effective leadership in and collaboration among these three components, which not only oversee but also support animal users, are necessary (Lowman 2008; Van Sluyters 2008). In addition, interactions with regulatory and funding agencies and accreditation organizations are an integral part of the Program.

As summarized here and discussed throughout the *Guide*, the primary oversight responsibilities in the Program rest with the IO, the AV, and the IACUC. Their roles fit in a defined organizational structure where the reporting relationships, authorities, and responsibilities of each are clearly defined and transparent. Together they establish policies and procedures, ensure regulatory compliance, monitor Program performance, and support high-quality science and humane animal use. A Program that includes these elements and establishes a balance among them has the best chance of efficiently using resources while attaining the highest standards of animal well-being and scientific quality (Bayne and Garnett 2008; Van Sluyters 2008).

### Program Management Responsibility

#### *The Institutional Official*

The *institutional official* (IO) bears ultimate responsibility for the Program, although overall Program direction should be a shared responsibility among the IO, AV, and IACUC. The IO has the authority to allocate the resources needed to ensure the Program's overall effectiveness. Program needs should be clearly and regularly communicated to the IO by the AV, the IACUC, and others associated with the Program (e.g., facilities management staff, occupational health and safety personnel, scientists). As a

*Institutional official:* The individual who, as a representative of senior administration, bears ultimate responsibility for the Program and is responsible for resource planning and ensuring alignment of Program goals with the institution's mission.

representative of senior administration, the IO is responsible for resource planning and ensuring the alignment of Program goals of quality animal care and use with the institution's mission.

### *The Attending Veterinarian*

The *attending veterinarian* (AV) is responsible for the health and well-being of all laboratory animals used at the institution. The institution must provide the AV with sufficient authority, including access to all animals, and resources to manage the program of veterinary care. The AV should oversee other aspects of animal care and use (e.g., husbandry, housing) to ensure that the Program complies with the *Guide*.

*Attending veterinarian:* The veterinarian responsible for the health and well-being of all laboratory animals used at the institution.

Institutional mission, programmatic goals, including the nature of animal use at the institution, and Program size will determine whether full-time, part-time, or consultative veterinary services are needed. If a full-time veterinarian is not available on site, a consulting or part-time veterinarian should be available in visits at intervals appropriate to programmatic needs. In such instances, there must be an individual with assigned responsibility for daily animal care and use and facility management. While institutions with large animal care and use programs may employ multiple veterinarians, the management of veterinary medicine, animal care, and facility operations by a single administrative unit is often an efficient mechanism to administer all aspects of the Program.

The *Guide* endorses the American College of Laboratory Animal Medicine's (ACLAM) "Guidelines for Adequate Veterinary Care" (ACLAM 1996). These guidelines include veterinary access to all animals and their medical records, regular veterinary visits to facilities where animals are or may be housed or used, provisions for appropriate and competent clinical, preventive, and emergency veterinary care, and a system for legal animal procurement and transportation. Other responsibilities of the AV are outlined in the Program Oversight section below and in later chapters. For a Program to work effectively, there should be clear and regular communication between the AV and the IACUC.

### *The Institutional Animal Care and Use Committee*

The IACUC (or institutional equivalent) is responsible for assessment and oversight of the institution's Program components and facilities. It should have sufficient authority and resources (e.g., staff, training, comput-

ers and related equipment) to fulfill this responsibility. Detailed information on the role and function of the IACUC is provided later in this chapter.

### *Collaborations*

Interinstitutional collaboration has the potential to create ambiguities about responsibility for animal care and use. In cases of such collaboration involving animal use (beyond animal transport), the participating institutions should have a formal written understanding (e.g., a contract, memorandum of understanding, or agreement) that addresses the responsibility for offsite animal care and use, animal ownership, and IACUC review and oversight (AAALAC 2003). In addition, IACUCs from the participating institutions may choose to review protocols for the work being conducted.

## **Personnel Management**

### *Training and Education*

All personnel involved with the care and use of animals must be adequately educated, trained, and/or qualified in basic principles of laboratory animal science to help ensure high-quality science and animal well-being. The number and qualifications of personnel required to conduct and support a Program depend on several factors, including the type and size of the institution, the administrative structure for providing adequate animal care, the characteristics of the physical plant, the number and species of animals maintained, and the nature of the research, testing, teaching, and production activities. Institutions are responsible for providing appropriate resources to support personnel training (Anderson 2007), and the IACUC is responsible for providing oversight and for evaluating the effectiveness of the training program (Foshay and Tinkey 2007). All Program personnel training should be documented.

*Veterinary and Other Professional Staff* Veterinarians providing clinical and/or Program oversight and support must have the experience, training, and expertise necessary to appropriately evaluate the health and well-being of the species used in the context of the animal use at the institution. Veterinarians providing broad Program direction should be trained or have relevant experience in laboratory animal facility administration and management. Depending on the scope of the Program, professionals with expertise in other specific areas may be needed—in, for example, facility design and renovation, human resource management, pathology of laboratory animals, comparative genomics, facility and equipment maintenance, diagnostic laboratory operations, and behavioral management. Laboratory

animal science and medicine are rapidly changing and evolving disciplines. The institution should provide opportunities and support for regular professional development and continuing education to ensure both that professional staff are knowledgeable about the latest practices and procedures and that laboratory animals receive high-quality care (Colby et al. 2007).

*Animal Care Personnel* Personnel caring for animals should be appropriately trained (see Appendix A, Education), and the institution should provide for formal and/or on-the-job training to facilitate effective implementation of the Program and the humane care and use of animals. Staff should receive training and/or have the experience to complete the tasks for which they are responsible. According to the Program scope, personnel with expertise in various disciplines (e.g., animal husbandry, administration, veterinary medical technology) may be required.

There are a number of options for training animal care personnel and technicians (Pritt and Duffee 2007). Many colleges have accredited programs in veterinary technology (AVMA 2010); most are 2-year programs that award Associate of Science degrees, some are 4-year programs that award Bachelor of Science degrees. Nondegree training, via certification programs for laboratory animal technicians and technologists, is available from the American Association for Laboratory Animal Science (AALAS), and there are various commercially available training materials appropriate for self-guided study (Appendix A).

Personnel caring for laboratory animals should also regularly engage in continuing education activities and should be encouraged to participate in local and national laboratory animal science meetings and in other relevant professional organizations. On-the-job training, supplemented with institution-sponsored discussion and training programs and reference materials applicable to their jobs and the species in their care, should be provided to each employee responsible for animal care (Kreger 1995).

Coordinators of institutional training programs can seek assistance from the Animal Welfare Information Center (AWIC), the Laboratory Animal Welfare and Training Exchange (LAWTE), AALAS, and ILAR (NRC 1991). The *Guide to the Care and Use of Experimental Animals* by the Canadian Council on Animal Care (CCAC 1993) and guidelines from other countries are valuable additions to the libraries of laboratory animal scientists (Appendix A).

*The Research Team* The institution should provide appropriate education and training to members of research teams—including principal investigators, study directors, research technicians, postdoctoral fellows, students, and visiting scientists—to ensure that they have the necessary knowledge and expertise for the specific animal procedures proposed and the species

used (Conarello and Shepard 2007). Training should be tailored to the particular needs of research groups; however, all research groups should receive training in animal care and use legislation, IACUC function, ethics of animal use and the concepts of the Three Rs, methods for reporting concerns about animal use, occupational health and safety issues pertaining to animal use, animal handling, aseptic surgical technique, anesthesia and analgesia, euthanasia, and other subjects, as required by statute. Continuing education programs should be offered to reinforce training and provide updates that reflect changes in technology, legislation, and other relevant areas. Frequency of training opportunities should ensure that all animal users have adequate training before beginning animal work.

*The IACUC* It is the institution's responsibility to ensure that IACUC members are provided with training opportunities to understand their work and role. Such training should include formal orientation to introduce new members to the institution's Program; relevant legislation, regulations, guidelines, and policies; animal facilities and laboratories where animal use occurs; and the processes of animal protocol and program review (Greene et al. 2007). Ongoing opportunities to enhance their understanding of animal care and use in science should also be provided. For example, IACUC members may meet with animal care personnel and research teams; be provided access to relevant journals, materials, and web-based training; and be given opportunities to attend meetings or workshops.

### *Occupational Health and Safety of Personnel*

Each institution must establish and maintain an occupational health and safety program (OHSP) as an essential part of the overall Program of animal care and use (CFR 1984a,b,c; DHHS 2009; PHS 2002). The OHSP must be consistent with federal, state, and local regulations and should focus on maintaining a safe and healthy workplace (Gonder 2002; Newcomer 2002; OSHA 1998a). The nature of the OHSP will depend on the facility, research activities, hazards, and animal species involved. The National Research Council's publication *Occupational Health and Safety in the Care and Use of Research Animals* (NRC 1997) contains guidelines and references for establishing and maintaining an effective, comprehensive OHSP (also see Appendix A). An effective OHSP requires coordination between the research program (as represented by the investigator), the animal care and use Program (as represented by the AV, IO, and IACUC), the environmental health and safety program, occupational health services, and administration (e.g., human resources, finance, and facility maintenance personnel). Establishment of a safety committee may facilitate communication and promote ongoing evaluation of health and safety in the workplace. In some cases



there is a regulatory requirement for such a committee. Operational and day-to-day responsibility for safety in the workplace resides with the laboratory or facility supervisor (e.g., principal investigator, facility director, or a staff veterinarian) and depends on safe work practices by all employees.

*Control and Prevention Strategies* A comprehensive OHSP should include a hierarchy of control and prevention strategies that begins with the identification of hazards and the assessment of risk associated with those hazards. Managing risk involves the following steps: first, the appropriate design and operation of facilities and use of appropriate safety equipment (engineering controls); second, the development of processes and standard operating procedures (SOPs; administrative controls); and finally, the provision of appropriate personal protective equipment (PPE) for employees. Special safety equipment should be used in combination with appropriate management and safety practices (NIH 2002; OSHA 1998a,b). Managing risk using these strategies requires that personnel be trained, maintain good personal hygiene, be knowledgeable about the hazards in their work environment, understand the proper selection and use of equipment, follow established procedures, and use the PPE provided.

*Hazard Identification and Risk Assessment* The institutional OHSP should identify potential hazards in the work environment and conduct a critical assessment of the associated risks. An effective OHSP ensures that the risks associated with the experimental use of animals are identified and reduced to minimal and acceptable levels. Hazard identification and risk assessment are ongoing processes that involve individuals qualified to assess dangers associated with the Program and implement commensurate safeguards. Health and safety specialists with knowledge in relevant disciplines should be involved in risk assessment and the development of procedures to manage such risks.

Potential hazards include experimental hazards such as biologic agents (e.g., infectious agents or toxins), chemical agents (e.g., carcinogens and mutagens), radiation (e.g., radionuclides, X-rays, lasers), and physical hazards (e.g., needles and syringes). The risks associated with unusual experimental conditions such as those encountered in field studies or wildlife research should also be addressed. Other potential hazards—such as animal bites, exposure to allergens, chemical cleaning agents, wet floors, cage washers and other equipment, lifting, ladder use, and zoonoses—that are inherent in or intrinsic to animal use should be identified and evaluated. Once potential hazards have been identified, a critical ongoing assessment of the associated risks should be conducted to determine appropriate strategies to minimize or manage the risks.

The extent and level of participation of personnel in the OHSP should be based on the hazards posed by the animals and materials used (the

severity or seriousness of the hazard); the exposure intensity, duration, and frequency (prevalence of the hazard); to some extent, the susceptibility (e.g., immune status) of the personnel; and the history of occupational illness and injury in the particular workplace (Newcomer 2002; NRC 1997). Ongoing identification and evaluation of hazards call for periodic inspections and reporting of potential hazardous conditions or “near miss” incidents.

*Facilities, Equipment, and Monitoring* The facilities required to support the OHSP will vary depending on the scope and activities of the Program. Their design should preferentially use engineering controls and equipment to minimize exposure to anticipated hazards (also see Chapter 5). Because a high standard of personal cleanliness is essential, changing, washing, and showering facilities and supplies appropriate to the Program should be available.

Where biologic agents are used, the Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH) publication *Bio-safety in Microbiological and Biomedical Laboratories* (BMBL; DHHS 2009) and the USDA standards (USDA 2002) should be consulted for appropriate facility design and safety procedures. These design and safety features are based on the level of risk posed by the agents used. Special facilities and safety equipment may be needed to protect the animal care and investigative staff, other occupants of the facility, the public, animals, and the environment from exposure to hazardous biologic, chemical, and physical agents used in animal experimentation (DHHS 2009; Frasier and Talka 2005; NIH 2002). When necessary, these facilities should be separated from other animal housing and support areas, research and clinical laboratories, and patient care facilities. They should be appropriately identified and access to them limited to authorized personnel.

Facilities, equipment, and procedures should also be designed, selected, and developed to reduce the possibility of physical injury or health risk to personnel (NIOSH 1997a,b). Engineering controls and equipment that address the risk of ergonomic injury in activities such as the lifting of heavy equipment or animals should be considered (AVMA 2008). Those are also frequently used to limit or control personnel exposure to animal allergens (Harrison 2001; Huerkamp et al. 2009). The potential for repetitive motion injuries in animal facilities (e.g., maintenance of large rodent populations and other husbandry activities) should also be assessed.

The selection of appropriate animal housing systems requires professional knowledge and judgment and depends on the nature of the hazards in question, the types of animals used, the limitations or capabilities of the facilities, and the design of the experiments. Experimental animals should be housed so that possibly contaminated food and bedding, feces, and urine can be handled in a controlled manner. Appropriate facilities, equipment,

and procedures should be used for bedding disposal. Safety equipment should be properly maintained and its function periodically validated. Appropriate methods should be used for assessing and monitoring exposure to potentially hazardous biologic, chemical, and physical agents where required (e.g., ionizing radiation) or where the possibility of exceeding permissible exposure limits exists (CFR 1984b).

*Personnel Training* As a general rule, safety depends on trained personnel who rigorously follow safe practices. Personnel at risk should be provided with clearly defined procedures and, in specific situations, personal protective equipment to safely conduct their duties, understand the hazards involved, and be proficient in implementing the required safeguards. They should be trained regarding zoonoses, chemical, biologic, and physical hazards (e.g., radiation and allergies), unusual conditions or agents that might be part of experimental procedures (e.g., the use of human tissue in immunocompromised animals), handling of waste materials, personal hygiene, the appropriate use of PPE, and other considerations (e.g., precautions to be taken during pregnancy, illness, or immunosuppression) as appropriate to the risk imposed by their workplace.

*Personal Hygiene* The use of good personal hygiene will often reduce the possibility of occupational injury and cross contamination. Appropriate policies should be established and enforced, and the institution should supply suitable attire and PPE (e.g., gloves, masks, face shields, head covers, coats, coveralls, shoes or shoe covers) for use in the animal facility and laboratories in which animals are used. Soiled attire should be disposed of, laundered, or decontaminated by the institution as appropriate, and may require that special provisions be implemented if outside vendors are used. Personnel should wash and/or disinfect their hands and change clothing as often as necessary to maintain good personal hygiene. Outer garments worn in the animal rooms should not be worn outside the animal facility unless covered (NRC 1997). Personnel should not be permitted to eat, drink, use tobacco products, apply cosmetics, or handle or apply contact lenses in rooms and laboratories where animals are housed or used (DHHS 2009; NRC 1997; OSHA 1998a).

*Animal Experimentation Involving Hazards* When selecting specific safeguards for animal experimentation with hazardous agents, careful attention should be given to procedures for animal care and housing, storage and distribution of the agents, dose preparation and administration, body fluid and tissue handling, waste and carcass disposal, items that might be used temporarily and removed from the site (e.g., written records, experimental devices, sample vials), and personal protection.

Institutions should have written policies and procedures governing experimentation with hazardous biologic, chemical, and physical agents. An oversight process (such as the use of a safety committee) should be developed to involve persons who are knowledgeable in the evaluation and safe use of hazardous materials or procedures and should include review of the procedures and facilities to be used for specific safety concerns. Formal safety programs should be established to assess hazards, determine the safeguards needed for their control, and ensure that staff have the necessary training and skills and that facilities are adequate for the safe conduct of the research. Technical support should be provided to monitor and ensure compliance with institutional safety policies. A collaborative approach involving the investigator and research team, attending veterinarian, animal care technician, and occupational health and safety professionals may enhance compliance.

The BMBL (DHHS 2009) and NRC (1997) recommend practices and procedures, safety equipment, and facility requirements for working with hazardous biologic agents and materials. Facilities that handle agents of unknown risk should consult with appropriate CDC personnel about hazard control and medical surveillance. The use of highly pathogenic “select agents and toxins” in research requires that institutions develop a program and procedures for procuring, maintaining, and disposing of these agents (CFR 1998, 2002a,b; NRC 2004; PL 107-56; PL 107-188; Richmond et al. 2003). The use of immunodeficient or genetically modified animals (GMAs) susceptible to or shedding human pathogens, the use of human tissues and cell lines, or any infectious disease model can lead to an increased risk to the health and safety of personnel working with the animals (Lassnig et al. 2005; NIH 2002).

Hazardous agents should be contained in the study environment, for example through the use of airflow control during the handling and administering of hazardous agents, necropsies on contaminated animals (CDC and NIH 2000), and work with chemical hazards (Thomann 2003). Waste anesthetic gases should be scavenged to limit exposure.

*Personal Protection* While engineering and administrative controls are the first considerations for the protection of personnel, PPE appropriate for the work environment, including clean institution-issued protective clothing, should be provided as often as necessary. Protective clothing and equipment should not be worn beyond the boundary of the hazardous agent work area or the animal facility (DHHS 2009). If appropriate, personnel should shower when they leave the animal care, procedure, or dose preparation areas. Personnel with potential exposure to hazardous agents or certain species should be provided with PPE appropriate to the situation (CFR 1984c); for example, personnel exposed to nonhuman primates should have PPE such

as gloves, arm protectors, suitable face masks, face shields, and goggles (NRC 2003a). Hearing protection should be available in high-noise areas (OSHA 1998c). Personnel working in areas where they might be exposed to contaminated airborne particulate material or vapors should have suitable respiratory protection (Fechter 1995; McCullough 2000; OSHA 1998d), with respirator fit testing and training in the proper use and maintenance of the respirator (OSHA 1998d; Sargent and Gallo 2003).

*Medical Evaluation and Preventive Medicine for Personnel* Development and implementation of a program of medical evaluation and preventive medicine should involve input from trained health professionals, such as occupational health physicians and nurses. Confidentiality and other medical and legal factors must be considered in the context of appropriate federal, state, and local regulations (e.g., PL 104-191).

A preemployment health evaluation and/or a health history evaluation before work assignment is advisable to assess potential risks for individual employees. Periodic medical evaluations are advisable for personnel in specific risk categories. For example, personnel required to use respiratory protection may also require medical evaluation to ensure that they are physically and psychologically able to use the respirator properly (Sargent and Gallo 2003). An appropriate immunization schedule should be adopted. It is important to immunize animal care personnel against tetanus (NRC 1997), and preexposure immunization should be offered to people at risk of infection or exposure to specific agents such as rabies virus (e.g., if working with species at risk for infection) or hepatitis B virus (e.g., if working with human blood or human tissues, cell lines, or stocks). Vaccination is recommended if research is to be conducted on infectious diseases for which effective vaccines are available. More specific recommendations are available in the BMBL (DHHS 2009). Preemployment or preexposure serum collection is advisable only in specific circumstances as determined by an occupational health and safety professional (NRC 1997). In such cases, identification, traceability, retention, and storage conditions of samples should be considered, and the purpose for which the serum samples will be used must be consistent with applicable federal and state laws.

Laboratory animal allergy has become a significant issue for individuals in contact with laboratory animals (Bush and Stave 2003; Gordon 2001; Wolfle and Bush 2001; Wood 2001). The medical surveillance program should promote the early diagnosis of allergies (Bush 2001; Bush and Stave 2003; Seward 2001) and include evaluation of an individual's medical history for preexisting allergies. Personnel training should include information about laboratory animal allergies, preventive control measures, early recognition and reporting of allergy symptoms, and proper techniques for working with animals (Gordon et al. 1997; Schweitzer et al. 2003; Thulin

et al. 2002). PPE should be used to supplement, not replace, engineering or process controls (Harrison 2001; Reeb-Whitaker et al. 1999). If PPE for respiratory protection is necessary, appropriate fit testing and training should be provided.

Zoonosis surveillance should be a part of an OHSP (DHHS 2009; NRC 1997). Personnel should be instructed to notify their supervisors of potential or known exposures and of suspected health hazards and illnesses. Non-human primate diseases that are transmissible to humans can be serious hazards (NRC 2003a). Animal technicians, veterinarians, investigators, students, research technicians, maintenance workers, and others who have contact with nonhuman primates or their tissues and body fluids or who have duties in nonhuman primate housing areas should be routinely screened for tuberculosis. Because of the potential for exposure to *Macacine herpesvirus 1* (formerly *Cercopithecine herpesvirus 1* or Herpes B virus), personnel who work with or handle biologic samples (blood and tissues) from macaques should have access to and be instructed in the use of bite and scratch emergency care stations (Cohen et al. 2002). Injuries associated with macaques, their tissues or body fluids, or caging and equipment with which the animals have had direct contact, should be carefully evaluated and appropriate postexposure treatment and follow-up implemented (ibid.; NRC 2003a).

Clear procedures should be established for reporting all accidents, bites, scratches, and allergic reactions (NRC 1997), and medical care for such incidents should be readily available (Cohen et al. 2002; DHHS 2009).

### *Personnel Security*

While contingency plans normally address natural disasters, they should also take into account the threats that criminal activities such as personnel harassment and assault, facility trespassing, arson, and vandalism pose to laboratory animals, research personnel, equipment and facilities, and biomedical research at the institution. Preventive measures should be considered, including preemployment screening and physical and information technology security (Miller 2007).

### *Investigating and Reporting Animal Welfare Concerns*

Safeguarding animal welfare is the responsibility of every individual associated with the Program. The institution must develop methods for reporting and investigating animal welfare concerns, and employees should be aware of the importance of and mechanisms for reporting animal welfare concerns. In the United States, responsibility for review and investigation of these concerns rests with the IO and the IACUC. Response to such reports should include communication of findings to the concerned

employee(s), unless such concerns are reported anonymously; corrective actions if deemed necessary; and a report to the IO of the issue, findings, and actions taken. Reported concerns and any corrective actions taken should be documented.

Mechanisms for reporting concerns should be posted in prominent locations in the facility and on applicable institutional website(s) with instructions on how to report the concern and to whom. Multiple points of contact, including senior management, the IO, IACUC Chair, and AV, are recommended. The process should include a mechanism for anonymity, compliance with applicable whistleblower policies, nondiscrimination against the concerned/reporting party, and protection from reprisals.

Training and regular communication with employees (including personnel such as custodial, maintenance, and administrative staff, who are farther removed from the animal use) about the institution's animal use activities may reduce potential concerns.

## **PROGRAM OVERSIGHT**

### **The Role of the IACUC**

#### *IACUC Constitution and Function*

The responsibility of the IACUC is to oversee and routinely evaluate the Program. It is the institution's responsibility to provide suitable orientation, background materials, access to appropriate resources, and, if necessary, specific training to assist IACUC members in understanding their roles and responsibilities and evaluating issues brought before the committee.

Committee membership includes the following:

- a Doctor of Veterinary Medicine either certified (e.g., by ACLAM, ECLAM, JCLAM, KCLAM) or with training and experience in laboratory animal science and medicine or in the use of the species at the institution
- at least one practicing scientist experienced in research involving animals
- at least one member from a nonscientific background, drawn from inside or outside the institution
- at least one public member to represent general community interests in the proper care and use of animals.

Public members should not be laboratory animal users, affiliated in any way with the institution, or members of the immediate family of a person who is affiliated with the institution. The public member may receive

compensation for participation and ancillary expenses (e.g., meals, parking, travel), but the amount should be sufficiently modest that it does not become a substantial source of income and thus risk compromising the member's association with the community and public at large.

For large institutions with many administrative units or departments, no more than three voting members should be associated with a single administrative unit (USDA 1985). The size of the institution and the nature and extent of the Program will determine the number of members of the committee and their terms of appointment. Institutions with broad research programs may need to choose scientists from a number of disciplines and experience to properly evaluate animal use protocols.

The committee is responsible for oversight and evaluation of the entire Program and its components as described in other sections of the *Guide*. Its oversight functions include review and approval of proposed animal use (protocol review) and of proposed significant changes to animal use; regular inspection of facilities and animal use areas; regular review of the Program; ongoing assessment of animal care and use; and establishment of a mechanism for receipt and review of concerns involving the care and use of animals at the institution. The committee must meet as often as necessary to fulfill its responsibilities, and records of committee meetings and results of deliberations should be maintained. Program review and facilities inspections should occur at least annually or more often as required (e.g., by the Animal Welfare Act and PHS Policy). After review and inspection, a written report (including any minority views) should be provided to the IO about the status of the Program.

### *Protocol Review*

The animal use protocol is a detailed description of the proposed use of laboratory animals. The following topics should be considered in the preparation of the protocol by the researcher and its review by the IACUC:

- rationale and purpose of the proposed use of animals
- a clear and concise sequential description of the procedures involving the use of animals that is easily understood by all members of the committee
- availability or appropriateness of the use of less invasive procedures, other species, isolated organ preparation, cell or tissue culture, or computer simulation (see Appendix A, Alternatives)
- justification of the species and number of animals proposed; whenever possible, the number of animals and experimental group sizes should be statistically justified (e.g., provision of a power analysis; see Appendix A, Experimental Design and Statistics)



- unnecessary duplication of experiments
- nonstandard housing and husbandry requirements
- impact of the proposed procedures on the animals' well-being
- appropriate sedation, analgesia, and anesthesia (indices of pain or invasiveness might aid in the preparation and review of protocols; see Appendix A, Anesthesia, Pain, and Surgery)
- conduct of surgical procedures, including multiple operative procedures
- postprocedural care and observation (e.g., inclusion of post-treatment or postsurgical animal assessment forms)
- description and rationale for anticipated or selected endpoints
- criteria and process for timely intervention, removal of animals from a study, or euthanasia if painful or stressful outcomes are anticipated
- method of euthanasia or disposition of animals, including planning for care of long-lived species after study completion
- adequacy of training and experience of personnel in the procedures used, and roles and responsibilities of the personnel involved
- use of hazardous materials and provision of a safe working environment.

While the responsibility for scientific merit review normally lies outside the IACUC, the committee members should evaluate scientific elements of the protocol as they relate to the welfare and use of the animals. For example, hypothesis testing, sample size, group numbers, and adequacy of controls can relate directly to the prevention of unnecessary animal use or duplication of experiments. For some IACUC questions, input from outside experts may be advisable or necessary. In the absence of evidence of a formal scientific merit review, the IACUC may consider conducting or requesting such a review (Mann and Prentice 2004). IACUC members named in protocols or who have other conflicts must recuse themselves from decisions concerning these protocols.

At times, protocols include procedures that have not been previously encountered or that have the potential to cause pain or distress that cannot be reliably predicted or controlled. Relevant objective information about the procedures and the purpose of the study should be sought from the literature, veterinarians, investigators, and others knowledgeable about the effects on animals. If little is known about a specific procedure, limited pilot studies, designed to assess both the procedure's effects on the animals and the skills of the research team and conducted under IACUC oversight, are appropriate. General guidelines for protocol or method evaluation for some of these situations are provided below, but they may not apply in all instances.

### *Special Considerations for IACUC Review*

Certain animal use protocols include procedures or approaches that require special consideration during the IACUC review process due to their potential for unrelieved pain or distress or other animal welfare concerns. The topics below are some of the most common requiring special IACUC consideration. For these and other areas the IACUC is obliged to weigh the objectives of the study against potential animal welfare concerns. By considering opportunities for refinement, the use of appropriate nonanimal alternatives, and the use of fewer animals, both the institution and the principal investigator (PI) can begin to address their shared obligations for humane animal care and use.

*Experimental and Humane Endpoints* The experimental endpoint of a study occurs when the scientific aims and objectives have been reached. The humane endpoint is the point at which pain or distress in an experimental animal is prevented, terminated, or relieved. The use of humane endpoints contributes to refinement by providing an alternative to experimental endpoints that result in unrelieved or severe animal pain and distress, including death. The humane endpoint should be relevant and reliable (Hendriksen and Steen 2000; Olfert and Godson 2000; Sass 2000; Stokes 2002). For many invasive experiments, the experimental and humane endpoints are closely linked (Wallace 2000) and should be carefully considered during IACUC protocol review. While all studies should employ endpoints that are humane, studies that commonly require special consideration include those that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, and models of cardiovascular shock.

The PI, who has precise knowledge of both the objectives of the study and the proposed model, should identify, explain, and include in the animal use protocol a study endpoint that is both humane and scientifically sound. The identification of humane endpoints is often challenging, however, because multiple factors must be weighed, including the model, species (and sometimes strain or stock), animal health status, study objectives, institutional policy, regulatory requirements, and occasionally conflicting scientific literature. Determination of humane endpoints should involve the PI, the veterinarian, and the IACUC, and should be defined when possible before the start of the study (Olfert and Godson 2000; Stokes 2000).

Information that is critical to the IACUC's assessment of appropriate endpoint consideration in a protocol includes precise definition of the humane endpoint (including assessment criteria), the frequency of animal observation, training of personnel responsible for assessment and recognition of the

humane endpoint, and the response required upon reaching the humane endpoint. An understanding of preemptive euthanasia (Toth 2000), behavioral or physiologic definitions of the moribund state (*ibid.*), and the use of study-specific animal assessment records (Morton 2000; Paster et al. 2009) can aid the PI and IACUC when considering or developing proposed endpoints. When novel studies are proposed or information for an alternative endpoint is lacking, the use of pilot studies is an effective method for identifying and defining humane endpoints and reaching consensus among the PI, IACUC, and veterinarian. A system for communication with the IACUC should be in place both during and after such studies. Numerous publications address specific proposals for the application and use of humane endpoints (e.g., CCAC 1998; ILAR 2000; OECD 1999; Toth 1997; UKCCCR 1997).

*Unexpected Outcomes* Fundamental to scientific inquiry is the investigation of novel experimental variables. Because of the potential for unexpected outcomes that may affect animal well-being when highly novel variables are introduced, more frequent monitoring of animals may be required. With their inherent potential for unanticipated phenotypes, GMAs are an example of models for which increased monitoring for unexpected outcomes could be implemented (Dennis 1999).

GMAs, particularly mice and fish, are important animal models, and new methods and combinations of genetic manipulation are constantly being developed (Gondo 2008). Regardless of whether genetic manipulation is targeted or random, the phenotype that initially results is often unpredictable and may lead to expected or unexpected outcomes that affect the animal's well-being or survival at any stage of life. For example, in some instances genetic modification has led to unforeseen immunodeficiency, requiring the GMA offspring to be held under specialized bioexclusion conditions (Mumphrey et al. 2007); and the promoter sequences used to direct expression of transgenes to specific tissues have varying degrees of specificity ("leakiness") that can lead to unanticipated phenotypes (Moorehead et al. 2003). These examples illustrate the diversity of unanticipated outcomes and emphasize the need for diligent monitoring and professional judgment to ensure the animals' well-being (Dennis 2000). The first offspring of a newly generated GMA line should be carefully observed from birth into early adulthood for signs of disease, pain, or distress. Investigators may find that the phenotype precludes breeding of particular genotypes or that unexpected infertility occurs, situations that could lead to increases in the numbers of animals used and revision of the animal use protocol. When the initial characterization of a GMA reveals a condition that negatively affects animal well-being, this should be reported to the IACUC, and more extensive analysis may be required to better define the phenotype (Brown et al. 2000; Crawley 1999; Dennis 2000). Such monitoring and reporting may

help to determine whether proactive measures can circumvent or alleviate the impact of the genetic modification on the animal's well-being and to establish humane endpoints specific to the GMA line.

*Physical Restraint* Physical restraint is the use of manual or mechanical means to limit some or all of an animal's normal movement for the purpose of examination, collection of samples, drug administration, therapy, or experimental manipulation. Animals are restrained for brief periods, usually minutes, in many research applications.

Restraint devices should be suitable in size, design, and operation to minimize discomfort, pain, distress, and the potential for injury to the animal and the research staff. Dogs, nonhuman primates, and many other animals can be trained, through use of positive reinforcement techniques, to cooperate with research procedures or remain immobile for brief periods (Boissy et al. 2007; Laule et al. 2003; Meunier 2006; Prescott and Buchanan-Smith 2003; Reinhardt 1991, 1995; Saucedo and Schmidt 2000; Yeates and Main 2009).

Prolonged restraint, including chairing of nonhuman primates, should be avoided unless it is essential for achieving research objectives and is specifically approved by the IACUC (NRC 2003b). Systems that do not limit an animal's ability to make normal postural adjustments (e.g., subcutaneous implantation of osmotic minipumps in rodents, backpack-fitted infusion pumps in dogs and nonhuman primates, and free-stall housing for farm animals) should be used when compatible with protocol objectives. Animals that do not adapt to necessary restraint systems should be removed from the study. When restraint devices are used, they should be specifically designed to accomplish research goals that are impossible or impractical to accomplish by other means or to prevent injury to animals or personnel.

The following are important guidelines for restraint:

- Restraint devices should not be considered a normal method of housing, and must be justified in the animal use protocol.
- Restraint devices should not be used simply as a convenience in handling or managing animals.
- Alternatives to physical restraint should be considered.
- The period of restraint should be the minimum required to accomplish the research objectives.
- Animals to be placed in restraint devices should be given training (with positive reinforcement) to adapt to the equipment and personnel.
- Animals that fail to adapt should be removed from the study.
- Provision should be made for observation of the animal at appropriate intervals, as determined by the IACUC.

- Veterinary care must be provided if lesions or illnesses associated with restraint are observed. The presence of lesions, illness, or severe behavioral change often necessitates the temporary or permanent removal of the animal from restraint.
- The purpose of the restraint and its duration should be clearly explained to personnel involved with the study.

*Multiple Survival Surgical Procedures* Surgical procedures in the laboratory setting may be categorized as major or minor (USDA 1985). Whether a procedure is major or minor should be evaluated on a case-by-case basis, as determined by the veterinarian and IACUC (NRC 2003b; Silverman et al. 2007; for additional discussion see Chapter 4, Surgical Procedures).

Regardless of classification, multiple surgical procedures on a single animal should be evaluated to determine their impact on the animal's well-being. Multiple major surgical procedures on a single animal are acceptable only if they are (1) included in and essential components of a single research project or protocol, (2) scientifically justified by the investigator, or (3) necessary for clinical reasons. Conservation of scarce animal resources may justify the conduct of multiple major surgeries on a single animal, but the application of such a practice on a single animal used in separate protocols is discouraged and should be reviewed critically by the IACUC. When applicable, the IO must submit a request to the USDA/APHIS and receive approval in order to allow a regulated animal to undergo multiple major survival surgical procedures in separate unrelated research protocols (USDA 1985, 1997a). Justifications for allowing animals not regulated by the USDA to undergo multiple survival procedures that meet the above criteria should conform to those required for regulated species. If multiple survival surgery is approved, the IACUC should pay particular attention to animal well-being through continuing evaluation of outcomes. Cost savings alone is not an adequate reason for performing multiple major survival surgical procedures.

Some procedures characterized as minor may induce substantial post-procedural pain or impairment and should similarly be scientifically justified if performed more than once in a single animal.

*Food and Fluid Regulation* Regulation of food or fluid intake may be required for the conduct of some physiological, neuroscience, and behavioral research protocols. The regulation process may entail *scheduled access* to food or fluid sources, so an animal consumes as much as desired at regular intervals, or *restriction*, in which the total volume of food or fluid consumed is strictly monitored and controlled (NRC 2003b). The objective when these studies are being planned and executed should be to use the

least restriction necessary to achieve the scientific objective while maintaining animal well-being.

The development of animal protocols that involve the use of food or fluid regulation requires the evaluation of three factors: the necessary level of regulation, potential adverse consequences of regulation, and methods for assessing the health and well-being of the animals (NRC 2003b). In addition, the following factors influence the amount of food or fluid restriction that can be safely used in a specific protocol: the species, strain, or stock, gender, and age of the animals; thermoregulatory demand; type of housing; time of feeding, nutritive value, and fiber content of the diet (Heiderstadt et al. 2000; Rowland 2007); and prior experimental manipulation. The degree of food or fluid restriction necessary for consistent behavioral performance is influenced by the difficulty of the task, the individual animal, the motivation required of the animal, and the effectiveness of animal training for a specific protocol-related task.

The animals should be closely monitored to ensure that food and fluid intake meets their nutritional needs (Toth and Gardiner 2000). Body weights should be recorded at least weekly and more often for animals requiring greater restrictions (NRC 2003b). Written records should be maintained for each animal to document daily food and fluid consumption, hydration status, and any behavioral and clinical changes used as criteria for temporary or permanent removal of an animal from a protocol (Morton 2000; NRC 2003b). In the case of conditioned-response research protocols, use of a highly preferred food or fluid as positive reinforcement, instead of restriction, is recommended. Caloric restriction, as a husbandry technique and means of weight control, is discussed in Chapter 3.

*Use of Non-Pharmaceutical-Grade Chemicals and Other Substances* The use of pharmaceutical-grade chemicals and other substances ensures that toxic or unwanted side effects are not introduced into studies conducted with experimental animals. They should therefore be used, when available, for all animal-related procedures (USDA 1997b). The use of non-pharmaceutical-grade chemicals or substances should be described and justified in the animal use protocol and be approved by the IACUC (Wolff et al. 2003); for example, the use of a non-pharmaceutical-grade chemical or substance may be necessary to meet the scientific goals of a project or when a veterinary or human pharmaceutical-grade product is unavailable. In such instances, consideration should be given to the grade, purity, sterility, pH, pyrogenicity, osmolality, stability, site and route of administration, formulation, compatibility, and pharmacokinetics of the chemical or substance to be administered, as well as animal welfare and scientific issues relating to its use (NIH 2008).

*Field Investigations* Investigations may involve the observation or use of nondomesticated vertebrate species under field conditions. Many field investigations require international, federal, state, and/or local permits, which may call for an evaluation of the scientific merit of the proposed study and a determination of the potential impact on the population or species to be studied.

Additionally, occupational health and safety issues, including zoonoses, should be reviewed by the institution's health and safety committee or office, with assurances to the IACUC that the field study does not compromise the health and safety of either animals or persons in the field. Principal investigators conducting field research should be knowledgeable about relevant zoonotic diseases, associated safety issues, and any laws or regulations that apply. Exceptions to the above should be clearly defined and evaluated by the IACUC.

In preparing the design of a field study, investigators are encouraged to consult with relevant professional societies and available guidelines (see Appendix A). Veterinary input may be needed for projects involving capture, individual identification, sedation, anesthesia, surgery, recovery, holding, transportation, release, or euthanasia. Issues associated with these activities are similar if not identical to those for species maintained and used in the laboratory. When species are removed from the wild, the protocol should include plans for either a return to their habitat or their final disposition, as appropriate.

The *Guide* does not purport to be a compendium of all information regarding field biology and methods used in wildlife investigations, but the basic principles of humane care and use apply to animals living under natural conditions. IACUCs engaged in the review of field studies are encouraged to consult with a qualified wildlife biologist.

*Agricultural Animals* The use of agricultural animals in research is subject to the same ethical considerations as for other animals in research, although it is often categorized as either biomedical or agricultural because of government regulations and policies, institutional policies, administrative structure, funding sources, and/or user goals (Stricklin et al. 1990). This categorization has led to a dual system with different criteria for evaluating protocols and standards of housing and care for animals of the same species on the basis of stated biomedical or agricultural research objectives (Stricklin and Mench 1994). With some studies, differences in research goals may lead to a clear distinction between biomedical and agricultural research. For example, animal models of human diseases, organ transplantation, and major surgery are considered biomedical uses; and studies on food and fiber production, such as feeding trials, are usually considered agricultural uses. But when the distinction is unclear, as in the case of some nutrition and

disease studies, administrators, regulators, and IACUCs face a dilemma in deciding how to handle such studies (Stricklin et al. 1990). Decisions on categorizing research uses of agricultural animals and defining standards for their care and use should be made by the IACUC based on both the researcher's goals and concern for animal well-being. Regardless of the category of research, institutions are expected to provide oversight of all research animals and ensure that pain and distress are minimized.

The protocol, rather than the category of research, should determine the setting (farm or laboratory). Housing systems for agricultural animals used in biomedical research may or may not differ from those used in agricultural research; animals used in either type of research can be housed in cages, stalls, paddocks, or pastures (Tillman 1994). Some agricultural studies need uniform conditions to minimize environmental variability, and some biomedical studies are conducted in farm settings. Agricultural research often necessitates that animals be managed according to contemporary farm production practices (Stricklin and Mench 1994), and natural environmental conditions might be desirable for agricultural research, whereas control of environmental conditions to minimize variation might be desirable in biomedical research (Tillman 1994).

The *Guide* applies to agricultural animals used in biomedical research, including those maintained in typical farm settings. For animals maintained in a farm setting, the *Guide for the Care and Use of Agricultural Animals in Research and Teaching* (FASS 2010) is a useful resource. Information about environmental enrichment, transport, and handling may be helpful in both agricultural and biomedical research settings. Additional information about facilities and management of farm animals in an agricultural setting is available from the Midwest Plan Service (1987) and from agricultural engineers or animal science experts.

### **Postapproval Monitoring**

Continuing IACUC oversight of animal activities is required by federal laws, regulations, and policies. A variety of mechanisms can be used to facilitate ongoing protocol assessment and regulatory compliance. Postapproval monitoring (PAM) is considered here in the broadest sense, consisting of all types of protocol monitoring after the IACUC's initial protocol approval.

PAM helps ensure the well-being of the animals and may also provide opportunities to refine research procedures. Methods include continuing protocol review; laboratory inspections (conducted either during regular facilities inspections or separately); veterinary or IACUC observation of selected procedures; observation of animals by animal care, veterinary, and IACUC staff and members; and external regulatory inspections and assess-



ments. The IACUC, veterinary, animal care, and compliance staff may all conduct PAM, which may also serve as an educational tool.

Continuing protocol review typically consists of an annual update or review as well as the triennial review required by the PHS. The depth of such reviews varies from a cursory update to a full committee review of the entire protocol. Some institutions use the annual review as an opportunity for the investigator to submit proposed amendments for future procedures, to provide a description of any adverse or unanticipated events, and to provide updates on work progress. For the triennial review, many institutions require a complete new protocol submission and may request a progress report on the use of animals during the previous 3 years.

Both the Health Research Extension Act and the AWA require the IACUC to inspect animal care and use facilities, including sites used for animal surgeries, every 6 months. As part of a formal PAM program some institutions combine inspection of animal study sites with concurrent review of animal protocols. Based on risks to animals and their handlers, other study areas may require more or less frequent inspections. Examples of effective monitoring strategies include

- examination of surgical areas, including anesthetic equipment, use of appropriate aseptic technique, and handling and use of controlled substances
- review of protocol-related health and safety issues
- review of anesthetic and surgical records
- regular review of adverse or unexpected experimental outcomes affecting the animals
- observation of laboratory practices and procedures and comparison with approved protocols.

Institutions may also consider the use of veterinary staff and/or animal health technicians to observe increased risk procedures for adverse events (e.g., novel survival surgeries, pain studies, tumor growth studies) and report their findings for review by the IACUC. The level of formality and intensity of PAM should be tailored to institutional size and complexity, and in all cases should support a culture of care focusing on the animals' well-being (Klein and Bayne 2007). Regardless of the methods used or who conducts and coordinates the monitoring, PAM programs are more likely to succeed when the institution encourages an educational partnership with investigators (Banks and Norton 2008; Collins 2008; Dale 2008; Lowman 2008; Plante and James 2008; Van Sluyters 2008).

## DISASTER PLANNING AND EMERGENCY PREPAREDNESS

Animal facilities may be subject to unexpected conditions that result in the catastrophic failure of critical systems or significant personnel absenteeism, or other unexpected events that severely compromise ongoing animal care and well-being (ILAR 2010). Facilities must therefore have a disaster plan. The plan should define the actions necessary to prevent animal pain, distress, and deaths due to loss of systems such as those that control ventilation, cooling, heating, or provision of potable water. If possible the plan should describe how the facility will preserve animals that are necessary for critical research activities or are irreplaceable. Knowledge of the geographic locale may provide guidance as to the probability of a particular type of disaster.

Disaster plans should be established in conjunction with the responsible investigator(s), taking into consideration both the priorities for triaging animal populations and the institutional needs and resources. Animals that cannot be relocated or protected from the consequences of the disaster must be humanely euthanized. The disaster plan should identify essential personnel who should be trained in advance in its implementation. Efforts should be taken to ensure personnel safety and provide access to essential personnel during or immediately after a disaster. Such plans should be approved by the institution and be part of the overall institutional disaster response plan that is coordinated by the IO or another senior-level administrator. Law enforcement and emergency personnel should be provided with a copy of the plan for comment and integration into broader, areawide planning (Vogelweid 1998).

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# 3

## Environment, Housing, and Management

This chapter provides guidelines for the environment, housing, and management of laboratory animals used or produced for research, testing, and teaching. These guidelines are applicable across species and are relatively general; additional information should be sought about how to apply them to meet the specific needs of any species, strain, or use (see Appendix A for references). The chapter is divided into recommendations for terrestrial (page 42) and aquatic animals (page 77), as there are fundamental differences in their environmental requirements as well as animal husbandry, housing, and care needs. Although formulated specifically for vertebrate species, the general principles of humane animal care as set out in the *Guide* may also apply to invertebrate species.

The design of animal facilities combined with appropriate animal housing and management are essential contributors to animal well-being, the quality of animal research and production, teaching or testing programs involving animals, and the health and safety of personnel. An appropriate Program (see Chapter 2) provides environments, housing, and management that are well suited for the species or strains of animals maintained and takes into account their physical, physiologic, and behavioral needs, allowing them to grow, mature, and reproduce normally while providing for their health and well-being.

Fish, amphibians, and reptiles are *poikilothermic* animals: their core temperature varies with environmental conditions and they have limited ability (compared with birds and mammals) to metabolically maintain core temperature. The majority of poikilothermic laboratory animals are aquatic species—for example, fish and most amphibians—although some, such as



reptiles and certain amphibian species, are terrestrial. Personnel working with aquatic animals should be familiar with management implications, e.g., the importance of providing appropriate temperature ranges for basic physiologic function.

## TERRESTRIAL ANIMALS

### Terrestrial Environment

#### *Microenvironment and Macroenvironment*

The *microenvironment* of a terrestrial animal is the physical environment immediately surrounding it; that is, the primary enclosure such as the cage, pen, or stall. It contains all the resources with which the animals come directly in contact and also provides the limits of the animals' immediate environment. The microenvironment is characterized by many factors, including illumination, noise, vibration, temperature, humidity, and gaseous and particulate composition of the air. The physical environment

*Microenvironment:* The immediate physical environment surrounding the animal (i.e., the environment in the primary enclosure such as the cage, pen, or stall).

of the secondary enclosure, such as a room, a barn, or an outdoor habitat, constitutes the *macroenvironment*.

Although the microenvironment and the macroenvironment are generally related, the microenvironment can be appreciably different and affected by several factors, including the design of the primary enclosure and macroenvironmental conditions.

*Macroenvironment:* The physical environment of the secondary enclosure (e.g., a room, a barn, or an outdoor habitat).

Evaluation of the microenvironment of small enclosures can be difficult. Available data indicate that temperature, humidity, and concentrations of gases and particulate matter are often higher in the animal microenvironment than in the macroenvironment (Besch 1980; Hasenau

et al. 1993; Perkins and Lipman 1995; E. Smith et al. 2004), while light levels are usually lower. Microenvironmental conditions can directly affect physiologic processes and behavior and may alter disease susceptibility (Baer et al. 1997; Broderson et al. 1976; Memarzadeh et al. 2004; Schoeb et al. 1982; Vesell et al. 1976).

### *Temperature and Humidity*

Maintenance of body temperature within normal circadian variation is necessary for animal well-being. Animals should be housed within temperature and humidity ranges appropriate for the species, to which they can adapt with minimal stress and physiologic alteration.

The ambient temperature range in which thermoregulation occurs without the need to increase metabolic heat production or activate evaporative heat loss mechanisms is called the *thermoneutral zone (TNZ)* and is bounded by the lower and upper critical temperatures (LCTs and UCTs; Gordon 2005). To maintain body temperature under a given environmental temperature animals adjust physiologically (including their metabolism) and behaviorally (including their activity level and resource use). For example, the TNZ of mice ranges between 26°C and 34°C (Gordon 1993); at lower temperatures, building nests and huddling for resting and sleeping allow them to thermoregulate by behaviorally controlling their microclimate. Although mice choose temperatures below their LCT of 26°C during activity periods, they strongly prefer temperatures above their LCT for maintenance and resting behaviors (Gaskill et al. 2009; Gordon 2004; Gordon et al. 1998). Similar LCT values are found in the literature for other rodents, varying between 26-30°C for rats and 28-32°C for gerbils (Gordon 1993). The LCTs of rabbits (15-20°C; Gonzalez et al. 1971) and cats and dogs (20-25°C) are slightly lower, while those of nonhuman primates and farm animals vary depending on the species. In general, dry-bulb temperatures in animal rooms should be set below the animals' LCT to avoid heat stress. This, in turn, means that animals should be provided with adequate resources for thermoregulation (nesting material, shelter) to avoid cold stress. Adequate resources for thermoregulation are particularly important for newborn animals whose LCT is normally considerably higher than that of their adult conspecifics.

Environmental temperature and relative humidity can be affected by husbandry and housing design and can differ considerably between primary and secondary enclosures as well as within primary enclosures. Factors that contribute to variation in temperature and humidity between and within enclosures include housing design; construction material; enrichment devices such as shelters and nesting material; use of filter tops; number, age, type, and size of the animals in each enclosure; forced ventilation of enclosures; and the type and frequency of contact bedding changes (Besch 1980).

Exposure to wide temperature and humidity fluctuations or extremes may result in behavioral, physiologic, and morphologic changes, which might negatively affect animal well-being and research performance as well as outcomes of research protocols (Garrard et al. 1974; Gordon 1990,

1993; Pennycuik 1967). These effects can be multigenerational (Barnett 1965, 1973).

The dry-bulb temperatures listed in Table 3.1 are broad and generally reflect tolerable limits for common adult laboratory animal species, provided they are housed with adequate resources for behavioral thermoregulation; temperatures should normally be selected and maintained with minimal fluctuation near the middle of these ranges. Depending on the specific housing system employed, the selection of appropriate macro- and micro-environmental temperatures will differ based on a variety of factors, including but not limited to the species or strain, age, numbers of animals in the enclosure, size and construction of the primary enclosure, and husbandry conditions (e.g., use/provision of contact bedding, nesting material and/or shelter, individually ventilated cages). Poikilotherms and young birds of some species generally require a thermal gradient in their primary enclosure to meet basic physiological processes. The temperature ranges shown may not apply to captive wild animals, wild animals maintained in their natural environment, or animals in outdoor enclosures that have the opportunity to adapt by being exposed to seasonal changes in ambient conditions.

Some conditions require increased environmental temperatures for housing (e.g., postoperative recovery, neonatal animals, rodents with hairless phenotypes, reptiles and amphibians at certain stages of reproduction). The magnitude of the temperature increase depends on housing details; sometimes raising the temperature in the microenvironment alone (e.g., by using heating pads for postoperative recovery or radiant heat sources for reptiles) rather than raising the temperature of the macroenvironment is sufficient and preferable.

Relative humidity should also be controlled, but not nearly as narrowly as temperature for many mammals; the acceptable range of relative humidity is considered to be 30% to 70% for most mammalian species. Micro-

TABLE 3.1 Recommended Dry-Bulb Macroenvironmental Temperatures for Common Laboratory Animals

Animal	Dry-Bulb Temperature	
	°C	°F
Mouse, rat, hamster, gerbil, guinea pig <sup>a</sup>	20-26	68-79
Rabbit	16-22	61-72
Cat, dog, nonhuman primate	18-29	64-84
Farm animals, poultry	16-27	61-81

<sup>a</sup>Dry-bulb room temperature settings for rodents are typically set below the animals' LCT to avoid heat stress, and should reflect different species-specific LCT values. Animals should be provided with adequate resources for thermoregulation (nesting material, shelter) to avoid cold stress.

environmental relative humidity may be of greater importance for animals housed in a primary enclosure in which the environmental conditions differ greatly from those of the macroenvironment (e.g., in static filter-top [isolator] cages).

Some species may require conditions with high relative humidity (e.g., selected species of nonhuman primates, tropical reptiles, and amphibians; Olson and Palotay 1983). In mice, both abnormally high and low humidity may increase preweaning mortality (Clough 1982). In rats, low relative humidity, especially in combination with temperature extremes, may lead to ringtail, a condition involving ischemic necrosis of the tail and sometimes toes (Crippa et al. 2000; Njaa et al. 1957; Totten 1958). For some species, elevated relative humidity may affect an animal's ability to cope with thermal extremes. Elevated microenvironmental relative humidity in rodent isolator cages may also lead to high intracage ammonia concentrations (Corning and Lipman 1991; Hasenau et al. 1993), which can be irritating to the nasal passages and alter some biologic responses (Gordon et al. 1980; Manninen et al. 1998). In climates where it is difficult to provide a sufficient level of environmental relative humidity, animals should be closely monitored for negative effects such as excessively flaky skin, ecdysis (molting) difficulties in reptiles, and desiccation stress in semiaquatic amphibians.

### *Ventilation and Air Quality*

The primary purpose of ventilation is to provide appropriate air quality and a stable environment. Specifically, ventilation provides an adequate oxygen supply; removes thermal loads caused by the animals, personnel, lights, and equipment; dilutes gaseous and particulate contaminants including allergens and airborne pathogens; adjusts the moisture content and temperature of room air; and, where appropriate, creates air pressure differentials (directional air flow) between adjoining spaces. Importantly, ventilating the room (i.e., the macroenvironment) does not necessarily ensure adequate ventilation of an animal's primary enclosure (i.e., the microenvironment), that is, the air to which the animal is actually exposed. The type of primary enclosure may considerably influence the differences between these two environments—for example, differences may be negligible when animals are housed in open caging or pens, whereas they can be significant when static isolator cages are used.

The volume and physical characteristics of the air supplied to a room and its diffusion pattern influence the ventilation of an animal's primary enclosure and are important determinants of the animal's microenvironment. The type and location of supply air diffusers and exhaust registers in relation to the number, arrangement, location, and type of primary and secondary enclosures affect how well the microenvironments are ventilated

and should therefore be considered. The use of computer modeling for assessing those factors in relation to heat loading, air diffusion patterns, and particulate movement may be helpful in optimizing ventilation of micro- and macroenvironments (Hughes and Reynolds 1995).

Direct exposure of animals to air moving at high velocity (drafts) should be avoided as the speed of air to which animals are exposed affects the rate at which heat and moisture are removed from an animal. For example, air at 20°C moving at 60 linear feet per minute (18.3 m/min) has a cooling effect of approximately 7°C (Weihe 1971). Drafts can be particularly problematic for neonatal homeotherms (which may be hairless and have poorly developed mechanisms for thermoregulatory control), for mutants lacking fur, and for semiaquatic amphibians that can desiccate.

Provision of 10 to 15 fresh air changes per hour in animal housing rooms is an acceptable guideline to maintain macroenvironmental air quality by constant volume systems and may also ensure microenvironmental air quality. Although this range is effective in many animal housing settings, it does not take into account the range of possible heat loads; the species, size, and number of animals involved; the type of primary enclosure and bedding; the frequency of cage changing; the room dimensions; or the efficiency of air distribution both in the macroenvironment and between the macro- and microenvironments. In some situations, the use of such a broad guideline might overventilate a macroenvironment containing few animals, thereby wasting energy, or underventilate a microenvironment containing many animals, allowing heat, moisture, and pollutants to accumulate.

Modern heating, ventilation, and air conditioning (HVAC) systems (e.g., variable air volume, or VAV, systems) allow ventilation rates to be set in accordance with heat load and other variables. These systems offer considerable advantages with respect to flexibility and energy conservation, but should always provide a minimum amount of air exchange, as recommended for general use laboratories (Bell 2008; DiBerardinis et al. 2009).

Individually ventilated cages (IVCs) and other types of specialized primary enclosures, that either directly ventilate the enclosure using filtered room air or are ventilated independently of the room, can effectively address animals' ventilation requirements without the need to increase macroenvironmental ventilation. However, cautions mentioned above regarding high-velocity air should be considered (Baumans et al. 2002; Krohn et al. 2003). Nevertheless, the macroenvironment should be ventilated sufficiently to address heat loads, particulates, odors, and waste gases released from primary enclosures (Lipman 1993).

If ventilated primary enclosures have adequate filtration to address contamination risks, air exhausted from the microenvironment may be returned to the room in which animals are housed, although it is generally prefer-

able to exhaust these systems directly into the building's exhaust system to reduce heat load and macroenvironmental contamination.

Static isolation caging (without forced ventilation), such as that used in some types of rodent housing, restricts ventilation (Keller et al. 1989). To compensate, it may be necessary to adjust husbandry practices, including sanitation and cage change frequency, selection of contact bedding, placement of cages in a secondary enclosure, animal densities in cages, and/or decrease in macroenvironmental relative humidity to improve the microenvironment and heat dissipation.

The use of recycled air to ventilate animal rooms may save energy but entails risks. Because many animal pathogens can be airborne or travel on fomites (e.g., dust), exhaust air recycled into HVAC systems that serve multiple rooms presents a risk of cross contamination. Recycling air from nonanimal use areas (e.g., some human occupancy areas and food, bedding, and supply storage areas) may require less intensive filtration or conditioning and pose less risk of infection. The risks in some situations, however, might be too great to consider recycling (e.g., in the case of non-human primates and biohazard areas). The exhaust air to be recycled should be filtered, at minimum, with 85-95% ASHRAE efficient filters to remove airborne particles before it is recycled (NAFA 1996). Depending on the air source, composition, and proportion of recycled air used (e.g., ammonia and other gases emitted from excrement in recirculating air from animal rooms), consideration should also be given to filtering volatile substances. In areas that require filtration to ensure personnel and/or animal safety (e.g., hazardous containment holding), filter efficiency, loading, and integrity should be assessed.

The successful operation of any HVAC system requires regular preventive maintenance and evaluation, including measurement of its function at the level of the secondary enclosure. Such measurements should include supply and exhaust air volumes, fluctuation in temperature and relative humidity, and air pressure differentials between spaces as well as critical mechanical operating parameters.

### *Illumination*

Light can affect the physiology, morphology, and behavior of various animals (Azar et al. 2008; Brainard et al. 1986; Erkert and Grober 1986; Newbold et al. 1991; Tucker et al. 1984). Potential photostressors include inappropriate photoperiod, photointensity, and spectral quality of the light (Stoskopf 1983).

Numerous factors can affect animals' needs for light and should be considered when an appropriate illumination level is being established for an animal holding room. These include light intensity and wavelength as

well as the duration of the animal's current and prior exposure to light, and the animal's pigmentation, circadian rhythm, body temperature, hormonal status, age, species, sex, and stock or strain (Brainard 1989; Duncan and O'Steen 1985; O'Steen 1980; Saltarelli and Coppola 1979; Semple-Rowland and Dawson 1987; Wax 1977). More recent studies in rodents and primates have shown the importance of intrinsically photosensitive retinal ganglion cells (distinct from rods and cones) for neuroendocrine, circadian, and neurobehavioral regulation (Berson et al. 2002; Hanifin and Brainard 2007). These cells can respond to light wavelengths that may differ from other photoreceptors and may influence the type of lighting, light intensity, and wavelength selected for certain types of research.

In general, lighting should be diffused throughout an animal holding area and provide sufficient illumination for the animals' well-being while permitting good housekeeping practices, adequate animal inspection including for the bottom-most cages in racks, and safe working conditions for personnel. Light in animal holding rooms should provide for both adequate vision and neuroendocrine regulation of diurnal and circadian cycles (Brainard 1989).

Photoperiod is a critical regulator of reproductive behavior in many animal species (Brainard et al. 1986; Cherry 1987), so inadvertent light exposure during the dark cycle should be minimized or avoided. Because some species, such as chickens (Apeldoorn et al. 1999), will not eat in low light or darkness, such illumination schedules should be limited to a duration that will not compromise their well-being. A time-controlled lighting system should be used to ensure a regular diurnal cycle, and system performance should be checked regularly to ensure proper cycling.

Most commonly used laboratory rodents are nocturnal. Because albino rodents are more susceptible to phototoxic retinopathy than other animals (Beaumont 2002), they have been used as a basis for establishing room illumination levels (Lanum 1979). Data for room light intensities for other animals, based on scientific studies, are not available. Light levels of about 325 lux (30-ft candles) approximately 1 m (3.3 ft) above the floor appear to be sufficient for animal care and do not cause clinical signs of phototoxic retinopathy in albino rats (Bellhorn 1980). Levels up to 400 lux (37-ft candles) as measured in an empty room 1 m from the floor have been found to be satisfactory for rodents if management practices are used to prevent retinal damage in albinos (Clough 1982). However, the light experience of an individual animal can affect its sensitivity to phototoxicity; light of 130-270 lux above the light intensity under which it was raised has been reported to be near the threshold of retinal damage in some individual albino rats according to histologic, morphometric, and electrophysiologic evidence (Semple-Rowland and Dawson 1987). Some guidelines recommend a light intensity as low as 40 lux at the position of the animal in

midcage (NASA 1988). Rats and mice generally prefer cages with low light intensity (Blom et al. 1996), and albino rats prefer areas with a light intensity of less than 25 lux (Schlingmann et al. 1993a). Young mice prefer much lower illumination than adults (Wax 1977). For animals that have been shown to be susceptible to phototoxic retinopathy, light should be between 130 and 325 lux in the room at cage level.

Light intensity decreases with the square of the distance from its source. Thus the location of a cage on a rack affects the intensity of light to which the animals within are exposed. Light intensity may differ as much as 80-fold in transparent cages from the top to the bottom of a rack, and differences up to 20-fold have been recorded within a cage (Schlingmann et al. 1993a,b). Management practices, such as rotating cage position relative to the light source (Greenman et al. 1982) or providing animals with ways to control their own light exposure by behavioral means (e.g., nesting or bedding material adequate for tunneling), can reduce inappropriate light stimulation. Variable-intensity lights are often used to accommodate the needs of research protocols, certain animal species, and energy conservation. However, such a system should also provide for the observation and care of the animals. Caution should be exercised as increases in daytime room illumination for maintenance purposes have been shown to change photoreceptor physiology and can alter circadian regulation (NRC 1996; Reme et al. 1991; Terman et al. 1991).

### *Noise and Vibration*

Noise produced by animals and animal care activities is inherent in the operation of an animal facility (Pfaff and Stecker 1976) and noise control should be considered in facility design and operation (Pekrul 1991). Assessment of the potential effects of noise on an animal warrants consideration of the intensity, frequency, rapidity of onset, duration, and vibration potential of the sound and the hearing range, noise exposure history, and sound effect susceptibility of the species, stock, or strain. Similarly, occupational exposure to animal or animal care practices that generate noise may be of concern for personnel and, if of sufficient intensity, may warrant hearing protection.

Separation of human and animal areas minimizes disturbances to both human and animal occupants of the facility. Noisy animals, such as dogs, swine, goats, nonhuman primates, and some birds (e.g., zebra finches), should be housed away from quieter animals, such as rodents, rabbits, and cats. Environments should be designed to accommodate animals that make noise rather than resorting to methods of noise reduction. Exposure to sound louder than 85 dB can have both auditory and nonauditory effects (Fletcher 1976; Peterson 1980)—for example, eosinopenia, increased adrenal gland weights, and reduced fertility in rodents (Geber et al. 1966; Nayfield and



Besch 1981; Rasmussen et al. 2009), and increased blood pressure in nonhuman primates (Peterson et al. 1981)—and may necessitate hearing protection for personnel (OSHA 1998). Many species can hear sound frequencies inaudible to humans (Brown and Pye 1975; Heffner and Heffner 2007); rodents, for example, are very sensitive to ultrasound (Olivier et al. 1994). The potential effects of equipment (such as video display terminals; Sales 1991; Sales et al. 1999) and materials that produce noise in the hearing range of nearby animals can thus become an uncontrolled variable for research experiments and should therefore be carefully considered (Turner et al. 2007; Willott 2007). To the greatest extent possible, activities that generate noise should be conducted in rooms or areas separate from those used for animal housing.

Because changes in patterns of sound exposure have different effects on different animals (Armario et al. 1985; Clough 1982), personnel should try to minimize the production of unnecessary noise. Excessive and intermittent noise can be minimized by training personnel in alternatives to noisy practices, the use of cushioned casters and bumpers on carts, trucks, and racks, and proper equipment maintenance (e.g., castor lubrication). Radios, alarms, and other sound generators should not be used in animal rooms unless they are part of an approved protocol or enrichment program. Any radios or sound generators used should be switched off at the end of the working day to minimize associated adverse physiologic changes (Baldwin 2007).

While some vibration is inherent to every facility and animal housing condition, excessive vibration has been associated with biochemical and reproductive changes in laboratory animals (Briese et al. 1984; Carman et al. 2007) and can become an uncontrolled variable for research experiments. The source of vibrations may be located within or outside the animal facility. In the latter case, groundborne vibration may affect both the structure and its contents, including animal racks and cages. Housing systems with moving components, such as ventilated caging system blowers, may create vibrations that could affect the animals housed within, especially if not functioning properly. Like noise, vibration varies with intensity, frequency, and duration. A variety of techniques may be used to isolate groundborne (see Chapter 5) and equipment-generated vibration (Carman et al. 2007). Attempts should be made to minimize the generation of vibration, including from humans, and excessive vibration should be avoided.

## **Terrestrial Housing**

### *Microenvironment (Primary Enclosure)*

All animals should be housed under conditions that provide sufficient space as well as supplementary structures and resources required to meet

physical, physiologic, and behavioral needs. Environments that fail to meet the animals' needs may result in abnormal brain development, physiologic dysfunction, and behavioral disorders (Garner 2005; van Praag et al. 2000; Würbel 2001) that may compromise both animal well-being and scientific validity. The primary enclosure or space may need to be enriched to prevent such effects (see also section on Environmental Enrichment).

An appropriate housing space or enclosure should also account for the animals' social needs. Social animals should be housed in stable pairs or groups of compatible individuals unless they must be housed alone for experimental reasons or because of social incompatibility (see also section on Behavioral and Social Management). Structural adjustments are frequently required for social housing (e.g., perches, visual barriers, refuges), and important resources (e.g., food, water, and shelter) should be provided in such a way that they cannot be monopolized by dominant animals (see also section on Environmental Enrichment).

The primary enclosure should provide a secure environment that does not permit animal escape and should be made of durable, nontoxic materials that resist corrosion, withstand the rigors of cleaning and regular handling, and are not detrimental to the health and research use of the animals. The enclosure should be designed and manufactured to prevent accidental entrapment of animals or their appendages and should be free of sharp edges or projections that could cause injury to the animals or personnel. It should have smooth, impervious surfaces with minimal ledges, angles, corners, and overlapping surfaces so that accumulation of dirt, debris, and moisture is minimized and cleaning and disinfecting are not impaired. All enclosures should be kept in good repair to prevent escape of or injury to animals, promote physical comfort, and facilitate sanitation and servicing. Rusting or oxidized equipment, which threatens the health or safety of animals, needs to be repaired or replaced. Less durable materials, such as wood, may be appropriate in select situations, such as outdoor corrals, perches, climbing structures, resting areas, and perimeter fences for primary enclosures. Wooden items may need to be replaced periodically because of damage or difficulties with sanitation. Painting or sealing wood surfaces with nontoxic materials may improve durability in many instances.

Flooring should be solid, perforated, or slatted with a slip-resistant surface. In the case of perforated or slatted floors, the holes and slats should have smooth edges. Their size and spacing need to be commensurate with the size of the housed animal to minimize injury and the development of foot lesions. If wire-mesh flooring is used, a solid resting area may be beneficial, as this floor type can induce foot lesions in rodents and rabbits (Drescher 1993; Fullerton and Gilliatt 1967; Rommers and Meijerhof 1996). The size and weight of the animal as well as the duration of housing on wire-mesh floors may also play a role in the development of this condi-

tion (Peace et al. 2001). When given the choice, rodents prefer solid floors (with bedding) to grid or wire-mesh flooring (Blom et al. 1996; Manser et al. 1995, 1996).

Animals should have adequate bedding substrate and/or structures for resting and sleeping. For many animals (e.g., rodents) contact bedding expands the opportunities for species-typical behavior such as foraging, digging, burrowing, and nest building (Armstrong et al. 1998; Ivy et al. 2008). Moreover, it absorbs urine and feces to facilitate cleaning and sanitation. If provided in sufficient quantity to allow nest building or burrowing, bedding also facilitates thermoregulation (Gordon 2004). Breeding animals should have adequate nesting materials and/or substitute structures based on species-specific requirements (mice: Sherwin 2002; rats: Lawlor 2002; gerbils: Waiblinger 2002).

Specialized housing systems (e.g., isolation-type cages, IVCs, and *gnotobiotic*<sup>1</sup> isolators) are available for rodents and certain species. These systems, designed to minimize the spread of airborne particles between cages or groups of cages, may require different husbandry practices, such as alterations in the frequency of bedding change, the use of aseptic handling techniques, and specialized cleaning, disinfecting, or sterilization regimens to prevent microbial transmission by other than airborne routes.

Appropriate housing strategies for a particular species should be developed and implemented by the animal care management, in consultation with the animal user and veterinarian, and reviewed by the IACUC. Housing should provide for the animals' health and well-being while being consistent with the intended objectives of animal use. Expert advice should be sought when new species are housed or when there are special requirements associated with the animals or their intended use (e.g., genetically modified animals, invasive procedures, or hazardous agents). Objective assessments should be made to substantiate the adequacy of the animal's environment, housing, and management. Whenever possible, routine procedures for maintaining animals should be documented to ensure consistency of management and care.

### *Environmental Enrichment*

The primary aim of environmental enrichment is to enhance animal well-being by providing animals with sensory and motor stimulation, through structures and resources that facilitate the expression of species-typical behaviors and promote psychological well-being through physical

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<sup>1</sup>Gnotobiotic: germ-free animals or formerly germ-free animals in which the composition of any associated microbial flora, if present, is fully defined (Stedman's Electronic Medical Dictionary 2006. Lippincott Williams & Wilkins).

exercise, manipulative activities, and cognitive challenges according to species-specific characteristics (NRC 1998a; Young 2003). Examples of enrichment include structural additions such as perches and visual barriers for nonhuman primates (Novak et al. 2007); elevated shelves for cats (Overall and Dyer 2005; van den Bos and de Cock Buning 1994) and rabbits (Stauffacher 1992); and shelters for guinea pigs (Baumans 2005), as well as manipulable resources such as novel objects and foraging devices for nonhuman primates; manipulable toys for nonhuman primates, dogs, cats, and swine; wooden chew sticks for some rodent species; and nesting material for mice (Gaskill et al. 2009; Hess et al. 2008; Hubrecht 1993; Lutz and Novak 2005; Olsson and Dahlborn 2002). Novelty of enrichment through rotation or replacement of items should be a consideration; however, changing animals' environment too frequently may be stressful.

Well-conceived enrichment provides animals with choices and a degree of control over their environment, which allows them to better cope with environmental stressors (Newberry 1995). For example, visual barriers allow nonhuman primates to avoid social conflict; elevated shelves for rabbits and shelters for rodents allow them to retreat in case of disturbances (Baumans 1997; Chmiel and Noonan 1996; Stauffacher 1992); and nesting material and deep bedding allow mice to control their temperature and avoid cold stress during resting and sleeping (Gaskill et al. 2009; Gordon 1993, 2004).

Not every item added to the animals' environment benefits their well-being. For example, marbles are used as a stressor in mouse anxiety studies (De Boer and Koolhaas 2003), indicating that some items may be detrimental to well-being. For nonhuman primates, novel objects can increase the risk of disease transmission (Bayne et al. 1993); foraging devices can lead to increased body weight (Brent 1995); shavings can lead to allergies and skin rashes in some individuals; and some objects can result in injury from foreign material in the intestine (Hahn et al. 2000). In some strains of mice, cage dividers and shelters have induced overt aggression in groups of males, resulting in social stress and injury (e.g., Bergmann et al. 1994; Haemisch et al. 1994). Social stress was most likely to occur when resources were monopolized by dominant animals (Bergmann et al. 1994).

Enrichment programs should be reviewed by the IACUC, researchers, and veterinarian on a regular basis to ensure that they are beneficial to animal well-being and consistent with the goals of animal use. They should be updated as needed to ensure that they reflect current knowledge. Personnel responsible for animal care and husbandry should receive training in the behavioral biology of the species they work with to appropriately monitor the effects of enrichment as well as identify the development of adverse or abnormal behaviors.

Like other environmental factors (such as space, light, noise, temperature, and animal care procedures), enrichment affects animal phenotype

and may affect the experimental outcome. It should therefore be considered an independent variable and appropriately controlled.

Some scientists have raised concerns that environmental enrichment may compromise experimental standardization by introducing variability, adding not only diversity to the animals' behavioral repertoire but also variation to their responses to experimental treatments (e.g., Bayne 2005; Eskola et al. 1999; Gärtner 1999; Tsai et al. 2003). A systematic study in mice did not find evidence to support this viewpoint (Wolfer et al. 2004), indicating that housing conditions can be enriched without compromising the precision or reproducibility of experimental results. Further research in other species may be needed to confirm this conclusion. However, it has been shown that conditions resulting in higher-stress reactivity increase variation in experimental data (e.g., Macrì et al. 2007). Because adequate environmental enrichment may reduce anxiety and stress reactivity (Chapillon et al. 1999), it may also contribute to higher test sensitivity and reduced animal use (Baumans 1997).

### *Sheltered or Outdoor Housing*

Sheltered or outdoor housing (e.g., barns, corrals, pastures, islands) is a primary housing method for some species and is acceptable in many situations. Animals maintained in outdoor runs, pens, or other large enclosures must have protection from extremes in temperature or other harsh weather conditions and adequate opportunities for retreat (for subordinate animals). These goals can normally be achieved by providing windbreaks, species-appropriate shelters, shaded areas, areas with forced ventilation, heat-radiating structures, and/or means of retreat to conditioned spaces, such as an indoor portion of a run. Shelters should be large enough to accommodate all animals housed in the enclosure, be accessible at all times to all animals, have sufficient ventilation, and be designed to prevent buildup of waste materials and excessive moisture. Houses, dens, boxes, shelves, perches, and other furnishings should be constructed in a manner and made of materials that allow cleaning or replacement in accord with generally accepted husbandry practices.

Floors or ground-level surfaces of outdoor housing facilities may be covered with dirt, absorbent bedding, sand, gravel, grass, or similar material that can be removed or replaced when needed to ensure appropriate sanitation. Excessive buildup of animal waste and stagnant water should be avoided by, for example, using contoured or drained surfaces. Other surfaces should be able to withstand the elements and be easily maintained.

Successful management of outdoor housing relies on stable social groups of compatible animals; sufficient and species-appropriate feeding and resting places; an adequate acclimation period in advance of seasonal

changes when animals are first introduced to outdoor housing; training of animals to cooperate with veterinary and investigative personnel (e.g., to enter chutes or cages for restraint or transport); and adequate security via a perimeter fence or other means.

### *Naturalistic Environments*

Areas such as pastures and islands may provide a suitable environment for maintaining or producing animals and for some types of research. Their use results in the loss of some control over nutrition, health care and surveillance, and pedigree management. These limitations should be balanced against the benefits of having the animals live in more natural conditions. Animals should be added to, removed from, and returned to social groups in this setting with appropriate consideration of the effects on the individual animals and on the group. Adequate supplies of food, fresh water, and natural or constructed shelter should be ensured.

### *Space*

*General Considerations for All Animals* An animal's space needs are complex and consideration of only the animal's body weight or surface area may be inadequate. Important considerations for determining space needs include the age and sex of the animal(s), the number of animals to be cohoused and the duration of the accommodation, the use for which the animals are intended (e.g., production vs. experimentation), and any special needs they may have (e.g., vertical space for arboreal species or thermal gradient for poikilotherms). In many cases, for example, adolescent animals, which usually weigh less than adults but are more active, may require more space relative to body weight (Ikemoto and Panksepp 1992). Group-housed, social animals can share space such that the amount of space required per animal may decrease with increasing group size; thus larger groups may be housed at slightly higher stocking densities than smaller groups or individual animals. Socially housed animals should have sufficient space and structural complexity to allow them to escape aggression or hide from other animals in the pair or group. Breeding animals will require more space, particularly if neonatal animals will be raised together with their mother or as a breeding group until weaning age. Space quality also affects its usability. Enclosures that are complex and environmentally enriched may increase activity and facilitate the expression of species-specific behaviors, thereby increasing space needs. Thus there is no ideal formula for calculating an animal's space needs based only on body size or weight and readers should take the performance indices discussed in this section into consideration when utilizing the species-specific guidelines presented in the following pages.

Consideration of floor area alone may not be sufficient in determining adequate cage size; with some species, cage volume and spatial arrangement may be of greater importance. In this regard, the *Guide* may differ from the US Animal Welfare Regulations (AWRs) or other guidelines. The height of an enclosure can be important to allow for expression of species-specific behaviors and postural adjustments. Cage height should take into account the animal's typical posture and provide adequate clearance for the animal from cage structures, such as feeders and water devices. Some species—for example, nonhuman primates, cats, and arboreal animals—use the vertical dimensions of the cage to a greater extent than the floor. For these animals, the ability to stand or to perch with adequate vertical space to keep their body, including their tail, above the cage floor can improve their well-being (Clarence et al. 2006; MacLean et al. 2009).

Space allocations should be assessed, reviewed, and modified as necessary by the IACUC considering the performance indices (e.g., health, reproduction, growth, behavior, activity, and use of space) and special needs determined by the characteristics of the animal strain or species (e.g., obese, hyperactive, or arboreal animals) and experimental use (e.g., animals in long-term studies may require greater and more complex space). At a minimum, animals must have enough space to express their natural postures and postural adjustments without touching the enclosure walls or ceiling, be able to turn around, and have ready access to food and water. In addition, there must be sufficient space to comfortably rest away from areas soiled by urine and feces. Floor space taken up by food bowls, water containers, litter boxes, and enrichment devices (e.g., novel objects, toys, foraging devices) should not be considered part of the floor space.

The space recommendations presented here are based on professional judgment and experience. They should be considered the minimum for animals housed under conditions commonly found in laboratory animal housing facilities. Adjustments to the amount and arrangement of space recommended in the following tables should be reviewed and approved by the IACUC and should be based on performance indices related to animal well-being and research quality as described in the preceding paragraphs, with due consideration of the AWRs and PHS Policy and other applicable regulations and standards.

It is not within the scope of the *Guide* to discuss the housing requirements of all species used in research. For species not specifically indicated, advice should be sought from the scientific literature and from species-relevant experts.

*Laboratory Rodents* Table 3.2 lists recommended minimum space for commonly used laboratory rodents housed in groups. If they are housed singly or in small groups or exceed the weights in the table, more space per

TABLE 3.2 Recommended Minimum Space for Commonly Used Laboratory Rodents Housed in Groups\*

Animals	Weight, g	Floor Area/Animal, <sup>a</sup> in. <sup>2</sup> (cm <sup>2</sup> )	Height, <sup>b</sup> in. (cm)	Comments
Mice in groups <sup>c</sup>	<10	6 (38.7)	5 (12.7)	Larger animals may require more space to meet the performance standards.
	Up to 15	8 (51.6)	5 (12.7)	
	Up to 25	12 (77.4)	5 (12.7)	
	>25	≥15 (≥96.7)	5 (12.7)	
Female + litter		51 (330) (recommended space for the housing group)	5 (12.7)	Other breeding configurations may require more space and will depend on considerations such as number of adults and litters, and size and age of litters. <sup>d</sup>
Rats in groups <sup>c</sup>	<100	17 (109.6)	7 (17.8)	Larger animals may require more space to meet the performance standards.
	Up to 200	23 (148.35)	7 (17.8)	
	Up to 300	29 (187.05)	7 (17.8)	
	Up to 400	40 (258.0)	7 (17.8)	
	Up to 500	60 (387.0)	7 (17.8)	
Female + litter		124 (800) (recommended space for the housing group)	7 (17.8)	Other breeding configurations may require more space and will depend on considerations such as number of adults and litters, and size and age of litters. <sup>d</sup>
Hamsters <sup>c</sup>	<60	10 (64.5)	6 (15.2)	Larger animals may require more space to meet the performance standards.
	Up to 80	13 (83.8)	6 (15.2)	
	Up to 100	16 (103.2)	6 (15.2)	
	>100	≥19 (≥122.5)	6 (15.2)	
Guinea pigs <sup>c</sup>	Up to 350	60 (387.0)	7 (17.8)	Larger animals may require more space to meet the performance standards.
	>350	≥101 (≥651.5)	7 (17.8)	

\*The interpretation of this table should take into consideration the performance indices described in the text beginning on page 55.

<sup>a</sup>Singly housed animals and small groups may require more than the applicable multiple of the indicated floor space per animal.

<sup>b</sup>From cage floor to cage top.

<sup>c</sup>Consideration should be given to the growth characteristics of the stock or strain as well as the sex of the animal. Weight gain may be sufficiently rapid that it may be preferable to provide greater space in anticipation of the animal's future size. In addition, juvenile rodents are highly active and show increased play behavior.

<sup>d</sup>Other considerations may include culling of litters or separation of litters from the breeding group, as well as other methods of more intensive management of available space to allow for the safety and well-being of the breeding group. Sufficient space should be allocated for mothers with litters to allow the pups to develop to weaning without detrimental effects for the mother or the litter.



animal may be required, while larger groups may be housed at slightly higher densities.

Studies have recently evaluated space needs and the effects of social housing, group size, and density (Andrade and Guimaraes 2003; Bartolomucci et al. 2002, 2003; Georgsson et al. 2001; Gonder and Laber 2007; Perez et al. 1997; A.L. Smith et al. 2004), age (Arakawa 2005; Davidson et al. 2007; Yildiz et al. 2007), and housing conditions (Gordon et al. 1998; Van Loo et al. 2004) for many different species and strains of rodents, and have reported varying effects on behavior (such as aggression) and experimental outcomes (Karolewicz and Paul 2001; Laber et al. 2008; McGlone et al. 2001; Rock et al. 1997; Smith et al. 2005; Van Loo et al. 2001). However, it is difficult to compare these studies due to the study design and experimental variables that have been measured. For example, variables that may affect the animals' response to different cage sizes and housing densities include, but are not limited to, species, strain (and social behavior of the strain), phenotype, age, gender, quality of the space (e.g., vertical access), and structures placed in the cage. These issues remain complex and should be carefully considered when housing rodents.

*Other Common Laboratory Animals* Tables 3.3 and 3.4 list recommended minimum space for other common laboratory animals and for avian species. These allocations are based, in general, on the needs of pair- or group-housed animals. Space allocations should be reevaluated to provide for enrichment or to accommodate animals that exceed the weights in the tables, and should be based on species characteristics, behavior, compatibility of the animals, number of animals, and goals of the housing situation (Held et al. 1995; Lupo et al. 2000; Raje 1997; Turner et al. 1997). Singly housed animals may require more space per animal than that recommended for group-housed animals, while larger groups may be housed at slightly higher densities. For cats, dogs, and some rabbits, housing enclosures that allow greater freedom of movement and less restricted vertical space are preferred (e.g., kennels, runs, or pens instead of cages). Dogs and cats, especially when housed individually or in smaller enclosures (Bayne 2002), should be allowed to exercise and provided with positive human interaction. Species-specific plans for housing and management should be developed. Such plans should also include strategies for environmental enrichment.

*Nonhuman Primates* The recommended minimum space for nonhuman primates detailed in Table 3.5 is based on the needs of pair- or group-housed animals. Like all social animals, nonhuman primates should normally have social housing (i.e., in compatible pairs or in larger groups of compatible animals) (Hotchkiss and Paule 2003; NRC 1998a; Weed and Watson 1998;

TABLE 3.3 Recommended Minimum Space for Rabbits, Cats, and Dogs Housed in Pairs or Groups\*

Animals	Weight, <sup>a</sup> kg	Floor Area/ Animal, <sup>b</sup> ft <sup>2</sup> (m <sup>2</sup> )	Height, <sup>c</sup> in. (cm)	Comments
Rabbits	<2	1.5 (0.14)	16 (40.5)	Larger rabbits may require more cage height to allow animals to sit up.
	Up to 4	3.0 (0.28)	16 (40.5)	
	Up to 5.4	4.0 (0.37)	16 (40.5)	
	>5.4 <sup>c</sup>	≥5.0 (≥0.46)	16 (40.5)	
Cats	≤4	3.0 (0.28)	24 (60.8)	Vertical space with perches is preferred and may require additional cage height.
	>4 <sup>d</sup>	≥4.0 (≥0.37)	24 (60.8)	
Dogs <sup>e</sup>	<15	8.0 (0.74)	— <sup>f</sup>	Cage height should be sufficient for the animals to comfortably stand erect with their feet on the floor.
	Up to 30	12.0 (1.2)	— <sup>f</sup>	
	>30 <sup>d</sup>	≥24.0 (≥2.4)	— <sup>f</sup>	

\*The interpretation of this table should take into consideration the performance indices described in the text beginning on page 55.

<sup>a</sup>To convert kilograms to pounds, multiply by 2.2.

<sup>b</sup>Singly housed animals may require more space per animal than recommended for pair- or group-housed animals.

<sup>c</sup>From cage floor to cage top.

<sup>d</sup>Larger animals may require more space to meet performance standards (see text).

<sup>e</sup>These recommendations may require modification according to body conformation of individual animals and breeds. Some dogs, especially those toward the upper limit of each weight range, may require additional space to ensure compliance with the regulations of the Animal Welfare Act. These regulations (USDA 1985) mandate that the height of each cage be sufficient to allow the occupant to stand in a "comfortable position" and that the minimal square feet of floor space be equal to the "mathematical square of the sum of the length of the dog in inches (measured from the tip of its nose to the base of its tail) plus 6 inches; then divide the product by 144."

<sup>f</sup>Enclosures that allow greater freedom of movement and unrestricted height (i.e., pens, runs, or kennels) are preferable.

Wolfensohn 2004). Group composition is critical and numerous species-specific factors such as age, behavioral repertoire, sex, natural social organization, breeding requirements, and health status should be taken into consideration when forming a group. In addition, due to conformational differences of animals within groups, more space or height may be required to meet the animals' physical and behavioral needs. Therefore, determination of the appropriate cage size is not based on body weight alone, and professional judgment is paramount in making such determinations (Kaufman et al. 2004; Williams et al. 2000).

TABLE 3.4 Recommended Minimum Space for Avian Species Housed in Pairs or Groups\*

Animals	Weight, <sup>a</sup> kg	Floor area/animal, <sup>b</sup> ft <sup>2</sup> (m <sup>2</sup> )	Height
Pigeons	—	0.8 (0.07)	Cage height should be sufficient for the animals to comfortably stand erect with their feet on the floor.
Quail	—	0.25 (0.023)	
Chickens	<0.25	0.25 (0.023)	
	Up to 0.5	0.50 (0.046)	
	Up to 1.5	1.00 (0.093)	
	Up to 3.0	2.00 (0.186)	
	>3.0 <sup>c</sup>	≥3.00 (≥0.279)	

\*The interpretation of this table should take into consideration the performance indices described in the text beginning on page 55.

<sup>a</sup>To convert kilograms to pounds, multiply by 2.2.

<sup>b</sup>Singly housed birds may require more space per animal than recommended for pair- or group-housed birds.

<sup>c</sup>Larger animals may require more space to meet performance standards (see text).

If it is necessary to house animals singly—for example, when justified for experimental purposes, for provision of veterinary care, or for incompatible animals—this arrangement should be for the shortest duration possible. If single animals are housed in small enclosures, an opportunity for periodic release into larger enclosures with additional enrichment items should be considered, particularly for animals housed singly for extended periods of time. Singly housed animals may require more space per animal than recommended for pair- or group-housed animals, while larger groups may be housed at slightly higher densities. Because of the many physical and behavioral characteristics of nonhuman primate species and the many factors to consider when using these animals in a biomedical research setting, species-specific plans for housing and management should be developed. Such plans should include strategies for environmental and psychological enrichment.

*Agricultural Animals* Table 3.6 lists recommended minimum space for agricultural animals commonly used in a laboratory setting. As social animals, they should be housed in compatible pairs or larger groups of compatible animals. When animals exceed the weights in the table, more space is required. For larger animals (particularly swine) it is important that the configuration of the space allow the animals to turn around and move freely (Becker et al. 1989; Bracke et al. 2002). Food troughs and water devices should be provided in sufficient numbers to allow ready access for all animals. Singly housed animals may require more space than recommended in

TABLE 3.5 Recommended Minimum Space for Nonhuman Primates Housed in Pairs or Groups\*

Animals	Weight, <sup>a</sup> kg	Floor area/animal, <sup>b</sup> ft <sup>2</sup> (m <sup>2</sup> )	Height, <sup>c</sup> in. (cm)	Comments
Monkeys <sup>d</sup> (including baboons)				Cage height should be sufficient for the animals to comfortably stand erect with their feet on the floor. Baboons, patas monkeys, and other longer-legged species may require more height than other monkeys, as might long-tailed animals and animals with prehensile tails. Overall cage volume and linear perch space should be considerations for many neotropical and arboreal species. For brachiating species cage height should be such that an animal can, when fully extended, swing from the cage ceiling without having its feet touch the floor. Cage design should enhance brachiating movement.
Group 1	Up to 1.5	2.1 (0.20)	30 (76.2)	
Group 2	Up to 3	3.0 (0.28)	30 (76.2)	
Group 3	Up to 10	4.3 (0.4)	30 (76.2)	
Group 4	Up to 15	6.0 (0.56)	32 (81.3)	
Group 5	Up to 20	8.0 (0.74)	36 (91.4)	
Group 6	Up to 25	10 (0.93)	46 (116.8)	
Group 7	Up to 30	15 (1.40)	46 (116.8)	
Group 8	>30 <sup>e</sup>	≥25 (≥2.32)	60 (152.4)	
Chimpanzees ( <i>Pan</i> )				For other apes and large brachiating species cage height should be such that an animal can, when fully extended, swing from the cage ceiling without having its feet touch the floor. Cage design should enhance brachiating movement.
Juveniles	Up to 10	15 (1.4)	60 (152.4)	
Adults <sup>f</sup>	>10	≥25 (≥2.32)	84 (213.4)	

\*The interpretation of this table should take into consideration the performance indices described in the text beginning on page 55.

<sup>a</sup>To convert kilograms to pounds, multiply by 2.2.

<sup>b</sup>Singly housed primates may require more space than the amount allocated per animal when group housed.

<sup>c</sup>From cage floor to cage top.

<sup>d</sup>Callitrichidae, Cebidae, Cercopithecidae, and Papio.

<sup>e</sup>Larger animals may require more space to meet performance standards (see text).

<sup>f</sup>Apes weighing over 50 kg are more effectively housed in permanent housing of masonry, concrete, and wire-panel structure than in conventional caging.

TABLE 3.6 Recommended Minimum Space for Agricultural Animals\*

Animals/Enclosure	Weight, <sup>a</sup> kg	Floor Area/Animal, <sup>b</sup> ft <sup>2</sup> (m <sup>2</sup> )
Sheep and Goats		
1	<25	10.0 (0.9)
	Up to 50	15.0 (1.35)
	>50 <sup>c</sup>	≥20.0 (≥1.8)
2-5	<25	8.5 (0.76)
	Up to 50	12.5 (1.12)
	>50 <sup>c</sup>	≥17.0 (≥1.53)
>5	<25	7.5 (0.67)
	Up to 50	11.3 (1.02)
	>50 <sup>c</sup>	≥15.0 (≥1.35)
Swine		
1	<15	8.0 (0.72)
	Up to 25	12.0 (1.08)
	Up to 50	15.0 (1.35)
	Up to 100	24.0 (2.16)
	Up to 200	48.0 (4.32)
	>200 <sup>c</sup>	≥60.0 (≥5.4)
2-5	<25	6.0 (0.54)
	Up to 50	10.0 (0.9)
	Up to 100	20.0 (1.8)
	Up to 200	40.0 (3.6)
	>200 <sup>c</sup>	≥52.0 (≥4.68)
	>5	<25
Up to 50	9.0 (0.81)	
Up to 100	18.0 (1.62)	
Up to 200	36.0 (3.24)	
>200 <sup>c</sup>	≥48.0 (≥4.32)	
Cattle		
1	<75	24.0 (2.16)
	Up to 200	48.0 (4.32)
	Up to 350	72.0 (6.48)
	Up to 500	96.0 (8.64)
	Up to 650	124.0 (11.16)
	>650 <sup>c</sup>	≥144.0 (≥12.96)
2-5	<75	20.0 (1.8)
	Up to 200	40.0 (3.6)
	Up to 350	60.0 (5.4)
	Up to 500	80.0 (7.2)
	Up to 650	105.0 (9.45)
	>650 <sup>c</sup>	≥120.0 (≥10.8)

>5	<75	18.0 (1.62)
	Up to 200	36.0 (3.24)
	Up to 350	54.0 (4.86)
	Up to 500	72.0 (6.48)
	Up to 650	93.0 (8.37)
	>650 <sup>c</sup>	≥108.0 (≥9.72)
Horses	—	144.0 (12.96)
Ponies		
1-4	—	72.0 (6.48)
>4/Pen	≤200	60.0 (5.4)
	>200 <sup>c</sup>	≥72.0 (≥6.48)

\*The interpretation of this table should take into consideration the performance indices described in the text beginning on page 55.

<sup>a</sup>To convert kilograms to pounds, multiply by 2.2.

<sup>b</sup>Floor area configuration should be such that animals can turn around and move freely without touching food or water troughs, have ready access to food and water, and have sufficient space to comfortably rest away from areas soiled by urine and feces (see text).

<sup>c</sup>Larger animals may require more space to meet performance standards including sufficient space to turn around and move freely (see text).

the table to enable them to turn around and move freely without touching food or water troughs, have ready access to food and water, and have sufficient space to comfortably rest away from areas soiled by urine and feces.

## Terrestrial Management

### *Behavioral and Social Management*

*Activity Animal Activity* typically implies motor activity but also includes cognitive activity and social interaction. Animals' natural behavior and activity profile should be considered during evaluation of suitable housing or behavioral assessment.

Animals maintained in a laboratory environment are generally restricted in their activities compared to free-ranging animals. Forced activity for reasons other than attempts to meet therapeutic or approved protocol objectives should be avoided. High levels of repetitive, unvarying behavior (stereotypies, compulsive behaviors) may reflect disruptions of normal behavioral control mechanisms due to housing conditions or management practices (Garner 2005; NRC 1998a).

Dogs, cats, rabbits, and many other animals benefit from positive human interaction (Augustsson et al. 2002; Bayne et al. 1993; McCune 1997; Poole 1998; Rennie and Buchanan-Smith 2006; Rollin 1990). Dogs can be given

additional opportunities for activity by being walked on a leash, having access to a run, or being moved into areas for social contact, play, or exploration (Wolff and Rupert 1991). Loafing areas, exercise lots, and pastures are suitable for large farm animals, such as sheep, horses, and cattle.

*Social Environment* Appropriate social interactions among members of the same species (conspecifics) are essential to normal development and well-being (Bayne et al. 1995; Hall 1998; Novak et al. 2006). When selecting a suitable social environment, attention should be given to whether the animals are naturally territorial or communal and whether they should be housed singly, in pairs, or in groups. An understanding of species-typical natural social behavior (e.g., natural social composition, population density, ability to disperse, familiarity, and social ranking) is key to successful social housing.

Not all members of a social species are necessarily socially compatible. Social housing of incompatible animals can induce chronic stress, injury, and even death. In some species, social incompatibility may be sex biased; for example, male mice are generally more prone to aggression than female mice, and female hamsters are generally more aggressive than male hamsters. Risks of social incompatibility are greatly reduced if the animals to be grouped are raised together from a young age, if group composition remains stable, and if the design of the animals' enclosure and their environmental enrichment facilitate the avoidance of social conflicts. Social stability should be carefully monitored; in cases of severe or prolonged aggression, incompatible individuals need to be separated.

For some species, developing a stable social hierarchy will entail antagonistic interactions between pair or group members, particularly for animals introduced as adults. Animals may have to be introduced to each other over a period of time and should be monitored closely during this introductory period and thereafter to ensure compatibility.

Single housing of social species should be the exception and justified based on experimental requirements or veterinary-related concerns about animal well-being. In these cases, it should be limited to the minimum period necessary, and where possible, visual, auditory, olfactory, and tactile contact with compatible conspecifics should be provided. In the absence of other animals, enrichment should be offered such as positive interaction with the animal care staff and additional enrichment items or addition of a companion animal in the room or housing area. The need for single housing should be reviewed on a regular basis by the IACUC and veterinarian.

*Procedural Habituation and Training of Animals* Habituating animals to routine husbandry or experimental procedures should be encouraged whenever possible as it may assist the animal to better cope with a captive environment by reducing stress associated with novel procedures or people.

The type and duration of habituation needed will be determined by the complexity of the procedure. In most cases, principles of operant conditioning may be employed during training sessions, using progressive behavioral shaping, to induce voluntary cooperation with procedures (Bloomsmith et al. 1998; Laule et al. 2003; NRC 2006a; Reinhardt 1997).

### *Husbandry*

*Food* Animals should be fed palatable, uncontaminated diets that meet their nutritional and behavioral needs at least daily, or according to their particular requirements, unless the protocol in which they are being used requires otherwise. Subcommittees of the National Research Council Committee on Animal Nutrition have prepared comprehensive reports of the nutrient requirements of laboratory animals (NRC 1977, 1982, 1993, 1994, 1995a, 1998b, 2000, 2001, 2003a, 2006b,c, 2007); these publications consider issues of quality assurance, freedom from chemical or microbial contaminants and natural toxicants in feedstuffs, bioavailability of nutrients in feeds, and palatability.

There are several types of diets classified by the degree of refinement of their ingredients. *Natural-ingredient diets* are formulated with agricultural products and byproducts and are commercially available for all species commonly used in the laboratory. Although not a significant factor in most instances, the nutrient composition of ingredients varies, and natural ingredients may contain low levels of naturally occurring or artificial contaminants (Ames et al. 1993; Knapka 1983; Newberne 1975; NRC 1996; Thigpen et al. 1999, 2004). Contaminants such as pesticide residues, heavy metals, toxins, carcinogens, and phytoestrogens may be at levels that induce few or no health sequelae yet may have subtle effects on experimental results (Thigpen et al. 2004). *Certified diets* that have been assayed for contaminants are commercially available for use in select studies, such as preclinical toxicology, conducted in compliance with FDA Good Laboratory Practice standards (CFR 2009). *Purified diets* are refined such that each ingredient contains a single nutrient or nutrient class; they have less nutrient concentration variability and the potential for chemical contamination is lower. *Chemically defined diets* contain the most elemental ingredients available, such as individual amino acids and specific sugars (NRC 1996). The latter two types of diet are more likely to be used for specific types of studies in rodents but are not commonly used because of cost, lower palatability, and a reduced shelf life.

Animal colony managers should be judicious when purchasing, transporting, storing, and handling food to minimize the introduction of diseases, parasites, potential disease vectors (e.g., insects and other vermin), and chemical contaminants in animal colonies. Purchasers are encouraged to consider manufacturers' and suppliers' procedures and practices (e.g., storage, vermin control, and handling) for protecting and ensuring diet quality.



Institutions should urge feed vendors to periodically provide data from laboratory-based feed analyses for critical nutrients. The user should know the date of manufacture and other factors that affect the food's shelf life. Stale food or food transported and stored inappropriately can become deficient in nutrients. Upon receipt, bags of feed should be examined to ensure that they are intact and unstained to help ensure that their contents have not been potentially exposed to vermin, penetrated by liquids, or contaminated. Careful attention should be paid to quantities received in each shipment, and stock should be rotated so that the oldest food is used first.

Areas in which diets and diet ingredients are processed or stored should be kept clean and enclosed to prevent the entry of pests. Food stocks should be stored off the floor on pallets, racks, or carts in a manner that facilitates sanitation. Opened bags of food should be stored in vermin-proof containers to minimize contamination and to avoid the potential spread of pathogens. Exposure to elevated storage room temperatures, extremes in relative humidity, unsanitary conditions, and insects and other vermin hastens food deterioration. Storage of natural-ingredient diets at less than 21°C (70°F) and below 50% relative humidity is recommended. Precautions should be taken if perishable items—such as meats, fruits, and vegetables and some specialty diets (e.g., select medicated or high-fat diets)—are fed, because storage conditions may lead to variation in food quality.

Most natural-ingredient, dry laboratory animal diets stored properly can be used up to 6 months after manufacture. Nonstabilized vitamin C in manufactured feeds generally has a shelf life of only 3 months, but commonly used stabilized forms can extend the shelf life of feed. Refrigeration preserves nutritional quality and lengthens shelf life, but food storage time should be reduced to the lowest practical period and the manufacturers' recommendations considered. Purified and chemically defined diets are often less stable than natural-ingredient diets and their shelf life is usually less than 6 months (Fullerton et al. 1982); they should be stored at 4°C (39°F) or lower.

Irradiated and fortified autoclavable diets are commercially available and are commonly used for axenic and microbiologically defined rodents, and immunodeficient animals (NRC 1996). The use of commercially fortified autoclavable diets ensures that labile vitamin content is not compromised by steam and/or heat (Caulfield et al. 2008; NRC 1996). But consideration should be given to the impact of autoclaving on pellets as it may affect their hardness and thus palatability and also lead to chemical alteration of ingredients (Thigpen et al. 2004; Twaddle et al. 2004). The date of sterilization should be recorded and the diet used quickly.

Feeders should be designed and placed to allow easy access to food and to minimize contamination with urine and feces, and maintained in good condition. When animals are housed in groups, there should be enough space and enough feeding points to minimize competition for food and

ensure access to food for all animals, especially if feed is restricted as part of the protocol or management routine. Food storage containers should not be transferred between areas that pose different risks of contamination without appropriate treatment, and they should be cleaned and sanitized regularly.

Management of caloric intake is an accepted practice for long-term housing of some species, such as some rodents, rabbits, and nonhuman primates, and as an adjunct to some clinical, experimental, and surgical procedures (for more discussion of food and fluid regulation as an experimental tool see Chapter 2 and NRC 2003a). Benefits of moderate caloric restriction in some species may include increased longevity and reproduction, and decreased obesity, cancer rates, and neurogenerative disorders (Ames et al. 1993; Colman et al. 2009; Keenan et al. 1994, 1996; Lawler et al. 2008; Weindruch and Walford 1988).

Under standard housing conditions, changes in biologic needs commensurate with aging should be taken into consideration. For example, there is good evidence that mice and rats with continuous access to food can become obese, with attendant metabolic and cardiovascular changes such as insulin resistance and higher blood pressure (Martin et al. 2010). These and other changes along with a more sedentary lifestyle and lack of exercise increase the risk of premature death (*ibid.*). Caloric management, which may affect physiologic adaptations and alter metabolic responses in a species-specific manner (Leveille and Hanson 1966), can be achieved by reducing food intake or by stimulating exercise.

In some species (e.g., nonhuman primates) and on some occasions, varying nutritionally balanced diets and providing “treats,” including fresh fruit and vegetables, can be appropriate and improve well-being. Scattering food in the bedding or presenting part of the diet in ways that require the animals to work for it (e.g., puzzle feeders for nonhuman primates) gives the animals the opportunity to forage, which, in nature, normally accounts for a large proportion of their daily activity. A diet should be nutritionally balanced; it is well documented that many animals offered a choice of unbalanced or balanced foods do not select a balanced diet and become malnourished or obese through selection of high-energy, low-protein foods (Moore 1987). Abrupt changes in diet, which can be difficult to avoid at weaning, should be minimized because they can lead to digestive and metabolic disturbances; these changes occur in omnivores and carnivores, but herbivores (Eadie and Mann 1970) are especially sensitive.

*Water* Animals should have access to potable, uncontaminated drinking water according to their particular requirements. Water quality and the definition of potable water can vary with locality (Homerberger et al. 1993). Periodic monitoring for pH, hardness, and microbial or chemical contamination may be necessary to ensure that water quality is acceptable, particularly for use in studies in which normal components of water in a given locality

can influence the results. Water can be treated or purified to minimize or eliminate contamination when protocols require highly purified water. The selection of water treatments should be carefully considered because many forms of water treatment have the potential to cause physiologic alterations, reduction in water consumption, changes in microflora, or effects on experimental results (Fidler 1977; Hall et al. 1980; Hermann et al. 1982; Homberger et al. 1993; NRC 1996).

Watering devices, such as drinking tubes and automated water delivery systems, should be checked frequently to ensure appropriate maintenance, cleanliness, and operation. Animals sometimes have to be trained to use automated watering devices and should be observed regularly until regular usage has been established to prevent dehydration. It is better to replace water bottles than to refill them, because of the potential for microbiologic cross contamination; if bottles are refilled, care should be taken to return each bottle to the cage from which it was removed. Automated watering distribution systems should be flushed or disinfected regularly. Animals housed in outdoor facilities may have access to water in addition to that provided in watering devices, such as that available in streams or in puddles after a heavy rainfall. Care should be taken to ensure that such accessory sources of water do not constitute a hazard, but their availability need not routinely be prevented. In cold weather, steps should be taken to prevent freezing of outdoor water sources.

*Bedding and Nesting Materials* Animal bedding and nesting materials are controllable environmental factors that can influence experimental data and improve animal well-being in most terrestrial species. Bedding is used to absorb moisture, minimize the growth of microorganisms, and dilute and limit animals' contact with excreta, and specific bedding materials have been shown to reduce the accumulation of intracage ammonia (Perkins and Lipman 1995; E. Smith et al. 2004). Various materials are used as both contact and noncontact bedding; the desirable characteristics and methods of evaluating bedding have been described (Gibson et al. 1987; Jones 1977; Kraft 1980; Thigpen et al. 1989; Weichbrod et al. 1986). The veterinarian or facility manager, in consultation with investigators, should select the most appropriate bedding and nesting materials. A number of species, most notably rodents, exhibit a clear preference for specific materials (Blom et al. 1996; Manser et al. 1997, 1998; Ras et al. 2002), and mice provided with appropriate nesting material build better nests (Hess et al. 2008). Bedding that enables burrowing is encouraged for some species, such as mice and hamsters.

No type of bedding is ideal for all species under all management and experimental conditions. For example, in nude or hairless mice that lack eyelashes, some forms of paper bedding with fines (i.e., very small particles found in certain types of bedding) can result in periorbital abscesses (White

et al. 2008), while cotton nestlets may lead to conjunctivitis (Bazille et al. 2001). Bedding can also influence mucosal immunity (Sanford et al. 2002) and endocytosis (Buddaraju and Van Dyke 2003).

Softwood beddings have been used, but the use of untreated softwood shavings and chips is contraindicated for some protocols because they can affect metabolism (Vesell 1967; Vesell et al. 1973, 1976). Cedar shavings are not recommended because they emit aromatic hydrocarbons that induce hepatic microsomal enzymes and cytotoxicity (Torronen et al. 1989; Weichbrod et al. 1986, 1988) and have been reported to increase the incidence of cancer (Jacobs and Dieter 1978; Vlahakis 1977). Prior treatment with high heat (kiln drying or autoclaving) may, depending on the material and the concentration of aromatic hydrocarbon constituents, reduce the concentration of volatile organic compounds, but the amounts remaining may be sufficient to affect specific protocols (Cunliffe-Beamer et al. 1981; Nevalainen and Vartiainen 1996).

The purchase of bedding products should take into consideration vendors' manufacturing, monitoring, and storage methods. Bedding may be contaminated with toxins and other substances, bacteria, fungi, and vermin. It should be transported and stored off the floor on pallets, racks, or carts in a fashion consistent with maintenance of quality and avoidance of contamination. Bags should be stored sufficiently away from walls to facilitate cleaning. During autoclaving, bedding can absorb moisture and as a result lose absorbency and support the growth of microorganisms. Therefore, appropriate drying times and storage conditions should be used or, alternatively, gamma-irradiated materials if sterile bedding is indicated.

Bedding should be used in amounts sufficient to keep animals dry between cage changes, and, in the case of small laboratory animals, it should be kept from coming into contact with sipper tubes as such contact could cause leakage of water into the cage.

*Sanitation* *Sanitation*—the maintenance of environmental conditions conducive to health and well-being—involves bedding change (as appropriate), cleaning, and disinfection. *Cleaning* removes excessive amounts of excrement, dirt, and debris, and *disinfection* reduces or eliminates unacceptable concentrations of microorganisms. The goal of any sanitation program is to maintain sufficiently clean and dry bedding, adequate air quality, and clean cage surfaces and accessories.

The frequency and intensity of cleaning and disinfection should depend on what is necessary to provide a healthy environment for an animal. Methods and frequencies of sanitation will vary with many factors, including the normal physiologic and behavioral characteristics of the animals; the type, physical characteristics, and size of the enclosure; the type, number, size, age, and reproductive status of the animals; the use and type of bedding materials; temperature and relative humidity; the nature of the materials that

create the need for sanitation; and the rate of soiling of the surfaces of the enclosure. Some housing systems or experimental protocols may require specific husbandry techniques, such as aseptic handling or modification in the frequency of bedding change.

Agents designed to mask animal odors should not be used in animal housing facilities. They cannot substitute for good sanitation practices or for the provision of adequate ventilation, and they expose animals to volatile compounds that might alter basic physiologic and metabolic processes.

*Bedding/Substrate Change* Soiled bedding should be removed and replaced with fresh materials as often as necessary to keep the animals clean and dry and to keep pollutants, such as ammonia, at a concentration below levels irritating to mucous membranes. The frequency of bedding change depends on multiple factors, such as species, number, and size of the animals in the primary enclosure; type and size of the enclosure; macro- and microenvironmental temperature, relative humidity, and direct ventilation of the enclosure; urinary and fecal output and the appearance and wetness of bedding; and experimental conditions, such as those of surgery or debilitation, that might limit an animal's movement or access to clean bedding. There is no absolute minimal frequency of bedding changes; the choice is a matter of professional judgment and consultation between the investigator and animal care personnel. It typically varies from daily to weekly. In some instances frequent bedding changes are contraindicated; examples include portions of the pre- or postpartum period, research objectives that will be affected, and species in which scent marking is critical and successful reproduction is pheromone dependent.

*Cleaning and Disinfection of the Microenvironment* The frequency of sanitation of cages, cage racks, and associated equipment (e.g., feeders and watering devices) is governed to some extent by the types of caging and husbandry practices used, including the use of regularly changed contact or noncontact bedding, regular flushing of suspended catch pans, and the use of wire-bottom or perforated-bottom cages. In general, enclosures and accessories, such as tops, should be sanitized at least once every 2 weeks. Solid-bottom caging, bottles, and sipper tubes usually require sanitation at least once a week. Some types of cages and housing systems may require less frequent cleaning or disinfection; such housing may include large cages with very low animal density and frequent bedding changes, cages containing animals in gnotobiotic conditions with frequent bedding changes, individually ventilated cages, and cages used for special situations. Other circumstances, such as filter-topped cages without forced-air ventilation, animals that urinate excessively (e.g., diabetic or renal patients), or densely populated enclosures, may require more frequent sanitation.

The increased use of individually ventilated cages (IVCs) for rodents has led to investigations of the maintenance of a suitable microenvironment with extended cage sanitation intervals and/or increased housing densi-

ties (Carissimi et al. 2000; Reeb-Whitaker et al. 2001; Schondelmeyer et al. 2006). By design, ventilated caging systems provide direct continuous exchange of air, compared to static caging systems that depend on passive ventilation from the macroenvironment. As noted above, decreased sanitation frequency may be justified if the microenvironment in the cages, under the conditions of use (e.g., cage type and manufacturer, bedding, species, strain, age, sex, density, and experimental considerations), is not compromised (Reeb et al. 1998). Verification of microenvironmental conditions may include measurement of pollutants such as ammonia and CO<sub>2</sub>, microbiologic load, observation of the animals' behavior and appearance, and the condition of bedding and cage surfaces.

Primary enclosures can be disinfected with chemicals, hot water, or a combination of both.<sup>2</sup> Washing times and conditions and postwashing processing procedures (e.g., sterilization) should be sufficient to reduce levels or eliminate vegetative forms of opportunistic and pathogenic bacteria, adventitious viruses, and other organisms that are presumed to be controllable by the sanitation program. Disinfection from the use of hot water alone is the result of the combined effect of the temperature and the length of time that a given temperature (cumulative heat factor) is applied to the surface of the item. The same cumulative heat factor can be obtained by exposing organisms either to very high temperatures for short periods or to lower temperatures for longer periods (Wardrip et al. 1994, 2000). Effective disinfection can be achieved with wash and rinse water at 143-180°F or more. The traditional 82.2°C (180°F) temperature requirement for rinse water refers to the water in the tank or in the sprayer manifold. Detergents and chemical disinfectants enhance the effectiveness of hot water but should be thoroughly rinsed from surfaces before reuse of the equipment. Their use may be contraindicated for some aquatic species, as residue may be highly deleterious. Mechanical washers (e.g., cage and rack, tunnel, and bottle washers) are recommended for cleaning quantities of caging and movable equipment.

Sanitation of cages and equipment by hand with hot water and detergents or disinfectants can also be effective but requires considerable attention to detail. It is particularly important to ensure that surfaces are rinsed free of residual chemicals and that personnel have appropriate equipment to protect themselves from exposure to hot water or chemical agents used in the process.

Water bottles, sipper tubes, stoppers, feeders, and other small pieces of equipment should be washed with detergents and/or hot water and, where

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<sup>2</sup>Rabbits and some rodents, such as guinea pigs and hamsters, produce urine with high concentrations of proteins and minerals. These compounds often adhere to cage surfaces and necessitate treatment with acid solutions before and/or during washing.

appropriate, chemical agents to destroy microorganisms. Cleaning with ultrasound may be a useful method for small pieces of equipment.

If automated watering systems are used, some mechanism to ensure that microorganisms and debris do not build up in the watering devices is recommended (Meier et al. 2008); the mechanism can be periodic flushing with large volumes of water or appropriate chemical agents followed by a thorough rinsing. Constant recirculation loops that use properly maintained filters, ultraviolet lights, or other devices to disinfect recirculated water are also effective. Attention should be given to the routine sanitation of automatic water delivery valves (i.e., lixits) during primary enclosure cleaning.

Conventional methods of cleaning and disinfection are adequate for most animal care equipment. However, it may be necessary to also sterilize caging and associated equipment to ensure that pathogenic or opportunistic microorganisms are not introduced into specific-pathogen-free or immunocompromised animals, or that experimental biologic hazards are destroyed before cleaning. Sterilizers should be regularly evaluated and monitored to ensure their safety and effectiveness.

For pens or runs, frequent flushing with water and periodic use of detergents or disinfectants are usually appropriate to maintain sufficiently clean surfaces. If animal waste is to be removed by flushing, this will need to be done at least once a day. During flushing, animals should be kept dry. The timing of pen or run cleaning should take into account the normal behavioral and physiologic processes of the animals; for example, the gastrocolic reflex in meal-fed animals results in defecation shortly after food consumption.

*Cleaning and Disinfection of the Macroenvironment* All components of the animal facility, including animal rooms and support spaces (e.g., storage areas, cage-washing facilities, corridors, and procedure rooms) should be regularly cleaned and disinfected as appropriate to the circumstances and at a frequency based on the use of the area and the nature of likely contamination. Vaporized hydrogen peroxide or chlorine dioxide are effective compounds for room decontamination, particularly following completion of studies with highly infectious agents (Krause et al. 2001) or contamination with adventitious microbial agents.

Cleaning implements should be made of materials that resist corrosion and withstand regular sanitation. They should be assigned to specific areas and should not be transported between areas with different risks of contamination without prior disinfection. Worn items should be replaced regularly. The implements should be stored in a neat, organized fashion that facilitates drying and minimizes contamination or harborage of vermin.

*Assessing the Effectiveness of Sanitation* Monitoring of sanitation practices should fit the process and materials being cleaned and may include visual inspection and microbiologic and water temperature monitoring (Compton et al. 2004a,b; Ednie et al. 1998; Parker et al. 2003). The intensity of animal odors, particularly that of ammonia, should not be used as the

sole means of assessing the effectiveness of the sanitation program. A decision to alter the frequency of cage bedding changes or cage washing should be based on such factors as ammonia concentration, bedding condition, appearance of the cage and animals, and the number and size of animals housed in the cage.

Mechanical washer function should be evaluated regularly and include examination of mechanical components such as spray arms and moving headers as well as spray nozzles to ensure that they are functioning appropriately. If sanitation is temperature dependent, the use of temperature-sensing devices (e.g., thermometers, probes, or temperature-sensitive indicator strips) is recommended to ensure that the equipment being sanitized is exposed to the desired conditions.

Whether the sanitation process is automated or manual, regular evaluation of sanitation effectiveness is recommended. This can be performed by evaluating processed materials by microbiologic culture or the use of organic material detection systems (e.g., adenosine triphosphate [ATP] bioluminescence) and/or by confirming the removal of artificial soil applied to equipment surfaces before washing.

*Waste Disposal* Conventional, biologic, and hazardous waste should be removed and disposed of regularly and safely (Hill 1999). There are several options for effective waste disposal. Contracts with licensed commercial waste disposal firms usually provide some assurance of regulatory compliance and safety. On-site incineration should comply with all federal, state, and local regulations (Nadelkov 1996).

Adequate numbers of properly labeled waste receptacles should be strategically placed throughout the facility. Waste containers should be leak-proof and equipped with tight-fitting lids. It is good practice to use disposable liners and to wash containers and implements regularly. There should be a dedicated waste storage area that can be kept free of insects and other vermin. If cold storage is used to hold material before disposal, a properly labeled, dedicated refrigerator, freezer, or cold room should be used that is readily sanitized.

Hazardous wastes must be rendered safe by sterilization, containment, or other appropriate means before their removal from the facility (DHHS 2009 or most recent edition; NRC 1989, 1995b). Radioactive wastes should be kept in properly labeled containers and their disposal closely coordinated with radiation safety specialists in accord with federal and state regulations; the federal government and most states and municipalities have regulations controlling disposal of hazardous wastes. Compliance with regulations concerning hazardous-agent use (see Chapter 2) and disposal is an institutional responsibility.

Infectious animal carcasses can be incinerated on site or collected by a licensed contractor. Use of chemical digesters (alkaline hydrolysis treat-



ment) may be considered in some situations (Kaye et al. 1998; Murphy et al. 2009). Procedures for on-site packaging, labeling, transportation, and storage of these wastes should be integrated into occupational health and safety policies (Richmond et al. 2003).

Hazardous wastes that are toxic, carcinogenic, flammable, corrosive, reactive, or otherwise unstable should be placed in properly labeled containers and disposed of as recommended by occupational health and safety specialists. In some circumstances, these wastes can be consolidated or blended. Sharps and glass should be disposed of in a manner that will prevent injury to waste handlers.

*Pest Control* Programs designed to prevent, control, or eliminate the presence of or infestation by pests are essential in an animal environment. A regularly scheduled and documented program of control and monitoring should be implemented. The ideal program prevents the entry of vermin and eliminates their harborage in the facility (Anadon et al. 2009; Easterbrook et al. 2008). For animals in outdoor facilities, consideration should be given to eliminating or minimizing the potential risk associated with pests and predators.

Pesticides can induce toxic effects on research animals and interfere with experimental procedures (Gunasekara et al. 2008). They should be used in animal areas only when necessary and investigators whose animals may be exposed to them should be consulted beforehand. Use of pesticides should be recorded and coordinated with the animal care management staff and be in compliance with federal, state, or local regulations. Whenever possible, nontoxic means of pest control, such as insect growth regulators (Donahue et al. 1989; Garg and Donahue 1989; King and Bennett 1989; Verma 2002) and nontoxic substances (e.g., amorphous silica gel), should be used. If traps are used, methods should be humane; traps that catch pests alive require frequent observation and humane euthanasia after capture (Mason and Littin 2003; Meerburg et al. 2008).

*Emergency, Weekend, and Holiday Care* Animals should be cared for by qualified personnel every day, including weekends and holidays, both to safeguard their well-being and to satisfy research requirements. Emergency veterinary care must be available after work hours, on weekends, and on holidays.

In the event of an emergency, institutional security personnel and fire or police officials should be able to reach people responsible for the animals. Notification can be enhanced by prominently posting emergency procedures, names, or telephone numbers in animal facilities or by placing them in the security department or telephone center. Emergency procedures for handling special facilities or operations should be prominently posted and personnel trained in emergency procedures for these areas. A disaster plan

that takes into account both personnel and animals should be prepared as part of the overall safety plan for the animal facility. The colony manager or veterinarian responsible for the animals should be a member of the appropriate safety committee at the institution, an “official responder” in the institution, and a participant in the response to a disaster (Vogelweid 1998).

### *Population Management*

*Identification* Animal records are useful and variable, ranging from limited information on identification cards to detailed computerized records for individual animals (Field et al. 2007). Means of animal identification include room, rack, pen, stall, and cage cards with written, bar-coded, or radio frequency identification (RFID) information. Identification cards should include the source of the animal, the strain or stock, names and contact information for the responsible investigator(s), pertinent dates (e.g., arrival date, birth date, etc.), and protocol number when applicable. Genotype information, when applicable, should also be included, and consistent, unambiguous abbreviations should be used when the full genotype nomenclature (see below) is too lengthy.

In addition, the animals may wear collars, bands, plates, or tabs or be marked by colored stains, ear notches/punches and tags, tattoos, subcutaneous transponders, and freeze brands. As a method of identification of small rodents, toe-clipping should be used only when no other individual identification method is feasible. It may be the preferred method for neonatal mice up to 7 days of age as it appears to have few adverse effects on behavior and well-being at this age (Castelhano-Carlos et al. 2010; Schaefer et al. 2010), especially if toe clipping and genotyping can be combined. Under all circumstances aseptic practices should be followed. Use of anesthesia or analgesia should be commensurate with the age of the animals (Hankenson et al. 2008).

*Recordkeeping* Records containing basic descriptive information are essential for management of colonies of large long-lived animals and should be maintained for each animal (Dyke 1993; Field et al. 2007; NRC 1979a). These records often include species, animal identifier, sire and/or dam identifier, sex, birth or acquisition date, source, exit date, and final disposition. Such animal records are essential for genetic management and historical assessments of colonies. Records of rearing and housing histories, mating histories, and behavioral profiles are useful for the management of many species, especially nonhuman primates (NRC 1979a). Relevant recorded information should be provided when animals are transferred between institutions.

Medical records for individual animals can also be valuable, especially for dogs, cats, nonhuman primates, and agricultural animals (Suckow and Doerning 2007). They should include pertinent clinical and diagnostic information,

date of inoculations, history of surgical procedures and postoperative care, information on experimental use, and necropsy findings where applicable.

Basic demographic information and clinical histories enhance the value of individual animals for both breeding and research and should be readily accessible to investigators, veterinary staff, and animal care staff.

*Breeding, Genetics, and Nomenclature* Genetic characteristics are important with regard to the selection and management of animals for use in breeding colonies and in biomedical research (see Appendix A). Pedigree information allows appropriate selection of breeding pairs and of experimental animals that are unrelated or of known relatedness.

Outbred animals are widely used in biomedical research. Founding populations should be large enough to ensure the long-term genetic heterogeneity of breeding colonies. To facilitate direct comparison of research data derived from outbred animals, genetic management techniques should be used to maintain genetic variability and equalize founder representations (Hartl 2000; Lacy 1989; Poiley 1960; Williams-Blangero 1991). Genetic variability can be monitored with computer simulations, biochemical markers, DNA markers and sequencing, immunologic markers, or quantitative genetic analyses of physiologic variables (MacCluer et al. 1986; Williams-Blangero 1993).

Inbred strains of various species, especially rodents, have been developed to address specific research needs (Festing 1979; Gill 1980). When inbred animals or their F1 progeny are used, it is important to periodically monitor genetic authenticity (Festing 1982; Hedrich 1990); several methods of monitoring have been developed that use immunologic, biochemical, and molecular techniques (Cramer 1983; Festing 2002; Groen 1977; Hoffman et al. 1980; Russell et al. 1993). Appropriate management systems (Green 1981; Kempthorne 1957) should be designed to minimize genetic contamination resulting from mutation and mismating.

Genetically modified animals (GMAs) represent an increasingly large proportion of animals used in research and require special consideration in their population management. Integrated or altered genes can interact with species or strain-specific genes, other genetic manipulations, and environmental factors, in part as a function of site of integration, so each GMA line can be considered a unique resource. Care should be taken to preserve such resources through standard genetic management procedures, including maintenance of detailed pedigree records and genetic monitoring to verify the presence and zygosity of transgenes and other genetic modifications (Conner 2005). Cryopreservation of fertilized embryos, ova, ovaries, or spermatozoa should also be considered as a safeguard against alterations in transgenes over time or accidental loss of GMA lines (Conner 2002; Liu et al. 2009).

Generation of animals with multiple genetic alterations often involves crossing different GMA lines and can lead to the production of offspring with genotypes that are not of interest to the researcher (either as experimental or control animals) as well as unexpected phenotypes. Carefully designed breeding strategies and accurate genotype assessment can help to minimize the generation of animals with unwanted genotypes (Linder 2003). Newly generated genotypes should be carefully monitored and new phenotypes that negatively affect well-being should be reported to the IACUC and managed in a manner to ensure the animals' health and well-being.

Accurate recording, with standardized nomenclature when available, of both the strain and substrain or of the genetic background of animals used in a research project is important (NRC 1979b). Several publications provide rules developed by international committees for standardized nomenclature of outbred rodents and rabbits (Festing et al. 1972), inbred rats, inbred mice, and transgenic animals (FELASA 2007; Linder 2003). In addition, the International Committee on Standardized Genetic Nomenclature for Mice and the Rat Genome and Nomenclature Committee maintain online guidelines for these species (MGI 2009).

## AQUATIC ANIMALS

The variety of needs for fish and aquatic or semiaquatic reptiles and amphibians is as diverse as the number of species considered. This section is intended to provide facility managers, veterinarians, and IACUCs with basic information related to the management of aquatic animal systems (Alworth and Harvey 2007; Alworth and Vazquez 2009; Browne et al. 2007; Browne and Zippel 2007; Denardo 1995; DeTolla et al. 1995; Koerber and Kalishman 2009; Lawrence 2007; Matthews et al. 2002; Pough 2007). Specific recommendations are available in texts and journal reviews, and it will be necessary to review other literature and consult with experienced caregivers for further detail on caring for aquatic species (see Appendix A).

### Aquatic Environment

#### *Microenvironment and Macroenvironment*

As with terrestrial systems, the *microenvironment* of an aquatic animal is the physical environment immediately surrounding it—the primary enclosure such as the tank, raceway, or pond. It contains all the resources with which the animals are in direct contact and also provides the limits of the animals' immediate environment. The microenvironment is characterized by many factors, including water quality, illumination, noise, vibration, and

temperature. The physical environment of the secondary enclosure, such as a room, constitutes the *macroenvironment*.

### *Water Quality*

The composition of the water (*water quality*) is essential to aquatic animal well-being, although other factors that affect terrestrial microenvironments are also relevant. Water quality parameters and life support systems for aquatic animals will vary with the species, life stage, the total biomass supported, and the animals' intended use (Blaustein et al. 1999; Fisher 2000; Gresens 2004; Overstreet et al. 2000; Schultz and Dawson 2003). The success and adequacy of the system depend on its ability to match the laboratory habitat to the natural history of the species (Godfrey and Sanders 2004; Green 2002; Lawrence 2007; Spence et al. 2008).

Characteristics of the water that may affect its appropriateness include temperature, pH, alkalinity, nitrogen waste products (ammonia, nitrite, and nitrate), phosphorus, chlorine/bromine, oxidation-reduction potential, conductivity/salinity, hardness (osmolality/dissolved minerals), dissolved oxygen, total gas pressure, ion and metal content, and the established microbial ecology of the tank. Water quality parameters can directly affect animal well-being; different classes, species, and ages in a species may have different water quality needs and sensitivities to changes in water quality parameters.

Routine measurement of various water characteristics (water quality testing) is essential for stable husbandry. Standards for acceptable water quality, appropriate parameters to test, and testing frequency should be identified at the institutional level and/or in individual animal use protocols depending on the size of the aquatic program. Staff managing aquatic systems need to be trained in biologically relevant aspects of water chemistry, how water quality parameters may affect animal health and well-being, how to monitor water quality results, and how water quality may affect life support system function (e.g., biologic filtration).

The specific parameters and frequency of testing vary widely (depending on the species, life stage, system, and other factors), from continuous monitoring to infrequent spot checks. Recently established systems and/or populations, or changes in husbandry procedures, may require more frequent assessment as the system ecology stabilizes; stable environments may require less frequent testing. Toxins from system components, particularly in newly constructed systems, may require special consideration such as leaching of chemicals from construction materials, concrete, joint compounds, and sealants (DeTolla et al. 1995; Nickum et al. 2004). Chlorine and chloramines used to disinfect water for human consumption or to disinfect equipment are toxic to fish and amphibians and must be removed

or neutralized before use in aquatic systems (Tompkins and Tsai 1976; Wedemeyer 2000).

### *Life Support System*

The phrase *life support system* refers to the physical structure used to contain the water and the animals as well as the ancillary equipment used to move and/or treat the water. Life support systems may be simple (e.g., a container to hold the animal and water) or extremely complex (e.g., a fully automated recirculating system). The type of life support system used depends on several factors including the natural habitat of the species, age/size of the species, number of animals maintained, availability and characteristics of the water required, and the type of research.

Life support systems typically fall into three general categories: recirculating systems where water (all or part) is moved around a system, flow-through systems where water is constantly replaced, or static systems where water is stationary and periodically replenished or replaced. The water may be fresh, brackish, or salt and is maintained at specific temperatures depending on the species' needs.

The source of water for these systems typically falls into four general categories: treated wastewater (e.g., municipal tap water), surface water (e.g., rivers, lakes, or oceans), protected water (e.g., well or aquifer water), or artificial water (e.g., reverse osmosis or distilled water). Artificial saltwater may be created by adding appropriate salt to freshwater sources. Source water selection should be based on the provision of a consistent or constant supply, incoming biosecurity level requirements, water volumes needed, species selection, and research considerations.

Recirculating systems are common in indoor research settings where high-density housing systems are often needed. Most recirculating systems are designed to exchange a specific volume of water per unit time and periodically introduce fresh water into the system. These systems are the most mechanically advanced, containing biologic filters (*biofilters*) that promote conversion of ammonia to nitrite and nitrate via nitrifying bacteria, protein skimmers (foam fractionators) and particulate filters to remove undissolved and dissolved proteins and particulate matter, carbon filters to remove dissolved chemicals, and ultraviolet or ozone units to disinfect the water. The systems generally contain components to aerate and degas the water (to prevent gas oversaturation) and to heat or cool it, as well as automated dosing systems to maintain appropriate pH and conductivity. Not all elements are present in all systems and some components may accomplish multiple functions. Recirculating systems may be designed so that multiple individual tanks are supplied with treated water from a single source, as is the case with "rack" systems used for zebrafish (*Danio rerio*) and *Xenopus*

*laevis* and *X. tropicalis*, as examples (Fisher 2000; Koerber and Kalishman 2009; Schultz and Dawson 2003).

The development and maintenance of the biofilter is critical for limiting ammonia and nitrite accumulation in recirculating systems. The biofilter must be of sufficient size (i.e., contain a sufficient quantity of bacteria) to be capable of processing the bioload (level of nitrogenous waste) entering the system. The microorganisms supported by the biofilter require certain water quality parameters. Alterations in the aquatic environment (e.g., rapid changes in salinity, temperature, and pH) as well as the addition of chemicals or antimicrobials may significantly affect the microbial ecology of the system and therefore water quality and animal well-being. If damaged, biofilter recovery may take weeks (Fisher 2000). Changes in water quality parameters (e.g., pH, ammonia, and nitrite) may negatively affect animal health and the efficiency of the biofilter, so species sensitive to change in water quality outside of a narrow range require more frequent monitoring.

Continuous or timed flow-through systems can be used where suitable water is available to support the species to be housed (e.g., in aquaculture facilities). These systems may use extremely large volumes of water as it is not reused. The water may be used “as is” or processed before use, for example by removing sediments, excessive dissolved gases, chlorine, or chloramines, and by disinfecting with UV or ozone (Fisher 2000; Overstreet et al. 2000). Static systems vary in size from small tanks to large inground ponds, and may use mechanical devices to move and aerate water.

### *Temperature, Humidity, and Ventilation*

The general concepts discussed in the Terrestrial Animals section also apply to the aquatic setting. Most aquatic or semiaquatic species (fish, amphibians, and reptiles) used in research are poikilotherms, which depend, for the most part, on the temperature of their environment to sustain physiologic processes, such as metabolism, reproduction, and feeding behavior (Browne and Edwards 2003; Fraile et al. 1989; Maniero and Carey 1997; Pough 1991). Temperature requirements are based on the natural history of the species and can vary depending on life stage (Green 2002; Pough 1991; Schultz and Dawson 2003). Water temperature may be controlled at its source, within the life support system, or by controlling the macroenvironment. Some semiopen systems (e.g., raceways by a river) depend on source water temperature and thus enclosure water temperature will vary with that of the source water.

The volume of water contained in a room can affect room temperature, temperature stability, and relative humidity. Likewise the thermal load produced by chiller/heater systems can affect the stability of the macroenvironmental temperature. Air handling systems need to be designed to com-

pensate for these thermal and moisture loads. Macroenvironmental relative humidity levels are generally defined by safety issues and staff comfort, since room humidity is not critical for aquatic species; however, excessive moisture may result in condensation on walls, ceilings, and tank lids, which may support microbial growth and serve as a source of contamination or create a conducive environment for metal corrosion. In a dry environment (e.g., indoor heating during cold weather or outdoor housing in some climates/seasons), evaporation rates may be higher, potentially requiring the addition of large quantities of water to the system and monitoring for increases in salinity/conductivity, contaminants, or other water quality aberrations. Some amphibians and reptiles may need elevated microenvironmental humidity (in excess of 50-70% relative humidity), which may require maintaining elevated macroenvironmental humidity levels (Pough 1991; St. Claire et al. 2005).

Room air exchange rates are typically governed by thermal and moisture loads. For fish and some aquatic amphibians, the microenvironmental air quality may affect water quality (i.e., gas exchange), but appropriate life support system design may reduce its importance. Airborne particulates and compounds (e.g., volatile organic compounds and ammonia) may dissolve in tank water and affect animal health (Koerber and Kalishman 2009). As the aerosolization of water can lead to the spread of aquatic animal pathogens (e.g., protozoa, bacteria) within or throughout an aquatic animal facility, this process should be minimized as much as possible (Roberts-Thomson et al. 2006; Wooster and Bowser 2007; Yanong 2003).

### *Illumination*

Aquatic and semiaquatic species are often sensitive to changes in photoperiod, light intensity, and wavelength (Brenner and Brenner 1969). Lighting characteristics will vary by species, their natural history, and the research being conducted. Gradual changes in room light intensity are recommended, as rapid changes in light intensity can elicit a startle response in fish and may result in trauma. Some aquatic and semiaquatic species may need full-spectrum lighting and/or heat lamps to provide supplemental heating to facilitate adequate physiological function (e.g., aquatic turtles provided with a basking area; Pough 1991).

### *Noise and Vibration*

General concepts discussed in the Terrestrial Animals section apply to aquatic animals. These animals may be sensitive to noise and vibration, which are readily transmitted through water. Species vary in their response and many fish species acclimate to noise and vibration, although



these may cause subclinical effects (Smith et al. 2007). Vibration through floors can be reduced by using isolation pads under aquaria racks. Some facilities elect to place major components of the life support system (e.g., filters, pumps, and biofilters) outside the animal rooms to reduce vibration and noise.

## **Aquatic Housing**

### *Microenvironment (Primary Enclosure)*

The primary enclosure (a tank, raceway, pond, or pen holding water and the animal) defines the limits of an animal's immediate environment. In research settings, acceptable primary enclosures

- allow for the normal physiological and behavioral needs of the animals, including excretory function, control and maintenance of body temperature, normal movement and postural adjustments, and, where indicated, reproduction. In some poikilothermic reptiles and amphibians, microenvironmental temperature gradients may be needed for certain physiologic functions such as feeding and digestion.
- allow conspecific social interactions (e.g., schooling in fish species).
- provide a balanced, stable environment that supports the animal's physiologic needs.
- provide the appropriate water quality and characteristics, and permit monitoring, filling, refilling, and changing of water.
- allow access to adequate food and removal of food waste.
- restrict escape or accidental entrapment of animals or their appendages.
- are free of sharp edges and/or projections that could cause injury.
- allow for observation of the animals with minimal disturbance.
- are constructed of nontoxic materials that do not leach toxicants or chemicals into the aquatic environment.
- do not present electrical hazards directly or indirectly.

### *Environmental Enrichment and Social Housing*

Environmental enrichment strategies for many aquatic species are not well established. The implications of a barren versus an enriched environment on well-being, general research, growth, and development are unknown or poorly defined, as is true of individual versus group (social)

housing for many species. When used, enrichment should elicit species-appropriate behaviors and be evaluated for safety and utility.

Generally, schooling fish species are housed with conspecifics, and many amphibians, especially anuran species, may be group housed. Aggression in aquatic animals does occur (van de Nieuwegiessen et al. 2008; Speedie and Gerlai 2008) and, as for terrestrial animals, appropriate monitoring and intervention may be necessary (Matthews et al. 2002; Torreilles and Green 2007). Some species need appropriate substrate (e.g., gravel) to reproduce or need substrate variety to express basic behaviors and maintain health (Overstreet et al. 2000). Improved breeding success in enriched environments has been reported but further research in this area is needed (Carfagnini et al. 2009). For many species (including, e.g., *X. laevis*), visual barriers, hides, and shading are appropriate (Alworth and Vasquez 2009; Torreilles and Green 2007). Most semiaquatic reptiles spend some time on land (basking, feeding, digesting, and ovipositing) and terrestrial areas should be provided as appropriate.

### *Sheltered, Outdoor, and Naturalistic Housing*

Animals used in aquaculture are often housed in situations that mimic agricultural rearing and may be in outdoor and/or sheltered raceways, ponds, or pens with high population densities. In these settings, where natural predation and mortalities occur, it may be appropriate to measure animal “numbers” by using standard aquaculture techniques such as final production biomass (Borski and Hodson 2003).

### *Space*

Space recommendations and housing density vary extensively with the species, age/size of the animals, life support system, and type of research (Browne et al. 2003; Green 2009; Gresens 2004; Hilken et al. 1995; Matthews et al. 2002). In the United States, for example, adult zebrafish (*Danio rerio*) in typical biomedical research settings are generally housed 5 adult fish per liter of water (Matthews et al. 2002), but this housing density varies when breeding and for housing younger animals (Matthews et al. 2002). This guidance is not necessarily relevant for other species of fish, and may change as research advances (Lawrence 2007). *X. laevis* adults may be housed at 2 liters of water per frog (NRC 1974), but a wide variety of housing systems are currently used in research settings (Green 2009). Institutions, investigators, and IACUC members should evaluate the appropriate needs of each species during program evaluations and facility inspections and continue to review ongoing research in these areas.

## Aquatic Management

### *Behavior and Social Management*

Visual evaluations of aquatic and semiaquatic animals are typically used for monitoring. To avoid damage to the protective mucus layers of the skin and negative effects on immune function (De Veer et al. 2007; Subramanian et al. 2007; Tsutsui et al. 2005), handling of these species should be kept to the minimum required (Bly et al. 1997). Appropriate handling techniques vary widely depending on the species, age/size, holding system, and specific research need (Fisher 2000; Matthews et al. 2002; Overstreet et al. 2000); they should be identified at the facility or individual protocol level.

Latex gloves have been associated with toxicity in some amphibians (Gutleb et al. 2001). The use of appropriate nets by well-trained personnel can reduce skin damage and thus stress. Nets should be cleaned and disinfected appropriately when used in different systems and should be dedicated to animals of similar health status whenever possible.

Exercise and activity levels for aquatic species are minimally described but informed decisions may be extrapolated from studies of behavior of the same or similar species in the wild (Spence et al. 2008). Some aquatic species do not rest and constantly swim; others may rest all or a significant portion of the day. Water flow rates and the provision of hides or terrestrial resting platforms (e.g., for some reptiles and amphibians) need to be appropriate for species and life stage.

### *Husbandry*

*Food* The general principles relating to feeding of terrestrial animals are applicable to aquatic animals. Food should be stored in a type-appropriate manner to preserve nutritional content, minimize contamination, and prevent entry of pests. Food delivery methods should ensure that all animals are able to access food for a sufficient period of time while minimizing feeding aggression and nutrient loss. Feeding methods and frequency vary widely depending on the species, age/size of species, and type of life support system. Many aquatic or semiaquatic species are not provided with food ad libitum in the tank, and in some cases may not be fed daily.

Commercial diets (e.g., pellets, flakes) are available for certain species and storage time should be based on manufacturer recommendations or follow commonly accepted practices. In aquatic systems, particularly in fish rearing or when maintaining some amphibian and reptile species, the use of live foods (e.g., *Artemia* sp. larva, crickets, or mealworm beetle larvae) is common. Live food sources need to be maintained and managed to ensure a

steady supply and the health and suitability of the organism as a food. Care should be taken to feed a complete diet to avoid nutritional deficiencies.

*Water (see also section on Water Quality)* Aquatic animals need access to appropriately conditioned water. Fully aquatic animals obtain water in their habitat or absorb it across their gills or skin. Some semiaquatic amphibians and reptiles may need “bowls” of water for soaking and drinking, and water quality should be appropriate (see Terrestrial Animals section). Chlorine or chloramines may be present in tap water at levels that could be toxic to some species.

*Substrate* Substrates can provide enrichment for aquatic animals by promoting species-appropriate behavior such as burrowing, foraging, or enhanced spawning (Fisher 2000; Matthews et al. 2002; Overstreet et al. 2000). They may be an integral and essential component of the life support system by providing increased surface area for denitrifying bacteria (e.g., systems with undergravel filtration), and need routine siphoning (i.e., hydrocleaning) to remove organic debris. System design and species needs should be evaluated to determine the amount, type, and presentation of substrate.

*Sanitation* Sanitation of the aquatic environment in recirculating systems is provided through an appropriately designed and maintained life support system, regular removal of solid waste materials from the enclosure bottom, and periodic water changes. The basic concept of sanitation (i.e., to provide conditions conducive to animal health and welfare) is the same for terrestrial and aquatic systems. However, sanitation measures in aquatic systems differ from those for terrestrial systems because much of the nitrogenous waste (feces and urine) and respiratory output (carbon dioxide) is dissolved in the water.

A properly functioning life support system, designed to process the bioload, will maintain nitrogenous wastes within an acceptable range. Solids may be removed in a variety of ways, depending on the design of the system; generally they are removed by siphoning (hydrocleaning) and/or filtration. Depending on the type, filters need routine cleaning or replacement or, if self-cleaning, proper maintenance; in saltwater systems dissolved proteins may be removed by protein skimmers. Reducing organic solids limits the quantities of nitrogen and phosphorus that need to be removed from the system, both of which can accumulate to levels that are toxic to fish and amphibians. The biologic filter (denitrifying bacteria) typically removes ammonia and nitrite, potential toxins, from aquatic systems. Nitrate, the end product of this process, is less toxic to aquatic animals but at high levels can be problematic; it is generally removed through water changes, although large systems may have a specialized denitrification unit to reduce levels.

Disinfection is usually accomplished through water treatment (e.g., filtration and application of UV light or ozone) and/or water changes. Chlorine and most chemical disinfectants are inappropriate for aquatic systems containing animals as they are toxic at low concentrations; when used to disinfect an entire system or system components, extreme care must be taken to ensure that residual chlorine, chemical, and reactive byproducts are neutralized or removed. The type of monitoring and frequency varies depending on the disinfection method, the system, and the animals.

Algal growth is common in aquatic systems and increases with the presence of nitrogen and phosphorus, particularly in the presence of light. Excessive growth may be an indication of elevated nitrogen or phosphorus levels. Algal species seen with recirculating systems are generally nontoxic, although species capable of producing toxins exist. Algae are typically removed using mechanical methods (i.e., scrubbing or scraping). Limiting algal growth is important to allow viewing of the animals in the enclosure. Cyanobacteria (commonly called blue-green algae) growth is also possible and may be common in freshwater aquaculture. The same factors that promote algae growth also promote cyanobacteria growth. As with algae, while most species are harmless, some species can produce clinically relevant toxic compounds (Smith et al. 2008).

Tank (cage) changing and disinfection are conducted at frequencies using methods that often differ from terrestrial systems. Because waste is dissolved in the water and/or removed as solids by siphoning or filtration, regular changing of tanks is not integral to maintaining adequate hygiene in typical aquatic systems. The frequency of cleaning and disinfection should be determined by water quality, which should permit adequate viewing of the animals, and animal health monitoring. System components such as lids on fish tanks, which may accumulate feed, may require sanitation as often as weekly depending on the frequency and type of feed and the system's design.

*Cleaning and Disinfection of the Macroenvironment* As with terrestrial systems, all components of the animal facility, including animal rooms and support spaces (e.g., storage areas, cage-washing facilities, corridors, and procedure rooms), should be regularly cleaned and disinfected as appropriate to the circumstances and at a frequency determined by the use of the area and the nature of likely contamination. Cleaning agents should be chosen and used with care to ensure there is no secondary contamination of the aquatic systems.

Cleaning implements should be made of materials that resist corrosion and withstand regular sanitation. They should be assigned to specific areas and should not be transported between areas with different risks of contamination without prior disinfection. Worn items should be replaced regularly. The implements should be stored in a neat, organized fashion that facilitates drying and minimizes contamination or harborage of vermin.

*Waste Disposal* Wastewater treatment and disposal may be necessary in some facilities depending on water volume, quality, and chemical constituents. Local regulations may limit or control the release of wastewater.

*Pest Control* Terrestrial animal pest control principles apply to aquatic systems but, due to transcutaneous absorption, aquatic and semiaquatic species may be more sensitive to commonly used pest control agents than terrestrial animals. Before use, an appropriate review of chemicals and methods of application is necessary.

*Emergency, Weekend, and Holiday Care* As with terrestrial species, aquatic animals should receive daily care from qualified personnel who have a sufficient understanding of the housing system to identify malfunctions and, if they are unable to address a system failure of such magnitude that it requires resolution before the next workday, access to staff who can respond to the problem. Automated monitoring systems are available and may be appropriate depending on system size and complexity. Appropriate emergency response plans should be developed to address major system failures.

### *Population Management*

*Identification* Identification principles are similar to those for terrestrial animals. Identification criteria are based on the species and housing system. Identification methods available for use in aquatic species include fin clipping, genetic testing (Matthews et al. 2002; Nickum et al. 2004), identification tags, subcutaneous injections of elastomeric or other materials (Nickum et al. 2004), individual transponder tags (in animals of sufficient size), and, as applicable, external features such as individual color patterns. Because it can be difficult to individually identify some small aquatic animals throughout their life, group identification may be more appropriate in some situations (Koerber and Kalishman 2009; Matthews et al. 2002).

*Aquatic Animal Recordkeeping* Adequate recordkeeping is necessary in aquatic system management. In general, the same standards used for terrestrial animals apply to aquatic and semiaquatic species, although modifications may be necessary to account for species or system variations (Koerber and Kalishman 2009).

Although many aquatic animals are maintained using group (vs. individual) identification, detailed animal records are still necessary. Animal information that may routinely be captured, particularly in biomedical research with fish, includes species; genetic information (parental stock identification, genetic composition); stock source; stock numbers in system; tank identification; system life support information; breeding; deaths;

illnesses; animal transfers within and out of the facility; and fertilization/hatching information (Koerber and Kalishman 2009; Matthews et al. 2002). Records should be kept concerning feeding information (e.g., food offered, acceptance), nonexpired food supplies to ensure sustenance of nutritional profile, and any live cultures (e.g., hatch rates and information to ensure suppliers' recommendations are being met; Matthews et al. 2002).

Records of water quality testing for system and source water and maintenance activities of the life support system components are important for tracking and ensuring water quality. The exact water quality parameters tested and testing frequency should be clearly established and will vary with such factors as the type of life support system, animals, and research, as discussed under Water Quality. Detailed tracking of animal numbers in aquatic systems is often possible with accurate records of transfers, breeding, and mortalities (Matthews et al. 2002). In some cases where animals are housed in large groups (e.g., some *Xenopus* colonies) periodic censuses may be undertaken to obtain an exact count. In large-scale aquaculture research it may be more appropriate to measure biomass of the system versus actual numbers of animals (Borski and Hodson 2003).

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## Veterinary Care

**V**eterinary care is an essential part of an animal care and use Program. The primary focus of the veterinarian is to oversee the well-being and clinical care of animals used in research, testing, teaching, and production. This responsibility extends to monitoring and promoting animal well-being at all times during animal use and during all phases of the animal's life. Well-being is determined by considering physical, physiologic, and behavioral indicators, which vary by species. The number, species, and use of animals housed in an institution may influence the complexity of the veterinary care program, but a veterinary program that offers a high quality of care and ethical standards must be provided, regardless of the number of animals or species maintained.

An adequate veterinary care program consists of assessment of animal well-being and effective management of

- animal procurement and transportation
- preventive medicine (including quarantine, animal biosecurity, and surveillance)
- clinical disease, disability, or related health issues
- protocol-associated disease, disability, and other sequelae
- surgery and perioperative care
- pain and distress
- anesthesia and analgesia
- euthanasia.



The veterinary care program is the responsibility of the attending veterinarian (AV), who is certified or has training or experience in laboratory animal science and medicine or is otherwise qualified in the care of the species being used. Some aspects of the veterinary care program can be conducted by persons other than a veterinarian, but a mechanism for direct and frequent communication should be established to ensure that timely and accurate information is conveyed to the responsible veterinarian about issues associated with animal health, behavior, and well-being, and that appropriate treatment or euthanasia is administered. The AV should provide guidance to investigators and all personnel involved in the care and use of animals to ensure appropriate husbandry, handling, medical treatment, immobilization, sedation, analgesia, anesthesia, and euthanasia. In addition, the AV should provide guidance and oversight to surgery programs and perioperative care involving animals.

## **ANIMAL PROCUREMENT AND TRANSPORTATION**

### **Animal Procurement**

All animals must be acquired lawfully, and the receiving institution should ensure that all procedures involving animal procurement are conducted in a lawful manner. Before procuring animals, the principal investigator should confirm that there are sufficient facilities and expertise to house and manage the species being acquired. Procurement of animals should be linked to the prior approval of animal use and number by the IACUC (see Chapter 2, Protocol Review). If dogs and cats are obtained from random sources, such as shelters or pounds, the animals should be inspected for tattoos or identification devices such as subcutaneous transponders (NRC 2009b); such identification might indicate that an animal was a pet, and if so, ownership should be verified. Attention should also be given to the population status of the species under consideration; the threatened or endangered status of species is updated annually by the Fish and Wildlife Service (DOI 2007). Appropriate records and other forms of documentation should be maintained for animals acquired by an institution for its investigators.

Potential vendors should be evaluated for the quality of animals they supply. As a rule, vendors of purpose-bred animals (e.g., USDA Class A dealers) regularly provide information that describes the genetic and pathogen status of their colonies or individual animals and relevant clinical history (e.g., vaccination status and anthelmintic administration). The use of purpose-bred and preconditioned animals is therefore preferable when consistent with the research, teaching, and testing objectives. In general, animals used for scientific purposes should not be obtained from pet stores or pet distributors due to the unknown or uncontrolled background of animals

from these sources and the potential for introducing health risks to personnel and other facility animals. Breeding colonies should be established based on need and managed according to principles of animal reduction such as cryopreservation for rodent stocks or strains (Robinson et al. 2003).

### **Transportation of Animals**

Transportation of animals is governed by a number of US regulatory agencies and international bodies. The Animal Welfare Regulations (USDA 1985) set standards for interstate and export/import transportation of regulated species; the International Air Transport Association (IATA) updates the Live Animals Regulations annually and IATA member airlines and many countries agree to comply with these regulations to ensure the safe and humane transport of animals by air (IATA 2009). The Centers for Disease Control and Prevention and USDA enforce regulations to prevent the introduction, transmission, or spread of communicable diseases and regulate the importation of any animal or animal product capable of carrying a zoonotic disease. The US Fish and Wildlife Service regulates importation/exportation of wild vertebrate and invertebrate animals and their tissues. As the national authority arm of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), the US Fish and Wildlife Service also regulates movement of CITES-listed species that are captive bred, including nonhuman primates (DOI 2007). Institutions should contact appropriate authorities to ensure compliance with any relevant statutes and other animal transportation requirements that must be met for animals to cross international boundaries, including those not of the country of final destination. The NRC publication *Guidelines for the Humane Transportation of Research Animals* provides a comprehensive review of this topic (NRC 2006); additional references on transportation of animals are available in Appendix A.

Animal transportation may be intrainstitutional, interinstitutional, or between a commercial or noncommercial source and a research facility. For wildlife, transportation may occur between the capture site and field holding facilities. Careful planning for all types of transportation should occur to ensure animal safety and well-being. The process of transportation should provide an appropriate level of animal biosecurity (see definition on page 109) while minimizing zoonotic risks, protecting against environmental extremes, avoiding overcrowding, providing for the animals' physical, physiologic, or behavioral needs and comfort, and protecting the animals and personnel from physical trauma (Maher and Schub 2004).

Movement of animals within or between sites or institutions should be planned and coordinated by responsible and well-trained persons at the sending and receiving sites to minimize animal transit time or delays in

receipt. Shipping should be coordinated to ensure that animals arrive during normal business hours or, if delivery occurs outside of this time, that someone is available to receive them. Defining and delegating responsibility to the appropriate persons, who are knowledgeable about the needs of the species being shipped, will help ensure effective communication and planning of animal transport (AVMA 2002).

All animals in transit within and between institutions or jurisdictions should be accompanied by appropriate documentation to minimize delays in shipping and receipt. Documentation may include health certificates, sending and receiving institutions' addresses and contacts, emergency procedures and veterinary contact information, and agency permits as needed.

For noncommercial sources of animals, in particular, it is important for the veterinarian or the veterinarian's designee to review the health status and other housing and husbandry requirements before authorizing shipment of animals. This action will ensure that effective quarantine practices are implemented for incoming animals and address any special requirements needed to ensure animal well-being (Otto and Tolwani 2002). Special considerations may be necessary for transporting animals during certain phases of their life or in certain conditions, such as pregnant, perinatal, and geriatric animals; animals with preexisting medical conditions (e.g., diabetes mellitus); and animals surgically prepared by the supplier (FASS 2010).

Although ensuring animal biosecurity during transportation is always important, it is of particular importance for immunocompromised, genetically modified, and specific pathogen-free rodents (Jacoby and Lindsey 1998). For these animals, reinforced disposable shipping containers with filter-protected ventilation openings and internal food and water sources help ensure that microbial contamination does not occur during transit. Commercial vendors are experienced in animal transport and typically use dedicated transport systems and protocols to minimize microbiologic contamination. Noncommercial or interinstitutional transfer of rodents poses a higher risk of microbial contamination since the individuals involved may lack the required knowledge and animal biosecurity capabilities to maintain the animals' health status. Risks due to in-transit microbial contamination of shipping container surfaces can be reduced by decontaminating the surfaces before placement of the containers in clean sites of animal facilities (NRC 1996, 2006). Transportation of animals in private vehicles is discouraged because of potential animal biosecurity, safety, health, and liability risks for the animals, personnel, and institution.

For aquatic species and amphibians, special considerations are required for transportation in an aqueous or sufficiently moist environment, and special attention should be given to avoiding temperature extremes for poikilotherms.

In all cases, appropriate loading and unloading facilities should be provided for the safe and secure transfer of animals at an institution. Facilities and procedures should be in place to help ensure that the environment at the site does not pose risks to animal well-being or personnel safety. During times of extreme temperatures animal transport may be detrimental to animal well-being and therefore may not be possible unless an appropriately heated or cooled means of transportation is available (Robertshaw 2004; Schrama et al. 1996).

## PREVENTIVE MEDICINE

Disease prevention is an essential component of comprehensive veterinary medical care and biosecurity programs. Effective preventive medicine enhances the research value of animals by maintaining healthy animals and minimizing nonprotocol sources of variation associated with disease and inapparent infection, thus minimizing animal waste and potential effects on well-being. Preventive medicine programs consist of various combinations of policies, procedures, and equipment related to quarantine and stabilization and the separation of animals by species, source, and health status.

### Animal Biosecurity

*Animal biosecurity* refers to all measures taken to identify, contain, prevent, and eradicate known or unknown infections that may cause clinical disease or alter physiologic and behavioral responses or otherwise make the animals unsuitable for research. Animal biosecurity practices should be applied to all species, but they are most important when housing large numbers of animals in intensive housing conditions (e.g., laboratory rodents). Limiting exposure of animals to infectious disease agents requires consideration of physical plant layout and operational practices. Separation of clean and soiled caging and equipment, and sometimes the associated staff, is often fundamental to success.

*Animal biosecurity* includes all measures to control known or unknown infections in laboratory animals.

A successful animal biosecurity program incorporates a number of elements: procedures that ensure that only animals of a desired defined health status enter the facility; personnel and materials, especially consumables, that do not serve as fomites; practices that reduce the likelihood of cross contamination if an infectious agent is inadvertently introduced; a comprehensive ongoing system for evaluating animals' health status, including access to all animals; and containment and eradication, if desired, of

introduced infectious agents. Related components include procedures for evaluating and selecting appropriate animal suppliers (these may include quarantine and determination of animal health status if unknown); treatment of animals or their products at entry to minimize disease risks (e.g., surface disinfection of fish eggs); a comprehensive pest control program that may include evaluation of the health status of feral animals; procedures to ensure that all biologics administered to animals are free of contamination; and procedures for intra- and interfacility animal transport (e.g., transport of animals to laboratory and other facilities outside the animal facility can present challenges to animal biosecurity) (Balaban and Hampshire 2001). Additional details pertaining to these topics are available in the sections of Chapter 2 that deal with occupational health and safety.

### **Quarantine and Stabilization**

*Quarantine* is the separation of newly received animals from those already in the facility, in a way that prevents potential spread of contaminants, until the health and possibly the microbial status of the newly received animals have been determined. Transportation can be stressful and may induce recrudescence of subclinical infections harbored by an animal.

An effective quarantine program minimizes the risk of introduction of pathogens into an established colony. The veterinary medical staff should implement procedures for evaluating the health and, if appropriate, the pathogen status of newly received animals, and the procedures should reflect acceptable veterinary medical practice and federal and state regulations applicable to zoonoses (Butler et al. 1995). Effective quarantine procedures are particularly helpful in limiting human exposure to zoonotic infections from nonhuman primates, such as mycobacterial infections, which necessitate specific guidelines for handling of these animals (Lerche et al. 2008; Roberts and Andrews 2008).

Information from suppliers about animal quality should be sufficient to enable a veterinarian to establish the length of quarantine, define the potential risks to personnel and animals in the colony, determine whether therapy is required before animals are released from quarantine, and, in the case of rodents, determine whether rederivation (cesarean or embryo transfer) is necessary to free the animals of specific pathogens. Rodents may not require quarantine if data from the vendor or provider are sufficiently current, complete, and reliable to define the health status of the incoming animals and if the potential for exposure to pathogens during transit is considered. When quarantine is indicated, animals from one shipment should be handled separately or be physically separated from animals from other shipments to preclude transfer of infectious agents between groups.

Depending on the health status of the colony animals and consistent with the animal biosecurity program in place, rodents or other animals being moved outside an animal facility for procedures (e.g., imaging or behavioral testing) may need to be held separately from their colony of origin until their health status is evaluated.

Regardless of whether the animals are quarantined, newly received animals should be given a period for physiologic, behavioral, and nutritional acclimation before their use (Obernier and Baldwin 2006). The length of time for acclimation will depend on the type and duration of animal transportation, the species, and the intended use of the animals. For animals not typically housed in research settings, consideration should be given to providing means to assist with their acclimation (e.g., shearing sheep before they are brought indoors). The need for an acclimation period has been demonstrated in mice, rats, guinea pigs, nonhuman primates, and goats, and time for acclimation is likely important for other species as well (Capitanio et al. 2006; Conour et al. 2006; Kagira et al. 2007; Landi et al. 1982; Prasad et al. 1978; Sanhouri et al. 1989; Tuli et al. 1995).

### Separation by Health Status and Species

Physical separation of animals by species is recommended to prevent interspecies disease transmission and to eliminate the potential for anxiety and physiologic and behavioral changes due to interspecies conflict (Arndt et al. 2010). Such separation is usually accomplished by housing different species in separate rooms, but in some instances it may be possible with cubicles, laminar flow units, cages that have filtered air or separate ventilation, or isolators. It may also be acceptable to house different species in the same room—for example, two species that have a similar pathogen status and are behaviorally compatible (Pritchett-Corning et al. 2009), or aquatic species, as long as nets and other animal handling devices remain separate between systems.

In some species subclinical or latent infections can cause clinical disease if transmitted to another species. A few examples may serve as a guide in determining the need for separate housing by species:

- *Helicobacter bilis* can infect rats and mice and may induce clinical disease in both species (Haines et al. 1998; Jacoby and Lindsey 1998; Maggio-Price et al. 2002).
- As a rule, New World (South and Central American), Old World African, and Old World Asian species of nonhuman primates should be housed in separate rooms. Simian hemorrhagic fever (Renquist 1990) and simian immunodeficiency virus (Hirsch et al. 1991; Murphey-Corb et al. 1986), for example, cause only subclinical

infections in African species but induce clinical disease in Asian species.

- Some species should be housed in separate rooms even though they are from the same geographic region. For example, squirrel monkeys (*Saimiri sciureus*) and tamarins (*Saguinus oedipus*) may be latently infected with herpesviruses (*Herpesvirus saimiri* and *H. tamarinus*, respectively), which could be transmitted to and cause a fatal epizootic disease in owl monkeys (*Aotus trivirgatus*) (Barahona et al. 1975; Hunt and Melendez 1966; Murphy et al. 1971).

Intraspecies separation may be essential when animals obtained from multiple sites or sources, either commercial or institutional, differ in pathogen status—for example, with respect to rat theilovirus in rats, mouse hepatitis virus in mice, bacterial gill disease in rainbow trout, *Pasteurella multocida* in rabbits, *Macacine herpesvirus 1* (B virus) in macaque species, and *Mycoplasma hyopneumoniae* in swine.

### **Surveillance, Diagnosis, Treatment, and Control of Disease**

All animals should be observed for signs of illness, injury, or abnormal behavior by a person trained to recognize such signs. As a rule, such observation should occur at least daily, but more frequent observations may be required, such as during postoperative recovery, when animals are ill or have a physical deficit, or when animals are approaching a study endpoint. Professional judgment should be used to ensure that the frequency and character of observations minimize risks to individual animals and do not compromise the research for which the animals are used.

Appropriate procedures should be in place for disease surveillance and diagnosis. Unexpected deaths and signs of illness, distress, or other deviations from normal in animals should be reported promptly and investigated, as necessary, to ensure appropriate and timely delivery of veterinary medical care. Animals that show signs of a contagious disease should be isolated from healthy animals. If an entire room or enclosure of animals is known or believed to be exposed to an infectious agent (e.g., *Mycobacterium tuberculosis* in nonhuman primates), the group should be kept intact during the process of diagnosis, treatment, and control.

Procedures for disease prevention, diagnosis, and therapy should be those currently accepted in veterinary and laboratory animal practice. Health monitoring programs also include veterinary herd/flock health programs for livestock and colony health monitoring programs for aquatic and rodent species. Access to diagnostic laboratory services facilitates veterinary medical care and can include gross and microscopic pathology, hematology, microbiology, parasitology, clinical chemistry, molecular diagnostics,

and serology. If a disease or infectious agent is identified in a facility or colony, the choice of therapy should be made by the veterinarian in consultation with the investigator. If the animal is to remain in the study, the selected treatment plan should be therapeutically sound and, when possible, interfere minimally with the research process.

Subclinical microbial infections (see Appendix A, Pathology, Clinical Pathology, and Parasitology) occur frequently in conventionally maintained rodents but can also occur in facilities designed and maintained for production and use of pathogen-free rodents if the microbial barrier is breached. Examples of infectious agents that can be subclinical but that may induce immunologic changes or alter physiologic, pharmacologic, or toxicologic responses are noroviruses, parvoviruses, mouse hepatitis virus, lymphocytic choriomeningitis virus, and *Helicobacter* spp. (Besselsen et al. 2008; Clifford and Watson 2008; NRC 1991a,b,c). Scientific objectives of a particular protocol, the consequences of infection in a specific strain of rodent, the potential for zoonotic disease, and the adverse effects that infectious agents may have on other animals or protocols in a facility should determine the characteristics of rodent health surveillance programs and strategies for keeping rodents free of specific pathogens.

The principal methods for detecting microbial infections in animal populations are serologic tests (e.g., flow cytometric bead immunoassays, immunofluorescent assays) but other methods, such as DNA analysis using polymerase chain reaction (PCR), microbial culture, clinical chemistry (e.g., lactate dehydrogenase virus), histopathology, and other validated emerging technologies, can also be used to make or confirm a diagnosis.

Transplantable tumors, hybridomas, cell lines, blood products, and other biologic materials can be sources of both murine and human viruses that can contaminate rodents or pose risks to laboratory personnel (Nicklas et al. 1993); rapid and effective assays are available to monitor microbiologic contamination and should be considered before introducing such material into animals (Peterson 2008).

Because health monitoring programs are dependent on the size and complexity of the Program, the species involved, and the institutional research focus, it is beyond the scope of the *Guide* to go into details about health monitoring programs for all species; additional references are in Appendix A (under Disease Surveillance, Diagnosis, and Treatment; Pathology, Clinical Pathology, and Parasitology; and Species-Specific References).

## CLINICAL CARE AND MANAGEMENT

Healthy, well-cared-for animals are a prerequisite for good-quality animal-based science. The structure of the veterinary care program, including the number of qualified veterinarians, should be appropriate to fulfill the



program's requirements, which will vary by institution, species used, and the nature of the animal use. To be effective in providing clinical care, the veterinarian should be familiar with the species and various uses of animals in the institutional research, teaching, testing, or production programs and have access to medical and experimental treatment records.

### **Medical Management**

There should be a timely and accurate method for communication of any abnormalities in or concerns about animal health, behavior, and well-being to the veterinarian or the veterinarian's designee. The responsibility for communicating these concerns rests with all those involved with animal care and use. Reports should be triaged to ensure that animals most in need receive priority attention, and the veterinarian or veterinarian's designee should perform an objective assessment of the animal(s) to determine an appropriate course of action.

Well-planned experiments with clearly delineated scientific and humane endpoints will help to ensure that a contingency plan is in place for problems that may arise during the study (see Chapter 2, Experimental and Humane Endpoints). For animals on research protocols, the veterinarian or veterinarian's designee should make every effort to discuss any problems with the principal investigator or project director to jointly determine the most appropriate course of treatment or action. Standard operating procedures (SOPs) may be developed for recurrent health conditions to expedite treatment. Recurrent or significant problems involving experimental animal health should be communicated to the IACUC, and all treatments and outcomes should be documented (USDA 1997).

### **Emergency Care**

Procedures must be in place to provide for emergency veterinary care both during and outside of regularly scheduled hours. Such procedures must enable animal care and research staff to make timely reports of animal injury, illness, or death. A veterinarian or the veterinarian's designee must be available to expeditiously assess the animal's condition, treat the animal, investigate an unexpected death, or advise on euthanasia. In the case of a pressing health problem, if the responsible person (e.g., investigator) is not available or if the investigator and veterinary staff cannot reach consensus on treatment, the veterinarian must have the authority, delegated by senior administration (see Chapter 2, Institutional Official and Attending Veterinarian) and the IACUC, to treat the animal, remove it from the experiment, institute appropriate measures to relieve severe pain or distress, or perform euthanasia if necessary.

## **Recordkeeping**

Medical records are a key element of the veterinary care program and are considered critical for documenting animal well-being as well as tracking animal care and use at a facility. A veterinarian should be involved in establishing, reviewing, and overseeing medical and animal use records (Field et al. 2007; Suckow and Doerning 2007). All those involved in animal care and use must comply with federal laws and regulations regarding human and veterinary drugs and treatments. Drug records and storage procedures should be reviewed during facility inspections.

## **SURGERY**

Successful surgical outcomes require appropriate attention to presurgical planning, personnel training, anesthesia, aseptic and surgical technique, assessment of animal well-being, appropriate use of analgesics, and animal physiologic status during all phases of a protocol involving surgery and postoperative care (see Appendix A, Anesthesia, Pain, and Surgery). The individual impact of those factors will vary according to the complexity of procedures involved and the species of animal used. A team approach to a surgical project often increases the likelihood of a successful outcome by providing input from persons with different expertise (Brown and Schofield 1994; Brown et al. 1993).

Surgical outcomes should be continually and thoroughly assessed to ensure that appropriate procedures are followed and timely corrective changes are instituted. Modification of standard techniques may be required (for instance, in aquatic or field surgery), but should not compromise the well-being of the animals. In the event of modification, close assessment of outcomes may have to incorporate criteria other than clinical morbidity and mortality. Such assessments rely on continuing communication among technical staff, investigators, veterinarians, and the IACUC.

## **Training**

Researchers conducting surgical procedures must have appropriate training to ensure that good surgical technique is practiced—that is, asepsis, gentle tissue handling, minimal dissection of tissue, appropriate use of instruments, effective hemostasis, and correct use of suture materials and patterns (Brown et al. 1993; Heon et al. 2006). Training may have to be tailored to accommodate the wide range of educational backgrounds frequently encountered in research settings. For example, persons trained in human surgery may need training in interspecies variations in anatomy, physiology, the effects of anesthetic and analgesic drugs, and/or postoperative care requirements.

Technical staff performing rodent surgery may have had little formal training in surgical techniques and asepsis and may require general surgical training as well as training for the specific techniques they are expected to perform (Stevens and Dey 2007).

Training guidelines for research surgery commensurate with an individual's background are available (ASR 2009) to assist institutions in developing appropriate training programs. The IACUC, together with the AV, is responsible for determining that personnel performing surgical procedures are appropriately qualified and trained in the procedures (Anderson 2007).

### **Presurgical Planning**

Presurgical planning should include input from all members of the surgical team (e.g., the surgeon, anesthetist, veterinarian, surgical technicians, animal care staff, and investigator). The surgical plan should identify personnel, their roles and training needs, and equipment and supplies required for the procedures planned (Cunliffe-Beamer 1993); the location and nature of the facilities in which the procedures will be conducted; and perioperative animal health assessment and care (Brown and Schofield 1994). A veterinarian should be involved in discussions of the selection of anesthetic agents and doses as well as the plan for perioperative analgesic use. If a nonsterile part of an animal, such as the gastrointestinal tract, is to be surgically exposed or if a procedure is likely to cause immunosuppression, preoperative antibiotics may be appropriate (Klement et al. 1987); however, the routine use of antibiotics should never be considered a replacement for proper aseptic surgical techniques.

Presurgical planning should specify the requirements for postsurgical monitoring, care, and recordkeeping, including the personnel who will perform these duties. The investigator and veterinarian share responsibility for ensuring that postsurgical care is appropriate.

### **Surgical Facilities**

Unless an exception is specifically justified as an essential component of the research protocol and approved by the IACUC, aseptic surgery should be conducted in dedicated facilities or spaces. When determining the appropriate location for a surgical procedure (either a dedicated operating room/suite or an area that provides separation from other activities), the choice may depend on the species, the nature of the procedure (major, minor, or emergency), and the potential for physical impairment or postoperative complications, such as infection. Most bacteria are carried on airborne particles or fomites, so surgical facilities should be maintained and operated in a manner that ensures cleanliness and minimizes unnecessary

traffic (AORN 2006; Bartley 1993). If it is necessary to use an operating room for other purposes, it is imperative that the room be returned to an appropriate level of hygiene before its use for major survival surgery.

Generally, agricultural animals maintained for biomedical research should undergo surgery with techniques and in facilities compatible with the guidelines set forth in this section. However, some minor and emergency procedures commonly performed in clinical veterinary practice and in commercial agricultural settings may take place under field conditions. Even when conducted in an agricultural setting, however, these procedures require the use of appropriate aseptic technique, sedatives, analgesics, anesthetics, and conditions commensurate with the risk to the animal's health and well-being.

### **Surgical Procedures**

Surgical procedures are categorized as major or minor and, in the laboratory setting, can be further divided into survival and nonsurvival. As a general guideline, major survival surgery (e.g., laparotomy, thoracotomy, joint replacement, and limb amputation) penetrates and exposes a body cavity, produces substantial impairment of physical or physiologic functions, or involves extensive tissue dissection or transection (Brown et al. 1993). Minor survival surgery does not expose a body cavity and causes little or no physical impairment; this category includes wound suturing, peripheral vessel cannulation, percutaneous biopsy, routine agricultural animal procedures such as castration, and most procedures routinely done on an "outpatient" basis in veterinary clinical practice. Animals recovering from these minor procedures typically do not show significant signs of postoperative pain, have minimal complications, and return to normal function in a relatively short time. When attempting to categorize a particular surgical procedure, the following should be considered: the potential for pain and other postoperative complications; the nature of the procedure as well as the size and location of the incision(s); the duration of the procedure; and the species, health status, and age of the animal.

Laparoscopic surgeries and some procedures associated with neuroscience research (e.g., craniotomy, neurectomy) may be classified as major or minor surgery depending on their impact on the animal (Devitt et al. 2005; Hancock et al. 2005; NRC 2003; Perret-Gentil et al. 1999, 2000). For example, laparoscopic techniques with minimal associated trauma and sequelae (e.g., avian sexing and oocyte collection) could be considered minor, whereas others (e.g., hepatic lobectomy and cholecystectomy) should be considered major. Although minor laparoscopic procedures are often performed on an "outpatient" basis, appropriate aseptic technique, instruments, anesthesia, and analgesia are necessary. Whether a laparoscopic procedure is deemed

major or minor should be evaluated on a case-by-case basis by the veterinarian and IACUC.

Emergency situations sometimes require immediate surgical attention under less than ideal conditions. For example, if an animal maintained outdoors needs surgical attention, movement to a surgical facility might be impractical or pose an unacceptable risk to the animal. Such situations often require more intensive aftercare and may pose a greater risk of postoperative complications. The appropriate course of action requires veterinary medical judgment.

In nonsurvival surgery, an animal is euthanized before recovery from anesthesia. It may not be necessary to follow all the techniques outlined in this section if nonsurvival surgery is performed but, at a minimum, the surgical site should be clipped, the surgeon should wear gloves, and the instruments and surrounding area should be clean (Slattum et al. 1991). For nonsurvival procedures of extended duration, attention to aseptic technique may be more important in order to ensure stability of the model and a successful outcome.

### **Aseptic Technique**

Aseptic technique is used to reduce microbial contamination to the lowest possible practical level (Mangram et al. 1999). No procedure, piece of equipment, or germicide alone can achieve that objective (Schonholtz 1976): aseptic technique requires the input and cooperation of everyone who enters the surgery area (Belkin 1992; McWilliams 1976). The contribution and importance of each practice varies with the procedure. Regardless of the species, aseptic technique includes preparation of the patient, such as hair or feather removal and disinfection of the operative site (Hofmann 1979); preparation of the surgeon, such as the provision of appropriate surgical attire, face masks, and sterile surgical gloves (Chamberlain and Houang 1984; Pereira et al. 1990; Schonholtz 1976); sterilization of instruments, supplies, and implanted materials (Bernal et al. 2009; Kagan 1992b); and the use of operative techniques to reduce the likelihood of infection (Ayliffe 1991; Kagan 1992a; Lovaglio and Lawson 1995; Ritter and Marmion 1987; Schofield 1994; Whyte 1988).

While the species of animal may influence the manner in which principles of aseptic technique are achieved (Brown 1994; Cunliffe-Beamer 1983; Gentry and French 1994), inadequate or improper technique may lead to subclinical infections that can cause adverse physiologic and behavioral responses (Beamer 1972; Bradfield et al. 1992; Cunliffe-Beamer 1990; Waynforth 1980, 1987) affecting surgical success, animal well-being, and research results (Cooper et al. 2000). General principles of aseptic technique should be followed for all survival surgical procedures (ACLAM 2001).

Specific sterilization methods should be selected on the basis of the physical characteristics of the materials to be sterilized (Callahan et al. 1995; Schofield 1994) and sterilization indicators should be used to validate that materials have been properly sterilized (Berg 1993). Autoclaving and plasma and gas sterilization are effective methods most commonly used to sterilize instruments and materials. Alternative methods, used primarily for rodent surgery, include liquid chemical sterilants and dry heat sterilization. Liquid chemical sterilants should be used with appropriate contact times and instruments should be rinsed with sterile water or saline before use. Bead or dry heat sterilizers are an effective and convenient means of rapidly sterilizing the working surfaces of surgical instruments but care should be taken to ensure that the instrument surfaces have cooled sufficiently before touching animal tissues to minimize the risk of burns. Alcohol is neither a sterilant nor a high-level disinfectant (Rutala 1990) but may be acceptable for some procedures if prolonged contact times are used (Huerkamp 2002).

### **Intraoperative Monitoring**

Careful monitoring and timely attention to problems increase the likelihood of a successful surgical outcome (Kuhlman 2008). Monitoring includes routine evaluation of anesthetic depth and physiologic functions and conditions, such as body temperature, cardiac and respiratory rates and pattern (Flegal et al. 2009), and blood pressure (Kuhlman 2008), and should be appropriately documented. Use of balanced anesthesia, including the addition of an intraoperative analgesic agent, can help minimize physiologic fluctuations during surgery. Maintenance of normal body temperature minimizes cardiovascular and respiratory disturbances caused by anesthetic agents (Dardai and Heavner 1987; Flegal et al. 2009; Fox et al. 2008), and is of particular importance in small animals where the high ratio of surface area to body weight may easily lead to hypothermia. Fluid replacement may be a necessary component of intraoperative therapy depending on the duration and nature of the procedure. For aquatic species (including amphibians), care should be taken to keep the skin surfaces moist and minimize drying during surgical procedures.

### **Postoperative Care**

An important component of postsurgical care is observation of the animal and intervention as necessary during recovery from anesthesia and surgery (Haskins and Eisele 1997). The intensity of monitoring will vary with the species and the procedure and may be greater during the immediate anesthetic recovery period. During this period, animals should be in a clean, dry, and comfortable area where they can be observed frequently by

trained personnel. Particular attention should be given to thermoregulation, cardiovascular and respiratory function, electrolyte and fluid balance, and management of postoperative pain or discomfort. Additional care may be warranted, including long-term administration of parenteral fluids, analgesics, and other drugs, as well as care of surgical incisions. Appropriate medical records should also be maintained.

After recovery from anesthesia, monitoring is often less intense but should include attention to basic biologic functions of intake and elimination and to behavioral signs of postoperative pain, monitoring for postsurgical infections, monitoring of the surgical incision site for dehiscence, bandaging as appropriate, and timely removal of skin sutures, clips, or staples (UFAW 1989).

### PAIN AND DISTRESS

An integral component of veterinary medical care is prevention or alleviation of pain associated with procedural and surgical protocols. Pain is a complex experience that typically results from stimuli that damage or have the potential to damage tissue; such stimuli prompt withdrawal and evasive action. The ability to experience and respond to pain is widespread in the animal kingdom and extends beyond vertebrates (Sherwin 2001).

Pain is a stressor and, if not relieved, can lead to unacceptable levels of stress and distress in animals. Furthermore, unrelieved pain may lead to “wind-up,” a phenomenon in which central pain sensitization results in a pain response to otherwise nonpainful stimuli (allodynia; Joshi and Ogunnaike 2005). For these reasons, the proper use of anesthetics and analgesics in research animals is an ethical and scientific imperative. *Recognition and Alleviation of Pain in Laboratory Animals* (NRC 2009a) is an excellent source of information about the basis and control of distress and pain (see also Appendix A, Anesthesia, Pain, and Surgery).

Fundamental to the relief of pain in animals is the ability to recognize its clinical signs in specific species (Bateson 1991; Carstens and Moberg 2000; Hawkins 2002; Holton et al. 1998; Hughes and Lang 1983; Karas et al. 2008; Martini et al. 2000; Roughan and Flecknell 2000, 2003, 2004; Sneddon 2006). Species vary in their response to pain (Baumans et al. 1994; Kohn et al. 2007; Morton et al. 2005; Viñuela-Fernández et al. 2007), and criteria for assessing pain in various species differ. The U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (see Appendix B) state that in general, unless the contrary is known or established, it should be considered that procedures that cause pain in humans may also cause pain in other animals (IRAC 1985).

Certain species-specific behavioral manifestations are used as indicators of pain or distress—for example, vocalization (dogs), depression

(all), anorexia (all), rapid or labored respiration (rodents, birds, fish), lack of grooming (mammals and birds), increased aggression (mammals and birds), periocular and nasal porphyrin discharge (rodents), abnormal appearance or posture (all), and immobility (all) (NRC 2008, 2009a). However, some species may mask signs of pain until they are quite severe (NRC 2009a). It is therefore essential that personnel caring for and using animals be trained in species-specific and individual clinical, behavioral, physiologic, and biochemical indicators of well-being (Dubner 1987; Karas 2002; Murrell and Johnson 2006; Rose 2002; Stoskopf 1994; Valverde and Gunkel 2005).

Distress may be defined as an aversive state in which an animal fails to cope or adjust to various stressors with which it is presented. But distress may not induce an immediate and observable pathologic or behavioral alteration, making it difficult to monitor and evaluate the animal's state when it is present. Both the duration and intensity of the state are important considerations when trying to prioritize attention to and treatment of animal distress. For example, an injection requiring brief immobilization may produce acute stress lasting only seconds, while long-term individual housing of a social species in a metabolic cage may produce chronic distress. Implementation of clear, appropriate, and humane experimental endpoints for animals, combined with close observation during invasive periods of experimentation, will assist in minimizing distress experienced by animals used in research, teaching, testing, and production. *Recognition and Alleviation of Distress in Laboratory Animals* (NRC 2008) is a resource with important information about distress in experimental animals.

## ANESTHESIA AND ANALGESIA

The selection of appropriate analgesics and anesthetics should reflect professional veterinary judgment as to which best meets clinical and humane requirements as well as the needs of the research protocol. The selection depends on many factors, such as the species, age, and strain or stock of the animal, the type and degree of pain, the likely effects of particular agents on specific organ systems, the nature and length of the surgical or pain-inducing procedure, and the safety of the agent, particularly if a physiologic deficit is induced by a surgical or other experimental procedure (Kona-Boun et al. 2005).

Preemptive analgesia (the administration of preoperative and intraoperative analgesia) enhances intraoperative patient stability and optimizes postoperative care and well-being by reducing postoperative pain (Coderre et al. 1993; Hedenqvist et al. 2000). Analgesia may be achieved through timely enteral or parenteral administration of analgesic agents as well as by blocking nociceptive signaling via local anesthetics (e.g., bupivacaine).



Alleviation of chronic pain may be more challenging than postprocedural pain; commercially available opiate slow-release transdermal patches or implantable analgesic-containing osmotic minipumps may be useful for such relief. Because of wide individual variation in response to analgesics, regardless of the initial plan for pain relief, animals should be closely monitored during and after painful procedures and should receive additional drugs, as needed, to ensure appropriate analgesic management (Karas et al. 2008; Paul-Murphy et al. 2004). Nonpharmacologic control of pain may be effective and should not be overlooked as an element of postprocedural or perioperative care for research animals (NRC 2009a; Spinelli 1990). Appropriate nursing support may include a quiet, darkened recovery or resting place, timely wound or bandage maintenance, increased ambient warmth and a soft resting surface, rehydration with oral or parenteral fluids, and a return to normal feeding through the use of highly palatable foods or treats.

Most anesthetics cause a dose-dependent depression of physiologic homeostasis and the changes can vary considerably with different agents. The level of consciousness, degree of antinociception (lack of response to noxious stimuli), and status of the cardiovascular, respiratory, musculoskeletal, and thermoregulatory systems should all be used to assess the adequacy of the anesthetic regimen. Interpretation and appropriate response to the various parameters measured require training and experience with the anesthetic regimen and the species. Loss of consciousness occurs at a light plane of anesthesia, before antinociception, and is sufficient for purposes of restraint or minor, less invasive procedures, but painful stimuli can induce a return to consciousness. Antinociception occurs at a surgical plane of anesthesia and must be ascertained before surgery. Individual animal responses vary widely and a single physiologic or nociceptive reflex response may not be adequate for assessing the surgical plane or level of analgesia (Mason and Brown 1997).

For anesthesia delivery, precision vaporizers and monitoring equipment (e.g., pulse oximeter for determining arterial blood oxygen saturation levels) increase the safety and choices of anesthetic agents for use in rodents and other small species. For injectable anesthetic protocols, specific reversal agents can minimize the incidence of some side effects related to prolonged recovery and recumbency. Guidelines for the selection and proper use of analgesic and anesthetic drugs should be developed and periodically reviewed and updated as standards and techniques are refined. Agents that provide anesthesia and analgesia must be used before their expiration dates and should be acquired, stored, their use recorded, and disposed of legally and safely.

Some classes of drugs such as sedatives, anxiolytics, and neuromuscular blocking agents may not provide analgesia but may be useful when

used in combination with appropriate analgesics and anesthetics to provide balanced anesthesia and to minimize stress associated with perioperative procedures. Neuromuscular blocking agents (e.g., pancuronium) are sometimes used to paralyze skeletal muscles during surgery in which general anesthetics have been administered (Klein 1987); because this paralysis eliminates many signs and reflexes used to assess anesthetic depth, autonomic nervous system changes (e.g., sudden changes in heart rate and blood pressure) can be indicators of pain related to an inadequate depth of anesthesia. It is imperative that any proposed use of neuromuscular blocking drugs be carefully evaluated by the veterinarian and IACUC to ensure the well-being of the animal. Acute stress is believed to be a consequence of paralysis in a conscious state and it is known that humans, if conscious, can experience distress when paralyzed with these drugs (NRC 2008; Van Sluyters and Oberdorfer 1991). If paralyzing agents are to be used, the appropriate amount of anesthetic should first be defined on the basis of results of a similar procedure using the anesthetic without a blocking agent (NRC 2003, 2008, 2009a).

## EUTHANASIA

*Euthanasia* is the act of humanely killing animals by methods that induce rapid unconsciousness and death without pain or distress. Unless a deviation is justified for scientific or medical reasons, methods should be consistent with the *AVMA Guidelines on Euthanasia* (AVMA 2007 or later editions). In evaluating the appropriateness of methods, some of the criteria that should be considered are ability to induce loss of consciousness and death with no or only momentary pain, distress, or anxiety; reliability; irreversibility; time required to induce unconsciousness; appropriateness for the species and age of the animal; compatibility with research objectives; and the safety of and emotional effect on personnel.

Euthanasia may be planned and necessary at the end of a protocol or as a means to relieve pain or distress that cannot be alleviated by analgesics, sedatives, or other treatments. Criteria for euthanasia include protocol-specific endpoints (such as degree of a physical or behavioral deficit or tumor size) that will enable a prompt decision by the veterinarian and the investigator to ensure that the endpoint is humane and, whenever possible, the scientific objective of the protocol is achieved (see Chapter 2).

Standardized methods of euthanasia that are predictable and controllable should be developed and approved by the AV and IACUC. Euthanasia should be carried out in a manner that avoids animal distress. Automated systems for controlled and staged delivery of inhalants may offer advantages for species killed frequently or in large numbers, such as rodents (McIntyre et al. 2007). Special consideration should be given to euthanasia of fetuses

and larval life forms depending on species and gestational age (Artwohl et al. 2006).

The selection of specific agents and methods for euthanasia will depend on the species involved, the animal's age, and the objectives of the protocol. Generally, chemical agents (e.g., barbiturates, nonexplosive inhalant anesthetics) are preferable to physical methods (e.g., cervical dislocation, decapitation, use of a penetrating captive bolt); however, scientific considerations may preclude the use of chemical agents for some protocols.

Although carbon dioxide (CO<sub>2</sub>) is a commonly used method for rodent euthanasia, there is ongoing controversy about its aversive characteristics as an inhalant euthanasia agent. This is an area of active research (Conlee et al. 2005; Danneman et al. 1997; Hackbarth et al. 2000; Kirkden et al. 2008; Leach et al. 2002; Niel et al. 2008) and further study is needed to optimize the methods for CO<sub>2</sub> euthanasia in rodents (Hawkins et al. 2006). The acceptability of CO<sub>2</sub> as a euthanasia agent for small rodents should be evaluated as new data become available. Furthermore, because neonatal rodents are resistant to the hypoxia-inducing effects of CO<sub>2</sub> and require longer exposure times to the agent (Artwohl et al. 2006), alternative methods should be considered (e.g., injection with chemical agents, cervical dislocation, or decapitation; Klaunberg et al. 2004; Pritchett-Corning 2009).

It is essential that euthanasia be performed by personnel skilled in methods for the species in question and in a professional and compassionate manner. Special attention is required to ensure proficiency when a physical method of euthanasia is used. Death must be confirmed by personnel trained to recognize cessation of vital signs in the species being euthanized. A secondary method of euthanasia (e.g., thoracotomy or exsanguination) can be also used to ensure death. All methods of euthanasia should be reviewed and approved by the veterinarian and IACUC.

Euthanizing animals is psychologically difficult for some animal care, veterinary, and research personnel, particularly if they perform euthanasia repetitively or are emotionally attached to the animals being euthanized (Arluke 1990; NRC 2008; Rollin 1986; Wolfle 1985). When delegating euthanasia responsibilities, supervisors should be sensitive to this issue.

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## Physical Plant

### GENERAL CONSIDERATIONS

A well-planned, well-designed, well-constructed, properly maintained and managed facility is an important element of humane animal care and use as it facilitates efficient, economical, and safe operation (see Appendix A, Design and Construction of Animal Facilities). The design and size of an animal facility depend on the scope of institutional research activities, the animals to be housed, the physical relationship to the rest of the institution, and the geographic location.

Effective planning and design should include input from personnel experienced with animal facility design, engineering, and operation, as well as from representative users of the proposed facility. Computational fluid dynamics (CFD), building information modeling, and literature on postoccupancy analysis of space use may provide benefits when designing facilities and caging (Eastman et al. 2008; Reynolds 2008; Ross et al. 2009). An animal facility should be designed and constructed in accord with all applicable building codes; in areas with substantial seismic activity the building planning and design should incorporate the recommendations of the Building Seismic Safety Council (BSSC 2001; Vogelweid et al. 2005). Because animal model development and use can be expected to change during the life cycle of an animal facility, facilities should be designed to accommodate changes in use. Modular units (such as custom-designed trailers or prefabricated structures) should comply with construction guidelines described in this chapter.

Building materials for animal facilities should be selected to facilitate efficient and hygienic operation. Durable, moisture- and vermin-proof, fire-resistant, seamless materials are most desirable for interior surfaces, which should be highly resistant to the effects of cleaning agents, scrubbing, high-pressure sprays, and impact. Paints and glazes should be nontoxic if used on surfaces with which animals will have direct contact. In the construction of outdoor facilities, consideration should be given to surfaces that withstand the elements and can be easily maintained.

### **Location**

Quality animal management and human comfort and health protection require separation of animal facilities from personnel areas, such as offices and conference rooms. Separation can be accomplished by having the animal quarters in a separate building, wing, floor, or room. Careful planning should make it possible to place animal housing areas next to or near research laboratories but separated from them by barriers, such as entry locks, corridors, or floors. Additional considerations include the impact of noise and vibration generated from within the facility and from surrounding areas of the building, as well as security of the facility.

Animals should be housed in facilities dedicated to or assigned for that purpose, not in laboratories merely for convenience. If animals must be maintained in a laboratory to satisfy the scientific aims of a protocol, that space should be appropriate to house and care for the animals and its use limited to the period during which it is required. If needed, measures should be taken to minimize occupational hazards related to exposure to animals both in the research area and during transport to and from the area.

### **Centralization Versus Decentralization**

In a physically centralized animal facility, support, care, and use areas are adjacent to the animal housing space. Decentralized animal housing and use occur in space that is not solely dedicated to animal care or support or is physically separated from the support areas and animal care personnel. Centralization often reduces operating costs, providing a more efficient flow of animal care supplies, equipment, and personnel; more efficient use of environmental controls; and less duplication of support services. Centralization reduces the needs for transporting animals between housing and study sites, thereby minimizing the risks of transport stress and exposure to disease agents; affords greater security by providing the opportunity to control facility access; and increases the ease of monitoring staff and animals.

Decentralized animal facilities generally cost more to construct because of the requirement for specialized environmental systems and

controls in multiple sites. Duplicate equipment (e.g., cage washers) may be needed, or soiled materials may need to be moved distances for processing. But decentralization may be preferred for certain specialized research services such as imaging, quarantine, and proximity to research facilities, or for biosecurity reasons. Decentralization may be necessary to accommodate large or complex equipment, such as magnetic resonance imaging, or to permit space sharing by users from multiple facilities or institutions. The opportunity for exposure to disease agents is much greater in these situations and special consideration should be given to biosecurity, including transportation to and from the site, quarantine before or after use of the specialized research area, and environmental and equipment decontamination.

The decisions leading to selection of physically centralized versus decentralized animal facilities should be made early and carefully and should involve all stakeholders (NRC 1996; Ruys 1991).

### FUNCTIONAL AREAS

Professional judgment should be exercised in the development of a practical, functional, and efficient physical plant for animal care and use. The size, nature, and intensity of an institutional Program (see Chapter 2) will determine the specific facility and support functions needed. In facilities that are small, maintain few animals, or maintain animals under special conditions—such as facilities used exclusively for housing gnotobiotic or specific pathogen-free (SPF) colonies or animals in runs, pens, or outdoor housing—some functional areas listed below may be unnecessary or may be included in a multipurpose area.

Space is required for the following:

- animal housing, care, and sanitation
- receipt, quarantine, separation, and/or rederivation of animals
- separation of species or isolation of individual projects when necessary
- storage.

Most multipurpose animal facilities may also include the following:

- specialized laboratories or space contiguous with or near animal housing areas for such activities as surgery, intensive care, necropsy, irradiation, preparation of special diets, experimental procedures, behavioral testing, imaging, clinical treatment, and diagnostic laboratory procedures

- containment facilities or equipment, if hazardous biologic, physical, or chemical agents are to be used
- barrier facilities for housing of SPF rodents, especially valuable genetically modified animals, or irreplaceable animal models
- receiving and storage areas for food, bedding, pharmaceuticals, biologics, and supplies
- space for washing and sterilizing equipment and supplies and, depending on the volume of work, machines for washing cages, bottles, glassware, racks, and waste cans; a utility sink; a sterilizer for equipment, food, and bedding; and separate areas for holding soiled and clean equipment
- space for storing wastes before incineration or removal
- space for cold storage or disposal of carcasses
- space for administrative and supervisory personnel, including space for staff training and education
- showers, sinks, lockers, toilets, and break areas for personnel
- security features, such as card-key systems, electronic surveillance, and alarms
- areas for maintenance and repair of specialized animal housing systems and equipment.

## CONSTRUCTION GUIDELINES

### Corridors

Corridors should be wide enough to facilitate the movement of personnel and equipment; a width of 6 to 8 feet can accommodate the needs of most facilities. Floor-wall junctions should be designed to facilitate cleaning. Protective rails or bumpers are recommended and, if provided, should be sealed or manufactured to prevent vermin access. In corridors leading to dog or swine housing facilities, cage-washing facilities, and other high-noise areas, double-door entry vestibules or other noise traps should be considered. Similar entries are advisable for areas leading to nonhuman primate housing as a means to reduce the potential for escape. Double-door entry vestibules also permit air locks in these and other areas where directional airflow is critical for containment or protection. Wherever possible, water lines, drainpipes, reheat coils and valves, electric service connections, and other utilities should be accessible via interstitial space or through access panels or chases in corridors outside the animal rooms. Fire alarms, fire extinguishers, and telephones should be recessed, installed high enough, or shielded by protective guards to prevent damage from the movement of large equipment.

### **Animal Room Doors**

Doors should be large enough (approximately 42 × 84 in.) to allow the easy passage of racks and equipment and they should fit tightly in their frames. Both doors and frames should be appropriately sealed to prevent vermin entry or harborage. Doors should be constructed of and, where appropriate, coated with materials that resist corrosion. Self-closing doors equipped with recessed or shielded handles, sweeps, and kickplates and other protective hardware are usually preferable. Hospital or terminated stops are useful to aid in cleaning (Harris 2005). For safety, doors should open into animal rooms; if it is necessary that they open toward a corridor, there should be a recessed vestibule.

Where room-level security is necessary or it is desirable to limit access (as with the use of hazardous agents), room doors should be equipped with locks or electronic security devices. For personnel safety, doors should be designed to open from the inside without a key.

Doors with viewing windows may be needed for safety and other reasons, but the ability to cover these windows may be considered if exposure to light or hallway activities would be undesirable (e.g., to avoid disturbing the animals' circadian rhythm). Red-tinted windows, which do not transmit specific wavelengths of visible light between corridors and animal rooms, have proved useful for mouse and rat holding rooms as both species have a limited ability to detect light in the red portions of the spectrum (Jacobs et al. 2001; Lyubarsky et al. 1999; Sun et al. 1997).

### **Exterior Windows**

The presence of windows in an animal facility, particularly in animal rooms, creates a potential security risk and should generally be avoided. Windows also create problems with temperature control of the area and prevent strict control of the photoperiod, which is often required in animal-related protocols (and is a critical consideration in rodent breeding colonies). However, in specific situations, windows can provide environmental enrichment for some species, such as nonhuman primates.

### **Floors**

Floors should be moisture resistant, nonabsorbent, impact resistant, and relatively smooth, although textured surfaces may be required in some high-moisture areas and for some species (e.g., farm animals). Floors should be easy to repair and resistant to both the action of urine and other biologic materials and the adverse effects of hot water and cleaning agents. They should be capable of supporting racks, equipment, and stored items without



becoming gouged, cracked, or pitted. Depending on their use, floors should be monolithic or have a minimal number of joints. Some materials that have proved satisfactory are epoxy resins, hard-surface sealed concrete, methyl methacrylate, polyurethane, and special hardened rubber-base aggregates. The latter are useful in areas where noise reduction is important. Correct installation is essential to ensure the long-term stability of the surface. If sills are installed at the entrance to a room, they should be designed to allow for convenient passage of equipment.

### **Drainage**

Where floor drains are used, the floors should be sloped and drain traps kept filled with liquid. To minimize prolonged increases in humidity, drainage should allow rapid removal of water and drying of surfaces (Gorton and Besch 1974). Drainpipes should be at least 4 in. (10.2 cm) in diameter, although in some areas, such as dog kennels and agricultural animal facilities, larger drainpipes ( $\geq 6$  in.) are recommended. A rim- and/or trap-flushing drain or an in-line comminutor may be useful for the disposal of solid waste. When drains are not in use for long periods, they should be capped and sealed to prevent backflow of sewer gases, vermin, and other contaminants; lockable drain covers may be advisable for this purpose in some circumstances.

Floor drains are not essential in all animal rooms, particularly those housing rodents. Floors in such rooms can be sanitized satisfactorily by wet vacuuming or mopping with appropriate cleaning compounds or disinfectants. But the installation of floor drains that are capped when not in use may provide flexibility for future housing of nonrodent species.

### **Walls and Ceilings**

Walls and ceilings should be smooth, moisture resistant, nonabsorbent, and resistant to damage from impact. They should be free of cracks, unsealed utility penetrations, and imperfect junctions with doors, ceilings, floors, walls, and corners. Surface materials should be capable of withstanding cleaning with detergents and disinfectants and the impact of water under high pressure. The use of curbs, guardrails or bumpers, and corner guards should be considered to protect walls and corners from damage, and such items should be solid or sealed to prevent access and harborage of vermin.

Ceilings formed by the concrete slab above are satisfactory if they are smooth and sealed or painted. Suspended ceilings are generally undesirable in animal holding rooms unless they are sealed from the space above with gaskets and clips. When used, they should be fabricated of impervi-

ous materials, have a washable surface, and be free of imperfect junctions. Exposed plumbing, ductwork, and light fixtures are undesirable unless the surfaces can be readily cleaned.

### **Heating, Ventilation, and Air Conditioning (HVAC)**

A properly designed and functioning HVAC system is essential to provide environmental and space pressurization control. Temperature and humidity control minimizes variations due either to changing climatic conditions or to differences in the number and kind of animals and equipment in an animal holding space (e.g., a room or cubicle). Pressurization assists in controlling airborne contamination and odors by providing directional airflow between spaces. Areas for quarantine, housing and use of animals exposed to hazardous materials, and housing of nonhuman primates should be kept under relative negative pressure, whereas areas for surgery or clean equipment storage should be kept under relative positive pressure with clean air.

HVAC systems should be designed for reliability (including redundancy where applicable), ease of maintenance, and energy conservation; able to meet requirements for animals as discussed in Chapter 3; and flexible and adaptable to the changing types and numbers of animals and equipment maintained during the life of the facility (ASHRAE 2007a). They should be capable of adjustments in and ideally maintain dry-bulb temperatures of  $\pm 1^{\circ}\text{C}$  ( $\pm 2^{\circ}\text{F}$ ). Relative humidity should generally be maintained within a range of 30-70% throughout the year. Although maintenance of humidification within a limited range over extended periods is extremely difficult, daily fluctuations (recognizing the effects of routine husbandry especially when caring for large animal species) in relative humidity should be minimized; if excursions outside the desired range are infrequent, minimal, and of short duration, they are unlikely to negatively affect animal well-being. Ideally relative humidity should be maintained within  $\pm 10\%$  of set point; however, this may not be achievable under some circumstances.

Constant-volume systems have been most commonly used in animal facilities, but variable-volume (VAV) systems may offer design and operational advantages, such as allowing ventilation rates to be set in accordance with heat load and other variables. These systems offer considerable advantages with respect to flexibility and energy conservation (see Chapter 3).

Previously specified temperature and humidity ranges can be modified to meet special animal needs in circumstances in which all or most of the animal facility is designed exclusively for acclimated species with similar requirements (e.g., when animals are held in a sheltered or outdoor facility). In addition, modifications may need to take into account the microenvironment in some primary enclosures, such as rodent isolator cages, where humidity and temperature may exceed room levels.

Temperature is best regulated by having thermostatic control for each holding space. Use of zonal control for multiple spaces can result in temperature variations between spaces in the zone because of differences in animal densities and heat gain or loss in ventilation ducts and other surfaces within the zone. Individual space control is generally accomplished by providing each space with a dedicated reheat coil. Valves controlling reheat coils should fail in the closed position; steam coils should be avoided or equipped with a high-temperature cut-off system to prevent space overheating and animal loss with valve failure.

Humidification is typically controlled and supplemented on a system or zone basis. Control of humidification in individual holding spaces may be desirable for selected species with reduced tolerance for low relative (e.g., nonhuman primates) or high humidity (e.g., rabbits).

Most HVAC systems are designed for average high and low temperatures and humidities experienced in a geographic area within  $\pm 5\%$  variation (ASHRAE 2009). Moderate fluctuations in temperature and relative humidity outside suggested ranges are generally well tolerated by most species commonly used in research as long as they are brief and infrequent; holding spaces should be designed to minimize drafts and temperature gradients. Consideration should be given to measures that minimize fluctuations in temperature and relative humidity outside the recommended ranges due to extremes in the external ambient environment. Such measures can include partial redundancy, partial air recirculation, altered ventilation rates, or the use of auxiliary equipment. In the event of an HVAC system or component failure, systems should at the minimum supply facility needs at a reduced level, address the adverse effects of loss of temperature control, and, where necessary, maintain critical pressurization gradients. It is essential that life-threatening heat accumulation or loss be prevented during mechanical failure. Temporary needs for ventilation of sheltered or outdoor facilities can usually be met with auxiliary equipment.

Air handling system intake locations should avoid entrainment of fumes from vehicles, equipment, and system exhaust. While 100% outside air is typically provided, when recirculated air is used its quality and quantity should be in accord with recommendations in Chapter 3. The type and efficiency of supply and exhaust air treatment should be matched to the quantity and types of contaminants and to the risks they pose. Supply air is usually filtered with 85–95% dust spot efficient filters (ASHRAE 2008). In certain instances, higher efficiency filters (e.g., HEPA) may be beneficial for recirculated supply air and air supplied to or exhausted from specialized areas such as surgical and containment facilities (Kowalski et al. 2002).

### **Power and Lighting**

The electrical system should be safe and provide appropriate lighting, a sufficient number of power outlets, and suitable amperage for specialized equipment. In the event of power failure, an alternative or emergency power supply should be available to maintain critical services (e.g., the HVAC system, ventilated caging systems [Huerkamp et al. 2003], or life support systems for aquatic species) or support functions (e.g., freezers and isolators) in animal rooms, operating suites, and other essential areas. Consideration should be given to outfitting movable equipment for which uninterrupted power is essential (e.g., ventilated racks), with twist-lock plugs to prevent accidental removal from the power supply.

Light fixtures, timers, switches, and outlets should be properly sealed to prevent vermin access. Recessed energy-efficient fluorescent lights are commonly used in animal facilities. Spectral quality of lights may be important for some species when maintained in the laboratory; in these cases full spectrum lamps may be appropriate. A time-controlled lighting system should be used to ensure a uniform diurnal lighting cycle. Override systems should be equipped with an automatic timeout or a warning light to indicate the system is in override mode, and system performance and override functions should be regularly evaluated to ensure proper cycling. Dual-level lighting may be considered when housing species that are sensitive to high light intensity, such as albino rodents; low-intensity lighting is provided during the light phase of the diurnal cycle, and higher-intensity lighting is provided as needed (e.g., when personnel require enhanced visibility). Light bulbs or fixtures should be equipped with protective covers to ensure the safety of the animals and personnel. Moisture-resistant switches and outlets and ground-fault interrupters should be used in areas with high water use, such as cage-washing areas and aquarium-maintenance areas.

### **Storage Areas**

Adequate space should be available for storage of equipment, supplies, food, bedding, and refuse. Corridors are not appropriate storage areas. Storage space can be decreased when delivery of materials and supplies is reliable and frequent; however, it should be ample enough to accommodate storage of essential commodities to ensure the animals' uninterrupted husbandry and care (e.g., if delivery is delayed). Bedding and food should be stored in a separate area free from vermin and protected from the risk of contamination from toxic or hazardous substances. Areas used for food storage should not be subject to elevated temperatures or relative humidity for prolonged periods. Refuse storage areas should be separated from other

storage areas. Refrigerated storage, separated from other cold storage, is essential for storage of dead animals and animal tissue waste; this storage area should be kept below 7°C (44.6°F) to reduce putrefaction of wastes and animal carcasses and should be constructed in a manner that facilitates cleaning.

### **Noise Control**

Noise control is an important consideration in an animal facility and should be addressed during the planning stages of new facility design or renovation (see Chapter 3). Noise-producing support functions, such as cage washing, are commonly separated from housing and experimental functions. Masonry walls, due to their density, generally have excellent sound-attenuating properties, but similar sound attenuation can be achieved using many different materials and partition designs. For example, sanitizable sound-attenuating materials bonded to walls or ceilings may be appropriate for noise control in some situations, whereas acoustic materials applied directly to the ceiling or as part of a suspended ceiling in an animal room present problems for sanitation and vermin control and are not recommended. Experience has shown that well-constructed corridor doors, sound-attenuating doors, or double-door entry vestibules can help to control the transmission of sound along corridors. An excellent resource on partition design for sound control is available in *Noise Control in Buildings: A Practical Guide for Architects and Engineers* (Warnock and Quirt 1994).

Attention should be paid to attenuating noise generated by equipment (ASHRAE 2007b). Fire and environmental-monitoring alarm systems and public address systems should be selected and positioned to minimize potential animal disturbance. The location of equipment capable of generating sound at ultrasonic frequencies is important as some species can hear such high frequencies. Selecting equipment for rodent facilities that does not generate noise in the ultrasonic range should be considered.

### **Vibration Control**

Vibration may arise from mechanical equipment, electrical switches, and other building components, or from remote sources (via groundborne transmission). Regarding the latter, special consideration should be given to the building structure type especially if the animal facility will be located over, under, or adjacent to subways, trains, or automobile and truck traffic. Like noise, different species can detect and be affected by vibrations of different frequencies and wavelengths, so attempts should be made to identify all vibration sources and isolate or dampen them with vibration suppression systems (ASHRAE 2007b).

### **Facilities for Sanitizing Materials**

A dedicated central area for sanitizing cages and ancillary equipment should be provided. Mechanical cage-washing equipment is generally needed and should be selected to match the types of caging and equipment used. Consideration should be given to such factors as the following:

- location with respect to animal rooms and waste disposal and storage areas
- ease of access, including doors of sufficient width to facilitate movement of equipment
- sufficient space for staging and maneuvering of equipment
- soiled waste disposal and prewashing activities
- ease of cleaning and disinfection of the area
- traffic flow that separates animals and equipment moving between clean and soiled areas
- air pressurization between partitioned spaces to reduce the potential of cross contamination between soiled and clean equipment
- insulation of walls and ceilings where necessary
- sound attenuation
- utilities, such as hot and cold water, steam, floor drains, and electric power
- ventilation, including installation of vents or canopies and provisions for dissipation of steam and fumes from sanitizing processes
- vibration, especially if animals are housed directly above, below, or adjacent to the washing facility
- personnel safety, by ensuring that safety showers, eyewash stations, and other equipment are provided as required by code; exposed hot water and steam lines are properly insulated; procedures with a propensity to generate aerosols are appropriately contained; and equipment, such as cage/rack washers, and bulk sterilizers, which personnel enter, are equipped with functioning safety devices that prevent staff from becoming trapped inside.

### **Environmental Monitoring**

Monitoring of environmental conditions in animal holding spaces and other environmentally sensitive areas in the facility should be considered. Automated monitoring systems, which notify personnel of excursions in environmental conditions, including temperature and photoperiod, are advisable to prevent animal loss or physiologic changes as a result of system malfunction. The function and accuracy of such systems should be regularly verified.

## SPECIAL FACILITIES

### Surgery

The design of a surgical facility should accommodate the species to be operated on and the complexity of the procedures to be performed (Hessler 1991; see also Appendix A, Design and Construction of Animal Facilities). The facility, including that used for rodents, by necessity becomes larger and more complex as the number and size of animals or the complexity of procedures increase. For instance, a larger facility may be required to accommodate procedures on agricultural species, large surgical teams, imaging devices, robotic surgical systems, and/or laparoscopic equipment towers. Surgical facilities for agricultural species may additionally require floor drains, special restraint devices, and hydraulic operating tables.

For most survival surgery performed on rodents and other small species such as aquatics and birds, an animal procedure laboratory is recommended; the space should be dedicated to surgery and related activities when used for this purpose, and managed to minimize contamination from other activities conducted in the room at other times. The association of surgical facilities with diagnostic laboratories, imaging facilities, animal housing, staff offices, and so on should be considered in the overall context of the complexity of the surgical program. Centralized surgical facilities are cost-effective in equipment, conservation of space and personnel resources, and reduced transit of animals. They also enable enhanced personnel safety and professional oversight of both facilities and procedures.

For most surgical programs, functional components of aseptic surgery include surgical support, animal preparation, surgeon's scrub, operating room, and postoperative recovery. The areas that support those functions should be designed to minimize traffic flow and separate the related non-surgical activities from the surgical procedure in the operating room. The separation is best achieved by physical barriers (AORN 1993) but may also be achieved by distance between areas or by the timing of appropriate cleaning and disinfection between activities.

Surgical facilities should be sufficiently separate from other areas to minimize unnecessary traffic and decrease the potential for contamination (Humphreys 1993). The number of personnel and their level of activity have been shown to be directly related to the level of bacterial contamination and the incidence of postoperative wound infection (Fitzgerald 1979). Traffic in the operating room can be reduced by the installation of an observation window, a communication system (such as an intercom system), and judicious location of doors.

Control of contamination and ease of cleaning should be key considerations in the design of a surgical facility. The interior surfaces should be

constructed of materials that are monolithic and impervious to moisture. Ventilation systems supplying filtered air at positive pressure can reduce the risk of postoperative infection (Ayscue 1986; Bartley 1993; Schonholtz 1976). Careful location of air supply and exhaust ducts and appropriate room ventilation rates are also recommended to minimize contamination (Ayliffe 1991; Bartley 1993; Holton and Ridgway 1993; Humphreys 1993). To facilitate cleaning, the operating rooms should have as little fixed equipment as possible (Schonholtz 1976; UFAW 1989). Other operating room features to consider include surgical lights to provide adequate illumination (Ayscue 1986); sufficient electric outlets for support equipment; gases to support anesthesia, surgical procedures, and gas-powered equipment; vacuum; and gas-scavenging capability.

The surgical support area should be designed for washing and sterilizing instruments and for storing instruments and supplies. Autoclaves are commonly placed in this area. It is often desirable to have a large sink in the animal preparation area to facilitate cleaning of the animal and the operating facilities. A dressing area should be available for personnel to change into surgical attire; a multipurpose locker room can serve this function. There should be a scrub area for surgeons, equipped with foot, knee, or electric-eye surgical sinks (Knecht et al. 1981). To minimize the potential for contamination of the surgical site by aerosols generated during scrubbing, the scrub area should usually be outside the operating room and animal preparation area.

A postoperative recovery area should provide the physical environment to support the needs of the animal during the period of anesthetic and immediate postsurgical recovery and should be sited to allow adequate observation of the animal during this period. The electric and mechanical requirements of monitoring and support equipment should be considered. The type of caging and support equipment will depend on the species and types of procedures but should be designed to be easily cleaned and to support physiologic functions, such as thermoregulation and respiration. Depending on the circumstances, a postoperative recovery area for farm animals may be modified or nonexistent in some field situations, but precautions should be taken to minimize risk of injury to recovering animals.

### **Barrier Facilities**

Barrier facilities are designed and constructed to exclude the introduction of adventitious infectious agents from areas where animals of a defined health status are housed and used. They may be a portion of a larger facility or a free-standing unit. While once used primarily for rodent production facilities and to maintain immunodeficient rodents, many newer facilities incorporate barrier features for housing specific pathogen-free (SPF) mice



and rats, especially valuable genetically engineered animals, and SPF animals of other species.

Barrier facilities typically incorporate airlock or special entries (e.g., air or wet showers) for staff and supplies. Staff generally wear dedicated clothing and footwear, or freshly laundered, sterile, or disposable outer garments such as gowns, head and shoe covers, gloves, and sometimes face masks prior to entry. Consumables, such as feed or bedding, that may harbor infectious agents are autoclaved or are gamma-irradiated by the supplier and surface decontaminated on entry. Drinking water may be autoclaved or subject to specialized treatment (e.g., reverse osmosis filtration) to remove infectious agents. Caging and other materials with which the animals have direct contact may be sterilized after washing before reuse. Strict operational procedures are frequently established to preclude intermingling of clean and soiled supplies and personnel groups, depending on work function. Only animals of defined health status are received into the barrier, and once they leave they are prohibited from reentering without retesting. Personnel entry is restricted and those with access are appropriately trained in procedures that minimize the introduction of contaminants.

Engineering features may include high-level filtration of supply air (e.g., HEPA or 95% efficient filters), pressurization of the barrier with respect to surrounding areas, and directional airflow from clean to potentially contaminated areas. Specialized equipment augmenting the barrier may include isolator cages, individually ventilated cages, and animal changing stations.

Detailed information on barrier design, construction, and operations has been recently published (Hessler 2008; Lipman 2006, 2008).

## Imaging

In vivo imaging offers noninvasive methods for evaluating structure and function at the level of the whole animal, tissue, or cell, and allows for the sequential study of temporal events (Chatham and Blackband 2001; Cherry and Gambhir 2001). Imaging devices vary in the technology used to generate an image, body targets imaged, resolution, hazard exposure, and requirements for use. The devices may be self-shielded and require no modifications of the surrounding structure to operate safely, or they may require concrete, solid core masonry, lead-, steel-, or copper-lined walls, or other construction features to operate safely or minimize interference with devices and activities in adjacent areas. Because imaging devices are often expensive to acquire and maintain, and may require specialized support space and highly trained personnel to operate, shared animal imaging resources may be preferable.

Consideration should be given to the location of the imaging resource. Whether located in the animal facility or in a separate location, cross

contamination between groups of animals, different animal species, or between animals and humans (if the device is used for both animal and human subjects) is possible because these devices may be difficult to sanitize (Klaunberg and Davis 2008; Lipman 2006). If the imaging resource is located outside the animal facility, appropriate transportation methods and routes should be developed to avoid inappropriate exposure of humans to animals in transit. If possible, animals should not be moved past offices, lunch rooms, or public areas where people are likely to be present.

As imaging may require the subject to be immobile, often for extended time periods during image acquisition, provisions should be made for delivery of anesthetics and carrier gas, the scavenging of waste anesthetic gas, and adequate animal monitoring (Balaban and Hampshire 2001). Remote storage of gas tanks is generally required in facilities where magnetic resonance (MR) scanners are used as the magnetic field requires ferrous materials to be kept a safe distance away from the magnet. Site selection of MR scanners requires special attention because of their weight, the fringe field generated (especially from unshielded magnets), and the impact of ferrous elements of the building structure or its components, especially those that are not static (e.g., elevators), as they may affect field homogeneity. Most MR scanners are superconducting and require the use of cryogenes. Because cryogen boil-off can lead to asphyxiation of both personnel and animals, rooms with MR scanners or in which cryogen gases are stored must be equipped with oxygen sensors and a method for increasing room ventilation to exhaust inert gases during cryogen filling (Klaunberg and Davis 2008).

Many imaging devices, especially those designed for small animals, are self-contained and require no special physical plant considerations. Provisions should be made to locate the operating console away from imaging devices that emit ionizing or magnetic radiation. Imaging devices with components that are difficult to sanitize should be covered with a disposable or sanitizable material when not in use.

### **Whole Body Irradiation**

Total body irradiation of small laboratory animals may be accomplished using devices that emit either gamma- or X-rays. Devices are usually self-shielded and, because of the weight of the shielding material, may require special site considerations. Devices with gamma-emitting sources are subject to regulations that require adherence to specific security, monitoring, and personnel clearance requirements (Nuclear Regulatory Commission 2008). The site selected for irradiators should also take into account whether they are to be used for animals and biologics, as well as the source and microbial status of the animals to be irradiated. Locating them in the animal facility may require access for personnel who would normally not

require it or may necessitate bringing animals into a facility where they are not normally housed.

### **Hazardous Agent Containment**

The goal of containment is to “reduce or eliminate exposure of laboratory workers, other persons, and the outside environment to potential hazardous agents” (DHHS 2010). This is accomplished by employing appropriate practices and equipment, vaccinating personnel if a vaccine is available, and ensuring the proper design and operation of the physical plant.

Animal facilities used to study biologic agents that are infectious to humans are categorized into different biosafety levels of escalating containment requirements as described in *Biosafety in Microbiological and Biomedical Laboratories* (BMBL; DHHS 2009 or most recent version). Each animal biosafety level (ABSL) reflects a combination of practices, safety equipment, and facilities based on risk of human infection. As described in the 2009 edition of the BMBL, ABSL-1 contains agents not known to cause human infection; ABSL-2 contains agents of moderate risk that cause human disease by ingestion or percutaneous or mucosal exposure; ABSL-3 contains agents that cause serious and potentially lethal infections and have known potential for aerosol transmission; and ABSL-4 contains nonindigenous (exotic) agents that pose high individual risk of life-threatening disease and for which there is no available vaccine or treatment. Facility design, engineering criteria, construction methods and materials, commissioning, and validation become more important with each increasing level. The BMBL should be consulted for specific design and engineering requirements. Considerable care should be taken when selecting the team of professionals responsible for the design, engineering, construction, and commissioning of a containment facility.

Guidelines have also been developed for containing agricultural pathogens (USDA ARS 2002), recombinant DNA molecules (NIH 2002), arthropod vectors (ACME, ASTMH 2003), and hazardous chemicals (NRC 1995). Biologic agents and toxins pose a threat to animal and plant health or public health and safety, and facilities in which they are used must adhere to APHIS, USDA, and CDC Select Agent Regulations (CFR 2005; CDC and DHHS 1996; PL 107-56; PL 107-188;) and/or other applicable federal, state, or local regulations. These regulations stipulate, among other requirements, that the institution registered to use select agents establish and adhere to stringent security measures.

The specific facility features, equipment, and safety practices to be employed will depend, to a considerable extent, on whether a specific hazard is a particulate, volatile, or both. Facility features applicable to all hazards include isolation of the animals and their waste, provision of sealed

monolithic room surfaces that do not promote dust accumulation and are easy to sanitize, increased air exchange rates to dilute environmental contamination if it occurs, air pressure differentials to ensure that areas containing hazards have negative pressure with respect to surrounding areas, specialized housing systems, if available, and appropriate safety equipment such as a biologic safety cabinet or chemical hood (CDC and NIH 2007). A number of references are available to provide an overview of the issues related to hazardous material containment (Frazier and Talka 2005; Lehner et al. 2008; Lieberman 1995; NRC 1989, 1995)

### **Behavioral Studies**

When planning a behavioral facility, special attention should be given to all aspects of facility design, construction, equipment, and use that may generate conditions that inappropriately stimulate the senses of the test animals. It is frequently necessary to maintain animals in an environment, especially during periods of testing and observation, with strict control over auditory, visual, tactile, and olfactory stimuli. The facility site, as well as the engineering and construction methods used, should be carefully selected to minimize airborne transmission of noise and groundborne transmission of vibration.

Noise and vibration may arise from the building's structure, its equipment, or from human activities (see section on Noise). The frequencies and intensity of sound, which stimulate auditory responses in the species being investigated, should guide the selection of construction materials, techniques, and equipment to minimize intrusions. For instance, the HVAC system should be designed and components selected to ensure that noise, including ultrasonic frequencies, is not generated; fire alarm annunciators that emit sound at a frequency not audible to rodents should be used; hardware should be provided on doors to enable them to close quietly; nonessential noise-generating equipment should be housed outside the study area; and personnel traffic should be minimized both in animal testing areas and in areas contiguous to them (Heffner and Heffner 2007). Attention should be given to the control of aberrant visual cues, especially in circadian studies. The selection of the type, intensity, and control of lighting will likely differ from other animal facility areas. A variety of specialized housing and testing systems may also need to be accommodated in the facility.

Special construction features may also be desirable. Double-door vestibule entries to the behavioral facility, testing suites, or individual testing rooms may be useful as they can prevent noise, odors, and light from entering the behavioral testing area. Floor coverings that reduce sound transmission should be selected. Testing rooms may require floor drains, water sources, and increased floor loading to support specific behavioral testing apparatus.

Consideration should be given to the types and amount of electronics and other equipment used to ensure that the HVAC system can accommodate the associated heat loads. Airlocks and air pressure differentials between spaces can provide olfactory segregation of species and activities and thus reduce the risk of altered behavioral responses (ASHRAE 2007c).

When possible, testing equipment should be designed in such a way as to allow surface disinfection between studies. Components that cannot be cleaned or disinfected, such as computers and recording equipment, should be located in areas where contact with animals is unlikely and should be covered when not in use (the use of computer keyboard covers may also be beneficial). Provision of sufficient space for storage of behavioral apparatus and equipment should also be considered. As transportation to and from the testing area may alter behavioral responses, consideration should be given to providing housing areas contiguous with those used for testing; if such areas are provided, they should meet the requirements specified in the *Guide*.

### **Aquatic Species Housing**

Many of the construction features described above are applicable to those for aquatic species, but particular consideration should be given to the housing systems used and the methods for maintaining the aquatic environment.

The complexity of the life support system depends on the species housed and the size, type, and number of tanks and animals supported. All systems require a water source, which may require prior treatment (e.g., ultraviolet sterilization and particulate, carbon, and ultrafiltration). Holding areas for aquatic species should be provided with drains of a suitable size and number to accommodate water released during system operation and maintenance or as a result of life support system or tank failure. Drains should not permit passage of animals or hazardous materials into the sanitary system without appropriate treatment.

Materials used for floors, walls, and ceilings should be impervious to water while floors should be slip resistant and able to withstand the loads inherent with large quantities of water. Electrical receptacles or circuits should be ground-fault interrupted to prevent electrocution of personnel and animals. Doors and frames, supply diffusers, exhaust registers, lighting fixtures, HVAC ducts and components (exposed to high levels of moisture or corrosives), and other metallic elements should be made of moisture- and corrosion-resistant materials. Housing systems, life support system components, and plumbing used to distribute water after treatment, including adhesives to connect components, should be constructed of materials that are nontoxic and biologically inert. If the macroenvironmental/room HVAC system is used as the primary method for tempering the aquatic environment, sufficient ventila-

tion should be provided to prevent moisture buildup on room surfaces and maintain suitable temperatures for the species housed.

### SECURITY AND ACCESS CONTROL

Recent episodes of domestic terrorism have heightened awareness of the importance of animal facility security, but there are other reasons why security and access control should be provided. Most animals maintained for research are vulnerable to infection with adventitious agents and therefore access to them should be strictly controlled and made available only to personnel who have received appropriate training and have a legitimate need for access. Animals used in studies with hazardous materials require special precautions for personnel before access, and staff entering the animal facility should have completed the institution's occupational health and safety training.

When possible, the animal facility should be located within another structure with its own independent set of security features. Vehicular access should be limited and, when provided, controlled and monitored.

Security and access control are generally provided in zones, starting at the perimeter with areas of highest security located within other zones. Control measures may consist of security personnel, physical barriers, and control devices. The scope of the security system should depend on the size of the facility as well as the nature of the activities conducted within. Increasingly, access control is extended from the facility's perimeter to each animal holding room. Microprocessor-controlled security systems are frequently employed because of the large number of control points and staff requiring access. These systems typically use electronic key or proximity cards and associated readers, which, in addition to controlling access, enable recording of the time, location, and personal identification of each entry. In more sensitive areas, biometric reading devices such as thumb or palm readers or retinal scanners may be more suitable because key cards can be shared. Security may be enhanced with electronic and video surveillance systems. These systems may be monitored by personnel or motion-activated recording devices.

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# Addendum

## Guide for the Care and Use of Laboratory Animals Eighth Edition

### **ADDENDUM: LIST OF EDITORIAL CHANGES FROM THE PREPUBLICATION VERSION<sup>1</sup>**

1. Page 22. Original sentence: "Personnel training should include information on laboratory animal allergies, preventive control measures and proper techniques for working with animals (Gordon et al. 1997; Schweitzer et al. 2003; Thulin et al. 2002)." "...early recognition and reporting of allergy symptoms" was added to clarify the guidance and reflect the cited references.
2. Page 31. Original sentence: "They should therefore be used, when available, for all animal-related procedures (NIH 2008; USDA 1997b)." The NIH reference was removed because it applies only to the NIH intramural animal research program.
3. Page 32. Original sentence: "Principal investigators conducting field research should be knowledgeable of relevant zoonotic diseases, associated safety issues, and, when working in an international environment, any local laws or regulations that apply." Compliance with laws and regulations applies to field investigations irrespective of location, so "when working in an international environment" and "local" were deleted.

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<sup>1</sup>Page numbers reflect placement of revisions in this report.

4. Page 32. Original sentence: "Appropriate veterinary input is needed for projects involving capture, individual identification, sedation, anesthesia, surgery, recovery, holding, transportation, release, or euthanasia." Beginning of sentence changed to "Veterinary input may be needed..." to clarify the intent of the sentence.
5. Page 43. Original sentence: "The ambient temperature range in which thermoregulation occurs without the need to increase metabolic heat production is called the *thermoneutral zone (TNZ)* and is bounded by the upper (UCT) and lower critical temperatures (LCT)." The phrase "or activate evaporative heat loss mechanisms" and reference to Gordon 2005 were added to provide a more complete definition of thermoneutral zone.
6. Page 45. Original sentence: "In climates where it is difficult to provide a sufficient level of environmental relative humidity, animals should be closely monitored for negative effects such as excessively flaky skin in birds and mammals, ecdysis (molting) difficulties in reptiles, and desiccation stress in semiaquatic amphibians." Because the significance of excessive flaky skin varies among species, "in birds and mammals" was deleted.
7. Page 55. Original sentence: "Thus there is no ideal formula for calculating an animal's space needs based only on body size or weight." The phrase "and readers should take the performance indices discussed in this section into consideration when utilizing the species-specific guidelines presented in the following pages" was added to further clarify the intent of this section.
8. Pages 57-63. The phrase "the interpretation of this table should take into consideration the performance indices described in the text beginning on page 55" was added as a footnote to tables as additional guidance to their interpretation. Additionally, the symbol " $\geq$ " was restored (due to mistaken deletion) in Table 3.2 (mice in groups; rats in groups; hamsters; guinea pigs) and added to Tables 3.5 (group 8) and 3.6 (sheep and goats)
9. Page 69. Original sentence: "Cedar shavings are not recommended because they emit aromatic hydrocarbons that induce hepatic microsomal enzymes and cytotoxicity (Torrönen et al. 1989; Weichbrod et al. 1986, 1988)." Text mistakenly deleted was restored to the end of the sentence: "and have been reported to increase the incidence of cancer (Jacobs and Dieter 1978; Vlahakis 1977)."

10. Page 107. Original sentence: "The Centers for Disease Control and Prevention enforces regulations to prevent the introduction, transmission, or spread of communicable diseases and regulate the importation of any animal or animal product capable of carrying a zoonotic disease." Because USDA also has jurisdiction over imports, it was added to the sentence.
11. Page 107. Original sentence: "The US Fish and Wildlife Service regulates importation/exportation and interstate trade of wild vertebrate and invertebrate animals and their tissues." Because US Fish and Wildlife Services does not regulate interstate trade except for species listed under the Endangered Species Act, "and interstate trade" was deleted
12. Page 120. Original sentence: "Additional care might be warranted, including long-term administration of parenteral fluids (FBR 1987), analgesics and other drugs; and care of surgical incisions." Because this is now standard veterinary medical practice and the cited reference is no longer in print, the reference was removed.
13. Page 120. Original sentence: "In general, unless the contrary is known or established, it should be considered that procedures that cause pain in humans may also cause pain in vertebrate species (IRAC 1985)." For consistency with the text of the U.S. Government Principles the phrase "The U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (see Appendix B) state that..." was added and the words "in vertebrate species" were replaced with "in other animals."
14. Page 143. Original phrase: "Vibration, especially if animals are housed directly above the washing facility," was expanded because animals housed below or adjacent to the washing facility are also subject to potential vibration.
15. Added references: pages 163; 169; 179; 182; 192.



# Appendices



## APPENDIX

# A

## Additional Selected References

### SUBJECT MATTER

#### USE OF LABORATORY ANIMALS

Alternatives  
Ethics and Welfare  
Experimental Design and Statistics  
Research and Testing Methodology

#### PROGRAM MANAGEMENT

General References  
Laws, Regulations, and Policies  
Education  
Monitoring the Care and Use of Animals  
Occupational Health and Safety

#### ENVIRONMENT, HOUSING, AND MANAGEMENT

General References  
Environmental Enrichment  
Genetics and Genetically Modified Animals  
Species-Specific References—Environment, Housing, and Management  
    Agricultural Animals  
    Amphibians, Reptiles, and Fish  
    Birds  
    Cats and Dogs  
    Exotic, Wild, and Zoo Animals



Nonhuman Primates  
 Rodents and Rabbits  
 Other Animals

## VETERINARY CARE

Transportation  
 Anesthesia, Pain, and Surgery  
 Disease Surveillance, Diagnosis, and Treatment  
 Pathology, Clinical Pathology, and Parasitology  
 Species-Specific References—Veterinary Care  
 Agricultural Animals  
 Amphibians, Reptiles, and Fish  
 Birds  
 Cats and Dogs  
 Exotic, Wild, and Zoo Animals  
 Nonhuman Primates  
 Rodents and Rabbits

## DESIGN AND CONSTRUCTION OF ANIMAL FACILITIES

### USE OF LABORATORY ANIMALS

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## APPENDIX

# B

## U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training

The development of knowledge necessary for the improvement of the health and well-being of humans as well as other animals requires in vivo experimentation with a wide variety of animal species. Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the following principles shall be considered; and whenever these agencies actually perform or sponsor such procedures, the responsible Institutional Official shall ensure that these principles are adhered to:

- I. The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C. 2131 et. seq.) and other applicable Federal laws, guidelines, and policies.<sup>1</sup>
- II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.
- III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered.

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<sup>1</sup>For guidance throughout these Principles, the reader is referred to the *Guide for the Care and Use of Laboratory Animals* prepared by the Institute for Laboratory Animal Research, National Academy of Sciences.

- IV. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.
- V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.
- VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
- VII. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care shall be provided as indicated.
- VIII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.
- IX. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as an institutional animal care and use committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.

## APPENDIX

### C

## Statement of Task

The use of laboratory animals for biomedical research, testing and education is guided by the principles of the Three Rs, replacement of animals where acceptable non-animal models exist, reduction in the number of animals to the fewest needed to obtain statistically significant data, and refinement of animal care and use to minimize pain and distress and to enhance animal well-being. The *Guide for the Care and Use of Laboratory Animals* has been a critical international publication that provides information to scientists, veterinarians and animal care personnel when the decision has been made that animal use is necessary. A committee will update the 1996 version of the *Guide for the Care and Use of Laboratory Animals* (the *Guide*) to reflect new scientific information related to the issues already covered in the *Guide*, and to add discussion and guidance on new topics of laboratory animal care and use related to contemporary animal research programs.

The committee will review the scientific literature published since the release of the 1996 *Guide* and determine whether the information in the *Guide* concurs with current scientific evidence. The committee will also review the literature on new technologies related to laboratory animal care and use and determine where new guidance is necessary to ensure the best scientific outcomes and optimal animal welfare. The committee will also take into consideration all materials and discussions provided to it, including those submitted to NIH in response to the Request for Information NOT-OD-O6-011 that requested information related to the need to update the *Guide*. Where scientifically warranted, the guidance and recommendations of the 1996 *Guide* will be changed to reflect new scientific



evidence, while maintaining the performance standards of the 1996 *Guide*. The committee will ensure that any recommendations in the *Guide* will be consistent with current Public Health Service Policy, the Animal Welfare Regulations, and the most recent Report of the American Veterinary Medical Association Panel on Euthanasia.

In addition to the published report, the updated *Guide* will be posted on the Internet in a pdf or equivalent format such that users will be able to search the entire document at one time.

## APPENDIX

### D

## About the Authors

**Janet C. Garber** (Chair), DVM, PhD, received her Doctor of Veterinary Medicine degree from Iowa State University and her PhD in pathophysiology from the University of Wisconsin. Her experiences have included infectious disease research at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), primate medicine and research, GLP device and materials evaluation, and transplantation immunology. Her current interests are in the areas of laboratory animal facility management, infectious diseases, occupational health and safety, and research program management. She most recently was Vice President, Safety Assessment, at Baxter Healthcare Corporation and is now a consultant with Garber Consulting, LLC in North Carolina. Dr. Garber is currently a member of the Council on Accreditation, AAALAC, International, and previously served as Chair of the Council. She served on the ILAR Committee to Revise the *Guide for the Care and Use of Laboratory Animals* and the Committee on Occupational Health and Safety in the Care and Use of Research Animals.

**R. Wayne Barbee**, PhD, is Professor and Associate Director of Research at the Department of Emergency Medicine, School of Medicine, Senior VCURES (Virginia Commonwealth University Reanimation Engineering Science Center) Fellow and Chair of the IACUC at the Virginia Commonwealth University. Dr. Barbee holds a master's degree and doctorate in physiology with three decades of research involving a wide variety of animals (bats, cats, crabs, dogs, rodents, and swine) in a number of experimental settings. His research has focused on circulatory shock and resuscitation, acute and chronic rodent surgery, and analysis of rodent hemodynamics. He has

been associated with IACUCs at small, medium, and large institutions for over two decades and is familiar with the oversight of animal care and use programs. He has served on multiple study sections for both the NIH and DOD. Dr. Barbee also served as an Oxford, UK 2006 fellow (recipient, VCU Harris-Manchester Award) where he examined policies, training, and security issues related to animal care and use within the UK.

**Joseph T. Bielitzki**, MS, DVM, is Research Manager, University of Central Florida. Dr. Bielitzki has worked with non-human primates in the laboratory environment for 20 years. Over this period he has worked with macaques (pig-tail, long-tail, Japanese, rhesus, stump-tail), baboons (yellow, green and hybrids) squirrel monkeys, capuchin monkeys, mangabeys, gibbons, chimpanzees, orangutans, bonobos, and gorillas. In the area of non-human primates his area of expertise is in enteric diseases, nursery rearing, and colony management. He has also worked with mice and rats in a variety of international facilities. He was instrumental in the writing and acceptance of the NASA Bioethical Principles for the Use of Animals in Research (NPD 8910.1). He speaks frequently on IACUC function and the importance of ethics in the use of animals. His background includes experience in academia, industry, and government in the roles of attending veterinarian, program manager, and researcher.

**Leigh Ann Clayton**, DVM, is Director of Animal Health at the National Aquarium in Baltimore where she also chairs the Animal Welfare Committee. Dr. Leigh Clayton has worked in the zoo/aquarium field or the exotic pet medicine field exclusively since 2000. As she has worked with animals held in aquatics systems both in recirculating fresh and salt water, she is experienced in managing disease and accomplishing preventive health programs for fishes, amphibians, and reptiles as well as birds and mammals. She is a Diplomate of the American Board of Veterinary Practitioners (Avian). Dr. Clayton has routinely used her knowledge of nitrogen cycling and the basics of a variety of life support system designs to solve health issues in these captive settings and help ensure adequate animal health. She has served on the Executive Board of the Association of Reptilian and Amphibian Veterinarians, a role that allowed her to routinely liaise with leading researchers in the amphibian medicine field.

**John C. Donovan**, DVM, is President of BioResources Inc. Dr. Donovan has over 30 years' experience working as a veterinarian in biomedical research and is board certified by the American College of Laboratory Animal Medicine (ACLAM). After 7 years in the U.S. Army's Medical Research and Development Command, he spent 10 years at the National Institutes of Health, becoming the Director of the National Cancer Institute's Office

of Laboratory Animal Science. He began his career in the pharmaceutical industry in 1994 as Senior Director of Worldwide Laboratory Animal Resources for Rhone Poulenc-Rorer Pharmaceuticals, leading to his position as Vice President of Laboratory Animal Science and Welfare for Aventis Pharmaceuticals in 1999. In 2001 he moved to Wyeth Pharmaceuticals where he was Vice President of BioResources until his retirement in 2007. During his career, Dr. Donovan served in numerous professional leadership positions including President of ACLAM and President of the Board of Directors of the Pennsylvania Society for Biomedical Research (PSBR). He also served on several boards including those of the National Association for Biomedical Research, ACLAM, PSBR, and the New Jersey Association for Biomedical Research.

**Dennis F. Kohn**, DVM, PhD, is Professor Emeritus of Clinical Comparative Pathology at Columbia University. He received his DVM from Ohio State University and a doctorate in Medical Microbiology from West Virginia University. He is board certified by the American College of Laboratory Animal Medicine. He has directed laboratory animal resource/comparative medicine programs at West Virginia University Medical Center, University of Texas Medical School at Houston, and the Health Sciences Division, Columbia University. His research interests have dealt primarily with the pathogenicity of *Mycoplasma pulmonis* in the respiratory tract of laboratory rats, and the experimental pathology induced within the CNS and joints of rats inoculated with *M. pulmonis*. He is a past president of the American College of Laboratory Animal Medicine and the American Society of Laboratory Animal Practitioners, and as chair of a number of American Association of Laboratory Animal Science committees. He has served as a Council member of AAALAC-International, as a member of the 1986 American Veterinary Medical Association's Panel on Euthanasia, and the 1996 Institute of Laboratory Animal Resources' committee to revise the *Guide*.

**Neil S. Lipman**, VMD, is Director of the Center of Comparative Medicine and Pathology serving the Memorial Sloan-Kettering Cancer Center (MSKCC) and the Weill Medical College of Cornell University and is Professor of Veterinary Medicine in Pathology and Laboratory Medicine at Weill Cornell as well as a Laboratory Member at the Sloan-Kettering Institute at MSKCC. Dr. Lipman is a Diplomate of the American College of Laboratory Animal Medicine with over 25 years' experience in laboratory animal medicine and science. Dr. Lipman has expertise in vivarium design, engineering, and operations, having designed over 1.5 million gross square feet of vivarium space and overseen the operation of a number of major academic animal resource programs. His research interests are principally translational and include development and analysis of new technologies especially with

respect to rodent housing systems and monoclonal antibody production, the characterization of various animal models, understanding the etiopathogenesis of endocrinologic disorders affecting laboratory animal species, and development and analysis of novel therapeutic strategies. Throughout his career, Dr. Lipman has been extensively involved in the postgraduate training of laboratory animal specialists.

**Paul Locke**, MPH, JD, DrPH, an environmental health scientist and attorney, is Associate Professor at the Johns Hopkins University Bloomberg School of Public Health in the Department of Environmental Health Sciences, Division of Toxicology. He holds an MPH from Yale University School of Medicine, a DrPH from the Johns Hopkins University Bloomberg School of Public Health and a JD degree from Vanderbilt University School of Law. Prior to joining the Department of Environmental Health, he was the Deputy Director of the Pew Environmental Health Commission and the Director of the Center for Public Health and Law at the Environmental Law Institute. Dr. Locke's research and practice focus on how decision makers use environmental health science and toxicology in regulation and policy making and how environmental health sciences influence the policy-making process. His areas of study include alternatives to animal testing in biomedical research, with particular emphasis on toxicity testing. He also maintains an active research program in radiation studies and radiation protection policy. Dr. Locke directs the Doctor of Public Health degree program in the Department of Environmental Health Sciences and is co-director of the Johns Hopkins certificate program in Humane Science and Toxicology. From 2004 until 2009 he was a member of the National Academy of Sciences Nuclear and Radiation Studies Board, and has served on five National Academy of Sciences/National Research Council expert committees. He is admitted to practice law before the bars of the states of New York and New Jersey, the District of Columbia, the United States Court of Appeals for the Second Circuit and the United States Supreme Court.

**The Honorable John Melcher**, DVM, a graduate of the College of Veterinary Medicine of the Iowa State University, was a practicing veterinarian in the state of Montana until 1969, in which year he was elected to the U.S. House of Representatives. He served as a Congressman for 8 years and as a Senator for 12 years. In both the House and the Senate, Senator Melcher was noted for his interest in agriculture, protection of public lands, notably Forest Service and Bureau of Land Management lands, and animal welfare and animal health protections. In 1984 he contributed to the Animal Welfare Act with an amendment requiring consideration of the psychological well being of primates used in medical research. After retiring from Congress, Senator Melcher established a second career as a consultant for the

American Veterinary Medical Association and the American Association of Veterinary Medical Colleges. Senator Melcher represents the public's perspective.

**Fred W. Quimby**, VMD, PhD, is a board-certified laboratory animal veterinarian, with a doctorate in pathology, specialized in the assessment of immune function in animals. Prior to his retirement in 2007 he was Associate Vice President at Rockefeller University, while over the past 35 years he oversaw the research animal programs at three Universities (Tufts, Cornell, and Rockefeller) and held the position of Professor at Cornell's Colleges of Medicine and Veterinary Medicine. He conducted research and lectured in the fields of immunology, pathology and environmental toxicology where he focused his research on toxic shock syndrome, environmental intoxication with polychlorinated biphenyls (PCBs), and immune dysfunction in pet dogs. As a laboratory animal professional he has designed and overseen the construction of five animal facilities for research animals and a zoological park. Dr. Quimby has had broad experience with a wide assortment of laboratory animals including rodents, dogs, primates, livestock, poultry, and fish, and published on the diseases, care, and /or housing of each of them. He has served on various NAS/NRC committees including the *Guide* committee, the Committee on Immunologically Compromised Rodents (Chair), the Transgenic Animal Committee, the Committee to Develop Standards for Dogs (Chair), the Monoclonal Antibody Production Committee, and the Committee Evaluating Increasing Veterinary Involvement in Biomedical Research. He served as a member of the ILAR Council and chaired the Editorial Committee of the ILAR News. He is currently serving as a member of the Committee to Assess the Current and Future Workforce Needs in Veterinary Medicine. He was a charter member of the Society for Veterinary Ethics, a member of the Board of Directors for the National Association for Biomedical Research and a member of the Strategic Planning Committee for AAALAC International.

**Patricia V. Turner**, MS, DVM, DVSc, is Associate Professor and Program Leader of Laboratory Animal Science in the Department of Pathobiology at the University of Guelph, Canada, where she also is currently Chair of the Animal Care Committee. She has a doctorate in comparative pathology and is a Diplomate of both the American College of Laboratory Animal Medicine and the American Board of Toxicology. Dr. Turner has experience managing Canadian Council of Animal Care-compliant animal facilities that house a full range of species (fish, rodents and rabbits, dogs and cats, swine and sheep, nonhuman primates) in both academic and industry (GLP) settings. Dr. Turner serves as an AAALAC international ad hoc specialist with excellent knowledge of current US guidelines and

regulations concerning research animal care and use. Her research interests include innate immunity and infectious disease, toxicologic pathology, and the interactions between rodents and their environment as they relate to disease susceptibility. In 2007 she was the inaugural recipient of the North American Animal Welfare Award, co-sponsored by Procter & Gamble and the Humane Society of the United States.

**Geoffrey A. Wood**, DVM, PhD, DVSc, is Associate Professor in the Department of Pathobiology at the Ontario Veterinary College, University of Guelph, Canada. Dr. Wood has a doctorate in cancer biology and a doctorate in veterinary pathology. He has been involved in design or pathologic characterization of hundreds of genetically engineered rodents, both as the former Associate Director of Pathology at the Centre for Modeling Human Disease in Toronto, and in his current position. His lab conducts research on cancer genetics and the process of metastasis, with a focus on bone and prostate cancer. Dr. Wood's research collaborations include projects investigating various aspects of a wide range of different cancer types, as well as studies on stem cell biology, immunity, and inflammation.

**Hanno Würbel**, Dr.sc.nat, is Professor of Animal Welfare and Ethology at the Justus Liebig University in Giessen, Germany. He has studied biology (zoology) at the University of Berne, Switzerland and graduated from the ETH Zürich, Switzerland with a doctorate in natural sciences. He has experience in animal behavior and in the scientific assessment of animal well-being, and has mostly worked with rodents, but also with rabbits, dogs, poultry, and horses. His research focuses on environment-dependent plasticity of brain and behavior in relation to questions of animal husbandry and animal welfare. In 2005 Dr. Würbel received the Hessian Animal Welfare Research Prize and in 2009 the Felix Wankel Animal Welfare Research Award. He is a member of the Animal Welfare Council of the German government, Central Animal Welfare Officer of the University of Giessen, and head of the University's Central Animal Facility. He is also a council member of the International Society of Applied Ethology (ISAE), editor of the *Journal of Applied Animal Welfare Science*, and editorial board member of the journal *Applied Animal Behaviour Science*.

# Index

## A

- Acclimation and adaptation, 111, 188  
(*see also* Procedural habitation and training)  
caloric management and, 67  
to noise and vibrations, 81-82  
to outdoor housing, 44, 54-55  
to physical restraint, 29
- Acquisition of animals (*see* Procurement)
- Activity and exercise, xiv, 43, 52-53, 55, 56, 57, 58, 63-64, 67, 84 (*see also* Enrichment)
- Agricultural animals, 2  
biomedical vs. agricultural research, 32-33  
environment and housing, 29, 33, 43, 44, 137, 176-177  
floor drains, 137, 138  
information resources, 33, 176-177, 191-192  
protocol review, 32-33  
space requirements, 60, 62-63  
surgery, 117, 144, 145  
veterinary care, 145, 191-182
- Air pressure, 45, 47, 139, 145-146, 149-150
- Air quality and airborne contaminants, 45-47
- Airflow (*see* Ventilation and airflow)
- Albino animals, 48-49, 141
- Allergens and allergic reactions, 18, 19, 20, 22-23, 45, 155
- Alternatives to laboratory animal use, 3, 5, 12, 25, 27, 162-167
- American Association for Laboratory Animal Science, 16
- American College of Laboratory Animal Medicine, 24  
Guidelines for Adequate Veterinary Care, xvii, 14
- Ammonia, 45, 47, 68, 70, 71, 72-73, 78, 79, 80, 81, 85
- Amphibians, 41-42, 44-45, 46, 77, 78-79, 80, 81, 82, 83, 84, 85, 108, 119, 156, 178-179, 192 (*see also* Aquatic species)
- Anesthesia and analgesia  
considerations in selection of agents, 75, 121  
equipment/delivery, 34, 122, 145, 147  
euthanasia agent, 124  
field conditions, 32, 117  
monitoring, 119-120, 122, 123  
neuromuscular blocking agents, 122-123  
oversight, 34, 156  
pain management, 12, 121-122  
preemptive analgesia, 121  
principles governing use, 12, 14, 26  
recommended reading, 188-190  
recordkeeping, 34



- surgery, 115, 116, 117, 118, 119-120, 122-123, 145, 188-190
  - training, 17, 106, 115, 122
  - waste gas management, 21, 147
  - Animal and Plant Health Inspection Service (APHIS), 30, 148
  - Animal care and use program
    - attending veterinarian, 14
    - collaborations, 15
    - defined, 6
    - disaster planning and emergency preparedness, 35
    - IACUC, 14-15, 24-33
    - institutional official, 13-14
    - oversight, 24-34
    - personnel management, 15-24
    - program management, 13-24
    - recommended reading, 167-172
    - regulations, policies, and principles, 12-13
    - responsibilities, 13-15
  - Animal care personnel, (*see also* Personnel) training and education, 16
  - Animal training (*see* Procedural habituation and training)
  - Animal Welfare Act, 1, 4, 25, 34, 199
  - Animal Welfare Information Center, xv, 16
  - Animal Welfare Regulations, 1, 12
    - housing guidelines, 56, 59
    - IACUC, 25
    - transportation of animals, 107
    - veterinary care, 30
  - Antibiotics, 116
  - Anxiolytics, 122-123
  - Apes (*see* Nonhuman primates)
  - Aquatic species, 2 (*see also* Amphibians; Fish; Reptiles)
    - algal growth, 86
    - behavior and social management, 84
    - diseases, 112
    - emergency, weekend, and holiday care, 87
    - enrichment and social housing, 82-83
    - environment, 77-82
    - facilities, 150-151
    - food and feeding, 84-85
    - housing, 82-83, 150-151
    - husbandry, 84-87
    - identification, 87
    - illumination, 81
    - life support system, 79-80
    - macroenvironment, 77-78, 86
    - management, 84-88
    - microenvironment, 77-78, 82-83
    - noise and vibration, 81-82
    - pest control, 87
    - population management, 87-88
    - recommended reading, 178-179, 192-193
    - recordkeeping, 87-88
    - sanitation, 85-86
    - sheltered, outdoor, and naturalistic housing, 83
    - space, 83
    - substrates, 85
    - temperature, humidity, and ventilation, 80-81
    - water quality, 78-79, 85
  - Aseptic practices, 17, 34, 52, 70, 75, 115, 116, 117, 118-119, 144
  - Attending veterinarian, 3, 4, 13, 14, 15, 17, 21, 24, 28, 106, 114, 116 (*see also* Veterinary care)
  - Autoclaving
    - bedding material, 69, 146
    - drinking water, 146
    - feed, 66, 146
    - surgical instruments, 119, 145
  - Avian species (*see* Birds)
- B**
- Bacterial gill disease, 112
  - Barriers
    - access control, 151
    - facilities, 113, 136, 145-146
    - separation of housing and research/surgery areas, 134, 144
    - visual, 51, 53, 83
  - Bedding, nesting, and substrates
    - aquatic species, 85
    - autoclaving, 69, 136, 146
    - behavioral aspects, 52
    - changing, 46, 47, 52, 69, 70, 73
    - disposal, 19, 20
    - enrichment aspects, 67
    - environmental aspects, 43, 44, 46, 47, 49, 52, 53, 69, 71
    - experimental influences, 68, 69
    - illumination and, 49
    - materials, 68-69
    - outdoor facilities, 54
    - storage, 136, 141
    - terrestrial species, 52, 68-69

Behavioral and social management  
 acclimation, 111  
 activity and exercise, 63-64, 84  
 airflow and ventilation and, 150  
 aquatic species, 82, 83, 84, 85  
 bedding, nesting, and substrate materials  
 and, 49, 52, 85  
 enrichment, 52-53, 54, 60, 83, 85  
 food and feeding, 65  
 illumination and, 47, 48, 49  
 procedural habituation and training, 29,  
 64-65  
 recordkeeping, 75  
 sanitation and, 72  
 social environment, 51, 58, 59, 64, 111  
 space considerations, 55, 56, 57, 58, 59  
 temperature and humidity and, 43, 44,  
 80  
 terrestrial species, 83-85  
 training of personnel, 53, 121  
 veterinary care and, 107, 111, 112, 114

Behavioral changes  
 infections and, 118  
 monitoring animals for, 112  
 moribund state, 28  
 pain and distress, 120-121, 123  
 physical restraint and, 29  
 sanitation and, 71  
 stereotypies and compulsive behaviors,  
 63  
 transportation of animals and, 150

Behavioral research, 30, 31, 111, 135,  
 149-150

Bioexclusion, 28 (see also Barriers)

Biologic agents and hazards, 18, 19, 20, 21,  
 111, 112-113, 148, 170-172

Biosecurity, animal, xviii, 105, 107, 108,  
 109-110, 111, 135, 170-172

Birds, 41, 44, 48, 49, 60, 121, 144, 156,  
 179-180, 193

Bites and scratches, 18, 23

Breeding and reproduction  
 aquatic animals, 44, 80, 82, 83, 87, 88  
 caloric restriction and, 67  
 cryopreservation of fertilized embryos,  
 ova, ovaries, or spermatozoa, 76,  
 107  
 enriched environments and, 83  
 genetic management, 76, 77  
 GMAs, 28, 76  
 lighting and, 48, 137

nesting, bedding and substrates, 52, 70,  
 83  
 nomenclature, 77  
 nonhuman primates, 59  
 recordkeeping, 76, 77, 87, 88  
 rodents and rabbits, xviii, 57, 77, 107  
 sanitation activities and, 70  
 space requirements, 55, 56, 57, 33  
 temperature and humidity and, 44, 80, 82  
 vibration and, 50

Building Seismic Safety Council, 133

## C

Cages and caging (see also Housing;  
 Microenvironment)  
 cleaning and sanitation, 18, 46, 47, 52,  
 69, 70-71, 72, 73, 86, 142, 143, 145  
 dimensions and space allocation, xviii,  
 56, 57, 58, 59, 60, 61, 133  
 dividers and shelters in, 53  
 flooring, 70  
 isolators, 45, 47, 52, 111, 139, 146  
 light intensity in, 46, 49  
 location on cage rack, 46, 49  
 mechanical washers, 71, 72, 86, 135,  
 136, 141, 143  
 metabolic, 121  
 in secondary enclosures, 47  
 ventilated, 44, 46, 47, 50, 58, 70-71,  
 111, 141, 146  
 vibration of, 50

Caloric management, 31, 57, 67

Canadian Council on Animal Care, 16

Carcass disposal, 20, 73-74, 138, 142

Cardiovascular shock models, 27

Cats  
 behavioral and social management, 58,  
 59, 63-64, 180-181  
 enrichment, 53  
 environmental requirements, 43, 44, 53,  
 180-181  
 housing and space, 49, 56, 58, 59,  
 180-181  
 procurement, 106  
 recommended reading, 180-181, 193  
 recordkeeping, 75-76  
 veterinary care, 193

Cattle, 62-63, 64, 176-177, 191-192 (see  
 also Agricultural animals)

Cedar shavings, 69, 156

- Ceilings, 56, 81, 142  
Centers for Disease Control and Prevention,  
19, 21, 107, 148, 157  
*Cercopithecine herpesvirus 1*, 23  
Chairing, 29  
Chemical agents  
  cleaning materials, 71, 72  
  non-pharmaceutical-grade, 31  
  hazardous, 18, 19, 20, 21, 136  
Chickens, 48, 60  
Chimpanzees, xviii, 61  
Chlorines and chloramines, 72, 78-79, 80,  
85, 86  
Circadian rhythm, 43, 48, 49, 137, 149  
Cleaning agents, 18, 71, 72 (see also  
Sanitation)  
  (see also Vetterinary care)  
Clinical care and management  
  emergency care, 114  
  medical management, 114  
  recordkeeping, 115  
Clothing and footwear, 20, 21, 146  
Cold storage and refrigeration, 66, 73, 136,  
142  
Cold stress, 43, 44, 53  
Collaborations, interinstitutional, 15  
Computer modeling  
  alternative to animal use, 5, 12, 25, 199  
  facility design, 46, 133  
  genetic variability, 76  
Conditioned-response protocols, 31  
Construction guidelines, 136-143  
Containment of hazardous materials, 21,  
148-149  
Contaminants  
  airborne, 22, 45, 46-47, 139, 140, 143,  
145, 146-147, 149  
  bedding, 69, 141, 146  
  cleaning implements, 72, 85  
  food, 19, 65, 66, 67, 84, 141, 146  
  genetic, 76  
  microbial, 72, 81, 108, 109, 110, 113,  
118, 144-145  
  recommended readings  
  water, 67-68, 81, 86, 138  
Convention on International Trade in  
  Endangered Species of Wild Fauna  
  and Flora, 107  
Corridors, 86, 134, 136, 137, 141, 142  
Cryogenics, 147  
Cryopreservation, 76, 107  
Cyanobacteria, 86
- ## D
- Defecation, 72  
Definitions  
  animal biosecurity, 109  
  animal care and use program, 6, 11  
  animal use, 2  
  attending veterinarian, 14  
  engineering standard, 6  
  humane care, 6  
  institutional animal care and use  
  committee, 14  
  institutional official, 13  
  laboratory animals, 2  
  life support system, 79  
  macroenvironment, 42  
  "may," 8  
  microenvironment, 42  
  "must," 8  
  performance standard, 6-7  
  policies, 7  
  practice standard, 7  
  principles, 7  
  procedures, 7  
  "should," 8  
  thermoneutral zone, 43  
  three Rs, 4-5  
Dehydration, 68  
Desiccation stress, 45, 46  
Diet and dietary control (see also Food and  
  feeding)  
  abrupt changes in, 67  
  aquatic animals, 84, 85  
  autoclavable, 66  
  caloric management, 31, 57, 67  
  certified diets, 65  
  chemically defined diets, 65, 66  
  natural-ingredient, 65, 66  
  nutritionally balanced, 67  
  purified diets, 65, 66  
  quality assurance, 65, 66  
  treats, 67  
Disaster planning, 35, 74-75  
Disease control, 23, 72, 81, 108, 109, 110,  
112-113, 118, 144-145, 190  
Disease susceptibility, 19, 42

Disinfection, 20, 51, 52, 68, 69, 70-72, 78, 79, 80, 84, 86, 110, 118, 119, 138, 143, 144, 150

Disposable clothing, 146

Distress (see *also* Pain and distress)

- defined, 121
- neuromuscular blocking agents and, 122-123
- recommended reading, 188-190

Diurnal cycles, 48, 141

Dogs

- behavioral and social management, 29, 59, 63-64, 180-181
- enrichment, 53
- environmental requirements, 43, 44, 180-181
- housing and space, 49, 58, 59, 136, 138, 180-181
- infusion pumps, 29
- pain and distress, 121
- procurement, 106
- recommended reading, 180-181, 193
- recordkeeping, 75-76
- veterinary care, 193

Doors, 136, 137, 138, 142, 143, 144, 149, 150

Drafts, 46, 140

Drainage, 54, 136, 138, 143, 144, 149, 150

## E

Ecdysis (molting), 45, 156

Education (see Training and education)

Electric power, 136, 141, 142, 143, 145, 150

Emergency, weekend, and holiday care

- husbandry, 35, 74-75, 87
- medical, 114, 118

Enclosures (see Cages and caging; Primary enclosures; Secondary enclosures)

Endangered Species Act, 157

Endpoints (see *also* Experimental endpoints; Humane endpoints)

- IACUC review, 26, 27-28

Engineering standards, 6, 7

Enrichment, xiv, xviii, 33, 43, 50, 52-54, 55, 56, 58, 60, 64, 82-83, 85, 137, 173-175 (see *also* Social environment)

Entrapment, accidental, 51, 82

Environment (see *also* Enrichment; Housing; Macroenvironment; Microenvironment; Social environment)

- aquatic species, 77-82
- recommended reading, 172-175
- terrestrial species, 42-50

Eosinopenia, 49

Ergonomic injury, 19

Ethical considerations, xiii, xvii, 4-5, 12

- recommended reading, 163-164
- training in, 17

Euthanasia (see *also* Humane endpoints)

- AV responsibility, 106, 114, 156
- AVMA Guidelines, 123
- carbon dioxide for rodents, 124
- criteria for, 123
- defined, 123
- disaster planning, 35
- fetuses and larval life forms, 123-124
- field studies, 32
- methods, 123-124
- pest control, 74
- preemptive, 28
- psychological effects on personnel, 124
- training, 17, 124

Exercise (see Activity and exercise)

Exotic, wild, and zoo animals, 2, 18, 32, 44, 84, 107, 181-182, 193-194

Experimental design and statistics, recommended reading, 164-165 (see *also* Protocols)

Experimental endpoints, 27-28, 112, 121

## F

Facilities (see *also* Physical plant)

- aquatic species housing, 150-151
- barrier facilities, 145-146
- for behavioral studies, 149-150
- hazardous agent containment, 148-149
- imaging, 146-147
- irradiation, whole-body, 157-158
- recommended reading on design and construction, 196-197
- for sanitizing materials, 143
- surgical, 116-117, 144-145

Farm animals (see Agricultural animals)

Field studies, 18, 32, 155 (see *also* Exotic, wild, and zoo animals)

Fish (see *also* Aquatic species)

air quality considerations, 81  
 biosecurity, 110  
 food and feeding, 84-85  
 GMAs, 28  
 illumination, 81  
 noise and vibration, 81-82  
 pain and distress, 121  
 recirculating systems, 79-80  
 recommended reading, 178-179, 192-193  
 recordkeeping, 87-88  
 sanitation, 85, 86  
 schooling, 82, 83  
 space requirements, 83  
 temperature, 41-42  
 toxic substances, 78-79, 85  
 veterinary care, 192-193  
 Flaky skin, 45, 156  
 Floors, 137-138  
 Food and Drug Administration Good Laboratory Practice standards, 65  
 Food and feeding (*see also* Diet)  
   aquatic species, 84-85  
   enrichment activities with, 67  
   feeders, 66-67  
   management of caloric intake, 67  
   restricted or scheduled access, 30-31  
   sanitation of feeders and waterers, 71-72  
   storage, vermin control, and handling, 65-66  
   terrestrial species, 65-67

**G**

Genetically modified animals (GMAs)  
   breeding, 76  
   humane endpoints, 29  
   monitoring for unexpected outcomes, 28-29  
   occupational health and safety considerations, 21  
   recommended reading, 175-176  
 Genetics, recommended reading, 175-176  
 Gerbils, 43, 44, 52  
 Gnotobiotic animals, 52, 70, 135  
 Goats, 49, 62, 111, 156, 177, 192  
 Guinea pigs, 44, 51, 57, 71 n.2, 111, 156  
   (*see also* Rodents)

**H**

Hamsters, 44, 57, 64, 68, 71 n.2, 156 (*see also* Rodents)  
 Hazard identification and risk assessment, 18-19  
 Hazardous agents, 20-21  
 Health Research Extension Act, 34  
 Heat stress, 43, 44  
 Heating and air-conditioning, 139-140  
*Helicobacter* spp, 111, 113  
 Hepatitis B virus, 22  
*Herpesvirus*, 23, 112  
 Horses and ponies, 63, 64  
 Housing (*see also* Cages and caging; Macroenvironment; Microenvironment; Secondary enclosures; Space requirements; and *specific animals*)  
   aquatic species, 82-83  
   design considerations, 51  
   environmental enrichment, 52-54, 82-83, 173-175  
   flooring, 51-52, 54  
   life support system, 79-80  
   naturalistic environments, 55, 83  
   occupational health and safety considerations, 19-20  
   recommended reading, 172-173  
   repair or replacement, 51  
   sheltered or outdoor, 42, 44, 51, 54-55, 68, 74, 81, 83, 118, 134, 135, 139, 140  
   social, 51, 55, 58-59, 60, 82-83  
   terrestrial species, 50-63  
 Humane care, defined, 6  
 Humane endpoints, xvii, 5, 12, 27-28, 29, 114, 123, 165-166  
 Humidity (*see* Temperature and humidity)  
 Husbandry (*see also* Sanitation)  
   aquatic species, 84-87  
   bedding and nesting materials and substrates, 68-69, 85  
   caloric restriction, 30-31, 67  
   emergency, weekend, and holiday care, 35, 74-75, 87  
   food, 65-67, 84-85  
   pest control, 74, 87  
   terrestrial species, 65-75  
   waste disposal, 73-74  
   water, 67-68

Hydrogen peroxide, 72  
Hygiene, personal, 18, 19, 20

## I

Identification of animals, 75, 87  
Illumination/lighting, 47-49, 81, 141  
Imaging facilities, 146-147  
Immunization, 22  
Immunodeficient animals, 21, 28, 66, 145  
Infectious agents (see Biologic agents and hazards)  
Infectious disease research, 27  
Inspection of facilities and equipment, 34  
Institute for Laboratory Animal Resources (ILAR), 2, 16  
Institutional Animal Care and Use Committee  
  agricultural animals, 32-33  
  animal care and use programs and, 6, 11, 13  
  collaborating institutions, 15  
  endpoint considerations, 27-28  
  field investigations, 32  
  food and fluid regulation, 30-31  
  investigating and reporting animal welfare concerns, 23  
  membership and function of committee, 17, 24-25  
  multiple survival surgical procedures, 30  
  non-pharmaceutical-grade chemicals or substances, 31  
  occupational health and safety and, 17  
  physical restraint, 29-30  
  program management and, 13, 14-15  
  protocol review, 25-26  
  recommended reading, 169-170  
  special considerations during review process, 27-33  
  surgery and, 115-118  
  surgical procedures, 30  
  training and education, 15  
  unexpected outcomes, 28-29  
Institutional official, 13-14, 17, 23, 24, 25, 30, 35  
International Air Transport Association, 107  
International Committee on Standardized Genetic Nomenclature for Mice, 77  
Invertebrate animals, 2  
Irradiation facilities, 157-158

## L

Laboratory Animal Welfare and Training Exchange, 16  
Latex toxicity, 84  
Laws, regulations, and policies (see also Animal Welfare Act; Animal Welfare Regulations; Public Health Service Policy; *other specific acts and policies*)  
  recommended reading, 168  
  training in, 17  
Lighting (see Illumination/lighting)  
Lymphocytic choriomeningitis virus, 113

## M

*Macacine herpesvirus*, 23, 112  
Macaques, 23, 112  
Macroenvironment  
  aquatic species, 77-78, 86  
  defined, 42  
  terrestrial species, 42  
Management of animals (see Behavioral and social management; Husbandry; Population management)  
  aquatic species, 84-88  
  medical, 114  
  recommended reading, 172-173  
  terrestrial species, 63-77  
Mice (see also Rodents)  
  acclimation, 111  
  aggression in males, 53, 64  
  anxiety studies, 53  
  bedding and nesting materials, 52, 53, 68  
  breeding animals, 52  
  caloric restriction, 67  
  enrichment, 53, 54  
  GMAs, 28, 68, 145-146  
  housing, 53, 57, 145-146  
  identification/nomenclature, 77  
  illumination, 49, 137  
  infections, 111, 112  
  nude or hairless animals, 68  
  recommended reading, 184-187, 194-196  
  social stress, 53  
  space requirements, 57, 156  
  specific pathogen-free mice, 145-146  
  temperature and humidity, 43, 45  
  toe-clipping, 75

Microenvironment (primary enclosure)  
 aquatic species, 77-78, 82-83  
 defined, 42  
 terrestrial species, 42, 50-52  
 Midwest Plan Service, 33  
 Monitoring and surveillance  
 disease prevention, 112-113  
 facilities, equipment, and exposure, 19-20  
 food and fluid intake, 31  
 GMAs, 28  
 intraoperative, 119  
 postapproval, 33-34  
 postoperative care, 119  
 restrained animals, 29  
 sanitation practices, 72-73  
 Monkeys (see Nonhuman primates)  
 Monoclonal antibody production, 27  
 Moribund state, 28  
 Mouse hepatitis virus, 112, 113  
*Mycoplasma hyopneumoniae*, 112

## N

National Institutes of Health, 19, 155  
 National Research Council Committee on  
 Animal Nutrition, 65  
 Necropsies, 21  
 Nesting (see Bedding, nesting, and  
 substrates)  
 Neuromuscular blocking agents, 122-123  
 Nocturnal animals, 48  
 Noise and vibration  
 aquatic animals, 81-82  
 control, 142, 143  
 hearing protection for personnel, 22, 49  
 terrestrial animals, 49-50  
 Non-pharmaceutical-grade chemicals or  
 substances, 31-32  
 Nonhuman primates  
 acclimation, 111  
 behavioral and social management, xviii,  
 29, 53  
 enrichment, 53, 67, 137  
 environment, 43, 44, 45, 50, 139  
 food and feeding, 67  
 housing, xviii, 49, 111-112, 136  
 illumination, 48  
 infections, 23, 111-112  
 infusion pumps, 29  
 noise and vibration effects, 50  
 personal protective equipment for staff,  
 21-22  
 recommended reading, 182-184, 194  
 recordkeeping, 75-76  
 restraint, 29  
 space requirements, xviii, 56, 58-60, 61  
 temperature and humidity, 43, 44, 45,  
 140  
 transport, 107  
 ventilation, 47, 139  
 veterinary care, 194  
 zoonosis surveillance and, 23, 110  
 Noroviruses, 113

## O

Occupational health and safety program  
 administrative controls, 18  
 animal housing systems, 19-20  
 collaborative approach, 17, 21  
 control and prevention strategies, 18  
 engineering controls, 18, 19  
 facility and equipment support, 19-20  
 field studies or wildlife research, 18  
 hazard identification and risk  
 assessment, 18-19  
 hazardous animal experimentation, 18,  
 20-21  
 hazardous material containment, 149  
 hygiene, 18, 19, 20  
 medical evaluation and preventive  
 medicine for personnel, 22-23  
 monitoring, 19-20  
 noise exposure, 22, 49  
 personal protective equipment, 18, 20,  
 21, 23, 109, 146, 148, 167-172  
 recommended reading, 17, 19, 21,  
 170-172  
 regulations, 17, 18, 20, 21  
 reporting requirements, 23-24  
 responsibility, 18  
 safety committee, 17-18, 21, 32  
 security, 23  
 training, 17, 18, 20, 21, 22, 24  
 Organ or system failure research, 27  
 Other animals, recommended reading,  
 187-188  
 Outdoor enclosures/habitats, 42, 44, 51,  
 54-55, 68, 74, 81, 83, 118, 134, 135,  
 139, 140  
 Oversight (see also Institutional Animal Care  
 and Use Committee)  
 postapproval monitoring, 33-34

- recommended reading, 169-170
- responsibility for, 13
- Owl monkeys (*Aotus trivirgatus*), 112

## P

- Pain and distress (*see also* Distress)
  - analgesics and anesthetics, 12, 121-123
  - chronic, 122
  - guidelines and, 12, 199-200
  - humane endpoints, 5, 27, 123
  - indicators of, 120-121, 123
  - modeling/studies, 28
  - monitoring GMAs for, 29
  - multiple survival surgical procedures, 30
  - postoperative, 117, 120
  - prevention or alleviation, 5, 12, 26, 33, 35, 105, 114, 120-121, 200
  - recommended reading, 120, 188-190
  - restraint devices, 29
  - studies of, 34
  - "wind-up" phenomenon, 120
- Parvoviruses, 113
- Pasteurella multocida*, 112
- Pedigree management, 55, 76, 87
- Performance standard, defined, 6-7
- Personnel (*see also* Occupational health and safety program; Training and education; *specific personnel*)
  - animal welfare concerns and, 23-24
  - hygiene, 18, 19, 20
  - management, 15-24
  - medical evaluation and preventive medicine for, 22-23
  - occupational health and safety program, 17-23
  - protection, 21-22
  - security, 23
- Pest control, 74, 87, 110
- Pesticides, 65, 74
- Photoperiod, 47, 48, 81, 137, 143
- Photostressors, 47 (*see also* Illumination/lighting)
- Phototoxic retinopathy, 48, 49
- Physical hazards, 18, 19
- Physical plant (*see also* Facilities)
  - centralized vs. decentralized, 134-135
  - construction guidelines, 136-143, 196-197
  - corridors, 136
  - doors to animal rooms, 137
  - drainage, 138
  - floors, 137-138
  - functional areas, 135-136
  - general considerations, 133-135
  - HVAC, xviii, 46-47, 139-140
  - location, 134
  - noise control, 142
  - power and lighting, 141
  - recommended reading, 196-197
  - security and access control, 151
  - storage areas, 141-142
  - vibration control, 142
  - walls and ceilings, 138-139
  - windows, exterior, 137
- Phytoestrogens, 65
- Pigeons, 60, 180, 193
- Pilot studies, 26, 28
- Poikilothermic animals, 41, 44, 55, 80, 82, 108
- Policies, defined, 7
- Population management
  - aquatic species, 87-88
  - breeding, genetics, and nomenclature, 75-76
  - identification, 75, 87
  - recordkeeping, 75-76, 87-88
  - terrestrial species, 75-77
- Poultry, 44, 48, 60
- Practice standard, 7, 12
- Preventive medicine
  - animal biosecurity, xviii, 79, 105, 107, 108, 109-110, 111, 135
  - disease surveillance, diagnosis, and treatment, 112-113
  - quarantine and stabilization, 110-111
  - separation of animals by health status and species, 111-112
- Primary enclosures, 42, 43, 44-45, 46, 50-52, 72, 77, 82 (*see also* Cages and caging; Microenvironment)
- Primates (*see* Nonhuman primates)
- Principal investigator, 5, 16, 18, 27, 28, 32, 114, 155
- Principles (*see also* U.S. Government Principles)
  - defined, 7
  - the *Guide*, 1
- Procedural habituation and training, 29, 64-65
- Procedures, defined, 7
- Procurement of animals, 106-107



- Protocols for animal use  
 alternatives to animal use, 3, 5, 12, 25, 27, 162-164  
 conditioned-response, 31  
 food and fluid regulation, 30-31  
 IACUC review, 26-33  
 number of animals used, 5, 12, 15, 25, 26, 28, 106, 199, 201  
 postapproval monitoring, 33-34  
 reuse of animals, 5, 30  
 special considerations, 27-33  
 Three Rs, xvii, 3, 4-5, 17, 201  
 topics considered, 25-26
- Public Health Service Policy on Humane Care and Use of Laboratory Animals, 1, 12, 25, 56

## Q

- Quail, 60, 180, 193  
 Quarantine and stabilization, 110-111

## R

- Rabbits  
 behavioral and social management, 63  
 enrichment, 54  
 environment, 43, 44, 49, 54, 140  
 food and feeding, 67  
 housing, 51, 53, 58, 59  
 infections, 112  
 nomenclature, 77  
 recommended reading, 184-187  
 sanitation of cages, 71 n.2  
 space requirements, xviii, 59
- Rabies, 22
- Radiation hazards, 18, 20, 73, 147
- Rainbow trout, 112
- Rat Genome and Nomenclature Committee, 77
- Rat theilovirus, 112
- Rats (see *also* Rodents)  
 acclimation, 111  
 albino, 48-49  
 bedding and nesting materials, 52  
 breeding animals, 52  
 caloric restriction, 67  
 diseases, 45, 111, 112  
 GMAs, 145-146  
 identification/nomenclature, 77
- illumination, 48-49, 137  
 recommended reading, 184-187, 194-196  
 space requirements, 57, 156  
 temperature and humidity, 43, 44, 45
- Recordkeeping  
 clinical care, 115  
 population management, 75-76, 87-88
- Removal of animals from protocol, 26, 29, 31
- Reporting  
 accidents, bites, scratches, and allergic reactions, 23  
 animal welfare concerns, 17, 23-24  
 hazardous conditions or "near miss" incidents, 19  
 status of Animal care and use program, 25
- Reproduction (see Breeding and reproduction)
- Reptiles, 41-42, 44, 45, 77, 80, 81, 82, 83, 84, 85, 156, 178-179, 192-193
- Research and testing methodology, recommended reading, 165-166
- Research team, training and education, 16-17
- Respirators and respiratory protection, 22, 23
- Restraint, 29-30, 55, 122, 144
- Reuse of animals, 5
- Ringtail, 45
- Rodents, laboratory (see *also individual species*)  
 acclimation, 111  
 aggression in males, 53, 64  
 albino animals, 48-49, 141  
 anxiety studies, 53  
 barrier facilities, 145-146  
 bedding and nesting materials, 52, 53, 68-69  
 breeding, xviii, 49, 52, 57  
 caloric restriction, 67  
 diseases, 111, 112, 113  
 enrichment, 53, 54  
 euthanasia, 124  
 GMAs, 28, 68, 145-146  
 housing, 53, 57, 145-146  
 identification/nomenclature, 77  
 illumination, 48, 49, 137  
 implanted systems, 29  
 noise and vibration effects, 49, 50

pain and distress, 121-122  
 recommended reading, 184-187,  
 194-196  
 social stress, 53  
 space requirements, xviii, 56-58, 156  
 temperature and humidity, 43, 45  
 thermoneutral zone, 43

## S

Sanitation  
 aquatic species, 85-86  
 assessing effectiveness of, 72-73  
 bedding/substrate change, 70  
 defined, 69-70  
 facilities for sanitizing materials, 143  
 macroenvironment, 72-73  
 microenvironment, 70-72  
 Secondary enclosures, 42, 43, 45-46, 47, 78  
 (see also Macroenvironment)  
 Security, 23, 55, 151 (see also Biosecurity)  
 Separation of animals by health status and  
 species, 111-112  
 Sheep, 62, 64, 111, 156, 176-177, 191-192  
 Simian hemorrhagic fever, 111-112  
 Simian immunodeficiency virus, 111-112  
 Social environment, xviii, 51, 53, 64, 82-83,  
 121 (see also Behavioral and social  
 management; Enrichment; Housing)  
 Space requirements  
 agricultural animals, 60-63  
 aquatic species, 83  
 general considerations, 55-56  
 IACUC review, 56  
 laboratory rodents, xviii, 56-58  
 "minimum," xviii  
 nonhuman primates, 58-61  
 other common species (dogs, cats,  
 rabbits; pigeons, quail, chickens), 58,  
 59, 60  
 rabbits, xviii  
 Specific pathogen-free animals, 72, 108,  
 113, 135, 136, 145-146  
 Squirrel monkeys (*Saimiri sciureus*), 112  
 Statement of task, xix, 201-202  
 Storage areas, 141-142  
 Surgery  
 aseptic technique, 17, 34, 115, 116, 117,  
 118-119, 144  
 facilities, 116-117, 144-145  
 intraoperative monitoring, 119  
 multiple survival procedures, 30

oversight, 34  
 postoperative care, 44, 119-120  
 presurgical planning, 116  
 procedures, 117-118  
 recommended reading, 188-190  
 training, 115-116  
 Swine, 49, 53, 60, 62, 112, 136

## T

Tamarins (*Saguinus oedipus*), 112  
 Temperature and humidity  
 aquatic species, 41-42, 80-81  
 HVAC systems and, 139-140  
 terrestrial species, 43-45  
 Terrestrial species  
 activity, 63-64  
 bedding and nesting materials, 68-69  
 behavioral and social management,  
 83-85  
 breeding, genetics, and nomenclature,  
 75-76  
 emergency, weekend, and holiday care,  
 74-75  
 enrichment, 52-54  
 environment, 42-50  
 food and feeding, 65-67  
 housing, 50-63  
 husbandry, 65-75  
 identification, 75  
 illumination, 47-49  
 macroenvironment, 42  
 management, 63-77  
 microenvironment, 42, 50-52  
 noise and vibration, 49-50  
 pest control, 74  
 population management, 75-77  
 procedural habituation and training,  
 64-65  
 recordkeeping, 75-76  
 social environment, 64  
 space requirements, 55-63  
 temperature and humidity, 43-45  
 ventilation and air quality, 45-47  
 waste disposal, 73-74  
 water, 67-68  
 Tetanus, 22  
 Thermoneutral zone, 43, 156  
 Three Rs (replacement, reduction, and  
 refinement), xvii, 3, 4-5, 17, 201  
 Toxicology research, 27  
 Toxins (see Biologic agents and hazards)

Training and education, 20, 115-116  
 animal care personnel and technicians,  
 16, 50, 78  
 aquatic systems, 78  
 emergency preparedness, 35  
 IACUC members, 17  
 IACUC oversight of, 15  
 noise reduction, 50  
 postapproval review as, 34  
 recommended reading, 168-169  
 research team, 16-17  
 U.S. Government Principles, 12,  
 199-200  
 veterinary and other professional staff,  
 15-16  
 Transportation of animals, 12, 14, 32, 105,  
 107-109, 110, 111, 134, 135, 147,  
 150, 156, 188, 199  
 Trauma research, 27  
 Tuberculosis, 23, 112  
 Tumor models/studies, 27, 34

## U

Unexpected outcomes, 28-29, 34  
 US Department of Agriculture, 19, 30, 107,  
 148, 157  
 US Fish and Wildlife Service, 106, 107, 157  
 U.S. Government Principles for the  
 Utilization and Care of Vertebrate  
 Animals Used in Testing, Research,  
 and Training, 4, 12, 199-200  
 Uses and users of the *Guide*, 4-5

## V

Vaccine challenges/studies, 27  
 Ventilation and airflow (*see also* Air quality)  
 aquatic species, 80-81  
 containment of hazardous agents, 21, 47  
 filtered, 47  
 for static isolation caging, 47  
 HVAC system, 46, 47, 139-140  
 individually ventilated cages, 44, 46, 50,  
 58, 70-71, 111, 141, 146  
 preventive maintenance and evaluation,  
 47  
 recommended reading, 196-197  
 recycling air, 46-47  
 terrestrial species, 43, 45-47

Veterinary care (*see also* Clinical care and  
 management; Preventive medicine;  
 Surgery)  
 anesthesia and analgesia, 121-123  
 euthanasia, 123-124  
 pain and distress, 120-121  
 principles, 12  
 procurement of animals, 106-107  
 recommended reading, 188-196  
 responsibilities of attending veterinarian,  
 14  
 training and education of professional  
 staff, 15-16  
 transportation of animals, 12, 32, 33, 55,  
 107-109, 156, 195  
 Vibration (*see* Noise and vibration)

## W

Walls and ceilings, 138-139  
 Waste management (*see also* Sanitation)  
 anesthetic gases, 21, 147  
 disposal options, 73-74  
 drainage, 54, 138  
 flushing, 72  
 gases from primary enclosures, 46  
 hazardous materials, 20, 73-74, 148-149  
 soiled bedding, 85, 143  
 storage before incineration or removal,  
 136, 142  
 training, 20, 74  
 wastewater, 80, 87  
 Water/fluids  
 devices and delivery systems, 68  
 outdoor sources, 68  
 quality for aquatic species, 78-79, 85  
 regulated, 30-31  
 terrestrial species, 67-68  
 Windows, exterior, 137

## X

*Xenopus* spp., 79-80, 83, 88, 178-179,  
 192-193

## Z

Zebrafish, 79, 83  
 Zoonosis surveillance, 23, 32, 110



37 is not affiliated with the institution in any way other than as a member of the IACUC,  
38 and is not a member of the immediate family of a person who is affiliated with the  
39 institution. This individual should represent community interests and concerns.

40 a. Categories of Membership: There are two categories of IACUC members, regular  
41 voting members and ad hoc non-voting members. The ad hoc non-voting  
42 members should serve to provide consultation expertise to the IACUC. A  
43 permanent ad hoc seat is available to the Chair of the Research Committee. No  
44 more than three regular, voting members are allowed to represent the same  
45 university department or administrative unit. Members serve three year terms  
46 that can be continually renewed upon mutual agreement of a quorum of the  
47 committee and the member in question. However, rotation of membership  
48 should be encouraged to educate researchers in animal care policies and  
49 procedures. Membership tenure will be reviewed annually at the first meeting of  
50 the calendar year. The IACUC chair should serve a term of no longer than 6 years,  
51 and be replaced by someone with at least one year of IACUC committee  
52 experience.

53 b. Confidentiality Agreement: All voting members of the IACUC will sign a non-  
54 disclosure agreement regarding confidential research information in research  
55 protocols. This disclosure is not intended to conflict with compliance with PHS  
56 and AWS policies on the free reporting of incidents or concerns with animal care  
57 and use.

58 c. Subcommittees: Specialty or ad hoc subcommittees are formed by the IACUC  
59 when the need arises. The chair of the IACUC will be responsible for assigning  
60 IACUC members to subcommittees. Each subcommittee consists of several  
61 faculty members and one or more veterinarians that are assigned to the  
62 subcommittee by the IACUC Chair. The IACUC Chair also appoints a  
63 subcommittee chair. The subcommittee Chairs function to educate new IACUC  
64 members placed on their subcommittee as to the process of protocol review and  
65 to assist in prompting reviewers delinquent on a specific protocol.

66 d. IACUC Member Training: Training is a requirement for IACUC membership. All  
67 members of the IACUC receive training upon joining the IACUC. New members  
68 are expected to familiarize themselves with both TUN and federal animal care  
69 and use guidelines via IACUC subscribed training, which may include attend a  
70 training session offered by the IACUC Chair or an IACUC member designated by  
71 the Chair, online training, and/or IACUC specified training sessions available  
72 through the IACUC's subscription to AALAS. In addition, IACUC members may be  
73 assigned to receive training in specific areas of animal care and use as required  
74 for special IACUC reviews. Members are generally expected to become familiar

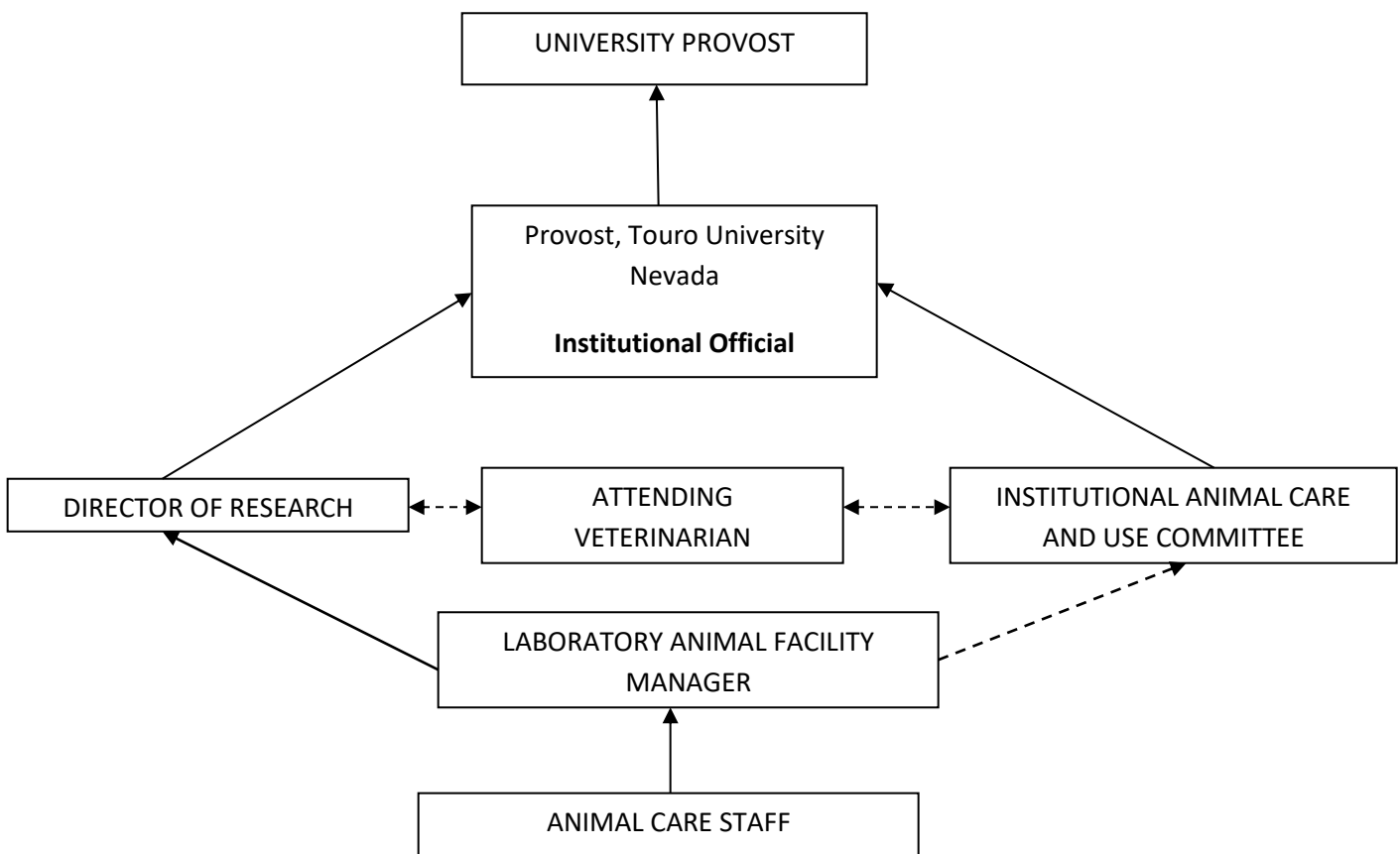
75 with local and federal policies through the monthly IACUC meetings and through  
76 discussions of policy, procedure or scientific issues. All members are encouraged  
77 to attend IACUC training workshops sponsored by Scientists Center for Animal  
78 Welfare.

- 79 e. Termination of Membership- Any member of the IACUC may be removed from  
80 the IACUC with or without cause by the TUN Institutional Official.

81 IV. ROLES AND RESPONSIBILITIES OF THE IACUC: As an agent of TUN, the IACUC shall:

- 82 a. Review, at least once every six months, the University's program for humane  
83 care and use of animals, using the Guide for the Care and Use of Laboratory  
84 Animals (Guide), NRC 2009, as a basis for evaluation.
- 85 b. Inspect, at least once every six months, all of the university's animal facilities  
86 (including, satellite facilities and investigator-managed housing facilities and use  
87 sites) using the Guide as a basis for evaluation.
- 88 c. Prepare reports of the IACUC evaluations conducted as required by a. and b.  
89 above, and submit these reports to the Institutional Official. The reports are  
90 updated at least once every six months upon completion of the required  
91 semiannual evaluations. Such reports contain a description of the nature and  
92 extent of adherence to, and also identify and explain departures from, the Guide  
93 and NIH/USDA Policy. The reports distinguish significant deficiencies from minor  
94 deficiencies. A significant deficiency being one which, consistent with NIH/USDA  
95 Policy, and, in the judgment of the IACUC and the Institutional Official, is or may  
96 be a threat to the health or safety of the animals. If program or facility  
97 deficiencies are noted, the reports must contain a reasonable and specific plan  
98 and schedule for correcting each deficiency. The reports are signed by a majority  
99 of the IACUC members and minority opinions are included.
- 100 d. Review concerns involving the care and use of animals at TUN.
- 101 e. Make recommendations to the Institutional Official regarding any aspect of the  
102 university's animal program, facilities, or personnel training.
- 103 f. Review and approve required modifications in (to secure approval) or withhold  
104 approval of activities related to the care and use of animals.
- 105 g. Review and approve required modifications in (to secure approval), or withhold  
106 approval of proposed significant changes regarding the use of animals in ongoing  
107 activities.
- 108 h. Review and approve required documentation of standard operating procedures  
109 for the Animal Resource Facility and individual protocols.
- 110 i. Be authorized to suspend an activity involving animals. If the IACUC suspends an  
111 activity involving animals, the Institutional Official, in consultation with the  
112 IACUC, will review the reasons for suspension, take appropriate corrective

- 113 actions, and, if public funds are used to support animal studies at TUN, report  
 114 that action to the NIH Office of Laboratory Animal Welfare (OLAW).
- 115 j. Ensure that all personnel involved with animal care, treatment or use are  
 116 provided with training on humane practice and the concept, availability and use  
 117 of research, teaching or testing methods that replace, reduce, or refine the use  
 118 of animals or animal distress.
- 119 k. Ensure that all personnel involved with animal care, treatment or use are  
 120 provided with training on occupational health and safety programs, their  
 121 implementation and function in promoting employee well-being.
- 122 V. LINES OF AUTHORITY: The IACUC authority and responsibility for oversight of TUN's  
 123 animal care and use program and ensuring compliance as follows:



- 124
- 125 a. The Laboratory Animal Facility Manager is responsible for the day to day  
 126 operations of the facility and supervision of Animal Care Staff. The Facility  
 127 manager reports to and is under the institutional supervision of the Director of  
 128 Research. The Facility Manager consults with the Attending Veterinarian on  
 129 matters of animal care, welfare, and housing. Matters involving the management  
 130 of the physical and financial management of the Facility are reported to the  
 131 Director of Research. The Facility manager also reports Facility status and any

132 incidents to the IACUC. The IACUC is responsible for monitoring all protocols for  
133 animal use, facility status and standard operating procedures for the facility. The  
134 IACUC and Attending Veterinarian report to the Institutional Official and consult  
135 with the Director of Research on fiscal matters. The Institutional Official reports  
136 to the University Provost.

137 VI. MEETINGS: The IACUC will meet normally meet monthly at a time agreed upon by  
138 the IACUC. Special meetings may be called for extenuating circumstances by the  
139 Chair of the IACUC. A meeting quorum consists of one more than half of the regular  
140 IACUC voting members. Sections of the IACUC meeting involving Protocol review  
141 issues may include investigators, invited as guests, whose protocols are under  
142 consideration, and/or other persons adding expertise on the issues of concern.  
143 Invited guests will be asked to remove his/herself from the room when discussions  
144 related to voting on a protocol are conducted. Approved minutes of the IACUC  
145 meetings are kept by the IACUC Chair and are posted on TUN's IACUC Blackboard  
146 Organization for review.

147 VII. RECORDS RETENTION: Approved minutes of the IACUC meetings are to be kept for a  
148 minimum of three years, with the exception of records that relate directly to  
149 protocols which must be kept for the duration of the activity and for an additional  
150 three years after completion of the activity. Records documenting such activities as  
151 the provision of adequate veterinary care, training, and occupational safety, are  
152 expected to conform to the recommendations of the Guide and commonly accepted  
153 professional standards. The IACUC is responsible for maintaining the following  
154 records:

- 155 a. OLAW Assurance documentation
- 156 b. Minutes of IACUC meetings
- 157 c. Records of IACUC activities and deliberations
- 158 d. Minority IACUC views
- 159 e. Documentation of protocols reviewed by the IACUC, proposed significant  
160 changes to protocols, and Progress Reports
- 161 f. IACUC semiannual program evaluations and facility inspections, including  
162 deficiencies identified and plans for correction
- 163 g. Accrediting body and USDA determinations.

164 VIII. IACUC OPERATING PROCEDURES

- 165 a. Review of Standard Operating Procedures (SOP): The IACUC is responsible for  
166 the identification, review and approval of standard operating procedures ARC  
167 Facility management and, as necessary, in areas of importance to researchers.  
168 Special SOPs for hazardous chemical or biohazard use specific to a protocol may  
169 be required by the IACUC or other University Committee. The IACUC may require



170 that such specific SOPs be appended to animal care and use protocols or prior  
171 approval from the appropriate University Committee (e.g. Biosafety Committee).  
172 Such SOP approvals may be required before the IACUC protocol approval can be  
173 processed. All general and facility SOPs approved by the IACUC will be displayed  
174 online for use by researchers. SOPs will be reviewed for potential amendment  
175 over time as necessary. The IACUC will review policies by regular voting  
176 procedures. SOPs may be reviewed as appropriate. Three main types of SOP will  
177 be recognized and certified by the IACUC:

- 178 i. IACUC guidelines and methods for common procedures as deemed  
179 necessary for uniform quality of animal care and use (e.g.CO2 euthanasia;  
180 isoflurane anesthesia). These SOPs may be authored at any level as  
181 directed by the IACUC.
  - 182 ii. SOPs that are related to an animal housing or other facility. These SOPs  
183 are generally authored by the respective managers and caretakers of the  
184 facilities as required for uniform quality of animal care and facility  
185 operations.
  - 186 iii. SOPs for species that are maintained by particular researchers, either  
187 singly or in collaboration. These will be typically authored by the  
188 researcher using the species and attached to a protocol as required by  
189 the IACUC.
- 190 b. ACTIONS ON CONCERNS FOR ANIMAL WELFARE: The IACUC will be responsible  
191 for establishing a procedure for the reporting of concerns regarding animal care  
192 in accordance with regulatory guidelines. The IACUC will also be responsible for  
193 the management of reported allegations as described below and enforcing  
194 corrective action as necessary
- 195 i. Reporting of Concerns: The mechanism for the reporting of concerns will  
196 include a reporting notice, also published on the Blackboard Research  
197 webpage and posted throughout the Animal Resource Center facility,  
198 which defines the mechanism for reporting concerns to the IACUC. The  
199 complete notice is given in Appendix I. Contact information and the  
200 names of the individuals to be contacted in the notice may be updated or  
201 amended as necessary without a formal amendment of these Bylaws. The  
202 IACUC Animal Welfare Hotline is posted throughout the Animal Resource  
203 Center as part of signage indicating who may be contacted with concerns  
204 regarding the program is posted in all animal housing areas. The IACUC  
205 will ensure that the Hotline is monitored on a regular basis and that an  
206 individual has been designated to review the automatically generated

207 line messages. A confirmation of Hotline status and any reports will be on  
208 the minutes of every meeting.

209 ii. Receiving and Managing Allegations: Reports of concerns involving the  
210 care and use of animals submitted to one of the above listed individuals  
211 or the hotline will be immediately distributed to the IACUC Chair,  
212 Attending Veterinarian, and Animal Resource Center Manager as  
213 appropriate. The Attending Veterinarian, or a designate, will investigate  
214 the allegation as soon as possible to determine the immediate health and  
215 well-being of the animals. The IACUC Chairman will refer allegations  
216 related to biological, chemical, or radiological safety to the appropriate  
217 University Committee Chair or Officer. Deficiencies which could  
218 compromise the immediate health and welfare of the animals will be  
219 remedied immediately by the Attending Veterinarian or designate. This  
220 may include the immediate suspension of the protocol pending further  
221 investigation, if necessary. Deficiencies which could compromise the  
222 immediate health and well-being of humans will be remedied  
223 immediately by referral to the appropriate University official by the  
224 IACUC Chair. Following any immediate actions taken to ensure animal  
225 welfare and/or human occupational health and safety concerns, the  
226 IACUC Chair will thoroughly investigate all aspects of the allegation and  
227 prepare a written incident report. At the discretion of the IACUC Chair,  
228 the investigation and report may be assigned to an individual or  
229 subcommittee. The incident report will be submitted to the IACUC for  
230 review and discussion. The IACUC Chair will send a letter outlining the  
231 alleged noncompliance issues to the Principal Investigator (PI) involved  
232 and inviting him/her to appear at an IACUC meeting. The letter will also  
233 inform the investigator of his/her option to appeal the decision by writing  
234 the IACUC Chair within 10 days of receipt of the letter, detailing the basis  
235 of the appeal and requesting a second meeting with the IACUC. The  
236 IACUC Chair will copy all noncompliance letters to the Institutional  
237 Official (IO). The Institutional Official, in consultation with the IACUC, may  
238 impose further corrective actions/sanctions for the investigator or  
239 support the IACUC's recommended corrective actions/sanctions. The  
240 IACUC Chairman will inform the originator of the allegation of the  
241 IACUC's disposition of the allegation. The objectives of the investigation  
242 within the meeting are to:

243 1. Review the incident report and discuss the allegations with the  
244 investigator(s) involved

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2. Substantiate the validity of the allegation by a majority opinion of the IACUC
  3. Record a listing of noncompliance issues
  4. Record all minority opinions of the noncompliance issues
  5. Record a listing of recommended corrective actions/sanctions for the investigator
  6. Record all minority opinions of the recommended corrective actions/sanctions
  7. Decide on the response to the originator of the allegation
  8. Record decisions and actions on these objectives within the minutes of the IACUC meeting.
- iii. Determination of Corrective Actions/Sanctions: All issues reported to the TUN IACUC involving known or suspected noncompliance with federal regulations and /or IACUC requirements or determinations governing animal research shall be submitted for review by the IACUC as described above. If the IACUC, by majority vote, finds the allegations have merit and represent noncompliance the following guidelines are to be used to determine corrective actions/sanctions:
1. For Serious or Continuous Noncompliance Issues: Acts of noncompliance are deemed serious if they can or do affect the health, safety or well-being of animals or personnel. The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description of the activity as stated in the protocol and approved by the IACUC. If the IACUC chooses to suspend or terminate a protocol, or replace a PI, this decision and the reason(s) for it will be reported to the Institutional Official and any appropriate oversight or funding organizations within one week of the decision. If the IACUC determines that the reported problem represents serious or continuing noncompliance with federal regulations and/or IACUC requirements or determinations it may, in consideration of the nature of the research study and the reported problem, institute one or more of the following sanctions:
    - a. Termination of the IACUC approval of the respective research study.
    - b. Suspension of the IACUC approval of the respective research study pending completion and acceptance by the

- 283 IACUC of an independent audit of the study and/or the  
284 submission, by the PI, of a written plan for the correction  
285 and/or prevention of the problem.
- 286 c. Suspension of further animal orders for the research study  
287 pending completion and acceptance by the IACUC of an  
288 independent audit of the study and/or the submission, by  
289 the PI, of a written plan for the correction and/or  
290 prevention of the problem
- 291 d. Institution of an IACUC-mandated corrective action plan  
292 and independent audit of the study.
- 293 e. Take such other action as the IACUC deems appropriate
- 294 2. Minor Noncompliance Issues: Acts of noncompliance are deemed  
295 minor if they do not affect the health, safety or well-being of  
296 animals or personnel. If the IACUC determines that the reported  
297 problem represents a minor noncompliance with federal  
298 regulations and/or IACUC requirements or determinations it may,  
299 in consideration of the nature of the research study and the  
300 reported problem take one or more of the following actions:
- 301 3. Elect to make corrective action only.
- 302 4. Provide a verbal and/or written listing of the issue of  
303 noncompliance to the investigator and require a corrective action  
304 plan at a regular meeting of the IACUC and recording this incident  
305 in the IACUC minutes.
- 306 5. Provide a written listing of the issue of noncompliance to the  
307 investigator and requiring a corrective action plan within a specific  
308 time period. The letter may or may not be copied to the  
309 investigator's department chair depending on the IACUC's  
310 decision on the sanction.
- 311 iv. Requests for Reconsideration: The procedure for request for  
312 reconsideration of any IACUC issues is as follows:
- 313 1. The PI of the study must submit in writing to the IACUC Chairman  
314 the details and rationale of the request within ten (10) days of  
315 being notified of the IACUC's decision.
- 316 2. The IACUC Chair will decide if the issue requires Full Committee  
317 Review (FCR) for further action.
- 318 3. The PI will be informed of the decision and may be asked to  
319 appear before either the full IACUC or the Subcommittee to  
320 discuss her/his concerns.

- 321 4. Following the discussion of concerns, the IACUC or Subcommittee  
322 will meet to reconsider the issue.
- 323 5. A written record of the discussion and reconsideration meetings  
324 will be made.
- 325 6. A summary of the written record along with the IACUC's  
326 reconsideration decision will be sent to the PI and the Institutional  
327 Official.
- 328 7. If the PI is dissatisfied with the result, further reconsideration of  
329 the matter may be requested in writing by appealing to the  
330 Institutional Official in writing. Such written requests must be filed  
331 with the IACUC Chair within ten (10) days of the IACUC's  
332 reconsideration of the decision being rendered.
- 333 8. The Institutional Official will meet with the IACUC or  
334 Subcommittee for further discussion if warranted.
- 335 9. A written record will be made of the meeting between the IACUC  
336 and the Institutional Official and a summary provided to the PI  
337 along with the final decision on the issue.

338 IX. PROTOCOL REVIEW AND APPROVAL PROCESS: The IACUC reviews all animal research  
339 and testing procedures. No animal experimentation or use is permitted at TUN  
340 without written approval by the IACUC. As such, all animal users at TUN must  
341 complete the TUN Animal Study Proposal, which may be obtained from the Division  
342 of Research Blackboard Organization or the IACUC Folder under the TUN Faculty and  
343 Staff Organization, webpage <https://bb-tun.touro.edu>. Only full-time TUN faculty  
344 may serve as PI on any TUN IACUC protocol. Non TUN faculty may be permitted to  
345 serve as PI with the sponsorship of a full time faculty member, who agrees to take  
346 responsibility for the research activities described in the protocol.

347 a. Application Submission

348 i. The PI must send the application to the IACUC Chair as an email  
349 attachment. Application forms, checklists and instructions are available  
350 to Faculty on the Department of Research's Blackboard page, the IACUC  
351 folder under the TUN Faculty and Staff Blackboard page, or by request  
352 submitted to [iacuc@tun.touro.edu](mailto:iacuc@tun.touro.edu).

353 ii. Investigators must also submit appropriate notifications to the Research  
354 and Biosafety Committee offices. Protocols will not be reviewed until  
355 they include a Research Registration Number, and dates for approval of  
356 biohazardous materials as issued after review by the Institutional  
357 Biosafety Committee.

- 358                   iii. Investigators are encouraged to submit protocols early enough to allow a  
359 pre-review. Pre-review is conducted by the attending veterinarian and  
360 IACUC members with expertise in specific related disciplines where  
361 possible or by recruited outside reviewers if it is determined that some  
362 particular expertise is required for protocol evaluation. The purpose of  
363 the pre-review is to suggest changes which will facilitate full IACUC  
364 approval. Feedback from these reviews is presented for the  
365 investigator's consideration. If the investigator concurs with the  
366 suggestions, he/she may make the recommended changes in the  
367 protocol. If the investigator disagrees with the suggestions, the reasons  
368 for disagreement may be reflected in changes to the protocol submitted  
369 to the IACUC. Alternatively, the investigator may disregard the  
370 suggestions and allow the unchanged protocol to be forwarded for FCR.
- 371                   iv. Protocols must be received by one week prior to the next scheduled  
372 IACUC meeting in order to be considered at that meeting.
- 373           b. Protocol Application Processing and Review: The application is received  
374 electronically by the IACUC Chair or her/his Designee from the Investigator.
- 375                   i. The Investigator is sent an email confirming application receipt by the  
376 IACUC Chair or her/his Designee.
- 377                   ii. Applications are processed in the order that they are received by the  
378 IACUC Chair or her/his Designee.
- 379                   iii. The IACUC Chair or her/his Designee will review the application for  
380 accuracy and completeness.
- 381                   iv. The IACUC Chair or her/his Designee will return the application to the  
382 Investigator if the application is incomplete or if there are any questions  
383 that need to be addressed before the application can be sent to the  
384 IACUC for review.
- 385                   v. Once the application is determined to be complete, the IACUC Chair  
386 assigns a protocol number to the protocol and updates the IACUC  
387 database. The protocol information will be entered into the database and  
388 an electronic copy of the application will be saved and posted under  
389 "Protocols Pending Review" on the IACUC's Blackboard Organization. The  
390 IACUC protocol review requires assessment of the following items:
- 391                           1. Federal Criteria for Granting IACUC Approval -TUN IACUC review  
392 of all protocols will be based on federal criteria as indicated in the  
393 Guide for the Care and use of Laboratory Animals, Eighth Ed.  
394 National Academies Press, including compliance in the areas of  
395 activities, pain/distress, surgery, euthanasia, Housing/health,

396 consideration of alternatives to painful procedures, necessity for  
397 animal use as opposed to alternative models, rational and  
398 methods, qualifications of personnel, and unnecessary duplication  
399 of studies.

- 400 2. Justification of deviations from requirements- any deviations from  
401 standard or federal criteria must be scientifically justified in  
402 writing.
- 403 3. Documentation of appropriate training and education for all  
404 personnel in the protocol in both species specific and general  
405 facility procedures.

406 vi. The IACUC Chair will then determine if the protocol is eligible for  
407 Designated Member review (DMR), if requested or the default full  
408 committee review process. No IACUC member can participate in the  
409 review of an activity in which that member has a conflicting or  
410 participatory interest except to provide information requested by the  
411 IACUC.

- 412 1. Designated Member Review: Protocols eligible for review will use  
413 the DMR process as described in NOT-OD-09-035.
  - 414 a. Protocols that do not involve unrelieved pain or distress  
415 may, at the assignment of the Chair, be reviewed by a  
416 designated IACUC member. The IACUC veterinarian is also  
417 asked to review the protocol for veterinary concerns. At  
418 the time of assignment to a designated reviewer, all IACUC  
419 members are notified by email of the protocol  
420 investigator, title, and a brief summary of proposed work.
  - 421 b. IACUC members also have access to the full protocol via a  
422 Blackboard Organization site established for the IACUC.
  - 423 c. All IACUC members have 3 working days to call for a FCR.
  - 424 d. If no individual calls for FCR, the decision of the designated  
425 reviewer to approve the protocol, request clarifications of  
426 the PI, or refer to FCR stands.
  - 427 e. As described below, the IACUC may vote to use the DMR  
428 process to review IACUC requested revisions in the  
429 protocol submitted the investigator.
- 430 2. Full Committee Review: The application will be sent electronically  
431 to IACUC members for review.
  - 432 a. A subcommittee may be designated for review; however,  
433 in addition, any IACUC member will have the opportunity

- 434 to volunteer to review the protocol. Reviews are expected  
435 to be completed in two weeks.
- 436 b. Once all IACUC reviewers have returned their reviews of  
437 the application, the IACUC Chair will render all questions  
438 anonymous and submit the compiled list to the  
439 Investigator and IACUC members. The Investigator must  
440 answer all questions and place their response directly  
441 below the question asked. The Investigator must also  
442 submit a revised protocol application with changes  
443 highlighted to reflect their responses.
- 444 c. The IACUC Chair will send the Investigator's responses and  
445 revised protocol application back to the IACUC reviewers  
446 for approval. This process continues until all IACUC  
447 reviewers have approved the protocol application.
- 448 d. The IACUC reviewers can decide to recommend approval  
449 of the protocol application, request the protocol be  
450 further reviewed by the full IACUC, or not approve the  
451 protocol. The IACUC may also decide to allow DMR of  
452 revisions by the PI at this time.
- 453 e. The Investigator will be notified immediately if it has been  
454 decided that the protocol will not be approved and the  
455 reason for the action explained.
- 456 f. Any reviewer may request that the entire IACUC review  
457 the application at the monthly protocol meeting.
- 458 g. Information regarding the IACUC's deliberations will be  
459 sent to the Investigator along with a list of any further  
460 actions the IACUC requires. Investigators may address the  
461 IACUC if they wish at the monthly meeting.
- 462 vii. Following review at the monthly meeting, the IACUC may approve a  
463 proposal as submitted, approve it after requested modifications have  
464 been made or reject a proposal outright. The process for these actions is  
465 as follows:
- 466 1. Approve: The IACUC considers that all significant points have been  
467 addressed by the investigator and that no question has been  
468 raised by any elements of the proposed study. The protocol will  
469 be submitted to the Biosafety Officer, ARC Manager, Facility  
470 Veterinarian and IACUC chair for signatures. Final approval from  
471 the IACUC chair will be withheld until all necessary training has



472 been completed by all individuals associated with the protocol. It  
473 is the responsibility of the PI to provide all necessary  
474 documentation of training to the IACUC chair. As a result of this  
475 approval, the investigator has permission of the IACUC to conduct  
476 the experiments on the number of animals described in the  
477 proposal. This permission does not supersede the rights of other  
478 committees or officials to restrict or modify research at TUN.  
479 IACUC protocol approval is provided for a time period of three  
480 years as specified by PHS Policy IV C 5. This policy requires de  
481 novo review of the protocol after three years. Protocols that have  
482 not significantly changed in the three years since their original  
483 submission can be resubmitted as renewals, and be reviewed by  
484 DMR rather than FCR (\*see – Modifications to Approved Protocols  
485 for definition of significant change). A final report of the previous  
486 execution of the protocol must be submitted before renewal will  
487 be considered, and the PI must demonstrate that the renewal is  
488 not an unnecessary repetition of the already completed protocol  
489 to be eligible for renewal. An approval letter or email is generated  
490 by the IACUC Chair and delivered to the Investigator after the  
491 renewal has been approved. An official written letter may also be  
492 generated and addressed to the granting agency for submission  
493 and verification of IACUC review and approval if needed.

494 2. Require Changes: The IACUC may request that the investigator  
495 amend the protocol to adhere to guidelines or concerns. The  
496 Chair will notify the PI of the IACUC's recommendations or  
497 required amendments. For the protocol to be considered for  
498 further action by the IACUC, the investigator must amend the  
499 protocol in compliance with the IACUC's  
500 recommendations/requirements or attach a letter explaining why  
501 the recommended changes should not be made. The IACUC may  
502 then consider the Investigator's response for approval, require  
503 further changes or disapprove the protocol. The IACUC may also  
504 decide to allow review of requested revisions by the DMR  
505 process. Under these circumstances, the Designated Member may  
506 approve changes and allow the protocol to proceed or not  
507 approve the revisions and refer the protocol back to the full  
508 IACUC for action.

509 3. Disapprove: The IACUC may disapprove a protocol if it does not  
510 believe that the protocol as submitted can be revised sufficiently  
511 to warrant approval or if the investigators refuse to modify their  
512 proposal or fail to supply information showing that their  
513 laboratory has appropriate facilities, training and/or staff for the  
514 proposed research. The reasons for disapproval will be presented  
515 to the investigator in writing. If an investigator chooses to  
516 resubmit a proposal which has been previously disapproved, it  
517 can be reconsidered at the next available IACUC meeting. The  
518 appeal should include the provision of additional evidence by the  
519 investigator or the solicitation of experts able to assist the IACUC  
520 in their concerns, or include the changes requested by the  
521 previous review. In all cases in which there is lack of IACUC  
522 unanimity, the reasons for disapproval by the majority or minority  
523 membership will be presented to the investigator in writing. The  
524 IACUC protocol review records will reflect this diversity of opinion.  
525 Ultimately the TUN IACUC has responsibility for the use of animals  
526 at the TUN. The disapproved proposals cannot be administratively  
527 approved by a higher authority. However, the opposite is not  
528 true; an IACUC approved protocol can be administratively  
529 disapproved due to financial, facility related or other  
530 considerations.

531 c. Other IACUC Protocol Actions

532 i. Termination: For failure to report annually and failure to complete  
533 required training, the PI is given a 30 day notice prior to termination  
534 date. PI will be notified of protocol termination by campus mail, phone  
535 call and/or email message. Renewal reports and documentation of  
536 training must be received 24 hours before the due date to avoid  
537 termination of the protocol. The ARC is notified of all IACUC terminated  
538 protocols and the Facility Manager in consultation with the Attending  
539 Veterinarian will decide the disposition of study animals. The IACUC will  
540 not review new or renewal protocols for any PIs who are non-compliant  
541 with renewals or annual reports. For failure to renew an expired protocol,  
542 termination will occur automatically on the due date. PIs will be notified  
543 of the impending expiration date at least one month before. Expiring  
544 protocols must have both a final report and renewal protocol filed before  
545 the expiration date to be renewed. Renewals will not be considered  
546 without an accompanying final report. Renewals must be received two

547 weeks prior to the expiration date to ensure they can be approved before  
548 the expiration date. Renewals received after this two week mark but  
549 before the expiration date will be considered, but continued work on the  
550 protocol will NOT be permitted past the expiration date until the renewal  
551 is approved, and violating this will result in termination of the protocol  
552 and denial of renewal. Animals housed in the vivarium on protocols  
553 awaiting renewal can be moved to the ARC's holding protocol for up to  
554 two months. ARC is notified of all IACUC expired protocols and the  
555 Facility Manager in consultation with the Attending Veterinarian will  
556 decide the disposition of study animals. The IACUC may terminate an  
557 approved protocol due to the following reasons:

- 558 1. Non-compliance issues- For non-compliance issues, particularly  
559 those that involve animal welfare concerns, protocols may be  
560 terminated immediately, as described above under animal care  
561 concerns procedures. However, a protocol may also be  
562 terminated for failure of the PI to comply with protocol review or  
563 investigation procedures.
  - 564 2. Failure to renew the protocol before the termination date
  - 565 3. Failure to submit annual reports before the due date
  - 566 4. Failure to complete or renew required training
- 567 ii. Withdrawal: The IACUC may withdraw any pending protocol from the  
568 review process if the PI does not respond in a timely fashion during the  
569 review process. This occurs when questions are sent to the PI and the PI  
570 takes longer than 2 months to respond. The IACUC will send notice to the  
571 PI that the protocol will be withdrawn from the review process if a  
572 response is not forthcoming.

573 d. ANNUAL PROGRESS REPORTING: Although the PHS Policy grants protocol  
574 approval for a three year period, the Animal Welfare Act requires continuing  
575 review of activities involving animals at appropriate intervals as determined by  
576 the IACUC, but not less than annually. To satisfy this AWA requirement, the  
577 TUN's IACUC requires each active protocol to go through the annual renewal  
578 process. The annual progress report review is the IACUC's method of satisfying  
579 the USDA requirement to annually monitor ongoing, approved activities that  
580 involve the use of animals. The purpose of this monitoring is to ensure that no  
581 changes have inadvertently taken place in the approved activity that might  
582 require further review by the IACUC. In addition, the monitoring ensures that  
583 any new requirements of the PHS, USDA, or the TUN have been addressed and  
584 are in compliance. Therefore the Annual Progress Report requires supplying only

585 basic, current information on the status of the project. Records for the Review  
586 Process will be maintained by the IACUC Chair and the ARC Facility Manager. The  
587 PI will be sent a reminder along with an Annual Progress Report for Approval to  
588 Use Vertebrate Animals in Research. However, it will be the responsibility of the  
589 PI to ensure that Progress Reports are completed in a timely fashion. Renewal  
590 review generally follows the same procedure described for new protocol review  
591 as outlined below:

- 592 i. As a courtesy, the Chairman will a reminder to the investigator renew  
593 along with a protocol-specific renewal application via email from the  
594 IACUC Chair 30 days before the renewal application has to be approved.
- 595 ii. The application is completed and emailed to the IACUC Chair by the PI
- 596 iii. Applications are processed in the order that they are received at the  
597 IACUC office.
- 598 iv. The IACUC Chair or designated IACUC member will review the renewal  
599 application and compare the application to the original protocol and any  
600 previously approved modifications for accuracy.
- 601 v. The Investigator is sent an email confirming application receipt.
- 602 vi. The IACUC records will be updated and both a paper copy and an  
603 electronic copy of the application will be saved.
- 604 vii. IACUC Chair or a designated IACUC Member checks that all required  
605 training programs and medical surveillance monitoring procedures for  
606 the protocol have been completed by each individual listed as working on  
607 the protocol.
- 608 viii. The IACUC Chair will return the progress report to the Investigator if the  
609 application is incomplete, inaccurate, or training and medical surveillance  
610 requirements have not been met.
- 611 ix. The Progress Report, along with the original IACUC approved protocol,  
612 will be distributed to members by posting to the IACUC Blackboard  
613 Organization under "Protocols pending review". An email will be sent to  
614 all members with a request for questions regarding the report, or  
615 consent for DMR approval.
- 616 x. Progress reports which have questions or concerns from IACUC members  
617 will be managed through the regular IACUC review process as outlined  
618 above. The PI must adequately address all concerns. FCR may be  
619 requested at any time by any IACUC Member.
- 620 xi. Once the application is approved, the IACUC Chair updates the IACUC  
621 database and delivers the approval letter to the Investigator.

- 622                   xii. Non-compliance Procedure: Protocols for which the PI does not submit a  
623 progress report will have their IACUC approval terminated. The  
624 termination process is as follows:
- 625                   1. The investigator receives email notices of the need to renew 30  
626 days before required renewal.
  - 627                   2. If the progress report is not received 24 hours before the due  
628 date, the IACUC will terminate the approval of the protocol on the  
629 progress report due date.
  - 630                   3. A protocol termination notification will be sent to the Animal  
631 Resource Center and any animals assigned to the protocol will be  
632 confiscated. The Attending Veterinarian and Facility Manager will  
633 decide on the disposition of confiscated animals.
  - 634                   4. If the progress report is received before the deadline but review  
635 of it cannot be completed by the due date, the PI will be granted  
636 conditional approval to continue the protocol, pending the official  
637 approval of the progress report.
  - 638                   5. No new protocols or protocol renewals will be reviewed for PIs  
639 who are non-compliant.
- 640 e. PROCESS FOR MODIFICATIONS TO APPROVED PROTOCOLS: Both the AWA and  
641 PHS Policy require that the IACUC review and approve, prior to initiation,  
642 proposed modifications to ongoing activities using animals. Modifications are  
643 submitted to the IACUC using a regular protocol application form with the  
644 submission designation of modification. The types of modifications which may be  
645 accepted for consideration as an amendment of the original protocol include:
- 646                   i. An Administrative Modification is an addition or deletion of personnel,  
647 protocol title change, funding source change, change in the animal source  
648 or vendor, or changes in laboratory address or addition of a laboratory to  
649 an original IACUC approved protocol. Administrative modification should  
650 be submitted via specialized forms, and requests will be reviewed by the  
651 IACUC Chair and do not require review by the IACUC. Modified protocols  
652 will be identified by the addition of  $Mn$  at the end of the protocol ID,  
653 where  $n$  = the number of revisions accepted. Administrative  
654 modifications do not need to be re-signed. The Chair will then provide an  
655 electronic copy of the new approved version of the protocol to the PI.
  - 656                   ii. Other modifications to an original IACUC approved protocol that are  
657 acceptable to be submitted as a modification must be presented in the  
658 text of a revised protocol application, and include:
    - 659                   1. changes in the anesthetic or the analgesic being used

- 660 2. changes in the method of euthanasia
- 661 3. changes in any surgical procedures or addition of a surgical
- 662 procedure,
- 663 4. requests for additional animals,
- 664 5. changes in any non-surgical procedures involving animals
- 665 6. changes in the animal strain, changes in the previously approved
- 666 USDA Pain/Distress Category
- 667 7. requests for additional test agents and other changes that
- 668 logically relate to the specific aims of the original protocol
- 669 application.
- 670 iii. Requests to change the PI of a protocol must be accompanied by a
- 671 revised version of the new protocol application, with all demographic,
- 672 funding and personnel information appropriately revised.
- 673 iv. The following types of changes cannot be requested as a modification
- 674 and must be reconsidered as a new protocol. Requests to make such
- 675 modifications will not be processed:
- 676 1. Changing the species used.
- 677 2. Requests to add new procedures that are unrelated to the specific
- 678 aims of the original protocol.
- 679 3. An unrelated change in the scientific aims of the original protocol
- 680 application
- 681 4. Switching survivability of surgery.
- 682 5. Switching from single to multiple survival surgeries.
- 683 6. Changes to a protocol that present animal welfare issues not
- 684 addressed in the original protocol.
- 685 v. It is the responsibility of the PI to clearly explain why the modification is
- 686 being requested and how it relates to the original specific aims of the
- 687 previously approved protocol. Modifications are reviewed in the same
- 688 manner as new protocols.
- 689 X. Internal Program Review: The IACUC will review policies by regular voting
- 690 procedures. SOPs may be reviewed as appropriate.
- 691 a. Semi Annual Facilities Inspections: According to PHS Policy and USDA
- 692 Regulations, the IACUC is required to inspect all TUN animal facilities every six
- 693 months. This includes all animal facilities in the Animal Resource Center and any
- 694 locations outside the ARC where animals are under TUN oversight are taken or
- 695 used. The USDA Regulations require inspection of the centrally designated or
- 696 managed animal resource facilities as well as any other animal containment
- 697 facilities in which animals are kept for more than twelve hours. PHS Policy

698 requires inspection of all surgical facilities and areas in which animals are  
699 maintained longer than 24 hours. These inspections provide an ongoing  
700 mechanism for ensuring that the university maintains compliance with the  
701 applicable animal care and use policies, guidelines and laws. The interaction of  
702 the IACUC and the animal care personnel at TUN is to be constructive, and not  
703 adversarial, as both ultimately share the same goals of responsible animal care.

704 i. TUN Facilities Inspection Procedure

- 705 1. The TUN IACUC Chair schedules the inspections of ARC facilities,  
706 which usually occur in the months of March and September, but  
707 not less than twice per year.
- 708 2. IACUC members are asked to volunteer for facility inspection on  
709 specific dates, usually to coincide with the monthly meetings and  
710 the Attending Veterinarian.
- 711 3. At least two IACUC members inspect each facility as required by  
712 the USDA Regulations.
- 713 4. No IACUC members are excluded should he/she wish to attend a  
714 particular inspection and additional ad hoc consultants may be  
715 used. The inspection team must have a working knowledge of the  
716 Guide and USDA Regulations in order to fully evaluate the  
717 facilities that are being inspected. In addition, each IACUC  
718 member can avail themselves to the Semiannual Program and  
719 Facility Review Checklist.

720 ii. Outside Facilities Inspection Procedure: For facilities outside the ARC, an  
721 updated list of all facilities to be inspected is maintained by the ARC  
722 facility Manager.

- 723 1. All proposals submitted to the IACUC must contain details on the  
724 locations at which animal research is to be performed.
- 725 2. The IACUC Chair and at least one other IACUC member inspect  
726 these facilities outside the ARC every six months. The inspection  
727 criteria are the same as used in ARC facilities.
- 728 3. The IACUC Chair notifies the supervisory personnel of housing  
729 facilities and animal-use sites to be inspected of the date and time  
730 of an inspection. Advance notification allows individuals to be  
731 available to answer questions.
- 732 4. If the appropriate personnel are not available on the scheduled  
733 date, the IACUC Chair and other IACUC members may return at  
734 their own discretion, without advance notice.

- 735 5. Notes are taken throughout the inspection by the IACUC Chair to  
736 assist in preparation of the final report.
- 737 6. Apparent deficiencies are discussed with the person in charge of  
738 the facility to ensure the accuracy of the team's findings.
- 739 7. The IACUC Chair prepares a draft report after the visit, noting  
740 deficiencies and the location.
- 741 iii. Deficiencies: Deficiencies are categorized as minor or significant. USDA  
742 Regulations and PHS Policy define a significant deficiency as one of  
743 significant threat to animal health or safety. Copies of the draft report are  
744 sent to the supervisors responsible for the areas cited and the ARC  
745 Facility Manager. Deficiencies are managed as follows:
- 746 1. A timetable and corrective action plans are requested for all  
747 deficiencies. All individuals to be involved in the corrections are to  
748 be consulted to ensure that the plan is realistic.
- 749 2. The timetable and plans are submitted to the IACUC Chair.  
750 Deficiencies noted as corrected immediately are inspected by the  
751 IACUC Chair to verify resolution. The remaining deficiencies and  
752 corrective action plans are presented to the IACUC regular  
753 meetings following the inspection.
- 754 3. The Format of the Facility Review Checklist is used for  
755 documentation.
- 756 4. The IACUC reviews the report to verify that all comments have  
757 been reported and that the corrective actions planned are  
758 adequate.
- 759 5. The IACUC Chair then uses this information to prepare the  
760 semiannual report to the Institutional Official on the status of the  
761 animal care and use facilities at TUN.
- 762 6. If the institution is unable to meet the corrective action plans  
763 proposed in the semi-annual report, the IACUC, through the  
764 Institutional Official, must inform Animal and Plant Health  
765 Inspection Service (APHIS) officials within fifteen working days of  
766 the lapsed deadline. If the activity is federally funded, the relevant  
767 agency also must be informed.
- 768 b. Semi Annual Program Review: Both the PHS Policy and USDA Regulations include  
769 a requirement that, semiannually, the IACUC conduct an evaluation of the  
770 animal care and use program. Key aspects of an animal care and use program  
771 that are emphasized in the semiannual evaluation include IACUC functions and  
772 procedures, including protocol review practices, provisions for dealing with a



773 "whistle blower" or other concerns regarding animal care and use, and the  
774 procedures employed to meet reporting requirements. In addition, the  
775 institution's occupational health program, veterinary care procedures and  
776 personnel qualification review process are evaluated. Program evaluation deals  
777 principally with administrative aspects of the animal care and use program.  
778 Ongoing review of established practices allows the opportunity for the IACUC to  
779 detect a gradual change in practices from written procedures, thereby allowing  
780 modification of one or the other as appropriate.

781 i. Program Review Procedure

- 782 1. Program reviews will be conducted generally at the same time as  
783 Facility reviews, typically at the March or September IACUC  
784 meetings.
- 785 2. The Sample Semiannual Program Review Checklist is used for  
786 guidance.
- 787 3. The IACUC will review and approve a draft report prepared for by  
788 the IACUC Chair from the program review comments.
- 789 4. Deficiencies will be categorized as minor or significant.
- 790 5. Copies of the draft report are sent to the parties responsible for  
791 the areas cited and a timetable and corrective action plans are  
792 requested for all deficiencies.
- 793 6. The IACUC Chair then uses this information to prepare the  
794 semiannual report to the Institutional Official on the status of the  
795 animal care and use facilities at TUN.
- 796 7. The IACUC will follow the progress of correction of deficiencies at  
797 monthly meetings until resolved.

798 XI. ANIMAL CARE AND USE COMPONENT OF THE INSTITUTIONAL OCCUPATIONAL  
799 HEALTH AND SAFETY PROGRAM: The IACUC is responsible for oversight of those  
800 portions of TUN's occupational health and safety program that directly relate to the  
801 care and use of animals. This includes the establishment of policies and oversight of  
802 training programs that involve animal use as outlined in the Program "Occupation  
803 Health Program for Persons with Animal Contact-TUN". The IACUC will review the  
804 Program as part of its Semiannual Review Process. The IACUC in coordination with  
805 designated Occupational Health and Safety personnel will make any  
806 changes/recommendations as necessary.

807 XII. PERSONNEL TRAINING FOR ANIMAL CARE AND USE AT TUN: The TUN IACUC will be  
808 responsible for monitoring and modifying where necessary, the general training  
809 program for animal care and use at TUN. General ARC facility training will be  
810 administered and documented by the ARC Facility manager. The Manager will

811 maintain training records of all persons with Facility access. Specific protocol related  
812 training must be documented as part of the protocol approval process. Records of  
813 IACUC required training for specific protocols will be maintained by the IACUC Chair  
814 and the PI. The animal care use training will consist of:

- 815 a. A general orientation to the ARC and animal care and use policies and  
816 procedures.
- 817 b. Species specific training for animals used within the ARC.
- 818 c. An orientation to animal care and use occupational health and safety.
- 819 d. Any additional or protocol specific training that the IACUC deems to be  
820 necessary for appropriate animal care and use.

821

## 822 Appendix I

823 The Animal Care and Use Committee at Touro University Nevada investigates all concerns  
824 regarding the care, treatment, and use of animals for research or teaching at the university. To  
825 report a concern, please contact any or all of the following:

- 826 • **Dr. Kimberly Congdon, Ph.D.**, IACUC Chair, [Kimberly.Congdon@tun.touro.edu](mailto:Kimberly.Congdon@tun.touro.edu),  
827 Telephone-702-777-4771
- 828 • **Dr. Roger Van Andel, DVM, Ph.D., ACLAM-** Attending Veterinarian, Animal Resource  
829 Center [ryanandel@ocm.utah.edu](mailto:ryanandel@ocm.utah.edu), telephone 510-642-9232.
- 830 • **Ms. Minnette Smith, LATG** - Animal Facility Manager [minnette.moore@tun.touro.edu](mailto:minnette.moore@tun.touro.edu),  
831 Telephone- 702-777-4774
- 832 • **Dr. Valeri Sarukhanov**- ARC- On-Call Veterinarian, [vals1999@gmail.com](mailto:vals1999@gmail.com), Telephone-  
833 702-635-4677
- 834 • **Dr. Mahboob Qureshi, M.D., Ph.D.** Dean of Research, ARC supervisor,  
835 [mahboob.qureshi@tun.touro.edu](mailto:mahboob.qureshi@tun.touro.edu), Telephone-702-777-1807

836

837 Reports can be made to any member of the University's Animal Care and  
838 Use Committee. Anonymous concerns may also be submitted through TUN's designated Hotline  
839 for Reporting Animal Use Concerns – 702-777-3888. Anonymous concerns are acceptable and  
840 will be investigated. Federal laws prohibit discrimination or reprisal for reporting violations of  
841 standards and regulations promulgated under the Animal Welfare Act.

842

# TUN

# Biosafety Manual



This Manual was updated: August, 2020

Approved by the IBC on August 26, 2020

## Table of Contents

Forward .....	13
Biosafety Program Administration .....	14
Introduction .....	14
1. Provost .....	14
2. Institutional Biosafety Committee (IBC).....	14
3. Biosafety Officer .....	15
4. Departmental Chairperson .....	16
5. Principal Investigator (PI)/Faculty Member.....	16
6. Student Workers.....	17
7. Staff.....	<b>Error! Bookmark not defined.</b>
TUN Institutional Biosafety Committee .....	19
Contact Information .....	19
IBC Chair.....	19
IBC Members: .....	19
Section I – BIOLOGICAL SAFETY PURPOSE .....	20
Section II – RIGHT TO KNOW GUIDELINES.....	21
A. Declaration .....	21
B. Introduction to Universal and Standard Precautions: .....	22
Section III – LABORATORY SAFETY TRAINING .....	23
A. Policy .....	23
B. Laboratory Safety Training Curriculum .....	24
Section IV – GENERAL LABORATORY SAFETY .....	26
A. Housekeeping .....	26
B. Protective Clothing.....	26
C. Eating, Drinking, and Applying Cosmetics .....	26
D. Pipetting.....	26
E. Needles and Pasteur Pipettes .....	26

F. Broken Glassware.....	26
G. Gas Cylinders .....	27
H. Hazard Warnings.....	27
I. Electrical Equipment.....	27
J. Fire Safety .....	27
K. Visitors (Unauthorized Personnel) .....	29
L. Waste Disposal .....	29
M. General Personnel Protection .....	29
N. Pregnancy Protection .....	30
O. Emergencies/First Aid .....	30
P. Absorbent Paper .....	30
Q. Disinfectants.....	30
R. Autoclave Operation .....	31
S. Mailing Etiological Agents .....	31
T. Vaccination .....	31
U. Biological Waste Handling Procedure.....	32
Section V – WARNING SIGNAGE .....	34
1. Hazardous Material Information System.....	34
2. Global Harmonized System Pictograms .....	36
3. Warning Symbols .....	37
4. Laboratory Waste Disposal .....	37
Section VI – BIOLOGICAL SAFETY .....	39
Introduction.....	39
A. Rules, Regulations and Guidelines: .....	40
B. Biological Safety Routes of Infection:.....	42
1. Through the mouth by:.....	42
2. Through the skin by: .....	42
3. Through the eye by:.....	42
4. Through the lungs by: .....	42
C. Biological Risk Assessment .....	43

1.	Custom of usage (or prevailing professional practice) .....	43
2.	Best available practice, highest practicable protection, and lowest practicable exposure .....	43
3.	Degree of necessity or benefit .....	43
4.	No detectable adverse effects .....	44
5.	Principal knowledge .....	44
D.	Risk Management .....	44
1.	Risk Groups .....	44
2.	Criteria for Risk Groups .....	45
3.	Comprehensive Risk Assessment .....	45
4.	Biosafety Levels.....	46
	Summary of Recommended Biosafety Levels for Infectious Agents .....	47
5.	Working with tissue culture .....	48
6.	Clinical Laboratory guidelines .....	49
7.	Preventing the spread of tuberculosis.....	49
E.	Administrative Controls .....	50
	Biohazard Warning Sign.....	50
	Training .....	50
	Bloodborne Pathogen (BBP) Program .....	50
	Recombinant DNA Program.....	51
	CDC Select Agents Requirements .....	51
	Institutional Biosafety Committee (IBC).....	51
F.	Engineering Controls.....	51
1.	Biological Safety Cabinets (BSCs).....	51
2.	Negative Pressure Rooms .....	52
3.	Other Safety Equipment.....	52
G.	Personal Protective Equipment (PPE) .....	53
1.	Face Protection.....	53
2.	Laboratory Clothing.....	53
3.	Gloves.....	53

4.	Respirators .....	54
H.	Recommended work practices .....	54
	Biosafety Cabinets Recommended procedures: .....	54
	Pipettes and Pipetting Aids .....	54
	Syringes and Needles .....	55
	Cryostats .....	55
	Centrifuge Equipment.....	56
	Blenders, Ultrasonic Disrupters, Grinders and Lyophilizes.....	57
	Safety Blenders .....	57
	Lyophilizer and Ampoules .....	57
	Loop Sterilizers and Bunsen Burners.....	58
	Vacuum Lines, Filters, and Traps.....	58
	Freezers and Refrigerators .....	58
	General Equipment .....	58
	Aerosol .....	58
	Experimental Work with Infectious Agents .....	59
	Human Material with reference to bloodborne pathogens.....	59
	Laundry .....	59
	Hand Hygiene .....	59
	Housekeeping .....	60
	Transportation of Material Out of the BSL2 Lab .....	60
I.	Disposal of Contaminated Materials .....	60
	Paper and Disposable Plastics.....	60
	a. Things to Be Returned:.....	61
	b. Things NOT to be returned: .....	61
	c. Methods to be followed: .....	61
	d. Used Syringes, Needles and Pasteur Pipettes .....	61
J.	Procedures Following Biohazardous Material Spill.....	61
	Small Spills (To Not Exceed 50 ml).....	61
	Large Spills .....	62



Hazardous Spill Report .....	62
K. What to do in the Event of Personal Exposure or Injury Involving Biohazardous Material.....	62
General Considerations.....	63
For Bleeding and Wound Care.....	63
Burns – Heat/Chemical .....	63
Eye Splash Chemical .....	63
Eye – Foreign Body (dust or metal, paint, wood chips) .....	63
L. Interstate Shipment of Infectious Agents.....	64
1. “Biological Substance” .....	64
2. “Infectious Substance” .....	64
3. “Interstate Traffic”.....	64
4. Volume not exceeding 50 ml.....	65
5. Volume greater than 50 ml.....	65
6. Dry Ice .....	65
7. Identification.....	65
8. Damaged Packages.....	66
9. Registered Mail or Equivalent System .....	66
10. Notice of Delivery, Failure to Receive .....	67
11. Requirements; Variations.....	67
M. Importation Permits for Etiologic Agents .....	67
a) General .....	68
b) Importation Permits.....	68
c) Federal Regulations.....	68
d) Letter of Authorization.....	69
e) Packaging Requirements.....	69
f) Other Permits .....	69
g) Exports of Infectious Materials.....	69
N. Final Rule: Additional Requirements for Facilities Transferring or Receiving Select Agents .....	70

O.	Select Agents .....	70
	Viruses: .....	70
	Rickettsia.....	70
	Fungi .....	71
	Toxins.....	71
P.	Standard microbiology lab practice at the Touro University Nevada .....	71
	a) Standard Microbiological Practices .....	71
	b) Special Practices .....	72
	c) Safety Equipment (Primary Barriers) .....	75
	d) Laboratory Facilities (Secondary Barriers).....	76
Q.	Research Involving Recombinant DNA .....	77
	Experiments Using Risk Group 2, Risk Group 3, or Restricted Agents as Host Vector Systems .....	77
	Experiments in which DNA from Risk Group 2, Risk Group 3, or Restricted Agents is cloned into Non-Pathogenic Prokaryotic or Lower Eukaryotic Host-Vector System. ....	77
	Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation .....	78
	Biosafety Considerations for Research with Lentiviral Vectors .....	78
	Exempt Experiments .....	78
	For Your Information .....	79
	Section VII – Laboratory Animals .....	80
	A. Care and Use of Laboratory Animals .....	80
	B. Care and Handling of Infected Animals .....	80
	C. Procedures appropriate for the handling of infected animals are given below .	81
	D. General Guidelines that Apply to Animal Room Maintenance.....	81
	E. Cage Cleaning .....	82
	F. Transportation of Research Animals .....	83
	G. Transportation of materials between the animal facility and the research labs	83
	H. Visitors (Unauthorized Personnel).....	83
	Appendix A Bloodborne Pathogens Exposure Control Plan .....	85

Purpose .....	85
Exposure determination .....	85
Compliance methods .....	86
Universal precautions .....	86
Engineering and work practices controls .....	86
Sharp containers .....	86
Safe medical devices .....	86
Work practices .....	86
Personal protective equipment (PPE) .....	87
Storage area .....	87
PPE use and disposal .....	87
Housekeeping .....	88
Contaminated laundry .....	88
Regulated waste .....	88
Labels and signs .....	89
Hepatitis B vaccine .....	89
Exposure incident and post-exposure evaluation and follow-up .....	89
Procedures for Evaluating the Circumstances Surrounding an Exposure Incident ....	90
Information provided to the health care professional .....	90
Health care professional’s written opinion .....	91
Training and training records .....	91
Record keeping .....	92
Plan evaluation and review .....	92
Appendix B Select Agents (CDC) .....	93
HHS and USDA Select Agents and Toxins .....	93
HHS Select Agents and Toxins .....	93
USDA Select Agents and Toxins .....	94
USDA PLANT PROTECTION AND QUARANTINE (PPQ) Select Agents and Toxins .....	95
OVERLAP Select Agents and toxins .....	95

Exempt Amounts Select Agent Toxins Permissible Per Principal Investigator.....	96
Appendix C USA PATRIOT Act of 2001 .....	97
Title VII - Strengthening the Criminal Laws Against Terrorism Section 817- Expansion of the Biological Weapons Statues Overview: .....	97
What "biological agents" are covered by the Act? .....	97
What "toxins" are covered by the Act? .....	97
What are the "Select Agents"? .....	97
Who is a "restricted person"? .....	97
What is the responsibility of the Principal Investigator? .....	98
Appendix D Appropriate Chemical Disinfection Properties and Applications of Disinfectants.....	99
Liquid .....	99
Gas .....	99
Alcohols .....	100
Formalin.....	100
Glutaraldehyde .....	100
Phenol and Phenol Derivatives.....	100
Quaternary Ammonium Compounds (Quats).....	100
Halogens (Chlorine and Iodine) .....	101
Vapors and Gases .....	101
Room Decontamination .....	101
Autoclaving Procedures .....	101
Appendix E Definitions from the NIH Guidelines for the Use of Exempt rDNA Molecules .....	103
Section III-F. Exempt Experiments .....	103
Section III-F-1 .....	103
Interpretation/Examples: .....	103
Section III-F-2 .....	103
Interpretation/Example: .....	103
Section III-F-3 .....	104
Interpretation/Example: .....	104

Section III-F-4 .....	104
Interpretation/Example: .....	104
Section III-F-5 .....	104
Interpretation/Example: .....	104
A list of those organisms that are known to exchange DNA.....	105
Section III-F-6 .....	106
Interpretation/Example .....	106
Exemption C1.....	106
Exceptions to Exemption C1 .....	106
Exemption C2.....	107
Exceptions to Exemption C2 .....	107
Exemption C3.....	107
Exemption C4.....	107
Exceptions to exemption C4.....	107
Exemption C5.....	108
Appendix F TUN IBC Biosafety Risk Assessment Summary.....	109
Risk Factor Assessment Outline .....	109
Pathogenicity/virulence .....	109
Infectious dose .....	110
Route of spread.....	110
Communicability .....	110
Environmental stability .....	110
Host range.....	110
Economic aspects .....	111
Availability of prophylactic and therapeutic treatments.....	111
Vectors .....	111
Concentration/volume .....	111
Recombinant properties .....	111
Appendix G Touro University Nevada Hazardous Materials Spill Report Form.....	113
Appendix H Pest Management.....	114

REFERENCES AVAILABLE..... 120

## Forward

This Biosafety Manual has been developed by the Biosafety Officer (BSO) and Institutional Biosafety Committee (IBC) at Touro University Nevada (TUN). The manual's purpose is to accomplish the following goals:

- To protect personnel from exposure to infectious agents.
- To prevent environmental contamination.
- To provide an environment for high-quality research while maintaining a safe workplace.
- To comply with applicable federal, state, and local requirements.
- To create a secure laboratory environment to prevent unauthorized utilization of the biological agent.

The Biosafety Manual provides university-wide safety guidelines, policies, and procedures for the use and handling and disposal of biohazards. Although the implementation of these procedures is the responsibility of the Principal Investigator (PI), its success depends largely on the combined efforts of laboratory supervisors and employees. Planning for and implementation of biological safety must be part of every laboratory activity in which biohazardous materials are used.

Recommendations in the Manual define a "standard of practice" that laboratories should follow.

In general, the handling and disposal of biological agents and toxins, including recombinant DNA molecules, requires the use of various precautionary measures depending on the material(s) involved. This manual will provide assistance in the evaluation, containment, and control of these biohazards. All parties involved or working with these materials should be familiar with the contents of this manual and must complete the required training. The IBC Chairperson and the BSO at TUN are available to provide additional advice when requested.

# Biosafety Program Administration

## Introduction

The rules and procedures set forth in the Biosafety Manual have two major purposes: (1) to protect students, employees, and others against unnecessary and potentially harmful biohazardous materials exposure and (2) to provide for an atmosphere of biosecurity on campus. For these rules and procedures to be effective, it is important to have a structured administrative format in place to define the roles and responsibilities of each person or administrative office.

### 1. Provost

The Provost is ultimately responsible for assuring that comprehensive campus-wide programs are in place for the safe handling of all biohazardous materials at TUN.

### 2. Department of Research

The Chief Research Officer (CRO) has responsibility for ensuring that research is conducted in full conformity with the provisions of the safety manuals and all federal, state, and local regulations. The CRO is ultimately responsible for:

- Promoting the importance of safety in all research activities.
- Supporting the laboratory safety programs that protect all TUN faculty, staff, students and our laboratory visitors.
- Working closely with the Senior Provost/CEO and/or Provost of TUN in appointing an IBC member who works closely with the Department of Research to develop and effectively implement biosafety and Chemical Hygiene Plan at TUN.
- Supporting the provisions of this document for facilities working with biologically and chemically hazardous materials.
- Referring protocols to the Institutional Biosafety Committee as deemed necessary.

### 3. Institutional Biosafety Committee (IBC)

The Institutional Biosafety Committee (IBC) has been charged by Federal law with the planning and implementation of the campus Biosafety Program with a purpose to ensure the health and safety of all personnel working with biohazardous materials. At this Institution, membership on the IBC is appointed by the Provost and consists of the Chairperson, faculty, and community representatives. At least two community members, with no Institutional affiliation other than membership on the IBC, is required and appointed to represent the interest of the surrounding community



with respect to health and the protection of the environment. The IBC as a whole represents collective expertise and research experience in biohazardous materials and biosafety in experiments that may pose potential risks to health or the environment.

The IBC is responsible for ensuring that research conducted at the Institution is in compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) and the Select Agent Rule, drafting campus biosafety policies and procedures, and reviewing individual research proposals for biosafety concerns. The IBC provides a review of IBC protocols that originate with researchers at TUN and its clinic.

PIs who wish to perform research using biohazardous materials must submit an application to the IBC (application form found on Box). The full Committee reviews all applications. Studies that involve work at Biological Safety Level (BSL) 2 or higher containment are pre-reviewed by a primary and secondary reviewer. Research involving wild type BSL1 organisms, as defined by the CDC/NIH Guidelines on Biosafety in Microbiological and Biomedical Laboratories (BMBL) manual, also requires an application to the IBC for approval. For complete description of protocol review and approval procedures, please refer to the IBC bylaws (found on Box). All reviews include an assessment of the a) containment levels required by the NIH Guidelines for the proposed research, b) laboratory facilities procedures and practices, and c) training and expertise of personnel involved in the research activity.

The IBC is authorized by the Provost to limit or suspend any research that does not comply with biosafety policies and procedures set forth in this Biosafety Manual and in the NIH Guidelines. Additionally, noncompliance with basic procedures as determined during the laboratory inspection may result in the halting of research until corrective action is taken. The Biosafety Officer (BSO) will consult with the IBC Chairperson and/or the Associate Dean for Research or designee to determine if non-compliance to established procedures poses a threat to public health.

#### **4. Biosafety Officer**

The Biosafety Officer (BSO) serves as the campus expert for biological safety and is responsible for providing guidance for all aspects of the biosafety program at TUN. The Biosafety Officer duties include, but are not necessarily limited to:

- Providing regular biosafety training to all faculty, staff, students and members of the IBC.

- Reviewing all research protocols submitted to the IBC and providing technical guidance.
- Preparing the Biosafety Manual and revising as necessary.
- Distributing the Biosafety Manual to any faculty member working with biological materials.
- Conducting periodic laboratory visits to provide biosafety guidance and monitor compliance with the TUN Biosafety Program.
- Investigating accidents involving infectious agents.
- Informing the IBC of pertinent biosafety information and program administration issues.
- Providing guidance on purchase of biological safety equipment including biological safety cabinets.
- Providing consultation for shipping infectious agents.
- Providing support for clean-up and decontamination of biological materials.

The BSO, together with 1 or 2 members of IBC will oversee BSL-2 laboratory inspections to ensure that established safety standards are rigorously maintained (see [Box>IBC](#) for the laboratory inspection worksheets) and the Institutional training program for biosafety. The BSO will also act as the Responsible Official to ensure that the requirements of 42 CFR Part 73 entitled, "Possession, use, and transfer of select agents and toxins rule" are met on behalf of the Institution.

## 5. Deans

The Dean shall be responsible for the overall conduct of scientific research carried out in their respective college.

## 6. Departmental Chairperson

Departmental Chairs are responsible for the implementation of safe practices and procedures in their schools or departments. They are responsible for:

- Promoting a positive safety culture in their departments,
- Ensuring that their department's activities are compliant with relevant research safety policies, regulations, laws, and guidelines,
- Ensuring that all faculty, staff, and students in their purview have had appropriate safety instructions.

## 7. Principal Investigator (PI) or Responsible Faculty Member

PI is directly responsible for assuring that all laboratory personnel, including student workers, follow the institutional safety policies and procedures and that the laboratory is operated in a safe manner. His or her knowledge and judgment are

critical in assessing risks and appropriately applying the biosafety guidelines. The PI shall have available in the laboratory a biosafety manual containing generalized and specific information for laboratory personnel as required by the IBC. Specific duties include but are not limited to:

- Creating a safe culture in the laboratory that is positive and encourages open discussion of biosafety concerns, problems or violations of procedure.
- Completing laboratory specific Standard Operating Procedures (SOP) for their level of research and ensuring that all laboratory staff are knowledgeable in the biosafety SOPs.
- Maintaining and making available to their staff a copy of the TUN Biosafety Program Manual.
- Ensuring that all laboratory staff, maintenance personnel, and laboratory visitors have been appraised of the biological risks present in the laboratory.
- Registering all necessary projects (recombinant DNA; human infectious agent research; research involving human blood, cells, tissues and other potentially infectious human materials (OPIM), research involving biological toxins; and research involving select agents) with the TUN IBC
- Not initiating or modifying the above listed projects without prior approval of the IBC.
- Assuring that personnel working with hazardous biological materials are adequately experienced and trained for the safe handling of such materials.
- Training must be documented and retained with this manual for at least 3 years after the employee leaves that laboratory.
- Informing HR before engaging any individuals not employed by TUN in activities that might expose them to biological and chemical hazardous materials.
- Immediately reporting to the BSO any significant violations of the biosafety policies and procedures or any potential exposure to hazardous biological materials.

## **8. Student Workers**

Student workers will be required to take appropriate training available online and onsite in their research lab and/or animal research center. They are the direct responsibility of individual faculty member/PI who will serve as the research mentor for the student. The student must follow the general safety rules and regulations in the TUN Biosafety Manual as appropriate.

## 9. Other Laboratory Users

Other laboratory users will be required to complete the training modules as appropriate for their role in their respective areas of activities and type of engagement. They should avail online and on-site training materials as appropriate. All laboratory users should follow general safety rules and regulations as outlined in the TUN Biosafety Manual. All laboratory users should be responsible for applying their judgment and making critical decisions at the time of need in the labs, ARC, and clinic. Specific duties under this policy include, but are not limited to:

- Following all laboratory and TUN biosafety and security practices and procedures.
- Reading the entire laboratory customized TUN Biosafety Program manual and asking for assistance understanding any portions that are not comprehended.
- Reviewing and familiarizing themselves with all protocols and organisms used in the laboratory regardless of whether they are working directly with the organism.
- Completing all required in-person, lab-specific safety training.
- Knowing all emergency and spill response procedures established by the Principal Investigator or supervisor.
- Reporting to the Principal Investigator or supervisor all problems, violations in procedure, exposure events or spills as soon as they occur.

# TUN Institutional Biosafety Committee

## Contact Information

### IBC Chair

Tarik Zaman, PhD (702) 777- 3105 [tarik.zaman@tun.touro.edu](mailto:tarik.zaman@tun.touro.edu)

### IBC Members:

#### Biosafety Officer

Vladimir Bondarenko, PhD  
(702) 777-1806 [vladimir.bondarenko@tun.touro.edu](mailto:vladimir.bondarenko@tun.touro.edu)

#### Committee Members

Daniel Bollard, MPH, Director, Environmental Health and Safety (EHS)  
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Marina Ioudina, MD, PhD, Assistant Professor of Physiology  
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Daniela Rodriguez, BS, Lab Manager  
(702) 895-5782 [daniela.rodriquez@unlv.edu](mailto:daniela.rodriquez@unlv.edu)

**EMERGENCIES (from a campus phone): 5-911(police/fire) 007 (Security) or 702-358-6701 (Security Cell)**

## Section I – BIOLOGICAL SAFETY PURPOSE

The purpose of this Laboratory Safety Manual is to provide information concerning TUN's Safety Policy and Procedures, thereby promoting a safe working environment. Although the manual is primarily designed for compliance by the Institute's scientific, technical, and supportive staff, all other employees must be knowledgeable about these safety policies, and the procedures for implementation. In 1983, the Federal Occupational Safety and Health Administration (OSHA) set forth the Occupational Safety and Health Standard entitled "Hazard Communication Standard" (29 CFR 1910.1200) and Laboratory Standards (29 CFR 1910.1450). These standards, and similar existing, state and local governmental ordinances, have been commonly called the "Worker's Right to Know" laws which provide minimum standards that employers must adhere to for informing employees about occupational-related hazards in the workplace. On August 28, 1987, OSHA published the Final Rule (Standard) (See Final Rule: Additional Requirements for Facilities Transferring or Receiving Select Agents), which supersedes all State and Local Regulations regarding the use of toxic substances in laboratories. The policies, regulations, and procedures defined in this manual are one method of compliance with the Worker's Right to Know Laws. However, this manual has a much broader scope than occupational-related hazards. It is not just a means for the Institute to meet its obligation to inform its employees, but it is also a guide to follow in making the Institute a safer workplace. Accordingly, this manual covers a wide spectrum of safety precautions, ranging from daily housekeeping chores to procedures to follow in emergencies. It addresses the following specific issues:

1. General Laboratory Safety.
2. Biological Safety.
3. Role and Responsibility of the Institute's Biosafety Committee, and the Institute's Biosafety Officer.

It is the responsibility of each employee, student, volunteer, visiting faculty, and staff to follow the rules of laboratory safety. It is the responsibility of each laboratory employee, particularly the Principal Investigator, to read and understand the information contained in the Manual, and to keep the Manual readily accessible for review and emergency usage. The Manual will be updated as new safety information or governmental regulations are obtained. TUN reserves the right to delete, add or amend the contents of this Manual. Occupational hazard regulatory rules will undoubtedly continue to be changed. Accordingly, no representation can be made, or responsibility is undertaken by TUN regarding the completeness, accuracy, or continuing validity of the contents of this Manual. In the final analysis, each employee must assume his or

her responsibility to work in a safe manner, thereby avoiding personal harm or endangering others.

## Section II – RIGHT TO KNOW GUIDELINES

### A. Declaration

**Note:** This section is required to be reviewed and signed upon acceptance of a position or before the employee begins working at TUN.

Biomedical research often requires the use of hazardous materials, including radioisotopes, infectious agents, and hazardous chemicals. While working at TUN, it is likely that you will be required to handle such materials. It will be your specific right and obligation to know, before using a hazardous material in an experiment, what is the nature of the material, its specific hazard, and the proper procedures for its use. Radioactive material is not currently in use at TUN. However, if using radiation in other collaborative settings please seek advice from that institution's Radiation Safety Office. Prior to utilizing any substance, each employee of TUN has the right and obligation to be educated in the proper use and risks associated with the substance. If, as an employee of TUN, you have any questions about any substance you work with, you should contact your Principal Investigator or the BSO. See TUN Institutional Biosafety Committee on page 19 for telephone numbers. With your Right to Know, come specific responsibilities for your protection and the protection of others. It is mandatory that all employees adhere to government and TUN's guidelines and regulations in the use and disposal of any hazardous materials. In addition, all reasonable precautions to assure the safety of yourself and others must be taken. If you are ever in doubt, have a problem with the use of any materials, or have a complaint about experiments done by others, the following procedures are to be followed:

1. Discuss the problem with your immediate supervisor.
2. If unsatisfied, discuss the problem with the Institute's Biosafety Officer.
3. If still unsatisfied, contact the Institute's Biosafety Committee Chair.

It is the policy of TUN to provide a safe working environment for personnel and to provide documentation of policies and procedures which have been implemented to eliminate or reduce employee exposure to bloodborne pathogens. Procedures have been developed to identify those individuals with occupational exposure to blood, and other potentially infectious materials, and provide them with training, protective equipment, hepatitis B vaccine, and post-exposure follow-up in accordance with the OSHA Standard on Occupational Exposure to Bloodborne Pathogens (See 29 CFR Part 1910.1030) <http://www.osha.gov/SLTC/bloodbornepathogens/standards.html> and current recommendations from the Centers for Disease Control and Prevention (CDC). All research laboratory personnel who have any exposure to bloodborne pathogens

should contact the Touro University Health Clinic immediately. If it is after business hours, the employee should call the BSO or 5-911 if urgent.

### **B. Introduction to Universal and Standard Precautions:**

Universal Precautions were explicitly developed to prevent infections from bloodborne pathogens. Standard Precautions basically expand upon Universal Precautions by covering more body fluids and tissues. All human blood and certain body fluids are treated as if they are known to be infectious for HBV, HIV, and other bloodborne pathogens. Universal Precautions are intended to prevent parenteral, mucous membrane, and non-intact skin exposures of workers to bloodborne pathogens. Universal Precautions apply to blood and body fluids containing visible blood, tissues, semen, vaginal secretions, cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids. Universal Precautions do not apply to feces, nasal secretions, sputum, sweat, tears, urine, vomit, or saliva unless they contain visible blood.

**See Appendix A for Touro University Nevada’s Bloodborne Pathogen Exposure Control Plan**



## Section III – LABORATORY SAFETY TRAINING

### A. Policy

As an integral part of TUN, all laboratory personnel must participate in the mandatory Chemical Hygiene Course provided online. Laboratory safety training will be obtained in accordance with TUN's Safety Policies and Procedures. The PI working in a research laboratory is responsible for ensuring that all laboratory activities under his or her control are conducted in a manner that presents the least possible hazard to employees and the surrounding community. The Principal Investigator must ensure that all safety policies and regulations are enforced, and that necessary safety equipment is available in the laboratory. The Principal Investigator has the primary responsibility for the health and safety of all personnel under his/her jurisdiction, including employees, students, guest scientists, and visitors. The Principal Investigator's responsibilities include:

1. Identification of hazards and assessment of the risks associated with operations.
2. Ensuring that laboratory personnel is aware of hazards and of the precautions they should take in carrying out their assigned tasks.
3. Selection of proper laboratory safety practices, and engineering controls necessary to minimize personal injury or property damage.
4. Informing laboratory personnel of the rationale for selection of appropriate preventive medical practices, serologic monitoring, and immunization protocols in conjunction with Human Resources, Institutional Biosafety Committee, and Biosafety Officer.
5. Providing instruction and demonstration for personnel in the practices and techniques required for their assigned tasks and laboratory operations.
6. Maintaining the Laboratory Safety Manual.
7. Ensuring that necessary safety equipment is available in the laboratory, used when required, and adequately maintained.
8. Establishing, and periodically reviewing emergency procedures for accidental spills, and any overt exposure to hazardous substances in conjunction with the Institutional Biosafety Committee and Safety Office.
9. Complying with all policies and procedures as outlined in this Manual.

Each employee and student working in a research laboratory has the following responsibilities:

1. Complying with the Institute's Safety Policies and Procedures.

2. Maintaining awareness of the risks associated with assigned duties.
3. Taking all necessary and appropriate safety precautions relevant to the performance of their duties.
4. Becoming familiar with emergency procedures prior to accidental spills, overt personal exposures, fire, etc.
5. Reporting unsafe conditions or practices to the Principal Investigator, BSO, Research Administrator, or Chair of the Institutional Biosafety Committee.
6. Reporting all incidents resulting in injury or exposure to hazardous agents, to employee's supervisor and Employee Health Services.

Health and safety awareness will be promoted among principal investigators, managers, supervisors, employees, students, and others (visitors, contractors, community members) through orientation programs, and available online education and training sessions, as appropriate.

## **B. Laboratory Safety Training Curriculum**

The Safety Training curriculum shall include, but not be limited to, the following list of topics, depending on the roles and responsibility of the faculty, staff, or student:

- Chemical Hygiene
- Laboratory Safety
- Basic Biosafety
- Animal Biosafety
- OSHA Personal Protective Equipment
- OSHA Bloodborne Pathogens
- Human Gene Transfer
- NIH-Recombinant DNA Guidelines
- Select Agents, Biosecurity and Bioterrorism
- Emergency and incident response
- Shipping and Transport of Regulated Material

All personnel are required to complete the OSHA Bloodborne Pathogen training and are required by law to renew their certification annually. All personnel and students who have access to any laboratory on TUN's campus are required to complete the Bloodborne Pathogen Course.

Training needs to be renewed annually or as needed based on policy or procedure changes. All training will be refreshed every three years.

## Section IV – GENERAL LABORATORY SAFETY

### A. Housekeeping

Many safety and health problems can be avoided through observance of good housekeeping procedures, including cleaning the work area, and general maintenance of the laboratory. All unnecessary glassware and materials must be removed from benchtops after use to avoid clutter that may cause accidents. Floors should be kept free of boxes, instruments, and supplies by storing them properly.

### B. Protective Clothing

A laboratory coat must be worn when in a laboratory while conducting experiments. Laboratory coats are worn to protect regular clothes from hazardous materials and should be removed whenever leaving the laboratory environment. Open-toed footwear should not be worn in laboratories at TUN. As a further precautionary measure, disposable gloves, chemical aprons, respirators, goggles or eye shields must be used when appropriate. Furthermore, disposable gloves are not to be worn outside of the laboratories, i.e., gloves must never be worn in hallways, elevators, or public areas of the Institute. With the exception when transporting hazardous materials, one hand must be gloved for protection, leaving the other hand ungloved to facilitate opening doors, pressing elevator buttons, etc.

### C. Eating, Drinking and Applying Cosmetics

Eating, drinking, food preparation, and the application of cosmetics in laboratories are forbidden. Food, including lunches, MUST NOT be stored in laboratory refrigerators.

### D. Pipetting

Pipetting by mouth is forbidden. This regulation is important. There are many alternatives to mouth pipetting. With a little practice, it is possible to work both quickly and accurately with mechanical devices.

### E. Needles and Pasteur Pipettes

Attempts to re-sheath needles or remove them from the syringe should be avoided as they result in accidents. Unsheathed needles must be carefully placed in the special sharps container for disposal. The container must be sealed with tape and marked: "Autoclave and Discard," as specified in the Institute's Policy and Procedure.

### F. Broken Glassware

Recommended procedures:

1. Dispose of any damaged glassware.
2. Do not use cracked or chipped glassware.
3. When disposing of cracked, chipped, or broken glassware, use forceps and heavy gloves.

Place disposable glassware in appropriate containers located in the laboratory.

## G. Gas Cylinders

All cylinders, including empty cylinders must be firmly secured to the wall, bench, or cart. Proper regulators must be used. Do not lubricate, modify or tamper with a cylinder or regulator valve.

## H. Hazard Warnings

As a precautionary measure, all equipment used for chemical and biological purposes must be clearly identified with appropriate labels, signs, or other conspicuous identification. High voltage electrical equipment must be labeled accordingly.

Removal of Warnings: Radioactive and Biohazard Warning Labels can only be removed after appropriate decontamination or sterilization procedures have rendered them safe for further usage.

Multipurpose Warnings: The Safety Officer provides the necessary safety information concerning approved laboratory signage based on regulatory requirements. These signs have been or will be placed on the door(s) of the respective laboratory with the appropriate hazard warning information.

## I. Electrical Equipment

Recommended procedures:

1. Inspect electrical equipment periodically for frayed cords, faulty control switches, and thermostats.
2. Do not try to repair any equipment yourself, contact the Facility Director immediately.
3. Never by-pass the ground or safety devices on a piece of electrical equipment.

## J. Fire Safety

Fire safety is a precaution applicable to all personnel. At the Institute, there are three basic elements to the Fire Safety Program.

***Prevention: The ability to identify potential fire risks and eliminate them. Some of the procedures to eliminate fire risks are:***

1. **Practice Good Housekeeping**
  - a. Do not allow trash to accumulate.

- b. Use the proper trash receptacles.
- c. Keep combustibles to a minimum in your work area.
- d. Keep flammable liquids properly stored.
- e. Keep corridors, aisles, and doors free of clutter to assure safe passage in the event of an emergency.
- f. Smoking is not permitted on the TUN property.

**2. Practice Electrical Safety**

- a. Do not overload outlets.
- b. Do not use extension cords in place of permanent wiring.
- c. Do not use damaged equipment.
- d. Do not store combustible or flammable material near electrical appliances that produce heat.

***Detection: Even with a good program of prevention in place, the possibility of fire exists. In the event of fire remember***

**RACE**

**R** = rescue people in immediate danger.

**A** = alarm (activate a manual pull station and call the emergency operator).

**C** = contain the fire by closing the door to the room.

**E** = evacuate patients, visitors, students, and employees to safe areas.

***Extinguish: In accordance with TUN’s Fire Safety Program, all employees are trained in the proper procedures regarding fire safety.***

**Types of Fire Extinguishers**

<b>Class</b>	<b>Material</b>	<b>Extinguisher</b>
Class A	Wood, Cloth, Paper	Water or dry chemical or Halon
Class B	Greases, Gasoline, Oils	CO2 or dry chemical or Halon
Class C	Electrical Devices	Chemical or Halon
Class D	Combustible Metals	Special Technique

***Exercise good judgment when deciding to extinguish the fire!  
You must determine to “fight or flight.”***

**Use of the Fire extinguisher**

**PASS**      **P** = pull the pin.

- A** = aim the extinguisher at the base of the fire.
- S** = squeeze the handle while holding the extinguisher upright.
- S** = sweep the nozzle from left to right to extinguish the fire.

**Remember:** Do NOT let the fire get between you and the exit!

Accordingly, all personnel upon employment should know where the nearest:

- a. Location of the fire alarm is and how to use it.
- b. Fire extinguisher is and how to use it.
- c. Locate where the evacuation route is.

If the fire alarm sounds – leave the building by the nearest (or designated) fire exit. Close all doors behind you (on the basis of last person out). Use stairways. Do not use elevators.

#### **K. Visitors (Unauthorized Personnel)**

Unauthorized personnel are prohibited from entering the laboratories and animal facilities. Individuals under 18 years of age, immunosuppressed persons, and pregnant visitors are not allowed to enter the laboratories of the Institute. As is the case for all personnel and visitors in a research laboratory, the Principal Investigator is responsible for training, assigning appropriate tasks, and monitoring for safety practices.

#### **L. Waste Disposal**

Waste disposal depends on the nature of the material. Hazardous chemicals and flammable solvents are collected in special containers and disposed of by licensed Environmental Services. Biological and infectious waste (bleached or autoclaved) are also collected by approved removal services. Our current service provider for biohazardous waste is Republic Services.

#### **M. General Personnel Protection**

1. Hallways and laboratory exits must never be blocked with equipment, file cabinets, and other laboratory supplies.
2. Safety showers and eyewash stations are located in designated areas of the facility; find the one nearest your workspace. Safety showers and eyewash stations should be free from obstructions and hazards.
3. All volatile substances should be used in fume hoods and stored in explosion-proof solvent storage cabinets. Keep all flames away from volatile solvents.

4. Special gloves and safety glasses should be part of your laboratory equipment if the nature of your work includes the danger of spills, breakage and explosive materials.
5. Ear protection should be used when working with high-frequency sonic cell disrupters and homogenizers. Sonicators should be operated in a closed cabinet.
6. Glass jugs – preferably, safety-approved bottle carriers should be used instead of glass jugs for transporting liquids. When glass jugs are used, the jug should not be carried by the handle. Instead, one hand should support the base of the jug.

#### **N. Pregnancy Protection**

The pregnant woman and her fetus are uniquely susceptible to the effects of ionizing radiation, toxic chemicals, and infectious agents present in the laboratory. The time of greatest risk is the first 8 to 12 weeks of pregnancy, during which the woman may not know she is pregnant. The following precautions should be taken:

1. If you are pregnant, it is at your discretion to declare your pregnancy to the Institute's Employee Health Service. If you choose to declare your pregnancy, the radiation exposure limits will be reduced by a factor of ten (10).
2. Avoid using known teratogens (embryotoxins) if at all possible. Commonly used laboratory teratogens include formamide, organmercurials, lead compounds, and anesthetic agents.
3. Discuss your work with your physician to determine what additional precautions should be followed. If your duties require you to work with infectious agents, consider all possible consequences to yourself and your child.

#### **O. Emergencies/First Aid**

First Aid Kits in laboratories and offices are for minor injuries. In the case of a serious injury or illness, call for emergency action immediately at **5-911** and Security at ext. 007 or cell 702-358-6701.

#### **P. Absorbent Paper**

Plastic-backed absorbent paper on laboratory benchtops will help control spills only if it is placed plastic side down.

#### **Q. Disinfectants**

Disinfectants commonly used are: (a) Spor-Klenz containing hydrogen peroxide; (b) Clorox and Alcide containing sodium hypochlorite; (c) iodine compounds; (d) phenolics; (e) ammonium compounds, and (f) 70% alcohol. It is recommended that



disinfectants have an Environmental Protection Agency (EPA) Registration Number and be effective against tuberculosis. The investigator should examine the expiration date and determine whether the disinfectant is corrosive (i.e., Clorox). Contact time dictates the effectiveness of any disinfectant. See the package labeling for recommended contact time. If contact time is not specified, keep surface wet with disinfectant for at least 10 minutes. See Appendix for more information on disinfectants.

#### **R. Autoclave Operation (*only authorized personnel are allowed to operate autoclaves*)**

Autoclaves use pressurized steam to destroy microorganisms and are the most dependable system available for the decontamination of laboratory waste. All biosafety waste from C1404 is to be autoclaved prior to entering the general biohazard waste flow. The autoclave needs to be tested monthly for effectiveness. This is accomplished through a biologics test using sensitive spores. The testing and logging of autoclave verification is the responsibility of the BSO or their designated representative (the Lab Manager).

#### **S. Mailing Etiological Agents**

Based on the CDC recommendations, the U. S. Postal Service has adopted regulations for the packaging and labeling of etiological agents. According to these rules, such substances may be mailed only if they are intended for medical or research purposes and if they are properly packaged to prevent leaks or spills. All shipments and mailings are to be processed through the Shipping Department utilizing certified packers and labels. Specific restrictions and special permit requirements are mandated by federal guidelines, referred to as The Final Rule (See Interstate Shipment of Infectious Agents and Importation Permits for Etiologic Agents for an explanation of definitions and details for packaging, labeling, and mailing etiological elements).

#### **T. Vaccination**

TUN, in keeping with Section 6(b) of the OSHA Act of 1970, 29 U.S.C. 655 will offer hepatitis B vaccine at no cost to all employees at risk for HBV infection. The program can be scheduled through the Touro Health Clinic. The Institution will also offer all employees who may be at risk for other infectious agents (e.g., rabies, tetanus, and booster for chickenpox, measles, mumps, and rubella) a complete vaccination series free of charge through the Touro Health Clinic. The need for these specific vaccinations is determined by the supervisor in conjunction with the medical consultant, and they are scheduled as needed.

Individuals requiring immunization for any infectious agents must sign a release form indicating their comprehension of the need for immunization and their agreement

to be or not to be immunized. Immunization requirements should be determined in conjunction with the Infection Control Plan, which indicates who is at risk.

## U. Biological Waste Handling Procedure

The generator must segregate biological waste from other types of waste at the point of origin into the following categories:

### Infectious, Potentially Infectious, or R-DNA Biological Waste (Category 1)

- Any material containing or contaminated with human pathogens.
  - Any material containing or contaminated with animal pathogens.
  - Any material containing or contaminated with plant pathogens.
  - Any material containing or contaminated with recombinant DNA or recombinant organisms.
- Laboratory and clinical wastes, containing human or primate blood, blood products, tissue, cell cultures, and other potentially infectious material (OPIM), including:
- Used, absorbent materials contaminated with blood, blood products, or OPIM
  - Non-absorbent, disposable devices that have been contaminated with blood, body fluids, or OPIM.
- All cultures Laboratory waste containing infectious, potentially infectious, or rDNA must be inactivated prior to leaving the facility. The preferred method is steam sterilization (autoclaving), although incineration or chemical inactivation (e.g., treatment with household bleach) may be appropriate in some cases.
  - Storage of all non-inactivated waste in this category is restricted to within the generating laboratory. Infectious or pathogenic waste must be held in a closed/covered biowaste container and may not be stored longer than 24 hours prior to inactivation.
  - Biological waste containers and bags for material that is infectious/potentially infectious to humans must be labeled with the biohazard symbol.
  - Filled or partially filled biological waste containers and boxes should not be held for more than 30 days.

### Non-infectious Biological Waste

This category includes the following:

- Used labware (tissue culture dishes and flasks, Petri dishes, centrifuge tubes, test tubes, pipettes, vials, etc.) from clinical or biomedical labs that are NOT contaminated with any of the biological wastes listed in category 1 above
- Gloves used in clinical or biomedical labs that are NOT contaminated with any of the biological wastes listed in category 1 above

- Disposable personal protective equipment used in clinical or biomedical labs that are NOT contaminated with any of the biological wastes listed in category 1 above
- Unused medical devices
- Items contaminated with blood from animals not known to or expected to, contain pathogens

The material should be placed in the red bag-lined cardboard biological/biomedical waste box

Note that chemically contaminated material (i.e., DNA extraction tubes contaminated with phenol/chloroform, specimen cups containing formalin, chemically contaminated gloves, etc.) must be handled as chemical waste.

## Section V – WARNING SIGNAGE

### 1. Hazardous Material Information System

Health – Blue	Flammability – Red	Reactivity – Yellow	Specific – White
4- Deadly	4 – Flash point <73F	4 – May detonate	Oxy – Oxidizer
3 – Extreme Danger	3 – Flash point <100F	3 – Shock & Heat May Detonate	Acid – Acid Alk – Alkali
2 – Hazardous	2- Flash point <200F	2 – Violent Chemical Change	Cor – Corrosive
1 – Slightly Hazardous	1 – Flash point >200F	1 – Unstable at Elev. Temp	W Use no water
0 – Normal Material	0 – Will not burn	0 – Stable	Rad –Radiation

**Note: Each diamond represents a warning symbol based on the particular hazard classification.**



## 2. Global Harmonized System Pictograms

# CHEMICAL HAZARD SYMBOLS

Chemical hazard symbols are found on some home products, as well as bottles of chemical reagents in the lab. Here, we take a look at European hazard symbols and the various dangers that they warn of.



### ENVIRONMENTAL HAZARD

Indicates substances that are toxic to aquatic organisms, or may cause long lasting environmental effects. They should be disposed of responsibly.



### ACUTELY TOXIC

Indicates life-threatening effects, in some cases even after limited exposure. Any form of ingestion and skin contact should be avoided.



### GAS UNDER PRESSURE

Container contains pressurised gas. This may be cold when released, and explosive when heated. Containers should not be heated.



### CORROSIVE

May cause burns to skin and damage to eyes. May also corrode metals. Avoid skin & eye contact, and do not breathe vapours.



### EXPLOSIVE

May explode as a consequence of fire, heat, shock or friction. Chemicals with this label should be kept away from potential ignition sources.



### FLAMMABLE

Flammable when exposed to heat, fire or sparks, or give off flammable gases when reacting with water. Ignition sources should be avoided.



### MODERATE HAZARD

May irritate the skin, or exhibit minor toxicity. The chemical should be kept away from the skin and the eyes as a precaution.



### OXIDISING

Burns even in the absence of air, and can intensify fires in combustible materials. Should be kept away from ignition sources.



### HEALTH HAZARD

Short or long term exposure could cause serious long term health effects. Skin contact and ingestion of this chemical should be avoided.

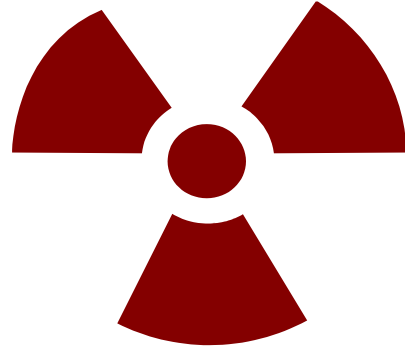


### 3. Warning Symbols

**Biohazard Warning Symbol**



**Radiation Warning Symbol**



### 4. Laboratory Waste Disposal

<b>Laboratory Material</b>	<b>Infectious Waste/Sharps (Red Bag, Cardboard Box, Or Sharps Container)</b>
Ampules	Yes
Animal Wastes	Yes, if exposed to zoonotic Infection or human pathogens
Broken Glass	Yes
Chemotherapeutic Agents (antineoplastics)	No
Chromatography Columns	Yes
Cloning and sequencing equipment	Yes
Cotton tips Swabs (wooden)	Yes (*)
Coverslips	Yes
Culture Dishes	Yes
Culture Flasks	Yes
Culture tubes & tops, plastic	Yes

Electrophoresis plates	Yes
Gauze	Yes (*)
Rods (glass or hard plastic)	Yes
Scalpel Blades	Yes
Slides	Yes
Specimen Containers, hard plastic or glass	Yes
Specimen Containers, soft Plastic	Yes
Syringes/needles	Yes
Test Tubes	Yes
Tubing (glass)	Yes
Cautery, handheld	Yes
Patient Treatment Items	Yes (*)
Sharps Boxes, full	Yes (*)
Rods (glass or hard plastic)	Yes
Scalpel Blades	Yes

*(\*) If contaminated with blood/body fluids/infectious agents*



## Section VI – BIOLOGICAL SAFETY

Almost any form of biological research involves the use of some potentially hazardous biological materials. A successful program to ensure biological safety and environmental control in the laboratory depends on careful observance of regulatory laws and meticulous attention to safe laboratory practices. The term “containment” is used in describing safe methods for managing infectious agents in the laboratory environment where they are being handled or maintained. The purpose of containment is to reduce or eliminate exposure of laboratory personnel, other persons, and the outside environment to potentially hazardous agents. Emphasis should be placed on the use of containment equipment to protect laboratory personnel. In this regard, having each laboratory worker dedicated to maintaining good safety practices is the most important element in a safety program.

### Introduction

Biohazardous materials are defined as materials of biological origin that have the capacity to produce deleterious effects on humans or animals, including:

1. recombinant DNA molecules
2. micro-organisms containing recombinant DNA molecules
3. micro-organisms classified as risk group 1 (RG-1) non-exempt, RG-2, RG-3, or RG-4
4. biological products derived from RG-1 (non-exempt), RG-2, RG-3, or RG-4 microorganisms
5. diagnostic specimens used in research known or reasonably expected to contain pathogens in RG-1 (non-exempt), RG-2, RG-3, or RG-4
6. clinical/medical waste used in research derived from the medical treatment of humans.

All studies using RG-2 or higher biohazardous materials must undergo an IBC review. These experiments must be reviewed and approved by the full IBC prior to the initiation of experiments. Some experiments using RG-1 organisms are exempt, and thus full board review by the IBC is not required. All recombinant DNA research using RG-1 organisms and experiments using RG-1 organisms without recombinant DNA work is still required to be registered with the Research Committee and the IBC. Please go to Box to obtain registration forms.

## **A. Rules, Regulations, and Guidelines:**

The following is a brief summary of the regulatory authorities that either regulate or provide guidelines for the use of biological materials, infectious agents, and recombinant DNA molecules. Copies of these documents are available by access to the appropriate website.

### **1. National Institute of Health (NIH): Guidelines for Research Involving Recombinant DNA *Molecules*, April 2002**

<http://www4.od.nih.gov/oba/rac/guidelines02/NIHguidelinesapr02.htm>

These guidelines address the safe conduct of research that involves the construction and handling of recombinant DNA (rDNA) molecules and organisms containing them. In 1974, a recombinant DNA Advisory Committee (RAC) was established to determine appropriate biological and physical containment practices and procedures for experiments that potentially posed risks to human health and the environment. Because of the committee's activity, the initial version of the NIH Guidelines was published in 1976. It has been amended and revised many times since then. Included in the NIH Guidelines is a requirement for the institution to establish an Institutional Biosafety Committee (IBC) with authority to approve or disapprove proposed rDNA research using the NIH Guidelines as a minimum standard.

### **2. Centers for Disease Control and Prevention (CDC) and the National Institute of Health (NIH) Guidelines on Biosafety in Microbiological and Biomedical Laboratories, 5th Edition, 2007 (BMBL manual)**

<http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm>

In 1984, the CDC/NIH published the first edition of the BMBL Manual. This document describes combinations of standard and special microbiological practices, safety equipment, and facilities that constitute Biosafety Levels 1-4, which are recommended for working with a variety of infectious agents in various laboratory settings. This manual has been revised several times and is commonly seen as the standard for biosafety.

### **3. Occupational Safety and Health Administration: Bloodborne Pathogens (BBP) Standard**

[http://www.osha.gov/pls/oshaweb/owadisp.show\\_document?p\\_table=STANDARDS&p9\\_id=10051](http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p9_id=10051)

In 1992, the Occupational Safety and Health Administration (OSHA) promulgated a rule to deal with the occupational health risk caused by exposure to human blood and other potentially infectious materials. OSHA's rule includes a combination of

engineering and work practice controls, personal protective clothing and equipment, training and medical follow-up of exposure incidents, vaccination, and other provisions. All employees of TUN will be required to complete BBP training annually.

#### **4. Department of Health and Human Services (HHS): Select Agent Rule**

[http://www.cdc.gov/od/sap/final\\_rule.htm](http://www.cdc.gov/od/sap/final_rule.htm)

In 1996, HHS published a set of rules that require facilities and institutions to be registered and approved in order to transfer or receive certain biological agents and toxins. HHS requires TUN to comply with the BMBL manual (see above), OSHA's Laboratory Safety Standard 29 CFR 1910.1450, and 42 CFR Part 73. A list of select agents is available, and exempt quantities are listed in Appendix B Select Agents (CDC). Also, refer to the USA PATRIOT Act of 2001 for additional information concerning the possession of Select Agents Appendix

#### **5. Packaging, shipment, and transportation requirements for infectious substances, diagnostic specimens, and biological products are addressed in the following rules and guidelines:**

- *Recommendations of the Committee of Experts on the Transportation of Dangerous Goods*
- International Civil Aviation Organization (ICAO)
- Technical Instructions for the Safe Transport of Dangerous Goods by Air
- International Air Transport Association (IATA)  
Dangerous Goods Regulations

<http://www.iata.org>

U.S. Department of  
Transportation 49 CFR Part 72

<http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=200649>

U.S. Public Health Service  
42 CFR Part 72

U.S. Postal Service  
39 CFR Part 111

U.S. Department of Labor, OSHA  
29 CFR 1910.1030

#### **6. Importation permits**

Importation permits are required for infectious agents, biological materials, and animals as outlined in U.S. Public Health Service, 42 CFR Part 71, *Foreign Quarantine*. In addition, the Department of Agriculture (USDA) Animal and Plant Health Inspection

Service (APHIS) requires permits for importation and transportation of controlled materials, certain organisms or vectors. This includes animal and plant pathogens, certain tissue cultures and live animals. APHIS also regulates the importation, interstate movement, or environmental release of genetically engineered organisms as regulated under 7 CFR Part 340. 10

### **7. Select Agent Regulation (42 CFR Part 73)**

This regulation became effective on March 18, 2005, Provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 are implemented through these regulations. These regulations supersede those regulations as outlined in the Antiterrorism and Effective Death Penalty Act of 1996. The Final Rule can be found at [http://www.cdc.gov/od/sap/final\\_rule.htm](http://www.cdc.gov/od/sap/final_rule.htm).

## **B. Biological Safety Routes of Infection:**

Working in a biological research environment, it is reasonable to expect that a laboratory person working with infectious materials is more likely to become infected than members of the general community. An infection occurs when disease-causing microorganisms enter the human body in sufficient numbers and by a particular route and overcome the body's defense system. The following routes of infection have been reported for laboratory-acquired infections:

### **1. Through the mouth by:**

- eating, drinking and smoking in the laboratory
- mouth pipetting
- transfer of microorganisms to the mouth by contaminated fingers or articles

### **2. Through the skin by:**

- Accidental inoculation with a hypodermic needle, other sharps instrument or glass
- cuts or scratches

### **3. Through the eye by:**

- splashes of infectious material into the eye
- transfer of microorganisms to the eye by contaminated fingers

### **4. Through the lungs by:**

- inhalation of airborne microorganisms

The general laboratory procedures outlined in this manual provide guidance in handling infectious or potentially infectious materials.

### **C. Biological Risk Assessment**

The assessment of risk is an essential element of safety in the laboratory. For most situations, guidelines and regulations have clearly defined the procedures and practices to be followed in order to achieve safety in the workplace. However, a newly isolated agent or toxin, or a new procedure never before employed needs further evaluation. Questions concerning the appropriate safety equipment, training, and waste disposal need to be addressed, as well as safety procedures and practices. Something is considered safe if the risk associated with it is judged acceptable. However, since individual judgment involves both personal and social values, opinions on what is safe or not can vary significantly. In order to find common ground for an acceptable risk assessment, the "rule of reason" needs to be applied. Refer to Appendix F TUN IBC Biosafety Risk Assessment Summary for additional information on performing a risk assessment. Some general factors to consider include:

#### **1. Custom of usage (or prevailing professional practice)**

Many laboratory procedures involve the maintenance of sterility and cleanliness. These procedures are commonly considered safe since adverse effects would have been obvious over time. However, because a procedure has been used for many years does not necessarily imply that it is safe. The best example is mouth pipetting, which was used for centuries and finally considered a very dangerous procedure and habit.

#### **2. Best available practice, highest practicable protection, and lowest practicable exposure**

It should be common practice in the laboratory to use the best available procedures with the highest level of protection. This not only provides a safe work environment but also fosters excellence in scientific conduct.

#### **3. Degree of necessity or benefit**

The common question to ask is, are the benefits worth the risk? There is no need to use a human pathogen, causing severe gastroenteritis in a teaching laboratory when principal microbiological practices can be taught with an organism that is not considered to be infectious.

#### **4. No detectable adverse effects**

This can be a very weak criterion since it involves uncertainty or even ignorance.

#### **5. Principal knowledge**

Many times, existing procedures are modified, which involve the same or similar biological agents. For that reason, similar safety procedures should be applied. If new agents are isolated, an assessment of what is known about the close relatives is done. Many agents of known etiologic character are already categorized in risk groups allowing for the selection of the appropriate biosafety level. New isolates from infected animals or humans with known infectious relatives warrant, at a minimum, the same level of protection.

Taking the above-mentioned factors, as well as others into consideration will allow for a reasonable approach to a new challenge. The IBC is available to assist in this process and should be contacted for questions concerning biological safety. Once a risk assessment is completed, the results should be communicated to everyone involved in the process. Written standard operating procedures (SOPs) should be established and communicated with all personnel within the laboratory.

### **D. Risk Management**

#### **1. Risk Groups**

Agents are classified into four Risk Groups (RGs) according to their relative pathogenicity for healthy adult humans by the following criteria:

- a. Risk Group 1 (RG1) (low individual and community risk). Any biological agent that is unlikely to cause disease in healthy workers or animals.
- b. Risk Group 2 (RG2) (moderate individual risk, low community risk). Any pathogen that can cause human disease but, under normal circumstances, is unlikely to be a serious hazard to laboratory workers, the community, livestock, or the environment. Laboratory exposure rarely causes infection leading to serious disease; effective treatment and preventive measures are available, and the risk of spread is limited.
- c. Risk Group 3 (RG3) (high individual risk, low community risk). Any pathogen that usually causes serious human disease or can result in serious economic consequences but does not ordinarily spread by casual contact from one individual to another or that causes diseases treatable by antimicrobial or anti-parasitic agents.

- d. Risk Group 4 (RG4) (high individual risk, high community risk). Any pathogen that usually produces very serious human disease, often untreatable, and may be readily transmitted from one individual to another, or from animal to human or vice-versa, directly or indirectly, or by casual contact.

## 2. Criteria for Risk Groups

The classification of agents (See Appendix B Select Agents (CDC)) is based on the potential effect of a biological agent on a healthy adult and does not account for instances in which an individual may have increased susceptibility to such agents. Such instances would include pre-existing diseases, medications, compromised immunity, pregnancy, or breastfeeding (which may increase exposure of infants to some agents). Personnel may need periodic medical surveillance to ascertain fitness to perform certain activities; they may also need to be offered prophylactic vaccines and boosters. Employee Health Services can be consulted as needed.

## 3. Comprehensive Risk Assessment

In deciding on the appropriate containment for an experiment, the initial risk assessment from the Classification of Human Etiologic Agents on the Basis of Hazard should be followed by a thorough consideration of the agent itself and how it is to be manipulated. Factors to be considered in determining the level of containment, include agent factors such as virulence, pathogenicity, infectious dose, environmental stability, route of spread, communicability, operations, quantity, availability of vaccine or treatment, and gene product effects such as toxicity, physiological activity, and allergenicity. Any strain that is known to be more hazardous than the parent (wild-type) strain should be considered for handling at a higher containment level. Certain attenuated strains or strains that have demonstrated irreversible loss of known virulence factors may qualify for a reduction of the containment level compared to the Risk Group assigned to the parent strain. Biological risk assessment is a subjective process requiring consideration of many hazardous characteristics of agents and procedures, with judgments based often on incomplete information. The following 5 step approach gives structure to the risk assessment process:

Step 1. Identify agent hazards and perform an initial assessment of risk.

Step 2. Identify laboratory procedure hazards.

Step 3. Make a final determination of the appropriate biosafety level and select additional precautions indicated by the risk assessment.

Step 4. Evaluate the proficiencies of staff regarding safe practices and the integrity of safety equipment.

Step 5. Review the risk assessment with a biosafety professional, subject matter expert, and IBC.

#### **4. Biosafety Levels**

Four BSLs are described, which consist of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities. Each combination is specifically appropriate for the operations performed, the documented or suspected routes of transmission of the infectious agents, and the laboratory function or activity. The BSLs described should be differentiated from Risk Groups, as described in the NIH Guidelines and the World Health Organization Laboratory Biosafety Manual. Risk groups are the result of a classification of microbiological agents based on their association with and resulting severity of diseases in humans. The risk group of an agent should be one factor to be considered in association with mode of transmission, procedural protocols, experience of staff, and other factors in determining the BSL in which the work will be conducted. While all four BSL levels are described, TUN is currently cleared for work in BSL 1 and BSL 2

##### **A. Biosafety Level 1**

Suitable for work involving well-characterized agents not known to cause disease in healthy adult humans, and of minimal potential hazard to laboratory personnel and the environment. The laboratory is not necessarily separated from the general traffic patterns in the building. Work is generally conducted on open bench tops using standard microbiological practices. Special containment equipment or facility design is not required nor generally used. Laboratory personnel has specific training in the procedures conducted in the laboratory and are supervised by a scientist with general training in microbiology or a related field.

##### **B. Biosafety Level 2**

Similar to Biosafety Level 1 and is suitable for work involving agents of the moderate potential hazard to personnel and the environment. It differs in that (1) laboratory personnel have specific training in handling pathogenic agents and are directed by competent scientists, (2) access to the laboratory is limited when work is being conducted, (3) extreme precautions are taken with contaminated sharp items, and (4) certain procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.



### C. Biosafety Level 3

Applicable to clinical, diagnostic, teaching, research or production facilities in which work is done with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route. Laboratory personnel have specific training in handling pathogenic and potentially lethal agents and are supervised by competent scientists who are experienced in working with these agents. All procedures involving the manipulation of infectious materials are conducted within biological safety cabinets by personnel wearing appropriate personal protective equipment. The laboratory has special engineering and design features. Access to the laboratory is strictly controlled by the Facility Manager or Principal Investigator. The facility is either in a separate building or in a controlled area within a building, which is completely isolated from all other areas of the building. A specific facility operations manual is prepared and adopted.

### D. Biosafety Level 4

Required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease. Agents with a close or identical antigenic relationship to Biosafety Level 4 agents are handled at this level until sufficient data are obtained either to confirm continued work at this level or to work with them at a lower level. Members of the laboratory staff have specific and thorough training in handling extremely hazardous infectious agents, and they understand the primary and secondary containment functions of the standard and special practices, the containment equipment, and the laboratory design characteristics. They are supervised by competent scientists who are trained and experienced in working with these agents.

## Summary of Recommended Biosafety Levels for Infectious Agents

### Biosafety Level 1 (BSL1)

Agents	Not known to cause disease in healthy adult humans
Practices	Standard microbiological practices
Safety Equipment (Primary Barriers)	None required
Facilities (Secondary Barriers)	Open benchtop with sink available

## Biosafety Level 2 (BSL2)

Agents	Moderate risk agents that are present in the community and associated with human disease of mild to moderate severity
Practices	BL1 practice plus limited access, biohazard warning signs, “sharps” precautions, and an SOP is defining any needed waste decontamination or medical surveillance policies.
Safety Equipment (Primary Barriers)	Primary barriers include a Class I or II Biological Safety Cabinet (BSC) or other physical containment devices used for the manipulation of agents that cause splashes or aerosols of infectious materials; Personal Protective Equipment (PPE) including laboratory coats, gloves, face and eye protection as needed
Facilities (Secondary Barriers)	BL1 plus the availability of an autoclave for decontamination.

## Biosafety Level 3 (BSL3) and Biosafety Level 4 (BSL4)

Agents	Indigenous or exotic agents with a potential for aerosol transmission; and which may cause serious or potentially lethal infection
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**Guidelines.** It is important to realize, however, that none of the lists is inclusive. In addition, those agents not listed in RG-2, RG-3, and RG-4 are not automatically classified in RG-1. Those unlisted agents need to be subjected to a risk assessment based on the known and potential properties of the agents and their relationship to agents that are listed.

### 5. Working with tissue culture

When cell cultures are known to contain an etiologic agent or an oncogenic virus, the cell line can be classified at the same RG level as that recommended for the agent. The Centers for Disease Control and Prevention (CDC) and OSHA recommend that all cell lines of human origin be handled at BSL2 level.

Cell lines that are non-primate or are of normal primate origin, which do not harbor a primate virus, which are not contaminated with bacteria or fungi and which are well established, may be considered Class I cell lines and handled at a Biosafety Level 1. Appropriate tests should confirm this assessment.

Primate cell lines derived from lymphoid or tumor tissue, all cell lines exposed to or transformed by a primate oncogenic virus, all clinical material (e.g., samples of human tissues and fluids obtained after surgical resection or autopsy), all primate tissue, all cell lines new to the laboratory (until shown to be free of all adventitious agents) and all virus and Mycoplasma-containing primate cell lines are classified as RG-2 and should be handled at a Biosafety Level 2.

## 6. Clinical Laboratory guidelines

Clinical laboratories receive clinical specimens with requests for a variety of diagnostic services. The infectious nature of this material is largely unknown. In most circumstances, the initial processing of clinical specimens and the identification of microbial isolates can be done safely at BL2. A primary barrier, such as a BSC, should be used:

- when it is anticipated that splashing, spraying or splattering of clinical materials may occur,
- for initial processing of clinical specimens where it is suggested that an agent transmissible by infectious aerosols may be present (e.g., *M. tuberculosis*),
- to protect the integrity of the specimen

All laboratory personnel who handle human source materials are included in the Bloodborne Pathogens Program, as outlined in *TUN Bloodborne Pathogen Exposure Control Plan* (Appendix A). "**Universal Precautions**" need to be followed when handling human blood, blood products, body fluids or tissues.

The segregation of clinical laboratory functions and restricting access to specific areas is the responsibility of the Laboratory Director. It is also the director's responsibility to establish the standard, written procedures that address the potential hazards and the required precautions to be implemented. Additional recommendations specific for clinical laboratories may be obtained from the National Committee for Clinical Laboratory Standards (NCCLS).

## 7. Preventing the spread of tuberculosis

Since 1985, the incidence of tuberculosis in the United States has been increasing steadily, reversing a 30-year downward trend. Recently, drug-resistant

strains of *Mycobacterium tuberculosis* have become a serious concern. Outbreaks of tuberculosis, including drug-resistant strains, have occurred in healthcare environments. Several hundred employees have become infected after workplace exposure to tuberculosis, requiring medical treatment. A number of healthcare workers have died. In December 2005, the CDC published *Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Setting, 2005* (MMWR. 54[No.RR-17]). The guidelines contain specific information on ventilation requirements, respiratory protection, medical surveillance and training for those personnel who are considered at risk for exposure to tuberculosis. Propagation and/or manipulation of *Mycobacterium tuberculosis* and *M. bovis* cultures in the laboratory or animal room must be performed at BL3 and require IBC approval.

### **E. Administrative Controls**

#### **Biohazard Warning Sign**

A biohazard label is required for all areas or equipment in which RG-2 or RG-3 agents are handled or stored or where BSL2 or BSL3 procedures are required. The appropriate place for posting the label is at the main entrance door(s) to laboratories and animal rooms, and on equipment such as refrigerators, incubators, transport containers, and/or lab benches.

#### **Training**

Good microbiological and laboratory practices are essential for a safe work environment. Training and education on these practices and procedures are required. All personnel working with RG-1, RG-2 or RG-3 agents are required to receive laboratory-specific training from the Principal Investigator (PI) or laboratory supervisor. In addition, all personnel listed on active IBC protocols must complete the web-based General Biosafety training provided by CITI. Specific training in BSL-3 practices and/or the utilization of Select Agents may also be assigned based on the protocol needs. Training should include at a minimum:

- good laboratory and animal use practices as applicable
- site-specific information on risks, hazards, and procedures
- laboratory or environment-specific BSL2 procedures as applicable

#### **Bloodborne Pathogen (BBP) Program**

In accordance with OSHA requirements, TUN has established an Exposure Control Plan covering the potential exposure to bloodborne pathogens (e.g., HIV, Hepatitis B virus) found in human blood, serum, and tissue, as well as in other potentially infectious materials. BBP training is required on an annual basis and available through a University-sponsored web-based training program by CITI.

## Recombinant DNA Program

All research at the Institution involving recombinant DNA, independent of the funding source, needs to be in compliance with the requirements of the NIH Guidelines and is subject to IBC review and approval.

## CDC Select Agents Requirements

The Centers for Disease Control and Prevention (CDC) mandates specific requirements for facilities transferring or receiving certain infectious agents and toxins (HHS: *Additional Requirements for Facilities Transferring or Receiving Select Agents*).

## Institutional Biosafety Committee (IBC)

The IBC provides oversight on all projects involving biohazardous agents (RG-1, RG-2, and RG-3) and certain toxins.

## F. Engineering Controls

### 1. Biological Safety Cabinets (BSCs)

BSCs are designated to provide personnel, environmental, and product protection when appropriate practices and procedures are followed. Three kinds of BSCs, designated as Class I, II and III have been developed to meet various research and clinical needs. Biological safety cabinets use high-efficiency particulate air (HE PA) filters in their exhaust and/or supply systems. BSCs must not be confused with other Laminar flow devices or "clean benches": in particular, horizontal flow cabinets that direct air towards the operator.

Clean benches should never be used for handling infectious, toxic, or sensitizing materials. Confine pipetting of biohazardous or toxic fluids inside a BSC if possible.

Laboratory personnel must be trained in the correct use and maintenance of BSCs to ensure that personnel and product protection (where applicable) are maintained. Before selecting any biosafety cabinet for purchase, contact the Biosafety Officer for guidance.

### Class I Biological Safety Cabinet

This is a ventilated cabinet for personnel protection with an unrecirculated inward airflow away from the operator. This unit is fitted with a HEPA filter to protect the environment from discharged agents. The Class I BSC is suitable for work involving low to moderate risk agents, where there is a need for containment, but not for product protection (e.g., sterility).

## **Class II Biological Safety Cabinet**

This is a ventilated cabinet for personnel, product, and environmental protection that provide inward airflow and HEPA-filtered supply and exhaust air. The Class II cabinet has four designs depending on how much air is recirculated and/or exhausted and if the BSC is hard-ducted to the ventilation system or not. Most laboratories need only a Class II, A1 (not exhausted), or a Class II, A2 (thimble connected exhaust) for the work they perform. A Class II, B2 hard ducted hood is rarely needed and should only be considered under unique circumstances. Contact the BSO for additional guidance for selecting a BSC.

## **Class III Biological Safety Cabinet**

The Class III cabinet is a totally enclosed ventilated cabinet that is gas-tight and maintained under negative air pressure (0.5 inches water gauge). The supply air is HEPA-filtered, and the exhaust air has two HEPA filters in series. Work is performed in the cabinet by the use of attached rubber gloves.

## **2. Negative Pressure Rooms**

Anatomy laboratories where a ducted exhaust air ventilation system is provided and where the directional airflow draws air into the laboratory, i.e. negative pressure, must have a method to monitor whether or not the direction of airflow is proper.

In special containment laboratory areas (BSL3 labs and autopsy suites), quantitative electronic monitoring of the airflow should be conducted at least annually to test for proper operation.

Exhaust systems with HEPA filters require a mechanism to monitor the proper functioning of the filter to determine when replacement is needed.

## **3. Other Safety Equipment**

### **Safety Showers**

Safety showers provide an immediate water drench of an affected person. It is your responsibility to be aware of the location of the safety showers in the lab in which you are working.

### **Eyewash Stations**

Eyewash stations are available in all laboratories where injurious or corrosive chemicals are used or stored and where employees perform tasks that might result in splashes of potentially infectious materials. It is your responsibility to be aware of the location and function of the eyewash stations in the lab in which you are working.

## Ventilation Controls

Ventilation controls are those controls intended to minimize employee exposure to hazardous chemicals and infectious or toxic substances by removing air contaminants from the worksite.

## G. Personal Protective Equipment (PPE)

PPE is used to protect personnel from contact with hazardous materials and infectious agents. Appropriate clothing may also protect the experiment from contamination. Personal protective devices and safety equipment must be provided to all employees under the appropriate circumstances, and employees have the responsibility of properly using the equipment. All PPE used must be decontaminated or disposed of in a way that is appropriate for the Biosafety level of the materials used. The following PPE is recommended for regular use:

### 1. Face Protection

Splash goggles or safety glasses with solid side shields in combination with masks, or chin-length face shields or other splatter guards are required for anticipated splashes, sprays or splatters of infectious or other hazardous materials to the face

### 2. Laboratory Clothing

This category includes laboratory coats, smocks, scrub suits, and gowns. Long-sleeved garments should be used to minimize the contamination of skin or street clothes. In circumstances where it is anticipated that splashes may occur, the garment must be resistant to liquid penetration to protect clothing from contamination. If the garment is not disposable, it must be capable of withstanding sterilization in the event it becomes contaminated. At a minimum, a laboratory coat should be worn in all laboratories working at a BSL2. Additional criteria for selecting clothing are comfort, appearance, closure types and location, antistatic properties and durability. Protective clothing must be removed and left in the laboratory before leaving for non-laboratory areas. Disposables should be available for visitors, maintenance and service workers in the event it is required. Personnel must not take laboratory clothing home.

### 3. Gloves

Gloves must be selected based on the hazards involved and the activity to be conducted. Gloves must be worn when working with biohazards, toxic substances, hazardous chemicals, and other physically hazardous agents. Temperature resistant gloves must be worn when handling hot material or dry ice. Delicate work requiring a high degree of precision dictates the use of thin-walled gloves. Protection from contact

with toxic or corrosive chemicals may also be required. Powdered latex gloves should not be used on the TUN campus.

#### 4. Respirators

For certain protocols and projects, additional PPE like respiratory protection may be required. Respirator selection is based on the hazard, and the protection factor required.

### H. Recommended work practices

#### Biosafety Cabinets Recommended procedures:

- a. Wipe down the work surface of the biosafety cabinet with a disinfectant (SporKlenz or Alcide followed by 20% ethanol). If the biosafety cabinet was turned off overnight, allow five (5) minutes of running time before starting your work.
- b. Assemble your materials and equipment BEFORE working in the biosafety cabinet.
- c. Minimize room activity, especially near the biosafety cabinet. Never walk behind someone working at a cabinet.
- d. Employ aseptic technique as you would on the bench-top — separate clean from dirty items.
- e. Clean-up promptly and thoroughly when you are finished. Wipe down the work surface with disinfectant. Decontaminate any supplies that were used inside the biosafety cabinet.

#### Pipettes and Pipetting Aids

Mouth pipetting is strictly prohibited. Mechanical pipetting aids must be used. If pipetting is done on the open bench, use absorbent pads or paper on the bench. The following precautions should be followed:

1. Always use cotton-plugged pipettes when pipetting biohazardous or toxic fluids.
2. Biohazardous materials should not be forcibly discharged from pipettes. Use "to deliver pipettes rather than those requiring "blowout."
3. Do not discharge biohazardous material from a pipette at a height. Whenever possible, allow the discharge to run down the container wall.
4. Place contaminated reusable pipettes horizontally in a pan containing enough liquid disinfectant to cover them completely.
5. Autoclave the pan and pipettes as a unit before processing them for reuse.
6. Discard contaminated Pasteur pipettes in an appropriate size sharps container.



7. When work is performed inside a biosafety cabinet, all pans or sharps containers for contaminated glassware should be placed inside the cabinet as well while in use.

### Syringes and Needles

Syringes and hypodermic needles are dangerous objects that need to be handled with extreme caution to avoid accidental injection and aerosol generation. Generally, the use of syringes and needles should be restricted to procedures for which there is no alternative. Do not use a syringe and needle as a substitute for a pipette.

Use needle locking syringes or disposable syringe-needle units in which the needle is an integral part of the syringe. When using syringes and needles with biohazardous or potentially infectious agents:

1. Work in a BSC whenever possible.
2. Wear gloves.
3. Fill the syringe carefully to minimize air bubbles.
4. Expel air, liquid, and bubbles from the syringe vertically into a cotton pad moistened with a disinfectant.

Needles should not be bent, sheared, replaced in the sheath or guard (capped), or removed from the syringe following use. If it is essential that a contaminated needle is recapped or removed from a syringe, the use of a mechanical device or the one-handed scoop method must be used. Always dispose of needle and syringe unit promptly into an approved sharps container. Do not overfill sharps containers (2/3 filled = full) before discarding.

### Cryostats

Frozen sections of unfixed human or animal tissue infected with an etiologic agent pose a risk because accidents can occur. Freezing tissue does not necessarily inactivate infectious agents. Freezing propellants under pressure should not be used for frozen sections as they may cause spattering of droplets of infectious material. Gloves should be worn during the preparation of frozen sections. When working with biohazardous material in a cryostat, the following is recommended:

1. Consider the contents of the cryostat to be contaminated and decontaminate it frequently with 70% ethanol or any other disinfectant suitable for the agent(s) in use.

2. Consider trimmings and sections of tissue that accumulate in the cryostat to be potentially infectious and remove them during decontamination,
3. Defrost and decontaminate the cryostat with a tuberculocidal hospital-type disinfectant once a week, and immediately after the tissue is known to contain bloodborne pathogens, *M. tuberculosis*, or other infectious agents is cut.
4. Handle Microtome knives with extreme care. Stainless steel mesh gloves should be worn when changing knife blades.
5. Consider solutions for staining potentially infected frozen sections to be contaminated.

### Centrifuge Equipment

Hazards associated with centrifuging include mechanical failure and the creation of aerosols. To minimize the risk of mechanical failure, centrifuges must be maintained and used according to the manufacturer's instructions. Users should be properly trained, and operating instructions including safety precautions should be prominently posted on the unit. Aerosols are created by practices such as filling centrifuge tubes, removing supernatant, and re-suspending sediment pellets. The greatest aerosol hazard is created if a tube breaks during centrifugation. To minimize the generation of aerosols when centrifuging biohazardous material, the following procedures should be followed:

1. Use sealed tubes and safety buckets that seal with O-rings. Before use, inspect tubes, O-rings, and buckets for cracks, chips, erosions, bits of broken glass, etc. Do not use aluminum foil to cap centrifuge tubes because it may detach or rupture during centrifugation.
2. Fill and open centrifuge tubes, rotors, and accessories in a BSC. Avoid overfilling of centrifuge tubes so that closures do not become wet. After tubes are filled and sealed, wipe them down with disinfectant.
3. Add disinfectant to the space between the tube and the bucket to disinfect material in case of breakage during centrifugation.
4. Always balance buckets, tubes, and rotors properly before centrifugation.
5. Do not decant or pour off supernatant. Use a vacuum system with appropriate in-line reservoirs and filters.
6. Work in a BSC when resuspending sediment material. Use a swirling rotary motion rather than shaking. If shaking is necessary, wait a few minutes to permit the aerosol to settle before opening the tube.
7. Small low - speed centrifuges may be placed in a BSC during use to reduce the aerosol escape. High-speed centrifuges pose additional hazards. Precautions should be taken to filter the exhaust air from vacuum lines to avoid metal fatiguing, resulting in disintegration of rotors and to use proper cleaning

techniques and centrifuge components. Manufacturer's recommendations must be meticulously followed to avoid metal fatigue, distortion, and corrosion.

Avoid the use of celluloid (cellulose nitrate) tubes with biohazardous materials. Celluloid centrifuge tubes are highly flammable and prone to shrinkage with age. They distort on boiling and can be highly explosive in an autoclave. If celluloid tubes must be used, appropriate chemical disinfectants are necessary for decontamination.

### **Blenders, Ultrasonic Disrupters, Grinders, and Lyophilizes**

The use of any of these devices results in considerable aerosol production. Blending, cell-disrupting, and grinding equipment should be used in a BSC when working with biohazardous materials.

#### **Safety Blenders**

Safety blenders, although expensive, are designed to prevent leakage from the bottom of the blender jar, provide a cooling jacket to avoid biological inactivation, and to withstand sterilization by autoclaving. If blender containers are not leak-proof, they should be tested with sterile saline or dye solution prior to use with biohazardous material. The use of glass blender jars is not recommended because of the breakage potential. If they must be used, glass jars should be covered with a polypropylene jar to prevent spraying of glass and contents in the event the blender jar breaks. A towel moistened with disinfectant should be placed over the top of the blender during use. Before opening the blender jar, allow the unit to rest for at least one minute to allow the aerosol to settle. The device should be decontaminated promptly after use.

#### **Lyophilizer and Ampoules**

Depending on lyophilizer design, aerosol production may occur when a material is loaded or removed from the lyophilizer unit. If possible, sample material should be loaded in a BSC. The vacuum pump exhaust should be filtered to remove any hazardous agents or, alternatively, the pump can be vented into a BSC. After lyophilization is completed, all surfaces of the unit that have been exposed to the agent should be disinfected. If the lyophilizer is equipped with a removable chamber, it should be closed off and moved to a BSC for unloading and decontamination. Handling of cultures should be minimized, and vapor traps should be used wherever possible.

Opening ampoules containing liquid or lyophilized infectious culture material should be performed in a BSC to control the aerosol produced. Gloves must be worn. To open, nick the neck of the ampoule with a file, wrap it in a soaked disinfectant towel, hold the ampoule upright and snap it open at the nick. Reconstitute the contents of the

ampoule by slowly adding liquid to avoid aerosolization of the dried material. Mix the container. Discard the towel and ampoule top and bottom as biohazardous waste.

Ampoules used to store biohazardous material in liquid nitrogen have exploded, causing eye injuries and exposure to the infectious agent. The use of polypropylene tubes eliminates this hazard. These tubes are available dust-free or pre-sterilized and are fitted with polyethylene caps with silicone washers.

### **Loop Sterilizers and Bunsen Burners**

Sterilization of inoculating loops or needles in an open flame generates small particle aerosols that may contain viable microorganisms. The use of a shielded electric incinerator or hot bead sterilizers minimizes aerosol production during loop sterilization. Alternatively, disposable plastic loops and needles may be used for culture work where electric incinerators or gas flames are not available or recommended. Continuous flame gas burners should not be used in BSCs. These burners can produce turbulence that disturbs the protective airflow patterns of the cabinet. Additionally, the heat produced by the continuous flame may damage the HEPA filter,

### **Vacuum Lines, Filters, and Traps**

When the building vacuum line or when portable vacuum pumps are used, suitable traps or filters (such as Millipore or Gelman Vacushield filters) should be interposed to ensure that pathogens do not enter the central system. Vacuum flasks should contain disinfectants such as Clorox with a final concentration of 20%.

### **Freezers and Refrigerators**

Freezers and refrigerators should be cleaned out periodically. All infectious or toxic material stored in refrigerators or freezers should be properly labeled. Do not place flammable solvents (i.e., ether) in normal refrigerators – use explosion-proof refrigerators and freezers.

### **General Equipment**

All non-autoclaved equipment should be treated with disinfectant immediately after use. Disinfectants do not work instantaneously but must be given several minutes to work before rinsing off.

### **Aerosol**

Sonification, blending, or any procedure that produces an infectious aerosol should be avoided. If it is necessary to perform these procedures, they must be carried out in a biological safety cabinet. Special precautions such as protective clothing and

breathing devices should be used. Glass containers should not be used because of potential breakage. All instruments must be sterilized or disinfected after use.

### **Experimental Work with Infectious Agents**

Ensure that all virulent fluid cultures or viable powdered infectious materials are transported and stored in easily handled, non-breakable, sealed, leak-proof containers. Water baths used to inactivate or incubate infectious materials should contain a disinfectant.

### **Human Material with reference to bloodborne pathogens**

Investigators use body fluids and tissues for their experimental work. All materials should be treated as potentially infectious and handled as biohazards, using Standard Precautions (Page 22).

### **Laundry**

Apparel contaminated with human blood or other potentially infectious materials should be handled as little as possible and needs to be collected in a special hamper (labeled or color-coded) or in biohazard bags. Materials containing a drippable biohazardous agent or those contaminated with an RG-3 agent should be decontaminated by steam sterilization. The decontaminated materials should subsequently be sent for cleaning. All other materials can be placed in biohazard bags and given to the laundry for cleaning prior to decontamination. Laundry services are performed by approved vendors.

### **Hand Hygiene**

Hand-washing with soap and water has been considered an important measure of personal hygiene, whether working within the confines of a research laboratory or within the everyday private environment. Washing of hands when handling biohazardous agents is the major method for the prevention of disease transmission. In the research and health care setting, a number of developments have led to new guidelines designed to improve hand hygiene practices in the research laboratory. Most of the reports describe handwashing practices in the healthcare setting; however, these guidelines also have application to the research laboratory.

For an in-depth review of hand hygiene practices, refer to the recently published report by the CDC. (Center for Disease Control and Prevention, Guidelines for Hand Hygiene in Health Care Settings: Recommendation of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA hand hygiene task force. MMWR 2002; 51 [No. RR-16]).

## Housekeeping

Good housekeeping in laboratories is essential to reduce risks and protect the integrity of biological experiments. Routine housekeeping must be relied upon to provide work areas free of significant sources of contamination. Housekeeping procedures should be based on the highest degree of risk to which personnel and experimental integrity may be subjected.

Laboratory personnel are responsible for cleaning laboratory benches, equipment, and areas that require specialized technical knowledge (see Appendix C for appropriate chemicals). Additional laboratory housekeeping concerns include:

1. Keep the laboratory neat and free of clutter. Surfaces should be clean and free of infrequently used chemicals, glassware, and equipment. Access to sinks, eyewash stations, emergency showers and exits, and fire extinguishers must not be blocked.
2. Proper disposal of chemicals and wastes. Old and unused chemicals should be disposed of properly on a regular basis.
3. Providing a workplace that is free of physical hazards. Aisles and corridors should be free of tripping hazards. Attention should be paid to electrical safety, especially as it relates to the use of extension cords, proper grounding of equipment, and avoidance of the creation of electrical hazards in wet areas.
4. All laboratory equipment needs to be cleaned and certified of being free of hazards before being released for repair or maintenance.

## Transportation of Material Out of the BSL2 Lab

Any materials or containers to be transported out of the lab for research, storage, or disposal purposes must first be treated to decontaminate external surfaces. Biological materials must be held within capped, spill-proof plastic containers. Containers are sprayed with virucide, wiped with a paper towel, and the dried containers are then placed in an appropriate Plexiglas box or carrying container for transport.

### I. Disposal of Contaminated Materials

#### Paper and Disposable Plastics

All waste paper and plastic materials contaminated with potentially hazardous biological materials must be placed in red biohazard bags for disposal. They are to be

sealed with tape and disposed of through the red bag waste system. High-risk material (BSL-3) should be autoclaved prior to disposal

Recommended procedures:

**a. Things to Be Returned:**

- All laboratory glassware
- All bottles, except those used to contain toxic chemicals
- Caps, stoppers, etc.
- Pipette cans
- Culture tube racks
- Petri dish cans

**b. Things NOT to be returned:**

- Chemicals
- Radioactive materials
- Animals or Animals parts
- Plastic disposals

**c. Methods to be followed:**

Dirty glassware should be placed in plastic trays only after the trays have been lined with an autoclavable bag. Do not put dirty glassware in an unlined tray. Potentially dangerous items such as Pasteur pipettes, hypodermic needles, syringes, etc., are not to be returned for glassware washing.

**d. Used Syringes, Needles and Pasteur Pipettes**

Only syringes of the Luer-Lok type should be used with infectious materials. Used syringes, needles, and Pasteur pipettes must be placed in an approved sharps container to be collected by licensed Environmental Service.

**J. Procedures Following Biohazardous Material Spill**

If an accident occurs involving the possible spread of potentially dangerous biologicals (virus, etc.), immediate steps must be taken to decontaminate the area. The amounts of material and hazards involved will determine the appropriate action.

**Small Spills (To Not Exceed 50 ml)**

For a small amount of liquid (not exceeding 50 ml with little or no virulence), use a paper towel to absorb the spill, apply a disinfectant (Clorox) to the area, let stand for a minimum of 10 minutes, and wipe-up. Rather than pour the disinfectant directly to the

spill area and risk splashing, it is better to allow the disinfectant to flow onto the spill. Be sure to:

- a. Use Standard Precautions when handling potentially biologically hazardous materials
- b. Use double gloves to wipe-up the spill.
- c. Do not let the spill dry. A dried spill will allow contaminated dust to form and spread throughout the building.
- d. Dispose of absorbed materials into a biohazard bag.
- e. Document the spill using Hazardous Material Spill Report form (Appendix G)

### Large Spills

For a large volume spill of virulent material:

- a. Warn others
- b. Wash hands and any exposed body area.
- c. Post a notice on the door to warn others not to enter the room.
- d. Contact the Biosafety Officer with the exact location and the nature of the spill.
- e. Document the spill using Hazardous Material Spill Report form (Appendix G)

### Hazardous Spill Report

**Must be delivered** to BSO, who provides copies of the report to TUN Provost Office, TUN Associate Dean of Research, Director of EH&S, and Director of HR.

Each researcher must realize that in the event of an overt accident, research materials such as tissue cultures, media, entire experiments, and animals within biological safety cabinets may be lost to the spill.

## K. What to do in the Event of Personal Exposure or Injury Involving Biohazardous Material

In the event of an **emergency**, Dr. Bondarenko can be reached at:

702-777-1806 (**office**)

702-354-6321 (**cell**)

Daniel Bollard can be reached at:

702-777-1812 (**office**)

702-612-0792 (**cell**)



The following guidelines are strongly recommended to minimize the likelihood of infection following accidental exposure to infectious materials. In the event of a biohazard accident resulting in possible, probable or actual exposure across mucous membranes (eyes, nose, and mouth) or skin, you must react quickly to minimize potential for infection.

### General Considerations

1. Test plumbed eyewashes monthly; keep a log.
2. Remove chemical bottles from the work area of Facilities personnel working in laboratories.
3. Stock first aid kits with Band-Aids, 4X4 gauze, roller bandages, and ace bandages (no creams, ointments, etc.).
4. Report minor injuries to the supervisor after first aid has been administered.
5. Call 5-911 for serious injuries and true emergencies (fires, explosions, major spills, etc.).

### For Bleeding and Wound Care

1. Wear clean gloves.
2. Cover area with gauze (or clean paper towels).
3. Apply pressure to the bleeding area — have person sit or lie down.
4. If the wound is large or person is dizzy or weak, call 5-911 to transport person to Concentra Urgent Care or Emergency Room.

### Burns – Heat/Chemical

1. Heat burns: Run cool water over the area for 5 minutes, then report to supervisor. If burn area is large, cover with a cool, wet cloth and call 5-911.
2. Chemical burns (acid or alkaline): Flush with large amounts of cool running water for 15 minutes. For a small area, report to Urgent Care. For larger area or if person is weak or dizzy, call 5-911 for transport.

### Eye Splash Chemical

1. Flush with lukewarm (body temperature) running water; turn head side to side and have water run across both eyes.
2. Flush eyes for at least 15 minutes before going for further treatment at Urgent Care or Emergency Room.

### Eye – Foreign Body (dust or metal, paint, wood chips)

1. Cover or close eye.
2. Report to Urgent Care for evaluation.

**DO NOT POUR ANY CHEMICALS DOWN SINK DRAINS OR SEWER GRATES.**

You **MUST** report all injuries/exposures to your supervisor and to the TUN Biosafety

Officer and Department of Environmental Health and Safety (EH&S). It is the responsibility of each researcher and supervisor to see that each incident is evaluated for severity of risk.

## **L. Interstate Shipment of Infectious Agents**

The following are the requirements for transportation of etiologic agents in interstate traffic recommended by the Department of Transportation and other Federal Government agencies.

49 CFR Part 171-178

Federal Register, Vol. 45, No. 141-Monday, July 21, 1980

Part 72-Interstate shipment of Etiologic Agents 1

Centers for Disease Control and Prevention

Office of Health and Safety Biosafety Branch

(Date Last Revised: March 9, 1995)

### **1. “Biological Substance”**

“Category B” means any human or animal material including, but not limited to, excreta, secretions, blood and its components, tissue, and tissue fluids being shipped for purposes of diagnosis.

### **2. “Infectious Substance”**

A viable micro-organism or its toxin which causes, or may cause, human disease. They are those micro-organisms that cause disease in humans and include bacteria, bacterial toxins, viruses, fungi, rickettsia, protozoans, and parasites. These disease-causing micro-organisms may also be referred to as infectious agents or infectious substances. The materials such as body fluids and tissues that contain them are referred to as infectious materials. Organisms, such as mosquitoes, that may transmit infectious diseases to other humans are called vectors.

### **3. “Interstate Traffic”**

The movement of any conveyance or the transportation of persons or property, including any portion of such movement or transportation which is entirely within a state or possession: (a) from a point of origin in any state or possession to a point of destination in any other state or possession, or (b) between a point of origin and a point of destination in the same state or possession, but through any other state, possession, or contiguous foreign country. No person may knowingly transport or cause to be transported in interstate traffic, directly or indirectly, any material including, but not limited to, diagnostic specimens and biological products, if such person reasonably believes it may contain an etiologic agent. The exception is that such material is

packaged to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.

#### **4. Volume not exceeding 50 ml.**

The material should be placed in a securely closed, watertight and/or sift proof container (primary container (test tube, vial, etc.) which shall be enclosed in a second, durable watertight container (secondary container)). Several primary containers may be enclosed in a single secondary container if the total volume of all the primary containers does not exceed 50 ml. The space at the top, bottom, and sides between the primary and secondary containers shall contain sufficient non-particulate absorbent material (e.g. paper towel) to absorb the entire contents of the primary container(s) in case of breakage or leakage. Each set of primary and secondary containers shall then be enclosed in an outer shipping container constructed of corrugated fiberboard, cardboard, wood, or other material of equivalent strength. Multiple primary containers should be wrapped individually so as not to touch.

#### **5. Volume greater than 50 ml.**

Packaging of material in volumes of 50 ml or more shall comply with requirements specified in #4 of this section. In addition, a shock-absorbent material, in volume at least equal to that of the absorbent material between the primary and secondary containers, shall be placed at the top, bottom, and sides between the secondary container and the outer shipping container. Single primary containers shall not contain more than 1,000 ml of material. However, two or more primary containers whose combined volumes do not exceed 1,000 ml may be placed in a single, secondary container. The maximum amount of etiologic agent which may be enclosed within a single outer shipping container shall not exceed 4,000 ml.

#### **6. Dry Ice**

If dry ice is used as a refrigerant, it must be placed outside the secondary container(s). If dry ice is used between the second container and the outer shipping container, the shock-absorbent material shall be placed so that the secondary container does not become loose inside the outer shipping container as the dry ice sublimates. The shipping container must allow for release of carbon dioxide gas.

#### **7. Identification**

The outer shipping container of all materials containing etiologic agents transported in interstate traffic must bear a label described below: The color of the material on which the label is printed must be white, symbol red, and the printing in red or white. The label must be a rectangle measuring 51 millimeters (mm) (2 inches) by

10.25 mm (4 inches) long. The red symbol measuring 38 mm (1-1/2 inches) in diameter must be centered in a white square measuring 51 mm (2 inches) on each side.

Type size of the letters of the label shall be as follows:

- Etiologic agents – 10 pt.
- Biomedical material – 14 pt.
- In case of damage or leakage – 10 pt.
- Notify Director CDC, Atlanta, Georgia – 8pt.
- (404) 633-5313 – 10 pt.

An itemized list of contents between secondary and outer packaging. Outer package must be of sufficient size to bear all necessary labels and possess strength for its capacity.

Completed packages must pass drop test.

## **8. Damaged Packages**

Damaged packages should be treated as though they are contaminated until proven otherwise. Any evidence of wetness (including dried areas that have visibly been wet) should be treated as contaminated. Use appropriate biosafety PPE and engineering controls when handling a damaged package. Disinfect any contaminated packaging using a reagent that is effective against the packaged substances. First, the package should be inspected for leaks and visible wetness on the outside packaging. Next, remove exterior packaging and inspect the interior packaging for leaks and damage. Finally, remove the items from the interior packaging and inspect for leaks and damage. If leaks and/or damage are found on any of these items, carefully remove, disinfect, and discard the packaging. Document any damage on packages containing biohazardous material. Inform the shipper of damage and leaks as soon as possible.

## **9. Registered Mail or Equivalent System**

Transportation of the following etiologic agents shall be by registered mail, or an equivalent system, which requires or provides for sending notification of receipt to the sender immediately upon delivery:

- *Coccidioides immitis*
- Ebola Virus
- *Francisella (Pasteurella) tularensis*

- Hemorrhagic Fever agents including, but not limited to, Crimean Hemorrhagic Fever (Congo), Junin, Machupo viruses, and Korean Hemorrhagic Fever Viruses.
- Herpesvirus Simiae (B virus)
- *Histoplasma capsulatum*
- Lassa Virus
- Marburg Virus
- *Pseudomonas mallei*
- *Pseudomonas pseudomallei*
- Tick-borne Encephalitis Virus complex including, but not limited to, Russian Spring-Summer Encephalitis, Kyasanur Forest Disease, Omsk Hemorrhagic Fever, and Central European Encephalitis Viruses.
- Variola Major and Variola Minor and White Pox Virus.
- *Yersinia (Pasteurella) Pestis*.

Packing instructions and forms for shipment of hazardous materials can be found at the following web sites:

FedEx: <http://images.fedex.com/us/services/pdf/HazmatShippingGuide.pdf>

UPS: <http://www.ups.com/content/us/en/resources/ship/hazardous/index.html>

### **10. Notice of Delivery, Failure to Receive**

When notice of delivery of materials known to contain etiologic agents is not received by the sender within five days following the anticipated delivery of the package, the sender shall notify the Director for the Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., Atlanta, Georgia 30333 by telephone (404) 633-5313

### **11. Requirements; Variations**

The Director of CDC may approve variations from the requirements of this section if, upon review and evaluation, it is found that such variation(s) provide protection at least equivalent to that provided by compliance, with the requirements specified in this section, and such findings are made a matter of official record.

## **M. Importation Permits for Etiologic Agents**

Centers for Disease, Control and Prevention Etiologic Agent Import Permit Program

### **a) General**

If you question whether your situation requires an importation permit, the safe alternative is to obtain and complete the application from the CDC's Department of Biosafety.

### **b) Importation Permits**

Many etiologic agents, infectious materials, or vectors containing infectious agents are imported from foreign locations into the United States for domestic use and study. Packages containing etiologic agents originating in these foreign locations must have an Importation Permit issued by the United States Public Health Service. Importation Permits are issued only to the importer, who must be located in the United States. The Importation Permit, with the proper packaging and labeling, will expedite clearance of the package of infectious materials through the United States Public Health Service Division of Quarantine and released by the U. S. Customs Department. The importer bears responsibility for assuring that the personnel for the foreign shipper pack and label the infectious materials according to USPHS Regulations. Transfers of previously imported material within the U.S. also require a permit for the same reason. Shipping labels containing the universal biohazard symbol, the address of the importer, the permit numbers, and the expiration date are also issued to the importer with the permit. The importer must send the labels and one or more copies of the permit to the shipper. A label must be secured to each package, and a copy of the permit should also be attached to the package. The permit and labels inform the U. S. Customs Service and the U. S. Division of Quarantine Personnel of the package contents.

### **c) Federal Regulations**

The importation of etiologic agents is governed by the following federal regulation: USPHS 42 CFR – Part 71 foreign Quarantine. Part 71.54 Etiologic agents, hosts, and vectors.

- a. A person may not import into the United States, nor distribute after importation, any etiologic agent or an arthropod or other animal host or vector of human disease, or any exotic living arthropod or other animals capable of being a host or vector of human disease unless accompanied by a permit issued by the Director.
- b. Any import coming within the provisions of this section will not be released from custody prior to receipt by the Port Director of the U. S. Customs Service of a permit issued by the Director of the CDC.

#### **d) Letter of Authorization**

After review of an “Application to Import an Etiological Agent,” the issuing officer may issue a “Letter of Authorization” rather than an Importation Permit. The Letter of Authorization is issued for materials that are judged to be non-infectious, but which might be construed to be infectious by the U. S. Customs Inspection’s personnel. Letters of Authorization may be issued for items such as formalin-fixed tissues, sterile cell cultures, clinical materials such as human blood, serum, plasma, urine, cerebrospinal fluid, and other tissues or materials of human origin when there is no evidence or indication that such materials contain an infectious agent. A copy of a Letter of Authorization should be attached to the package and furnished to the courier or importation broker. Letters of Authorization are in effect for two years and do not require a shipping label to be issued by this office.

#### **e) Packaging Requirements**

Infectious materials imported into this country must be packaged to withstand leakage of contents and labeled as specified in the following federal regulations:

USPHS 42 CFR Part 72 – Interstate Shipment of Etiologic Agents

DOT 49 CFR Part 173 – Transportation of Etiologic Agents

For international shipments, the International Air Transport Association (IATA) Dangerous Goods Regulations should be consulted.

#### **f) Other Permits**

United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) Permits are required for infectious agents of livestock and biological materials containing animal materials, particularly livestock.

Tissue (cell) culture techniques customarily use bovine material as a stimulant for cell growth. Tissue culture materials and suspensions of cell culture grown viruses or other etiologic agents containing growth stimulants of bovine or other livestock origin are, therefore, controlled by the USDA due to the potential risk of the introduction of exotic animal diseases into the United States. Further information may be obtained by calling the USDA/APHIS at (301) 734-3277. United States Department of Interior (USDI) Permits are required for certain live animals and all live bats. (Call (800) 358-2104 for further information).

#### **g) Exports of Infectious Materials**

The export of infectious material may require a license from the Department of Commerce. Call (202) 482-0896 for further information.

Centers for Disease Control and Prevention Office of Health and Safety, Biosafety  
Branch

1600 Clifton Road – MS F-05 Atlanta, Georgia 30333

Phone (404) 639-3235 Fax (404) 639-229

**All shipments of infectious materials into and out of TUN should be authorized by the BSO.**

## **N. Final Rule: Additional Requirements for Facilities Transferring or Receiving Select Agents**

This section is a summary of the **Final Rule**, as stated in the Federal Register 42 CFR Part 71 On June 10, 1996, the CDC, the Department HHS issued a Notice of Proposed Rulemaking (NPRM) to implement Section 511 of Public Law 104-132, “The Antiterrorism and Effective Death Penalty Act of 1996,” which requires the Secretary of HHS to regulate the transfer of select agents. Current regulations specify requirements for the packaging, labeling, and transporting of select agents shipped through interstate commerce. This Final Rule places additional shipping and handling requirements on facilities that transfer or receive select agents.

## **O. Select Agents**

### **Viruses:**

1. Crimean-Congo Hemorrhagic Fever Virus
2. Eastern Equine Encephalitis Virus
3. Ebola Virus
4. Equine Morbillivirus
5. Lassa Fever Virus
6. Marburg Virus
7. Rift Valley Fever Virus
8. South American Hemorrhagic Fever Virus (Junin, Machupo, Sabia, Flexal, Guanarito).
9. Tick-borne Encephalitis Complex Viruses
10. Variola Major Virus (Smallpox Virus)
11. Venezuelan Equine Encephalitis Virus
12. Viruses causing Hantavirus Pulmonary Syndrome
13. Yellow Fever Virus

### **Rickettsia**

1. *Coxiella burnetii*



2. *Rickettsia prowazekii*
3. *Rickettsia rickettsii*

## Fungi

*Coccidioides immitis*

## Toxins

1. Abrin
2. Aflatoxins
3. Botulinum Toxins
4. *Clostridium Perfringens* Epsilon Toxin
5. Conotoxins
6. Diacetoxyscirpenol
7. Ricin
8. Saxitoxin
9. Shigatoxin
10. Staphylococcal Enterotoxins
11. Tetrodotoxin
12. T-2 Toxin

## P. Standard microbiology lab practice at the Touro University Nevada

The following standard and special practices, safety equipment, and facilities apply to agents assigned to Biosafety Level 2 in all labs on campus:

### a) Standard Microbiological Practices

1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.
2. Persons wash their hands after they handle viable materials, after removing gloves, and before leaving the laboratory.
3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the work areas. Food is stored outside the work area in cabinets or refrigerators designated for this purpose only.
4. Contact lenses are not recommended but are permitted. Appropriate safety eyewear is still required for those that use contact lens. Inform the lab supervisor of the use of contact lenses.
5. Mouth pipetting is prohibited; mechanical pipetting devices are used.
6. Policies for the safe handling of sharps are instituted.

7. All procedures are performed carefully to minimize the creation of splashes or aerosols.
8. Work surfaces are decontaminated on completion of work or at the end of the day and after any spill or splash of viable material with disinfectants that are effective against the agents of concern.
9. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leak-proof container and closed for transport from the laboratory. Materials to be decontaminated off-site from the facility are packaged in accordance with applicable local, state, and federal regulations.
10. An insect and rodent control program is in effect (see Appendix H Pest Management).

#### **b) Special Practices**

1. Access to the laboratory is limited or restricted by the laboratory director when work with infectious agents is in progress. In general, persons who are at increased risk of acquiring an infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at increased risk of acquiring infections. The laboratory director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory or animal room.
2. The laboratory director establishes policies and procedures whereby only persons who have been advised of the potential hazards and meet specific entry requirements (e.g., immunization) may enter the laboratory.
3. A biohazard sign must be posted on the entrance to the laboratory when etiologic agents are in use. Appropriate information to be posted include the agent(s) in use, the biosafety level, the required immunizations, the investigator's name, and telephone number, any personal protective equipment that must be worn in the laboratory, and any procedures required for exiting the laboratory.
4. Confidential medical surveillance is provided for all laboratory personnel. If any laboratory personnel have questions or concerns about their health in relation to work with biohazardous agents that they are strongly encouraged to contact the Medical Surveillance Practitioner, Dr. Ron Hedger, for a confidential medical consultation at 702-777-1818.
5. Laboratory personnel are provided appropriate immunizations, or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing). Contact the Medical

Surveillance Practitioner, Dr. Ron Hedger, at 702-777-1818 or the Touro University Nevada Health Clinic at 702-777-4809 to arrange for counseling or vaccinations.

- a. Recommended vaccines for all laboratory personnel are:
  - i. Hepatitis B Virus Vaccine
  - ii. Tetanus vaccine such as Tdap Vaccine
  - iii. Yearly Influenza Vaccine
6. Persons with changes to health, particularly changes to immune status, are encouraged to self-identify. Such changes may include chemotherapy, HIV status, pregnancy or intention to become pregnant.
7. When appropriate, considering the agent(s) handled, baseline serum samples for laboratory and other at-risk personnel are collected and stored. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the facility.
8. Biosafety procedures are incorporated into standard operating procedures or in a biosafety manual adopted or prepared specifically for the laboratory by the laboratory director. Personnel are advised of special hazards and are required to read and follow instructions on practices and procedures.
9. The laboratory director ensures that laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates or additional training as necessary for procedural or policy changes. The Institutional Biosafety Committee is responsible for verifying annual training and refresher training.
10. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.
  - a. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles.
  - b. Plasticware should be substituted for glassware whenever possible.

- c. Only needle-locking syringes or disposable syringe-needle units (i.e., the needle is integral to the syringe) are used for injection or aspiration of infectious materials. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
  - d. Syringes that re-sheath the needle, needleless systems and other safety devices are used when appropriate.
  - e. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass are decontaminated before disposal, according to any local, state, or federal regulations.
  - f. An annual review of the newest sharps engineering controls must occur and be documented. After review, updated best practices should be incorporated into use and lab personnel trained on proper use.
11. Cultures, tissues, specimens of body fluids, or potentially infectious wastes are placed in a container with a cover that prevents leakage during collection, handling, processing, storage, transport, or shipping.
12. Laboratory equipment and work surfaces should be decontaminated with an effective disinfectant on a routine basis, after work with infectious materials is finished, and especially after overt spills, splashes, or other contamination by infectious materials. Contaminated equipment must be decontaminated according to any local, state, or federal regulations before it is sent for repair or maintenance or packaged for transport in accordance with applicable local, state, or federal regulations, before removal from the facility.
13. Spills and accidents that result in overt exposures to infectious materials are immediately reported to the laboratory director. Medical evaluation, surveillance, and treatment are provided as appropriate, and written records are maintained.
14. Animals and plants not involved in the work being performed are not permitted in the lab.

### c) Safety Equipment (Primary Barriers)

1. Properly maintained biological safety cabinets, preferably Class II, or other appropriate personal protective equipment or physical containment devices are used whenever:
  - a. Procedures with a potential for creating infectious aerosols or splashes are conducted. These may include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers of infectious materials whose internal pressures may be different from ambient pressures, inoculating animals intranasally, and harvesting infected tissues from animals or embryonated eggs.
  - b. High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory if sealed rotor heads or centrifuge safety cups are used, and if these rotors or safety cups are opened only in a biological safety cabinet.
2. Face protection (goggles, mask, face shield, or another splatter guard) is used for anticipated splashes or sprays of infectious or other hazardous materials to the face when the microorganisms must be manipulated outside the BSC. Face Protection must be decontaminated or disposed of as appropriate for the biosafety level of the materials used.
3. Protective laboratory coats, gowns, smocks, or uniforms designated for lab use are worn while in the laboratory. This protective clothing is removed and left in the laboratory before leaving for non-laboratory areas (e.g., cafeteria, library, administrative offices). All protective clothing is either disposed of in the laboratory or laundered by the institution or an approved vendor only; it should never be taken home by personnel.
4. Gloves are worn when hands may contact potentially infectious materials, contaminated surfaces, or equipment. Wearing two pairs of gloves may be appropriate. Gloves are disposed of when overtly contaminated, and removed when work with infectious materials is completed or when the integrity of the glove is compromised. Gloves must be disposed of as appropriate for the biosafety level of the materials used. Disposable gloves are not washed, reused, or used for touching "clean" surfaces (keyboards, telephones, etc.), and they should not be worn outside the lab. Alternatives to powdered latex gloves should be available. Hands are washed following removal of gloves.

#### **d) Laboratory Facilities (Secondary Barriers)**

1. Provide lockable doors for facilities that house restricted agents (as defined in 42 CFR 72.6).
2. Consider locating new laboratories away from public areas.
3. Each laboratory contains a sink for handwashing.
4. The laboratory is designed so that it can be easily cleaned. Carpets and rugs in laboratories are inappropriate.
5. Benchtops are impervious to water and are resistant to moderate heat and the organic solvents, acids, alkalis, and chemicals used to decontaminate the work surfaces and equipment.
6. Laboratory furniture is capable of supporting anticipated loading and uses.
7. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a nonfabric material that can be easily decontaminated.
8. Install biological safety cabinets in such a manner that fluctuations of the room supply and exhaust air do not cause the biological safety cabinets to operate outside their parameters for containment. Locate biological safety cabinets away from doors, from windows that can be opened, from heavily traveled laboratory areas, and from other potentially disruptive equipment so as to maintain the biological safety cabinets' airflow parameters for containment.
9. An eyewash station is readily available.
10. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.
11. There are no specific ventilation requirements. However, the planning of new facilities should consider mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the laboratory. If the laboratory has windows that open to the exterior, they are fitted with fly screens.

## **Q. Research Involving Recombinant DNA**

See Appendix E Definitions from the NIH Guidelines for the Use of Exempt rDNA Molecules

### **Experiments Using Risk Group 2, Risk Group 3, or Restricted Agents as Host Vector Systems**

Experiments involving the introduction of recombinant DNA into Risk Group 2 Agents will usually be conducted at Biosafety Level (BSL-2) containment. Experiments with such agents will usually be conducted with whole animals at BSL-2 or BSL-2N (animals) containment. Experiments involving the introduction of recombinant DNA into Risk Group 3 Agents will usually be conducted at BSL-3 containment. Experiments with such agents will usually be conducted with whole animals at BSL-3 or BSL-3N containment. TUN does not have BSL containment, so any such work would require collaboration with appropriate laboratories.

### **Experiments in which DNA from Risk Group 2, Risk Group 3, or Restricted Agents is cloned into Non-Pathogenic Prokaryotic or Lower Eukaryotic Host-Vector System.**

Experiments in which DNA from Risk Group 2 or Risk Group 3 Agents are transferred into nonpathogenic prokaryotes or lower eukaryotes may be performed under BSL-2 containment. The Institute's Biosafety Committee may approve the specific lowering of containment for particular experiments to BSL-1. Experiments involving the formation of recombinant DNA for certain gene encoding for molecules toxic for vertebrates require NIHOBA approval. Experiments involving the cloning of toxin molecules with LD50 of less than 100 nanograms per kilogram body weight shall be conducted under NIH specified conditions. Containment conditions for experiments in which DNA from select agents is transferred into non-pathogenic prokaryotes or lower eukaryotes shall be determined by NIHOBA following a case-by-case review.

Recombinant DNA or RNA molecules derived from any source except for greater than two-thirds of the eukaryotic viral genome may be transferred to any non-human vertebrate or any invertebrate organism and propagated under conditions of physical containment comparable to BSL-1 or BSL-1N and appropriate to the organism under study. Animals that contain sequences from viral vectors, which do not lead to transmissible infection either directly or indirectly as a result of complementation or recombination in animals, may be propagated under conditions of physical containment comparable to BSL-1 or BSL-1N and appropriate to the organism under study. It is important that the investigator demonstrates that the fraction of the viral genome being utilized does not lead to productive infection.

## Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation

Recombinant DNA molecules containing no more than two-thirds of the genome of any eukaryotic virus (all viruses from a single-family being considered identical) may be propagated and maintained in cells in tissue culture using BSL-1 containment. For such experiments, it must be demonstrated that the cells lack a helper virus for the specific families of defective viruses being used. The DNA vector may contain fragments of the genome of viruses from more than one family, but each fragment shall be less than two-thirds of a genome. Experiments in which all components derived from non-pathogenic prokaryotes and non-pathogenic lower eukaryotes may be conducted at BSL-1 containment.

## Biosafety Considerations for Research with Lentiviral Vectors

A comprehensive risk assessment and determination of containment for research with lentiviral vectors should consider the nature of the vector system, transgene insert, and type of manipulations involved. For many experiments, either BSL-2 or enhanced BSL-2 will be appropriate. For more information visit the OBA website at [www.od.nih.gov/oba/rac/Guidance/LentiVirus\\_Containment/index.htm](http://www.od.nih.gov/oba/rac/Guidance/LentiVirus_Containment/index.htm)

## Exempt Experiments

The following recombinant DNA molecules are exempt from the NIH Guidelines, and approval from TUN's IBC should be obtained by submitting an Exempt BSL-1/ABSL-1 Registration Form. A research registration form should also be on file with the Associate Dean of Research.

1. Those that are not performed in organisms or viruses
2. Those that consist entirely of DNA segments from a single non-chromosomal source, though one or more of the segments may be a synthetic equivalent.
3. Those that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in the host (or a closely related strain of the same species).
4. Those that consist entirely of DNA from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).
5. Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the NIH Director with the advice of the RAC after appropriate notice and opportunity for public comment.



6. Those that do not present a significant risk to health or the environment as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment.

### **For Your Information**

Summary of the changes in NIH Guidelines for Recombinant DNA in relation to transgenic rodents:

1. Purchase or transfer of transgenic animals (from commercial or non-commercial sources) is exempt from the NIH guidelines and approval of the Institute's Biosafety Committee, provided the animals and experiments can be carried out at BSL-1 containment.
2. Generating new transgenic animals requires notification to the Institute's Biosafety Committee at the initiation of the experiment, provided the animals and experiments can be carried out at BSL-1 containment. Generating transgenics using DNA sequences from Risk Group 2 or 3 Agents will require prior approval by the Institute's Biosafety Committee for the appropriate containment level.

## Section VII – Laboratory Animals

### A. Care and Use of Laboratory Animals

Special attention must be given to the humane treatment of all laboratory animals in accordance with the Animal Welfare Act of 1996 as amended, the Public Health Service Policy on the Humane Care and Use of Laboratory Animals, and the policies of the Institute. The Institute's Attending Veterinarian and IACUC establish procedures to ensure the use of animals that are free of disease prejudicial to the proposed experiments, and free from carriers of disease or vectors such as ectoparasites, which endanger other experimental animals or personnel. Animal care technicians are well trained in the basic fundamentals of laboratory animal care. Appropriate training materials are available from a number of animal care associations or commercial organizations. Animal care technicians, scientists, or others routinely exposed to infected animals, potentially contaminated equipment, and animal waste must participate in preventative medical training and the medical surveillance programs of the Institute.

### B. Care and Handling of Infected Animals

There are four combinations of practices, safety equipment, and facilities for experiments with animals infected with agents that cause, or may cause, human infection. These four combinations designated Animal Biosafety Levels (ABSL) 1-4 provide increasing levels of protection to personnel and to the environment and are recommended as minimal standards of activities involving infected laboratory animals. The ABSLs describe animal facilities and practices applicable to work with animals infected with agents assigned to the appropriate Biosafety Levels.

<http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4s4.htm>

All Standard Microbiology procedures described previously are enforced in the animal facility and with infected animals (Standard microbiology lab practice at the Touro University Nevada).

Comprehensive reviews indicate that animals infected with a wide range of etiological agents are capable of shedding infectious micro-organisms in the saliva, urine, or feces. In the absence of specific information to the contrary, all infected animals should be regarded as potential shedders.

### **C. Procedures appropriate for the handling of infected animals are given below**

- a. Trained personnel carry out all the procedures, including necropsies using certified Biological Safety Cabinets. In the event that a procedure cannot be performed in a BSC, eye and face protection are required.
- b. Necropsies of potentially infected animals must be carried out under the same conditions, and additional precautions should be taken according to the specified hazards.
- c. Personal Protective Equipment (PPE) – Gowns, head covers, shoe covers, gloves, eye protection, and face masks as determined by risk assessment as assessed by the IBC and the IACUC while inside the animal facilities.
- d. It is recommended that for necropsies, dedicated instruments, and an appropriate board to position the animal be utilized. The board should be either disposable or made from a material that can be disinfected.
- e. All of the supplies for sample collection, including containers, swabs for cultures, slides, etc. should be prepared in advance.
- f. Upon completion of each necropsy, all potentially biohazardous materials should be disposed of in the appropriately labeled receptacles.
- g. The animal carcasses should be double bagged, appropriately labeled, and placed in the freezer.
- h. The cages should be placed in the dirty cage wash room, and labeled, indicating that they should be autoclaved before washing.
- i. Instruments and other supplies should be disinfected and carefully cleaned following the procedures approved by the Institute's Biosafety Committee and then autoclaved or disposed of.
- j. Any instrument that carries the risk of a sharp must be transported inside a hard-walled container.

### **D. General Guidelines that Apply to Animal Room Maintenance**

- a. Doors to animal rooms should be kept closed at all times, except for necessary entrances and exits.
- b. Unauthorized persons should not be permitted to enter animal rooms.
- c. A container of disinfectant is kept in each biohazard suite for disinfecting gloves and hands, and for general decontamination even though no infectious animals are present. Hands, floors, walls, equipment, and cage racks are washed with a quaternary disinfectant at the recommended strength as frequently as the supervisor directs.

- d. Floor drains in animal rooms, as well as floor drains throughout the building, should be flooded with water or disinfectant periodically to prevent backup of sewer gases.
- e. Animal bedding and other refuse on floors should not be washed down the floor drain because such refuse clogs the sewer lines.
- f. An insect and rodent control program should be maintained in all animal rooms and in animal food storage areas.
- g. Specific care should be taken to prevent live animals, especially mice, from finding their way into disposable trash.
- h. Spills are handled as described in section **Procedures Following Biohazardous Material Spill**
- i. Specific instructions involving the housing, care, and maintenance of laboratory animals are available from the following sources:
  - i Laboratory Safety Monograph, A Supplement to the NIH Guidelines for recombinant DNA Research, January 1979.
  - ii Occupational Health and Safety in the Care and Use of Research Animals, 1997.
  - iii Guide for the Care and Use of Laboratory Animals, 2011(Eighth Edition).
  - iv Biosafety in Microbiological and Biomedical Laboratories, CDC/NIH 2009 (Fifth Edition).

## **E. Cage Cleaning**

Biohazard cages should only be handled according to TUN IACUC Standard Operating Procedures.

1. Biohazardous animals must be contained in designated rooms with negative airflow and a sign posted on the room door with the following information:
  - a. PI name and contact person's phone number.
  - b. Protocol number.
  - c. Identification of hazard.
2. Cages that house infected animals must be labeled.
3. All personnel manipulating cages must wear personnel protective equipment including:
  - a. Gown
  - b. Disposable gloves
  - c. Shoe covers
  - d. Headcover

- e. Surgical or N95 mask depending on the situation
4. Changing of all cages containing biohazardous animals must be performed in an approved/certified biosafety cabinet.
5. Biosafety cabinets must be cleaned with the proper disinfectant before and after each use.
6. Animals are transferred from a dirty cage to clean cage using forceps that are decontaminated between cages, or using disinfected gloves between each cage.
7. After cage changing, all cages (including bedding, food, and water devices) are placed on a designated rack on the fourth floor of MRC.
8. All biohazardous cages must be autoclaved prior to washing.
9. All scientists are required to comply with institute policy regarding cage cleaning.
10. All animal cages contaminated with chemicals must be cleaned in compliance with institutional policy

## **F. Transportation of Research Animals**

Transportation of animals out of the TUN Animal Resource Center (ARC), is prohibited (unless there is IACUC approval that includes description of transportation methods).

## **G. Transportation of materials between the animal facility and the research labs**

Any materials or containers to be transported between the research lab and the animal facility for research, storage, or disposal purposes must first be treated to decontaminate external surfaces. Biological materials must be held within capped, spill-proof plastic containers. Containers are sprayed with virucide, wiped with a paper towel, and the dried containers are then placed in an appropriate Plexiglas box or carrying container for transport.

## **H. Visitors (Unauthorized Personnel)**

Unauthorized personnel are prohibited from entering the laboratories and animal facilities. Individuals under 18 years of age, immunosuppressed persons, and pregnant visitors are forbidden to enter the laboratories of the Institute. As is the case for all personnel and visitors in a research laboratory, the Principal Investigator is responsible for training, assigning appropriate tasks, and monitoring for safety practices. In addition, access to the research lab for a student needs to be processed through the Associate Dean of Research's Office.



## Appendix A Bloodborne Pathogens Exposure Control Plan

**Touro University Nevada** has made a commitment to the prevention of incidents or accidents that can result in employee injury or illness. This exposure control plan is an element of our safety and health program and complies with OSHA's ***Bloodborne Pathogens, 29 CFR 1910.1030***, requirements.

**TUN Biosafety Officer** has the authority and responsibility to ensure that all elements of the exposure plan are in place. Employees can read the plan on Box under the Research Document folder.

### Purpose

The purpose of this exposure plan is to eliminate or minimize employee occupational exposure to blood or other potentially infectious materials (OPIM), identify employees occupationally exposed to blood or OPIM in the performance of their regular job duties, provide information and training to employees exposed to blood and OPIM, and comply with OR-OSHA ***Bloodborne Pathogen standard, 1910.1030***.

### Exposure determination

Employees subject to the OR-OSHA bloodborne pathogens standard are those who are reasonably expected to have skin, eye, mucous membrane, or parenteral contact with blood and/or any body fluids that are contaminated with blood resulting from the performance of their assigned job duties. Although Good Samaritan acts are not covered under the bloodborne pathogen standard, it is our policy to provide evaluation and treatment of employees who sustain exposure to blood or OPIM who assist an injured employee but are not required to. Use Appendix F TUN IBC Biosafety Risk Assessment Summary for exposure determination.

**Table 1** lists example job classifications and associated tasks identifying employees at risk of exposure to blood or other potentially infectious materials. Exposure determinations are made without regard to the use of PPE. See the complete list at EH&S.

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Table 1: Employees at risk	
Job classification	Task or exposure
Example: Phlebotomist	Example: Collect human clinical samples

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**Table 2** lists example job classifications and tasks in which some employees may have occupational exposures to blood or OPIM. See the complete list at EH&S

<b>Table 2: Employees who may be at risk</b>	
Job classification	Task or exposure
Example: Housekeepers	Example: Handling Regulated Waste

## Compliance methods

### Universal precautions

Universal precautions is an approach to infection control in which all human blood and other potentially infectious materials are handled as if they were known to be infectious for bloodborne pathogens. Consider difficult- or impossible-to-identify body fluids as potentially infectious.

### Engineering and work practices controls

Use the following controls to eliminate or minimize occupational exposure.

#### Sharp containers

Place contaminated needles, blood-contaminated test tubes, and other sharp objects in a sharps container. Replace containers routinely and do not allow overfilling. Place reusable sharps in metal trays for decontamination. When moving containers of contaminated sharps from the area of use, close containers to prevent spillage or protrusion of contents.

#### Safe medical devices

Purchase and use safe medical devices whenever possible. Evaluate devices annually to determine the appropriateness of the device and to investigate new and safer options.

#### Work practices

Clean up blood spills or body fluids as soon as possible. Use disposable absorptive materials, such as paper towels or gauze pads, to soak up the fluids. Clean the area with chemical germicides or a 1:10 solution of liquid bleach. Place absorptive towels, pads, and other materials used to mop up spills in plastic bags or designated labeled containers, and treat as biohazardous waste.

Employees must wash their hands upon the removal of gloves and other protective gear. In an emergency, if soap and water are not immediately available, use disposable



antiseptic towelettes or germicidal gels to clean hands after removing gloves. Employees must wash their hands with soap and water as soon as possible.

Employees may not eat, drink, smoke, apply cosmetics or lip balm, or handle contact lenses where occupational exposure can occur. Do not store food or beverages in refrigerators and freezers and other sites used to store blood or other biohazardous material. Place biohazard labels on refrigerators or freezers used to store biohazardous material.

### **Personal protective equipment (PPE)**

PPE is provided at no cost to employees. Employees receive training in its use, maintenance, and disposal annually.

### **Storage area**

TUN Research Laboratory is the storage area for bloodborne protective gear. Supplies include disposable gloves; face shields; impervious disposable coveralls and booties; resuscitation devices; large, heavy-duty plastic bags and ties; sharps containers; biohazard signs or labels; absorbent pressure dressings for wounds; antiseptic towels, disposable absorptive material for cleaning up spilled blood; rubber gloves; and bleach solutions or germicides.

### **PPE use and disposal**

Employees engaging in activities that may involve direct contact with blood, OPIM, contaminated objects, mucous membranes, or open wounds must wear disposable gloves made of vinyl or latex. Use reusable rubber gloves (inspected and free of apparent defects) or disposable gloves to clean up spill areas. Disinfect reusable gloves with diluted liquid bleach or germicides after use.

Wear face shields or goggles with disposable surgical masks whenever splashes, spray or spatters of blood droplets or OPIM may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

Use laboratory coats or scrubs to prevent contamination of employee street clothing. Wear impermeable disposable coveralls and booties whenever contamination of skin not protected by gloves or face shields is anticipated, such as a traumatic injury with significant blood loss.

Use resuscitation devices, which minimize contact with mucous membranes, to perform cardiopulmonary resuscitation.

Remove used personal protective equipment at the exposure location or as soon as feasible to avoid contamination of other work areas. Place in a biohazard container or in a plastic bag with a biohazard label. PPE must not be taken from the worksite.

### Housekeeping

Employees who have received bloodborne pathogen training and who have been included under the exposure plan can clean up spills and work surfaces such as benchtops and blood processing areas.

Clean and decontaminate all equipment and working surfaces after completion of procedures in which blood or body fluids contaminated with blood are handled and immediately, or as soon as feasible when surfaces are overtly contaminated with blood and at the end of the work shift if the surface may have been contaminated since the last cleaning. Inspect all biohazardous waste receptacles and decontaminate weekly or immediately upon visible contamination.

Use chemical germicides or solutions of 5.25 percent sodium hypochlorite (liquid bleach) diluted 1:10 with water for cleaning. Chemical germicides approved for use as hospital disinfectants and effective against HIV can also be used.

Broken glassware or glass items must not be picked up directly with the hands. Use a mechanical means, such as a brush and dustpan, tongs, or forceps. Handle as biohazardous waste. Decontaminate equipment used to pick up glassware with a 1:10 bleach solution or an approved germicide.

### Contaminated laundry

Handle non-disposable linen, such as laboratory coats or scrubs, or any other clothing visibly contaminated with blood using disposable gloves. Minimize the time spent handling laundry. Bag laundry as close as possible to the location where it was used. Place laundry in a bag that prevents soak-through and/or leakage of fluids to the exterior; place a biohazard label on the bag.

Employees cannot wash contaminated items at home. Contaminated items will be laundered by approved vendors.

### Regulated waste

The Medical Division of Republic Service will pick up the regulated waste. Place regulated waste in containers that are closable, constructed to contain all contents and

prevent leakage, appropriately labeled or color-coded, and closed prior to removal to prevent spillage or protrusion of contents during handling.

### **Labels and signs**

Affix warning labels to laundry bags, containers of regulated waste, refrigerator units, and containers used to store, transport, or ship blood or OPIM. Red bags or red containers can be used instead of labels.

### **Hepatitis B vaccine**

The hepatitis B vaccine is offered at no cost, to exposed employees within 10 working days of initial assignment. Employees who have potential exposure to bloodborne pathogens but decline to take the vaccination must sign a declination statement. Employees who initially decline can still receive the vaccination should they decide at a later date to accept. Previously vaccinated new hires must provide a vaccination record that includes the vaccination dates. Employees must sign a declination statement if the vaccination record is not available, and revaccination is declined or not appropriate. TUN Occupational Health and Safety Officer will schedule vaccinations at the Touro University Nevada Clinic and will keep employees' vaccination records in their medical files.

### **Exposure incident and post-exposure evaluation and follow-up**

An exposure incident to bloodborne pathogens is defined as an eye, mouth, other mucous membranes, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties. It is Touro University Nevada's policy to include Good Samaritan acts performed by an employee at the worksite.

Whenever an exposure occurs, wash the contaminated skin immediately with soap and water. Immediately flush contaminated eyes or mucous membranes with copious amounts of water. Medically evaluate exposed employees as soon as possible after the exposure incident in order that post-exposure prophylaxis, if recommended, can be initiated promptly.

The medical evaluation is to include the route(s) of exposure and the exposure incident circumstances; identification and documentation of the source individual, where feasible; exposed employee blood collection and testing of blood for HBV and HIV serological status; post-exposure prophylaxis, where indicated; counseling; and evaluation of reported illnesses. Source test results and identity will be disclosed to the

exposed employee according to applicable laws and regulations concerning disclosure and confidentiality.

Touro University Nevada Clinic provides hepatitis B vaccinations and medical evaluations and post-exposure follow-up after an exposure incident and has a copy of the ***Bloodborne Pathogen Standard, 1910.1030***.

## **Procedures for Evaluating the Circumstances Surrounding an Exposure Incident**

The Institutional Biosafety Committee, along with the Biosafety Officer will review the circumstances of all exposure incidents to determine:

- **engineering controls in use at the time**
- **work practices followed**
- **a description of the device being used (including type and brand)**
- **protective equipment or clothing that was used at the time of the exposure incident (gloves, eye shields, etc.)**
- **location of the incident (Clinic, research lab or instruction lab)**
- **procedure being performed when the incident occurred**
- **employee's training (Name of Responsible Person) will record all percutaneous injuries from contaminated sharps in a Sharps Injury Log.**

If revisions to this Exposure Control Plan are necessary (Biosafety Committee along with the Biosafety Officer) will ensure that appropriate changes are made. (Changes may include an evaluation of safer devices, adding employees to the exposure determination list, etc.). All changes are to be approved by the Associate Dean for Research.

## **Information provided to the health care professional**

TUN Occupational Health and Safety Officer are responsible for ensuring that the health care professional who evaluated the employee after an exposure incident receives the following information:

- A description of the employee's duties as they relate to the exposure incident
- Documentation of the route(s) and circumstances of the exposure
- The results of the source individual's blood testing, if available
- All medical records relevant to the appropriate treatment of the employee, including vaccination status

## Health care professional's written opinion

TUN Occupational Health and Safety Officer will provide the employee with a copy of the health care professional's written opinion within 15 days after completion of the evaluation.

Limit the health care professional's written opinion(s) for the hepatitis B vaccination to whether the vaccination is indicated and whether the employee has received the vaccination.

Limit the health care professional's written opinion for the post-exposure evaluation to the following information:

- Whether the employee was informed of the evaluation results
- Whether the employee was told about any medical conditions resulting from exposure to blood or OPIM that may require further evaluation or treatment.

## Training and training records

All employees who have occupational exposure to bloodborne pathogens receive training on the epidemiology, symptoms, and mode of transmission of bloodborne pathogen diseases. In addition, the training program will include the following topics:

- An explanation of activities and tasks that may involve exposure to blood and OPIM
- How appropriate engineering controls, work practices, and PPE will prevent or reduce exposure
- The basis for the selection of PPE; the types, use, location, removal, handling, decontamination, and disposal procedures
- Hepatitis B vaccine information including that the vaccine is provided at no cost, the benefits of being vaccinated and methods of administration
- Employer responsibilities for post-exposure evaluation and medical follow-up; how and whom to contact should an exposure incident occur
- An explanation of the signs and hazard labels
- How to review or obtain a copy of the exposure control plan and the standard

Training by bloodborne pathogen specialists will be arranged, and web-based training will supplement the on-site training. Employees will be trained prior to initial assignment to tasks in which occupational exposure may occur. Training is repeated every 12 months or sooner when there are new tasks or changes to the existing procedures/tasks. Training records are maintained at the office of the Biosafety Officer

for three years and include the date(s) and content of the training program, name and qualifications of the trainer(s), and names and job titles of the attendees.

## Record keeping

Medical records for employees with occupational exposure to bloodborne pathogens include the employee's name, social security number, and hepatitis B vaccination status, including dates of hepatitis B vaccination and any medical records relative to the employee's ability to receive the vaccination. Medical records are kept for the duration of employment plus 30 years in accordance with OR-OSHA's **Access to Employee Exposure and Medical Records standard, 1910.1020**. Medical records are confidential. Employees must sign a written consent for disclosure.

In the event of an exposure incident, the following records will be kept in the employee's medical file:

- The results of any examination, medical testing, and follow-up procedures.
- A copy of the treating physician's written opinion to the employer.
- A copy of all information provided by the employer to the health care professional regarding the exposure incident.

Record every needle stick on the OSHA 300 Log and/or the Sharps Injury Log. Record all other exposure incidents that result in medical treatment (e.g., gamma globulin, hepatitis B immune globulin, hepatitis B vaccine, etc.) on the OSHA 300 log. Retain these records for five years.

## Plan evaluation and review

Review the exposure control plan and update it at least annually. Associate Dean for Research and the Biosafety Officer are responsible for the annual review.

## Appendix B Select Agents (CDC)

In order to prohibit the unlawful use and distribution of certain infectious organisms and toxins, the Centers for Disease Control and Prevention (CDC) (<http://www.cdc.gov/od/sap/>) have established certain restrictions. All agents included in the following list must be registered with the CDC. In order to receive any of these agents, all acquisition requests need to be handled by the CDC. This includes transfers in-between workgroups, universities or laboratories, purchasing from chemical manufacturers, as well as any other shipment or acquisition. Laboratories and Principal Investigators require IBC approval prior to receiving and working with these agents. The CDC is required to track these agents from the time of acquisition to final disposal. Contact the Biosafety Officer for more information. (Some of the agents listed below are classified as RG-4 and require containment procedures and facilities not available on the TUN campus.)

### HHS and USDA Select Agents and Toxins

**7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73**

#### HHS Select Agents and Toxins

Abrin

Botulinum neurotoxins

Botulinum neurotoxin producing species of *Clostridium*

Cercopithecine herpesvirus 1 (Herpes B virus)

*Clostridium perfringens epsilon toxin* *Coccidioides posadasii*/*Coccidioides immitis*

Conotoxins

*Coxiella burnetii*

Crimean-Congo hemorrhagic fever virus

Diacetoxyscirpenol

Eastern Equine Encephalitis virus

Ebola virus

*Francisella tularensis*

Lassa fever virus

Marburg virus

Monkeypox virus

Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments

(Reconstructed 1918 Influenza virus)

Ricin

*Rickettsia prowazekii*

*Rickettsia rickettsii*

Saxitoxin

Shiga-like ribosome-inactivating proteins

Shigatoxin

South American Haemorrhagic Fever viruses

Flexal

Guanarito

Junin

Machupo

Sabia

Staphylococcal enterotoxins

T-2 toxin

Tetrodotoxin

Tick-borne encephalitis complex (flavi) viruses

Central European Tick-borne encephalitis

Far Eastern Tick-borne encephalitis

Kyasanur Forest disease

Omsk Hemorrhagic Fever

Russian Spring and Summer encephalitis

Variola major virus (Smallpox virus)

Variola minor virus (Alastrim)

*Yersinia pestis*

### **USDA Select Agents and Toxins**

African horse sickness virus

African swine fever virus

Akabane virus

Avian influenza virus (highly pathogenic)

Bluetongue virus (exotic)

Bovine spongiform encephalopathy agent

Camel pox virus

Classical swine fever virus

Ehrlichia ruminantium (Heartwater)

Foot-and-mouth disease virus

Goat pox virus

Japanese encephalitis virus

Lumpy skin disease virus



Malignant catarrhal fever virus  
(Alcelaphine herpesvirus type 1)  
Menangle virus  
*Mycoplasma capricolum subspecies capripneumoniae*  
(contagious caprine pleuropneumonia) *Mycoplasma mycoides subspecies mycoides*  
small colony (*Mmm* SC) (contagious bovine pleuropneumonia)  
Peste des petits ruminants virus  
Rinderpest virus  
Sheep pox virus  
Swine vesicular disease virus  
Vesicular stomatitis virus (exotic): Indiana subtypes  
VSV-IN2, VSV-IN3  
Virulent Newcastle disease virus 1

### **USDA PLANT PROTECTION AND QUARANTINE (PPQ) Select Agents and Toxins**

*Peronosclerospora philippinensis*  
(*Peronosclerospora sacchari*)  
*Phoma glycinicola* (formerly *Pyrenochaeta glycinis*)  
*Ralstonia solanacearum* race 3, biovar 2  
*Rathayibacter toxicus*  
*Sclerophthora rayssiae var zea*  
*Synchytrium endobioticum*  
*Xanthomonas oryzae*  
*Xylella fastidiosa* (*citrus variegated chlorosis*)

### **OVERLAP Select Agents and toxins**

*Bacillus anthracis*  
*Brucella abortus*  
*Brucella melitensis*  
*Brucella suis*  
*Burkholderia mallei* (formerly *Pseudomonas mallei*)  
*Burkholderia pseudomallei* (formerly  
*Pseudomonas pseudomallei*)  
Hendra virus  
Nipah virus  
Rift Valley fever virus  
Venezuelan Equine Encephalitis virus

In small quantities, some of these toxins are exempt from select agent registration. See the table below. However, the **possession, use, or transfer of ANY select agent toxin, IN ANY QUANTITY, must be registered with the Institutional Biosafety Committee.**

### Exempt Amounts Select Agent Toxins Permissible Per Principal Investigator

HHS (CDC-listed) Toxins	Amount
Abrin	100 mg
Conotoxin	100 mg
Diacetoxyscirpenol (DAS)	1000 mg
Ricin	100 mg
Saxitoxin	100 mg
Shiga-like ribosome-inactivating proteins	100 mg
Tetrodotoxin	100 mg
Botulinum neurotoxins	0.5 mg
Staphylococcal enterotoxins	5.0 mg
Clostridium perfringens epsilon toxin	100 mg
Shigatoxin	100 mg
T-2 toxin	1000 mg

**Again, even exempt amount of toxins must be registered with the Institutional Biosafety Committee.**

## **Appendix C USA PATRIOT Act of 2001**

(Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, Public Law 107-56, HR 3162, October 26, 2001, composed of 10 Titles containing 159 Sections)

### **Title VII - Strengthening the Criminal Laws Against Terrorism Section 817- Expansion of the Biological Weapons Statues Overview:**

The first provision of this law makes it unlawful for an individual to possess certain "biological agents, toxins, or delivery systems" in quantity or of a type that "is not reasonably justified by a prophylactic, protective, bona fide research, or peaceful purpose." The second provision states that persons who meet the definition of "restricted persons" are prohibited from having access to or possessing any amount of the biological agent, or any of the toxins listed on the CDC's list of Select Agents.

#### **What "biological agents" are covered by the Act?**

The term "biological agent" is defined by the Act as any microorganism, virus, infectious substance, or biological product that may be engineered as a result of biotechnology, or any naturally occurring or bioengineered component of any such microorganism, virus, infectious substance, or biological product, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material or any kind; or deleterious alteration of the environment.

#### **What "toxins" are covered by the Act?**

A "toxin" means the toxic material of plants, animals, microorganism, viruses, fungi, or infectious substances, or a recombinant molecule, whatever its origin or method of production, including any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance.

#### **What are the "Select Agents"?**

See Appendix B Select Agents (CDC) of the Biosafety Manual.

#### **Who is a "restricted person"?**

According to the Act, the term "restricted person" means an individual who meets any one or more of the following criteria: is under indictment for a crime punishable by imprisonment for a term exceeding 1 year; has been convicted in any court of a crime

punishable by imprisonment for a term exceeding 1 year; is a fugitive from justice; is an unlawful user of any controlled substance; is an alien illegally or unlawfully in the United States; has been adjudicated as a mental defective or has been committed to any mental institution; is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country as to which the Secretary of State has made a determination that such country has repeatedly provided support for acts of international terrorism (As of April 30, 2001, these countries were Iran, Iraq, Syria, Libya, Cuba, North Korea, and the Sudan.); or has been discharged from the Armed Services of the United States under dishonorable conditions.

### **What is the responsibility of the Principal Investigator?**

The PI is responsible to comply with the requirements of the Institution for the reporting and securing of agents that fall within the bounds of the Act. The law does not create an affirmative duty on any individual's part to seek out information from current employees or students as to whether the "restricted persons" criteria apply to them. It is the responsibility of TUN to determine the availability of restricted agents and to develop procedures for performing necessary background checks as needed for new hires/graduate students and persons who already have access to restricted agents.

## Appendix D Appropriate Chemical Disinfection Properties and Applications of Disinfectants

There are many different liquid disinfectants available under a variety of trade names, in general, these can be categorized as halogens, acids or alkalines, heavy metal salts, quaternary ammonium compounds, aldehydes, ketones, alcohols, and amines. Use of an appropriate disinfectant depends on the organism being disposed of. Unfortunately, the most effective disinfectants are often very aggressive (corrosive) and toxic. Some of the more common ones are discussed below:

### Disinfectant Category\* Use Dilution Requirements Inactivates

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#### Liquid

Quat. Ammonium Cmps. (0.1%-2.0%) 10 m contact VB, LV  
Phenolic Cmps. (1.0%-5.0%) 10 m contact VB, LV  
Bleach. (0.5%-10%) 30 m contact VB, LV, NLV, MYC, BS  
Iodophor (0.5%-5%) 30 m contact VB, LV, NLV  
Alcohol, ethyl (75%-85%) 30 m contact VB, LV  
Alcohol, isopropyl (70%-85%) 30 m contact VB, LV  
Formaldehyde+ (0.2%-8.0%) 10 m contact VB, LV, NLV, MYC, BS  
Glutaraldehyde (2%) 30 m contact VB, LV, NLV, MYC, BS

#### Gas

Ethylene oxide+++ (8-23 g/ft<sup>3</sup>) 60 m, 37 C, 30% hum VB, LV, NLV, MYC, BS  
Paraformaldehyde+ (0.3 to 0.6g/ft<sup>3</sup>.) 4 hrs. <23 C, >60% hum VB, LV, NLV, MYC, BS

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Abbreviations: VB = vegetative bacteria, LV = lipoviruses, NLV = nonlipid viruses, MYC = Mycobacterium, BS = bacterial spores, m = minutes, hum = humidity, comps = compounds.

\*Small volumes of pourable disinfectant can be disposed in the sanitary sewer system.

Contact Chemical Safety for advice on the disposal of larger volumes.

+These chemicals are known carcinogens and require special procedures for disinfection.

Contact Chemical Safety for recommendations on use.

++This chemical is extremely flammable and requires special precautions for use.

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## Alcohols

Ethyl or isopropyl alcohols in concentration of 70% to 90% are good general-use disinfectants. However, they evaporate fast and therefore have limited exposure time. They are less active against non-lipid viruses and ineffective against bacterial spores. Concentrations above 90% are less effective.

## Formalin

Formalin is a 37% solution of formaldehyde in water. Dilution of Formalin to 5%, results in an effective disinfectant. Formaldehyde is a human carcinogen and creates respiration problems at low levels of concentration.

## Glutaraldehyde

This compound, although chemically related to formaldehyde, is more effective against all types of bacteria, fungi, and viruses. Vapors of glutaraldehydes are irritating to the eyes, nasal passages and upper respiratory tract. They should always be used in accordance with the instructions on the label and the appropriate personal protective equipment.

## Phenol and Phenol Derivatives

Phenol based disinfectants come in various concentrations ranging mostly from 5% to 10%. These derivatives, including phenol, have an odor, which can be somewhat unpleasant. Phenol itself is toxic, and appropriate personal protective equipment is necessary during application. The phenol disinfectants are used frequently for disinfecting contaminated surfaces (e.g., walls, floors, benches). They effectively kill bacteria, including *Mycobacterium tuberculosis*, fungi, and lipid-containing viruses. They are not active against spores or non-lipid viruses.

## Quaternary Ammonium Compounds (Quats)

Quats are cationic detergents with strong surface activity. They are acceptable for general-use disinfectants and are active against gram-positive bacteria and lipid-containing viruses. They are less active against gram-negative bacteria and are not active against nonlipid-containing viruses. Quats are easily inactivated by organic materials, anionic detergents or salts of metals found in water. If Quats are mixed with phenols, they are very effective disinfectants as well as cleaners. Quats are relatively nontoxic and can be used for decontamination of food equipment and for general cleaning.

## Halogens (Chlorine and Iodine)

Chlorine-containing solutions have broad-spectrum activity. Sodium hypochlorite is the most common base for chlorine disinfectants. Common household bleach (5% available chlorine) can be diluted 1/10 to 1/100 with water to yield a satisfactory disinfectant solution. Diluted solutions may be kept for extended periods if kept in a closed container and protected from light. However, it is recommended to use freshly prepared solutions for spill clean-up purposes. Chlorine-containing disinfectants are inactivated by excess organic materials. They are also strong oxidizers and very corrosive. Always use appropriate personal protective equipment when using these compounds. At high concentrations and extended contact time, hypochlorite solutions are considered cold sterilants since they inactivate bacterial spores. Iodine has similar properties to chlorine; iodophors (organically bound iodine) are recommended disinfectants. They are most often used as antiseptics and in surgical soaps and are relatively nontoxic to humans.

## Vapors and Gases

A variety of vapors and gases possess germicidal properties. The most commonly used are formaldehyde and ethylene oxide. Applied in closed systems under controlled conditions (e.g., humidity), these gases achieve sterility. Formaldehyde gas is primarily used in the decontamination of spaces or biological containment equipment like BSCs. Formaldehyde is a toxic substance and a suspected human carcinogen. Considerable caution must be exercised in handling, storing, and using formaldehyde. Ethylene oxide is used in gas sterilizers under controlled conditions. Ethylene oxide is also a human carcinogen, and monitoring is necessary during its use.

## Room Decontamination

Containment laboratories periodically undergo routine decontamination procedures using a disinfectant gas. Additionally, room decontamination may be required in an area where overt biohazardous agent contamination has occurred. To schedule decontamination, contact Vladimir Bondarenko, Ph.D., Biosafety Officer at 702-777-1806.

## Autoclaving Procedures

Autoclaves use pressurized steam to destroy microorganisms and are the most dependable system available for the decontamination of laboratory waste. All biosafety waste from C1404 is to be autoclaved prior to entering the general biohazard waste flow. The autoclave needs to be tested monthly for effectiveness. This is accomplished through a biologics test using sensitive spores. The testing and logging of autoclave verification

is the responsibility of the Institutional Biosafety Officer or their designated representative (the Lab Manager).



## Appendix E Definitions from the NIH Guidelines for the Use of Exempt rDNA Molecules

### Section III-F. Exempt Experiments

The following recombinant DNA molecules are exempt from the *NIH Guidelines*, and registration with the IBC using Exempt BSL-1/ABSL-1 Registration Form is required (a completed IBC protocol is not required to register this type of experimentation):

#### Section III-F-1

Those that are not in organisms or viruses.

#### Interpretation/Examples:

**Ligation of recombinant molecules and the study of these molecules without transferring to a bacterium, virus, or creating a virus.**

**Southern blot of plasmid DNA.**

**Synthetic DNA encapsulated in a synthetic delivery vehicle intended for injection into animals.**

**The cloning of a DNA segment produced by PCR.**

**Radiolabeling a probe for in situ hybridization.**

#### Section III-F-2

Those that consist entirely of DNA segments from a single nonchromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.

#### Interpretation/Example:

**The use of SV40 in tissue culture experiments or lambda bacteriophage DNA in *E. coli* (do not carry a foreign insert but can lead to alterations [mutations] in the sequence).**

## **The cloning of the 5' ends of cDNA (from mRNA) to determine the transcriptional start site.**

### **Section III-F-3**

Those that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well-established physiological means.

#### **Interpretation/Example:**

**Cloning Escherichia coli DNA using vector (plasmid) derived from E. coli or other Enterobacteriaceae (i.e., pBR322, pUC19, etc.) and using E. coli as a transforming host.**

**The statement “or when transferred to another host by well-established physiological means” is not interpreted to mean that “host” is another species and “host” may refer to another E. coli isolate/strain.**

### **Section III-F-4**

Those that consist entirely of DNA from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).

#### **Interpretation/Example:**

**Same interpretation as section III-F-3 above, except using a eukaryotic host (i.e., yeast such as *Saccharomyces cerevisiae*)**

### **Section III-F-5**

Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the NIH Director with the advice of the RAC after appropriate notice and opportunity for public comment (see Section IV-C-1-b-(1)-(c), *Major Actions*). See Appendices A-I through A-VI, *Exemptions Under Section III-F-5--Sublists of Natural Exchangers*, for a list of natural exchangers that are exempt from the *NIH Guidelines*.

#### **Interpretation/Example:**

**Certain microorganisms are known to exchange genetic information through a variety of mechanisms, including conjugation, transduction, etc.**

**Recombinant DNA experiments are exempt if cloning DNA from, for instance, *Pseudomonas aeruginosa* and transferring that DNA to *E. coli*. These two species are known to exchange DNA naturally.**

### **A list of those organisms that are known to exchange DNA**

Shown below (Identified as Appendix A by the NIH Guidelines, Exemptions under section III F-5 sub-lists of natural exchanges).

#### **Sublist A**

Genus *Escherichia*

Genus *Shigella*

Genus *Salmonella* - including *Arizona*

Genus *Enterobacter*

Genus *Citrobacter* - including *Levinea*

Genus *Klebsiella* - including *oxytoca*

Genus *Erwinia*

*Pseudomonas aeruginosa*, *Pseudomonas putida*, *Pseudomonas fluorescens*, and

*Pseudomonas mendocina*

*Serratia marcescens*

*Yersinia enterocolitica*

#### **Sublist B**

*Bacillus subtilis*

*Bacillus licheniformis*

*Bacillus pumilus*

*Bacillus globigii*

*Bacillus niger*

*Bacillus nato*

*Bacillus amyloliquefaciens*

*Bacillus atterimus*

#### **Sublist C**

*Streptomyces aureofaciens*

*Streptomyces rimosus*

*Streptomyces coelicolor*

### **Sublist D**

*Streptomyces griseus*  
*Streptomyces cyaneus*  
*Streptomyces venezuelae*

### **Sublist E**

One way transfer of *Streptococcus mutans* or *Streptococcus lactis* DNA into  
*Streptococcus sanguis*

### **Sublist F**

*Streptococcus sanguis*  
*Streptococcus pneumoniae*  
*Streptococcus faecalis*  
*Streptococcus pyogenes* *Streptococcus mutans* 32

## **Section III-F-6**

Those that do not present a significant risk to health or the environment (see Section IV-C-1-b-(1)-(c), Major Actions), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. See below, Exemptions under Section III-F-6 for other classes of experiments which are exempt from the NIH Guidelines.

### **Interpretation/Example**

**Recombinant DNA experiments associated with specific host systems are not considered a public health threat and are therefore exempt. These exemptions are listed below (Identified as Appendix C by the NIH Guidelines, Exemptions under section III-F-6).**

### **Exemption C1**

Recombinant DNA molecules containing less than one-half of any eukaryotic viral genome that is propagated and maintained in cells in tissue culture are exempt from these NIH Guidelines with the exceptions listed below

### **Exceptions to Exemption C1**

- a. Cloning a drug resistance marker not naturally known to be found in the organism.**
- b. Cloning of toxins with an LD50 of less than 100 ng/kg (botulinum toxin, tetanus toxin, diphtheria toxin, *Shigella dysenteriae* neurotoxin)**

- c. **Cloning of DNA from any Risk group 3 or 4 pathogen or cloning from cells known to be infections with a risk group 3 or 4 pathogen.**
- d. **Experiments involving the deliberate introduction of genes coding for the biosynthesis of molecules that are toxic for vertebrates.**
- e. **Whole plants regenerated from plant cells and tissue cultures are covered by the exemption provided they remain axenic cultures even though they differentiate into embryonic tissue and regenerate into plantlets.**

### Exemption C2

Recombinant DNA experiments that use E. coli K12 host-vector systems (almost all E. coli strains purchased from molecular biology sources are from the K12 lineage) provided that 1) the E. coli strain does not contain conjugative plasmids or prophages that are able to undergo transduction. 2) Lamboid or non-conjugative plasmids are used as cloning vectors (this includes pUC19, pGEM, and most all cloning vectors used in E. coli genetic experiments). However, a conjugative plasmid may be used if the DNA that is inserted is from organisms that naturally exchange DNA with E. coli (see Appendix A-1 sublist A above).

### Exceptions to Exemption C2

- a. Experiments involving DNA from Risk Groups 3 or 4 organisms.
- b. Large-scale experiments (e.g., more than 10 liters of culture).
- c. Experiments involving the cloning of toxin molecule genes coding for the biosynthesis of molecules toxic for vertebrates.

### Exemption C3

Recombinant DNA experiments involving *Saccharomyces cerevisiae* and *Saccharomyces uvarum* host-vector systems. **Exceptions to exemption C3:**

- a. **Experiments involving DNA from Risk Groups 3 or 4 organisms.**
- b. **Large-scale experiments (e.g., more than 10 liters of culture).**
- c. **Experiments involving the cloning of toxin molecule genes coding for the biosynthesis of molecules toxic for vertebrates.**

### Exemption C4

Recombinant DNA experiments involving asporogenic *Bacillus subtilis* or *Bacillus licheniformis* host-vector systems. *Bacillus* strains used must not form spores at a frequency greater than  $10^{-7}$ .

### Exceptions to exemption C4

- a. **Experiments involving DNA from Risk Groups 3 or 4 organisms.**

- b. Large-scale experiments (e.g., more than 10 liters of culture).**
- c. Experiments involving the cloning of toxin molecule genes coding for the biosynthesis of molecules toxic for vertebrates.**

### Exemption C5

Recombinant DNA molecules derived entirely from extrachromosomal elements (i.e. plasmids) of the gram-positive organisms listed below (including shuttle vectors comprised of vectors listed in Exemption C2 above), propagated and maintained in organisms listed below are exempt from the NIH Guidelines.

*Bacillus amyloliquefaciens*  
*Bacillus amylosacchariticus*  
*Bacillus anthracis*  
*Bacillus atterimus*  
*Bacillus brevis*  
*Bacillus cereus*  
*Bacillus globigii*  
*Bacillus licheniformis*  
*Bacillus megaterium*  
*Bacillus natto*  
*Bacillus niger*  
*Bacillus pumilus*  
*Bacillus sphaericus*  
*Bacillus stearothermophilus*  
*Bacillus subtilis*  
*Bacillus thuringiensis*  
*Clostridium acetobutylicum*  
*Lactobacillus casei*  
*Listeria grayi*  
*Listeria monocytogenes*  
*Listeria murrayi*  
*Pediococcus acidilactici*  
*Pediococcus damnosus*

*Pediococcus pentosaceus*  
*Staphylococcus aureus*  
*Staphylococcus carnosus*  
*Staphylococcus epidermidis*  
*Streptococcus agalactiae*  
*Streptococcus anginosus*  
*Streptococcus avium*  
*Streptococcus cremoris*  
*Streptococcus dorans*  
*Streptococcus equisimilis*  
*Streptococcus faecalis*  
*Streptococcus ferus*  
*Streptococcus lactis*  
*Streptococcus ferns*  
*Streptococcus mitior*  
*Streptococcus mutans*  
*Streptococcus pneumoniae*  
*Streptococcus pyogenes*  
*Streptococcus salivarius*  
*Streptococcus sanguis*  
*Streptococcus sobrinus*  
*Streptococcus thermophilus*

## Appendix F TUN IBC Biosafety Risk Assessment Summary

IBC# \_\_\_\_\_ (to be determined by the IBC Office)  
Title of Project \_\_\_\_\_  
Principal Investigator \_\_\_\_\_ Date \_\_\_\_\_  
Name of Person at Risk: \_\_\_\_\_  
Job Description: \_\_\_\_\_

### Risk Factor Risk Group

Pathogenicity/virulence	_____
Infectious Dose	_____
Route of Spread	_____
Communicability	_____
Environmental stability	_____
Host range	_____
Economic impact	_____
Availability of prophylactic/treatment	_____
Vectors	_____
Concentration/volume	_____
Recombinant properties	_____
Overall Risk Group	_____
Recommended Containment Level	_____

Notes: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

### Risk Factor Assessment Outline

#### Pathogenicity/virulence

RG1 Unlikely to cause disease, low individual, and community risk.

RG2 Mild or moderate disease with moderate individual risk and low community risk; any pathogen that can cause disease but under normal circumstances, is unlikely to be a serious hazard to a healthy worker, the community, livestock, or the environment.

RG3 Serious livestock, poultry, or wildlife disease with high individual risk and low community risk; any pathogen that usually causes serious disease or can result in

serious economic consequences or does not ordinarily spread by causal contact from one individual to another.

RG4 Severe livestock, poultry or wildlife disease with high individual risk and high community risk; any pathogen that usually produces very serious and often fatal disease, often untreatable and may be readily transmitted from one individual to another or from animal to human or vice-versa, directly or indirectly, or by casual contact.

### **Infectious dose**

RG1 Not applicable (rare cause of human disease)

RG2 High (>1,000 organisms)

RG3 Medium (10-1,000 organisms)

RG4 Low (1-10 organisms)

### **Route of spread**

RG1 Not applicable (rare cause of human disease)

RG2 Primary exposure hazards are through ingestion, inoculation, and mucous membrane route

RG3 May be transmitted through airborne route; direct contact or via vectors

RG4 Readily by aerosol transmission

### **Communicability**

RG1 Not applicable (rare cause of human disease)

RG2 Geographical risk of spread if released from the laboratory is limited.

RG3 Geographical risk of spread if released from the laboratory is moderate

RG4 Geographical risk of spread if released from the laboratory is high.

### **Environmental stability**

RG1 Not applicable

RG2 Short term survival (days), can survive under ideal conditions

RG3 Moderately resistant (days to months)

RG4 Highly resistant (months to years), e.g., spores.

### **Host range**

RG1 Not applicable

RG2 Infects a limited number of species

RG3 Infects multiple species



RG4 Infects many species

### **Economic aspects**

- RG1 Not applicable
- RG2 Limited economic impact
- RG3 Severe economic impact
- RG4 Extreme economic impact

### **Availability of prophylactic and therapeutic treatments**

- RG1 Not applicable
- RG2 Effective treatment and preventative measures are available
- RG3 Prophylactic and/or treatments may or may not be readily available
- RG4 Prophylactic and/or treatments are not available

### **Vectors**

- RG1 Not applicable
- RG2 Do not depend on vectors or intermediate hosts for transmission
- RG-3 May depend on vectors or intermediate host for transmission
- RG4 May depend on vectors or intermediate host for transmission.

### **Concentration/volume**

- RG1 Not applicable
- RG2 Low quantity of high titer
- RG3 High quantity (10 liters or more) of high titer as described by the BMBL
- RG4 Not applicable

### **Recombinant properties**

- RG1 Recombinant is an RG1 organism and modifications have not changed the risk; low probability of RG2 replication-incompetent virus becoming competent
  
- RG2 Recombinant is an RG2 organism, and modifications have not changed the risk, DNA from RG2 or RG3 organism is transferred into RG1 organism but not the whole genome, DNA from RG4 organism is transferred into RG1 organism or the recombinant is an RG3 or RG4 organism, and the modification has resulted in proven attenuation; moderate probability of RG2 replication-incompetent virus becoming competent

RG3 Recombinant is an RG3 organism and modifications have not change the risk, and the recombinant is based on an RG2 organism; however, the modifications have increased to RG3 organism.

**Do not store chemicals in a fume hood unless storage is the sole use of the hood.** Only chemicals necessary to perform the experiment should be left in the hood; all other chemicals should be stored in approved safety storage cabinets.

**Do not use a hood to evaporate hazardous chemicals or as a means of chemical disposal.** All chemicals inside hood must remain capped when not in use.

**Wear appropriate Personal Protective Equipment (PPE) when working with chemicals.** At a minimum, wear eye protection, gloves, and a lab coat when working with hazardous chemicals in the hood. Consult the material's Material Safety Data Sheet (MSDS) for appropriate PPE.

**Respirators should never be used in lieu of using the fume hood.**

**Adjust the hood baffles based on the type of work being performed inside hood.** Keep air exhaust baffles located at back wall hood unobstructed.

**Do not extend your head inside of the hood while experiments are being performed.**

# Appendix G Touro University Nevada Hazardous Materials Spill Report Form

## Hazardous Materials Spill Report


<b>PART I – REPORT TYPE</b>	
1. This is to report: <input type="checkbox"/> A) Chemical material spill <input type="checkbox"/> B) Biological material spill	
<b>PART II – GENERAL INCIDENT INFORMATION</b>	
2. Date and Time of Incident:	
3. Location of incident:	
4. Description of Spilled Hazardous Material:	
5. Size of spill:	
6. Person responsible:	
<b>PART III – DESCRIPTION OF EVENTS</b>	
Describe the sequence of events that led to the incident and the actions taken at the time it was discovered. Photographs and diagrams should be submitted if needed for clarification. Describe what was done to mitigate the effects of the spill. Continue on additional sheets if necessary. (Use additional pages if more space is needed.)	
<b>PART VI – RECOMMENDATIONS/ACTIONS TAKEN TO PREVENT RECURRENCE</b>	
Where you are able to do so, suggest or describe changes (such as additional training or improved operating procedures) to help prevent a recurrence. Provide recommendations for improvement to hazardous materials storage and handling at TUN. Continue on additional sheets if necessary. (Use additional pages if more space is needed.)	
<b>PART V – REPORTER'S CONTACT INFORMATION</b>	
Name:	Telephone Number:
Title:	E-mail:
Date:	
Signature:	
Form has been approved by TUN IBC	

E-mail, fax, or mail form TUN Biosafety Officer [Vladimir.bondarenko@tun.touro.edu](mailto:Vladimir.bondarenko@tun.touro.edu)

Vladimir Bondarenko, PhD  
 Fax: 702.777.1799

874 American Pacific Drive Henderson, NV 89014

## Appendix H Pest Management

 <b>Touro University Nevada</b>	<b>Page No.</b> 1 of 5	<b>Number:</b>
	<b>Effective Date:</b> 6/6/2019	
<b>POLICY &amp; PROCEDURE MANUAL</b>	<b>Required Review:</b> Annual	
<b>Reviewed:</b>		
<b>Revised:</b>		
<b>Policy</b> <input checked="" type="checkbox"/> <b>Procedure</b> <input type="checkbox"/>	<b>Responsible Position:</b> Director of EHS	
<b>Title:</b> Integrated Pest Management Plan		
<b>Approval Requirements:</b> Executive Council		

**PURPOSE:** To establish a sustainable approach to managing pests by combining biological, cultural, physical, and chemical tools in a way that minimizes economic, health and environmental risks.

**SCOPE:** All TUN-owned buildings and grounds.

**POLICY:**

INTRODUCTION

Pests are populations of living organisms (animals, plants, or microorganisms) that interfere with use of healthcare and other facilities for human purposes.

Integrated Pest Management (IPM) is an approach that establishes a sustainable approach to managing pests by combining biological, cultural, physical, and chemical tools in a way that minimizes economic, health, and environmental risks.

Touro University Nevada (TUN) has adopted this Integrated Pest Management Plan for the buildings and grounds that we manage. The plan outlines procedures to be followed to protect the health and safety of staff, students, patients, and visitors from pest and pesticide hazards. The plan is designed to voluntarily comply with policies and regulations promulgated by the United States Department of Agriculture (USDA) for public buildings and health care facilities.

Objectives of this IPM plan include:

- Elimination of significant threats caused by pests to the health and safety of staff, students, patients, and the public.
- Prevention of loss or damage to structures or property by pests.
- Protection of environmental quality inside and outside buildings.

This IPM plan will be stored on the TouroOne intranet under Policies and Procedures.

### IPM COORDINATOR

Bill Risley, the Director of Facilities, is TUN's IPM Coordinator and is responsible for implementing the IPM plan and for coordinating pest management-related communications between TUN and its service providers.

### SAFETY COMMITTEE

TUN's Institutional Safety Committee will maintain this IPM Plan with the responsibility for an annual review of the IPM plan and for assisting the IPM Coordinator in resolving pest-related issues. The committee will address IPM issues as needed and at least annually. Minutes will be taken of committee meetings and stored on the TouroOne intranet under Institutional Safety Committee. Membership will include the IPM Coordinator, Director of Environmental Health and Safety (EHS), and other members as constituted in its bylaws.

### POSTING AND NOTIFICATION OF PESTICIDE APPLICATIONS

The IPM Coordinator shall be responsible for the notification of planned and emergency applications of pesticides on facility grounds as well as inside-building applications.

When pesticide applications are scheduled in TUN-managed buildings or grounds, campus Service Providers and staff shall provide notification, including:

1. Posting a pest control information sign with the date, time, and location of the application and the product applied in an appropriate area and including contact information for additional details.
2. Providing this information to all individuals working in the building.

## RECORD KEEPING & PUBLIC ACCESS TO INFORMATION

TUN will maintain records of all Service Provider visits and pest control treatments for at least three (3) years. Information regarding pest management activities will be made available to the public at the TUN Facilities administrative office. Requests to be notified of pesticide applications may also be made to this office.

## TRAINING

Pesticide applications on TUN grounds will only be conducted by trained and certified applicators, and all such applications will be made within strict compliance with Nevada Department of Environmental Protection (NDEP) and Nevada Department of Agriculture (NDA) guidelines and requirements.

Additionally, the IPM coordinator and Director of EHS will receive advanced training on identifying pest infestations and pest-conducive conditions.

## GENERAL IPM STRATEGIES

Pest management strategies may include education, exclusion, sanitation, maintenance, biological and mechanical controls, and pre-approved, site-appropriate pesticides.

An Integrated Pest Management decision at TUN shall consist of the following steps:

1. Identify pest species.
2. Estimate pest populations and compare to established action thresholds.
3. Select the appropriate management tactics based on current on-site information.
4. Assess effectiveness of pest management.
5. Keep appropriate records.

Decisions concerning whether or not pesticides should be applied in a given situation will be based on a review of all available options. Efforts will be made to avoid the use of pesticides by adequate pest-proofing of facilities, good sanitation practices, selection of pest-resistant plant materials, and appropriate horticultural practices.

When it is determined that a pesticide must be used in order to meet pest management objectives, the least-hazardous material, adequate for the job, will be chosen.

All pesticide storage, transportation, and application will be conducted in accordance with the requirement of the Federal Insecticide, Fungicide, and Rodenticide Act (7 United States Code 136 et seq.), Environmental Protection Agency regulations in 40 CFR, Occupational Safety and Health Administration regulations, TUN policies and procedures, local ordinances, and NDEP and NDA requirements.

No person shall apply, store, or dispose of any pesticide on TUN-managed property without an appropriate pesticide applicator certification. All pesticide applicators will be trained in the principles and practices of IPM and the use of pesticides approved for use by TUN. All applicators must comply with the IPM policy and follow appropriate regulations and label precautions when using pesticides in or around TUN facilities.

### **Indoor IPM Strategies**

Typical Pests: Mice, Rats, Cockroaches, Ants, Flies, Spiders, Termites, and Microorganisms

*Entryways: Doorways, Overhead Doors, Windows, and Openings around pipes, electrical fixtures, and Duct (s).*

- Keep exterior doors shut when not in use
- Place weather-stripping around doors
- Caulk and seal openings in walls
- Keep vegetation at least one foot from the structure

*Classrooms/Offices: Including Performance Hall, Gymnasiums, Hallways, Offices, and Classrooms*

- Allow food and Beverages only in designated areas
- Keep indoor plants healthy
- Keep areas dry as possible by removing standing water and water damaged and wet materials
- In the all classrooms store animal foods in sealed containers and regularly clean cages
- In all areas remove dust and debris
- Routinely clean lockers and desks
- Frequently vacuum carpeted areas.

*Food Preparation and Serving Areas: Dining Hall, Kitchen, Teacher's Lounge, Vending Machine areas, and Food Storage Rooms*

- Store food in containers that are inaccessible to pest
- Store waste in containers that are inaccessible to pests
- Remove all waste at the end of each day
- Place screens on vents, windows, and floor drains.
- Remove all food debris including crumbs
- Fix dripping faucets and other water leaks
- Promptly clean food preparation equipment after use
- Caulk or paint to seal cracks and crevices

*Rooms with Extensive Plumbing: Bathrooms, rooms with sink, locker rooms, and crew spaces.*

- Promptly repair leaks and correct other plumbing problems
- Routinely clean floor drains, strainers, and grates
- Keep areas dry
- Store paper products or cardboard boxes away from moist areas and direct contact with the floors

*Maintenance Areas: Mechanical rooms, Janitorial rooms, etc.*

- Allow eating only in designated eating rooms
- Clean trash cans regularly
- Use plastic liners in trashcans
- Keep areas clean and dry as possible
- Store paper products or cardboard boxes away from moist areas and direct contact with the floors and walls.

### **Outdoor IPM Strategies**

Typical Pests: Mice and Rats. Turf Pests such as board-leaf and grassy weeds. Insects such as beetle grubs or sod webworms and turf disease. Ornamental pests such as plant diseases, insects such as thrips, aphids, Japanese beetles and bagworms.

*Parking Lots, Loading Docks, Refuse Dumpsters*

- Regularly clean trash containers and gutters
- Regularly remove all waste and paper debris
- Secure lids on trash containers
- Repair cracks in pavement and sidewalks
- Provide adequate drainage

### **TUN SERVICE PROVIDER ROLES**

TUN service providers, including cleaning, pest control, and landscape maintenance will be guided by written and signed contracts, including TUN-developed IPM Program Specifications for structural pest control providers.



Service providers will be directed to provide special attention to pest-vulnerable areas, including food storage, preparation and serving areas, washrooms, custodial closets, mechanical rooms, and entryways into the building.

Service providers or other IPM experts will be asked to provide input on any TUN facility renovation or reconstruction projects, including reviewing plans for pest-conducive conditions, suggesting pest-proofing measures, and inspecting construction where applicable to prevent and avoid pest problems.

Service providers will perform regular simple inspections in areas specified in the contract and will perform more intense inspections to determine source of pest problem as necessary. Regular monitoring and sampling will be performed to determine the magnitude of the pest problem in each specified area. Reports and logs of pest sightings will be provided by the service provider and kept in the office of the IPM Coordinator.

### TUN STAFF ROLES

TUN administration will provide support to assist the IPM Coordinator in maintaining an IPM program that relies on minimal pesticide use. Such support will include efforts to promptly address any structural, horticultural, or sanitation changes recommended by the coordinator to reduce or prevent pest problems.

Furthermore, TUN administration will assist the Coordinator in developing and delivering materials and programs for staff, students, and the public to educate them about the importance of good sanitation and pest control. Staff may submit Facilities work orders if a pest problem is known.

The Director of EHS is responsible for ensuring staff compliance with the IPM policy and plan.

Employees may submit a Facilities work order at any time if there is a suspected pest problem in any given area. They may also contact the IPM Coordinator directly at ext.1809.

## REFERENCES AVAILABLE

Centers for Disease Control (CDC)

Biosafety in Microbiological and Biomedical Laboratories (BMBL)

<http://www.cdc.gov/OD/ohs/biosfty/bmb14/bmb14toc.htm>

National Institute of Health (NIH) Guidelines for Research Involving  
Recombinant DNA Molecules (NIH Guidelines)

<http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>

Centers for Disease Control (CDC) Select Agent Program

<http://www.cdc.gov/od/sap>

Occupational Safety and Health Administration (OSHA) bloodborne  
pathogen

(29 CFR 1910.1030) and Needle-stick Prevention Standards

<http://www.osha.gov/SLTC/bloodbornepathogens/standards.html>

Centers for Disease Control (CDC) National Institute for Occupational  
Safety & Health (NIOSH)

<http://www.cdc.gov/niosh/topics/chemical-safety>

Selecting Gloves

[www.ansellpro.com/download/Ansell\\_7thEditionChemicalResistanceGuide.](http://www.ansellpro.com/download/Ansell_7thEditionChemicalResistanceGuide.pdf)

pdf <http://www.pacifica.com/NitrileGlovesChemicalResistance-BarrierGuide.pdf>

Office of Biosafety Administration

[http://www4.od.nih.gov/oba/rac/Guidance/LentiVirus\\_Containment/index.htm](http://www4.od.nih.gov/oba/rac/Guidance/LentiVirus_Containment/index.htm)



# Touro University Nevada

## Radiation Policy

### I. IRRP & RSO CONTACTS

A. CONTACT PERSON: The Individual Responsible for Radiation Protection (IRRP) is the Radiation Supervisor whose name is posted on the current Nevada Certificate of Registration and is responsible for all institutional radiation safety related to radiation-generating equipment. The Radiation Safety Officer (RSO) is the person whose name is on the current Nevada Radioactive Materials License and is responsible for all institutional radiation safety related to radioactive materials. The IRRP & the RSO have a complete copy of the applicable portion of the Nevada Radiation Protection Rules. Any questions regarding radionuclide spills should be directed to the RSO. For other radiation safety issues, dosimetry, etc. if you are uncertain as to which person to notify, you may notify either one.

The TUN Radiation Safety Officer (RSO) is Michael Laymon who can be contacted at:

Office - (702) 777-3051

E-mail - [Michael.laymon@tun.touro.edu](mailto:Michael.laymon@tun.touro.edu)

### II. GENERAL RADIATION SAFETY

#### A. AUTHORIZED OPERATION

1. STAFF RADIOGRAPHERS: Medical and research x-ray procedures shall be performed only by a qualified Radiographer minimally holding an appropriate current license from the Nevada Division of Public and Behavioral Health (DPBH) and only when and as authorized by a licensed physician or under and approved Institutional Review Board (IRB) protocol. Preferred qualifications include documented graduation from an AMA- approved Radiologic Technology program and/or registration with the American Registry of Radiologic Technologists (ARRT).

2. STUDENT RADIOGRAPHERS: Students may operate equipment under the direct supervision of a staff Radiographer only when and as authorized by a

licensed physician or under an active IRB approved protocol. Until competency has been met, a student may operate radiographic equipment only under direct supervision. After demonstrating competency on a specific procedure or examination, Students may operate radiologic equipment on those procedures or examinations under indirect supervision.

### III. BEAM RESTRICTION & GONADAL SHIELDING

- A. GENERAL: The beam shall be limited to the area of clinical interest during both radiographic and fluoroscopic examinations. At no time should exposures be made where the student could come in contact with the direct beam. This requires restricting the exposed field size to the actual area of interest and/or the image receptor, whichever is smaller.
- B. GONADAL SHIELDING: Shielding of the gonads on all patients, regardless of age, shall be employed for all radiographic procedures, if the gonads are in the primary beam and such shields do not interfere with the examination.

### IV. CONTROL BOOTH STANDARDS

- A. HAND CONTROLS: All hand exposure controls will be mounted in the control booth or a minimum of three feet from radiation source emitter in the case of pencil beam emitters such as Dual-energy X-ray Absorptiometry (DXA or DEXA), in such a way as to prevent the operator from making an exposure while in an unshielded position. This will be accomplished by permanent attachment of the hand control and/or by limiting the length of the exposure cord. No one shall make any alteration in attachment to the control or length of the cord without prior approval by the IRRP or RSO. If through wear or any other reason a hand control is found to be removable, the Radiology Supervisor shall be notified at once. The supervisors will determine whether the IRRP or RSO needs to be notified.
- B. UNSHIELDED PERSONNEL: All unshielded students, research subjects, or staff shall stand in such a position as to assure that their entire body is shielded by the control booth barrier or by a portable protective barrier during radiographic examinations involving stationary x-ray units.

### V. DOSIMETRY

- A. RADIATION BADGES: Radiation monitoring badge shall be worn by all students and staff at all times when operating any radiographic equipment (during clinical assignments, research protocols or present in the Radiography room for any other reason). At all times, the whole body radiation badge shall be worn on the collar outside of a lead apron.
- B. BADGE SUBMISSION: The radiation monitoring badge must be submitted for processing quarterly. Any student or staff losing or destroying their radiation badge must contact the Radiation Safety Officer (RSO) immediately. When a badge is reported lost,

the radiation monitoring company will be contacted for a new radiation badge to be issued. Radiation monitoring devices will be submitted for quarterly, yearly, and cumulative dosage readings.

- C. EXPOSURE REPORTING POLICY: Radiation badge reports are reviewed quarterly by the RSO. A summary of the review is presented to the Individual Responsible for Radiation Protection (IRRP). The review is conducted to identify:
1. Radiation badge readings that exceed the allowable limit
  2. Persistently high radiation readings that are within allowed limits
  3. Inconsistencies with radiation badge readings or expected exposure levels

Guidelines for the review are based upon the national standard exposure rates (10 CFR Part 20 Subpart C 20.1201) which requires that the annual occupational effective dose be limited to 5,000 mRem (fifty (50) mSv; not including medical and natural background exposure), with equivalent dose annual limits to the lens of the eye at 15,000 mrems (150 mSv) and the skin, hands, and feet at 50,000 mrems (500 mSv). The maximum dose limits are considered excessive by TUN standards; a strong promotion by the RSO and the IRRP of the principle of ALARA (as low as reasonably achievable) shall be implemented through frequent monitoring and discussions with the staff on radiation management. The IRRP, RSO, and/or the Dean of the College of Medicine will discuss corrective action(s) with any individual whose badge reports high or inconsistent readings. For student or staff review of their radiation exposure, quarterly badge reports are available by appointment with the RSO. Any student wishing to review a radiation badge report may discuss it with the IRRP, or RSO. If the reading indicates that the dose to an individual is in excess of the exposure standard, the IRRP or RSO shall conduct an investigation. The commercial radiation monitoring company may be contacted to aid in the investigation. If the IRRP or RSO determines that the individual has received a dose in excess of the limits, a report of overexposure shall be submitted to the facility Director, and any required State or Federal Department of Health, as required.

- D. STUDENT use of Radiographic Equipment: The students shall have personal radiation records reviewed with them by the IRRP or RSO at the end of every semester that included activities regarding radioactive sources. Based on the opinion of our radiation physicist, a radiation reading of 150+ mrem/quarter (50+ mrem/month or 600+ mrem/year) would be considered unusual. In support of the ALARA principles, any student or staff whose radiation badge report exceeds these criteria will be counseled by the IRRP or RSO on methods for reducing radiation exposure.
- E. OCCUPATIONAL EXPOSURE OF MINORS: For education, research and or training purposes it may be necessary to accept students under the age of eighteen (18) years

old. National Council on Radiation Protection and Measurement (NCRP) guidelines recommends that the annual occupational effective dose for minors be limited to 100 mrem (one (1) mSv; not including medical and natural background exposure), with equivalent dose annual limits to the lens of the eye at 1,500 mrems (fifteen (15) mSv) and the skin, hands, and feet at 5,000 mrems (fifty (50) mSv).

## VI. EQUIPMENT SAFETY

- A. PERFORMANCE TESTING: All radiography/fluoroscopy units will be surveyed on an annual basis by a physicist certified by the American Board of Radiology (ABR) in Radiological Physics (includes all areas) or in the area of Diagnostic Radiological Physics. Evidence of such certification shall be on file in the form of a photocopy of the ABR certificate. The survey shall include analysis of mR/mAs variations with time and current, determination of congruence of light localizer with the x-ray beam, measurement of half-value layers to determine filtration, and any other studies which may be necessary to meet local, state, and federal requirements and recommendations, as well as to assure the personnel and patients.
- B. QUALITY ASSURANCE: Since quality assurance results in lower patient and personnel exposure, an important part of the radiation survey is the assurance of proper operation of the unit including checks of kVp, linearity of exposure with time and current, and focal spot size. These checks are also made on all radiographic units annually. All lead aprons and lead gloves shall be inspected at least annually for integrity. There must be documentation available suitable for review that deficiencies found during the survey have been corrected or are in the process of being corrected.
- C. TECHNIQUE: The patient's region of interest should be calibrated correctly and the appropriate technical factors should be selected or set properly on the control panel. The radiograph shall be accurately marked (patient ID, right/left marker, etc.) prior to the exposure so as to be visible on the processed radiographic image. The patient shall be given specific instructions (holding breath, holding still, etc.) to minimize the number of exposures taken. During the exposure the main entrance door to the radiographic room shall be closed.
- D. UNSAFE EQUIPMENT: Any unsafe equipment or operating condition shall be reported to the Radiology Supervisor. The supervisor will determine if the RSO or IRRP needs to be notified. Equipment shall not be operated when its operation involves a significant risk to patients and/or personnel. If there is any reason to suspect a defect in the leaded gloves or lead aprons, they shall be taken out of service and replaced by non-defective equipment.
- E. HOLDING OF PATIENTS: Patients should be immobilized as necessary to prevent retakes. Occupationally-exposed students or staff shall not hold patients except in a true emergency. In such an emergency, or if a non-occupational exposed person (e.g.

parent/guardian) holds, the person who is holding the patient shall not place any portion of their body in the useful beam. Appropriate protective clothing such as a lead apron and/or lead gloves shall be worn by anyone holding a patient. Radiographic image receptors shall not be held by anyone other than the patient during the radiographic examination.

- F. PERSONNEL PRESENT DURING AN EXAMINATION: Only necessary persons shall be in the room during the radiographic procedure. However, TUN facilities embrace the principles of Family Centered care and the presence of persons (e.g. parent of guardian) who are not occupationally exposed are permitted in the radiographic room during their child's examination. It is the responsibility of the operators of the radiographic equipment to assure that exposed persons are adequately protected from the radiation source. The operator shall also maintain a minimal distance of six (6) feet from the non-occupationally exposed persons and the x-ray tube. In no case shall the operator(s) be permitted to stand in the primary beam. Protective leaded aprons shall be worn by all persons in the room.
  - G. RESTRICTED AREAS: The x-ray/DXA room is a restricted area during x-ray exposures. The authorized operator is responsible for controlling access to that room during exposures. The DXA room is not shielded; however, all adjacent areas may be treated as unrestricted areas. All radiographic rooms will have either radiation signs or warning lights above their entry doors that indicate radiation exposure is present. In addition, warning signs to alert potentially pregnant patients prior to exposure will be posted throughout the adjacent rooms and facilities.
  - H. PROPER SIGNAGE: Signage is important to operators, employees, and patient/visitors as it warns of the possibility of radiation exposure. The radiation sites will ensure that all areas involved in the production of ionizing radiation are properly signed, and that these signs are in plain sight, and are appropriate for all to see and understand.
- VII. PREGNANT PATIENTS/Research Subjects
- A. GENERAL: Protection of the embryo or fetus or the irradiation of women who may be pregnant shall be given special consideration. If the patient is pregnant or suspects that she is pregnant, the student and staff will consult with the Radiology Supervisor prior to continuing the radiographic examination.
  - B. LAST MENSTRUAL PERIOD (LMP): Any female of reproductive age (older than ten (10) years of age, or younger in some situations) which is scheduled for a radiographic examination, will be asked the following questions:
    - What was the date of your last menstrual period (LMP)?
    - Do you have any reason to believe you are pregnant?

This information shall be recorded on the x-ray requisition and history form. If the answer to the above questions indicates that the patient may be pregnant, the Radiographer will consult with the Supervising Radiologist before proceeding with the examination. The Supervising Radiologist may choose to:

1. Perform the examination because the patient's medical condition indicates immediate need.
2. Limit the number of views and/or restrict the field size that will yield the necessary clinical information.
3. In the case of a known pregnancy, defer the examination until the pregnancy is concluded
4. In the case of a possible pregnancy, defer the examination until the pregnancy is ruled out. This assumes that the examination could be postponed until the pregnancy is concluded if the woman was found to be pregnant
5. Cancel the examination

C. SHIELDING: Shielding of all potentially pregnant patients is required unless its presence interferes with the examination.

#### VIII. DXA RADIOGRAPHY LAB

A. DXA Radiography lab operators: Only Nevada-licensed medical physicians and Radiographers licensed nationally by the American Registry of Radiologic Technologists (ARRT) and locally by the Nevada Division of Public and Behavioral Health (DPBH) are authorized to operate the TUN DXA energized radiographic equipment located in the Human Performance Laboratory.

B. Usage of the TUN Radiography DXA Lab: The Touro University Nevada (TUN) DXA room radiographic DXA laboratory is only used for educational demonstration, and IRB approved research use. While radiographic exposures may be made, they are only performed on radiographic phantoms for demonstration, and subjects enrolled in a TUN IRB approved research project. At all times, any radiation exposures are made under the direct supervision of the authorized operators. At this time no diagnostic activities are being performed in this laboratory.

#### IX. YOUR ROLE IN RADIATION SAFETY

A. The most important aspect in radiation safety is YOU!!!!

1. YOU are controlling the radiographic equipment.
2. YOU are responsible for the patient's safety in the DXA room.
3. YOU must think carefully before making each exposure.
4. YOU can prevent most repeats.
5. YOU must decide when to follow the established technique chart and when to make adjustments because of a patient's body habitus, physical condition, and/or pathology.



X. REFERENCES

- A. National Council on Radiation Protection and Measurement: Limitation of Exposure to Ionizing Radiation. Report #116, 1993
- B. National Council on Radiation Protection and Measurement: Radiation Protection for Medical and Allied Health Personnel, Report #105, 1989
- C. National Council on Radiation Protection and Measurement: Radiation Structural Shielding Design and Evaluation for Medical, Use of X-Ray Gamma Rays of Energies Up to 10 MEV, Report #49, 1976
- D. National Council on Radiation Protection and Measurement: Radiation Protection in Pediatric Radiology, Report#68, 1981
- E. Nuclear Regulatory Guide #8.13, Instruction Concerning Parental Radiation Exposure, Nov/1975, Revision #3 Jun/1999

Last revision date: March/2019

Last review date:



# Touro University Nevada

## **FACULTY RESEARCH POLICIES**

### **PRINCIPAL INVESTIGATOR DEFINITION (“PI”)**

A Principal Investigator must have the technical competence and substantive capabilities (scientific, administrative and otherwise) to carry out a sponsored project. The following individuals are eligible to serve as principal investigators on proposals submitted to outside funding agencies in support of research, training or other sponsored activities at Touro.

### **ELIGIBLE FACULTY**

Professors

Associate Professors

Assistant Professors

Instructors

### **ELIGIBLE NON-FACULTY INDIVIDUALS**

Research Scientists

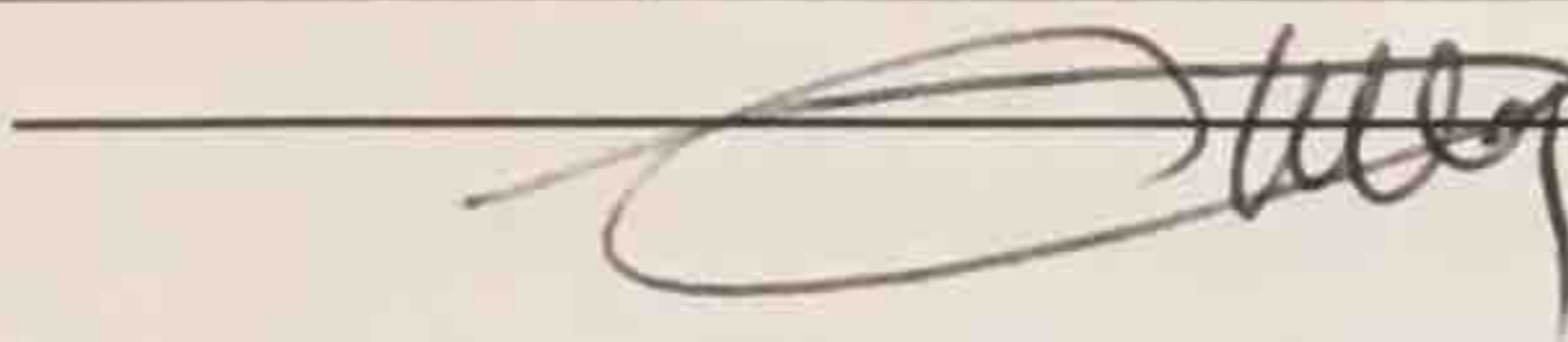
Associate Research Scientists

Assistant Research Scientists

Research Associates

Emeritus Faculty members are also eligible to serve as Principal Investigators, conditional on the availability of College resources, and subject to the approval by the Dean of the School submitting the proposal.

Any PI who is or has been debarred or suspended by the federal government must immediately notify his dean’s office and Touro’s Office of Sponsored Projects and will be precluded from receiving federally funded grant or contract awards and also from being paid with federal funds.

<b>Policy:</b> Sponsored Project Awards Management Policy	<b>Effective Date:</b> April 1, 2019	<b>Policy Version:</b> 1.2	<b>Policy Status:</b> FINAL
 <b>Provost for Biomedical Research:</b>		<b>Date:</b> March 27, 2019	

### 1.0 **PURPOSE**

This policy ensures that restricted funds provided from external sources to support research and other projects are administered in accordance with institutional policies as well as those of the sponsor. External sources include both governmental and private organizations.

### 2.0 **SCOPE**

This policy applies to all sponsored project awards that are funded by external sources; this policy does not generally apply to gifts.

### 3.0 **DEFINITIONS**

**3.1 Sponsored Project Awards:** Projects and/or other activities that are originated and conducted by Principal Investigators/Project Directors and that are supported wholly or in part by external restricted funds.

**3.2 Touro College and University System,** hereinafter referred to as “Touro” or “Institution”—*shall mean and include for purposes of this policy*—Touro College, Touro University California, and Touro University Nevada, Hebrew Theological College, and Touro University Worldwide, and their schools, divisions, departments, and entities (domestic and international) *but not* New York Medical College (“NYMC”).

**3.3 Provost for Biomedical Research/Chief Biomedical Research Officer (“PBR”):** The individual among the Senior Leadership with primary responsibility for guidance related to Institutional management of sponsored project awards and research conducted at Touro.

**3.4 Office of Sponsored Programs (“OSP”):** Touro has three separate OSPs, located at Touro College, Touro University California, and Touro University Nevada.

**3.5 Principal Investigator/Project Director (“PI/PD”):** The individual primarily responsible for and in charge of a sponsored project. The PI/PD normally is a member of the faculty, but in some instances may be a staff member or student depending upon the nature of the sponsored project and award.

#### **4.0 POLICY STATEMENTS**

Under the oversight of the PBR, OSP is the Institution's designated office charged with providing operational pre-award support for all sponsored project awards, and coordinating with other central administration and campus-centric offices and committees on matters pertaining to sponsored project awards.

Other funds awarded to support other areas of the Institution's activity but restrictive in nature may be subject to this policy. The OSP will oversee such projects as well. Where potential questions or ambiguities arise regarding whether an award is a sponsored project or a gift, and where OSP cannot resolve the issue solely, OSP and the Office of Institutional Advancement will: (a) obtain determination advice from the Office of General Counsel; (b) coordinate activities closely to ensure proper institutional policies are applied; and, (c) work together to avoid multiple/competing solicitations from the same private sources.

Sponsors include but are not limited to government agencies (federal, state, local), non-profit organizations (e.g., foundations), and corporations. Awards (grants, cooperative agreements, contracts, other agreements) either are directly issued to the Institution or are issued as pass-through awards of prime sponsor funds (e.g. subcontracts) to the Institution from other institutions of higher education or from other organizations.

#### **5.0 ROLES AND RESPONSIBILITIES**

##### **5.1 Provost for Biomedical Research/Chief Biomedical Research Officer ("PBR"):**

The PBR plays a fundamental Institutional role in the overall coordination of sponsored project awards management and related policy formulation at Touro on behalf of the President. The PBR is a senior member of the faculty, an established researcher, and a successful recipient of sponsored project awards, who advocates for the advancement of the academic research mission throughout Touro. The PBR brings those critical perspectives to bear on all administrative functions that are vital to Touro's research mission, while working to ensure that Touro carries out its legal, regulatory, and sponsor-mandated responsibilities. The PBR consults extensively with other members of the Senior Leadership and the members of their staffs, providing both broad guidance and targeted recommendations for action pertaining to sponsored project awards management. The PBR supervises OSP and ensures its services fulfill Institutional needs in support of sponsored project awards management.

**5.2 Office of Sponsored Programs ("OSP"):** The mission of the Office of Sponsored Programs is to advocate for and facilitate faculty research projects and other related endeavors (e.g., public service, training, demonstration projects), with a central focus on external funding, and acting as support for each research stakeholder. In this support and administrative role for sponsored projects, the key services provided by OSP are:

- Identifying and communicating funding opportunities, primarily through providing faculty with access to search tools.

- Providing guidance and assistance to faculty and staff in drafting, and preparing all institutional proposals to sponsors, reviewing proposals for conformity with sponsor and institutional policies, and submitting proposals to sponsors on behalf of Touro.
- Coordinating negotiation and acceptance of awards including consultation with and assistance from other administrative offices and securing the appropriate institutional signature as required.
- Ensuring compliance approvals for sponsored projects (e.g., human subjects, animal care and use, biohazards/biosafety, etc.) are in place where such approvals are required.
- Initiating the establishment of all institutional accounts for sponsored projects in the general ledger system by the Office of the Controller.
- Managing the establishment of subrecipient agreements under sponsored project awards.
- Interfacing with sponsors as needed and liaising with sponsors on issues as they arise, primarily on non-financial matters.
- Overseeing all prior approvals delegated to Touro by the sponsor, required to be secured from the sponsor, or required internally by Institutional policy, including but not limited to pre-award costs authorizations, no cost extensions of awards, closeouts of fixed-price contracts, etc.
- Coordinating periodic reporting on progress and compliance, as required.
- Interpreting, overseeing, and ensuring compliance with sponsor award requirements, in conjunction with other offices, etc. as appropriate.
- Informing key stakeholders about relevant regulatory developments and help craft responsive institutional policies and procedures.
- Ensuring institutional compliance with relevant regulatory and internal Touro Institution requirements, in conjunction with other offices, etc. as appropriate,
- Others duties specifically assigned reflecting campus-based operational structures and requirements.

OSP is responsible for developing, implementing, and ensuring compliance with procedures to fulfill these duties.

OSP also works closely with other central offices and with administrative and academic leadership, as necessary, to carry out these duties.

Each Director of OSP carries out these responsibilities at the respective campuses and collectively the Directors work together cooperatively to advance the research and other sponsored programs mission of the Institution. The Director of the OSP at Touro College (New York) is responsible for providing staff support to the PBR and assisting the PBR in providing overall Institutional-level guidance on sponsored projects pre-award and compliance policies and procedures for Touro and, similarly, working cooperatively with the Office of the Controller on Institutional-level post-award policies and procedures for Touro.

**5.3 Offices of the Controller and Budget Director:** The Office of the Controller is responsible for Touro's fiscal services in support of sponsored programs management, primarily through accounting. These "post-award" duties include:

- Assisting with processes and monitors adherence to sponsor regulations and standards and Touro fiscal and accounting policies and procedures related to fiscal reporting requirements for sponsored projects.
- Opening project account in the general ledger system upon receipt of sponsored project award and confirmation with OSP that all required compliance approvals are in place (e.g., human subjects, animal care and use, biosafety/biohazards).
- Coordinating with the Principal Investigator/Project Director on establishing the account budget in accordance with the sponsor award budget and terms, including any subsequent budget revisions based on award terms and/or required prior approvals.
- Reviewing the monthly transactions and making adjustments as may be required to assure that expenses to project accounts are necessary, reasonable, allowable, and allocable, are consistent with award and institutional policies, and that the general ledger project account is cleared of any expenses not applicable to the award.
- In consultation with the Principal Investigator/Project Director and/or school/Institution dean, transferring expenses not allowable and any overdrafts to other permissible fund sources.
- Reviewing subrecipient's audits, or secures appropriate representations from subrecipient, that demonstrate proper fiduciary responsibility by subrecipient of funds provided by Touro under a subrecipient agreement
- Preparing special project funding reports, financial reports, and summaries in collaboration with the sponsored project Principal Investigator/Project Director.
- Monitoring sponsored project accounting, audits, and fiscal reporting.
- Overseeing salary confirmation reporting.
- Overseeing Touro's indirect costs (Facilities and Administration) rate negotiations and all matters related to the charging of indirect costs to sponsored project awards in accordance with sponsor and institutional policies.

#### **5.4 Office of the General Counsel ("OGC")**

This office provides key institutional guidance and counsel to ensure legal compliance on behalf of the Institution and minimize legal risks. For sponsored project awards, the OGC's responsibilities include but are not limited to:

- Reviewing sponsored project proposals, awards and subrecipient agreements referred by OSP and engaging in negotiations as required.
- Approving model sponsored agreements and subrecipient agreements for use by OSP; approving exceptions to model agreements terms and conditions.
- Preparing or negotiating all memoranda of understanding, confidentiality agreements, and material transfer agreements.

- Overseeing patenting and licensing of intellectual property and technology transfer.

**5.5 Office of Institutional Compliance (“OIC”):** This office provides key institutional guidance and counsel to assist the Touro community in carrying out its academic mission with integrity and in accordance with the Institution’s regulatory and ethical responsibilities. For sponsored project awards, the OIC’s responsibilities include but are not limited to:

- Reviewing concerns by the DSP that Touro’s policies and procedures and related training are either not in place or have not been implemented by appropriate offices and committees.
- Collecting and conducting conflict of interest reviews.
- Providing advice, as required, and addressing specific compliance issues of concern.
- Review the DSP’s plans for establishing methods for the continuous assessment of compliance efforts.

**5.6 Principal Investigator/Project Director:** The Principal Investigator/Project Director (PI/PD) is responsible for leading and directing the project intellectually and logistically, including all scientific/technical aspects and related administrative and financial operational management. As a practical matter, it is often necessary and appropriate to delegate to staff members certain responsibilities. No matter whether delegated or not, the PI is ultimately responsible. PI responsibilities include:

- Conducting the sponsored project in a timely and professional manner.
- Adhering to research and academic integrity requirements. Complying with all terms and conditions of each award and all Institution policies and procedures.
- Authorizing all expenditures for a sponsored project and reviewing project accounts in a timely manner to confirm that all costs charged to an award are appropriate, specifically benefit the project, and are consistent with sponsor policies.
- Certifying/confirming that all time and effort reporting is accurate and that all subrecipient expenses are reasonable and appropriate prior to being charged to a sponsored project.
- Ensuring compliance with all reporting requirements of awards, including but not limited to periodic progress reports, annual reports of project accomplishments, reports of inventions, reports of publications generated, reports of major items of equipment acquired, cost sharing/matching reports, and financial reports.

**5.7 Academic Leadership:** The Provosts, Vice Presidents, Deans, and Department Chairs of the Institution are responsible for the intellectual leadership of their units and have overall responsibility for the direction of research and other programs conducted by the faculty, regardless of funding source. Additionally, as administrative officers, they are responsible for making certain that PI/PDs and other faculty and/ or staff under their administrative cognizance who are assigned to a sponsored project conduct work in a manner that is consistent with the

Institution's obligations under statutes, regulations, ordinances, and sponsor policies and with all Institution policies and procedures. As part of the abovementioned responsibilities, the academic leadership is responsible for:

- Reviewing all sponsored project proposals to assure that the proposed project is consistent with the educational and professional objectives of the program and/or Institution.
- Endorsing the sponsored project proposal's budget, including approving cost sharing/ matching fund commitments contained in a proposal and identifying the resources to meet those obligations, along with commitments related to space and other resources.
- Generally monitoring progress on sponsored projects through regular periodic updates, reports and performance discussions with faculty members and the P.I.
- Identifying appropriate unrestricted fund sources to cover any sponsored project overdrafts and/or disallowances

#### **5.8 Authorized Institutional Official/Authorized Organizational Representative:**

The President or his designee is the primary signatory for sponsored project proposals and awards. The President may designate individuals to serve as authorized organizational representatives to assume the obligations imposed by the applicable laws, regulations, ordinances, policies, terms and conditions that apply to sponsored program proposals and awards. These individuals are empowered to make certifications and assurances to sponsors, and can commit the organization to the conduct of a sponsored project.

#### **6.0 WHO REVIEWS AND APPROVES THIS POLICY**

This Policy is reviewed and approved by the Institution's Administration.

#### **7.0 APPLICABLE STATUTES, REGULATIONS, AND ORDINANCES, AND SPONSOR POLICIES**

Sponsored project proposals and award may be subject to:

- All federal, state, and local laws and regulations pertaining to the management of sponsored project awards, including but not limited to:
  - 2 CFR 200 (Uniform Administrative Requirement, Costs Principles, and Audit Requirements for Federal Awards)
  - Federal Acquisitions Regulations
  - Federal Agency-Specific Regulations and Policies
  - State and Local Government Agency-Specific Regulations and Policies
- The laws, regulations, and ordinances of the States of New York, Nevada and California and local jurisdictions in which Institution facilities are located at which sponsored projects are conducted.
- All sponsor policies published or issued with awards.
- In the event of a conflict, if any, between the terms of this policy and an applicable regulation, the regulation shall control.





# Touro University Nevada

## Office of Sponsored Projects Policies

EFFORT REPORTING .....	1
COST SHARING .....	4
INDIRECTS: POLICY & ACCESS .....	5
NO COST EXTENSION .....	6

### **EFFORT REPORTING**

Reference: Office of Management and Budget Circular Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (“Uniform Guidance”) 2 CFR 200.

The TUN Effort Reporting Policy is also available on TouroOne under Finance and Purchasing to learn more about charging compensation for personal services in support of sponsored projects.

#### INTRODUCTION

As a recipient of federal funding, the Touro University Nevada is required to comply with the Office of Management and Budget Circular Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (“Uniform Guidance”) 2 CFR 200. Documentation of personnel expenses (also known as effort certification, salary certification, or time and effort) is a process mandated by the Federal government to verify that direct labor charges to federally sponsored agreements and any associated cost share is reasonable and reflects the actual work performed. This policy must be applied consistently to ensure that the

salaries and wages charged to sponsored projects are accurate, allowable, reasonable, properly allocated, timely and consistently treated.

This system must document all effort, whether treated as direct or F&A or cost share for sponsored agreements. Of the options available, OSP has implemented the “Plan-Confirmation” method.

Under the “Plan-Confirmation” method, the distribution of salaries and wages of individuals applicable to sponsored agreements is based on budgeted, planned, or assigned work activity which is retroactively updated to reflect any significant changes in work distribution. A certification statement will be completed by the employee, principal investigator, or responsible official(s), using suitable means of verification that the work was performed as reported.

#### A. Purpose of Personnel Activity Reporting

The Office Sponsored Programs has established a manual Personal Activity Report (PAR) for employees as a means of satisfying these requirements.

Proper completion of Personnel Activity Report (PAR) forms is a federal requirement (Uniform Guidance 2 CFR 200) of the University. Reporting personnel activity on the PAR form provides after-the-fact certification to support the allocation of salaries and wages charged to federal funds. A reasonable estimate of effort is reported and verified by the employee or by a responsible official having firsthand knowledge of the work performed. The certification reflects the total time expended by the employee on each account/fund for that specific reporting period. A 5 % variance is allowed between the actual time spent and what is reported.

Salary charges not certified on the PAR form are subject to audit disallowance. Incomplete, improper, or untimely PAR reporting can jeopardize future federal research funding.

The information obtained from the PAR forms will be used to substantiate and document effort under federal contracts and grants. Failure to substantiate charges and confirm actual effort after the fact and/or to explain discrepancies will normally cause the federal auditors to disallow costs reported on federal projects.

#### **Effort Report Instructions**

1. Review the effort reported (commitment) shown for the period listed at the top of the report. If you expended any effort (worked) on a sponsored project not listed, please write-in the information.

2. Record your actual effort percentages (may be more or less than shown) for each project listed if different than in the space provided. Only whole numbers should be used when recording effort. A more precise level of measurement is not reasonable or expected.

Note: If the percentage recorded for a project represents a significant change in effort, a revised payroll authorization may be needed.

3. The sponsored activity percentages are subtracted from 100. The difference is recorded on the line labeled "Effort Category – Other Activity".

4. Certify that the actual percentages of effort recorded reasonably reflect your activities for the period by signing and dating the report.

5. Return the completed report as instructed.

### **Definitions**

Fund Number

The Banner fund associated with a particular project.

### **Account Function**

The major functions are sponsored research, administration, instruction and other institutional activities. Collectively, these functions represent an individual's responsibilities to the University as specified in their appointment letter.

### **Actual Percent Effort**

Actual percentage of time the individual worked on a particular activity during the reporting period. Effort is not based on 35, 40 or any specified number of hours in a work week.

### **Certification**

Principal Investigators are required to certify their own effort reports and must certify effort for their project staff unless they have the employee sign their own. However, in cases where the employee or principal investigator is not available, a responsible official may certify the effort

provided that s/he can document the basis for verifying that the actual work was performed. Any questions about the certification requirement, effort commitments or completion of the report should be directed to OSP.

## **COST SHARING**

Cost sharing is the portion of total project costs of a sponsored agreement that is not borne by the sponsoring agency. “Matching” and “in-kind” are other common terms used to describe cost sharing.

Cost sharing is auditable and must be allowable under cost principles and verifiable to records. The Office Sponsored Programs, Touro University Nevada, follows the criteria and requirements in accordance with the Federal Uniform Guidance (2CFR 220), Sponsor Agency requirements and Touro policies.

Cost Share is Mandatory when required by the sponsor, or Voluntary when the PI voluntarily commits to providing quantified resources to complete the Award objectives. OSP strongly recommends that PIs do not include cost-share on a project unless it is required by a sponsor/program. For federal programs, the Uniform Guidance states that federal grant programs may no longer consider cost-sharing during the merit review process unless it is statutorily required. Thus, voluntary committed cost-share at the proposal stage will no longer have an impact on the proposal’s review.

Additionally, the Uniform Guidance requires TUN to treat both federal and non-federal funds consistently. Thus, for non-federal projects, OSP recommends that PIs do not include cost-share unless it is required by the sponsor. There are several reasons for this:

- 1) Cost sharing can have the effect of eroding an institution’s Facilities and Administrative (F&A) cost rate;
- 2) All cost-sharing, even voluntary committed, must be tracked and accounted for in the University’s accounting records and leaves the University open for audit concerns if not addressed properly;
- 3) Certain faculty members who have many awards could become over committed, resulting in an inability to substantiate the promised levels of effort. Committed effort is not available for any new proposal until it is released when proposal is officially not funded.

### **Proposals with Cost Sharing**

When submitting proposals for grants or contracts that include cost sharing and/or matching, the TUN Cost Share Request Form must be completed. During the proposal meeting with the PI, OSP will work with the PI to determine if there will be a cost share commitment. OSP will review agency guidelines to ensure cost share compliance. If so, OSP will complete the Cost Share Request Form, in conjunction

with the PI, prior to proposal submission. Cost share commitment information will need to be approved by TUN signatories prior to final submission. All committed cost sharing information must be included in the budget and budget justification.

Please note that failure to comply with this process could result in a delay in submission of the proposal to the sponsoring agency. If you have any questions regarding cost share on your application, please contact Drew Ehlert, Grants Manager.

## **INDIRECTS: POLICY & ACCESS**

The University generally receives a reimbursement of indirect costs (i.e., overhead) from federal and non-federal sponsors of contracts and grants. The F&A rate is calculated by the University in accordance with the requirements contained in the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards. Current policy allows Principal investigators to accrue up to 1/6 of their IDC. Quarterly distributions of indirect cost recovery funds are based on actual reimbursements of indirect costs received by the OSP and not on budgeted amounts.

These funds are to be used for costs that are incurred for common or joint objectives and therefore cannot be identified readily and specifically with a particular sponsored project, an instructional activity, or any other institutional activity and would be used to enrich your project.

Examples of requests could be:

1. Purchase of equipment that could not be approved by a specific grant or would be used by several research projects
2. Maintenance contracts or repairs for equipment that is used for numerous projects and the benefit cannot be allocated to any specific project (for example an electron microscope in a core facility.)
3. Costs considered administrative in nature and not project specific or not submitted within the budget justification of a proposal
4. Can be used for publication costs associated with open source journal publications at the discretion of the Dean and the PI's. Publication is foundational to 1) dissemination of research findings and 2) building a foundation for future grant proposals.
5. Research related expenses and/or professional development support.
6. Additional travel not requested within the proposal or used to off-set costs of allowed travel
7. Items such as office supplies (including computers and software), postage, and memberships
8. Overdrafts of a closed grant year or project.

This list is not all-inclusive but can give you an idea of what these funds can be used for.

## **Additional Information for Equipment Purchases**

Using IDC funds for any equipment purchase over \$5,000 must follow TUN policy and procedures. This will require additional documents and, depending on amount requested, may require 2 - 4 weeks to complete the review/approval process before the order can be placed. All documents must be submitted to Purchasing with a FOAP supplied by OSP. Please go to TouroOne Finance and Purchasing page to review policy and procedures.

## **NO COST EXTENSION**

- Most NCE requests on federal awards may be approved by Touro University (the "grantee")
- Most agencies require 10-90 days' notice prior to the award's original end date
- NCEs typically do not exceed twelve months and do not request additional funds
- Only in exceptional cases will more than one NCE be approved by an agency
- The format for these requests varies according to the agency's requirements; check with OSP, Drew Ehlert to clarify the appropriate format for your NCE

**NIH Awards:** If NCEs are allowed on an NIH award, a link for "extension" is posted in the "status" area of the NIH Commons 90 days before the end date. Once the link is posted, OSP can submit the request. To initiate this request, the PI should submit a request to OSP, Grants Manager, Drew Ehlert, using the No Cost Request form under. [Additional NIH-specific information about NCEs.](#)

**NSF Awards:** The first NCE on an NSF award is considered a "notification," and can be approved by the grantee. If time is needed beyond the first extension a second NCE is considered a "request" that must be approved by NSF. "Notifications" and "requests" must be submitted by the Principal Investigator (PI) via Fastlane, and should include the information outlined in the bulleted section below.

### **Procedure if NIH award (under FDP) or NSF:**

The request to OSP for a no-cost extension under an NIH FDP award must be made no more than 90 days before the end of a project, and must be received by OSP within four working days prior to the end of the project.

Submit:

- No Cost Request form
- PI Assurance Certification
- NIH PI Certification

Copies of all applicable committee approvals must also be included with the request and must be current at the time of submission.

After receipt and review of the above information, the request will be approved by the Grants Manager at OSP and entered into the NIH Commons. Copies of the NIH Commons approval, which is

automatically generated by email within the Commons system, will then be distributed to the PI, and Accounting.

**Procedures for All Other Agencies:** PIs must submit requests for NCEs to all other agencies in writing. Approved requests are then forwarded to the agency.

PIs must submit requests for NCEs to the OSP Grants Manager (Drew Ehlert) by email for review/approval. The email or memo request must also include Dean's signature approval or designee.

Requests should include:

No Cost Action Form

- Sample No Cost Extension Request Letter -
- Justification for the NCE. The following reasons are acceptable:
  - Additional time beyond the initial end date is required to complete the project
  - The extension is necessary for an orderly phase-out of a project that will not receive continued support
- Length of the requested NCE
- An estimate of funds that are expected to remain unobligated on the scheduled end date
- A plan for how the funds will be used during the extension period
- Signature by the Director of the Office Sponsored Programs
- Other documents required: CHR or IACUC approvals.

Please note: Requesting additional time simply to spend down remaining funds is not considered a reasonable justification.

### **Effort Commitments during NCE**

A no-cost extension could be necessary when a project period has reached its end date and effort toward the project is still required. In these situations, the principal investigator and other key personnel\* have the following options with regard to effort:

- Continue original level of committed effort
- Reduce the level of committed effort
- Increase the level of committed effort

Subject to sponsor requirements, changes in committed effort should be communicated to the Sponsor with the notification of, or request for, a no-cost extension.

After the extension has been approved, Sponsored or Sponsored programs will adjust the commitment for effort reporting purposes.

#### Continue original level of committed effort

If committed effort contributed during the extension period will not be supported by sponsor funds, a Cost Share Commitment Form shall be submitted to the Office of Sponsored Programs with the request for extension. A cost-sharing budget shall be established to document this contribution.

#### Reduce the level of committed effort

Significant reductions (generally 25% or more) in committed effort shall be communicated to the sponsor with the notification of, or request for, a no-cost extension (subject to sponsor's requirements).

Reductions of effort less than 25% normally do not require sponsor notification. However, the award terms and conditions must be reviewed to ensure compliance.

If committed effort contributed during the extension period will not be supported by sponsor funds, a Cost Share Commitment Form and cost sharing budget may be required. Please refer to the Cost Sharing Procedures.

#### Increase the level of committed effort

If the increased committed effort contributed during the extension period will not be supported by sponsor funds, a Cost Share Commitment Form and cost sharing budget may be required. Please refer to the Cost Sharing Procedures.





Displaying title 2, up to date as of 11/08/2021. Title 2 was last amended 10/18/2021.

**ENHANCED CONTENT - TABLE OF CONTENTS**

<b>Part 200</b>	Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards	200.0 – 200.521
<b>Subpart A</b>	Acronyms and Definitions	200.0 – 200.1
	Acronyms	200.0 – 200.1
	§ 200.0 Acronyms.	
	§ 200.1 Definitions.	
<b>Subpart B</b>	General Provisions	200.100 – 200.113
	§ 200.100 Purpose.	
	§ 200.101 Applicability.	
	§ 200.102 Exceptions.	
	§ 200.103 Authorities.	
	§ 200.104 Supersession.	
	§ 200.105 Effect on other issuances.	
	§ 200.106 Agency implementation.	
	§ 200.107 OMB responsibilities.	
	§ 200.108 Inquiries.	
	§ 200.109 Review date.	
	§ 200.110 Effective/applicability date.	
	§ 200.111 English language.	
	§ 200.112 Conflict of interest.	
	§ 200.113 Mandatory disclosures.	
<b>Subpart C</b>	Pre-Federal Award Requirements and Contents of Federal Awards	200.200 – 200.216
	§ 200.200 Purpose.	
	§ 200.201 Use of grant agreements (including fixed amount awards), cooperative agreements, and contracts.	
	§ 200.202 Program planning and design.	
	§ 200.203 Requirement to provide public notice of Federal financial assistance programs.	
	§ 200.204 Notices of funding opportunities.	
	§ 200.205 Federal awarding agency review of merit of proposals.	
	§ 200.206 Federal awarding agency review of risk posed by applicants.	
	§ 200.207 Standard application requirements.	
	§ 200.208 Specific conditions.	
	§ 200.209 Certifications and representations.	
	§ 200.210 Pre-award costs.	
	§ 200.211 Information contained in a Federal award.	
	§ 200.212 Public access to Federal award information.	
	§ 200.213 Reporting a determination that a non-Federal entity is not qualified for a Federal award.	
	§ 200.214 Suspension and debarment.	
	§ 200.215 Never contract with the enemy.	
	§ 200.216 Prohibition on certain telecommunications and video surveillance services or equipment.	
<b>Subpart D</b>	Post Federal Award Requirements	200.300 – 200.346
	§ 200.300	Statutory and national policy requirements.
	§ 200.301	Performance measurement.
	§ 200.302	Financial management.
	§ 200.303	Internal controls.
	§ 200.304	Bonds.

<b>§ 200.305</b>	Federal payment.
<b>§ 200.306</b>	Cost sharing or matching.
<b>§ 200.307</b>	Program income.
<b>§ 200.308</b>	Revision of budget and program plans.
<b>§ 200.309</b>	Modifications to Period of Performance.
Property Standards	200.310 – 200.316
<b>§ 200.310</b> Insurance coverage.	
<b>§ 200.311</b> Real property.	
<b>§ 200.312</b> Federally-owned and exempt property.	
<b>§ 200.313</b> Equipment.	
<b>§ 200.314</b> Supplies.	
<b>§ 200.315</b> Intangible property.	
<b>§ 200.316</b> Property trust relationship.	
Procurement Standards	200.317 – 200.327
<b>§ 200.317</b> Procurements by states.	
<b>§ 200.318</b> General procurement standards.	
<b>§ 200.319</b> Competition.	
<b>§ 200.320</b> Methods of procurement to be followed.	
<b>§ 200.321</b> Contracting with small and minority businesses, women's business enterprises, and labor surplus area firms.	
<b>§ 200.322</b> Domestic preferences for procurements.	
<b>§ 200.323</b> Procurement of recovered materials.	
<b>§ 200.324</b> Contract cost and price.	
<b>§ 200.325</b> Federal awarding agency or pass-through entity review.	
<b>§ 200.326</b> Bonding requirements.	
<b>§ 200.327</b> Contract provisions.	
Performance and Financial Monitoring and Reporting	200.328 – 200.330
<b>§ 200.328</b> Financial reporting.	
<b>§ 200.329</b> Monitoring and reporting program performance.	
<b>§ 200.330</b> Reporting on real property.	
Subrecipient Monitoring and Management	200.331 – 200.333
<b>§ 200.331</b> Subrecipient and contractor determinations.	
<b>§ 200.332</b> Requirements for pass-through entities.	
<b>§ 200.333</b> Fixed amount subawards.	
Record Retention and Access	200.334 – 200.338
<b>§ 200.334</b> Retention requirements for records.	
<b>§ 200.335</b> Requests for transfer of records.	
<b>§ 200.336</b> Methods for collection, transmission, and storage of information.	
<b>§ 200.337</b> Access to records.	
<b>§ 200.338</b> Restrictions on public access to records.	
Remedies for Noncompliance	200.339 – 200.343
<b>§ 200.339</b> Remedies for noncompliance.	
<b>§ 200.340</b> Termination.	
<b>§ 200.341</b> Notification of termination requirement.	
<b>§ 200.342</b> Opportunities to object, hearings, and appeals.	
<b>§ 200.343</b> Effects of suspension and termination.	
Closeout	200.344
<b>§ 200.344</b> Closeout.	
Post-Closeout Adjustments and Continuing Responsibilities	200.345

<b>§ 200.345</b> Post-closeout adjustments and continuing responsibilities.	
Collection of Amounts Due	200.346
<b>§ 200.346</b> Collection of amounts due.	
<b>Subpart E</b> Cost Principles	200.400 – 200.476
General Provisions	200.400 – 200.401
<b>§ 200.400</b> Policy guide.	
<b>§ 200.401</b> Application.	
Basic Considerations	200.402 – 200.411
<b>§ 200.402</b> Composition of costs.	
<b>§ 200.403</b> Factors affecting allowability of costs.	
<b>§ 200.404</b> Reasonable costs.	
<b>§ 200.405</b> Allocable costs.	
<b>§ 200.406</b> Applicable credits.	
<b>§ 200.407</b> Prior written approval (prior approval).	
<b>§ 200.408</b> Limitation on allowance of costs.	
<b>§ 200.409</b> Special considerations.	
<b>§ 200.410</b> Collection of unallowable costs.	
<b>§ 200.411</b> Adjustment of previously negotiated indirect (F&A) cost rates containing unallowable costs.	
Direct and Indirect (F&A) Costs	200.412 – 200.415
<b>§ 200.412</b> Classification of costs.	
<b>§ 200.413</b> Direct costs.	
<b>§ 200.414</b> Indirect (F&A) costs.	
<b>§ 200.415</b> Required certifications.	
Special Considerations for States, Local Governments and Indian Tribes	200.416 – 200.417
<b>§ 200.416</b> Cost allocation plans and indirect cost proposals.	
<b>§ 200.417</b> Interagency service.	
Special Considerations for Institutions of Higher Education	200.418 – 200.419
<b>§ 200.418</b> Costs incurred by states and local governments.	
<b>§ 200.419</b> Cost accounting standards and disclosure statement.	
General Provisions for Selected Items of Cost	200.420 – 200.476
<b>§ 200.420</b> Considerations for selected items of cost.	
<b>§ 200.421</b> Advertising and public relations.	
<b>§ 200.422</b> Advisory councils.	
<b>§ 200.423</b> Alcoholic beverages.	
<b>§ 200.424</b> Alumni/ae activities.	
<b>§ 200.425</b> Audit services.	
<b>§ 200.426</b> Bad debts.	
<b>§ 200.427</b> Bonding costs.	
<b>§ 200.428</b> Collections of improper payments.	
<b>§ 200.429</b> Commencement and convocation costs.	
<b>§ 200.430</b> Compensation - personal services.	
<b>§ 200.431</b> Compensation - fringe benefits.	
<b>§ 200.432</b> Conferences.	
<b>§ 200.433</b> Contingency provisions.	
<b>§ 200.434</b> Contributions and donations.	
<b>§ 200.435</b> Defense and prosecution of criminal and civil proceedings, claims, appeals and patent infringements.	
<b>§ 200.436</b> Depreciation.	
<b>§ 200.437</b> Employee health and welfare costs.	
<b>§ 200.438</b> Entertainment costs.	
<b>§ 200.439</b> Equipment and other capital expenditures.	

- § 200.440 Exchange rates.
- § 200.441 Fines, penalties, damages and other settlements.
- § 200.442 Fund raising and investment management costs.
- § 200.443 Gains and losses on disposition of depreciable assets.
- § 200.444 General costs of government.
- § 200.445 Goods or services for personal use.
- § 200.446 Idle facilities and idle capacity.
- § 200.447 Insurance and indemnification.
- § 200.448 Intellectual property.
- § 200.449 Interest.
- § 200.450 Lobbying.
- § 200.451 Losses on other awards or contracts.
- § 200.452 Maintenance and repair costs.
- § 200.453 Materials and supplies costs, including costs of computing devices.
- § 200.454 Memberships, subscriptions, and professional activity costs.
- § 200.455 Organization costs.
- § 200.456 Participant support costs.
- § 200.457 Plant and security costs.
- § 200.458 Pre-award costs.
- § 200.459 Professional service costs.
- § 200.460 Proposal costs.
- § 200.461 Publication and printing costs.
- § 200.462 Rearrangement and reconversion costs.
- § 200.463 Recruiting costs.
- § 200.464 Relocation costs of employees.
- § 200.465 Rental costs of real property and equipment.
- § 200.466 Scholarships and student aid costs.
- § 200.467 Selling and marketing costs.
- § 200.468 Specialized service facilities.
- § 200.469 Student activity costs.
- § 200.470 Taxes (including Value Added Tax).
- § 200.471 Telecommunication costs and video surveillance costs.
- § 200.472 Termination costs.
- § 200.473 Training and education costs.
- § 200.474 Transportation costs.
- § 200.475 Travel costs.
- § 200.476 Trustees.

**Subpart F** Audit Requirements

200.500 – 200.521

General	200.500
§ 200.500 Purpose.	
Audits	200.501 – 200.507
§ 200.501 Audit requirements.	
§ 200.502 Basis for determining Federal awards expended.	
§ 200.503 Relation to other audit requirements.	
§ 200.504 Frequency of audits.	
§ 200.505 Sanctions.	
§ 200.506 Audit costs.	
§ 200.507 Program-specific audits.	
Auditees	200.508 – 200.512
§ 200.508 Auditee responsibilities.	
§ 200.509 Auditor selection.	
§ 200.510 Financial statements.	
§ 200.511 Audit findings follow-up.	
§ 200.512 Report submission.	
Federal Agencies	200.513
§ 200.513 Responsibilities.	
Auditors	200.514 – 200.520
§ 200.514 Scope of audit.	
§ 200.515 Audit reporting.	
§ 200.516 Audit findings.	
§ 200.517 Audit documentation.	
§ 200.518 Major program determination.	
§ 200.519 Criteria for Federal program risk.	
§ 200.520 Criteria for a low-risk auditee.	
Management Decisions	200.521
§ 200.521 Management decision.	
<b>Appendix I to Part 200</b>	
Full Text of Notice of Funding Opportunity	
<b>Appendix II to Part 200</b>	
Contract Provisions for Non-Federal Entity Contracts Under Federal Awards	
<b>Appendix III to Part 200</b>	
Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Institutions of Higher Education (IHEs)	
<b>Appendix IV to Part 200</b>	
Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Nonprofit Organizations	
<b>Appendix V to Part 200</b>	
State/Local Governmentwide Central Service Cost Allocation Plans	
<b>Appendix VI to Part 200</b>	
Public Assistance Cost Allocation Plans	
<b>Appendix VII to Part 200</b>	
States and Local Government and Indian Tribe Indirect Cost Proposals	
<b>Appendix VIII to Part 200</b>	
Nonprofit Organizations Exempted From Subpart E of Part 200	
<b>Appendix IX to Part 200</b>	
Hospital Cost Principles	

**Appendix X to Part 200**

Data Collection Form (Form SF-SAC)

**Appendix XI to Part 200**

Compliance Supplement

**Appendix XII to Part 200**

Award Term and Condition for Recipient Integrity and Performance Matters

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# Title 2

## **PART 200 - UNIFORM ADMINISTRATIVE REQUIREMENTS, COST PRINCIPLES, AND AUDIT REQUIREMENTS FOR FEDERAL AWARDS**

**Authority:** 31 U.S.C. 503**Source:** 78 FR 78608, Dec. 26, 2013, unless otherwise noted.

### **Subpart A - Acronyms and Definitions**

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#### ACRONYMS

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#### **§ 200.0 Acronyms.**

##### **Acronym Term**

CAS Cost Accounting Standards

CFR Code of Federal Regulations

CMIA Cash Management Improvement Act

COG Councils Of Governments

COSO Committee of Sponsoring Organizations of the Treadway Commission

EPA Environmental Protection Agency

ERISA Employee Retirement Income Security Act of 1974 (29 U.S.C. 1301-1461)

EUI Energy Usage Index

F&amp;A Facilities and Administration

FAC Federal Audit Clearinghouse

FAIN Federal Award Identification Number

FAPIS Federal Awardee Performance and Integrity Information System

FAR Federal Acquisition Regulation

FFATA Federal Funding Accountability and Transparency Act of 2006 or Transparency Act - Public Law 109-282, as amended by section 6202(a) of Public Law 110-252 (31 U.S.C. 6101)

FICA Federal Insurance Contributions Act

FOIA Freedom of Information Act

FR Federal Register

FTE Full-time equivalent

GAAP Generally Accepted Accounting Principles

GAGAS Generally Accepted Government Auditing Standards

GAO Government Accountability Office

GOCO Government owned, contractor operated

GSA General Services Administration

IBS Institutional Base Salary

IHE Institutions of Higher Education

IRC Internal Revenue Code

ISDEAA Indian Self-Determination and Education and Assistance Act

MTC Modified Total Cost

MTDC Modified Total Direct Cost

NFE Non-Federal Entity

OMB Office of Management and Budget

PII Personally Identifiable Information

PMS Payment Management System

PRHP Post-retirement Health Plans

PTE Pass-through Entity

REUI Relative Energy Usage Index

SAM System for Award Management

SFA Student Financial Aid

SNAP Supplemental Nutrition Assistance Program

SPOC Single Point of Contact

TANF Temporary Assistance for Needy Families

TFM Treasury Financial Manual

U.S.C. United States Code

VAT Value Added Tax

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75880, Dec. 19, 2014; 80 FR 43308, July 22, 2015; 85 FR 49529, Aug. 13, 2020]

## § 200.1 Definitions.

These are the definitions for terms used in this part. Different definitions may be found in Federal statutes or regulations that apply more specifically to particular programs or activities. These definitions could be supplemented by additional instructional information provided in governmentwide standard information collections. For purposes of this part, the following definitions apply:

**Acquisition cost** means the cost of the asset including the cost to ready the asset for its intended use. Acquisition cost for equipment, for example, means the net invoice price of the equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Acquisition costs for software includes those development costs capitalized in accordance with generally accepted accounting principles (GAAP). Ancillary charges, such as taxes, duty, protective in transit insurance, freight, and installation may be included in or excluded from the acquisition cost in accordance with the non-Federal entity's regular accounting practices.

**Advance payment** means a payment that a Federal awarding agency or pass-through entity makes by any appropriate payment mechanism, including a predetermined payment schedule, before the non-Federal entity disburses the funds for program purposes.

**Allocation** means the process of assigning a cost, or a group of costs, to one or more cost objective(s), in reasonable proportion to the benefit provided or other equitable relationship. The process may entail assigning a cost(s) directly to a final cost objective or through one or more intermediate cost objectives.

**Assistance listings** refers to the publicly available listing of Federal assistance programs managed and administered by the General Services Administration, formerly known as the Catalog of Federal Domestic Assistance (CFDA).

**Assistance listing number** means a unique number assigned to identify a Federal Assistance Listings, formerly known as the CFDA Number.

**Assistance listing program title** means the title that corresponds to the Federal Assistance Listings Number, formerly known as the CFDA program title.

**Audit finding** means deficiencies which the auditor is required by § 200.516(a) to report in the schedule of findings and questioned costs.

**Auditee** means any non-Federal entity that expends Federal awards which must be audited under subpart F of this part.

**Auditor** means an auditor who is a public accountant or a Federal, State, local government, or Indian tribe audit organization, which meets the general standards specified for external auditors in generally accepted government auditing standards (GAGAS). The term auditor does not include internal auditors of nonprofit organizations.

**Budget** means the financial plan for the Federal award that the Federal awarding agency or pass-through entity approves during the Federal award process or in subsequent amendments to the Federal award. It may include the Federal and non-Federal share or only the Federal share, as determined by the Federal awarding agency or pass-through entity.

**Budget period** means the time interval from the start date of a funded portion of an award to the end date of that funded portion during which recipients are authorized to expend the funds awarded, including any funds carried forward or other revisions pursuant to § 200.308.

**Capital assets** means:

- (1) Tangible or intangible assets used in operations having a useful life of more than one year which are capitalized in accordance with GAAP. Capital assets include:
  - (i) Land, buildings (facilities), equipment, and intellectual property (including software) whether acquired by purchase, construction, manufacture, exchange, or through a lease accounted for as financed purchase under Government Accounting Standards Board (GASB) standards or a finance lease under Financial Accounting Standards Board (FASB) standards; and
  - (ii) Additions, improvements, modifications, replacements, rearrangements, reinstallations, renovations or alterations to capital assets that materially increase their value or useful life (not ordinary repairs and maintenance).



- (2) For purpose of this part, capital assets do not include intangible right-to-use assets (per GASB) and right-to-use operating lease assets (per FASB). For example, assets capitalized that recognize a lessee's right to control the use of property and/or equipment for a period of time under a lease contract. See also § 200.465.

**Capital expenditures** means expenditures to acquire capital assets or expenditures to make additions, improvements, modifications, replacements, rearrangements, reinstallations, renovations, or alterations to capital assets that materially increase their value or useful life.

**Central service cost allocation plan** means the documentation identifying, accumulating, and allocating or developing billing rates based on the allowable costs of services provided by a State or local government or Indian tribe on a centralized basis to its departments and agencies. The costs of these services may be allocated or billed to users.

**Claim** means, depending on the context, either:

- (1) A written demand or written assertion by one of the parties to a Federal award seeking as a matter of right:
  - (i) The payment of money in a sum certain;
  - (ii) The adjustment or interpretation of the terms and conditions of the Federal award; or
  - (iii) Other relief arising under or relating to a Federal award.
- (2) A request for payment that is not in dispute when submitted.

**Class of Federal awards** means a group of Federal awards either awarded under a specific program or group of programs or to a specific type of non-Federal entity or group of non-Federal entities to which specific provisions or exceptions may apply.

**Closeout** means the process by which the Federal awarding agency or pass-through entity determines that all applicable administrative actions and all required work of the Federal award have been completed and takes actions as described in § 200.344.

**Cluster of programs** means a grouping of closely related programs that share common compliance requirements. The types of clusters of programs are research and development (R&D), student financial aid (SFA), and other clusters. "Other clusters" are as defined by OMB in the compliance supplement or as designated by a State for Federal awards the State provides to its subrecipients that meet the definition of a cluster of programs. When designating an "other cluster," a State must identify the Federal awards included in the cluster and advise the subrecipients of compliance requirements applicable to the cluster, consistent with § 200.332(a). A cluster of programs must be considered as one program for determining major programs, as described in § 200.518, and, with the exception of R&D as described in § 200.501(c), whether a program-specific audit may be elected.

**Cognizant agency for audit** means the Federal agency designated to carry out the responsibilities described in § 200.513(a). The cognizant agency for audit is not necessarily the same as the cognizant agency for indirect costs. A list of cognizant agencies for audit can be found on the Federal Audit Clearinghouse (FAC) website.

**Cognizant agency for indirect costs** means the Federal agency responsible for reviewing, negotiating, and approving cost allocation plans or indirect cost proposals developed under this part on behalf of all Federal agencies. The cognizant agency for indirect cost is not necessarily the same as the cognizant agency for audit. For assignments of cognizant agencies see the following:

- (1) For Institutions of Higher Education (IHEs): Appendix III to this part, paragraph C.11.
- (2) For nonprofit organizations: Appendix IV to this part, paragraph C.2.a.
- (3) For State and local governments: Appendix V to this part, paragraph F.1.
- (4) For Indian tribes: Appendix VII to this part, paragraph D.1.

**Compliance supplement** means an annually updated authoritative source for auditors that serves to identify existing important compliance requirements that the Federal Government expects to be considered as part of an audit. Auditors use it to understand the Federal program's objectives, procedures, and compliance requirements, as well as audit objectives and suggested audit procedures for determining compliance with the relevant Federal program.

**Computing devices** means machines used to acquire, store, analyze, process, and publish data and other information electronically, including accessories (or "peripherals") for printing, transmitting and receiving, or storing electronic information. See also the definitions of *supplies* and *information technology systems* in this section.

**Contract** means, for the purpose of Federal financial assistance, a legal instrument by which a recipient or subrecipient purchases property or services needed to carry out the project or program under a Federal award. For additional information on subrecipient and contractor determinations, see § 200.331. See also the definition of *subaward* in this section.

**Contractor** means an entity that receives a contract as defined in this section.

**Cooperative agreement** means a legal instrument of financial assistance between a Federal awarding agency and a recipient or a pass-through entity and a subrecipient that, consistent with 31 U.S.C. 6302-6305:

- (1) Is used to enter into a relationship the principal purpose of which is to transfer anything of value to carry out a public purpose authorized by a law of the United States (see 31 U.S.C. 6101(3)); and not to acquire property or services for the Federal Government or pass-through entity's direct benefit or use;
- (2) Is distinguished from a grant in that it provides for substantial involvement of the Federal awarding agency in carrying out the activity contemplated by the Federal award.
- (3) The term does not include:
  - (i) A cooperative research and development agreement as defined in 15 U.S.C. 3710a; or
  - (ii) An agreement that provides only:
    - (A) Direct United States Government cash assistance to an individual;
    - (B) A subsidy;
    - (C) A loan;
    - (D) A loan guarantee; or
    - (E) Insurance.

**Cooperative audit resolution** means the use of audit follow-up techniques which promote prompt corrective action by improving communication, fostering collaboration, promoting trust, and developing an understanding between the Federal agency and the non-Federal entity. This approach is based upon:

- (1) A strong commitment by Federal agency and non-Federal entity leadership to program integrity;
- (2) Federal agencies strengthening partnerships and working cooperatively with non-Federal entities and their auditors; and non-Federal entities and their auditors working cooperatively with Federal agencies;
- (3) A focus on current conditions and corrective action going forward;
- (4) Federal agencies offering appropriate relief for past noncompliance when audits show prompt corrective action has occurred; and
- (5) Federal agency leadership sending a clear message that continued failure to correct conditions identified by audits which are likely to cause improper payments, fraud, waste, or abuse is unacceptable and will result in sanctions.

**Corrective action** means action taken by the auditee that:

- (1) Corrects identified deficiencies;
- (2) Produces recommended improvements; or
- (3) Demonstrates that audit findings are either invalid or do not warrant auditee action.

**Cost allocation plan** means central service cost allocation plan or public assistance cost allocation plan.

**Cost objective** means a program, function, activity, award, organizational subdivision, contract, or work unit for which cost data are desired and for which provision is made to accumulate and measure the cost of processes, products, jobs, capital projects, etc. A cost objective may be a major function of the non-Federal entity, a particular service or project, a Federal award, or an indirect

(Facilities & Administrative (F&A)) cost activity, as described in subpart E of this part. See also the definitions of *final cost objective* and *intermediate cost objective* in this section.

**Cost sharing or matching** means the portion of project costs not paid by Federal funds or contributions (unless otherwise authorized by Federal statute). See also § 200.306.

**Cross-cutting audit finding** means an audit finding where the same underlying condition or issue affects all Federal awards (including Federal awards of more than one Federal awarding agency or pass-through entity).

**Disallowed costs** means those charges to a Federal award that the Federal awarding agency or pass-through entity determines to be unallowable, in accordance with the applicable Federal statutes, regulations, or the terms and conditions of the Federal award.

**Discretionary award** means an award in which the Federal awarding agency, in keeping with specific statutory authority that enables the agency to exercise judgment ("discretion"), selects the recipient and/or the amount of Federal funding awarded through a competitive process or based on merit of proposals. A discretionary award may be selected on a non-competitive basis, as appropriate.

**Equipment** means tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost which equals or exceeds the lesser of the capitalization level established by the non-Federal entity for financial statement purposes, or \$5,000. See also the definitions of *capital assets*, *computing devices*, *general purpose equipment*, *information technology systems*, *special purpose equipment*, and *supplies* in this section.

**Expenditures** means charges made by a non-Federal entity to a project or program for which a Federal award was received.

- (1) The charges may be reported on a cash or accrual basis, as long as the methodology is disclosed and is consistently applied.
- (2) For reports prepared on a cash basis, expenditures are the sum of:
  - (i) Cash disbursements for direct charges for property and services;
  - (ii) The amount of indirect expense charged;
  - (iii) The value of third-party in-kind contributions applied; and
  - (iv) The amount of cash advance payments and payments made to subrecipients.
- (3) For reports prepared on an accrual basis, expenditures are the sum of:
  - (i) Cash disbursements for direct charges for property and services;
  - (ii) The amount of indirect expense incurred;
  - (iii) The value of third-party in-kind contributions applied; and
  - (iv) The net increase or decrease in the amounts owed by the non-Federal entity for:
    - (A) Goods and other property received;
    - (B) Services performed by employees, contractors, subrecipients, and other payees; and
    - (C) Programs for which no current services or performance are required such as annuities, insurance claims, or other benefit payments.

**Federal agency** means an "agency" as defined at 5 U.S.C. 551(1) and further clarified by 5 U.S.C. 552(f).

**Federal Audit Clearinghouse (FAC)** means the clearinghouse designated by OMB as the repository of record where non-Federal entities are required to transmit the information required by subpart F of this part.

**Federal award** has the meaning, depending on the context, in either paragraph (1) or (2) of this definition:

- (1)
  - (i) The Federal financial assistance that a recipient receives directly from a Federal awarding agency or indirectly from a pass-through entity, as described in § 200.101; or

- (ii) The cost-reimbursement contract under the Federal Acquisition Regulations that a non-Federal entity receives directly from a Federal awarding agency or indirectly from a pass-through entity, as described in § 200.101.
- (2) The instrument setting forth the terms and conditions. The instrument is the grant agreement, cooperative agreement, other agreement for assistance covered in paragraph (2) of the definition of *Federal financial assistance* in this section, or the cost-reimbursement contract awarded under the Federal Acquisition Regulations.
- (3) Federal award does not include other contracts that a Federal agency uses to buy goods or services from a contractor or a contract to operate Federal Government owned, contractor operated facilities (GOCOs).
- (4) See also definitions of Federal financial assistance, grant agreement, and cooperative agreement.

**Federal award date** means the date when the Federal award is signed by the authorized official of the Federal awarding agency.

**Federal awarding agency** means the Federal agency that provides a Federal award directly to a non-Federal entity.

**Federal financial assistance** means

- (1) Assistance that non-Federal entities receive or administer in the form of:
  - (i) Grants;
  - (ii) Cooperative agreements;
  - (iii) Non-cash contributions or donations of property (including donated surplus property);
  - (iv) Direct appropriations;
  - (v) Food commodities; and
  - (vi) Other financial assistance (except assistance listed in paragraph (2) of this definition).
- (2) For § 200.203 and subpart F of this part, *Federal financial assistance* also includes assistance that non-Federal entities receive or administer in the form of:
  - (i) Loans;
  - (ii) Loan Guarantees;
  - (iii) Interest subsidies; and
  - (iv) Insurance.
- (3) For § 200.216, Federal financial assistance includes assistance that non-Federal entities receive or administer in the form of:
  - (i) Grants;
  - (ii) Cooperative agreements;
  - (iii) Loans; and
  - (iv) Loan Guarantees.
- (4) Federal financial assistance does not include amounts received as reimbursement for services rendered to individuals as described in § 200.502(h) and (i).

**Federal interest** means, for purposes of § 200.330 or when used in connection with the acquisition or improvement of real property, equipment, or supplies under a Federal award, the dollar amount that is the product of the:

- (1) The percentage of Federal participation in the total cost of the real property, equipment, or supplies; and
- (2) Current fair market value of the property, improvements, or both, to the extent the costs of acquiring or improving the property were included as project costs.

**Federal program** means:

- (1) All Federal awards which are assigned a single Assistance Listings Number.

- (2) When no Assistance Listings Number is assigned, all Federal awards from the same agency made for the same purpose must be combined and considered one program.
- (3) Notwithstanding paragraphs (1) and (2) of this definition, a cluster of programs. The types of clusters of programs are:
  - (i) Research and development (R&D);
  - (ii) Student financial aid (SFA); and
  - (iii) "Other clusters," as described in the definition of *cluster of programs* in this section.

**Federal share** means the portion of the Federal award costs that are paid using Federal funds.

**Final cost objective** means a cost objective which has allocated to it both direct and indirect costs and, in the non-Federal entity's accumulation system, is one of the final accumulation points, such as a particular award, internal project, or other direct activity of a non-Federal entity. See also the definitions of *cost objective* and *intermediate cost objective* in this section.

**Financial obligations**, when referencing a recipient's or subrecipient's use of funds under a Federal award, means orders placed for property and services, contracts and subawards made, and similar transactions that require payment.

**Fixed amount awards** means a type of grant or cooperative agreement under which the Federal awarding agency or pass-through entity provides a specific level of support without regard to actual costs incurred under the Federal award. This type of Federal award reduces some of the administrative burden and record-keeping requirements for both the non-Federal entity and Federal awarding agency or pass-through entity. Accountability is based primarily on performance and results. See §§ 200.102(c), 200.201(b), and 200.333.

**Foreign organization** means an entity that is:

- (1) A public or private organization located in a country other than the United States and its territories that is subject to the laws of the country in which it is located, irrespective of the citizenship of project staff or place of performance;
- (2) A private nongovernmental organization located in a country other than the United States that solicits and receives cash contributions from the general public;
- (3) A charitable organization located in a country other than the United States that is nonprofit and tax exempt under the laws of its country of domicile and operation, and is not a university, college, accredited degree-granting institution of education, private foundation, hospital, organization engaged exclusively in research or scientific activities, church, synagogue, mosque or other similar entities organized primarily for religious purposes; or
- (4) An organization located in a country other than the United States not recognized as a foreign public entity.

**Foreign public entity** means:

- (1) A foreign government or foreign governmental entity;
- (2) A public international organization, which is an organization entitled to enjoy privileges, exemptions, and immunities as an international organization under the International Organizations Immunities Act (22 U.S.C. 288-288f);
- (3) An entity owned (in whole or in part) or controlled by a foreign government; or
- (4) Any other entity consisting wholly or partially of one or more foreign governments or foreign governmental entities.

**General purpose equipment** means equipment which is not limited to research, medical, scientific or other technical activities. Examples include office equipment and furnishings, modular offices, telephone networks, information technology equipment and systems, air conditioning equipment, reproduction and printing equipment, and motor vehicles. See also the definitions of *equipment* and *special purpose equipment* in this section.

**Generally accepted accounting principles (GAAP)** has the meaning specified in accounting standards issued by the GASB and the FASB.

**Generally accepted government auditing standards (GAGAS)**, also known as the Yellow Book, means generally accepted government auditing standards issued by the Comptroller General of the United States, which are applicable to financial audits.

**Grant agreement** means a legal instrument of financial assistance between a Federal awarding agency or pass-through entity and a non-Federal entity that, consistent with 31 U.S.C. 6302, 6304:

- (1) Is used to enter into a relationship the principal purpose of which is to transfer anything of value to carry out a public purpose authorized by a law of the United States (see 31 U.S.C. 6101(3)); and not to acquire property or services for the Federal awarding agency or pass-through entity's direct benefit or use;
- (2) Is distinguished from a cooperative agreement in that it does not provide for substantial involvement of the Federal awarding agency in carrying out the activity contemplated by the Federal award.
- (3) Does not include an agreement that provides only:
  - (i) Direct United States Government cash assistance to an individual;
  - (ii) A subsidy;
  - (iii) A loan;

(vi) A loan guarantee; or

- (v) Insurance.

**Highest level owner** means the entity that owns or controls an immediate owner of the offeror, or that owns or controls one or more entities that control an immediate owner of the offeror. No entity owns or exercises control of the highest-level owner as defined in the Federal Acquisition Regulations (FAR) (48 CFR 52.204-17).

**Hospital** means a facility licensed as a hospital under the law of any state or a facility operated as a hospital by the United States, a state, or a subdivision of a state.

**Improper payment** means:

- (1) Any payment that should not have been made or that was made in an incorrect amount under statutory, contractual, administrative, or other *legally applicable* requirements.
  - (i) Incorrect amounts are overpayments or underpayments that are made to eligible recipients (including inappropriate denials of payment or service, any payment that does not account for credit for applicable discounts, payments that are for an incorrect amount, and duplicate payments). An improper payment also includes any payment that was made to an ineligible recipient or for an ineligible good or service, or payments for goods or services not received (except for such payments authorized by law).

**Note 1 to paragraph (1)(i) of this definition.** Applicable discounts are only those discounts where it is both advantageous and within the agency's control to claim them.

- (ii) When an agency's review is unable to discern whether a payment was proper as a result of insufficient or lack of documentation, this payment should also be considered an improper payment. When establishing documentation requirements for payments, agencies should ensure that all documentation requirements are necessary and should refrain from imposing additional burdensome documentation requirements.
- (iii) Interest or other fees that may result from an underpayment by an agency are not considered an improper payment if the interest was paid correctly. These payments are generally separate transactions and may be necessary under certain statutory, contractual, administrative, or other legally applicable requirements.
- (iv) A "questioned cost" (as defined in this section) should not be considered an improper payment until the transaction has been completely reviewed and is confirmed to be improper.
- (v) The term "payment" in this definition means any disbursement or transfer of Federal funds (including a commitment for future payment, such as cash, securities, loans, loan guarantees, and insurance subsidies) to any non-Federal person, non-Federal entity, or Federal employee, that is made by a Federal agency, a Federal contractor, a Federal grantee, or a governmental or other organization administering a Federal program or activity.
- (vi) The term "payment" includes disbursements made pursuant to prime contracts awarded under the Federal Acquisition Regulation and Federal awards subject to this part that are expended by recipients.

- (2) See definition of improper payment in OMB Circular A-123 appendix C, part I A (1) "What is an improper payment?" Questioned costs, including those identified in audits, are not an improper payment until reviewed and confirmed to be improper as defined in OMB Circular A-123 appendix C.

**Indian tribe** means any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. Chapter 33), which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians (25 U.S.C. 450b(e)). See annually published Bureau of Indian Affairs list of Indian Entities Recognized and Eligible to Receive Services.

**Institutions of Higher Education (IHEs)** is defined at 20 U.S.C. 1001.

**Indirect (facilities & administrative (F&A)) costs** means those costs incurred for a common or joint purpose benefitting more than one cost objective, and not readily assignable to the cost objectives specifically benefitted, without effort disproportionate to the results achieved. To facilitate equitable distribution of indirect expenses to the cost objectives served, it may be necessary to establish a number of pools of indirect (F&A) costs. Indirect (F&A) cost pools must be distributed to benefitted cost objectives on bases that will produce an equitable result in consideration of relative benefits derived.

**Indirect cost rate proposal** means the documentation prepared by a non-Federal entity to substantiate its request for the establishment of an indirect cost rate as described in appendices III through VII and appendix IX to this part.

**Information technology systems** means computing devices, ancillary equipment, software, firmware, and similar procedures, services (including support services), and related resources. See also the definitions of *computing devices* and *equipment* in this section.

**Intangible property** means property having no physical existence, such as trademarks, copyrights, patents and patent applications and property, such as loans, notes and other debt instruments, lease agreements, stock and other instruments of property ownership (whether the property is tangible or intangible).

**Intermediate cost objective** means a cost objective that is used to accumulate indirect costs or service center costs that are subsequently allocated to one or more indirect cost pools or final cost objectives. See also the definitions of *cost objective* and *final cost objective* in this section.

**Internal controls** for non-Federal entities means:

- (1) Processes designed and implemented by non-Federal entities to provide reasonable assurance regarding the achievement of objectives in the following categories:
  - (i) Effectiveness and efficiency of operations;
  - (ii) Reliability of reporting for internal and external use; and
  - (iii) Compliance with applicable laws and regulations.
- (2) Federal awarding agencies are required to follow internal control compliance requirements in OMB Circular No. A-123, Management's Responsibility for Enterprise Risk Management and Internal Control.

**Loan** means a Federal loan or loan guarantee received or administered by a non-Federal entity, except as used in the definition of *program income* in this section.

- (1) The term "direct loan" means a disbursement of funds by the Federal Government to a non-Federal borrower under a contract that requires the repayment of such funds with or without interest. The term includes the purchase of, or participation in, a loan made by another lender and financing arrangements that defer payment for more than 90 days, including the sale of a Federal Government asset on credit terms. The term does not include the acquisition of a federally guaranteed loan in satisfaction of default claims or the price support loans of the Commodity Credit Corporation.
- (2) The term "direct loan obligation" means a binding agreement by a Federal awarding agency to make a direct loan when specified conditions are fulfilled by the borrower.
- (3) The term "loan guarantee" means any Federal Government guarantee, insurance, or other pledge with respect to the payment of all or a part of the principal or interest on any debt obligation of a non-Federal borrower to a non-Federal lender, but does not include the insurance of deposits, shares, or other withdrawable accounts in financial institutions.

- (4) The term "loan guarantee commitment" means a binding agreement by a Federal awarding agency to make a loan guarantee when specified conditions are fulfilled by the borrower, the lender, or any other party to the guarantee agreement.

**Local government** means any unit of government within a state, including a:

- (1) County;
- (2) Borough;
- (3) Municipality;
- (4) City;
- (5) Town;
- (6) Township;
- (7) Parish;
- (8) Local public authority, including any public housing agency under the United States Housing Act of 1937;
- (9) Special district;
- (10) School district;
- (11) Intrastate district;
- (12) Council of governments, whether or not incorporated as a nonprofit corporation under State law; and
- (13) Any other agency or instrumentality of a multi-, regional, or intra-State or local government.

**Major program** means a Federal program determined by the auditor to be a major program in accordance with § 200.518 or a program identified as a major program by a Federal awarding agency or pass-through entity in accordance with § 200.503(e).

**Management decision** means the Federal awarding agency's or pass-through entity's written determination, provided to the auditee, of the adequacy of the auditee's proposed corrective actions to address the findings, based on its evaluation of the audit findings and proposed corrective actions.

**Micro-purchase** means a purchase of supplies or services, the aggregate amount of which does not exceed the micro-purchase threshold. Micro-purchases comprise a subset of a non-Federal entity's small purchases as defined in § 200.320.

**Micro-purchase threshold** means the dollar amount at or below which a non-Federal entity may purchase property or services using micro-purchase procedures (see § 200.320). Generally, the micro-purchase threshold for procurement activities administered under Federal awards is not to exceed the amount set by the FAR at 48 CFR part 2, subpart 2.1, unless a higher threshold is requested by the non-Federal entity and approved by the cognizant agency for indirect costs.

**Modified Total Direct Cost (MTDC)** means all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and up to the first \$25,000 of each subaward (regardless of the period of performance of the subawards under the award). MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward in excess of \$25,000. Other items may only be excluded when necessary to avoid a serious inequity in the distribution of indirect costs, and with the approval of the cognizant agency for indirect costs.

**Non-discretionary award** means an award made by the Federal awarding agency to specific recipients in accordance with statutory, eligibility and compliance requirements, such that in keeping with specific statutory authority the agency has no ability to exercise judgement ("discretion"). A non-discretionary award amount could be determined specifically or by formula.

**Non-Federal entity (NFE)** means a State, local government, Indian tribe, Institution of Higher Education (IHE), or nonprofit organization that carries out a Federal award as a recipient or subrecipient.

**Nonprofit organization** means any corporation, trust, association, cooperative, or other organization, not including IHEs, that:

- (1) Is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest;



- (2) Is not organized primarily for profit; and
- (3) Uses net proceeds to maintain, improve, or expand the operations of the organization.

**Notice of funding opportunity** means a formal announcement of the availability of Federal funding through a financial assistance program from a Federal awarding agency. The notice of funding opportunity provides information on the award, who is eligible to apply, the evaluation criteria for selection of an awardee, required components of an application, and how to submit the application. The notice of funding opportunity is any paper or electronic issuance that an agency uses to announce a funding opportunity, whether it is called a "program announcement," "notice of funding availability," "broad agency announcement," "research announcement," "solicitation," or some other term.

**Office of Management and Budget (OMB)** means the Executive Office of the President, Office of Management and Budget.

**Oversight agency for audit** means the Federal awarding agency that provides the predominant amount of funding directly (direct funding) (as listed on the schedule of expenditures of Federal awards, see § 200.510(b)) to a non-Federal entity unless OMB designates a specific cognizant agency for audit. When the direct funding represents less than 25 percent of the total Federal expenditures (as direct and sub-awards) by the non-Federal entity, then the Federal agency with the predominant amount of total funding is the designated oversight agency for audit. When there is no direct funding, the Federal awarding agency which is the predominant source of pass-through funding must assume the oversight responsibilities. The duties of the oversight agency for audit and the process for any reassignments are described in § 200.513(b).

**Participant support costs** means direct costs for items such as stipends or subsistence allowances, travel allowances, and registration fees paid to or on behalf of participants or trainees (but not employees) in connection with conferences, or training projects.

**Pass-through entity (PTE)** means a non-Federal entity that provides a subaward to a subrecipient to carry out part of a Federal program.

**Performance goal** means a target level of performance expressed as a tangible, measurable objective, against which actual achievement can be compared, including a goal expressed as a quantitative standard, value, or rate. In some instances (e.g., discretionary research awards), this may be limited to the requirement to submit technical performance reports (to be evaluated in accordance with agency policy).

**Period of performance** means the total estimated time interval between the start of an initial Federal award and the planned end date, which may include one or more funded portions, or budget periods. Identification of the period of performance in the Federal award per § 200.211(b)(5) does not commit the awarding agency to fund the award beyond the currently approved budget period.

**Personal property** means property other than real property. It may be tangible, having physical existence, or intangible.

**Personally Identifiable Information (PII)** means information that can be used to distinguish or trace an individual's identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual. Some information that is considered to be PII is available in public sources such as telephone books, public websites, and university listings. This type of information is considered to be Public PII and includes, for example, first and last name, address, work telephone number, email address, home telephone number, and general educational credentials. The definition of PII is not anchored to any single category of information or technology. Rather, it requires a case-by-case assessment of the specific risk that an individual can be identified. Non-PII can become PII whenever additional information is made publicly available, in any medium and from any source, that, when combined with other available information, could be used to identify an individual.

**Program income** means gross income earned by the non-Federal entity that is directly generated by a supported activity or earned as a result of the Federal award during the period of performance except as provided in § 200.307(f). (See the definition of *period of performance* in this section.) Program income includes but is not limited to income from fees for services performed, the use or rental of real or personal property acquired under Federal awards, the sale of commodities or items fabricated under a Federal award, license fees and royalties on patents and copyrights, and principal and interest on loans made with Federal award funds. Interest earned on advances of Federal funds is not program income. Except as otherwise provided in Federal statutes, regulations, or the terms and conditions of the Federal award, program income does not include rebates, credits, discounts, and interest earned on any of them. See also § 200.407. See also 35 U.S.C. 200-212 "Disposition of Rights in Educational Awards" applies to inventions made under Federal awards.

**Project cost** means total allowable costs incurred under a Federal award and all required cost sharing and voluntary committed cost sharing, including third-party contributions.

**Property** means real property or personal property. See also the definitions of *real property* and *personal property* in this section.

**Protected Personally Identifiable Information (Protected PII)** means an individual's first name or first initial and last name in combination with any one or more of types of information, including, but not limited to, social security number, passport number, credit card numbers, clearances, bank numbers, biometrics, date and place of birth, mother's maiden name, criminal, medical and financial records, educational transcripts. This does not include PII that is required by law to be disclosed. See also the definition of *Personally Identifiable Information (PII)* in this section.

**Questioned cost** means a cost that is questioned by the auditor because of an audit finding:

- (1) Which resulted from a violation or possible violation of a statute, regulation, or the terms and conditions of a Federal award, including for funds used to match Federal funds;
- (2) Where the costs, at the time of the audit, are not supported by adequate documentation; or
- (3) Where the costs incurred appear unreasonable and do not reflect the actions a prudent person would take in the circumstances.
- (4) Questioned costs are not an improper payment until reviewed and confirmed to be improper as defined in OMB Circular A-123 appendix C. (See also the definition of *Improper payment* in this section).

**Real property** means land, including land improvements, structures and appurtenances thereto, but excludes moveable machinery and equipment.

**Recipient** means an entity, usually but not limited to non-Federal entities that receives a Federal award directly from a Federal awarding agency. The term recipient does not include subrecipients or individuals that are beneficiaries of the award.

**Renewal award** means an award made subsequent to an expiring Federal award for which the start date is contiguous with, or closely follows, the end of the expiring Federal award. A renewal award's start date will begin a distinct period of performance.

**Research and Development (R&D)** means all research activities, both basic and applied, and all development activities that are performed by non-Federal entities. The term research also includes activities involving the training of individuals in research techniques where such activities utilize the same facilities as other research and development activities and where such activities are not included in the instruction function. "Research" is defined as a systematic study directed toward fuller scientific knowledge or understanding of the subject studied. "Development" is the systematic use of knowledge and understanding gained from research directed toward the production of useful materials, devices, systems, or methods, including design and development of prototypes and processes.

**Simplified acquisition threshold** means the dollar amount below which a non-Federal entity may purchase property or services using small purchase methods (see § 200.320). Non-Federal entities adopt small purchase procedures in order to expedite the purchase of items at or below the simplified acquisition threshold. The simplified acquisition threshold for procurement activities administered under Federal awards is set by the FAR at 48 CFR part 2, subpart 2.1. The non-Federal entity is responsible for determining an appropriate simplified acquisition threshold based on internal controls, an evaluation of risk, and its documented procurement procedures. However, in no circumstances can this threshold exceed the dollar value established in the FAR (48 CFR part 2, subpart 2.1) for the simplified acquisition threshold. Recipients should determine if local government laws on purchasing apply.

**Special purpose equipment** means equipment which is used only for research, medical, scientific, or other technical activities. Examples of special purpose equipment include microscopes, x-ray machines, surgical instruments, and spectrometers. See also the definitions of *equipment* and *general purpose equipment* in this section.

**State** means any state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and any agency or instrumentality thereof exclusive of local governments.

**Student Financial Aid (SFA)** means Federal awards under those programs of general student assistance, such as those authorized by Title IV of the Higher Education Act of 1965, as amended, (20 U.S.C. 1070-1099d), which are administered by the U.S. Department of Education, and similar programs provided by other Federal agencies. It does not include Federal awards under programs that provide fellowships or similar Federal awards to students on a competitive basis, or for specified studies or research.

**Subaward** means an award provided by a pass-through entity to a subrecipient for the subrecipient to carry out part of a Federal award received by the pass-through entity. It does not include payments to a contractor or payments to an individual that is a beneficiary of a Federal program. A subaward may be provided through any form of legal agreement, including an agreement that the pass-through entity considers a contract.

**Subrecipient** means an entity, usually but not limited to non-Federal entities, that receives a subaward from a pass-through entity to carry out part of a Federal award; but does not include an individual that is a beneficiary of such award. A subrecipient may also be a recipient of other Federal awards directly from a Federal awarding agency.

**Subsidiary** means an entity in which more than 50 percent of the entity is owned or controlled directly by a parent corporation or through another subsidiary of a parent corporation.

**Supplies** means all tangible personal property other than those described in the definition of *equipment* in this section. A computing device is a supply if the acquisition cost is less than the lesser of the capitalization level established by the non-Federal entity for financial statement purposes or \$5,000, regardless of the length of its useful life. See also the definitions of *computing devices* and *equipment* in this section.

**Telecommunications cost** means the cost of using communication and telephony technologies such as mobile phones, land lines, and internet.

**Termination** means the ending of a Federal award, in whole or in part at any time prior to the planned end of period of performance. A lack of available funds is not a termination.

**Third-party in-kind contributions** means the value of non-cash contributions (*i.e.*, property or services) that -

- (1) Benefit a federally-assisted project or program; and
- (2) Are contributed by non-Federal third parties, without charge, to a non-Federal entity under a Federal award.

**Unliquidated financial obligations** means, for financial reports prepared on a cash basis, financial obligations incurred by the non-Federal entity that have not been paid (liquidated). For reports prepared on an accrual expenditure basis, these are financial obligations incurred by the non-Federal entity for which an expenditure has not been recorded.

**Unobligated balance** means the amount of funds under a Federal award that the non-Federal entity has not obligated. The amount is computed by subtracting the cumulative amount of the non-Federal entity's unliquidated financial obligations and expenditures of funds under the Federal award from the cumulative amount of the funds that the Federal awarding agency or pass-through entity authorized the non-Federal entity to obligate.

**Voluntary committed cost sharing** means cost sharing specifically pledged on a voluntary basis in the proposal's budget on the part of the non-Federal entity and that becomes a binding requirement of Federal award. See also § 200.306.

[85 FR 49529, Aug. 13, 2020, as amended at 86 FR 10439, Feb. 22, 2021]

## Subpart B - General Provisions

### § 200.100 Purpose.

- (a) **Purpose.**
  - (1) This part establishes uniform administrative requirements, cost principles, and audit requirements for Federal awards to non-Federal entities, as described in § 200.101. Federal awarding agencies must not impose additional or inconsistent requirements, except as provided in §§ 200.102 and 200.211, or unless specifically required by Federal statute, regulation, or Executive order.
  - (2) This part provides the basis for a systematic and periodic collection and uniform submission by Federal agencies of information on all Federal financial assistance programs to the Office of Management and Budget (OMB). It also establishes Federal policies related to the delivery of this information to the public, including through the use of electronic media. It prescribes the manner in which General Services Administration (GSA), OMB, and Federal agencies that administer Federal financial assistance programs are to carry out their statutory responsibilities under the Federal Program Information Act (31 U.S.C. 6101-6106).

- (b) **Administrative requirements.** Subparts B through D of this part set forth the uniform administrative requirements for grant and cooperative agreements, including the requirements for Federal awarding agency management of Federal grant programs before the Federal award has been made, and the requirements Federal awarding agencies may impose on non-Federal entities in the Federal award.
- (c) **Cost principles.** Subpart E of this part establishes principles for determining the allowable costs incurred by non-Federal entities under Federal awards. The principles are for the purpose of cost determination and are not intended to identify the circumstances or dictate the extent of Federal Government participation in the financing of a particular program or project. The principles are designed to provide that Federal awards bear their fair share of cost recognized under these principles except where restricted or prohibited by statute.
- (d) **Single Audit Requirements and Audit Follow-up.** Subpart F of this part is issued pursuant to the Single Audit Act Amendments of 1996, (31 U.S.C. 7501-7507). It sets forth standards for obtaining consistency and uniformity among Federal agencies for the audit of non-Federal entities expending Federal awards. These provisions also provide the policies and procedures for Federal awarding agencies and pass-through entities when using the results of these audits.
- (e) **Guidance on challenges and prizes.** For OMB guidance to Federal awarding agencies on challenges and prizes, please see memo M-10-11 Guidance on the Use of Challenges and Prizes to Promote Open Government, issued March 8, 2010, or its successor.

[78 FR 78608, Dec. 26, 2013, as amended at 85 FR 49536, Aug. 13, 2020]

## § 200.101 Applicability.

- (a) **General applicability to Federal agencies.**
- (1) The requirements established in this part apply to Federal agencies that make Federal awards to non-Federal entities. These requirements are applicable to all costs related to Federal awards.
  - (2) Federal awarding agencies may apply subparts A through E of this part to Federal agencies, for-profit entities, foreign public entities, or foreign organizations, except where the Federal awarding agency determines that the application of these subparts would be inconsistent with the international responsibilities of the United States or the statutes or regulations of a foreign government.
- (b) **Applicability to different types of Federal awards.**
- (1) Throughout this part when the word “must” is used it indicates a requirement. Whereas, use of the word “should” or “may” indicates a best practice or recommended approach rather than a requirement and permits discretion.
  - (2) The following table describes what portions of this part apply to which types of Federal awards. The terms and conditions of Federal awards (including this part) flow down to subawards to subrecipients unless a particular section of this part or the terms and conditions of the Federal award specifically indicate otherwise. This means that non-Federal entities must comply with requirements in this part regardless of whether the non-Federal entity is a recipient or subrecipient of a Federal award. Pass-through entities must comply with the requirements described in subpart D of this part, §§ 200.331 through 200.333, but not any requirements in this part directed towards Federal awarding agencies unless the requirements of this part or the terms and conditions of the Federal award indicate otherwise.

Table 1 to Paragraph (b)

The following portions of this Part	Are applicable to the following types of Federal Awards and Fixed-Price Contracts and Subcontracts (except as noted in paragraphs (d) and (e) of this section):	Are NOT applicable to the following types of Federal Awards and Fixed-Price Contracts and Subcontracts:
Subpart A - Acronyms and Definitions	- All	

The following portions of this Part	Are applicable to the following types of Federal Awards and Fixed-Price Contracts and Subcontracts (except as noted in paragraphs (d) and (e) of this section):	Are NOT applicable to the following types of Federal Awards and Fixed-Price Contracts and Subcontracts:
Subpart B - General Provisions, except for §§ 200.111 English Language, 200.112 Conflict of Interest, 200.113 Mandatory Disclosures	- All	
§§ 200.111 English Language, 200.112 Conflict of Interest, 200.113 Mandatory Disclosures	- Grant Agreements and cooperative agreements	- Agreements for loans, loan guarantees, interest subsidies and insurance. - Procurement contracts awarded by Federal Agencies under the Federal Acquisition Regulation and subcontracts under those contracts.
Subparts C-D, except for §§ 200.203 Requirement to provide public notice of Federal financial assistance programs, 200.303 Internal controls, 200.331-333 Subrecipient Monitoring and Management	- Grant Agreements and cooperative agreements	- Agreements for loans, loan guarantees, interest subsidies and insurance. - Procurement contracts awarded by Federal Agencies under the Federal Acquisition Regulation and subcontracts under those contracts.
§ 200.203 Requirement to provide public notice of Federal financial assistance programs	- Grant Agreements and cooperative agreements - Agreements for loans, loan guarantees, interest subsidies and insurance	- Procurement contracts awarded by Federal Agencies under the Federal Acquisition Regulation and subcontracts under those contracts.
§§ 200.303 Internal controls, 200.331-333 Subrecipient Monitoring and Management	- All	

The following portions of this Part	Are applicable to the following types of Federal Awards and Fixed-Price Contracts and Subcontracts (except as noted in paragraphs (d) and (e) of this section):	Are NOT applicable to the following types of Federal Awards and Fixed-Price Contracts and Subcontracts:
Subpart E - Cost Principles	<ul style="list-style-type: none"> <li>- Grant Agreements and cooperative agreements, except those providing food commodities</li> <li>- All procurement contracts under the Federal Acquisition Regulations except those that are not negotiated</li> </ul>	<ul style="list-style-type: none"> <li>- Grant agreements and cooperative agreements providing foods commodities.</li> <li>- Fixed amount awards.</li> <li>- Agreements for loans, loans guarantees, interest subsidies and insurance.</li> <li>- Federal awards to hospitals (see Appendix IX Hospital Cost Principles).</li> </ul>
Subpart F - Audit Requirements	<ul style="list-style-type: none"> <li>- Grant Agreements and cooperative agreements</li> <li>- Contracts and subcontracts, except for fixed price contracts and subcontracts, awarded under the Federal Acquisition Regulation</li> <li>- Agreements for loans, loans guarantees, interest subsidies and insurance and other forms of Federal Financial Assistance as defined by the Single Audit Act Amendment of 1996</li> </ul>	<ul style="list-style-type: none"> <li>- Fixed-price contracts and subcontracts awarded under the Federal Acquisition Regulation.</li> </ul>

- (c) **Federal award of cost-reimbursement contract under the FAR to a non-Federal entity.** When a non-Federal entity is awarded a cost-reimbursement contract, only subpart D, §§ 200.331 through 200.333, and subparts E and F of this part are incorporated by reference into the contract, but the requirements of subparts D, E, and F are supplementary to the FAR and the contract. When the Cost Accounting Standards (CAS) are applicable to the contract, they take precedence over the requirements of this part, including subpart F of this part, which are supplementary to the CAS requirements. In addition, costs that are made unallowable under 10 U.S.C. 2324(e) and 41 U.S.C. 4304(a) as described in the FAR 48 CFR part 31, subpart 31.2, and 48 CFR 31.603 are always unallowable. For requirements other than those covered in subpart D, §§ 200.331 through 200.333, and subparts E and F of this part, the terms of the contract and the FAR apply. Note that when a non-Federal entity is awarded a FAR contract, the FAR applies, and the terms and conditions of the contract shall prevail over the requirements of this part.
- (d) **Governing provisions.** With the exception of subpart F of this part, which is required by the Single Audit Act, in any circumstances where the provisions of Federal statutes or regulations differ from the provisions of this part, the provision of the Federal statutes or regulations govern. This includes, for agreements with Indian tribes, the provisions of the Indian Self-Determination and Education and Assistance Act (ISDEAA), as amended, 25 U.S.C 450-458ddd-2.
- (e) **Program applicability.** Except for §§ 200.203, 200.216, and 200.331 through 200.333, the requirements in subparts C, D, and E of this part do not apply to the following programs:

- (1) The block grant awards authorized by the Omnibus Budget Reconciliation Act of 1981 (including Community Services), except to the extent that subpart E of this part apply to subrecipients of Community Services Block Grant funds pursuant to 42 U.S.C. 9916(a)(1)(B);
  - (2) Federal awards to local education agencies under 20 U.S.C. 7702-7703b, (portions of the Impact Aid program);
  - (3) Payments under the Department of Veterans Affairs' State Home Per Diem Program (38 U.S.C. 1741); and
  - (4) Federal awards authorized under the Child Care and Development Block Grant Act of 1990, as amended:
    - (i) Child Care and Development Block Grant (42 U.S.C. 9858).
    - (ii) Child Care Mandatory and Matching Funds of the Child Care and Development Fund (42 U.S.C. 9858).
- (f) **Additional program applicability.** Except for §§ 200.203 and 200.216, the guidance in subpart C of this part does not apply to the following programs:
- (1) Entitlement Federal awards to carry out the following programs of the Social Security Act:
    - (i) Temporary Assistance for Needy Families (title IV-A of the Social Security Act, 42 U.S.C. 601-619);
    - (ii) Child Support Enforcement and Establishment of Paternity (title IV-D of the Social Security Act, 42 U.S.C. 651-669b);
    - (iii) Foster Care and Adoption Assistance (title IV-E of the Act, 42 U.S.C. 670-679c);
    - (iv) Aid to the Aged, Blind, and Disabled (titles I, X, XIV, and XVI-AABD of the Act, as amended);
    - (v) Medical Assistance (Medicaid) (title XIX of the Act, 42 U.S.C. 1396-1396w-5) not including the State Medicaid Fraud Control program authorized by section 1903(a)(6)(B) of the Social Security Act (42 U.S.C. 1396b(a)(6)(B)); and
    - (vi) Children's Health Insurance Program (title XXI of the Act, 42 U.S.C. 1397aa-1397mm).
  - (2) A Federal award for an experimental, pilot, or demonstration project that is also supported by a Federal award listed in paragraph (f)(1) of this section.
  - (3) Federal awards under subsection 412(e) of the Immigration and Nationality Act and subsection 501(a) of the Refugee Education Assistance Act of 1980 (Pub. L. 96-422, 94 Stat. 1809), for cash assistance, medical assistance, and supplemental security income benefits to refugees and entrants and the administrative costs of providing the assistance and benefits (8 U.S.C. 1522(e)).
  - (4) Entitlement awards under the following programs of The National School Lunch Act:
    - (i) National School Lunch Program (section 4 of the Act, 42 U.S.C. 1753);
    - (ii) Commodity Assistance (section 6 of the Act, 42 U.S.C. 1755);
    - (iii) Special Meal Assistance (section 11 of the Act, 42 U.S.C. 1759a);
    - (iv) Summer Food Service Program for Children (section 13 of the Act, 42 U.S.C. 1761); and
    - (v) Child and Adult Care Food Program (section 17 of the Act, 42 U.S.C. 1766).
  - (5) Entitlement awards under the following programs of The Child Nutrition Act of 1966:
    - (i) Special Milk Program (section 3 of the Act, 42 U.S.C. 1772);
    - (ii) School Breakfast Program (section 4 of the Act, 42 U.S.C. 1773); and
    - (iii) State Administrative Expenses (section 7 of the Act, 42 U.S.C. 1776).
  - (6) Entitlement awards for State Administrative Expenses under The Food and Nutrition Act of 2008 (section 16 of the Act, 7 U.S.C. 2025).
  - (7) Non-discretionary Federal awards under the following non-entitlement programs:
    - (i) Special Supplemental Nutrition Program for Women, Infants and Children (section 17 of the Child Nutrition Act of 1966) 42 U.S.C. 1786;
    - (ii) The Emergency Food Assistance Programs (Emergency Food Assistance Act of 1983) 7 U.S.C. 7501 note; and

- (iii) Commodity Supplemental Food Program (section 5 of the Agriculture and Consumer Protection Act of 1973) 7 U.S.C. 612c note.

[85 FR 49536, Aug. 13, 2020, as amended at 86 FR 10439, Feb. 22, 2021]

### § 200.102 Exceptions.

- (a) With the exception of subpart F of this part, OMB may allow exceptions for classes of Federal awards or non-Federal entities subject to the requirements of this part when exceptions are not prohibited by statute. In the interest of maximum uniformity, exceptions from the requirements of this part will be permitted as described in this section.
- (b) Exceptions on a case-by-case basis for individual non-Federal entities may be authorized by the Federal awarding agency or cognizant agency for indirect costs, except where otherwise required by law or where OMB or other approval is expressly required by this part.
- (c) The Federal awarding agency may adjust requirements to a class of Federal awards or non-Federal entities when approved by OMB, or when required by Federal statutes or regulations, except for the requirements in subpart F of this part. A Federal awarding agency may apply less restrictive requirements when making fixed amount awards as defined in subpart A of this part, except for those requirements imposed by statute or in subpart F of this part.
- (d) Federal awarding agencies may request exceptions in support of innovative program designs that apply a risk-based, data-driven framework to alleviate select compliance requirements and hold recipients accountable for good performance. See also § 200.206.

[85 FR 49538, Aug. 13, 2020, as amended at 86 FR 10439, Feb. 22, 2021]

### § 200.103 Authorities.

This part is issued under the following authorities.

- (a) Subparts B through D of this part are authorized under 31 U.S.C. 503 (the Chief Financial Officers Act, Functions of the Deputy Director for Management), 41 U.S.C. 1101-1131 (the Office of Federal Procurement Policy Act), Reorganization Plan No. 2 of 1970, and Executive Order 11541 ("Prescribing the Duties of the Office of Management and Budget and the Domestic Policy Council in the Executive Office of the President"), the Single Audit Act Amendments of 1996, (31 U.S.C. 7501-7507), as well as The Federal Program Information Act (Pub. L. 95-220 and Pub. L. 98-169, as amended, codified at 31 U.S.C. 6101-6106).
- (b) Subpart E of this part is authorized under the Budget and Accounting Act of 1921, as amended; the Budget and Accounting Procedures Act of 1950, as amended (31 U.S.C. 1101-1125); the Chief Financial Officers Act of 1990 (31 U.S.C. 503-504); Reorganization Plan No. 2 of 1970; and Executive Order 11541, "Prescribing the Duties of the Office of Management and Budget and the Domestic Policy Council in the Executive Office of the President."
- (c) Subpart F of this part is authorized under the Single Audit Act Amendments of 1996, (31 U.S.C. 7501-7507).

[85 FR 49538, Aug. 13, 2020]

### § 200.104 Supersession.

As described in § 200.110, this part supersedes the following OMB guidance documents and regulations under title 2 of the Code of Federal Regulations:

- (a) A-21, "Cost Principles for Educational Institutions" (2 CFR part 220);
- (b) A-87, "Cost Principles for State, Local and Indian Tribal Governments" (2 CFR part 225) and also FEDERAL REGISTER notice 51 FR 552 (January 6, 1986);
- (c) A-89, "Federal Domestic Assistance Program Information";
- (d) A-102, "Grant Awards and Cooperative Agreements with State and Local Governments";
- (e) A-110, "Uniform Administrative Requirements for Awards and Other Agreements with Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations" (codified at 2 CFR 215);



- (f) A-122, "Cost Principles for Non-Profit Organizations" (2 CFR part 230);
- (g) A-133, "Audits of States, Local Governments and Non-Profit Organizations"; and
- (h) Those sections of A-50 related to audits performed under subpart F of this part.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75882, Dec. 19, 2014; 85 FR 49538, Aug. 13, 2020]

#### **§ 200.105 Effect on other issuances.**

- (a) **Superseding inconsistent requirements.** For Federal awards subject to this part, all administrative requirements, program manuals, handbooks and other non-regulatory materials that are inconsistent with the requirements of this part must be superseded upon implementation of this part by the Federal agency, except to the extent they are required by statute or authorized in accordance with the provisions in § 200.102.
- (b) **Imposition of requirements on recipients.** Agencies may impose legally binding requirements on recipients only through the notice and public comment process through an approved agency process, including as authorized by this part, other statutes or regulations, or as incorporated into the terms of a Federal award.

[85 FR 49538, Aug. 13, 2020]

#### **§ 200.106 Agency implementation.**

The specific requirements and responsibilities of Federal agencies and non-Federal entities are set forth in this part. Federal agencies making Federal awards to non-Federal entities must implement the language in subparts C through F of this part in codified regulations unless different provisions are required by Federal statute or are approved by OMB.

[85 FR 49538, Aug. 13, 2020]

#### **§ 200.107 OMB responsibilities.**

OMB will review Federal agency regulations and implementation of this part, and will provide interpretations of policy requirements and assistance to ensure effective and efficient implementation. Any exceptions will be subject to approval by OMB. Exceptions will only be made in particular cases where adequate justification is presented.

#### **§ 200.108 Inquiries.**

Inquiries concerning this part may be directed to the Office of Federal Financial Management Office of Management and Budget, in Washington, DC. Non-Federal entities' inquiries should be addressed to the Federal awarding agency, cognizant agency for indirect costs, cognizant or oversight agency for audit, or pass-through entity as appropriate.

#### **§ 200.109 Review date.**

OMB will review this part at least every five years after December 26, 2013.

#### **§ 200.110 Effective/applicability date.**

- (a) The standards set forth in this part that affect the administration of Federal awards issued by Federal awarding agencies become effective once implemented by Federal awarding agencies or when any future amendment to this part becomes final.
- (b) Existing negotiated indirect cost rates (as of the publication date of the revisions to the guidance) will remain in place until they expire. The effective date of changes to indirect cost rates must be based upon the date that a newly re-negotiated rate goes into effect for a specific non-Federal entity's fiscal year. Therefore, for indirect cost rates and cost allocation plans, the revised Uniform Guidance (as of the publication date for revisions to the guidance) become effective in generating proposals and negotiating a new rate (when the rate is re-negotiated).

[85 FR 49538, Aug. 13, 2020]

### § 200.111 English language.

- (a) All Federal financial assistance announcements and Federal award information must be in the English language. Applications must be submitted in the English language and must be in the terms of U.S. dollars. If the Federal awarding agency receives applications in another currency, the Federal awarding agency will evaluate the application by converting the foreign currency to United States currency using the date specified for receipt of the application.
- (b) Non-Federal entities may translate the Federal award and other documents into another language. In the event of inconsistency between any terms and conditions of the Federal award and any translation into another language, the English language meaning will control. Where a significant portion of the non-Federal entity's employees who are working on the Federal award are not fluent in English, the non-Federal entity must provide the Federal award in English and the language(s) with which employees are more familiar.

### § 200.112 Conflict of interest.

The Federal awarding agency must establish conflict of interest policies for Federal awards. The non-Federal entity must disclose in writing any potential conflict of interest to the Federal awarding agency or pass-through entity in accordance with applicable Federal awarding agency policy.

### § 200.113 Mandatory disclosures.

The non-Federal entity or applicant for a Federal award must disclose, in a timely manner, in writing to the Federal awarding agency or pass-through entity all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. Non-Federal entities that have received a Federal award including the term and condition outlined in appendix XII to this part are required to report certain civil, criminal, or administrative proceedings to SAM (currently FAPIIS). Failure to make required disclosures can result in any of the remedies described in § 200.339. (See also 2 CFR part 180, 31 U.S.C. 3321, and 41 U.S.C. 2313.)

[85 FR 49539, Aug. 13, 2020]

## Subpart C - Pre-Federal Award Requirements and Contents of Federal Awards

**Source:** 85 FR 49539, Aug. 13, 2020, unless otherwise noted.

### § 200.200 Purpose.

Sections 200.201 through 200.216 prescribe instructions and other pre-award matters to be used by Federal awarding agencies in the program planning, announcement, application and award processes.

### § 200.201 Use of grant agreements (including fixed amount awards), cooperative agreements, and contracts.

- (a) **Federal award instrument.** The Federal awarding agency or pass-through entity must decide on the appropriate instrument for the Federal award (*i.e.*, grant agreement, cooperative agreement, or contract) in accordance with the Federal Grant and Cooperative Agreement Act (31 U.S.C. 6301-08).
- (b) **Fixed amount awards.** In addition to the options described in paragraph (a) of this section, Federal awarding agencies, or pass-through entities as permitted in § 200.333, may use fixed amount awards (see *Fixed amount awards* in § 200.1) to which the following conditions apply:
  - (1) The Federal award amount is negotiated using the cost principles (or other pricing information) as a guide. The Federal awarding agency or pass-through entity may use fixed amount awards if the project scope has measurable goals and objectives and if adequate cost, historical, or unit pricing data is available to establish a fixed amount award based on a reasonable estimate of actual cost. Payments are based on meeting specific requirements of the Federal award. Accountability is based on performance and results. Except in the case of termination before completion of the Federal award, there is no governmental review of the actual costs incurred by the non-Federal entity in performance of the award. Some of the ways in which the Federal award may be paid include, but are not limited to:
    - (i) In several partial payments, the amount of each agreed upon in advance, and the "milestone" or event triggering the payment also agreed upon in advance, and set forth in the Federal award;

- (ii) On a unit price basis, for a defined unit or units, at a defined price or prices, agreed to in advance of performance of the Federal award and set forth in the Federal award; or,
  - (iii) In one payment at Federal award completion.
- (2) A fixed amount award cannot be used in programs which require mandatory cost sharing or match.
  - (3) The non-Federal entity must certify in writing to the Federal awarding agency or pass-through entity at the end of the Federal award that the project or activity was completed or the level of effort was expended. If the required level of activity or effort was not carried out, the amount of the Federal award must be adjusted.
  - (4) Periodic reports may be established for each Federal award.
  - (5) Changes in principal investigator, project leader, project partner, or scope of effort must receive the prior written approval of the Federal awarding agency or pass-through entity.

### § 200.202 Program planning and design.

The Federal awarding agency must design a program and create an Assistance Listing before announcing the Notice of Funding Opportunity. The program must be designed with clear goals and objectives that facilitate the delivery of meaningful results consistent with the Federal authorizing legislation of the program. Program performance shall be measured based on the goals and objectives developed during program planning and design. See § 200.301 for more information on performance measurement. Performance measures may differ depending on the type of program. The program must align with the strategic goals and objectives within the Federal awarding agency's performance plan and should support the Federal awarding agency's performance measurement, management, and reporting as required by Part 6 of OMB Circular A-11 (Preparation, Submission, and Execution of the Budget). The program must also be designed to align with the Program Management Improvement Accountability Act (Pub. L. 114-264).

### § 200.203 Requirement to provide public notice of Federal financial assistance programs.

- (a) The Federal awarding agency must notify the public of Federal programs in the Federal Assistance Listings maintained by the General Services Administration (GSA).
  - (1) The Federal Assistance Listings is the single, authoritative, governmentwide comprehensive source of Federal financial assistance program information produced by the executive branch of the Federal Government.
  - (2) The information that the Federal awarding agency must submit to GSA for approval by OMB is listed in paragraph (b) of this section. GSA must prescribe the format for the submission in coordination with OMB.
  - (3) The Federal awarding agency may not award Federal financial assistance without assigning it to a program that has been included in the Federal Assistance Listings as required in this section unless there are exigent circumstances requiring otherwise, such as timing requirements imposed by statute.
- (b) For each program that awards discretionary Federal awards, non-discretionary Federal awards, loans, insurance, or any other type of Federal financial assistance, the Federal awarding agency must, to the extent practicable, create, update, and manage Assistance Listings entries based on the authorizing statute for the program and comply with additional guidance provided by GSA in consultation with OMB to ensure consistent, accurate information is available to prospective applicants. Accordingly, Federal awarding agencies must submit the following information to GSA:
  - (1) **Program Description, Purpose, Goals, and Measurement.** A brief summary of the statutory or regulatory requirements of the program and its intended outcome. Where appropriate, the Program Description, Purpose, Goals, and Measurement should align with the strategic goals and objectives within the Federal awarding agency's performance plan and should support the Federal awarding agency's performance measurement, management, and reporting as required by Part 6 of OMB Circular A-11;
  - (2) **Identification.** Identification of whether the program makes Federal awards on a discretionary basis or the Federal awards are prescribed by Federal statute, such as in the case of formula grants.
  - (3) **Projected total amount of funds available for the program.** Estimates based on previous year funding are acceptable if current appropriations are not available at the time of the submission;
  - (4) **Anticipated source of available funds.** The statutory authority for funding the program and, to the extent possible, agency, sub-agency, or, if known, the specific program unit that will issue the Federal awards, and associated funding identifier (e.g., Treasury Account Symbol(s));

- (5) **General eligibility requirements.** The statutory, regulatory or other eligibility factors or considerations that determine the applicant's qualification for Federal awards under the program (e.g., type of non-Federal entity); and
- (6) **Applicability of Single Audit Requirements.** Applicability of Single Audit Requirements as required by subpart F of this part.

### § 200.204 Notices of funding opportunities.

For discretionary grants and cooperative agreements that are competed, the Federal awarding agency must announce specific funding opportunities by providing the following information in a public notice:

- (a) **Summary information in notices of funding opportunities.** The Federal awarding agency must display the following information posted on the OMB-designated governmentwide website for funding and applying for Federal financial assistance, in a location preceding the full text of the announcement:
  - (1) Federal Awarding Agency Name;
  - (2) Funding Opportunity Title;
  - (3) Announcement Type (whether the funding opportunity is the initial announcement of this funding opportunity or a modification of a previously announced opportunity);
  - (4) Funding Opportunity Number (required, if applicable). If the Federal awarding agency has assigned or will assign a number to the funding opportunity announcement, this number must be provided;
  - (5) Assistance Listings Number(s);
  - (6) Key Dates. Key dates include due dates for applications or Executive Order 12372 submissions, as well as for any letters of intent or pre-applications. For any announcement issued before a program's application materials are available, key dates also include the date on which those materials will be released; and any other additional information, as deemed applicable by the relevant Federal awarding agency.
- (b) **Availability period.** The Federal awarding agency must generally make all funding opportunities available for application for at least 60 calendar days. The Federal awarding agency may make a determination to have a less than 60 calendar day availability period but no funding opportunity should be available for less than 30 calendar days unless exigent circumstances require as determined by the Federal awarding agency head or delegate.
- (c) **Full text of funding opportunities.** The Federal awarding agency must include the following information in the full text of each funding opportunity. For specific instructions on the content required in this section, refer to appendix I to this part.
  - (1) Full programmatic description of the funding opportunity.
  - (2) Federal award information, including sufficient information to help an applicant make an informed decision about whether to submit an application. (See also § 200.414(c)(4)).
  - (3) Specific eligibility information, including any factors or priorities that affect an applicant's or its application's eligibility for selection.
  - (4) Application Preparation and Submission Information, including the applicable submission dates and time.
  - (5) Application Review Information including the criteria and process to be used to evaluate applications. See also §§ 200.205 and 200.206.
  - (6) Federal Award Administration Information. See also § 200.211.
  - (7) Applicable terms and conditions for resulting awards, including any exceptions from these standard terms.

### § 200.205 Federal awarding agency review of merit of proposals.

For discretionary Federal awards, unless prohibited by Federal statute, the Federal awarding agency must design and execute a merit review process for applications, with the objective of selecting recipients most likely to be successful in delivering results based on the program objectives outlined in section § 200.202. A merit review is an objective process of evaluating Federal award applications in accordance with written standards set forth by the Federal awarding agency. This process must be described or incorporated by reference in the applicable funding opportunity (see appendix I to this part.). See also § 200.204. The Federal awarding agency must also periodically review its merit review process.

## § 200.206 Federal awarding agency review of risk posed by applicants.

### (a) *Review of OMB-designated repositories of governmentwide data.*

- (1) Prior to making a Federal award, the Federal awarding agency is required by the Payment Integrity Information Act of 2019, 31 U.S.C. 3301 note, and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of governmentwide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR part 180 as well as individual Federal agency suspension and debarment regulations in title 2 of the Code of Federal Regulations.
- (2) In accordance 41 U.S.C. 2313, the Federal awarding agency is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. As required by Public Law 112-239, National Defense Authorization Act for Fiscal Year 2013, prior to making a Federal award, the Federal awarding agency must consider all of the information available through FAPIIS with regard to the applicant and any immediate highest level owner, predecessor (*i.e.*; a non-Federal entity that is replaced by a successor), or subsidiary, identified for that applicant in FAPIIS, if applicable. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. The Federal awarding agency may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with § 200.208.

### (b) *Risk evaluation.*

- (1) The Federal awarding agency must have in place a framework for evaluating the risks posed by applicants before they receive Federal awards. This evaluation may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If the Federal awarding agency determines that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. Criteria to be evaluated must be described in the announcement of funding opportunity described in § 200.204.
- (2) In evaluating risks posed by applicants, the Federal awarding agency may use a risk-based approach and may consider any items such as the following:
  - (i) **Financial stability.** Financial stability;
  - (ii) **Management systems and standards.** Quality of management systems and ability to meet the management standards prescribed in this part;
  - (iii) **History of performance.** The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
  - (iv) **Audit reports and findings.** Reports and findings from audits performed under subpart F of this part or the reports and findings of any other available audits; and
  - (v) **Ability to effectively implement requirements.** The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

### (c) *Risk-based requirements adjustment.* The Federal awarding agency may adjust requirements when a risk-evaluation indicates that it may be merited either pre-award or post-award.

### (d) *Suspension and debarment compliance.*

- (1) The Federal awarding agency must comply with the guidelines on governmentwide suspension and debarment in 2 CFR part 180, and must require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

[85 FR 49539, Aug. 13, 2020, as amended at 86 FR 10439, Feb. 22, 2021]

## § 200.207 Standard application requirements.

- (a) **Paperwork clearances.** The Federal awarding agency may only use application information collections approved by OMB under the Paperwork Reduction Act of 1995 and OMB's implementing regulations in 5 CFR part 1320 and in alignment with OMB-approved, governmentwide data elements available from the OMB-designated standards lead. Consistent with these requirements, OMB will authorize additional information collections only on a limited basis.
- (b) **Information collection.** If applicable, the Federal awarding agency may inform applicants and recipients that they do not need to provide certain information otherwise required by the relevant information collection.

### **§ 200.208 Specific conditions.**

- (a) Federal awarding agencies are responsible for ensuring that specific Federal award conditions are consistent with the program design reflected in § 200.202 and include clear performance expectations of recipients as required in § 200.301.
- (b) The Federal awarding agency or pass-through entity may adjust specific Federal award conditions as needed, in accordance with this section, based on an analysis of the following factors:
  - (1) Based on the criteria set forth in § 200.206;
  - (2) The applicant or recipient's history of compliance with the general or specific terms and conditions of a Federal award;
  - (3) The applicant or recipient's ability to meet expected performance goals as described in § 200.211; or
  - (4) A responsibility determination of an applicant or recipient.
- (c) Additional Federal award conditions may include items such as the following:
  - (1) Requiring payments as reimbursements rather than advance payments;
  - (2) Withholding authority to proceed to the next phase until receipt of evidence of acceptable performance within a given performance period;
  - (3) Requiring additional, more detailed financial reports;
  - (4) Requiring additional project monitoring;
  - (5) Requiring the non-Federal entity to obtain technical or management assistance; or
  - (6) Establishing additional prior approvals.
- (d) If the Federal awarding agency or pass-through entity is imposing additional requirements, they must notify the applicant or non-Federal entity as to:
  - (1) The nature of the additional requirements;
  - (2) The reason why the additional requirements are being imposed;
  - (3) The nature of the action needed to remove the additional requirement, if applicable;
  - (4) The time allowed for completing the actions if applicable; and
  - (5) The method for requesting reconsideration of the additional requirements imposed.
- (e) Any additional requirements must be promptly removed once the conditions that prompted them have been satisfied.

### **§ 200.209 Certifications and representations.**

Unless prohibited by the U.S. Constitution, Federal statutes or regulations, each Federal awarding agency or pass-through entity is authorized to require the non-Federal entity to submit certifications and representations required by Federal statutes, or regulations on an annual basis. Submission may be required more frequently if the non-Federal entity fails to meet a requirement of a Federal award.

### **§ 200.210 Pre-award costs.**

For requirements on costs incurred by the applicant prior to the start date of the period of performance of the Federal award, see § 200.458.

**§ 200.211 Information contained in a Federal award.**

A Federal award must include the following information:

- (a) **Federal award performance goals.** Performance goals, indicators, targets, and baseline data must be included in the Federal award, where applicable. The Federal awarding agency must also specify how performance will be assessed in the terms and conditions of the Federal award, including the timing and scope of expected performance. See §§ 200.202 and 200.301 for more information on Federal award performance goals.
- (b) **General Federal award information.** The Federal awarding agency must include the following general Federal award information in each Federal award:
  - (1) Recipient name (which must match the name associated with its unique entity identifier as defined at 2 CFR 25.315);
  - (2) Recipient's unique entity identifier;
  - (3) Unique Federal Award Identification Number (FAIN);
  - (4) Federal Award Date (see Federal award date in § 200.201);
  - (5) Period of Performance Start and End Date;
  - (6) Budget Period Start and End Date;
  - (7) Amount of Federal Funds Obligated by this action;
  - (8) Total Amount of Federal Funds Obligated;
  - (9) Total Approved Cost Sharing or Matching, where applicable;
  - (10) Total Amount of the Federal Award including approved Cost Sharing or Matching;
  - (11) Budget Approved by the Federal Awarding Agency;
  - (12) Federal award description, (to comply with statutory requirements (e.g., FFATA));
  - (13) Name of Federal awarding agency and contact information for awarding official,
  - (14) Assistance Listings Number and Title;
  - (15) Identification of whether the award is R&D; and
  - (16) Indirect cost rate for the Federal award (including if the de minimis rate is charged per § 200.414).
- (c) **General terms and conditions.**
  - (1) Federal awarding agencies must incorporate the following general terms and conditions either in the Federal award or by reference, as applicable:
    - (i) **Administrative requirements.** Administrative requirements implemented by the Federal awarding agency as specified in this part.
    - (ii) **National policy requirements.** These include statutory, executive order, other Presidential directive, or regulatory requirements that apply by specific reference and are not program-specific. See § 200.300 Statutory and national policy requirements.
    - (iii) **Recipient integrity and performance matters.** If the total Federal share of the Federal award may include more than \$500,000 over the period of performance, the Federal awarding agency must include the term and condition available in appendix XII of this part. See also § 200.113.
    - (iv) **Future budget periods.** If it is anticipated that the period of performance will include multiple budget periods, the Federal awarding agency must indicate that subsequent budget periods are subject to the availability of funds, program authority, satisfactory performance, and compliance with the terms and conditions of the Federal award.
    - (v) **Termination provisions.** Federal awarding agencies must make recipients aware, in a clear and unambiguous manner, of the termination provisions in § 200.340, including the applicable termination provisions in the Federal awarding agency's regulations or in each Federal award.

- (2) The Federal award must incorporate, by reference, all general terms and conditions of the award, which must be maintained on the agency's website.
  - (3) If a non-Federal entity requests a copy of the full text of the general terms and conditions, the Federal awarding agency must provide it.
  - (4) Wherever the general terms and conditions are publicly available, the Federal awarding agency must maintain an archive of previous versions of the general terms and conditions, with effective dates, for use by the non-Federal entity, auditors, or others.
- (d) **Federal awarding agency, program, or Federal award specific terms and conditions.** The Federal awarding agency must include with each Federal award any terms and conditions necessary to communicate requirements that are in addition to the requirements outlined in the Federal awarding agency's general terms and conditions. See also § 200.208. Whenever practicable, these specific terms and conditions also should be shared on the agency's website and in notices of funding opportunities (as outlined in § 200.204) in addition to being included in a Federal award. See also § 200.207.
- (e) **Federal awarding agency requirements.** Any other information required by the Federal awarding agency.

### § 200.212 Public access to Federal award information.

- (a) In accordance with statutory requirements for Federal spending transparency (e.g., FFATA), except as noted in this section, for applicable Federal awards the Federal awarding agency must announce all Federal awards publicly and publish the required information on a publicly available OMB-designated governmentwide website.
- (b) All information posted in the designated integrity and performance system accessible through SAM (currently FAPIIS) on or after April 15, 2011 will be publicly available after a waiting period of 14 calendar days, except for:
  - (1) Past performance reviews required by Federal Government contractors in accordance with the Federal Acquisition Regulation (FAR) 48 CFR part 42, subpart 42.15;
  - (2) Information that was entered prior to April 15, 2011; or
  - (3) Information that is withdrawn during the 14-calendar day waiting period by the Federal Government official.
- (c) Nothing in this section may be construed as requiring the publication of information otherwise exempt under the Freedom of Information Act (5 U.S.C 552), or controlled unclassified information pursuant to Executive Order 13556.

### § 200.213 Reporting a determination that a non-Federal entity is not qualified for a Federal award.

- (a) If a Federal awarding agency does not make a Federal award to a non-Federal entity because the official determines that the non-Federal entity does not meet either or both of the minimum qualification standards as described in § 200.206(a)(2), the Federal awarding agency must report that determination to the designated integrity and performance system accessible through SAM (currently FAPIIS), only if all of the following apply:
  - (1) The only basis for the determination described in this paragraph (a) is the non-Federal entity's prior record of executing programs or activities under Federal awards or its record of integrity and business ethics, as described in § 200.206(a)(2) (i.e., the entity was determined to be qualified based on all factors other than those two standards); and
  - (2) The total Federal share of the Federal award that otherwise would be made to the non-Federal entity is expected to exceed the simplified acquisition threshold over the period of performance.
- (b) The Federal awarding agency is not required to report a determination that a non-Federal entity is not qualified for a Federal award if they make the Federal award to the non-Federal entity and include specific award terms and conditions, as described in § 200.208.
- (c) If a Federal awarding agency reports a determination that a non-Federal entity is not qualified for a Federal award, as described in paragraph (a) of this section, the Federal awarding agency also must notify the non-Federal entity that -
  - (1) The determination was made and reported to the designated integrity and performance system accessible through SAM, and include with the notification an explanation of the basis for the determination;
  - (2) The information will be kept in the system for a period of five years from the date of the determination, as required by section 872 of Public Law 110-417, as amended (41 U.S.C. 2313), then archived;



- (3) Each Federal awarding agency that considers making a Federal award to the non-Federal entity during that five year period must consider that information in judging whether the non-Federal entity is qualified to receive the Federal award when the total Federal share of the Federal award is expected to include an amount of Federal funding in excess of the simplified acquisition threshold over the period of performance;
  - (4) The non-Federal entity may go to the awardee integrity and performance portal accessible through SAM (currently the Contractor Performance Assessment Reporting System (CPARS)) and comment on any information the system contains about the non-Federal entity itself; and
  - (5) Federal awarding agencies will consider that non-Federal entity's comments in determining whether the non-Federal entity is qualified for a future Federal award.
- (d) If a Federal awarding agency enters information into the designated integrity and performance system accessible through SAM about a determination that a non-Federal entity is not qualified for a Federal award and subsequently:
- (1) Learns that any of that information is erroneous, the Federal awarding agency must correct the information in the system within three business days; and
  - (2) Obtains an update to that information that could be helpful to other Federal awarding agencies, the Federal awarding agency is strongly encouraged to amend the information in the system to incorporate the update in a timely way.
- (e) Federal awarding agencies must not post any information that will be made publicly available in the non-public segment of designated integrity and performance system that is covered by a disclosure exemption under the Freedom of Information Act. If the recipient asserts within seven calendar days to the Federal awarding agency that posted the information that some or all of the information made publicly available is covered by a disclosure exemption under the Freedom of Information Act, the Federal awarding agency that posted the information must remove the posting within seven calendar days of receiving the assertion. Prior to reposting the releasable information, the Federal awarding agency must resolve the issue in accordance with the agency's Freedom of Information Act procedures.

### **§ 200.214 Suspension and debarment.**

Non-Federal entities are subject to the non-procurement debarment and suspension regulations implementing Executive Orders 12549 and 12689, 2 CFR part 180. The regulations in 2 CFR part 180 restrict awards, subawards, and contracts with certain parties that are debarred, suspended, or otherwise excluded from or ineligible for participation in Federal assistance programs or activities.

### **§ 200.215 Never contract with the enemy.**

Federal awarding agencies and recipients are subject to the regulations implementing Never Contract with the Enemy in 2 CFR part 183. The regulations in 2 CFR part 183 affect covered contracts, grants and cooperative agreements that are expected to exceed \$50,000 within the period of performance, are performed outside the United States and its territories, and are in support of a contingency operation in which members of the Armed Forces are actively engaged in hostilities.

### **§ 200.216 Prohibition on certain telecommunications and video surveillance services or equipment.**

- (a) Recipients and subrecipients are prohibited from obligating or expending loan or grant funds to:
- (1) Procure or obtain;
  - (2) Extend or renew a contract to procure or obtain; or
  - (3) Enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. As described in Public Law 115-232, section 889, covered telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).
    - (i) For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).
    - (ii) Telecommunications or video surveillance services provided by such entities or using such equipment.

- (iii) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.
- (b) In implementing the prohibition under Public Law 115-232, section 889, subsection (f), paragraph (1), heads of executive agencies administering loan, grant, or subsidy programs shall prioritize available funding and technical support to assist affected businesses, institutions and organizations as is reasonably necessary for those affected entities to transition from covered communications equipment and services, to procure replacement equipment and services, and to ensure that communications service to users and customers is sustained.
- (c) See Public Law 115-232, section 889 for additional information.
- (d) See also § 200.471.

## Subpart D - Post Federal Award Requirements

**Source:** 85 FR 49543, Aug. 13, 2020, unless otherwise noted.

### § 200.300 Statutory and national policy requirements.

- (a) The Federal awarding agency must manage and administer the Federal award in a manner so as to ensure that Federal funding is expended and associated programs are implemented in full accordance with the U.S. Constitution, Federal Law, and public policy requirements: Including, but not limited to, those protecting free speech, religious liberty, public welfare, the environment, and prohibiting discrimination. The Federal awarding agency must communicate to the non-Federal entity all relevant public policy requirements, including those in general appropriations provisions, and incorporate them either directly or by reference in the terms and conditions of the Federal award.
- (b) The non-Federal entity is responsible for complying with all requirements of the Federal award. For all Federal awards, this includes the provisions of FFATA, which includes requirements on executive compensation, and also requirements implementing the Act for the non-Federal entity at 2 CFR parts 25 and 170. See also statutory requirements for whistleblower protections at 10 U.S.C. 2409, 41 U.S.C. 4712, and 10 U.S.C. 2324, 41 U.S.C. 4304 and 4310.

### § 200.301 Performance measurement.

- (a) The Federal awarding agency must measure the recipient's performance to show achievement of program goals and objectives, share lessons learned, improve program outcomes, and foster adoption of promising practices. Program goals and objectives should be derived from program planning and design. See § 200.202 for more information. Where appropriate, the Federal award may include specific program goals, indicators, targets, baseline data, data collection, or expected outcomes (such as outputs, or services performance or public impacts of any of these) with an expected timeline for accomplishment. Where applicable, this should also include any performance measures or independent sources of data that may be used to measure progress. The Federal awarding agency will determine how performance progress is measured, which may differ by program. Performance measurement progress must be both measured and reported. See § 200.329 for more information on monitoring program performance. The Federal awarding agency may include program-specific requirements, as applicable. These requirements must be aligned, to the extent permitted by law, with the Federal awarding agency strategic goals, strategic objectives or performance goals that are relevant to the program. See also OMB Circular A-11, Preparation, Submission, and Execution of the Budget Part 6.
- (b) The Federal awarding agency should provide recipients with clear performance goals, indicators, targets, and baseline data as described in § 200.211. Performance reporting frequency and content should be established to not only allow the Federal awarding agency to understand the recipient progress but also to facilitate identification of promising practices among recipients and build the evidence upon which the Federal awarding agency's program and performance decisions are made. See § 200.328 for more information on reporting program performance.
- (c) This provision is designed to operate in tandem with evidence-related statutes (e.g., The Foundations for Evidence-Based Policymaking Act of 2018, which emphasizes collaboration and coordination to advance data and evidence-building functions in the Federal government). The Federal awarding agency should also specify any requirements of award recipients' participation in a federally funded evaluation, and any evaluation activities required to be conducted by the Federal award.

### **§ 200.302 Financial management.**

- (a) Each state must expend and account for the Federal award in accordance with state laws and procedures for expending and accounting for the state's own funds. In addition, the state's and the other non-Federal entity's financial management systems, including records documenting compliance with Federal statutes, regulations, and the terms and conditions of the Federal award, must be sufficient to permit the preparation of reports required by general and program-specific terms and conditions; and the tracing of funds to a level of expenditures adequate to establish that such funds have been used according to the Federal statutes, regulations, and the terms and conditions of the Federal award. See also § 200.450.
- (b) The financial management system of each non-Federal entity must provide for the following (see also §§ 200.334, 200.335, 200.336, and 200.337):
  - (1) Identification, in its accounts, of all Federal awards received and expended and the Federal programs under which they were received. Federal program and Federal award identification must include, as applicable, the Assistance Listings title and number, Federal award identification number and year, name of the Federal agency, and name of the pass-through entity, if any.
  - (2) Accurate, current, and complete disclosure of the financial results of each Federal award or program in accordance with the reporting requirements set forth in §§ 200.328 and 200.329. If a Federal awarding agency requires reporting on an accrual basis from a recipient that maintains its records on other than an accrual basis, the recipient must not be required to establish an accrual accounting system. This recipient may develop accrual data for its reports on the basis of an analysis of the documentation on hand. Similarly, a pass-through entity must not require a subrecipient to establish an accrual accounting system and must allow the subrecipient to develop accrual data for its reports on the basis of an analysis of the documentation on hand.
  - (3) Records that identify adequately the source and application of funds for federally-funded activities. These records must contain information pertaining to Federal awards, authorizations, financial obligations, unobligated balances, assets, expenditures, income and interest and be supported by source documentation.
  - (4) Effective control over, and accountability for, all funds, property, and other assets. The non-Federal entity must adequately safeguard all assets and assure that they are used solely for authorized purposes. See § 200.303.
  - (5) Comparison of expenditures with budget amounts for each Federal award.
  - (6) Written procedures to implement the requirements of § 200.305.
  - (7) Written procedures for determining the allowability of costs in accordance with subpart E of this part and the terms and conditions of the Federal award.

### **§ 200.303 Internal controls.**

The non-Federal entity must:

- (a) Establish and maintain effective internal control over the Federal award that provides reasonable assurance that the non-Federal entity is managing the Federal award in compliance with Federal statutes, regulations, and the terms and conditions of the Federal award. These internal controls should be in compliance with guidance in "Standards for Internal Control in the Federal Government" issued by the Comptroller General of the United States or the "Internal Control Integrated Framework", issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).
- (b) Comply with the U.S. Constitution, Federal statutes, regulations, and the terms and conditions of the Federal awards.
- (c) Evaluate and monitor the non-Federal entity's compliance with statutes, regulations and the terms and conditions of Federal awards.
- (d) Take prompt action when instances of noncompliance are identified including noncompliance identified in audit findings.
- (e) Take reasonable measures to safeguard protected personally identifiable information and other information the Federal awarding agency or pass-through entity designates as sensitive or the non-Federal entity considers sensitive consistent with applicable Federal, State, local, and tribal laws regarding privacy and responsibility over confidentiality.

### **§ 200.304 Bonds.**

The Federal awarding agency may include a provision on bonding, insurance, or both in the following circumstances:

- (a) Where the Federal Government guarantees or insures the repayment of money borrowed by the recipient, the Federal awarding agency, at its discretion, may require adequate bonding and insurance if the bonding and insurance requirements of the non-Federal entity are not deemed adequate to protect the interest of the Federal Government.
- (b) The Federal awarding agency may require adequate fidelity bond coverage where the non-Federal entity lacks sufficient coverage to protect the Federal Government's interest.
- (c) Where bonds are required in the situations described above, the bonds must be obtained from companies holding certificates of authority as acceptable sureties, as prescribed in 31 CFR part 223.

### **§ 200.305 Federal payment.**

- (a) For states, payments are governed by Treasury-State Cash Management Improvement Act (CMIA) agreements and default procedures codified at 31 CFR part 205 and Treasury Financial Manual (TFM) 4A-2000, "Overall Disbursing Rules for All Federal Agencies".
- (b) For non-Federal entities other than states, payments methods must minimize the time elapsing between the transfer of funds from the United States Treasury or the pass-through entity and the disbursement by the non-Federal entity whether the payment is made by electronic funds transfer, or issuance or redemption of checks, warrants, or payment by other means. See also § 200.302(b)(6). Except as noted elsewhere in this part, Federal agencies must require recipients to use only OMB-approved, governmentwide information collection requests to request payment.
  - (1) The non-Federal entity must be paid in advance, provided it maintains or demonstrates the willingness to maintain both written procedures that minimize the time elapsing between the transfer of funds and disbursement by the non-Federal entity, and financial management systems that meet the standards for fund control and accountability as established in this part. Advance payments to a non-Federal entity must be limited to the minimum amounts needed and be timed to be in accordance with the actual, immediate cash requirements of the non-Federal entity in carrying out the purpose of the approved program or project. The timing and amount of advance payments must be as close as is administratively feasible to the actual disbursements by the non-Federal entity for direct program or project costs and the proportionate share of any allowable indirect costs. The non-Federal entity must make timely payment to contractors in accordance with the contract provisions.
  - (2) Whenever possible, advance payments must be consolidated to cover anticipated cash needs for all Federal awards made by the Federal awarding agency to the recipient.
    - (i) Advance payment mechanisms include, but are not limited to, Treasury check and electronic funds transfer and must comply with applicable guidance in 31 CFR part 208.
    - (ii) Non-Federal entities must be authorized to submit requests for advance payments and reimbursements at least monthly when electronic fund transfers are not used, and as often as they like when electronic transfers are used, in accordance with the provisions of the Electronic Fund Transfer Act (15 U.S.C. 1693-1693r).
  - (3) Reimbursement is the preferred method when the requirements in this paragraph (b) cannot be met, when the Federal awarding agency sets a specific condition per § 200.208, or when the non-Federal entity requests payment by reimbursement. This method may be used on any Federal award for construction, or if the major portion of the construction project is accomplished through private market financing or Federal loans, and the Federal award constitutes a minor portion of the project. When the reimbursement method is used, the Federal awarding agency or pass-through entity must make payment within 30 calendar days after receipt of the billing, unless the Federal awarding agency or pass-through entity reasonably believes the request to be improper.
  - (4) If the non-Federal entity cannot meet the criteria for advance payments and the Federal awarding agency or pass-through entity has determined that reimbursement is not feasible because the non-Federal entity lacks sufficient working capital, the Federal awarding agency or pass-through entity may provide cash on a working capital advance basis. Under this procedure, the Federal awarding agency or pass-through entity must advance cash payments to the non-Federal entity to cover its estimated disbursement needs for an initial period generally geared to the non-Federal entity's disbursing cycle. Thereafter, the Federal awarding agency or pass-through entity must reimburse the non-Federal entity for its actual cash disbursements. Use of the working capital advance method of payment requires that the pass-through entity provide timely advance payments to any subrecipients in order to meet the subrecipient's actual cash disbursements. The working capital advance method of payment must not be used by the pass-through entity if the reason for using this method is the unwillingness or inability of the pass-through entity to provide timely advance payments to the subrecipient to meet the subrecipient's actual cash disbursements.
  - (5) To the extent available, the non-Federal entity must disburse funds available from program income (including repayments to a revolving fund), rebates, refunds, contract settlements, audit recoveries, and interest earned on such funds before requesting additional cash payments.

- (6) Unless otherwise required by Federal statutes, payments for allowable costs by non-Federal entities must not be withheld at any time during the period of performance unless the conditions of § 200.208, subpart D of this part, including § 200.339, or one or more of the following applies:
- (i) The non-Federal entity has failed to comply with the project objectives, Federal statutes, regulations, or the terms and conditions of the Federal award.
  - (ii) The non-Federal entity is delinquent in a debt to the United States as defined in OMB Circular A-129, "Policies for Federal Credit Programs and Non-Tax Receivables." Under such conditions, the Federal awarding agency or pass-through entity may, upon reasonable notice, inform the non-Federal entity that payments must not be made for financial obligations incurred after a specified date until the conditions are corrected or the indebtedness to the Federal Government is liquidated.
  - (iii) A payment withheld for failure to comply with Federal award conditions, but without suspension of the Federal award, must be released to the non-Federal entity upon subsequent compliance. When a Federal award is suspended, payment adjustments will be made in accordance with § 200.343.
  - (iv) A payment must not be made to a non-Federal entity for amounts that are withheld by the non-Federal entity from payment to contractors to assure satisfactory completion of work. A payment must be made when the non-Federal entity actually disburses the withheld funds to the contractors or to escrow accounts established to assure satisfactory completion of work.
- (7) Standards governing the use of banks and other institutions as depositories of advance payments under Federal awards are as follows.
- (i) The Federal awarding agency and pass-through entity must not require separate depository accounts for funds provided to a non-Federal entity or establish any eligibility requirements for depositories for funds provided to the non-Federal entity. However, the non-Federal entity must be able to account for funds received, obligated, and expended.
  - (ii) Advance payments of Federal funds must be deposited and maintained in insured accounts whenever possible.
- (8) The non-Federal entity must maintain advance payments of Federal awards in interest-bearing accounts, unless the following apply:
- (i) The non-Federal entity receives less than \$250,000 in Federal awards per year.
  - (ii) The best reasonably available interest-bearing account would not be expected to earn interest in excess of \$500 per year on Federal cash balances.
  - (iii) The depository would require an average or minimum balance so high that it would not be feasible within the expected Federal and non-Federal cash resources.
  - (iv) A foreign government or banking system prohibits or precludes interest-bearing accounts.
- (9) Interest earned amounts up to \$500 per year may be retained by the non-Federal entity for administrative expense. Any additional interest earned on Federal advance payments deposited in interest-bearing accounts must be remitted annually to the Department of Health and Human Services Payment Management System (PMS) through an electronic medium using either Automated Clearing House (ACH) network or a Fedwire Funds Service payment.
- (i) For returning interest on Federal awards paid through PMS, the refund should:
    - (A) Provide an explanation stating that the refund is for interest;
    - (B) List the PMS Payee Account Number(s) (PANs);
    - (C) List the Federal award number(s) for which the interest was earned; and
    - (D) Make returns payable to: Department of Health and Human Services.
  - (ii) For returning interest on Federal awards not paid through PMS, the refund should:
    - (A) Provide an explanation stating that the refund is for interest;
    - (B) Include the name of the awarding agency;
    - (C) List the Federal award number(s) for which the interest was earned; and
    - (D) Make returns payable to: Department of Health and Human Services.

- (10) Funds, principal, and excess cash returns must be directed to the original Federal agency payment system. The non-Federal entity should review instructions from the original Federal agency payment system. Returns should include the following information:
- (i) Payee Account Number (PAN), if the payment originated from PMS, or Agency information to indicate whom to credit the funding if the payment originated from ASAP, NSF, or another Federal agency payment system.
  - (ii) PMS document number and subaccount(s), if the payment originated from PMS, or relevant account numbers if the payment originated from another Federal agency payment system.
  - (iii) The reason for the return (e.g., excess cash, funds not spent, interest, part interest part other, etc.)
- (11) When returning funds or interest to PMS you must include the following as applicable:
- (i) For ACH Returns:
    - Routing Number: 051036706
    - Account number: 303000
    - Bank Name and Location: Credit Gateway - ACH Receiver St. Paul, MN
  - (ii) For Fedwire Returns<sup>1</sup>:
    - Routing Number: 021030004
    - Account number: 75010501
    - Bank Name and Location: Federal Reserve Bank Treas NYC/Funds Transfer Division New York, NY

<sup>1</sup> Please note that the organization initiating payment is likely to incur a charge from their Financial Institution for this type of payment.
  - (iii) For International ACH Returns:
    - Beneficiary Account: Federal Reserve Bank of New York/ITS (FRBNY/ITS)
    - Bank: Citibank N.A. (New York)
    - Swift Code: CITIUS33
    - Account Number: 36838868
    - Bank Address: 388 Greenwich Street, New York, NY 10013 USA
    - Payment Details (Line 70): Agency Locator Code (ALC): 75010501
    - Name (abbreviated when possible) and ALC Agency POC
  - (iv) For recipients that do not have electronic remittance capability, please make check<sup>2</sup> payable to: "The Department of Health and Human Services."
    - Mail Check to Treasury approved lockbox:
      - HHS Program Support Center, P.O. Box 530231, Atlanta, GA 30353-0231

<sup>2</sup> Please allow 4-6 weeks for processing of a payment by check to be applied to the appropriate PMS account.
  - (v) Questions can be directed to PMS at 877-614-5533 or [PMSSupport@psc.hhs.gov](mailto:PMSSupport@psc.hhs.gov).

### § 200.306 Cost sharing or matching.

- (a) Under Federal research proposals, voluntary committed cost sharing is not expected. It cannot be used as a factor during the merit review of applications or proposals, but may be considered if it is both in accordance with Federal awarding agency regulations and specified in a notice of funding opportunity. Criteria for considering voluntary committed cost

sharing and any other program policy factors that may be used to determine who may receive a Federal award must be explicitly described in the notice of funding opportunity. See also §§ 200.414 and 200.204 and appendix I to this part.

- (b) For all Federal awards, any shared costs or matching funds and all contributions, including cash and third-party in-kind contributions, must be accepted as part of the non-Federal entity's cost sharing or matching when such contributions meet all of the following criteria:
- (1) Are verifiable from the non-Federal entity's records;
  - (2) Are not included as contributions for any other Federal award;
  - (3) Are necessary and reasonable for accomplishment of project or program objectives;
  - (4) Are allowable under subpart E of this part;
  - (5) Are not paid by the Federal Government under another Federal award, except where the Federal statute authorizing a program specifically provides that Federal funds made available for such program can be applied to matching or cost sharing requirements of other Federal programs;
  - (6) Are provided for in the approved budget when required by the Federal awarding agency; and
  - (7) Conform to other provisions of this part, as applicable.
- (c) Unrecovered indirect costs, including indirect costs on cost sharing or matching may be included as part of cost sharing or matching only with the prior approval of the Federal awarding agency. Unrecovered indirect cost means the difference between the amount charged to the Federal award and the amount which could have been charged to the Federal award under the non-Federal entity's approved negotiated indirect cost rate.
- (d) Values for non-Federal entity contributions of services and property must be established in accordance with the cost principles in subpart E of this part. If a Federal awarding agency authorizes the non-Federal entity to donate buildings or land for construction/facilities acquisition projects or long-term use, the value of the donated property for cost sharing or matching must be the lesser of paragraph (d)(1) or (2) of this section.
- (1) The value of the remaining life of the property recorded in the non-Federal entity's accounting records at the time of donation.
  - (2) The current fair market value. However, when there is sufficient justification, the Federal awarding agency may approve the use of the current fair market value of the donated property, even if it exceeds the value described in paragraph (d)(1) of this section at the time of donation.
- (e) Volunteer services furnished by third-party professional and technical personnel, consultants, and other skilled and unskilled labor may be counted as cost sharing or matching if the service is an integral and necessary part of an approved project or program. Rates for third-party volunteer services must be consistent with those paid for similar work by the non-Federal entity. In those instances in which the required skills are not found in the non-Federal entity, rates must be consistent with those paid for similar work in the labor market in which the non-Federal entity competes for the kind of services involved. In either case, paid fringe benefits that are reasonable, necessary, allocable, and otherwise allowable may be included in the valuation.
- (f) When a third-party organization furnishes the services of an employee, these services must be valued at the employee's regular rate of pay plus an amount of fringe benefits that is reasonable, necessary, allocable, and otherwise allowable, and indirect costs at either the third-party organization's approved federally-negotiated indirect cost rate or, a rate in accordance with § 200.414(d) provided these services employ the same skill(s) for which the employee is normally paid. Where donated services are treated as indirect costs, indirect cost rates will separate the value of the donated services so that reimbursement for the donated services will not be made.
- (g) Donated property from third parties may include such items as equipment, office supplies, laboratory supplies, or workshop and classroom supplies. Value assessed to donated property included in the cost sharing or matching share must not exceed the fair market value of the property at the time of the donation.
- (h) The method used for determining cost sharing or matching for third-party-donated equipment, buildings and land for which title passes to the non-Federal entity may differ according to the purpose of the Federal award, if paragraph (h)(1) or (2) of this section applies.
- (1) If the purpose of the Federal award is to assist the non-Federal entity in the acquisition of equipment, buildings or land, the aggregate value of the donated property may be claimed as cost sharing or matching.

- (2) If the purpose of the Federal award is to support activities that require the use of equipment, buildings or land, normally only depreciation charges for equipment and buildings may be made. However, the fair market value of equipment or other capital assets and fair rental charges for land may be allowed, provided that the Federal awarding agency has approved the charges. See also § 200.420.
- (i) The value of donated property must be determined in accordance with the usual accounting policies of the non-Federal entity, with the following qualifications:
  - (1) The value of donated land and buildings must not exceed its fair market value at the time of donation to the non-Federal entity as established by an independent appraiser (e.g., certified real property appraiser or General Services Administration representative) and certified by a responsible official of the non-Federal entity as required by the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, as amended, (42 U.S.C. 4601-4655) (Uniform Act) except as provided in the implementing regulations at 49 CFR part 24, "Uniform Relocation Assistance And Real Property Acquisition For Federal And Federally-Assisted Programs".
  - (2) The value of donated equipment must not exceed the fair market value of equipment of the same age and condition at the time of donation.
  - (3) The value of donated space must not exceed the fair rental value of comparable space as established by an independent appraisal of comparable space and facilities in a privately-owned building in the same locality.
  - (4) The value of loaned equipment must not exceed its fair rental value.
- (j) For third-party in-kind contributions, the fair market value of goods and services must be documented and to the extent feasible supported by the same methods used internally by the non-Federal entity.
- (k) For IHEs, see also OMB memorandum M-01-06, dated January 5, 2001, Clarification of OMB A-21 Treatment of Voluntary Uncommitted Cost Sharing and Tuition Remission Costs.

### § 200.307 Program income.

- (a) **General.** Non-Federal entities are encouraged to earn income to defray program costs where appropriate.
- (b) **Cost of generating program income.** If authorized by Federal regulations or the Federal award, costs incidental to the generation of program income may be deducted from gross income to determine program income, provided these costs have not been charged to the Federal award.
- (c) **Governmental revenues.** Taxes, special assessments, levies, fines, and other such revenues raised by a non-Federal entity are not program income unless the revenues are specifically identified in the Federal award or Federal awarding agency regulations as program income.
- (d) **Property.** Proceeds from the sale of real property, equipment, or supplies are not program income; such proceeds will be handled in accordance with the requirements of the Property Standards §§ 200.311, 200.313, and 200.314, or as specifically identified in Federal statutes, regulations, or the terms and conditions of the Federal award.
- (e) **Use of program income.** If the Federal awarding agency does not specify in its regulations or the terms and conditions of the Federal award, or give prior approval for how program income is to be used, paragraph (e)(1) of this section must apply. For Federal awards made to IHEs and nonprofit research institutions, if the Federal awarding agency does not specify in its regulations or the terms and conditions of the Federal award how program income is to be used, paragraph (e)(2) of this section must apply. In specifying alternatives to paragraphs (e)(1) and (2) of this section, the Federal awarding agency may distinguish between income earned by the recipient and income earned by subrecipients and between the sources, kinds, or amounts of income. When the Federal awarding agency authorizes the approaches in paragraphs (e)(2) and (3) of this section, program income in excess of any amounts specified must also be deducted from expenditures.
  - (1) **Deduction.** Ordinarily program income must be deducted from total allowable costs to determine the net allowable costs. Program income must be used for current costs unless the Federal awarding agency authorizes otherwise. Program income that the non-Federal entity did not anticipate at the time of the Federal award must be used to reduce the Federal award and non-Federal entity contributions rather than to increase the funds committed to the project.
  - (2) **Addition.** With prior approval of the Federal awarding agency (except for IHEs and nonprofit research institutions, as described in this paragraph (e)) program income may be added to the Federal award by the Federal agency and the non-Federal entity. The program income must be used for the purposes and under the conditions of the Federal award.



- (3) **Cost sharing or matching.** With prior approval of the Federal awarding agency, program income may be used to meet the cost sharing or matching requirement of the Federal award. The amount of the Federal award remains the same.
- (f) **Income after the period of performance.** There are no Federal requirements governing the disposition of income earned after the end of the period of performance for the Federal award, unless the Federal awarding agency regulations or the terms and conditions of the Federal award provide otherwise. The Federal awarding agency may negotiate agreements with recipients regarding appropriate uses of income earned after the period of performance as part of the grant closeout process. See also § 200.344.
- (g) **License fees and royalties.** Unless the Federal statute, regulations, or terms and conditions for the Federal award provide otherwise, the non-Federal entity is not accountable to the Federal awarding agency with respect to program income earned from license fees and royalties for copyrighted material, patents, patent applications, trademarks, and inventions made under a Federal award to which 37 CFR part 401 is applicable.

### § 200.308 Revision of budget and program plans.

- (a) The approved budget for the Federal award summarizes the financial aspects of the project or program as approved during the Federal award process. It may include either the Federal and non-Federal share (see definition for *Federal share* in § 200.1) or only the Federal share, depending upon Federal awarding agency requirements. The budget and program plans include considerations for performance and program evaluation purposes whenever required in accordance with the terms and conditions of the award.
- (b) Recipients are required to report deviations from budget or project scope or objective, and request prior approvals from Federal awarding agencies for budget and program plan revisions, in accordance with this section.
- (c) For non-construction Federal awards, recipients must request prior approvals from Federal awarding agencies for the following program or budget-related reasons:
  - (1) Change in the scope or the objective of the project or program (even if there is no associated budget revision requiring prior written approval).
  - (2) Change in a key person specified in the application or the Federal award.
  - (3) The disengagement from the project for more than three months, or a 25 percent reduction in time devoted to the project, by the approved project director or principal investigator.
  - (4) The inclusion, unless waived by the Federal awarding agency, of costs that require prior approval in accordance with subpart E of this part as applicable.
  - (5) The transfer of funds budgeted for participant support costs to other categories of expense.
  - (6) Unless described in the application and funded in the approved Federal awards, the subawarding, transferring or contracting out of any work under a Federal award, including fixed amount subawards as described in § 200.333. This provision does not apply to the acquisition of supplies, material, equipment or general support services.
  - (7) Changes in the approved cost-sharing or matching provided by the non-Federal entity.
  - (8) The need arises for additional Federal funds to complete the project.
- (d) No other prior approval requirements for specific items may be imposed unless an exception has been approved by OMB. See also §§ 200.102 and 200.407.
- (e) Except for requirements listed in paragraphs (c)(1) through (8) of this section, the Federal awarding agency is authorized, at its option, to waive other cost-related and administrative prior written approvals contained in subparts D and E of this part. Such waivers may include authorizing recipients to do any one or more of the following:
  - (1) Incur project costs 90 calendar days before the Federal awarding agency makes the Federal award. Expenses more than 90 calendar days pre-award require prior approval of the Federal awarding agency. All costs incurred before the Federal awarding agency makes the Federal award are at the recipient's risk (*i.e.*, the Federal awarding agency is not required to reimburse such costs if for any reason the recipient does not receive a Federal award or if the Federal award is less than anticipated and inadequate to cover such costs). See also § 200.458.
  - (2) Initiate a one-time extension of the period of performance by up to 12 months unless one or more of the conditions outlined in paragraphs (e)(2)(i) through (iii) of this section apply. For one-time extensions, the recipient must notify the Federal awarding agency in writing with the supporting reasons and revised period of performance at least 10

calendar days before the end of the period of performance specified in the Federal award. This one-time extension must not be exercised merely for the purpose of using unobligated balances. Extensions require explicit prior Federal awarding agency approval when:

- (i) The terms and conditions of the Federal award prohibit the extension.
  - (ii) The extension requires additional Federal funds.
  - (iii) The extension involves any change in the approved objectives or scope of the project.
- (3) Carry forward unobligated balances to subsequent budget periods.
  - (4) For Federal awards that support research, unless the Federal awarding agency provides otherwise in the Federal award or in the Federal awarding agency's regulations, the prior approval requirements described in this paragraph (e) are automatically waived (*i.e.*, recipients need not obtain such prior approvals) unless one of the conditions included in paragraph (e)(2) of this section applies.
- (f) The Federal awarding agency may, at its option, restrict the transfer of funds among direct cost categories or programs, functions and activities for Federal awards in which the Federal share of the project exceeds the simplified acquisition threshold and the cumulative amount of such transfers exceeds or is expected to exceed 10 percent of the total budget as last approved by the Federal awarding agency. The Federal awarding agency cannot permit a transfer that would cause any Federal appropriation to be used for purposes other than those consistent with the appropriation.
  - (g) All other changes to non-construction budgets, except for the changes described in paragraph (c) of this section, do not require prior approval (see also § 200.407).
  - (h) For construction Federal awards, the recipient must request prior written approval promptly from the Federal awarding agency for budget revisions whenever paragraph (h)(1), (2), or (3) of this section applies:
    - (1) The revision results from changes in the scope or the objective of the project or program.
    - (2) The need arises for additional Federal funds to complete the project.
    - (3) A revision is desired which involves specific costs for which prior written approval requirements may be imposed consistent with applicable OMB cost principles listed in subpart E.
    - (4) No other prior approval requirements for budget revisions may be imposed unless an exception has been approved by OMB.
    - (5) When a Federal awarding agency makes a Federal award that provides support for construction and non-construction work, the Federal awarding agency may require the recipient to obtain prior approval from the Federal awarding agency before making any fund or budget transfers between the two types of work supported.
  - (i) When requesting approval for budget revisions, the recipient must use the same format for budget information that was used in the application, unless the Federal awarding agency indicates a letter of request suffices.
  - (j) Within 30 calendar days from the date of receipt of the request for budget revisions, the Federal awarding agency must review the request and notify the recipient whether the budget revisions have been approved. If the revision is still under consideration at the end of 30 calendar days, the Federal awarding agency must inform the recipient in writing of the date when the recipient may expect the decision.

### **§ 200.309 Modifications to Period of Performance.**

If a Federal awarding agency or pass-through entity approves an extension, or if a recipient extends under § 200.308(e)(2), the Period of Performance will be amended to end at the completion of the extension. If a termination occurs, the Period of Performance will be amended to end upon the effective date of termination. If a renewal award is issued, a distinct Period of Performance will begin.

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## PROPERTY STANDARDS

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### **§ 200.310 Insurance coverage.**

The non-Federal entity must, at a minimum, provide the equivalent insurance coverage for real property and equipment acquired or improved with Federal funds as provided to property owned by the non-Federal entity. Federally-owned property need not be insured unless required by the terms and conditions of the Federal award.

### § 200.311 Real property.

- (a) **Title.** Subject to the requirements and conditions set forth in this section, title to real property acquired or improved under a Federal award will vest upon acquisition in the non-Federal entity.
- (b) **Use.** Except as otherwise provided by Federal statutes or by the Federal awarding agency, real property will be used for the originally authorized purpose as long as needed for that purpose, during which time the non-Federal entity must not dispose of or encumber its title or other interests.
- (c) **Disposition.** When real property is no longer needed for the originally authorized purpose, the non-Federal entity must obtain disposition instructions from the Federal awarding agency or pass-through entity. The instructions must provide for one of the following alternatives:
  - (1) Retain title after compensating the Federal awarding agency. The amount paid to the Federal awarding agency will be computed by applying the Federal awarding agency's percentage of participation in the cost of the original purchase (and costs of any improvements) to the fair market value of the property. However, in those situations where the non-Federal entity is disposing of real property acquired or improved with a Federal award and acquiring replacement real property under the same Federal award, the net proceeds from the disposition may be used as an offset to the cost of the replacement property.
  - (2) Sell the property and compensate the Federal awarding agency. The amount due to the Federal awarding agency will be calculated by applying the Federal awarding agency's percentage of participation in the cost of the original purchase (and cost of any improvements) to the proceeds of the sale after deduction of any actual and reasonable selling and fixing-up expenses. If the Federal award has not been closed out, the net proceeds from sale may be offset against the original cost of the property. When the non-Federal entity is directed to sell property, sales procedures must be followed that provide for competition to the extent practicable and result in the highest possible return.
  - (3) Transfer title to the Federal awarding agency or to a third party designated/approved by the Federal awarding agency. The non-Federal entity is entitled to be paid an amount calculated by applying the non-Federal entity's percentage of participation in the purchase of the real property (and cost of any improvements) to the current fair market value of the property.

### § 200.312 Federally-owned and exempt property.

- (a) Title to federally-owned property remains vested in the Federal Government. The non-Federal entity must submit annually an inventory listing of federally-owned property in its custody to the Federal awarding agency. Upon completion of the Federal award or when the property is no longer needed, the non-Federal entity must report the property to the Federal awarding agency for further Federal agency utilization.
- (b) If the Federal awarding agency has no further need for the property, it must declare the property excess and report it for disposal to the appropriate Federal disposal authority, unless the Federal awarding agency has statutory authority to dispose of the property by alternative methods (e.g., the authority provided by the Federal Technology Transfer Act (15 U.S.C. 3710 (i)) to donate research equipment to educational and nonprofit organizations in accordance with Executive Order 12999, "Educational Technology: Ensuring Opportunity for All Children in the Next Century."). The Federal awarding agency must issue appropriate instructions to the non-Federal entity.
- (c) Exempt property means property acquired under a Federal award where the Federal awarding agency has chosen to vest title to the property to the non-Federal entity without further responsibility to the Federal Government, based upon the explicit terms and conditions of the Federal award. The Federal awarding agency may exercise this option when statutory authority exists. Absent statutory authority and specific terms and conditions of the Federal award, title to exempt property acquired under the Federal award remains with the Federal Government.

### § 200.313 Equipment.

See also § 200.439.

- (a) **Title.** Subject to the requirements and conditions set forth in this section, title to equipment acquired under a Federal award will vest upon acquisition in the non-Federal entity. Unless a statute specifically authorizes the Federal agency to vest title in the non-Federal entity without further responsibility to the Federal Government, and the Federal agency elects to do so, the title must be a conditional title. Title must vest in the non-Federal entity subject to the following conditions:

- (1) Use the equipment for the authorized purposes of the project during the period of performance, or until the property is no longer needed for the purposes of the project.
  - (2) Not encumber the property without approval of the Federal awarding agency or pass-through entity.
  - (3) Use and dispose of the property in accordance with paragraphs (b), (c), and (e) of this section.
- (b) **General.** A state must use, manage and dispose of equipment acquired under a Federal award by the state in accordance with state laws and procedures. Other non-Federal entities must follow paragraphs (c) through (e) of this section.
- (c) **Use.**
- (1) Equipment must be used by the non-Federal entity in the program or project for which it was acquired as long as needed, whether or not the project or program continues to be supported by the Federal award, and the non-Federal entity must not encumber the property without prior approval of the Federal awarding agency. The Federal awarding agency may require the submission of the applicable common form for equipment. When no longer needed for the original program or project, the equipment may be used in other activities supported by the Federal awarding agency, in the following order of priority:
    - (i) Activities under a Federal award from the Federal awarding agency which funded the original program or project, then
    - (ii) Activities under Federal awards from other Federal awarding agencies. This includes consolidated equipment for information technology systems.
  - (2) During the time that equipment is used on the project or program for which it was acquired, the non-Federal entity must also make equipment available for use on other projects or programs currently or previously supported by the Federal Government, provided that such use will not interfere with the work on the projects or program for which it was originally acquired. First preference for other use must be given to other programs or projects supported by Federal awarding agency that financed the equipment and second preference must be given to programs or projects under Federal awards from other Federal awarding agencies. Use for non-federally-funded programs or projects is also permissible. User fees should be considered if appropriate.
  - (3) Notwithstanding the encouragement in § 200.307 to earn program income, the non-Federal entity must not use equipment acquired with the Federal award to provide services for a fee that is less than private companies charge for equivalent services unless specifically authorized by Federal statute for as long as the Federal Government retains an interest in the equipment.
  - (4) When acquiring replacement equipment, the non-Federal entity may use the equipment to be replaced as a trade-in or sell the property and use the proceeds to offset the cost of the replacement property.
- (d) **Management requirements.** Procedures for managing equipment (including replacement equipment), whether acquired in whole or in part under a Federal award, until disposition takes place will, as a minimum, meet the following requirements:
- (1) Property records must be maintained that include a description of the property, a serial number or other identification number, the source of funding for the property (including the FAIN), who holds title, the acquisition date, and cost of the property, percentage of Federal participation in the project costs for the Federal award under which the property was acquired, the location, use and condition of the property, and any ultimate disposition data including the date of disposal and sale price of the property.
  - (2) A physical inventory of the property must be taken and the results reconciled with the property records at least once every two years.
  - (3) A control system must be developed to ensure adequate safeguards to prevent loss, damage, or theft of the property. Any loss, damage, or theft must be investigated.
  - (4) Adequate maintenance procedures must be developed to keep the property in good condition.
  - (5) If the non-Federal entity is authorized or required to sell the property, proper sales procedures must be established to ensure the highest possible return.
- (e) **Disposition.** When original or replacement equipment acquired under a Federal award is no longer needed for the original project or program or for other activities currently or previously supported by a Federal awarding agency, except as otherwise provided in Federal statutes, regulations, or Federal awarding agency disposition instructions, the non-Federal entity must request disposition instructions from the Federal awarding agency if required by the terms and conditions of the Federal award. Disposition of the equipment will be made as follows, in accordance with Federal awarding agency disposition instructions:

- (1) Items of equipment with a current per unit fair market value of \$5,000 or less may be retained, sold or otherwise disposed of with no further responsibility to the Federal awarding agency.
- (2) Except as provided in § 200.312(b), or if the Federal awarding agency fails to provide requested disposition instructions within 120 days, items of equipment with a current per-unit fair market value in excess of \$5,000 may be retained by the non-Federal entity or sold. The Federal awarding agency is entitled to an amount calculated by multiplying the current market value or proceeds from sale by the Federal awarding agency's percentage of participation in the cost of the original purchase. If the equipment is sold, the Federal awarding agency may permit the non-Federal entity to deduct and retain from the Federal share \$500 or ten percent of the proceeds, whichever is less, for its selling and handling expenses.
- (3) The non-Federal entity may transfer title to the property to the Federal Government or to an eligible third party provided that, in such cases, the non-Federal entity must be entitled to compensation for its attributable percentage of the current fair market value of the property.
- (4) In cases where a non-Federal entity fails to take appropriate disposition actions, the Federal awarding agency may direct the non-Federal entity to take disposition actions.

### § 200.314 Supplies.

See also § 200.453.

- (a) Title to supplies will vest in the non-Federal entity upon acquisition. If there is a residual inventory of unused supplies exceeding \$5,000 in total aggregate value upon termination or completion of the project or program and the supplies are not needed for any other Federal award, the non-Federal entity must retain the supplies for use on other activities or sell them, but must, in either case, compensate the Federal Government for its share. The amount of compensation must be computed in the same manner as for equipment. See § 200.313 (e)(2) for the calculation methodology.
- (b) As long as the Federal Government retains an interest in the supplies, the non-Federal entity must not use supplies acquired under a Federal award to provide services to other organizations for a fee that is less than private companies charge for equivalent services, unless specifically authorized by Federal statute.

### § 200.315 Intangible property.

- (a) Title to intangible property (see definition for *Intangible property* in § 200.1) acquired under a Federal award vests upon acquisition in the non-Federal entity. The non-Federal entity must use that property for the originally-authorized purpose, and must not encumber the property without approval of the Federal awarding agency. When no longer needed for the originally authorized purpose, disposition of the intangible property must occur in accordance with the provisions in § 200.313(e).
- (b) The non-Federal entity may copyright any work that is subject to copyright and was developed, or for which ownership was acquired, under a Federal award. The Federal awarding agency reserves a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so.
- (c) The non-Federal entity is subject to applicable regulations governing patents and inventions, including governmentwide regulations issued by the Department of Commerce at 37 CFR part 401, "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Awards, Contracts and Cooperative Agreements."
- (d) The Federal Government has the right to:
  - (1) Obtain, reproduce, publish, or otherwise use the data produced under a Federal award; and
  - (2) Authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes.
- (e)
  - (1) In response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under a Federal award that were used by the Federal Government in developing an agency action that has the force and effect of law, the Federal awarding agency must request, and the non-Federal entity must provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA. If the Federal awarding agency obtains the research data solely in response to a FOIA request, the Federal awarding agency may charge the requester a reasonable fee equaling the full

incremental cost of obtaining the research data. This fee should reflect costs incurred by the Federal agency and the non-Federal entity. This fee is in addition to any fees the Federal awarding agency may assess under the FOIA (5 U.S.C. 552(a)(4)(A)).

- (2) Published research findings means when:
- (i) Research findings are published in a peer-reviewed scientific or technical journal; or
  - (ii) A Federal agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law. "Used by the Federal Government in developing an agency action that has the force and effect of law" is defined as when an agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law.
- (3) Research data means the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: Preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This "recorded" material excludes physical objects (e.g., laboratory samples). Research data also do not include:
- (i) Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and
  - (ii) Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.

### **§ 200.316 Property trust relationship.**

Real property, equipment, and intangible property, that are acquired or improved with a Federal award must be held in trust by the non-Federal entity as trustee for the beneficiaries of the project or program under which the property was acquired or improved. The Federal awarding agency may require the non-Federal entity to record liens or other appropriate notices of record to indicate that personal or real property has been acquired or improved with a Federal award and that use and disposition conditions apply to the property.

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## PROCUREMENT STANDARDS

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### **§ 200.317 Procurements by states.**

When procuring property and services under a Federal award, a State must follow the same policies and procedures it uses for procurements from its non-Federal funds. The State will comply with §§ 200.321, 200.322, and 200.323 and ensure that every purchase order or other contract includes any clauses required by § 200.327. All other non-Federal entities, including subrecipients of a State, must follow the procurement standards in §§ 200.318 through 200.327.

### **§ 200.318 General procurement standards.**

- (a) The non-Federal entity must have and use documented procurement procedures, consistent with State, local, and tribal laws and regulations and the standards of this section, for the acquisition of property or services required under a Federal award or subaward. The non-Federal entity's documented procurement procedures must conform to the procurement standards identified in §§ 200.317 through 200.327.
- (b) Non-Federal entities must maintain oversight to ensure that contractors perform in accordance with the terms, conditions, and specifications of their contracts or purchase orders.
- (c)
  - (1) The non-Federal entity must maintain written standards of conduct covering conflicts of interest and governing the actions of its employees engaged in the selection, award and administration of contracts. No employee, officer, or agent may participate in the selection, award, or administration of a contract supported by a Federal award if he or she has a real or apparent conflict of interest. Such a conflict of interest would arise when the employee, officer, or agent, any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of the parties indicated herein, has a financial or other interest in or a tangible personal benefit from a firm considered for a contract. The officers, employees, and agents of the non-Federal entity may neither solicit nor accept gratuities, favors, or anything of monetary value from contractors or parties to subcontracts. However,

non-Federal entities may set standards for situations in which the financial interest is not substantial or the gift is an unsolicited item of nominal value. The standards of conduct must provide for disciplinary actions to be applied for violations of such standards by officers, employees, or agents of the non-Federal entity.

- (2) If the non-Federal entity has a parent, affiliate, or subsidiary organization that is not a State, local government, or Indian tribe, the non-Federal entity must also maintain written standards of conduct covering organizational conflicts of interest. Organizational conflicts of interest means that because of relationships with a parent company, affiliate, or subsidiary organization, the non-Federal entity is unable or appears to be unable to be impartial in conducting a procurement action involving a related organization.
- (d) The non-Federal entity's procedures must avoid acquisition of unnecessary or duplicative items. Consideration should be given to consolidating or breaking out procurements to obtain a more economical purchase. Where appropriate, an analysis will be made of lease versus purchase alternatives, and any other appropriate analysis to determine the most economical approach.
- (e) To foster greater economy and efficiency, and in accordance with efforts to promote cost-effective use of shared services across the Federal Government, the non-Federal entity is encouraged to enter into state and local intergovernmental agreements or inter-entity agreements where appropriate for procurement or use of common or shared goods and services. Competition requirements will be met with documented procurement actions using strategic sourcing, shared services, and other similar procurement arrangements.
- (f) The non-Federal entity is encouraged to use Federal excess and surplus property in lieu of purchasing new equipment and property whenever such use is feasible and reduces project costs.
- (g) The non-Federal entity is encouraged to use value engineering clauses in contracts for construction projects of sufficient size to offer reasonable opportunities for cost reductions. Value engineering is a systematic and creative analysis of each contract item or task to ensure that its essential function is provided at the overall lower cost.
- (h) The non-Federal entity must award contracts only to responsible contractors possessing the ability to perform successfully under the terms and conditions of a proposed procurement. Consideration will be given to such matters as contractor integrity, compliance with public policy, record of past performance, and financial and technical resources. See also § 200.214.
- (i) The non-Federal entity must maintain records sufficient to detail the history of procurement. These records will include, but are not necessarily limited to, the following: Rationale for the method of procurement, selection of contract type, contractor selection or rejection, and the basis for the contract price.
- (j)
  - (1) The non-Federal entity may use a time-and-materials type contract only after a determination that no other contract is suitable and if the contract includes a ceiling price that the contractor exceeds at its own risk. Time-and-materials type contract means a contract whose cost to a non-Federal entity is the sum of:
    - (i) The actual cost of materials; and
    - (ii) Direct labor hours charged at fixed hourly rates that reflect wages, general and administrative expenses, and profit.
  - (2) Since this formula generates an open-ended contract price, a time-and-materials contract provides no positive profit incentive to the contractor for cost control or labor efficiency. Therefore, each contract must set a ceiling price that the contractor exceeds at its own risk. Further, the non-Federal entity awarding such a contract must assert a high degree of oversight in order to obtain reasonable assurance that the contractor is using efficient methods and effective cost controls.
- (k) The non-Federal entity alone must be responsible, in accordance with good administrative practice and sound business judgment, for the settlement of all contractual and administrative issues arising out of procurements. These issues include, but are not limited to, source evaluation, protests, disputes, and claims. These standards do not relieve the non-Federal entity of any contractual responsibilities under its contracts. The Federal awarding agency will not substitute its judgment for that of the non-Federal entity unless the matter is primarily a Federal concern. Violations of law will be referred to the local, state, or Federal authority having proper jurisdiction.

[85 FR 49543, Aug. 13, 2020, as amended at 86 FR 10440, Feb. 22, 2021]

## § 200.319 Competition.

- (a) All procurement transactions for the acquisition of property or services required under a Federal award must be conducted in a manner providing full and open competition consistent with the standards of this section and § 200.320.
- (b) In order to ensure objective contractor performance and eliminate unfair competitive advantage, contractors that develop or draft specifications, requirements, statements of work, or invitations for bids or requests for proposals must be excluded from competing for such procurements. Some of the situations considered to be restrictive of competition include but are not limited to:
  - (1) Placing unreasonable requirements on firms in order for them to qualify to do business;
  - (2) Requiring unnecessary experience and excessive bonding;
  - (3) Noncompetitive pricing practices between firms or between affiliated companies;
  - (4) Noncompetitive contracts to consultants that are on retainer contracts;
  - (5) Organizational conflicts of interest;
  - (6) Specifying only a "brand name" product instead of allowing "an equal" product to be offered and describing the performance or other relevant requirements of the procurement; and
  - (7) Any arbitrary action in the procurement process.
- (c) The non-Federal entity must conduct procurements in a manner that prohibits the use of statutorily or administratively imposed state, local, or tribal geographical preferences in the evaluation of bids or proposals, except in those cases where applicable Federal statutes expressly mandate or encourage geographic preference. Nothing in this section preempts state licensing laws. When contracting for architectural and engineering (A/E) services, geographic location may be a selection criterion provided its application leaves an appropriate number of qualified firms, given the nature and size of the project, to compete for the contract.
- (d) The non-Federal entity must have written procedures for procurement transactions. These procedures must ensure that all solicitations:
  - (1) Incorporate a clear and accurate description of the technical requirements for the material, product, or service to be procured. Such description must not, in competitive procurements, contain features which unduly restrict competition. The description may include a statement of the qualitative nature of the material, product or service to be procured and, when necessary, must set forth those minimum essential characteristics and standards to which it must conform if it is to satisfy its intended use. Detailed product specifications should be avoided if at all possible. When it is impractical or uneconomical to make a clear and accurate description of the technical requirements, a "brand name or equivalent" description may be used as a means to define the performance or other salient requirements of procurement. The specific features of the named brand which must be met by offers must be clearly stated; and
  - (2) Identify all requirements which the offerors must fulfill and all other factors to be used in evaluating bids or proposals.
- (e) The non-Federal entity must ensure that all prequalified lists of persons, firms, or products which are used in acquiring goods and services are current and include enough qualified sources to ensure maximum open and free competition. Also, the non-Federal entity must not preclude potential bidders from qualifying during the solicitation period.
- (f) Noncompetitive procurements can only be awarded in accordance with § 200.320(c).

### **§ 200.320 Methods of procurement to be followed.**

The non-Federal entity must have and use documented procurement procedures, consistent with the standards of this section and §§ 200.317, 200.318, and 200.319 for any of the following methods of procurement used for the acquisition of property or services required under a Federal award or sub-award.

- (a) **Informal procurement methods.** When the value of the procurement for property or services under a Federal award does not exceed the *simplified acquisition threshold (SAT)*, as defined in § 200.1, or a lower threshold established by a non-Federal entity, formal procurement methods are not required. The non-Federal entity may use informal procurement methods to expedite the completion of its transactions and minimize the associated administrative burden and cost. The informal methods used for procurement of property or services at or below the SAT include:
  - (1) **Micro-purchases** -



- (i) **Distribution.** The acquisition of supplies or services, the aggregate dollar amount of which does not exceed the micro-purchase threshold (See the definition of *micro-purchase* in § 200.1). To the maximum extent practicable, the non-Federal entity should distribute micro-purchases equitably among qualified suppliers.
  - (ii) **Micro-purchase awards.** Micro-purchases may be awarded without soliciting competitive price or rate quotations if the non-Federal entity considers the price to be reasonable based on research, experience, purchase history or other information and documents it files accordingly. Purchase cards can be used for micro-purchases if procedures are documented and approved by the non-Federal entity.
  - (iii) **Micro-purchase thresholds.** The non-Federal entity is responsible for determining and documenting an appropriate micro-purchase threshold based on internal controls, an evaluation of risk, and its documented procurement procedures. The micro-purchase threshold used by the non-Federal entity must be authorized or not prohibited under State, local, or tribal laws or regulations. Non-Federal entities may establish a threshold higher than the Federal threshold established in the Federal Acquisition Regulations (FAR) in accordance with paragraphs (a)(1)(iv) and (v) of this section.
  - (iv) **Non-Federal entity increase to the micro-purchase threshold up to \$50,000.** Non-Federal entities may establish a threshold higher than the micro-purchase threshold identified in the FAR in accordance with the requirements of this section. The non-Federal entity may self-certify a threshold up to \$50,000 on an annual basis and must maintain documentation to be made available to the Federal awarding agency and auditors in accordance with § 200.334. The self-certification must include a justification, clear identification of the threshold, and supporting documentation of any of the following:
    - (A) A qualification as a low-risk auditee, in accordance with the criteria in § 200.520 for the most recent audit;
    - (B) An annual internal institutional risk assessment to identify, mitigate, and manage financial risks; or,
    - (C) For public institutions, a higher threshold consistent with State law.
  - (v) **Non-Federal entity increase to the micro-purchase threshold over \$50,000.** Micro-purchase thresholds higher than \$50,000 must be approved by the cognizant agency for indirect costs. The non-federal entity must submit a request with the requirements included in paragraph (a)(1)(iv) of this section. The increased threshold is valid until there is a change in status in which the justification was approved.
- (2) **Small purchases -**
- (i) **Small purchase procedures.** The acquisition of property or services, the aggregate dollar amount of which is higher than the micro-purchase threshold but does not exceed the simplified acquisition threshold. If small purchase procedures are used, price or rate quotations must be obtained from an adequate number of qualified sources as determined appropriate by the non-Federal entity.
  - (ii) **Simplified acquisition thresholds.** The non-Federal entity is responsible for determining an appropriate simplified acquisition threshold based on internal controls, an evaluation of risk and its documented procurement procedures which must not exceed the threshold established in the FAR. When applicable, a lower simplified acquisition threshold used by the non-Federal entity must be authorized or not prohibited under State, local, or tribal laws or regulations.
- (b) **Formal procurement methods.** When the value of the procurement for property or services under a Federal financial assistance award exceeds the SAT, or a lower threshold established by a non-Federal entity, formal procurement methods are required. Formal procurement methods require following documented procedures. Formal procurement methods also require public advertising unless a non-competitive procurement can be used in accordance with § 200.319 or paragraph (c) of this section. The following formal methods of procurement are used for procurement of property or services above the simplified acquisition threshold or a value below the simplified acquisition threshold the non-Federal entity determines to be appropriate:
- (1) **Sealed bids.** A procurement method in which bids are publicly solicited and a firm fixed-price contract (lump sum or unit price) is awarded to the responsible bidder whose bid, conforming with all the material terms and conditions of the invitation for bids, is the lowest in price. The sealed bids method is the preferred method for procuring construction, if the conditions.
    - (i) In order for sealed bidding to be feasible, the following conditions should be present:
      - (A) A complete, adequate, and realistic specification or purchase description is available;
      - (B) Two or more responsible bidders are willing and able to compete effectively for the business; and
      - (C) The procurement lends itself to a firm fixed price contract and the selection of the successful bidder can be made principally on the basis of price.

- (ii) If sealed bids are used, the following requirements apply:
  - (A) Bids must be solicited from an adequate number of qualified sources, providing them sufficient response time prior to the date set for opening the bids, for local, and tribal governments, the invitation for bids must be publicly advertised;
  - (B) The invitation for bids, which will include any specifications and pertinent attachments, must define the items or services in order for the bidder to properly respond;
  - (C) All bids will be opened at the time and place prescribed in the invitation for bids, and for local and tribal governments, the bids must be opened publicly;
  - (D) A firm fixed price contract award will be made in writing to the lowest responsive and responsible bidder. Where specified in bidding documents, factors such as discounts, transportation cost, and life cycle costs must be considered in determining which bid is lowest. Payment discounts will only be used to determine the low bid when prior experience indicates that such discounts are usually taken advantage of; and
  - (E) Any or all bids may be rejected if there is a sound documented reason.
- (2) **Proposals.** A procurement method in which either a fixed price or cost-reimbursement type contract is awarded. Proposals are generally used when conditions are not appropriate for the use of sealed bids. They are awarded in accordance with the following requirements:
  - (i) Requests for proposals must be publicized and identify all evaluation factors and their relative importance. Proposals must be solicited from an adequate number of qualified offerors. Any response to publicized requests for proposals must be considered to the maximum extent practical;
  - (ii) The non-Federal entity must have a written method for conducting technical evaluations of the proposals received and making selections;
  - (iii) Contracts must be awarded to the responsible offeror whose proposal is most advantageous to the non-Federal entity, with price and other factors considered; and
  - (iv) The non-Federal entity may use competitive proposal procedures for qualifications-based procurement of architectural/engineering (A/E) professional services whereby offeror's qualifications are evaluated and the most qualified offeror is selected, subject to negotiation of fair and reasonable compensation. The method, where price is not used as a selection factor, can only be used in procurement of A/E professional services. It cannot be used to purchase other types of services though A/E firms that are a potential source to perform the proposed effort.
- (c) **Noncompetitive procurement.** There are specific circumstances in which noncompetitive procurement can be used. Noncompetitive procurement can only be awarded if one or more of the following circumstances apply:
  - (1) The acquisition of property or services, the aggregate dollar amount of which does not exceed the micro-purchase threshold (see paragraph (a)(1) of this section);
  - (2) The item is available only from a single source;
  - (3) The public exigency or emergency for the requirement will not permit a delay resulting from publicizing a competitive solicitation;
  - (4) The Federal awarding agency or pass-through entity expressly authorizes a noncompetitive procurement in response to a written request from the non-Federal entity; or
  - (5) After solicitation of a number of sources, competition is determined inadequate.

### **§ 200.321 Contracting with small and minority businesses, women's business enterprises, and labor surplus area firms.**

- (a) The non-Federal entity must take all necessary affirmative steps to assure that minority businesses, women's business enterprises, and labor surplus area firms are used when possible.
- (b) Affirmative steps must include:
  - (1) Placing qualified small and minority businesses and women's business enterprises on solicitation lists;

- (2) Assuring that small and minority businesses, and women's business enterprises are solicited whenever they are potential sources;
- (3) Dividing total requirements, when economically feasible, into smaller tasks or quantities to permit maximum participation by small and minority businesses, and women's business enterprises;
- (4) Establishing delivery schedules, where the requirement permits, which encourage participation by small and minority businesses, and women's business enterprises;
- (5) Using the services and assistance, as appropriate, of such organizations as the Small Business Administration and the Minority Business Development Agency of the Department of Commerce; and
- (6) Requiring the prime contractor, if subcontracts are to be let, to take the affirmative steps listed in paragraphs (b)(1) through (5) of this section.

### **§ 200.322 Domestic preferences for procurements.**

- (a) As appropriate and to the extent consistent with law, the non-Federal entity should, to the greatest extent practicable under a Federal award, provide a preference for the purchase, acquisition, or use of goods, products, or materials produced in the United States (including but not limited to iron, aluminum, steel, cement, and other manufactured products). The requirements of this section must be included in all subawards including all contracts and purchase orders for work or products under this award.
- (b) For purposes of this section:
  - (1) "Produced in the United States" means, for iron and steel products, that all manufacturing processes, from the initial melting stage through the application of coatings, occurred in the United States.
  - (2) "Manufactured products" means items and construction materials composed in whole or in part of non-ferrous metals such as aluminum; plastics and polymer-based products such as polyvinyl chloride pipe; aggregates such as concrete; glass, including optical fiber; and lumber.

### **§ 200.323 Procurement of recovered materials.**

A non-Federal entity that is a state agency or agency of a political subdivision of a state and its contractors must comply with section 6002 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act. The requirements of Section 6002 include procuring only items designated in guidelines of the Environmental Protection Agency (EPA) at 40 CFR part 247 that contain the highest percentage of recovered materials practicable, consistent with maintaining a satisfactory level of competition, where the purchase price of the item exceeds \$10,000 or the value of the quantity acquired during the preceding fiscal year exceeded \$10,000; procuring solid waste management services in a manner that maximizes energy and resource recovery; and establishing an affirmative procurement program for procurement of recovered materials identified in the EPA guidelines.

### **§ 200.324 Contract cost and price.**

- (a) The non-Federal entity must perform a cost or price analysis in connection with every procurement action in excess of the Simplified Acquisition Threshold including contract modifications. The method and degree of analysis is dependent on the facts surrounding the particular procurement situation, but as a starting point, the non-Federal entity must make independent estimates before receiving bids or proposals.
- (b) The non-Federal entity must negotiate profit as a separate element of the price for each contract in which there is no price competition and in all cases where cost analysis is performed. To establish a fair and reasonable profit, consideration must be given to the complexity of the work to be performed, the risk borne by the contractor, the contractor's investment, the amount of subcontracting, the quality of its record of past performance, and industry profit rates in the surrounding geographical area for similar work.
- (c) Costs or prices based on estimated costs for contracts under the Federal award are allowable only to the extent that costs incurred or cost estimates included in negotiated prices would be allowable for the non-Federal entity under subpart E of this part. The non-Federal entity may reference its own cost principles that comply with the Federal cost principles.
- (d) The cost plus a percentage of cost and percentage of construction cost methods of contracting must not be used.

### **§ 200.325 Federal awarding agency or pass-through entity review.**

- (a) The non-Federal entity must make available, upon request of the Federal awarding agency or pass-through entity, technical specifications on proposed procurements where the Federal awarding agency or pass-through entity believes such review is needed to ensure that the item or service specified is the one being proposed for acquisition. This review generally will take place prior to the time the specification is incorporated into a solicitation document. However, if the non-Federal entity desires to have the review accomplished after a solicitation has been developed, the Federal awarding agency or pass-through entity may still review the specifications, with such review usually limited to the technical aspects of the proposed purchase.
- (b) The non-Federal entity must make available upon request, for the Federal awarding agency or pass-through entity pre-procurement review, procurement documents, such as requests for proposals or invitations for bids, or independent cost estimates, when:
  - (1) The non-Federal entity's procurement procedures or operation fails to comply with the procurement standards in this part;
  - (2) The procurement is expected to exceed the Simplified Acquisition Threshold and is to be awarded without competition or only one bid or offer is received in response to a solicitation;
  - (3) The procurement, which is expected to exceed the Simplified Acquisition Threshold, specifies a "brand name" product;
  - (4) The proposed contract is more than the Simplified Acquisition Threshold and is to be awarded to other than the apparent low bidder under a sealed bid procurement; or
  - (5) A proposed contract modification changes the scope of a contract or increases the contract amount by more than the Simplified Acquisition Threshold.
- (c) The non-Federal entity is exempt from the pre-procurement review in paragraph (b) of this section if the Federal awarding agency or pass-through entity determines that its procurement systems comply with the standards of this part.
  - (1) The non-Federal entity may request that its procurement system be reviewed by the Federal awarding agency or pass-through entity to determine whether its system meets these standards in order for its system to be certified. Generally, these reviews must occur where there is continuous high-dollar funding, and third-party contracts are awarded on a regular basis;
  - (2) The non-Federal entity may self-certify its procurement system. Such self-certification must not limit the Federal awarding agency's right to survey the system. Under a self-certification procedure, the Federal awarding agency may rely on written assurances from the non-Federal entity that it is complying with these standards. The non-Federal entity must cite specific policies, procedures, regulations, or standards as being in compliance with these requirements and have its system available for review.

### **§ 200.326 Bonding requirements.**

For construction or facility improvement contracts or subcontracts exceeding the Simplified Acquisition Threshold, the Federal awarding agency or pass-through entity may accept the bonding policy and requirements of the non-Federal entity provided that the Federal awarding agency or pass-through entity has made a determination that the Federal interest is adequately protected. If such a determination has not been made, the minimum requirements must be as follows:

- (a) A bid guarantee from each bidder equivalent to five percent of the bid price. The "bid guarantee" must consist of a firm commitment such as a bid bond, certified check, or other negotiable instrument accompanying a bid as assurance that the bidder will, upon acceptance of the bid, execute such contractual documents as may be required within the time specified.
- (b) A performance bond on the part of the contractor for 100 percent of the contract price. A "performance bond" is one executed in connection with a contract to secure fulfillment of all the contractor's requirements under such contract.
- (c) A payment bond on the part of the contractor for 100 percent of the contract price. A "payment bond" is one executed in connection with a contract to assure payment as required by law of all persons supplying labor and material in the execution of the work provided for in the contract.

### **§ 200.327 Contract provisions.**

The non-Federal entity's contracts must contain the applicable provisions described in appendix II to this part.

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## PERFORMANCE AND FINANCIAL MONITORING AND REPORTING

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### § 200.328 Financial reporting.

Unless otherwise approved by OMB, the Federal awarding agency must solicit only the OMB-approved governmentwide data elements for collection of financial information (at time of publication the Federal Financial Report or such future, OMB-approved, governmentwide data elements available from the OMB-designated standards lead. This information must be collected with the frequency required by the terms and conditions of the Federal award, but no less frequently than annually nor more frequently than quarterly except in unusual circumstances, for example where more frequent reporting is necessary for the effective monitoring of the Federal award or could significantly affect program outcomes, and preferably in coordination with performance reporting. The Federal awarding agency must use OMB-approved common information collections, as applicable, when providing financial and performance reporting information.

### § 200.329 Monitoring and reporting program performance.

- (a) **Monitoring by the non-Federal entity.** The non-Federal entity is responsible for oversight of the operations of the Federal award supported activities. The non-Federal entity must monitor its activities under Federal awards to assure compliance with applicable Federal requirements and performance expectations are being achieved. Monitoring by the non-Federal entity must cover each program, function or activity. See also § 200.332.
- (b) **Reporting program performance.** The Federal awarding agency must use OMB-approved common information collections, as applicable, when providing financial and performance reporting information. As appropriate and in accordance with above mentioned information collections, the Federal awarding agency must require the recipient to relate financial data and accomplishments to performance goals and objectives of the Federal award. Also, in accordance with above mentioned common information collections, and when required by the terms and conditions of the Federal award, recipients must provide cost information to demonstrate cost effective practices (e.g., through unit cost data). In some instances (e.g., discretionary research awards), this will be limited to the requirement to submit technical performance reports (to be evaluated in accordance with Federal awarding agency policy). Reporting requirements must be clearly articulated such that, where appropriate, performance during the execution of the Federal award has a standard against which non-Federal entity performance can be measured.
- (c) **Non-construction performance reports.** The Federal awarding agency must use standard, governmentwide OMB-approved data elements for collection of performance information including performance progress reports, Research Performance Progress Reports.
  - (1) The non-Federal entity must submit performance reports at the interval required by the Federal awarding agency or pass-through entity to best inform improvements in program outcomes and productivity. Intervals must be no less frequent than annually nor more frequent than quarterly except in unusual circumstances, for example where more frequent reporting is necessary for the effective monitoring of the Federal award or could significantly affect program outcomes. Reports submitted annually by the non-Federal entity and/or pass-through entity must be due no later than 90 calendar days after the reporting period. Reports submitted quarterly or semiannually must be due no later than 30 calendar days after the reporting period. Alternatively, the Federal awarding agency or pass-through entity may require annual reports before the anniversary dates of multiple year Federal awards. The final performance report submitted by the non-Federal entity and/or pass-through entity must be due no later than 120 calendar days after the period of performance end date. A subrecipient must submit to the pass-through entity, no later than 90 calendar days after the period of performance end date, all final performance reports as required by the terms and conditions of the Federal award. See also § 200.344. If a justified request is submitted by a non-Federal entity, the Federal agency may extend the due date for any performance report.
  - (2) As appropriate in accordance with above mentioned performance reporting, these reports will contain, for each Federal award, brief information on the following unless other data elements are approved by OMB in the agency information collection request:
    - (i) A comparison of actual accomplishments to the objectives of the Federal award established for the period. Where the accomplishments of the Federal award can be quantified, a computation of the cost (for example, related to units of accomplishment) may be required if that information will be useful. Where performance trend data and analysis would be informative to the Federal awarding agency program, the Federal awarding agency should include this as a performance reporting requirement.
    - (ii) The reasons why established goals were not met, if appropriate.
    - (iii) Additional pertinent information including, when appropriate, analysis and explanation of cost overruns or high unit costs.

- (d) **Construction performance reports.** For the most part, onsite technical inspections and certified percentage of completion data are relied on heavily by Federal awarding agencies and pass-through entities to monitor progress under Federal awards and subawards for construction. The Federal awarding agency may require additional performance reports only when considered necessary.
- (e) **Significant developments.** Events may occur between the scheduled performance reporting dates that have significant impact upon the supported activity. In such cases, the non-Federal entity must inform the Federal awarding agency or pass-through entity as soon as the following types of conditions become known:
  - (1) Problems, delays, or adverse conditions which will materially impair the ability to meet the objective of the Federal award. This disclosure must include a statement of the action taken, or contemplated, and any assistance needed to resolve the situation.
  - (2) Favorable developments which enable meeting time schedules and objectives sooner or at less cost than anticipated or producing more or different beneficial results than originally planned.
- (f) **Site visits.** The Federal awarding agency may make site visits as warranted by program needs.
- (g) **Performance report requirement waiver.** The Federal awarding agency may waive any performance report required by this part if not needed.

### § 200.330 Reporting on real property.

The Federal awarding agency or pass-through entity must require a non-Federal entity to submit reports at least annually on the status of real property in which the Federal Government retains an interest, unless the Federal interest in the real property extends 15 years or longer. In those instances where the Federal interest attached is for a period of 15 years or more, the Federal awarding agency or pass-through entity, at its option, may require the non-Federal entity to report at various multi-year frequencies (e.g., every two years or every three years, not to exceed a five-year reporting period; or a Federal awarding agency or pass-through entity may require annual reporting for the first three years of a Federal award and thereafter require reporting every five years).

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## SUBRECIPIENT MONITORING AND MANAGEMENT

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### § 200.331 Subrecipient and contractor determinations.

The non-Federal entity may concurrently receive Federal awards as a recipient, a subrecipient, and a contractor, depending on the substance of its agreements with Federal awarding agencies and pass-through entities. Therefore, a pass-through entity must make case-by-case determinations whether each agreement it makes for the disbursement of Federal program funds casts the party receiving the funds in the role of a subrecipient or a contractor. The Federal awarding agency may supply and require recipients to comply with additional guidance to support these determinations provided such guidance does not conflict with this section.

- (a) **Subrecipients.** A subaward is for the purpose of carrying out a portion of a Federal award and creates a Federal assistance relationship with the subrecipient. See definition for *Subaward* in § 200.1 of this part. Characteristics which support the classification of the non-Federal entity as a subrecipient include when the non-Federal entity:
  - (1) Determines who is eligible to receive what Federal assistance;
  - (2) Has its performance measured in relation to whether objectives of a Federal program were met;
  - (3) Has responsibility for programmatic decision-making;
  - (4) Is responsible for adherence to applicable Federal program requirements specified in the Federal award; and
  - (5) In accordance with its agreement, uses the Federal funds to carry out a program for a public purpose specified in authorizing statute, as opposed to providing goods or services for the benefit of the pass-through entity.
- (b) **Contractors.** A contract is for the purpose of obtaining goods and services for the non-Federal entity's own use and creates a procurement relationship with the contractor. See the definition of *contract* in § 200.1 of this part. Characteristics indicative of a procurement relationship between the non-Federal entity and a contractor are when the contractor:
  - (1) Provides the goods and services within normal business operations;
  - (2) Provides similar goods or services to many different purchasers;
  - (3) Normally operates in a competitive environment;

- (4) Provides goods or services that are ancillary to the operation of the Federal program; and
  - (5) Is not subject to compliance requirements of the Federal program as a result of the agreement, though similar requirements may apply for other reasons.
- (c) **Use of judgment in making determination.** In determining whether an agreement between a pass-through entity and another non-Federal entity casts the latter as a subrecipient or a contractor, the substance of the relationship is more important than the form of the agreement. All of the characteristics listed above may not be present in all cases, and the pass-through entity must use judgment in classifying each agreement as a subaward or a procurement contract.

### § 200.332 Requirements for pass-through entities.

All pass-through entities must:

- (a) Ensure that every subaward is clearly identified to the subrecipient as a subaward and includes the following information at the time of the subaward and if any of these data elements change, include the changes in subsequent subaward modification. When some of this information is not available, the pass-through entity must provide the best information available to describe the Federal award and subaward. Required information includes:
  - (1) Federal award identification.
    - (i) Subrecipient name (which must match the name associated with its unique entity identifier);
    - (ii) Subrecipient's unique entity identifier;
    - (iii) Federal Award Identification Number (FAIN);
    - (iv) Federal Award Date (see the definition of *Federal award date* in § 200.1 of this part) of award to the recipient by the Federal agency;
    - (v) Subaward Period of Performance Start and End Date;
    - (vi) Subaward Budget Period Start and End Date;
    - (vii) Amount of Federal Funds Obligated by this action by the pass-through entity to the subrecipient;
    - (viii) Total Amount of Federal Funds Obligated to the subrecipient by the pass-through entity including the current financial obligation;
    - (ix) Total Amount of the Federal Award committed to the subrecipient by the pass-through entity;
    - (x) Federal award project description, as required to be responsive to the Federal Funding Accountability and Transparency Act (FFATA);
    - (xi) Name of Federal awarding agency, pass-through entity, and contact information for awarding official of the Pass-through entity;
    - (xii) Assistance Listings number and Title; the pass-through entity must identify the dollar amount made available under each Federal award and the Assistance Listings Number at time of disbursement;
    - (xiii) Identification of whether the award is R&D; and
    - (xiv) Indirect cost rate for the Federal award (including if the de minimis rate is charged) per § 200.414.
  - (2) All requirements imposed by the pass-through entity on the subrecipient so that the Federal award is used in accordance with Federal statutes, regulations and the terms and conditions of the Federal award;
  - (3) Any additional requirements that the pass-through entity imposes on the subrecipient in order for the pass-through entity to meet its own responsibility to the Federal awarding agency including identification of any required financial and performance reports;
  - (4)
    - (i) An approved federally recognized indirect cost rate negotiated between the subrecipient and the Federal Government. If no approved rate exists, the pass-through entity must determine the appropriate rate in collaboration with the subrecipient, which is either:
      - (A) The negotiated indirect cost rate between the pass-through entity and the subrecipient; which can be based on a prior negotiated rate between a different PTE and the same subrecipient. If basing the rate on a previously negotiated rate, the pass-through entity is not required to collect information justifying this

rate, but may elect to do so;

- (B) The de minimis indirect cost rate.
  - (ii) The pass-through entity must not require use of a de minimis indirect cost rate if the subrecipient has a Federally approved rate. Subrecipients can elect to use the cost allocation method to account for indirect costs in accordance with § 200.405(d).
- (5) A requirement that the subrecipient permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements as necessary for the pass-through entity to meet the requirements of this part; and
- (6) Appropriate terms and conditions concerning closeout of the subaward.
- (b) Evaluate each subrecipient's risk of noncompliance with Federal statutes, regulations, and the terms and conditions of the subaward for purposes of determining the appropriate subrecipient monitoring described in paragraphs (d) and (e) of this section, which may include consideration of such factors as:
  - (1) The subrecipient's prior experience with the same or similar subawards;
  - (2) The results of previous audits including whether or not the subrecipient receives a Single Audit in accordance with Subpart F of this part, and the extent to which the same or similar subaward has been audited as a major program;
  - (3) Whether the subrecipient has new personnel or new or substantially changed systems; and
  - (4) The extent and results of Federal awarding agency monitoring (e.g., if the subrecipient also receives Federal awards directly from a Federal awarding agency).
- (c) Consider imposing specific subaward conditions upon a subrecipient if appropriate as described in § 200.208.
- (d) Monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward; and that subaward performance goals are achieved. Pass-through entity monitoring of the subrecipient must include:
  - (1) Reviewing financial and performance reports required by the pass-through entity.
  - (2) Following-up and ensuring that the subrecipient takes timely and appropriate action on all deficiencies pertaining to the Federal award provided to the subrecipient from the pass-through entity detected through audits, on-site reviews, and written confirmation from the subrecipient, highlighting the status of actions planned or taken to address Single Audit findings related to the particular subaward.
  - (3) Issuing a management decision for applicable audit findings pertaining only to the Federal award provided to the subrecipient from the pass-through entity as required by § 200.521.
  - (4) The pass-through entity is responsible for resolving audit findings specifically related to the subaward and not responsible for resolving crosscutting findings. If a subrecipient has a current Single Audit report posted in the Federal Audit Clearinghouse and has not otherwise been excluded from receipt of Federal funding (e.g., has been debarred or suspended), the pass-through entity may rely on the subrecipient's cognizant audit agency or cognizant oversight agency to perform audit follow-up and make management decisions related to cross-cutting findings in accordance with section § 200.513(a)(3)(vii). Such reliance does not eliminate the responsibility of the pass-through entity to issue subawards that conform to agency and award-specific requirements, to manage risk through ongoing subaward monitoring, and to monitor the status of the findings that are specifically related to the subaward.
- (e) Depending upon the pass-through entity's assessment of risk posed by the subrecipient (as described in paragraph (b) of this section), the following monitoring tools may be useful for the pass-through entity to ensure proper accountability and compliance with program requirements and achievement of performance goals:
  - (1) Providing subrecipients with training and technical assistance on program-related matters; and
  - (2) Performing on-site reviews of the subrecipient's program operations;
  - (3) Arranging for agreed-upon-procedures engagements as described in § 200.425.
- (f) Verify that every subrecipient is audited as required by Subpart F of this part when it is expected that the subrecipient's Federal awards expended during the respective fiscal year equaled or exceeded the threshold set forth in § 200.501.
- (g) Consider whether the results of the subrecipient's audits, on-site reviews, or other monitoring indicate conditions that necessitate adjustments to the pass-through entity's own records.



- (h) Consider taking enforcement action against noncompliant subrecipients as described in § 200.339 of this part and in program regulations.

[85 FR 49543, Aug. 13, 2020, as amended at 86 FR 10440, Feb. 22, 2021]

### § 200.333 Fixed amount subawards.

With prior written approval from the Federal awarding agency, a pass-through entity may provide subawards based on fixed amounts up to the Simplified Acquisition Threshold, provided that the subawards meet the requirements for fixed amount awards in § 200.201.

## RECORD RETENTION AND ACCESS

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### § 200.334 Retention requirements for records.

Financial records, supporting documents, statistical records, and all other non-Federal entity records pertinent to a Federal award must be retained for a period of three years from the date of submission of the final expenditure report or, for Federal awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report, respectively, as reported to the Federal awarding agency or pass-through entity in the case of a subrecipient. Federal awarding agencies and pass-through entities must not impose any other record retention requirements upon non-Federal entities. The only exceptions are the following:

- (a) If any litigation, claim, or audit is started before the expiration of the 3-year period, the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken.
- (b) When the non-Federal entity is notified in writing by the Federal awarding agency, cognizant agency for audit, oversight agency for audit, cognizant agency for indirect costs, or pass-through entity to extend the retention period.
- (c) Records for real property and equipment acquired with Federal funds must be retained for 3 years after final disposition.
- (d) When records are transferred to or maintained by the Federal awarding agency or pass-through entity, the 3-year retention requirement is not applicable to the non-Federal entity.
- (e) Records for program income transactions after the period of performance. In some cases recipients must report program income after the period of performance. Where there is such a requirement, the retention period for the records pertaining to the earning of the program income starts from the end of the non-Federal entity's fiscal year in which the program income is earned.
- (f) Indirect cost rate proposals and cost allocations plans. This paragraph applies to the following types of documents and their supporting records: Indirect cost rate computations or proposals, cost allocation plans, and any similar accounting computations of the rate at which a particular group of costs is chargeable (such as computer usage chargeback rates or composite fringe benefit rates).
  - (1) *If submitted for negotiation.* If the proposal, plan, or other computation is required to be submitted to the Federal Government (or to the pass-through entity) to form the basis for negotiation of the rate, then the 3-year retention period for its supporting records starts from the date of such submission.
  - (2) *If not submitted for negotiation.* If the proposal, plan, or other computation is not required to be submitted to the Federal Government (or to the pass-through entity) for negotiation purposes, then the 3-year retention period for the proposal, plan, or computation and its supporting records starts from the end of the fiscal year (or other accounting period) covered by the proposal, plan, or other computation.

### § 200.335 Requests for transfer of records.

The Federal awarding agency must request transfer of certain records to its custody from the non-Federal entity when it determines that the records possess long-term retention value. However, in order to avoid duplicate recordkeeping, the Federal awarding agency may make arrangements for the non-Federal entity to retain any records that are continuously needed for joint use.

### § 200.336 Methods for collection, transmission, and storage of information.

The Federal awarding agency and the non-Federal entity should, whenever practicable, collect, transmit, and store Federal award-related information in open and machine-readable formats rather than in closed formats or on paper in accordance with applicable legislative requirements. A machine-readable format is a format in a standard computer language (not English text) that can be read automatically by a web browser or computer system. The Federal awarding agency or pass-through entity must always provide or accept paper versions of Federal award-related information to and from the non-Federal entity upon request. If paper copies are submitted, the Federal awarding agency or pass-through entity must not require more than an original and two copies. When original records are electronic and cannot be altered, there is no need to create and retain paper copies. When original records are paper, electronic versions may be substituted through the use of duplication or other forms of electronic media provided that they are subject to periodic quality control reviews, provide reasonable safeguards against alteration, and remain readable.

### **§ 200.337 Access to records.**

- (a) **Records of non-Federal entities.** The Federal awarding agency, Inspectors General, the Comptroller General of the United States, and the pass-through entity, or any of their authorized representatives, must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts. The right also includes timely and reasonable access to the non-Federal entity's personnel for the purpose of interview and discussion related to such documents.
- (b) **Extraordinary and rare circumstances.** Only under extraordinary and rare circumstances would such access include review of the true name of victims of a crime. Routine monitoring cannot be considered extraordinary and rare circumstances that would necessitate access to this information. When access to the true name of victims of a crime is necessary, appropriate steps to protect this sensitive information must be taken by both the non-Federal entity and the Federal awarding agency. Any such access, other than under a court order or subpoena pursuant to a bona fide confidential investigation, must be approved by the head of the Federal awarding agency or delegate.
- (c) **Expiration of right of access.** The rights of access in this section are not limited to the required retention period but last as long as the records are retained. Federal awarding agencies and pass-through entities must not impose any other access requirements upon non-Federal entities.

### **§ 200.338 Restrictions on public access to records.**

No Federal awarding agency may place restrictions on the non-Federal entity that limit public access to the records of the non-Federal entity pertinent to a Federal award, except for protected personally identifiable information (PII) or when the Federal awarding agency can demonstrate that such records will be kept confidential and would have been exempted from disclosure pursuant to the Freedom of Information Act (5 U.S.C. 552) or controlled unclassified information pursuant to Executive Order 13556 if the records had belonged to the Federal awarding agency. The Freedom of Information Act (5 U.S.C. 552) (FOIA) does not apply to those records that remain under a non-Federal entity's control except as required under § 200.315. Unless required by Federal, state, local, and tribal statute, non-Federal entities are not required to permit public access to their records. The non-Federal entity's records provided to a Federal agency generally will be subject to FOIA and applicable exemptions.

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## REMEDIES FOR NONCOMPLIANCE

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### **§ 200.339 Remedies for noncompliance.**

If a non-Federal entity fails to comply with the U.S. Constitution, Federal statutes, regulations or the terms and conditions of a Federal award, the Federal awarding agency or pass-through entity may impose additional conditions, as described in § 200.208. If the Federal awarding agency or pass-through entity determines that noncompliance cannot be remedied by imposing additional conditions, the Federal awarding agency or pass-through entity may take one or more of the following actions, as appropriate in the circumstances:

- (a) Temporarily withhold cash payments pending correction of the deficiency by the non-Federal entity or more severe enforcement action by the Federal awarding agency or pass-through entity.
- (b) Disallow (that is, deny both use of funds and any applicable matching credit for) all or part of the cost of the activity or action not in compliance.
- (c) Wholly or partly suspend or terminate the Federal award.

- (d) Initiate suspension or debarment proceedings as authorized under 2 CFR part 180 and Federal awarding agency regulations (or in the case of a pass-through entity, recommend such a proceeding be initiated by a Federal awarding agency).
- (e) Withhold further Federal awards for the project or program.
- (f) Take other remedies that may be legally available.

### § 200.340 Termination.

- (a) The Federal award may be terminated in whole or in part as follows:
  - (1) By the Federal awarding agency or pass-through entity, if a non-Federal entity fails to comply with the terms and conditions of a Federal award;
  - (2) By the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities;
  - (3) By the Federal awarding agency or pass-through entity with the consent of the non-Federal entity, in which case the two parties must agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated;
  - (4) By the non-Federal entity upon sending to the Federal awarding agency or pass-through entity written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the Federal awarding agency or pass-through entity determines in the case of partial termination that the reduced or modified portion of the Federal award or subaward will not accomplish the purposes for which the Federal award was made, the Federal awarding agency or pass-through entity may terminate the Federal award in its entirety; or
  - (5) By the Federal awarding agency or pass-through entity pursuant to termination provisions included in the Federal award.
- (b) A Federal awarding agency should clearly and unambiguously specify termination provisions applicable to each Federal award, in applicable regulations or in the award, consistent with this section.
- (c) When a Federal awarding agency terminates a Federal award prior to the end of the period of performance due to the non-Federal entity's material failure to comply with the Federal award terms and conditions, the Federal awarding agency must report the termination to the OMB-designated integrity and performance system accessible through SAM (currently FAPIIS).
  - (1) The information required under paragraph (c) of this section is not to be reported to designated integrity and performance system until the non-Federal entity either -
    - (i) Has exhausted its opportunities to object or challenge the decision, see § 200.342; or
    - (ii) Has not, within 30 calendar days after being notified of the termination, informed the Federal awarding agency that it intends to appeal the Federal awarding agency's decision to terminate.
  - (2) If a Federal awarding agency, after entering information into the designated integrity and performance system about a termination, subsequently:
    - (i) Learns that any of that information is erroneous, the Federal awarding agency must correct the information in the system within three business days;
    - (ii) Obtains an update to that information that could be helpful to other Federal awarding agencies, the Federal awarding agency is strongly encouraged to amend the information in the system to incorporate the update in a timely way.
  - (3) Federal awarding agencies, must not post any information that will be made publicly available in the non-public segment of designated integrity and performance system that is covered by a disclosure exemption under the Freedom of Information Act. If the non-Federal entity asserts within seven calendar days to the Federal awarding agency who posted the information, that some of the information made publicly available is covered by a disclosure exemption under the Freedom of Information Act, the Federal awarding agency who posted the information must remove the posting within seven calendar days of receiving the assertion. Prior to reposting the releasable information, the Federal agency must resolve the issue in accordance with the agency's Freedom of Information Act procedures.

- (d) When a Federal award is terminated or partially terminated, both the Federal awarding agency or pass-through entity and the non-Federal entity remain responsible for compliance with the requirements in §§ 200.344 and 200.345.

### **§ 200.341 Notification of termination requirement.**

- (a) The Federal agency or pass-through entity must provide to the non-Federal entity a notice of termination.
- (b) If the Federal award is terminated for the non-Federal entity's material failure to comply with the U.S. Constitution, Federal statutes, regulations, or terms and conditions of the Federal award, the notification must state that -
- (1) The termination decision will be reported to the OMB-designated integrity and performance system accessible through SAM (currently FAPIIS);
  - (2) The information will be available in the OMB-designated integrity and performance system for a period of five years from the date of the termination, then archived;
  - (3) Federal awarding agencies that consider making a Federal award to the non-Federal entity during that five year period must consider that information in judging whether the non-Federal entity is qualified to receive the Federal award, when the Federal share of the Federal award is expected to exceed the simplified acquisition threshold over the period of performance;
  - (4) The non-Federal entity may comment on any information the OMB-designated integrity and performance system contains about the non-Federal entity for future consideration by Federal awarding agencies. The non-Federal entity may submit comments to the awardee integrity and performance portal accessible through SAM (currently CPARS).
  - (5) Federal awarding agencies will consider non-Federal entity comments when determining whether the non-Federal entity is qualified for a future Federal award.
- (c) Upon termination of a Federal award, the Federal awarding agency must provide the information required under FFATA to the Federal website established to fulfill the requirements of FFATA, and update or notify any other relevant governmentwide systems or entities of any indications of poor performance as required by 41 U.S.C. 417b and 31 U.S.C. 3321 and implementing guidance at 2 CFR part 77 (forthcoming at time of publication). See also the requirements for Suspension and Debarment at 2 CFR part 180.

### **§ 200.342 Opportunities to object, hearings, and appeals.**

Upon taking any remedy for non-compliance, the Federal awarding agency must provide the non-Federal entity an opportunity to object and provide information and documentation challenging the suspension or termination action, in accordance with written processes and procedures published by the Federal awarding agency. The Federal awarding agency or pass-through entity must comply with any requirements for hearings, appeals or other administrative proceedings to which the non-Federal entity is entitled under any statute or regulation applicable to the action involved.

### **§ 200.343 Effects of suspension and termination.**

Costs to the non-Federal entity resulting from financial obligations incurred by the non-Federal entity during a suspension or after termination of a Federal award or subaward are not allowable unless the Federal awarding agency or pass-through entity expressly authorizes them in the notice of suspension or termination or subsequently. However, costs during suspension or after termination are allowable if:

- (a) The costs result from financial obligations which were properly incurred by the non-Federal entity before the effective date of suspension or termination, are not in anticipation of it; and
- (b) The costs would be allowable if the Federal award was not suspended or expired normally at the end of the period of performance in which the termination takes effect.

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CLOSEOUT

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### **§ 200.344 Closeout.**

The Federal awarding agency or pass-through entity will close out the Federal award when it determines that all applicable administrative actions and all required work of the Federal award have been completed by the non-Federal entity. If the non-Federal entity fails to complete the requirements, the Federal awarding agency or pass-through entity will proceed to close out the Federal award with the information available. This section specifies the actions the non-Federal entity and Federal awarding agency or pass-through entity must take to complete this process at the end of the period of performance.

- (a) The recipient must submit, no later than 120 calendar days after the end date of the period of performance, all financial, performance, and other reports as required by the terms and conditions of the Federal award. A subrecipient must submit to the pass-through entity, no later than 90 calendar days (or an earlier date as agreed upon by the pass-through entity and subrecipient) after the end date of the period of performance, all financial, performance, and other reports as required by the terms and conditions of the Federal award. The Federal awarding agency or pass-through entity may approve extensions when requested and justified by the non-Federal entity, as applicable.
- (b) Unless the Federal awarding agency or pass-through entity authorizes an extension, a non-Federal entity must liquidate all financial obligations incurred under the Federal award no later than 120 calendar days after the end date of the period of performance as specified in the terms and conditions of the Federal award.
- (c) The Federal awarding agency or pass-through entity must make prompt payments to the non-Federal entity for costs meeting the requirements in Subpart E of this part under the Federal award being closed out.
- (d) The non-Federal entity must promptly refund any balances of unobligated cash that the Federal awarding agency or pass-through entity paid in advance or paid and that are not authorized to be retained by the non-Federal entity for use in other projects. See OMB Circular A-129 and see § 200.346, for requirements regarding unreturned amounts that become delinquent debts.
- (e) Consistent with the terms and conditions of the Federal award, the Federal awarding agency or pass-through entity must make a settlement for any upward or downward adjustments to the Federal share of costs after closeout reports are received.
- (f) The non-Federal entity must account for any real and personal property acquired with Federal funds or received from the Federal Government in accordance with §§ 200.310 through 200.316 and 200.330.
- (g) When a recipient or subrecipient completes all closeout requirements, the Federal awarding agency or pass-through entity must promptly complete all closeout actions for Federal awards. The Federal awarding agency must make every effort to complete closeout actions no later than one year after the end of the period of performance unless otherwise directed by authorizing statutes. Closeout actions include Federal awarding agency actions in the grants management and payment systems.
- (h) If the non-Federal entity does not submit all reports in accordance with this section and the terms and conditions of the Federal Award, the Federal awarding agency must proceed to close out with the information available within one year of the period of performance end date.
- (i) If the non-Federal entity does not submit all reports in accordance with this section within one year of the period of performance end date, the Federal awarding agency must report the non-Federal entity's material failure to comply with the terms and conditions of the award with the OMB-designated integrity and performance system (currently FAPIIS). Federal awarding agencies may also pursue other enforcement actions per § 200.339.

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## POST-CLOSEOUT ADJUSTMENTS AND CONTINUING RESPONSIBILITIES

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### **§ 200.345 Post-closeout adjustments and continuing responsibilities.**

- (a) The closeout of a Federal award does not affect any of the following:
  - (1) The right of the Federal awarding agency or pass-through entity to disallow costs and recover funds on the basis of a later audit or other review. The Federal awarding agency or pass-through entity must make any cost disallowance determination and notify the non-Federal entity within the record retention period.
  - (2) The requirement for the non-Federal entity to return any funds due as a result of later refunds, corrections, or other transactions including final indirect cost rate adjustments.
  - (3) The ability of the Federal awarding agency to make financial adjustments to a previously closed award such as resolving indirect cost payments and making final payments.
  - (4) Audit requirements in subpart F of this part.
  - (5) Property management and disposition requirements in §§ 200.310 through 200.316 of this subpart.

- (6) Records retention as required in §§ 200.334 through 200.337 of this subpart.
- (b) After closeout of the Federal award, a relationship created under the Federal award may be modified or ended in whole or in part with the consent of the Federal awarding agency or pass-through entity and the non-Federal entity, provided the responsibilities of the non-Federal entity referred to in paragraph (a) of this section, including those for property management as applicable, are considered and provisions made for continuing responsibilities of the non-Federal entity, as appropriate.

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## COLLECTION OF AMOUNTS DUE

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### § 200.346 Collection of amounts due.

- (a) Any funds paid to the non-Federal entity in excess of the amount to which the non-Federal entity is finally determined to be entitled under the terms of the Federal award constitute a debt to the Federal Government. If not paid within 90 calendar days after demand, the Federal awarding agency may reduce the debt by:
- (1) Making an administrative offset against other requests for reimbursements;
  - (2) Withholding advance payments otherwise due to the non-Federal entity; or
  - (3) Other action permitted by Federal statute.
- (b) Except where otherwise provided by statutes or regulations, the Federal awarding agency will charge interest on an overdue debt in accordance with the Federal Claims Collection Standards (31 CFR parts 900 through 999). The date from which interest is computed is not extended by litigation or the filing of any form of appeal.

## Subpart E - Cost Principles

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### GENERAL PROVISIONS

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### § 200.400 Policy guide.

The application of these cost principles is based on the fundamental premises that:

- (a) The non-Federal entity is responsible for the efficient and effective administration of the Federal award through the application of sound management practices.
- (b) The non-Federal entity assumes responsibility for administering Federal funds in a manner consistent with underlying agreements, program objectives, and the terms and conditions of the Federal award.
- (c) The non-Federal entity, in recognition of its own unique combination of staff, facilities, and experience, has the primary responsibility for employing whatever form of sound organization and management techniques may be necessary in order to assure proper and efficient administration of the Federal award.
- (d) The application of these cost principles should require no significant changes in the internal accounting policies and practices of the non-Federal entity. However, the accounting practices of the non-Federal entity must be consistent with these cost principles and support the accumulation of costs as required by the principles, and must provide for adequate documentation to support costs charged to the Federal award.
- (e) In reviewing, negotiating and approving cost allocation plans or indirect cost proposals, the cognizant agency for indirect costs should generally assure that the non-Federal entity is applying these cost accounting principles on a consistent basis during their review and negotiation of indirect cost proposals. Where wide variations exist in the treatment of a given cost item by the non-Federal entity, the reasonableness and equity of such treatments should be fully considered. See the definition of *indirect (facilities & administrative (F&A)) costs* in § 200.1 of this part.
- (f) For non-Federal entities that educate and engage students in research, the dual role of students as both trainees and employees (including pre- and post-doctoral staff) contributing to the completion of Federal awards for research must be recognized in the application of these principles.
- (g) The non-Federal entity may not earn or keep any profit resulting from Federal financial assistance, unless explicitly authorized by the terms and conditions of the Federal award. See also § 200.307.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75885, Dec. 19, 2014; 85 FR 49561, Aug. 13, 2020]

## § 200.401 Application.

- (a) **General.** These principles must be used in determining the allowable costs of work performed by the non-Federal entity under Federal awards. These principles also must be used by the non-Federal entity as a guide in the pricing of fixed-price contracts and subcontracts where costs are used in determining the appropriate price. The principles do not apply to:
- (1) Arrangements under which Federal financing is in the form of loans, scholarships, fellowships, traineeships, or other fixed amounts based on such items as education allowance or published tuition rates and fees.
  - (2) For IHEs, capitation awards, which are awards based on case counts or number of beneficiaries according to the terms and conditions of the Federal award.
  - (3) Fixed amount awards. See also § 200.1 Definitions and 200.201.
  - (4) Federal awards to hospitals (see appendix IX to this part).
  - (5) Other awards under which the non-Federal entity is not required to account to the Federal Government for actual costs incurred.
- (b) **Federal contract.** Where a Federal contract awarded to a non-Federal entity is subject to the Cost Accounting Standards (CAS), it incorporates the applicable CAS clauses, Standards, and CAS administration requirements per the 48 CFR Chapter 99 and 48 CFR part 30 (FAR Part 30). CAS applies directly to the CAS-covered contract and the Cost Accounting Standards at 48 CFR parts 9904 or 9905 takes precedence over the cost principles in this subpart E with respect to the allocation of costs. When a contract with a non-Federal entity is subject to full CAS coverage, the allowability of certain costs under the cost principles will be affected by the allocation provisions of the Cost Accounting Standards (e.g., CAS 414 - 48 CFR 9904.414, Cost of Money as an Element of the Cost of Facilities Capital, and CAS 417 - 48 CFR 9904.417, Cost of Money as an Element of the Cost of Capital Assets Under Construction), apply rather the allowability provisions of § 200.449. In complying with those requirements, the non-Federal entity's application of cost accounting practices for estimating, accumulating, and reporting costs for other Federal awards and other cost objectives under the CAS-covered contract still must be consistent with its cost accounting practices for the CAS-covered contracts. In all cases, only one set of accounting records needs to be maintained for the allocation of costs by the non-Federal entity.
- (c) **Exemptions.** Some nonprofit organizations, because of their size and nature of operations, can be considered to be similar to for-profit entities for purpose of applicability of cost principles. Such nonprofit organizations must operate under Federal cost principles applicable to for-profit entities located at 48 CFR 31.2. A listing of these organizations is contained in appendix VIII to this part. Other organizations, as approved by the cognizant agency for indirect costs, may be added from time to time.

[78 FR 78608, Dec. 26, 2013, as amended at 85 FR 49562, Aug. 13, 2020]

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## BASIC CONSIDERATIONS

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### § 200.402 Composition of costs.

**Total cost.** The total cost of a Federal award is the sum of the allowable direct and allocable indirect costs less any applicable credits.

### § 200.403 Factors affecting allowability of costs.

Except where otherwise authorized by statute, costs must meet the following general criteria in order to be allowable under Federal awards:

- (a) Be necessary and reasonable for the performance of the Federal award and be allocable thereto under these principles.
- (b) Conform to any limitations or exclusions set forth in these principles or in the Federal award as to types or amount of cost items.
- (c) Be consistent with policies and procedures that apply uniformly to both federally-financed and other activities of the non-Federal entity.
- (d) Be accorded consistent treatment. A cost may not be assigned to a Federal award as a direct cost if any other cost incurred for the same purpose in like circumstances has been allocated to the Federal award as an indirect cost.

- (e) Be determined in accordance with generally accepted accounting principles (GAAP), except, for state and local governments and Indian tribes only, as otherwise provided for in this part.
- (f) Not be included as a cost or used to meet cost sharing or matching requirements of any other federally-financed program in either the current or a prior period. See also § 200.306(b).
- (g) Be adequately documented. See also §§ 200.300 through 200.309 of this part.
- (h) Cost must be incurred during the approved budget period. The Federal awarding agency is authorized, at its discretion, to waive prior written approvals to carry forward unobligated balances to subsequent budget periods pursuant to § 200.308(e)(3).

*[78 FR 78608, Dec. 26, 2013, as amended at 85 FR 49562, Aug. 13, 2020]*

#### **§ 200.404 Reasonable costs.**

A cost is reasonable if, in its nature and amount, it does not exceed that which would be incurred by a prudent person under the circumstances prevailing at the time the decision was made to incur the cost. The question of reasonableness is particularly important when the non-Federal entity is predominantly federally-funded. In determining reasonableness of a given cost, consideration must be given to:

- (a) Whether the cost is of a type generally recognized as ordinary and necessary for the operation of the non-Federal entity or the proper and efficient performance of the Federal award.
- (b) The restraints or requirements imposed by such factors as: sound business practices; arm's-length bargaining; Federal, state, local, tribal, and other laws and regulations; and terms and conditions of the Federal award.
- (c) Market prices for comparable goods or services for the geographic area.
- (d) Whether the individuals concerned acted with prudence in the circumstances considering their responsibilities to the non-Federal entity, its employees, where applicable its students or membership, the public at large, and the Federal Government.
- (e) Whether the non-Federal entity significantly deviates from its established practices and policies regarding the incurrence of costs, which may unjustifiably increase the Federal award's cost.

*[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75885, Dec. 19, 2014]*

#### **§ 200.405 Allocable costs.**

- (a) A cost is allocable to a particular Federal award or other cost objective if the goods or services involved are chargeable or assignable to that Federal award or cost objective in accordance with relative benefits received. This standard is met if the cost:
  - (1) Is incurred specifically for the Federal award;
  - (2) Benefits both the Federal award and other work of the non-Federal entity and can be distributed in proportions that may be approximated using reasonable methods; and
  - (3) Is necessary to the overall operation of the non-Federal entity and is assignable in part to the Federal award in accordance with the principles in this subpart.
- (b) All activities which benefit from the non-Federal entity's indirect (F&A) cost, including unallowable activities and donated services by the non-Federal entity or third parties, will receive an appropriate allocation of indirect costs.
- (c) Any cost allocable to a particular Federal award under the principles provided for in this part may not be charged to other Federal awards to overcome fund deficiencies, to avoid restrictions imposed by Federal statutes, regulations, or terms and conditions of the Federal awards, or for other reasons. However, this prohibition would not preclude the non-Federal entity from shifting costs that are allowable under two or more Federal awards in accordance with existing Federal statutes, regulations, or the terms and conditions of the Federal awards.
- (d) Direct cost allocation principles: If a cost benefits two or more projects or activities in proportions that can be determined without undue effort or cost, the cost must be allocated to the projects based on the proportional benefit. If a cost benefits two or more projects or activities in proportions that cannot be determined because of the interrelationship of the work involved, then, notwithstanding paragraph (c) of this section, the costs may be allocated or transferred to



benefitted projects on any reasonable documented basis. Where the purchase of equipment or other capital asset is specifically authorized under a Federal award, the costs are assignable to the Federal award regardless of the use that may be made of the equipment or other capital asset involved when no longer needed for the purpose for which it was originally required. See also §§ 200.310 through 200.316 and 200.439.

- (e) If the contract is subject to CAS, costs must be allocated to the contract pursuant to the Cost Accounting Standards. To the extent that CAS is applicable, the allocation of costs in accordance with CAS takes precedence over the allocation provisions in this part.

*[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75885, Dec. 19, 2014; 85 FR 49562, Aug. 13, 2020]*

### **§ 200.406 Applicable credits.**

- (a) Applicable credits refer to those receipts or reduction-of-expenditure-type transactions that offset or reduce expense items allocable to the Federal award as direct or indirect (F&A) costs. Examples of such transactions are: purchase discounts, rebates or allowances, recoveries or indemnities on losses, insurance refunds or rebates, and adjustments of overpayments or erroneous charges. To the extent that such credits accruing to or received by the non-Federal entity relate to allowable costs, they must be credited to the Federal award either as a cost reduction or cash refund, as appropriate.
- (b) In some instances, the amounts received from the Federal Government to finance activities or service operations of the non-Federal entity should be treated as applicable credits. Specifically, the concept of netting such credit items (including any amounts used to meet cost sharing or matching requirements) must be recognized in determining the rates or amounts to be charged to the Federal award. (See §§ 200.436 and 200.468, for areas of potential application in the matter of Federal financing of activities.)

*[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75885, Dec. 19, 2014; 85 FR 49562, Aug. 13, 2020]*

### **§ 200.407 Prior written approval (prior approval).**

Under any given Federal award, the reasonableness and allocability of certain items of costs may be difficult to determine. In order to avoid subsequent disallowance or dispute based on unreasonableness or nonallocability, the non-Federal entity may seek the prior written approval of the cognizant agency for indirect costs or the Federal awarding agency in advance of the incurrence of special or unusual costs. Prior written approval should include the timeframe or scope of the agreement. The absence of prior written approval on any element of cost will not, in itself, affect the reasonableness or allocability of that element, unless prior approval is specifically required for allowability as described under certain circumstances in the following sections of this part:

- (a) § 200.201 Use of grant agreements (including fixed amount awards), cooperative agreements, and contracts, paragraph (b)(5);
- (b) § 200.306 Cost sharing or matching;
- (c) § 200.307 Program income;
- (d) § 200.308 Revision of budget and program plans;
- (e) § 200.311 Real property;
- (f) § 200.313 Equipment;
- (g) § 200.333 Fixed amount subawards;
- (h) § 200.413 Direct costs, paragraph (c);
- (i) § 200.430 Compensation - personal services, paragraph (h);
- (j) § 200.431 Compensation - fringe benefits;
- (k) § 200.438 Entertainment costs;
- (l) § 200.439 Equipment and other capital expenditures;
- (m) § 200.440 Exchange rates;
- (n) § 200.441 Fines, penalties, damages and other settlements;

- (o) § 200.442 Fund raising and investment management costs;
- (p) § 200.445 Goods or services for personal use;
- (q) § 200.447 Insurance and indemnification;
- (r) § 200.454 Memberships, subscriptions, and professional activity costs, paragraph (c);
- (s) § 200.455 Organization costs;
- (t) § 200.456 Participant support costs;
- (u) § 200.458 Pre-award costs;
- (v) § 200.462 Rearrangement and reconversion costs;
- (w) § 200.467 Selling and marketing costs;
- (x) § 200.470 Taxes (including Value Added Tax); and
- (y) § 200.475 Travel costs.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75885, Dec. 19, 2014; 85 FR 49562, Aug. 13, 2020]

### **§ 200.408 Limitation on allowance of costs.**

The Federal award may be subject to statutory requirements that limit the allowability of costs. When the maximum amount allowable under a limitation is less than the total amount determined in accordance with the principles in this part, the amount not recoverable under the Federal award may not be charged to the Federal award.

### **§ 200.409 Special considerations.**

In addition to the basic considerations regarding the allowability of costs highlighted in this subtitle, other subtitles in this part describe special considerations and requirements applicable to states, local governments, Indian tribes, and IHEs. In addition, certain provisions among the items of cost in this subpart are only applicable to certain types of non-Federal entities, as specified in the following sections:

- (a) Direct and Indirect (F&A) Costs (§§ 200.412-200.415) of this subpart;
- (b) Special Considerations for States, Local Governments and Indian Tribes (§§ 200.416 and 200.417) of this subpart; and
- (c) Special Considerations for Institutions of Higher Education (§§ 200.418 and 200.419) of this subpart.

[85 FR 49562, Aug. 13, 2020]

### **§ 200.410 Collection of unallowable costs.**

Payments made for costs determined to be unallowable by either the Federal awarding agency, cognizant agency for indirect costs, or pass-through entity, either as direct or indirect costs, must be refunded (including interest) to the Federal Government in accordance with instructions from the Federal agency that determined the costs are unallowable unless Federal statute or regulation directs otherwise. See also §§ 200.300 through 200.309 in subpart D of this part.

[85 FR 49562, Aug. 13, 2020]

### **§ 200.411 Adjustment of previously negotiated indirect (F&A) cost rates containing unallowable costs.**

- (a) Negotiated indirect (F&A) cost rates based on a proposal later found to have included costs that:
  - (1) Are unallowable as specified by Federal statutes, regulations or the terms and conditions of a Federal award; or
  - (2) Are unallowable because they are not allocable to the Federal award(s), must be adjusted, or a refund must be made, in accordance with the requirements of this section. These adjustments or refunds are designed to correct the proposals used to establish the rates and do not constitute a reopening of the rate negotiation. The adjustments or refunds will be made regardless of the type of rate negotiated (predetermined, final, fixed, or provisional).

- (b) For rates covering a future fiscal year of the non-Federal entity, the unallowable costs will be removed from the indirect (F&A) cost pools and the rates appropriately adjusted.
- (c) For rates covering a past period, the Federal share of the unallowable costs will be computed for each year involved and a cash refund (including interest chargeable in accordance with applicable regulations) will be made to the Federal Government. If cash refunds are made for past periods covered by provisional or fixed rates, appropriate adjustments will be made when the rates are finalized to avoid duplicate recovery of the unallowable costs by the Federal Government.
- (d) For rates covering the current period, either a rate adjustment or a refund, as described in paragraphs (b) and (c) of this section, must be required by the cognizant agency for indirect costs. The choice of method must be at the discretion of the cognizant agency for indirect costs, based on its judgment as to which method would be most practical.
- (e) The amount or proportion of unallowable costs included in each year's rate will be assumed to be the same as the amount or proportion of unallowable costs included in the base year proposal used to establish the rate.

## DIRECT AND INDIRECT (F&A) COSTS

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### § 200.412 Classification of costs.

There is no universal rule for classifying certain costs as either direct or indirect (F&A) under every accounting system. A cost may be direct with respect to some specific service or function, but indirect with respect to the Federal award or other final cost objective. Therefore, it is essential that each item of cost incurred for the same purpose be treated consistently in like circumstances either as a direct or an indirect (F&A) cost in order to avoid possible double-charging of Federal awards. Guidelines for determining direct and indirect (F&A) costs charged to Federal awards are provided in this subpart.

### § 200.413 Direct costs.

- (a) **General.** Direct costs are those costs that can be identified specifically with a particular final cost objective, such as a Federal award, or other internally or externally funded activity, or that can be directly assigned to such activities relatively easily with a high degree of accuracy. Costs incurred for the same purpose in like circumstances must be treated consistently as either direct or indirect (F&A) costs. See also § 200.405.
- (b) **Application to Federal awards.** Identification with the Federal award rather than the nature of the goods and services involved is the determining factor in distinguishing direct from indirect (F&A) costs of Federal awards. Typical costs charged directly to a Federal award are the compensation of employees who work on that award, their related fringe benefit costs, the costs of materials and other items of expense incurred for the Federal award. If directly related to a specific award, certain costs that otherwise would be treated as indirect costs may also be considered direct costs. Examples include extraordinary utility consumption, the cost of materials supplied from stock or services rendered by specialized facilities, program evaluation costs, or other institutional service operations.
- (c) The salaries of administrative and clerical staff should normally be treated as indirect (F&A) costs. Direct charging of these costs may be appropriate only if all of the following conditions are met:
  - (1) Administrative or clerical services are integral to a project or activity;
  - (2) Individuals involved can be specifically identified with the project or activity;
  - (3) Such costs are explicitly included in the budget or have the prior written approval of the Federal awarding agency; and
  - (4) The costs are not also recovered as indirect costs.
- (d) **Minor items.** Any direct cost of minor amount may be treated as an indirect (F&A) cost for reasons of practicality where such accounting treatment for that item of cost is consistently applied to all Federal and non-Federal cost objectives.
- (e) The costs of certain activities are not allowable as charges to Federal awards. However, even though these costs are unallowable for purposes of computing charges to Federal awards, they nonetheless must be treated as direct costs for purposes of determining indirect (F&A) cost rates and be allocated their equitable share of the non-Federal entity's indirect costs if they represent activities which:
  - (1) Include the salaries of personnel,
  - (2) Occupy space, and
  - (3) Benefit from the non-Federal entity's indirect (F&A) costs.

- (f) For nonprofit organizations, the costs of activities performed by the non-Federal entity primarily as a service to members, clients, or the general public when significant and necessary to the non-Federal entity's mission must be treated as direct costs whether or not allowable, and be allocated an equitable share of indirect (F&A) costs. Some examples of these types of activities include:
- (1) Maintenance of membership rolls, subscriptions, publications, and related functions. See also § 200.454.
  - (2) Providing services and information to members, legislative or administrative bodies, or the public. See also §§ 200.454 and 200.450.
  - (3) Promotion, lobbying, and other forms of public relations. See also §§ 200.421 and 200.450.
  - (4) Conferences except those held to conduct the general administration of the non-Federal entity. See also § 200.432.
  - (5) Maintenance, protection, and investment of special funds not used in operation of the non-Federal entity. See also § 200.442.
  - (6) Administration of group benefits on behalf of members or clients, including life and hospital insurance, annuity or retirement plans, and financial aid. See also § 200.431.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75885, Dec. 19, 2014; 85 FR 49562, Aug. 13, 2020]

### § 200.414 Indirect (F&A) costs.

- (a) **Facilities and administration classification.** For major Institutions of Higher Education (IHE) and major nonprofit organizations, indirect (F&A) costs must be classified within two broad categories: "Facilities" and "Administration." "Facilities" is defined as depreciation on buildings, equipment and capital improvement, interest on debt associated with certain buildings, equipment and capital improvements, and operations and maintenance expenses. "Administration" is defined as general administration and general expenses such as the director's office, accounting, personnel and all other types of expenditures not listed specifically under one of the subcategories of "Facilities" (including cross allocations from other pools, where applicable). For nonprofit organizations, library expenses are included in the "Administration" category; for IHEs, they are included in the "Facilities" category. Major IHEs are defined as those required to use the Standard Format for Submission as noted in appendix III to this part, and Rate Determination for Institutions of Higher Education paragraph C. 11. Major nonprofit organizations are those which receive more than \$10 million dollars in direct Federal funding.
- (b) **Diversity of nonprofit organizations.** Because of the diverse characteristics and accounting practices of nonprofit organizations, it is not possible to specify the types of cost which may be classified as indirect (F&A) cost in all situations. Identification with a Federal award rather than the nature of the goods and services involved is the determining factor in distinguishing direct from indirect (F&A) costs of Federal awards. However, typical examples of indirect (F&A) cost for many nonprofit organizations may include depreciation on buildings and equipment, the costs of operating and maintaining facilities, and general administration and general expenses, such as the salaries and expenses of executive officers, personnel administration, and accounting.
- (c) **Federal Agency Acceptance of Negotiated Indirect Cost Rates.** (See also § 200.306.)
- (1) The negotiated rates must be accepted by all Federal awarding agencies. A Federal awarding agency may use a rate different from the negotiated rate for a class of Federal awards or a single Federal award only when required by Federal statute or regulation, or when approved by a Federal awarding agency head or delegate based on documented justification as described in paragraph (c)(3) of this section.
  - (2) The Federal awarding agency head or delegate must notify OMB of any approved deviations.
  - (3) The Federal awarding agency must implement, and make publicly available, the policies, procedures and general decision-making criteria that their programs will follow to seek and justify deviations from negotiated rates.
  - (4) As required under § 200.204, the Federal awarding agency must include in the notice of funding opportunity the policies relating to indirect cost rate reimbursement, matching, or cost share as approved under paragraph (e)(1) of this section. As appropriate, the Federal agency should incorporate discussion of these policies into Federal awarding agency outreach activities with non-Federal entities prior to the posting of a notice of funding opportunity.
- (d) Pass-through entities are subject to the requirements in § 200.332(a)(4).
- (e) Requirements for development and submission of indirect (F&A) cost rate proposals and cost allocation plans are contained in Appendices III-VII and Appendix IX as follows:

- (1) Appendix III to Part 200 - Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Institutions of Higher Education (IHEs);
  - (2) Appendix IV to Part 200 - Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Nonprofit Organizations;
  - (3) Appendix V to Part 200 - State/Local Governmentwide Central Service Cost Allocation Plans;
  - (4) Appendix VI to Part 200 - Public Assistance Cost Allocation Plans;
  - (5) Appendix VII to Part 200 - States and Local Government and Indian Tribe Indirect Cost Proposals; and
  - (6) Appendix IX to Part 200 - Hospital Cost Principles.
- (f) In addition to the procedures outlined in the appendices in paragraph (e) of this section, any non-Federal entity that does not have a current negotiated (including provisional) rate, except for those non-Federal entities described in appendix VII to this part, paragraph D.1.b, may elect to charge a de minimis rate of 10% of modified total direct costs (MTDC) which may be used indefinitely. No documentation is required to justify the 10% de minimis indirect cost rate. As described in § 200.403, costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as a non-Federal entity chooses to negotiate for a rate, which the non-Federal entity may apply to do at any time.
- (g) Any non-Federal entity that has a current federally-negotiated indirect cost rate may apply for a one-time extension of the rates in that agreement for a period of up to four years. This extension will be subject to the review and approval of the cognizant agency for indirect costs. If an extension is granted the non-Federal entity may not request a rate review until the extension period ends. At the end of the 4-year extension, the non-Federal entity must re-apply to negotiate a rate. Subsequent one-time extensions (up to four years) are permitted if a renegotiation is completed between each extension request.
- (h) The federally negotiated indirect rate, distribution base, and rate type for a non-Federal entity (except for the Indian tribes or tribal organizations, as defined in the Indian Self Determination, Education and Assistance Act, 25 U.S.C. 450b(1)) must be available publicly on an OMB-designated Federal website.

*[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75886, Dec. 19, 2014; 85 FR 49563, Aug. 13, 2020]*

### **§ 200.415 Required certifications.**

Required certifications include:

- (a) To assure that expenditures are proper and in accordance with the terms and conditions of the Federal award and approved project budgets, the annual and final fiscal reports or vouchers requesting payment under the agreements must include a certification, signed by an official who is authorized to legally bind the non-Federal entity, which reads as follows: "By signing this report, I certify to the best of my knowledge and belief that the report is true, complete, and accurate, and the expenditures, disbursements and cash receipts are for the purposes and objectives set forth in the terms and conditions of the Federal award. I am aware that any false, fictitious, or fraudulent information, or the omission of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims or otherwise. (U.S. Code Title 18, Section 1001 and Title 31, Sections 3729-3730 and 3801-3812)."
- (b) Certification of cost allocation plan or indirect (F&A) cost rate proposal. Each cost allocation plan or indirect (F&A) cost rate proposal must comply with the following:
  - (1) A proposal to establish a cost allocation plan or an indirect (F&A) cost rate, whether submitted to a Federal cognizant agency for indirect costs or maintained on file by the non-Federal entity, must be certified by the non-Federal entity using the Certificate of Cost Allocation Plan or Certificate of Indirect Costs as set forth in appendices III through VII, and IX of this part. The certificate must be signed on behalf of the non-Federal entity by an individual at a level no lower than vice president or chief financial officer of the non-Federal entity that submits the proposal.
  - (2) Unless the non-Federal entity has elected the option under § 200.414(f), the Federal Government may either disallow all indirect (F&A) costs or unilaterally establish such a plan or rate when the non-Federal entity fails to submit a certified proposal for establishing such a plan or rate in accordance with the requirements. Such a plan or rate may be based upon audited historical data or such other data that have been furnished to the cognizant agency for indirect costs and for which it can be demonstrated that all unallowable costs have been excluded. When a cost

allocation plan or indirect cost rate is unilaterally established by the Federal Government because the non-Federal entity failed to submit a certified proposal, the plan or rate established will be set to ensure that potentially unallowable costs will not be reimbursed.

- (c) Certifications by nonprofit organizations as appropriate that they did not meet the definition of a major nonprofit organization as defined in § 200.414(a).
- (d) See also § 200.450 for another required certification.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75886, Dec. 19, 2014; 85 FR 49563, Aug. 13, 2020]

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## SPECIAL CONSIDERATIONS FOR STATES, LOCAL GOVERNMENTS AND INDIAN TRIBES

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### **§ 200.416 Cost allocation plans and indirect cost proposals.**

- (a) For states, local governments and Indian tribes, certain services, such as motor pools, computer centers, purchasing, accounting, etc., are provided to operating agencies on a centralized basis. Since Federal awards are performed within the individual operating agencies, there needs to be a process whereby these central service costs can be identified and assigned to benefitted activities on a reasonable and consistent basis. The central service cost allocation plan provides that process.
- (b) Individual operating agencies (governmental department or agency), normally charge Federal awards for indirect costs through an indirect cost rate. A separate indirect cost rate(s) proposal for each operating agency is usually necessary to claim indirect costs under Federal awards. Indirect costs include:
  - (1) The indirect costs originating in each department or agency of the governmental unit carrying out Federal awards and
  - (2) The costs of central governmental services distributed through the central service cost allocation plan and not otherwise treated as direct costs.
- (c) The requirements for development and submission of cost allocation plans (for central service costs and public assistance programs) and indirect cost rate proposals are contained in appendices V, VI and VII to this part.

[78 FR 78608, Dec. 26, 2013, as amended at 86 FR 10440, Feb. 22, 2021]

### **§ 200.417 Interagency service.**

The cost of services provided by one agency to another within the governmental unit may include allowable direct costs of the service plus a pro-rated share of indirect costs. A standard indirect cost allowance equal to ten percent of the direct salary and wage cost of providing the service (excluding overtime, shift premiums, and fringe benefits) may be used in lieu of determining the actual indirect costs of the service. These services do not include centralized services included in central service cost allocation plans as described in Appendix V to Part 200.

[85 FR 49564, Aug. 13, 2020]

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## SPECIAL CONSIDERATIONS FOR INSTITUTIONS OF HIGHER EDUCATION

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### **§ 200.418 Costs incurred by states and local governments.**

Costs incurred or paid by a state or local government on behalf of its IHEs for fringe benefit programs, such as pension costs and FICA and any other costs specifically incurred on behalf of, and in direct benefit to, the IHEs, are allowable costs of such IHEs whether or not these costs are recorded in the accounting records of the institutions, subject to the following:

- (a) The costs meet the requirements of § 200.402-411 of this subpart;
- (b) The costs are properly supported by approved cost allocation plans in accordance with applicable Federal cost accounting principles in this part; and
- (c) The costs are not otherwise borne directly or indirectly by the Federal Government.

[78 FR 78608, Dec. 26, 2013, as amended at 85 FR 49564, Aug. 13, 2020]

**§ 200.419 Cost accounting standards and disclosure statement.**

- (a) An IHE that receive an aggregate total \$50 million or more in Federal awards and instruments subject to this subpart (as specified in § 200.101) in its most recently completed fiscal year must comply with the Cost Accounting Standards Board's cost accounting standards located at 48 CFR 9905.501, 9905.502, 9905.505, and 9905.506. CAS-covered contracts and subcontracts awarded to the IHEs are subject to the broader range of CAS requirements at 48 CFR 9900 through 9999 and 48 CFR part 30 (FAR Part 30).
- (b) **Disclosure statement.** An IHE that receives an aggregate total \$50 million or more in Federal awards and instruments subject to this subpart (as specified in § 200.101) during its most recently completed fiscal year must disclose their cost accounting practices by filing a Disclosure Statement (DS-2), which is reproduced in Appendix III to Part 200. With the approval of the cognizant agency for indirect costs, an IHE may meet the DS-2 submission by submitting the DS-2 for each business unit that received \$50 million or more in Federal awards and instruments.
- (1) The DS-2 must be submitted to the cognizant agency for indirect costs with a copy to the IHE's cognizant agency for audit. The initial DS-2 and revisions to the DS-2 must be submitted in coordination with the IHE's indirect (F&A) rate proposal, unless an earlier submission is requested by the cognizant agency for indirect costs. IHEs with CAS-covered contracts or subcontracts meeting the dollar threshold in 48 CFR 9903.202-1(f) must submit their initial DS-2 or revisions no later than prior to the award of a CAS-covered contract or subcontract.
  - (2) An IHE must maintain an accurate DS-2 and comply with disclosed cost accounting practices. An IHE must file amendments to the DS-2 to the cognizant agency for indirect costs in advance of a disclosed practice being changed to comply with a new or modified standard, or when a practice is changed for other reasons. An IHE may proceed with implementing the change after it has notified the Federal cognizant agency for indirect costs. If the change represents a variation from 2 CFR part 200, the change may require approval by the Federal cognizant agency for indirect costs, in accordance with § 200.102(b). Amendments of a DS-2 may be submitted at any time. Resubmission of a complete, updated DS-2 is discouraged except when there are extensive changes to disclosed practices.
  - (3) **Cost and funding adjustments.** Cost adjustments must be made by the cognizant agency for indirect costs if an IHE fails to comply with the cost policies in this part or fails to consistently follow its established or disclosed cost accounting practices when estimating, accumulating or reporting the costs of Federal awards, and the aggregate cost impact on Federal awards is material. The cost adjustment must normally be made on an aggregate basis for all affected Federal awards through an adjustment of the IHE's future F&A costs rates or other means considered appropriate by the cognizant agency for indirect costs. Under the terms of CAS covered contracts, adjustments in the amount of funding provided may also be required when the estimated proposal costs were not determined in accordance with established cost accounting practices.
  - (4) **Overpayments.** Excess amounts paid in the aggregate by the Federal Government under Federal awards due to a noncompliant cost accounting practice used to estimate, accumulate, or report costs must be credited or refunded, as deemed appropriate by the cognizant agency for indirect costs. Interest applicable to the excess amounts paid in the aggregate during the period of noncompliance must also be determined and collected in accordance with applicable Federal agency regulations.
  - (5) **Compliant cost accounting practice changes.** Changes from one compliant cost accounting practice to another compliant practice that are approved by the cognizant agency for indirect costs may require cost adjustments if the change has a material effect on Federal awards and the changes are deemed appropriate by the cognizant agency for indirect costs.
  - (6) **Responsibilities.** The cognizant agency for indirect cost must:
    - (i) Determine cost adjustments for all Federal awards in the aggregate on behalf of the Federal Government. Actions of the cognizant agency for indirect cost in making cost adjustment determinations must be coordinated with all affected Federal awarding agencies to the extent necessary.
    - (ii) Prescribe guidelines and establish internal procedures to promptly determine on behalf of the Federal Government that a DS-2 adequately discloses the IHE's cost accounting practices and that the disclosed practices are compliant with applicable CAS and the requirements of this part.
    - (iii) Distribute to all affected Federal awarding agencies any DS-2 determination of adequacy or noncompliance.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75886, Dec. 19, 2014; 85 FR 49564, Aug. 13, 2020]

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**GENERAL PROVISIONS FOR SELECTED ITEMS OF COST**

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## **§ 200.420 Considerations for selected items of cost.**

This section provides principles to be applied in establishing the allowability of certain items involved in determining cost, in addition to the requirements of Subtitle II of this subpart. These principles apply whether or not a particular item of cost is properly treated as direct cost or indirect (F&A) cost. Failure to mention a particular item of cost is not intended to imply that it is either allowable or unallowable; rather, determination as to allowability in each case should be based on the treatment provided for similar or related items of cost, and based on the principles described in §§ 200.402 through 200.411. In case of a discrepancy between the provisions of a specific Federal award and the provisions below, the Federal award governs. Criteria outlined in § 200.403 must be applied in determining allowability. See also § 200.102.

*[85 FR 49564, Aug. 13, 2020]*

## **§ 200.421 Advertising and public relations.**

- (a) The term advertising costs means the costs of advertising media and corollary administrative costs. Advertising media include magazines, newspapers, radio and television, direct mail, exhibits, electronic or computer transmittals, and the like.
- (b) The only allowable advertising costs are those which are solely for:
  - (1) The recruitment of personnel required by the non-Federal entity for performance of a Federal award (See also § 200.463);
  - (2) The procurement of goods and services for the performance of a Federal award;
  - (3) The disposal of scrap or surplus materials acquired in the performance of a Federal award except when non-Federal entities are reimbursed for disposal costs at a predetermined amount; or
  - (4) Program outreach and other specific purposes necessary to meet the requirements of the Federal award.
- (c) The term “public relations” includes community relations and means those activities dedicated to maintaining the image of the non-Federal entity or maintaining or promoting understanding and favorable relations with the community or public at large or any segment of the public.
- (d) The only allowable public relations costs are:
  - (1) Costs specifically required by the Federal award;
  - (2) Costs of communicating with the public and press pertaining to specific activities or accomplishments which result from performance of the Federal award (these costs are considered necessary as part of the outreach effort for the Federal award); or
  - (3) Costs of conducting general liaison with news media and government public relations officers, to the extent that such activities are limited to communication and liaison necessary to keep the public informed on matters of public concern, such as notices of funding opportunities, financial matters, etc.
- (e) Unallowable advertising and public relations costs include the following:
  - (1) All advertising and public relations costs other than as specified in paragraphs (b) and (d) of this section;
  - (2) Costs of meetings, conventions, convocations, or other events related to other activities of the entity (see also § 200.432), including:
    - (i) Costs of displays, demonstrations, and exhibits;
    - (ii) Costs of meeting rooms, hospitality suites, and other special facilities used in conjunction with shows and other special events; and
    - (iii) Salaries and wages of employees engaged in setting up and displaying exhibits, making demonstrations, and providing briefings;
  - (3) Costs of promotional items and memorabilia, including models, gifts, and souvenirs;
  - (4) Costs of advertising and public relations designed solely to promote the non-Federal entity.

*[78 FR 76808, Dec. 26, 2013, as amended at 85 FR 49564, Aug. 13, 2020]*



**§ 200.422 Advisory councils.**

Costs incurred by advisory councils or committees are unallowable unless authorized by statute, the Federal awarding agency or as an indirect cost where allocable to Federal awards. See § 200.444, applicable to States, local governments, and Indian tribes.

[85 FR 49564, Aug. 13, 2020]

**§ 200.423 Alcoholic beverages.**

Costs of alcoholic beverages are unallowable.

**§ 200.424 Alumni/ae activities.**

Costs incurred by IHEs for, or in support of, alumni/ae activities are unallowable.

**§ 200.425 Audit services.**

- (a) A reasonably proportionate share of the costs of audits required by, and performed in accordance with, the Single Audit Act Amendments of 1996 (31 U.S.C. 7501-7507), as implemented by requirements of this part, are allowable. However, the following audit costs are unallowable:
- (1) Any costs when audits required by the Single Audit Act and subpart F of this part have not been conducted or have been conducted but not in accordance therewith; and
  - (2) Any costs of auditing a non-Federal entity that is exempted from having an audit conducted under the Single Audit Act and subpart F of this part because its expenditures under Federal awards are less than \$750,000 during the non-Federal entity's fiscal year.
- (b) The costs of a financial statement audit of a non-Federal entity that does not currently have a Federal award may be included in the indirect cost pool for a cost allocation plan or indirect cost proposal.
- (c) Pass-through entities may charge Federal awards for the cost of agreed-upon-procedures engagements to monitor subrecipients (in accordance with subpart D, §§ 200.331-333) who are exempted from the requirements of the Single Audit Act and subpart F of this part. This cost is allowable only if the agreed-upon-procedures engagements are:
- (1) Conducted in accordance with GAGAS attestation standards;
  - (2) Paid for and arranged by the pass-through entity; and
  - (3) Limited in scope to one or more of the following types of compliance requirements: activities allowed or unallowed; allowable costs/cost principles; eligibility; and reporting.

[78 FR 78608, Dec. 26, 2013, as amended at 85 FR 49564, Aug. 13, 2020]

**§ 200.426 Bad debts.**

Bad debts (debts which have been determined to be uncollectable), including losses (whether actual or estimated) arising from uncollectable accounts and other claims, are unallowable. Related collection costs, and related legal costs, arising from such debts after they have been determined to be uncollectable are also unallowable. See also § 200.428.

[85 FR 49565, Aug. 13, 2020]

**§ 200.427 Bonding costs.**

- (a) Bonding costs arise when the Federal awarding agency requires assurance against financial loss to itself or others by reason of the act or default of the non-Federal entity. They arise also in instances where the non-Federal entity requires similar assurance, including: bonds as bid, performance, payment, advance payment, infringement, and fidelity bonds for employees and officials.
- (b) Costs of bonding required pursuant to the terms and conditions of the Federal award are allowable.

- (c) Costs of bonding required by the non-Federal entity in the general conduct of its operations are allowable as an indirect cost to the extent that such bonding is in accordance with sound business practice and the rates and premiums are reasonable under the circumstances.

### § 200.428 Collections of improper payments.

The costs incurred by a non-Federal entity to recover improper payments are allowable as either direct or indirect costs, as appropriate. Amounts collected may be used by the non-Federal entity in accordance with cash management standards set forth in § 200.305.

[85 FR 49565, Aug. 13, 2020]

### § 200.429 Commencement and convocation costs.

For IHEs, costs incurred for commencements and convocations are unallowable, except as provided for in (B)(9) Student Administration and Services, in appendix III to this part, as activity costs.

[85 FR 49565, Aug. 13, 2020]

### § 200.430 Compensation - personal services.

- (a) **General.** Compensation for personal services includes all remuneration, paid currently or accrued, for services of employees rendered during the period of performance under the Federal award, including but not necessarily limited to wages and salaries. Compensation for personal services may also include fringe benefits which are addressed in § 200.431. Costs of compensation are allowable to the extent that they satisfy the specific requirements of this part, and that the total compensation for individual employees:
  - (1) Is reasonable for the services rendered and conforms to the established written policy of the non-Federal entity consistently applied to both Federal and non-Federal activities;
  - (2) Follows an appointment made in accordance with a non-Federal entity's laws and/or rules or written policies and meets the requirements of Federal statute, where applicable; and
  - (3) Is determined and supported as provided in paragraph (i) of this section, when applicable.
- (b) **Reasonableness.** Compensation for employees engaged in work on Federal awards will be considered reasonable to the extent that it is consistent with that paid for similar work in other activities of the non-Federal entity. In cases where the kinds of employees required for Federal awards are not found in the other activities of the non-Federal entity, compensation will be considered reasonable to the extent that it is comparable to that paid for similar work in the labor market in which the non-Federal entity competes for the kind of employees involved.
- (c) **Professional activities outside the non-Federal entity.** Unless an arrangement is specifically authorized by a Federal awarding agency, a non-Federal entity must follow its written non-Federal entity-wide policies and practices concerning the permissible extent of professional services that can be provided outside the non-Federal entity for non-organizational compensation. Where such non-Federal entity-wide written policies do not exist or do not adequately define the permissible extent of consulting or other non-organizational activities undertaken for extra outside pay, the Federal Government may require that the effort of professional staff working on Federal awards be allocated between:
  - (1) Non-Federal entity activities, and
  - (2) Non-organizational professional activities. If the Federal awarding agency considers the extent of non-organizational professional effort excessive or inconsistent with the conflicts-of-interest terms and conditions of the Federal award, appropriate arrangements governing compensation will be negotiated on a case-by-case basis.
- (d) **Unallowable costs.**
  - (1) Costs which are unallowable under other sections of these principles must not be allowable under this section solely on the basis that they constitute personnel compensation.
  - (2) The allowable compensation for certain employees is subject to a ceiling in accordance with statute. For the amount of the ceiling for cost-reimbursement contracts, the covered compensation subject to the ceiling, the covered employees, and other relevant provisions, see 10 U.S.C. 2324(e)(1)(P), and 41 U.S.C. 1127 and 4304(a)(16). For other types of Federal awards, other statutory ceilings may apply.

- (e) **Special considerations.** Special considerations in determining allowability of compensation will be given to any change in a non-Federal entity's compensation policy resulting in a substantial increase in its employees' level of compensation (particularly when the change was concurrent with an increase in the ratio of Federal awards to other activities) or any change in the treatment of allowability of specific types of compensation due to changes in Federal policy.
- (f) **Incentive compensation.** Incentive compensation to employees based on cost reduction, or efficient performance, suggestion awards, safety awards, etc., is allowable to the extent that the overall compensation is determined to be reasonable and such costs are paid or accrued pursuant to an agreement entered into in good faith between the non-Federal entity and the employees before the services were rendered, or pursuant to an established plan followed by the non-Federal entity so consistently as to imply, in effect, an agreement to make such payment.
- (g) **Nonprofit organizations.** For compensation to members of nonprofit organizations, trustees, directors, associates, officers, or the immediate families thereof, determination must be made that such compensation is reasonable for the actual personal services rendered rather than a distribution of earnings in excess of costs. This may include director's and executive committee member's fees, incentive awards, allowances for off-site pay, incentive pay, location allowances, hardship pay, and cost-of-living differentials.
- (h) **Institutions of Higher Education (IHEs).**
  - (1) Certain conditions require special consideration and possible limitations in determining allowable personnel compensation costs under Federal awards. Among such conditions are the following:
    - (i) Allowable activities. Charges to Federal awards may include reasonable amounts for activities contributing and directly related to work under an agreement, such as delivering special lectures about specific aspects of the ongoing activity, writing reports and articles, developing and maintaining protocols (human, animals, etc.), managing substances/chemicals, managing and securing project-specific data, coordinating research subjects, participating in appropriate seminars, consulting with colleagues and graduate students, and attending meetings and conferences.
    - (ii) Incidental activities. Incidental activities for which supplemental compensation is allowable under written institutional policy (at a rate not to exceed institutional base salary) need not be included in the records described in paragraph (i) of this section to directly charge payments of incidental activities, such activities must either be specifically provided for in the Federal award budget or receive prior written approval by the Federal awarding agency.
  - (2) **Salary basis.** Charges for work performed on Federal awards by faculty members during the academic year are allowable at the IBS rate. Except as noted in paragraph (h)(1)(ii) of this section, in no event will charges to Federal awards, irrespective of the basis of computation, exceed the proportionate share of the IBS for that period. This principle applies to all members of faculty at an institution. IBS is defined as the annual compensation paid by an IHE for an individual's appointment, whether that individual's time is spent on research, instruction, administration, or other activities. IBS excludes any income that an individual earns outside of duties performed for the IHE. Unless there is prior approval by the Federal awarding agency, charges of a faculty member's salary to a Federal award must not exceed the proportionate share of the IBS for the period during which the faculty member worked on the award.
  - (3) **Intra-Institution of Higher Education (IHE) consulting.** Intra-IHE consulting by faculty should be undertaken as an IHE responsibility requiring no compensation in addition to IBS. However, in unusual cases where consultation is across departmental lines or involves a separate or remote operation, and the work performed by the faculty member is in addition to his or her regular responsibilities, any charges for such work representing additional compensation above IBS are allowable provided that such consulting arrangements are specifically provided for in the Federal award or approved in writing by the Federal awarding agency.
  - (4) Extra Service Pay normally represents overload compensation, subject to institutional compensation policies for services above and beyond IBS. Where extra service pay is a result of Intra-IHE consulting, it is subject to the same requirements of paragraph (b) above. It is allowable if all of the following conditions are met:
    - (i) The non-Federal entity establishes consistent written policies which apply uniformly to all faculty members, not just those working on Federal awards.
    - (ii) The non-Federal entity establishes a consistent written definition of work covered by IBS which is specific enough to determine conclusively when work beyond that level has occurred. This may be described in appointment letters or other documentations.
    - (iii) The supplementation amount paid is commensurate with the IBS rate of pay and the amount of additional work performed. See paragraph (h)(2) of this section.

- (iv) The salaries, as supplemented, fall within the salary structure and pay ranges established by and documented in writing or otherwise applicable to the non-Federal entity.
  - (v) The total salaries charged to Federal awards including extra service pay are subject to the Standards of Documentation as described in paragraph (i) of this section.
- (5) **Periods outside the academic year.**
- (i) Except as specified for teaching activity in paragraph (h)(5)(ii) of this section, charges for work performed by faculty members on Federal awards during periods not included in the base salary period will be at a rate not in excess of the IBS.
  - (ii) Charges for teaching activities performed by faculty members on Federal awards during periods not included in IBS period will be based on the normal written policy of the IHE governing compensation to faculty members for teaching assignments during such periods.
- (6) **Part-time faculty.** Charges for work performed on Federal awards by faculty members having only part-time appointments will be determined at a rate not in excess of that regularly paid for part-time assignments.
- (7) **Sabbatical leave costs.** Rules for sabbatical leave are as follow:
- (i) Costs of leaves of absence by employees for performance of graduate work or sabbatical study, travel, or research are allowable provided the IHE has a uniform written policy on sabbatical leave for persons engaged in instruction and persons engaged in research. Such costs will be allocated on an equitable basis among all related activities of the IHE.
  - (ii) Where sabbatical leave is included in fringe benefits for which a cost is determined for assessment as a direct charge, the aggregate amount of such assessments applicable to all work of the institution during the base period must be reasonable in relation to the IHE's actual experience under its sabbatical leave policy.
- (8) **Salary rates for non-faculty members.** Non-faculty full-time professional personnel may also earn "extra service pay" in accordance with the non-Federal entity's written policy and consistent with paragraph (h)(1)(i) of this section.
- (i) **Standards for Documentation of Personnel Expenses**
- (1) Charges to Federal awards for salaries and wages must be based on records that accurately reflect the work performed. These records must:
    - (i) Be supported by a system of internal control which provides reasonable assurance that the charges are accurate, allowable, and properly allocated;
    - (ii) Be incorporated into the official records of the non-Federal entity;
    - (iii) Reasonably reflect the total activity for which the employee is compensated by the non-Federal entity, not exceeding 100% of compensated activities (for IHE, this per the IHE's definition of IBS);
    - (iv) Encompass federally-assisted and all other activities compensated by the non-Federal entity on an integrated basis, but may include the use of subsidiary records as defined in the non-Federal entity's written policy;
    - (v) Comply with the established accounting policies and practices of the non-Federal entity (See paragraph (h)(1)(ii) above for treatment of incidental work for IHEs.); and
    - (vi) [Reserved]
    - (vii) Support the distribution of the employee's salary or wages among specific activities or cost objectives if the employee works on more than one Federal award; a Federal award and non-Federal award; an indirect cost activity and a direct cost activity; two or more indirect activities which are allocated using different allocation bases; or an unallowable activity and a direct or indirect cost activity.
    - (viii) Budget estimates (i.e., estimates determined before the services are performed) alone do not qualify as support for charges to Federal awards, but may be used for interim accounting purposes, provided that:
      - (A) The system for establishing the estimates produces reasonable approximations of the activity actually performed;
      - (B) Significant changes in the corresponding work activity (as defined by the non-Federal entity's written policies) are identified and entered into the records in a timely manner. Short term (such as one or two months) fluctuation between workload categories need not be considered as long as the distribution of salaries and wages is reasonable over the longer term; and

- (C) The non-Federal entity's system of internal controls includes processes to review after-the-fact interim charges made to a Federal award based on budget estimates. All necessary adjustment must be made such that the final amount charged to the Federal award is accurate, allowable, and properly allocated.
- (ix) Because practices vary as to the activity constituting a full workload (for IHEs, IBS), records may reflect categories of activities expressed as a percentage distribution of total activities.
- (x) It is recognized that teaching, research, service, and administration are often inextricably intermingled in an academic setting. When recording salaries and wages charged to Federal awards for IHEs, a precise assessment of factors that contribute to costs is therefore not always feasible, nor is it expected.
- (2) For records which meet the standards required in paragraph (i)(1) of this section, the non-Federal entity will not be required to provide additional support or documentation for the work performed, other than that referenced in paragraph (i)(3) of this section.
- (3) In accordance with Department of Labor regulations implementing the Fair Labor Standards Act (FLSA) (29 CFR part 516), charges for the salaries and wages of nonexempt employees, in addition to the supporting documentation described in this section, must also be supported by records indicating the total number of hours worked each day.
- (4) Salaries and wages of employees used in meeting cost sharing or matching requirements on Federal awards must be supported in the same manner as salaries and wages claimed for reimbursement from Federal awards.
- (5) For states, local governments and Indian tribes, substitute processes or systems for allocating salaries and wages to Federal awards may be used in place of or in addition to the records described in paragraph (1) if approved by the cognizant agency for indirect cost. Such systems may include, but are not limited to, random moment sampling, "rolling" time studies, case counts, or other quantifiable measures of work performed.
- (i) Substitute systems which use sampling methods (primarily for Temporary Assistance for Needy Families (TANF), the Supplemental Nutrition Assistance Program (SNAP), Medicaid, and other public assistance programs) must meet acceptable statistical sampling standards including:
- (A) The sampling universe must include all of the employees whose salaries and wages are to be allocated based on sample results except as provided in paragraph (i)(5)(iii) of this section;
- (B) The entire time period involved must be covered by the sample; and
- (C) The results must be statistically valid and applied to the period being sampled.
- (ii) Allocating charges for the sampled employees' supervisors, clerical and support staffs, based on the results of the sampled employees, will be acceptable.
- (iii) Less than full compliance with the statistical sampling standards noted in subsection (5)(i) may be accepted by the cognizant agency for indirect costs if it concludes that the amounts to be allocated to Federal awards will be minimal, or if it concludes that the system proposed by the non-Federal entity will result in lower costs to Federal awards than a system which complies with the standards.
- (6) Cognizant agencies for indirect costs are encouraged to approve alternative proposals based on outcomes and milestones for program performance where these are clearly documented. Where approved by the Federal cognizant agency for indirect costs, these plans are acceptable as an alternative to the requirements of paragraph (i)(1) of this section.
- (7) For Federal awards of similar purpose activity or instances of approved blended funding, a non-Federal entity may submit performance plans that incorporate funds from multiple Federal awards and account for their combined use based on performance-oriented metrics, provided that such plans are approved in advance by all involved Federal awarding agencies. In these instances, the non-Federal entity must submit a request for waiver of the requirements based on documentation that describes the method of charging costs, relates the charging of costs to the specific activity that is applicable to all fund sources, and is based on quantifiable measures of the activity in relation to time charged.
- (8) For a non-Federal entity where the records do not meet the standards described in this section, the Federal Government may require personnel activity reports, including prescribed certifications, or equivalent documentation that support the records as required in this section.

*[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75886, Dec. 19, 2014; 85 FR 49565, Aug. 13, 2020]*

## § 200.431 Compensation - fringe benefits.

- (a) **General.** Fringe benefits are allowances and services provided by employers to their employees as compensation in addition to regular salaries and wages. Fringe benefits include, but are not limited to, the costs of leave (vacation, family-related, sick or military), employee insurance, pensions, and unemployment benefit plans. Except as provided elsewhere in these principles, the costs of fringe benefits are allowable provided that the benefits are reasonable and are required by law, non-Federal entity-employee agreement, or an established policy of the non-Federal entity.
- (b) **Leave.** The cost of fringe benefits in the form of regular compensation paid to employees during periods of authorized absences from the job, such as for annual leave, family-related leave, sick leave, holidays, court leave, military leave, administrative leave, and other similar benefits, are allowable if all of the following criteria are met:
- (1) They are provided under established written leave policies;
  - (2) The costs are equitably allocated to all related activities, including Federal awards; and,
  - (3) The accounting basis (cash or accrual) selected for costing each type of leave is consistently followed by the non-Federal entity or specified grouping of employees.
    - (i) When a non-Federal entity uses the cash basis of accounting, the cost of leave is recognized in the period that the leave is taken and paid for. Payments for unused leave when an employee retires or terminates employment are allowable in the year of payment.
    - (ii) The accrual basis may be only used for those types of leave for which a liability as defined by GAAP exists when the leave is earned. When a non-Federal entity uses the accrual basis of accounting, allowable leave costs are the lesser of the amount accrued or funded.
- (c) **Fringe benefits.** The cost of fringe benefits in the form of employer contributions or expenses for social security; employee life, health, unemployment, and worker's compensation insurance (except as indicated in § 200.447); pension plan costs (see paragraph (i) of this section); and other similar benefits are allowable, provided such benefits are granted under established written policies. Such benefits, must be allocated to Federal awards and all other activities in a manner consistent with the pattern of benefits attributable to the individuals or group(s) of employees whose salaries and wages are chargeable to such Federal awards and other activities, and charged as direct or indirect costs in accordance with the non-Federal entity's accounting practices.
- (d) **Cost objectives.** Fringe benefits may be assigned to cost objectives by identifying specific benefits to specific individual employees or by allocating on the basis of entity-wide salaries and wages of the employees receiving the benefits. When the allocation method is used, separate allocations must be made to selective groupings of employees, unless the non-Federal entity demonstrates that costs in relationship to salaries and wages do not differ significantly for different groups of employees.
- (e) **Insurance.** See also § 200.447(d)(1) and (2).
- (1) Provisions for a reserve under a self-insurance program for unemployment compensation or workers' compensation are allowable to the extent that the provisions represent reasonable estimates of the liabilities for such compensation, and the types of coverage, extent of coverage, and rates and premiums would have been allowable had insurance been purchased to cover the risks. However, provisions for self-insured liabilities which do not become payable for more than one year after the provision is made must not exceed the present value of the liability.
  - (2) Costs of insurance on the lives of trustees, officers, or other employees holding positions of similar responsibility are allowable only to the extent that the insurance represents additional compensation. The costs of such insurance when the non-Federal entity is named as beneficiary are unallowable.
  - (3) Actual claims paid to or on behalf of employees or former employees for workers' compensation, unemployment compensation, severance pay, and similar employee benefits (e.g., post-retirement health benefits), are allowable in the year of payment provided that the non-Federal entity follows a consistent costing policy.
- (f) **Automobiles.** That portion of automobile costs furnished by the non-Federal entity that relates to personal use by employees (including transportation to and from work) is unallowable as fringe benefit or indirect (F&A) costs regardless of whether the cost is reported as taxable income to the employees.
- (g) **Pension plan costs.** Pension plan costs which are incurred in accordance with the established policies of the non-Federal entity are allowable, provided that:
- (1) Such policies meet the test of reasonableness.
  - (2) The methods of cost allocation are not discriminatory.

- (3) Except for State and Local Governments, the cost assigned to each fiscal year should be determined in accordance with GAAP.
- (4) The costs assigned to a given fiscal year are funded for all plan participants within six months after the end of that year. However, increases to normal and past service pension costs caused by a delay in funding the actuarial liability beyond 30 calendar days after each quarter of the year to which such costs are assignable are unallowable. Non-Federal entity may elect to follow the "Cost Accounting Standard for Composition and Measurement of Pension Costs" (48 CFR 9904.412).
- (5) Pension plan termination insurance premiums paid pursuant to the Employee Retirement Income Security Act (ERISA) of 1974 (29 U.S.C. 1301-1461) are allowable. Late payment charges on such premiums are unallowable. Excise taxes on accumulated funding deficiencies and other penalties imposed under ERISA are unallowable.
- (6) Pension plan costs may be computed using a pay-as-you-go method or an acceptable actuarial cost method in accordance with established written policies of the non-Federal entity.
  - (i) For pension plans financed on a pay-as-you-go method, allowable costs will be limited to those representing actual payments to retirees or their beneficiaries.
  - (ii) Pension costs calculated using an actuarial cost-based method recognized by GAAP are allowable for a given fiscal year if they are funded for that year within six months after the end of that year. Costs funded after the six-month period (or a later period agreed to by the cognizant agency for indirect costs) are allowable in the year funded. The cognizant agency for indirect costs may agree to an extension of the six-month period if an appropriate adjustment is made to compensate for the timing of the charges to the Federal Government and related Federal reimbursement and the non-Federal entity's contribution to the pension fund. Adjustments may be made by cash refund or other equitable procedures to compensate the Federal Government for the time value of Federal reimbursements in excess of contributions to the pension fund.
  - (iii) Amounts funded by the non-Federal entity in excess of the actuarially determined amount for a fiscal year may be used as the non-Federal entity's contribution in future periods.
  - (iv) When a non-Federal entity converts to an acceptable actuarial cost method, as defined by GAAP, and funds pension costs in accordance with this method, the unfunded liability at the time of conversion is allowable if amortized over a period of years in accordance with GAAP.
  - (v) The Federal Government must receive an equitable share of any previously allowed pension costs (including earnings thereon) which revert or inure to the non-Federal entity in the form of a refund, withdrawal, or other credit.
- (h) **Post-retirement health.** Post-retirement health plans (PRHP) refers to costs of health insurance or health services not included in a pension plan covered by paragraph (g) of this section for retirees and their spouses, dependents, and survivors. PRHP costs may be computed using a pay-as-you-go method or an acceptable actuarial cost method in accordance with established written policies of the non-Federal entity.
  - (1) For PRHP financed on a pay-as-you-go method, allowable costs will be limited to those representing actual payments to retirees or their beneficiaries.
  - (2) PRHP costs calculated using an actuarial cost method recognized by GAAP are allowable if they are funded for that year within six months after the end of that year. Costs funded after the six-month period (or a later period agreed to by the cognizant agency) are allowable in the year funded. The Federal cognizant agency for indirect costs may agree to an extension of the six-month period if an appropriate adjustment is made to compensate for the timing of the charges to the Federal Government and related Federal reimbursements and the non-Federal entity's contributions to the PRHP fund. Adjustments may be made by cash refund, reduction in current year's PRHP costs, or other equitable procedures to compensate the Federal Government for the time value of Federal reimbursements in excess of contributions to the PRHP fund.
  - (3) Amounts funded in excess of the actuarially determined amount for a fiscal year may be used as the non-Federal entity contribution in a future period.
  - (4) When a non-Federal entity converts to an acceptable actuarial cost method and funds PRHP costs in accordance with this method, the initial unfunded liability attributable to prior years is allowable if amortized over a period of years in accordance with GAAP, or, if no such GAAP period exists, over a period negotiated with the cognizant agency for indirect costs.
  - (5) To be allowable in the current year, the PRHP costs must be paid either to:
    - (i) An insurer or other benefit provider as current year costs or premiums, or

- (ii) An insurer or trustee to maintain a trust fund or reserve for the sole purpose of providing post-retirement benefits to retirees and other beneficiaries.
  - (6) The Federal Government must receive an equitable share of any amounts of previously allowed post-retirement benefit costs (including earnings thereon) which revert or inure to the non-Federal entity in the form of a refund, withdrawal, or other credit.
- (i) **Severance pay.**
- (1) Severance pay, also commonly referred to as dismissal wages, is a payment in addition to regular salaries and wages, by non-Federal entities to workers whose employment is being terminated. Costs of severance pay are allowable only to the extent that in each case, it is required by
    - (i) Law;
    - (ii) Employer-employee agreement;
    - (iii) Established policy that constitutes, in effect, an implied agreement on the non-Federal entity's part; or
    - (iv) Circumstances of the particular employment.
  - (2) Costs of severance payments are divided into two categories as follows:
    - (i) Actual normal turnover severance payments must be allocated to all activities; or, where the non-Federal entity provides for a reserve for normal severances, such method will be acceptable if the charge to current operations is reasonable in light of payments actually made for normal severances over a representative past period, and if amounts charged are allocated to all activities of the non-Federal entity.
    - (ii) Measurement of costs of abnormal or mass severance pay by means of an accrual will not achieve equity to both parties. Thus, accruals for this purpose are not allowable. However, the Federal Government recognizes its responsibility to participate, to the extent of its fair share, in any specific payment. Prior approval by the Federal awarding agency or cognizant agency for indirect cost, as appropriate, is required.
  - (3) Costs incurred in certain severance pay packages which are in an amount in excess of the normal severance pay paid by the non-Federal entity to an employee upon termination of employment and are paid to the employee contingent upon a change in management control over, or ownership of, the non-Federal entity's assets, are unallowable.
  - (4) Severance payments to foreign nationals employed by the non-Federal entity outside the United States, to the extent that the amount exceeds the customary or prevailing practices for the non-Federal entity in the United States, are unallowable, unless they are necessary for the performance of Federal programs and approved by the Federal awarding agency.
  - (5) Severance payments to foreign nationals employed by the non-Federal entity outside the United States due to the termination of the foreign national as a result of the closing of, or curtailment of activities by, the non-Federal entity in that country, are unallowable, unless they are necessary for the performance of Federal programs and approved by the Federal awarding agency.
- (j) **For IHEs only.**
- (1) Fringe benefits in the form of undergraduate and graduate tuition or remission of tuition for individual employees are allowable, provided such benefits are granted in accordance with established non-Federal entity policies, and are distributed to all non-Federal entity activities on an equitable basis. Tuition benefits for family members other than the employee are unallowable.
  - (2) Fringe benefits in the form of tuition or remission of tuition for individual employees not employed by IHEs are limited to the tax-free amount allowed per section 127 of the Internal Revenue Code as amended.
  - (3) IHEs may offer employees tuition waivers or tuition reductions, provided that the benefit does not discriminate in favor of highly compensated employees. Employees can exercise these benefits at other institutions according to institutional policy. See § 200.466, for treatment of tuition remission provided to students.
- (k) **Fringe benefit programs and other benefit costs.** For IHEs whose costs are paid by state or local governments, fringe benefit programs (such as pension costs and FICA) and any other benefits costs specifically incurred on behalf of, and in direct benefit to, the non-Federal entity, are allowable costs of such non-Federal entities whether or not these costs are recorded in the accounting records of the non-Federal entities, subject to the following:
- (1) The costs meet the requirements of Basic Considerations in §§ 200.402 through 200.411;



- (2) The costs are properly supported by approved cost allocation plans in accordance with applicable Federal cost accounting principles; and
- (3) The costs are not otherwise borne directly or indirectly by the Federal Government.

[85 FR 49565, Aug. 13, 2020]

### **§ 200.432 Conferences.**

A conference is defined as a meeting, retreat, seminar, symposium, workshop or event whose primary purpose is the dissemination of technical information beyond the non-Federal entity and is necessary and reasonable for successful performance under the Federal award. Allowable conference costs paid by the non-Federal entity as a sponsor or host of the conference may include rental of facilities, speakers' fees, costs of meals and refreshments, local transportation, and other items incidental to such conferences unless further restricted by the terms and conditions of the Federal award. As needed, the costs of identifying, but not providing, locally available dependent-care resources are allowable. Conference hosts/sponsors must exercise discretion and judgment in ensuring that conference costs are appropriate, necessary and managed in a manner that minimizes costs to the Federal award. The Federal awarding agency may authorize exceptions where appropriate for programs including Indian tribes, children, and the elderly. See also §§ 200.438, 200.456, and 200.475.

[85 FR 49567, Aug. 13, 2020]

### **§ 200.433 Contingency provisions.**

- (a) Contingency is that part of a budget estimate of future costs (typically of large construction projects, IT systems, or other items as approved by the Federal awarding agency) which is associated with possible events or conditions arising from causes the precise outcome of which is indeterminable at the time of estimate, and that experience shows will likely result, in aggregate, in additional costs for the approved activity or project. Amounts for major project scope changes, unforeseen risks, or extraordinary events may not be included.
- (b) It is permissible for contingency amounts other than those excluded in paragraph (a) of this section to be explicitly included in budget estimates, to the extent they are necessary to improve the precision of those estimates. Amounts must be estimated using broadly-accepted cost estimating methodologies, specified in the budget documentation of the Federal award, and accepted by the Federal awarding agency. As such, contingency amounts are to be included in the Federal award. In order for actual costs incurred to be allowable, they must comply with the cost principles and other requirements in this part (see also §§ 200.300 and 200.403 of this part); be necessary and reasonable for proper and efficient accomplishment of project or program objectives, and be verifiable from the non-Federal entity's records.
- (c) Payments made by the Federal awarding agency to the non-Federal entity's "contingency reserve" or any similar payment made for events the occurrence of which cannot be foretold with certainty as to the time or intensity, or with an assurance of their happening, are unallowable, except as noted in §§ 200.431 and 200.447.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75886, Dec. 19, 2014; 85 FR 49567, Aug. 13, 2020]

### **§ 200.434 Contributions and donations.**

- (a) Costs of contributions and donations, including cash, property, and services, from the non-Federal entity to other entities, are unallowable.
- (b) The value of services and property donated to the non-Federal entity may not be charged to the Federal award either as a direct or indirect (F&A) cost. The value of donated services and property may be used to meet cost sharing or matching requirements (see § 200.306). Depreciation on donated assets is permitted in accordance with § 200.436, as long as the donated property is not counted towards cost sharing or matching requirements.
- (c) Services donated or volunteered to the non-Federal entity may be furnished to a non-Federal entity by professional and technical personnel, consultants, and other skilled and unskilled labor. The value of these services may not be charged to the Federal award either as a direct or indirect cost. However, the value of donated services may be used to meet cost sharing or matching requirements in accordance with the provisions of § 200.306.
- (d) To the extent feasible, services donated to the non-Federal entity will be supported by the same methods used to support the allocability of regular personnel services.

- (e) The following provisions apply to nonprofit organizations. The value of services donated to the nonprofit organization utilized in the performance of a direct cost activity must be considered in the determination of the non-Federal entity's indirect cost rate(s) and, accordingly, must be allocated a proportionate share of applicable indirect costs when the following circumstances exist:
- (1) The aggregate value of the services is material;
  - (2) The services are supported by a significant amount of the indirect costs incurred by the non-Federal entity;
    - (i) In those instances where there is no basis for determining the fair market value of the services rendered, the non-Federal entity and the cognizant agency for indirect costs must negotiate an appropriate allocation of indirect cost to the services.
    - (ii) Where donated services directly benefit a project supported by the Federal award, the indirect costs allocated to the services will be considered as a part of the total costs of the project. Such indirect costs may be reimbursed under the Federal award or used to meet cost sharing or matching requirements.
- (f) Fair market value of donated services must be computed as described in § 200.306.
- (g) Personal Property and Use of Space.
- (1) Donated personal property and use of space may be furnished to a non-Federal entity. The value of the personal property and space may not be charged to the Federal award either as a direct or indirect cost.
  - (2) The value of the donations may be used to meet cost sharing or matching share requirements under the conditions described in § 200.300 of this part. The value of the donations must be determined in accordance with § 200.300. Where donations are treated as indirect costs, indirect cost rates will separate the value of the donations so that reimbursement will not be made.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75886, Dec. 19, 2014; 85 FR 49567, Aug. 13, 2020]

### **§ 200.435 Defense and prosecution of criminal and civil proceedings, claims, appeals and patent infringements.**

- (a) *Definitions for the purposes of this section.*
- (1) **Conviction** means a judgment or conviction of a criminal offense by any court of competent jurisdiction, whether entered upon verdict or a plea, including a conviction due to a plea of nolo contendere.
  - (2) **Costs** include the services of in-house or private counsel, accountants, consultants, or others engaged to assist the non-Federal entity before, during, and after commencement of a judicial or administrative proceeding, that bear a direct relationship to the proceeding.
  - (3) **Fraud** means:
    - (i) Acts of fraud or corruption or attempts to defraud the Federal Government or to corrupt its agents,
    - (ii) Acts that constitute a cause for debarment or suspension (as specified in agency regulations), and
    - (iii) Acts which violate the False Claims Act (31 U.S.C. 3729-3732) or the Anti-kickback Act (41 U.S.C. 1320a-7b(b)).
  - (4) **Penalty** does not include restitution, reimbursement, or compensatory damages.
  - (5) **Proceeding** includes an investigation.
- (b) **Costs.**
- (1) Except as otherwise described herein, costs incurred in connection with any criminal, civil or administrative proceeding (including filing of a false certification) commenced by the Federal Government, a state, local government, or foreign government, or joined by the Federal Government (including a proceeding under the False Claims Act), against the non-Federal entity, (or commenced by third parties or a current or former employee of the non-Federal entity who submits a whistleblower complaint of reprisal in accordance with 10 U.S.C. 2409 or 41 U.S.C. 4712), are not allowable if the proceeding:
    - (i) Relates to a violation of, or failure to comply with, a Federal, state, local or foreign statute, regulation or the terms and conditions of the Federal award, by the non-Federal entity (including its agents and employees); and
    - (ii) Results in any of the following dispositions:

- (A) In a criminal proceeding, a conviction.
  - (B) In a civil or administrative proceeding involving an allegation of fraud or similar misconduct, a determination of non-Federal entity liability.
  - (C) In the case of any civil or administrative proceeding, the disallowance of costs or the imposition of a monetary penalty, or an order issued by the Federal awarding agency head or delegate to the non-Federal entity to take corrective action under 10 U.S.C. 2409 or 41 U.S.C. 4712.
  - (D) A final decision by an appropriate Federal official to debar or suspend the non-Federal entity, to rescind or void a Federal award, or to terminate a Federal award by reason of a violation or failure to comply with a statute, regulation, or the terms and conditions of the Federal award.
  - (E) A disposition by consent or compromise, if the action could have resulted in any of the dispositions described in paragraphs (b)(1)(ii)(A) through (D) of this section.
- (2) If more than one proceeding involves the same alleged misconduct, the costs of all such proceedings are unallowable if any results in one of the dispositions shown in paragraph (b) of this section.
- (c) If a proceeding referred to in paragraph (b) of this section is commenced by the Federal Government and is resolved by consent or compromise pursuant to an agreement by the non-Federal entity and the Federal Government, then the costs incurred may be allowed to the extent specifically provided in such agreement.
  - (d) If a proceeding referred to in paragraph (b) of this section is commenced by a state, local or foreign government, the authorized Federal official may allow the costs incurred if such authorized official determines that the costs were incurred as a result of:
    - (1) A specific term or condition of the Federal award, or
    - (2) Specific written direction of an authorized official of the Federal awarding agency.
  - (e) Costs incurred in connection with proceedings described in paragraph (b) of this section, which are not made unallowable by that subsection, may be allowed but only to the extent that:
    - (1) The costs are reasonable and necessary in relation to the administration of the Federal award and activities required to deal with the proceeding and the underlying cause of action;
    - (2) Payment of the reasonable, necessary, allocable and otherwise allowable costs incurred is not prohibited by any other provision(s) of the Federal award;
    - (3) The costs are not recovered from the Federal Government or a third party, either directly as a result of the proceeding or otherwise; and,
    - (4) An authorized Federal official must determine the percentage of costs allowed considering the complexity of litigation, generally accepted principles governing the award of legal fees in civil actions involving the United States, and such other factors as may be appropriate. Such percentage must not exceed 80 percent. However, if an agreement reached under paragraph (c) of this section has explicitly considered this 80 percent limitation and permitted a higher percentage, then the full amount of costs resulting from that agreement are allowable.
  - (f) Costs incurred by the non-Federal entity in connection with the defense of suits brought by its employees or ex-employees under section 2 of the Major Fraud Act of 1988 (18 U.S.C. 1031), including the cost of all relief necessary to make such employee whole, where the non-Federal entity was found liable or settled, are unallowable.
  - (g) Costs of prosecution of claims against the Federal Government, including appeals of final Federal agency decisions, are unallowable.
  - (h) Costs of legal, accounting, and consultant services, and related costs, incurred in connection with patent infringement litigation, are unallowable unless otherwise provided for in the Federal award.
  - (i) Costs which may be unallowable under this section, including directly associated costs, must be segregated and accounted for separately. During the pendency of any proceeding covered by paragraphs (b) and (f) of this section, the Federal Government must generally withhold payment of such costs. However, if in its best interests, the Federal Government may provide for conditional payment upon provision of adequate security, or other adequate assurance, and agreement to repay all unallowable costs, plus interest, if the costs are subsequently determined to be unallowable.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75886, Dec. 19, 2014]

## § 200.436 Depreciation.

- (a) Depreciation is the method for allocating the cost of fixed assets to periods benefitting from asset use. The non-Federal entity may be compensated for the use of its buildings, capital improvements, equipment, and software projects capitalized in accordance with GAAP, provided that they are used, needed in the non-Federal entity's activities, and properly allocated to Federal awards. Such compensation must be made by computing depreciation.
- (b) The allocation for depreciation must be made in accordance with Appendices III through IX.
- (c) Depreciation is computed applying the following rules. The computation of depreciation must be based on the acquisition cost of the assets involved. For an asset donated to the non-Federal entity by a third party, its fair market value at the time of the donation must be considered as the acquisition cost. Such assets may be depreciated or claimed as matching but not both. For the computation of depreciation, the acquisition cost will exclude:
  - (1) The cost of land;
  - (2) Any portion of the cost of buildings and equipment borne by or donated by the Federal Government, irrespective of where title was originally vested or where it is presently located;
  - (3) Any portion of the cost of buildings and equipment contributed by or for the non-Federal entity that are already claimed as matching or where law or agreement prohibits recovery;
  - (4) Any asset acquired solely for the performance of a non-Federal award; and
- (d) When computing depreciation charges, the following must be observed:
  - (1) The period of useful service or useful life established in each case for usable capital assets must take into consideration such factors as type of construction, nature of the equipment, technological developments in the particular area, historical data, and the renewal and replacement policies followed for the individual items or classes of assets involved.
  - (2) The depreciation method used to charge the cost of an asset (or group of assets) to accounting periods must reflect the pattern of consumption of the asset during its useful life. In the absence of clear evidence indicating that the expected consumption of the asset will be significantly greater in the early portions than in the later portions of its useful life, the straight-line method must be presumed to be the appropriate method. Depreciation methods once used may not be changed unless approved in advance by the cognizant agency. The depreciation methods used to calculate the depreciation amounts for indirect (F&A) rate purposes must be the same methods used by the non-Federal entity for its financial statements.
  - (3) The entire building, including the shell and all components, may be treated as a single asset and depreciated over a single useful life. A building may also be divided into multiple components. Each component item may then be depreciated over its estimated useful life. The building components must be grouped into three general components of a building: building shell (including construction and design costs), building services systems (e.g., elevators, HVAC, plumbing system and heating and air-conditioning system) and fixed equipment (e.g., sterilizers, casework, fume hoods, cold rooms and glassware/washers). In exceptional cases, a cognizant agency may authorize a non-Federal entity to use more than these three groupings. When a non-Federal entity elects to depreciate its buildings by its components, the same depreciation methods must be used for indirect (F&A) purposes and financial statements purposes, as described in paragraphs (d)(1) and (2) of this section.
  - (4) No depreciation may be allowed on any assets that have outlived their depreciable lives.
  - (5) Where the depreciation method is introduced to replace the use allowance method, depreciation must be computed as if the asset had been depreciated over its entire life (i.e., from the date the asset was acquired and ready for use to the date of disposal or withdrawal from service). The total amount of use allowance and depreciation for an asset (including imputed depreciation applicable to periods prior to the conversion from the use allowance method as well as depreciation after the conversion) may not exceed the total acquisition cost of the asset.
- (e) Charges for depreciation must be supported by adequate property records, and physical inventories must be taken at least once every two years to ensure that the assets exist and are usable, used, and needed. Statistical sampling techniques may be used in taking these inventories. In addition, adequate depreciation records showing the amount of depreciation must be maintained.

*[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75886, Dec. 19, 2014; 85 FR 49568, Aug. 13, 2020]*

### **§ 200.437 Employee health and welfare costs.**

- (a) Costs incurred in accordance with the non-Federal entity's documented policies for the improvement of working conditions, employer-employee relations, employee health, and employee performance are allowable.

- (b) Such costs will be equitably apportioned to all activities of the non-Federal entity. Income generated from any of these activities will be credited to the cost thereof unless such income has been irrevocably sent to employee welfare organizations.
- (c) Losses resulting from operating food services are allowable only if the non-Federal entity's objective is to operate such services on a break-even basis. Losses sustained because of operating objectives other than the above are allowable only:
  - (1) Where the non-Federal entity can demonstrate unusual circumstances; and
  - (2) With the approval of the cognizant agency for indirect costs.

### **§ 200.438 Entertainment costs.**

Costs of entertainment, including amusement, diversion, and social activities and any associated costs are unallowable, except where specific costs that might otherwise be considered entertainment have a programmatic purpose and are authorized either in the approved budget for the Federal award or with prior written approval of the Federal awarding agency.

### **§ 200.439 Equipment and other capital expenditures.**

- (a) See § 200.1 for the definitions of *capital expenditures*, *equipment*, *special purpose equipment*, *general purpose equipment*, *acquisition cost*, and *capital assets*.
- (b) The following rules of allowability must apply to equipment and other capital expenditures:
  - (1) Capital expenditures for general purpose equipment, buildings, and land are unallowable as direct charges, except with the prior written approval of the Federal awarding agency or pass-through entity.
  - (2) Capital expenditures for special purpose equipment are allowable as direct costs, provided that items with a unit cost of \$5,000 or more have the prior written approval of the Federal awarding agency or pass-through entity.
  - (3) Capital expenditures for improvements to land, buildings, or equipment which materially increase their value or useful life are unallowable as a direct cost except with the prior written approval of the Federal awarding agency, or pass-through entity. See § 200.436, for rules on the allowability of depreciation on buildings, capital improvements, and equipment. See also § 200.465.
  - (4) When approved as a direct charge pursuant to paragraphs (b)(1) through (3) of this section, capital expenditures will be charged in the period in which the expenditure is incurred, or as otherwise determined appropriate and negotiated with the Federal awarding agency.
  - (5) The unamortized portion of any equipment written off as a result of a change in capitalization levels may be recovered by continuing to claim the otherwise allowable depreciation on the equipment, or by amortizing the amount to be written off over a period of years negotiated with the Federal cognizant agency for indirect cost.
  - (6) Cost of equipment disposal. If the non-Federal entity is instructed by the Federal awarding agency to otherwise dispose of or transfer the equipment the costs of such disposal or transfer are allowable.
  - (7) Equipment and other capital expenditures are unallowable as indirect costs. See § 200.436.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75886, Dec. 19, 2014; 85 FR 49568, Aug. 13, 2020]

### **§ 200.440 Exchange rates.**

- (a) Cost increases for fluctuations in exchange rates are allowable costs subject to the availability of funding. Prior approval of exchange rate fluctuations is required only when the change results in the need for additional Federal funding, or the increased costs result in the need to significantly reduce the scope of the project. The Federal awarding agency must however ensure that adequate funds are available to cover currency fluctuations in order to avoid a violation of the Anti-Deficiency Act.
- (b) The non-Federal entity is required to make reviews of local currency gains to determine the need for additional federal funding before the expiration date of the Federal award. Subsequent adjustments for currency increases may be allowable only when the non-Federal entity provides the Federal awarding agency with adequate source documentation from a commonly used source in effect at the time the expense was made, and to the extent that sufficient Federal funds are available.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75886, Dec. 19, 2014]

### **§ 200.441 Fines, penalties, damages and other settlements.**

Costs resulting from non-Federal entity violations of, alleged violations of, or failure to comply with, Federal, state, tribal, local or foreign laws and regulations are unallowable, except when incurred as a result of compliance with specific provisions of the Federal award, or with prior written approval of the Federal awarding agency. See also § 200.435.

[85 FR 49568, Aug. 13, 2020]

### **§ 200.442 Fund raising and investment management costs.**

- (a) Costs of organized fund raising, including financial campaigns, endowment drives, solicitation of gifts and bequests, and similar expenses incurred to raise capital or obtain contributions are unallowable. Fund raising costs for the purposes of meeting the Federal program objectives are allowable with prior written approval from the Federal awarding agency. Proposal costs are covered in § 200.460.
- (b) Costs of investment counsel and staff and similar expenses incurred to enhance income from investments are unallowable except when associated with investments covering pension, self-insurance, or other funds which include Federal participation allowed by this part.
- (c) Costs related to the physical custody and control of monies and securities are allowable.
- (d) Both allowable and unallowable fund-raising and investment activities must be allocated as an appropriate share of indirect costs under the conditions described in § 200.413.

[85 FR 49568, Aug. 13, 2020]

### **§ 200.443 Gains and losses on disposition of depreciable assets.**

- (a) Gains and losses on the sale, retirement, or other disposition of depreciable property must be included in the year in which they occur as credits or charges to the asset cost grouping(s) in which the property was included. The amount of the gain or loss to be included as a credit or charge to the appropriate asset cost grouping(s) is the difference between the amount realized on the property and the undepreciated basis of the property.
- (b) Gains and losses from the disposition of depreciable property must not be recognized as a separate credit or charge under the following conditions:
  - (1) The gain or loss is processed through a depreciation account and is reflected in the depreciation allowable under §§ 200.436 and 200.439.
  - (2) The property is given in exchange as part of the purchase price of a similar item and the gain or loss is taken into account in determining the depreciation cost basis of the new item.
  - (3) A loss results from the failure to maintain permissible insurance, except as otherwise provided in § 200.447.
  - (4) Compensation for the use of the property was provided through use allowances in lieu of depreciation.
  - (5) Gains and losses arising from mass or extraordinary sales, retirements, or other dispositions must be considered on a case-by-case basis.
- (c) Gains or losses of any nature arising from the sale or exchange of property other than the property covered in paragraph (a) of this section, e.g., land, must be excluded in computing Federal award costs.
- (d) When assets acquired with Federal funds, in part or wholly, are disposed of, the distribution of the proceeds must be made in accordance with §§ 200.310 through 200.316 of this part.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75886, Dec. 19, 2014; 85 FR 49568, Aug. 13, 2020]

### **§ 200.444 General costs of government.**

- (a) For states, local governments, and Indian Tribes, the general costs of government are unallowable (except as provided in § 200.475). Unallowable costs include:

- (1) Salaries and expenses of the Office of the Governor of a state or the chief executive of a local government or the chief executive of an Indian tribe;
  - (2) Salaries and other expenses of a state legislature, tribal council, or similar local governmental body, such as a county supervisor, city council, school board, etc., whether incurred for purposes of legislation or executive direction;
  - (3) Costs of the judicial branch of a government;
  - (4) Costs of prosecutorial activities unless treated as a direct cost to a specific program if authorized by statute or regulation (however, this does not preclude the allowability of other legal activities of the Attorney General as described in § 200.435); and
  - (5) Costs of other general types of government services normally provided to the general public, such as fire and police, unless provided for as a direct cost under a program statute or regulation.
- (b) For Indian tribes and Councils of Governments (COGs) (see definition for *Local government* in § 200.1 of this part), up to 50% of salaries and expenses directly attributable to managing and operating Federal programs by the chief executive and his or her staff can be included in the indirect cost calculation without documentation.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75886, Dec. 19, 2014; 85 FR 49568, Aug. 13, 2020]

### **§ 200.445 Goods or services for personal use.**

- (a) Costs of goods or services for personal use of the non-Federal entity's employees are unallowable regardless of whether the cost is reported as taxable income to the employees.
- (b) Costs of housing (e.g., depreciation, maintenance, utilities, furnishings, rent), housing allowances and personal living expenses are only allowable as direct costs regardless of whether reported as taxable income to the employees. In addition, to be allowable direct costs must be approved in advance by a Federal awarding agency.

### **§ 200.446 Idle facilities and idle capacity.**

- (a) As used in this section the following terms have the meanings set forth in this section:
  - (1) Facilities means land and buildings or any portion thereof, equipment individually or collectively, or any other tangible capital asset, wherever located, and whether owned or leased by the non-Federal entity.
  - (2) Idle facilities means completely unused facilities that are excess to the non-Federal entity's current needs.
  - (3) Idle capacity means the unused capacity of partially used facilities. It is the difference between:
    - (i) That which a facility could achieve under 100 percent operating time on a one-shift basis less operating interruptions resulting from time lost for repairs, setups, unsatisfactory materials, and other normal delays and;
    - (ii) The extent to which the facility was actually used to meet demands during the accounting period. A multi-shift basis should be used if it can be shown that this amount of usage would normally be expected for the type of facility involved.
  - (4) Cost of idle facilities or idle capacity means costs such as maintenance, repair, housing, rent, and other related costs, e.g., insurance, interest, and depreciation. These costs could include the costs of idle public safety emergency facilities, telecommunications, or information technology system capacity that is built to withstand major fluctuations in load, e.g., consolidated data centers.
- (b) The costs of idle facilities are unallowable except to the extent that:
  - (1) They are necessary to meet workload requirements which may fluctuate and are allocated appropriately to all benefiting programs; or
  - (2) Although not necessary to meet fluctuations in workload, they were necessary when acquired and are now idle because of changes in program requirements, efforts to achieve more economical operations, reorganization, termination, or other causes which could not have been reasonably foreseen. Under the exception stated in this subsection, costs of idle facilities are allowable for a reasonable period of time, ordinarily not to exceed one year, depending on the initiative taken to use, lease, or dispose of such facilities.

- (c) The costs of idle capacity are normal costs of doing business and are a factor in the normal fluctuations of usage or indirect cost rates from period to period. Such costs are allowable, provided that the capacity is reasonably anticipated to be necessary to carry out the purpose of the Federal award or was originally reasonable and is not subject to reduction or elimination by use on other Federal awards, subletting, renting, or sale, in accordance with sound business, economic, or security practices. Widespread idle capacity throughout an entire facility or among a group of assets having substantially the same function may be considered idle facilities.

### § 200.447 Insurance and indemnification.

- (a) Costs of insurance required or approved and maintained, pursuant to the Federal award, are allowable.
- (b) Costs of other insurance in connection with the general conduct of activities are allowable subject to the following limitations:
  - (1) Types and extent and cost of coverage are in accordance with the non-Federal entity's policy and sound business practice.
  - (2) Costs of insurance or of contributions to any reserve covering the risk of loss of, or damage to, Federal Government property are unallowable except to the extent that the Federal awarding agency has specifically required or approved such costs.
  - (3) Costs allowed for business interruption or other similar insurance must exclude coverage of management fees.
  - (4) Costs of insurance on the lives of trustees, officers, or other employees holding positions of similar responsibilities are allowable only to the extent that the insurance represents additional compensation (see § 200.431). The cost of such insurance when the non-Federal entity is identified as the beneficiary is unallowable.
  - (5) Insurance against defects. Costs of insurance with respect to any costs incurred to correct defects in the non-Federal entity's materials or workmanship are unallowable.
  - (6) Medical liability (malpractice) insurance. Medical liability insurance is an allowable cost of Federal research programs only to the extent that the Federal research programs involve human subjects or training of participants in research techniques. Medical liability insurance costs must be treated as a direct cost and must be assigned to individual projects based on the manner in which the insurer allocates the risk to the population covered by the insurance.
- (c) Actual losses which could have been covered by permissible insurance (through a self-insurance program or otherwise) are unallowable, unless expressly provided for in the Federal award. However, costs incurred because of losses not covered under nominal deductible insurance coverage provided in keeping with sound management practice, and minor losses not covered by insurance, such as spoilage, breakage, and disappearance of small hand tools, which occur in the ordinary course of operations, are allowable.
- (d) Contributions to a reserve for certain self-insurance programs including workers' compensation, unemployment compensation, and severance pay are allowable subject to the following provisions:
  - (1) The type of coverage and the extent of coverage and the rates and premiums would have been allowed had insurance (including reinsurance) been purchased to cover the risks. However, provision for known or reasonably estimated self-insured liabilities, which do not become payable for more than one year after the provision is made, must not exceed the discounted present value of the liability. The rate used for discounting the liability must be determined by giving consideration to such factors as the non-Federal entity's settlement rate for those liabilities and its investment rate of return.
  - (2) Earnings or investment income on reserves must be credited to those reserves.
  - (3)
    - (i) Contributions to reserves must be based on sound actuarial principles using historical experience and reasonable assumptions. Reserve levels must be analyzed and updated at least biennially for each major risk being insured and take into account any reinsurance, coinsurance, etc. Reserve levels related to employee-related coverages will normally be limited to the value of claims:
      - (A) Submitted and adjudicated but not paid;
      - (B) Submitted but not adjudicated; and
      - (C) Incurred but not submitted.



- (ii) Reserve levels in excess of the amounts based on the above must be identified and justified in the cost allocation plan or indirect cost rate proposal.
- (4) Accounting records, actuarial studies, and cost allocations (or billings) must recognize any significant differences due to types of insured risk and losses generated by the various insured activities or agencies of the non-Federal entity. If individual departments or agencies of the non-Federal entity experience significantly different levels of claims for a particular risk, those differences are to be recognized by the use of separate allocations or other techniques resulting in an equitable allocation.
- (5) Whenever funds are transferred from a self-insurance reserve to other accounts (e.g., general fund or unrestricted account), refunds must be made to the Federal Government for its share of funds transferred, including earned or imputed interest from the date of transfer and debt interest, if applicable, chargeable in accordance with applicable Federal cognizant agency for indirect cost, claims collection regulations.
- (e) Insurance refunds must be credited against insurance costs in the year the refund is received.
- (f) Indemnification includes securing the non-Federal entity against liabilities to third persons and other losses not compensated by insurance or otherwise. The Federal Government is obligated to indemnify the non-Federal entity only to the extent expressly provided for in the Federal award, except as provided in paragraph (c) of this section.

[78 FR 78608, Dec. 26, 2013, as amended at 85 FR 49568, Aug. 13, 2020]

### § 200.448 Intellectual property.

#### (a) *Patent costs.*

- (1) The following costs related to securing patents and copyrights are allowable:
  - (i) Costs of preparing disclosures, reports, and other documents required by the Federal award, and of searching the art to the extent necessary to make such disclosures;
  - (ii) Costs of preparing documents and any other patent costs in connection with the filing and prosecution of a United States patent application where title or royalty-free license is required by the Federal Government to be conveyed to the Federal Government; and
  - (iii) General counseling services relating to patent and copyright matters, such as advice on patent and copyright laws, regulations, clauses, and employee intellectual property agreements (See also § 200.459).
- (2) The following costs related to securing patents and copyrights are unallowable:
  - (i) Costs of preparing disclosures, reports, and other documents, and of searching the art to make disclosures not required by the Federal award;
  - (ii) Costs in connection with filing and prosecuting any foreign patent application, or any United States patent application, where the Federal award does not require conveying title or a royalty-free license to the Federal Government.

#### (b) *Royalties and other costs for use of patents and copyrights.*

- (1) Royalties on a patent or copyright or amortization of the cost of acquiring by purchase a copyright, patent, or rights thereto, necessary for the proper performance of the Federal award are allowable unless:
  - (i) The Federal Government already has a license or the right to free use of the patent or copyright.
  - (ii) The patent or copyright has been adjudicated to be invalid, or has been administratively determined to be invalid.
  - (iii) The patent or copyright is considered to be unenforceable.
  - (iv) The patent or copyright is expired.
- (2) Special care should be exercised in determining reasonableness where the royalties may have been arrived at as a result of less-than-arm's-length bargaining, such as:
  - (i) Royalties paid to persons, including corporations, affiliated with the non-Federal entity.
  - (ii) Royalties paid to unaffiliated parties, including corporations, under an agreement entered into in contemplation that a Federal award would be made.

(iii) Royalties paid under an agreement entered into after a Federal award is made to a non-Federal entity.

- (3) In any case involving a patent or copyright formerly owned by the non-Federal entity, the amount of royalty allowed must not exceed the cost which would have been allowed had the non-Federal entity retained title thereto.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75886, Dec. 19, 2014; 85 FR 49569, Aug. 13, 2020]

## § 200.449 Interest.

- (a) **General.** Costs incurred for interest on borrowed capital, temporary use of endowment funds, or the use of the non-Federal entity's own funds, however represented, are unallowable. Financing costs (including interest) to acquire, construct, or replace capital assets are allowable, subject to the conditions in this section.
- (b) **Capital assets.**
- (1) Capital assets is defined as noted in § 200.1 of this part. An asset cost includes (as applicable) acquisition costs, construction costs, and other costs capitalized in accordance with GAAP.
  - (2) For non-Federal entity fiscal years beginning on or after January 1, 2016, intangible assets include patents and computer software. For software development projects, only interest attributable to the portion of the project costs capitalized in accordance with GAAP is allowable.
- (c) **Conditions for all non-Federal entities.**
- (1) The non-Federal entity uses the capital assets in support of Federal awards;
  - (2) The allowable asset costs to acquire facilities and equipment are limited to a fair market value available to the non-Federal entity from an unrelated (arm's length) third party.
  - (3) The non-Federal entity obtains the financing via an arm's-length transaction (that is, a transaction with an unrelated third party); or claims reimbursement of actual interest cost at a rate available via such a transaction.
  - (4) The non-Federal entity limits claims for Federal reimbursement of interest costs to the least expensive alternative. For example, a lease contract that transfers ownership by the end of the contract may be determined less costly than purchasing through other types of debt financing, in which case reimbursement must be limited to the amount of interest determined if leasing had been used.
  - (5) The non-Federal entity expenses or capitalizes allowable interest cost in accordance with GAAP.
  - (6) Earnings generated by the investment of borrowed funds pending their disbursement for the asset costs are used to offset the current period's allowable interest cost, whether that cost is expensed or capitalized. Earnings subject to being reported to the Federal Internal Revenue Service under arbitrage requirements are excludable.
  - (7) The following conditions must apply to debt arrangements over \$1 million to purchase or construct facilities, unless the non-Federal entity makes an initial equity contribution to the purchase of 25 percent or more. For this purpose, "initial equity contribution" means the amount or value of contributions made by the non-Federal entity for the acquisition of facilities prior to occupancy.
    - (i) The non-Federal entity must reduce claims for reimbursement of interest cost by an amount equal to imputed interest earnings on excess cash flow attributable to the portion of the facility used for Federal awards.
    - (ii) The non-Federal entity must impute interest on excess cash flow as follows:
      - (A) Annually, the non-Federal entity must prepare a cumulative (from the inception of the project) report of monthly cash inflows and outflows, regardless of the funding source. For this purpose, inflows consist of Federal reimbursement for depreciation, amortization of capitalized construction interest, and annual interest cost. Outflows consist of initial equity contributions, debt principal payments (less the pro-rata share attributable to the cost of land), and interest payments.
      - (B) To compute monthly cash inflows and outflows, the non-Federal entity must divide the annual amounts determined in step (i) by the number of months in the year (usually 12) that the building is in service.
      - (C) For any month in which cumulative cash inflows exceed cumulative outflows, interest must be calculated on the excess inflows for that month and be treated as a reduction to allowable interest cost. The rate of interest to be used must be the three-month Treasury bill closing rate as of the last business day of that month.
  - (8) Interest attributable to a fully depreciated asset is unallowable.

- (d) Additional conditions for states, local governments and Indian tribes. For costs to be allowable, the non-Federal entity must have incurred the interest costs for buildings after October 1, 1980, or for land and equipment after September 1, 1995.
  - (1) The requirement to offset interest earned on borrowed funds against current allowable interest cost (paragraph (c) (5), above) also applies to earnings on debt service reserve funds.
  - (2) The non-Federal entity will negotiate the amount of allowable interest cost related to the acquisition of facilities with asset costs of \$1 million or more, as outlined in paragraph (c)(7) of this section. For this purpose, a non-Federal entity must consider only cash inflows and outflows attributable to that portion of the real property used for Federal awards.
- (e) Additional conditions for IHEs. For costs to be allowable, the IHE must have incurred the interest costs after July 1, 1982, in connection with acquisitions of capital assets that occurred after that date.
- (f) Additional condition for nonprofit organizations. For costs to be allowable, the nonprofit organization incurred the interest costs after September 29, 1995, in connection with acquisitions of capital assets that occurred after that date.
- (g) The interest allowability provisions of this section do not apply to a nonprofit organization subject to "full coverage" under the Cost Accounting Standards (CAS), as defined at 48 CFR 9903.201-2(a). The non-Federal entity's Federal awards are instead subject to CAS 414 (48 CFR 9904.414), "Cost of Money as an Element of the Cost of Facilities Capital", and CAS 417 (48 CFR 9904.417), "Cost of Money as an Element of the Cost of Capital Assets Under Construction".

[78 FR 78608, Dec. 26, 2013, as amended at 80 FR 54409, Sept. 10, 2015; 85 FR 49569, Aug. 13, 2020]

### § 200.450 Lobbying.

- (a) The cost of certain influencing activities associated with obtaining grants, contracts, or cooperative agreements, or loans is an unallowable cost. Lobbying with respect to certain grants, contracts, cooperative agreements, and loans is governed by relevant statutes, including among others, the provisions of 31 U.S.C. 1352, as well as the common rule, "New Restrictions on Lobbying" published on February 26, 1990, including definitions, and the Office of Management and Budget "Governmentwide Guidance for New Restrictions on Lobbying" and notices published on December 20, 1989, June 15, 1990, January 15, 1992, and January 19, 1996.
- (b) **Executive lobbying costs.** Costs incurred in attempting to improperly influence either directly or indirectly, an employee or officer of the executive branch of the Federal Government to give consideration or to act regarding a Federal award or a regulatory matter are unallowable. Improper influence means any influence that induces or tends to induce a Federal employee or officer to give consideration or to act regarding a Federal award or regulatory matter on any basis other than the merits of the matter.
- (c) In addition to the above, the following restrictions are applicable to nonprofit organizations and IHEs:
  - (1) Costs associated with the following activities are unallowable:
    - (i) Attempts to influence the outcomes of any Federal, state, or local election, referendum, initiative, or similar procedure, through in-kind or cash contributions, endorsements, publicity, or similar activity;
    - (ii) Establishing, administering, contributing to, or paying the expenses of a political party, campaign, political action committee, or other organization established for the purpose of influencing the outcomes of elections in the United States;
    - (iii) Any attempt to influence:
      - (A) The introduction of Federal or state legislation;
      - (B) The enactment or modification of any pending Federal or state legislation through communication with any member or employee of the Congress or state legislature (including efforts to influence state or local officials to engage in similar lobbying activity);
      - (C) The enactment or modification of any pending Federal or state legislation by preparing, distributing, or using publicity or propaganda, or by urging members of the general public, or any segment thereof, to contribute to or participate in any mass demonstration, march, rally, fund raising drive, lobbying campaign or letter writing or telephone campaign; or
      - (D) Any government official or employee in connection with a decision to sign or veto enrolled legislation;

(iv) Legislative liaison activities, including attendance at legislative sessions or committee hearings, gathering information regarding legislation, and analyzing the effect of legislation, when such activities are carried on in support of or in knowing preparation for an effort to engage in unallowable lobbying.

(2) The following activities are excepted from the coverage of paragraph (c)(1) of this section:

- (i) Technical and factual presentations on topics directly related to the performance of a grant, contract, or other agreement (through hearing testimony, statements, or letters to the Congress or a state legislature, or subdivision, member, or cognizant staff member thereof), in response to a documented request (including a Congressional Record notice requesting testimony or statements for the record at a regularly scheduled hearing) made by the non-Federal entity's member of congress, legislative body or a subdivision, or a cognizant staff member thereof, provided such information is readily obtainable and can be readily put in deliverable form, and further provided that costs under this section for travel, lodging or meals are unallowable unless incurred to offer testimony at a regularly scheduled Congressional hearing pursuant to a written request for such presentation made by the Chairman or Ranking Minority Member of the Committee or Subcommittee conducting such hearings;
- (ii) Any lobbying made unallowable by paragraph (c)(1)(iii) of this section to influence state legislation in order to directly reduce the cost, or to avoid material impairment of the non-Federal entity's authority to perform the grant, contract, or other agreement; or
- (iii) Any activity specifically authorized by statute to be undertaken with funds from the Federal award.
- (iv) Any activity excepted from the definitions of "lobbying" or "influencing legislation" by the Internal Revenue Code provisions that require nonprofit organizations to limit their participation in direct and "grass roots" lobbying activities in order to retain their charitable deduction status and avoid punitive excise taxes, I.R.C. §§ 501(c)(3), 501(h), 4911(a), including:
  - (A) Nonpartisan analysis, study, or research reports;
  - (B) Examinations and discussions of broad social, economic, and similar problems; and
  - (C) Information provided upon request by a legislator for technical advice and assistance, as defined by I.R.C. § 4911(d)(2) and 26 CFR 56.4911-2(c)(1)-(c)(3).
- (v) When a non-Federal entity seeks reimbursement for indirect (F&A) costs, total lobbying costs must be separately identified in the indirect (F&A) cost rate proposal, and thereafter treated as other unallowable activity costs in accordance with the procedures of § 200.413.
- (vi) The non-Federal entity must submit as part of its annual indirect (F&A) cost rate proposal a certification that the requirements and standards of this section have been complied with. (See also § 200.415.)
- (vii)
  - (A) Time logs, calendars, or similar records are not required to be created for purposes of complying with the record keeping requirements in § 200.302 with respect to lobbying costs during any particular calendar month when:
    - (1) The employee engages in lobbying (as defined in paragraphs (c)(1) and (c)(2) of this section) 25 percent or less of the employee's compensated hours of employment during that calendar month; and
    - (2) Within the preceding five-year period, the non-Federal entity has not materially misstated allowable or unallowable costs of any nature, including legislative lobbying costs.
  - (B) When conditions in paragraph (c)(2)(vii)(A)(1) and (2) of this section are met, non-Federal entities are not required to establish records to support the allowability of claimed costs in addition to records already required or maintained. Also, when conditions in paragraphs (c)(2)(vii)(A)(1) and (2) of this section are met, the absence of time logs, calendars, or similar records will not serve as a basis for disallowing costs by contesting estimates of lobbying time spent by employees during a calendar month.
- (viii) The Federal awarding agency must establish procedures for resolving in advance, in consultation with OMB, any significant questions or disagreements concerning the interpretation or application of this section. Any such advance resolutions must be binding in any subsequent settlements, audits, or investigations with respect to that grant or contract for purposes of interpretation of this part, provided, however, that this must not be construed to prevent a contractor or non-Federal entity from contesting the lawfulness of such a determination.

[78 FR 78608, Dec. 26, 2013, as amended at 85 FR 49569, Aug. 13, 2020]

### **§ 200.451 Losses on other awards or contracts.**

Any excess of costs over income under any other award or contract of any nature is unallowable. This includes, but is not limited to, the non-Federal entity's contributed portion by reason of cost-sharing agreements or any under-recoveries through negotiation of flat amounts for indirect (F&A) costs. Also, any excess of costs over authorized funding levels transferred from any award or contract to another award or contract is unallowable. All losses are not allowable indirect (F&A) costs and are required to be included in the appropriate indirect cost rate base for allocation of indirect costs.

### **§ 200.452 Maintenance and repair costs.**

Costs incurred for utilities, insurance, security, necessary maintenance, janitorial services, repair, or upkeep of buildings and equipment (including Federal property unless otherwise provided for) which neither add to the permanent value of the property nor appreciably prolong its intended life, but keep it in an efficient operating condition, are allowable. Costs incurred for improvements which add to the permanent value of the buildings and equipment or appreciably prolong their intended life must be treated as capital expenditures (see § 200.439). These costs are only allowable to the extent not paid through rental or other agreements.

[85 FR 49569, Aug. 13, 2020]

### **§ 200.453 Materials and supplies costs, including costs of computing devices.**

- (a) Costs incurred for materials, supplies, and fabricated parts necessary to carry out a Federal award are allowable.
- (b) Purchased materials and supplies must be charged at their actual prices, net of applicable credits. Withdrawals from general stores or stockrooms must be charged at their actual net cost under any recognized method of pricing inventory withdrawals, consistently applied. Incoming transportation charges are a proper part of materials and supplies costs.
- (c) Materials and supplies used for the performance of a Federal award may be charged as direct costs. In the specific case of computing devices, charging as direct costs is allowable for devices that are essential and allocable, but not solely dedicated, to the performance of a Federal award.
- (d) Where federally-donated or furnished materials are used in performing the Federal award, such materials will be used without charge.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75887, Dec. 19, 2014]

### **§ 200.454 Memberships, subscriptions, and professional activity costs.**

- (a) Costs of the non-Federal entity's membership in business, technical, and professional organizations are allowable.
- (b) Costs of the non-Federal entity's subscriptions to business, professional, and technical periodicals are allowable.
- (c) Costs of membership in any civic or community organization are allowable with prior approval by the Federal awarding agency or pass-through entity.
- (d) Costs of membership in any country club or social or dining club or organization are unallowable.
- (e) Costs of membership in organizations whose primary purpose is lobbying are unallowable. See also § 200.450.

[78 FR 78608, Dec. 26, 2013, as amended at 85 FR 49569, Aug. 13, 2020]

### **§ 200.455 Organization costs.**

Costs such as incorporation fees, brokers' fees, fees to promoters, organizers or management consultants, attorneys, accountants, or investment counselor, whether or not employees of the non-Federal entity in connection with establishment or reorganization of an organization, are unallowable except with prior approval of the Federal awarding agency.

### **§ 200.456 Participant support costs.**

Participant support costs as defined in § 200.1 are allowable with the prior approval of the Federal awarding agency.

[85 FR 49569, Aug. 13, 2020]

### **§ 200.457 Plant and security costs.**

Necessary and reasonable expenses incurred for protection and security of facilities, personnel, and work products are allowable. Such costs include, but are not limited to, wages and uniforms of personnel engaged in security activities; equipment; barriers; protective (non-military) gear, devices, and equipment; contractual security services; and consultants. Capital expenditures for plant security purposes are subject to § 200.439.

[85 FR 49569, Aug. 13, 2020]

### **§ 200.458 Pre-award costs.**

Pre-award costs are those incurred prior to the effective date of the Federal award or subaward directly pursuant to the negotiation and in anticipation of the Federal award where such costs are necessary for efficient and timely performance of the scope of work. Such costs are allowable only to the extent that they would have been allowable if incurred after the date of the Federal award and only with the written approval of the Federal awarding agency. If charged to the award, these costs must be charged to the initial budget period of the award, unless otherwise specified by the Federal awarding agency or pass-through entity.

[85 FR 49569, Aug. 13, 2020]

### **§ 200.459 Professional service costs.**

- (a) Costs of professional and consultant services rendered by persons who are members of a particular profession or possess a special skill, and who are not officers or employees of the non-Federal entity, are allowable, subject to paragraphs (b) and (c) of this section when reasonable in relation to the services rendered and when not contingent upon recovery of the costs from the Federal Government. In addition, legal and related services are limited under § 200.435.
- (b) In determining the allowability of costs in a particular case, no single factor or any special combination of factors is necessarily determinative. However, the following factors are relevant:
  - (1) The nature and scope of the service rendered in relation to the service required.
  - (2) The necessity of contracting for the service, considering the non-Federal entity's capability in the particular area.
  - (3) The past pattern of such costs, particularly in the years prior to Federal awards.
  - (4) The impact of Federal awards on the non-Federal entity's business (i.e., what new problems have arisen).
  - (5) Whether the proportion of Federal work to the non-Federal entity's total business is such as to influence the non-Federal entity in favor of incurring the cost, particularly where the services rendered are not of a continuing nature and have little relationship to work under Federal awards.
  - (6) Whether the service can be performed more economically by direct employment rather than contracting.
  - (7) The qualifications of the individual or concern rendering the service and the customary fees charged, especially on non-federally funded activities.
  - (8) Adequacy of the contractual agreement for the service (e.g., description of the service, estimate of time required, rate of compensation, and termination provisions).
- (c) In addition to the factors in paragraph (b) of this section, to be allowable, retainer fees must be supported by evidence of bona fide services available or rendered.

[78 FR 78608, Dec. 26, 2013, as amended at 85 FR 49569, Aug. 13, 2020]

### **§ 200.460 Proposal costs.**

Proposal costs are the costs of preparing bids, proposals, or applications on potential Federal and non-Federal awards or projects, including the development of data necessary to support the non-Federal entity's bids or proposals. Proposal costs of the current accounting period of both successful and unsuccessful bids and proposals normally should be treated as indirect (F&A) costs and allocated currently to all activities of the non-Federal entity. No proposal costs of past accounting periods will be allocable to the current period.

**§ 200.461 Publication and printing costs.**

- (a) Publication costs for electronic and print media, including distribution, promotion, and general handling are allowable. If these costs are not identifiable with a particular cost objective, they should be allocated as indirect costs to all benefiting activities of the non-Federal entity.
- (b) Page charges for professional journal publications are allowable where:
  - (1) The publications report work supported by the Federal Government; and
  - (2) The charges are levied impartially on all items published by the journal, whether or not under a Federal award.
  - (3) The non-Federal entity may charge the Federal award during closeout for the costs of publication or sharing of research results if the costs are not incurred during the period of performance of the Federal award. If charged to the award, these costs must be charged to the final budget period of the award, unless otherwise specified by the Federal awarding agency.

*[78 FR 78608, Dec. 26, 2013, as amended at 85 FR 49569, Aug. 13, 2020]*

**§ 200.462 Rearrangement and reconversion costs.**

- (a) Costs incurred for ordinary and normal rearrangement and alteration of facilities are allowable as indirect costs. Special arrangements and alterations costs incurred specifically for a Federal award are allowable as a direct cost with the prior approval of the Federal awarding agency or pass-through entity.
- (b) Costs incurred in the restoration or rehabilitation of the non-Federal entity's facilities to approximately the same condition existing immediately prior to commencement of Federal awards, less costs related to normal wear and tear, are allowable.

**§ 200.463 Recruiting costs.**

- (a) Subject to paragraphs (b) and (c) of this section, and provided that the size of the staff recruited and maintained is in keeping with workload requirements, costs of "help wanted" advertising, operating costs of an employment office necessary to secure and maintain an adequate staff, costs of operating an aptitude and educational testing program, travel costs of employees while engaged in recruiting personnel, travel costs of applicants for interviews for prospective employment, and relocation costs incurred incident to recruitment of new employees, are allowable to the extent that such costs are incurred pursuant to the non-Federal entity's standard recruitment program. Where the non-Federal entity uses employment agencies, costs not in excess of standard commercial rates for such services are allowable.
- (b) Special emoluments, fringe benefits, and salary allowances incurred to attract professional personnel that do not meet the test of reasonableness or do not conform with the established practices of the non-Federal entity, are unallowable.
- (c) Where relocation costs incurred incident to recruitment of a new employee have been funded in whole or in part to a Federal award, and the newly hired employee resigns for reasons within the employee's control within 12 months after hire, the non-Federal entity will be required to refund or credit the Federal share of such relocation costs to the Federal Government. See also § 200.464.
- (d) Short-term, travel visa costs (as opposed to longer-term, immigration visas) are generally allowable expenses that may be proposed as a direct cost. Since short-term visas are issued for a specific period and purpose, they can be clearly identified as directly connected to work performed on a Federal award. For these costs to be directly charged to a Federal award, they must:
  - (1) Be critical and necessary for the conduct of the project;
  - (2) Be allowable under the applicable cost principles;
  - (3) Be consistent with the non-Federal entity's cost accounting practices and non-Federal entity policy; and
  - (4) Meet the definition of "direct cost" as described in the applicable cost principles.

*[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75887, Dec. 19, 2014; 85 FR 49569, Aug. 13, 2020]*

**§ 200.464 Relocation costs of employees.**

- (a) Relocation costs are costs incident to the permanent change of duty assignment (for an indefinite period or for a stated period of not less than 12 months) of an existing employee or upon recruitment of a new employee. Relocation costs are allowable, subject to the limitations described in paragraphs (b), (c), and (d) of this section, provided that:
- (1) The move is for the benefit of the employer.
  - (2) Reimbursement to the employee is in accordance with an established written policy consistently followed by the employer.
  - (3) The reimbursement does not exceed the employee's actual (or reasonably estimated) expenses.
- (b) Allowable relocation costs for current employees are limited to the following:
- (1) The costs of transportation of the employee, members of his or her immediate family and his household, and personal effects to the new location.
  - (2) The costs of finding a new home, such as advance trips by employees and spouses to locate living quarters and temporary lodging during the transition period, up to maximum period of 30 calendar days.
  - (3) Closing costs, such as brokerage, legal, and appraisal fees, incident to the disposition of the employee's former home. These costs, together with those described in (4), are limited to 8 per cent of the sales price of the employee's former home.
  - (4) The continuing costs of ownership (for up to six months) of the vacant former home after the settlement or lease date of the employee's new permanent home, such as maintenance of buildings and grounds (exclusive of fixing-up expenses), utilities, taxes, and property insurance.
  - (5) Other necessary and reasonable expenses normally incident to relocation, such as the costs of canceling an unexpired lease, transportation of personal property, and purchasing insurance against loss of or damages to personal property. The cost of canceling an unexpired lease is limited to three times the monthly rental.
- (c) Allowable relocation costs for new employees are limited to those described in paragraphs (b)(1) and (2) of this section. When relocation costs incurred incident to the recruitment of new employees have been charged to a Federal award and the employee resigns for reasons within the employee's control within 12 months after hire, the non-Federal entity must refund or credit the Federal Government for its share of the cost. If dependents are not permitted at the location for any reason and the costs do not include costs of transporting household goods, the costs of travel to an overseas location must be considered travel costs in accordance with § 200.474 Travel costs, and not this relocations costs of employees (See also § 200.464).
- (d) The following costs related to relocation are unallowable:
- (1) Fees and other costs associated with acquiring a new home.
  - (2) A loss on the sale of a former home.
  - (3) Continuing mortgage principal and interest payments on a home being sold.
  - (4) Income taxes paid by an employee related to reimbursed relocation costs.

*[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75887, Dec. 19, 2014; 85 FR 49570, Aug. 13, 2020]*

### **§ 200.465 Rental costs of real property and equipment.**

- (a) Subject to the limitations described in paragraphs (b) through (d) of this section, rental costs are allowable to the extent that the rates are reasonable in light of such factors as: rental costs of comparable property, if any; market conditions in the area; alternatives available; and the type, life expectancy, condition, and value of the property leased. Rental arrangements should be reviewed periodically to determine if circumstances have changed and other options are available.
- (b) Rental costs under "sale and lease back" arrangements are allowable only up to the amount that would be allowed had the non-Federal entity continued to own the property. This amount would include expenses such as depreciation, maintenance, taxes, and insurance.
- (c) Rental costs under "less-than-arm's-length" leases are allowable only up to the amount (as explained in paragraph (b) of this section). For this purpose, a less-than-arm's-length lease is one under which one party to the lease agreement is able to control or substantially influence the actions of the other. Such leases include, but are not limited to those between:
- (1) Divisions of the non-Federal entity;



- (2) The non-Federal entity under common control through common officers, directors, or members; and
- (3) The non-Federal entity and a director, trustee, officer, or key employee of the non-Federal entity or an immediate family member, either directly or through corporations, trusts, or similar arrangements in which they hold a controlling interest. For example, the non-Federal entity may establish a separate corporation for the sole purpose of owning property and leasing it back to the non-Federal entity.
- (4) Family members include one party with any of the following relationships to another party:
  - (i) Spouse, and parents thereof;
  - (ii) Children, and spouses thereof;
  - (iii) Parents, and spouses thereof;
  - (iv) Siblings, and spouses thereof;
  - (v) Grandparents and grandchildren, and spouses thereof;
  - (vi) Domestic partner and parents thereof, including domestic partners of any individual in 2 through 5 of this definition; and
  - (vii) Any individual related by blood or affinity whose close association with the employee is the equivalent of a family relationship.
- (5) Rental costs under leases which are required to be treated as capital leases under GAAP are allowable only up to the amount (as explained in paragraph (b) of this section) that would be allowed had the non-Federal entity purchased the property on the date the lease agreement was executed. The provisions of GAAP must be used to determine whether a lease is a capital lease. Interest costs related to capital leases are allowable to the extent they meet the criteria in § 200.449 Interest. Unallowable costs include amounts paid for profit, management fees, and taxes that would not have been incurred had the non-Federal entity purchased the property.
- (6) The rental of any property owned by any individuals or entities affiliated with the non-Federal entity, to include commercial or residential real estate, for purposes such as the home office workspace is unallowable.
- (d) Rental costs under leases which are required to be accounted for as a financed purchase under GASB standards or a finance lease under FASB standards under GAAP are allowable only up to the amount (as explained in paragraph (b) of this section) that would be allowed had the non-Federal entity purchased the property on the date the lease agreement was executed. Interest costs related to these leases are allowable to the extent they meet the criteria in § 200.449. Unallowable costs include amounts paid for profit, management fees, and taxes that would not have been incurred had the non-Federal entity purchased the property.
- (e) Rental or lease payments are allowable under lease contracts where the non-Federal entity is required to recognize an intangible right-to-use lease asset (per GASB) or right of use operating lease asset (per FASB) for purposes of financial reporting in accordance with GAAP.
- (f) The rental of any property owned by any individuals or entities affiliated with the non-Federal entity, to include commercial or residential real estate, for purposes such as the home office workspace is unallowable.

*[78 FR 78608, Dec. 26, 2013, as amended at 85 FR 49569, Aug. 13, 2020]*

### **§ 200.466 Scholarships and student aid costs.**

- (a) Costs of scholarships, fellowships, and other programs of student aid at IHEs are allowable only when the purpose of the Federal award is to provide training to selected participants and the charge is approved by the Federal awarding agency. However, tuition remission and other forms of compensation paid as, or in lieu of, wages to students performing necessary work are allowable provided that:
  - (1) The individual is conducting activities necessary to the Federal award;
  - (2) Tuition remission and other support are provided in accordance with established policy of the IHE and consistently provided in a like manner to students in return for similar activities conducted under Federal awards as well as other activities; and
  - (3) During the academic period, the student is enrolled in an advanced degree program at a non-Federal entity or affiliated institution and the activities of the student in relation to the Federal award are related to the degree program;

- (4) The tuition or other payments are reasonable compensation for the work performed and are conditioned explicitly upon the performance of necessary work; and
  - (5) It is the IHE's practice to similarly compensate students under Federal awards as well as other activities.
- (b) Charges for tuition remission and other forms of compensation paid to students as, or in lieu of, salaries and wages must be subject to the reporting requirements in § 200.430, and must be treated as direct or indirect cost in accordance with the actual work being performed. Tuition remission may be charged on an average rate basis. See also § 200.431.

[78 FR 78608, Dec. 26, 2013, as amended at 85 FR 49569, Aug. 13, 2020]

### **§ 200.467 Selling and marketing costs.**

Costs of selling and marketing any products or services of the non-Federal entity (unless allowed under § 200.421) are unallowable, except as direct costs, with prior approval by the Federal awarding agency when necessary for the performance of the Federal award.

[85 FR 49570, Aug. 13, 2020]

### **§ 200.468 Specialized service facilities.**

- (a) The costs of services provided by highly complex or specialized facilities operated by the non-Federal entity, such as computing facilities, wind tunnels, and reactors are allowable, provided the charges for the services meet the conditions of either paragraph (b) or (c) of this section, and, in addition, take into account any items of income or Federal financing that qualify as applicable credits under § 200.406.
- (b) The costs of such services, when material, must be charged directly to applicable awards based on actual usage of the services on the basis of a schedule of rates or established methodology that:
  - (1) Does not discriminate between activities under Federal awards and other activities of the non-Federal entity, including usage by the non-Federal entity for internal purposes, and
  - (2) Is designed to recover only the aggregate costs of the services. The costs of each service must consist normally of both its direct costs and its allocable share of all indirect (F&A) costs. Rates must be adjusted at least biennially, and must take into consideration over/under-applied costs of the previous period(s).
- (c) Where the costs incurred for a service are not material, they may be allocated as indirect (F&A) costs.
- (d) Under some extraordinary circumstances, where it is in the best interest of the Federal Government and the non-Federal entity to establish alternative costing arrangements, such arrangements may be worked out with the Federal cognizant agency for indirect costs.

[78 FR 78608, Dec. 26, 2013, as amended at 85 FR 49569, Aug. 13, 2020]

### **§ 200.469 Student activity costs.**

Costs incurred for intramural activities, student publications, student clubs, and other student activities, are unallowable, unless specifically provided for in the Federal award.

### **§ 200.470 Taxes (including Value Added Tax).**

- (a) For states, local governments and Indian tribes:
  - (1) Taxes that a governmental unit is legally required to pay are allowable, except for self-assessed taxes that disproportionately affect Federal programs or changes in tax policies that disproportionately affect Federal programs.
  - (2) Gasoline taxes, motor vehicle fees, and other taxes that are in effect user fees for benefits provided to the Federal Government are allowable.
  - (3) This provision does not restrict the authority of the Federal awarding agency to identify taxes where Federal participation is inappropriate. Where the identification of the amount of unallowable taxes would require an inordinate amount of effort, the cognizant agency for indirect costs may accept a reasonable approximation

thereof.

- (b) For nonprofit organizations and IHEs:
- (1) In general, taxes which the non-Federal entity is required to pay and which are paid or accrued in accordance with GAAP, and payments made to local governments in lieu of taxes which are commensurate with the local government services received are allowable, except for:
    - (i) Taxes from which exemptions are available to the non-Federal entity directly or which are available to the non-Federal entity based on an exemption afforded the Federal Government and, in the latter case, when the Federal awarding agency makes available the necessary exemption certificates,
    - (ii) Special assessments on land which represent capital improvements, and
    - (iii) Federal income taxes.
  - (2) Any refund of taxes, and any payment to the non-Federal entity of interest thereon, which were allowed as Federal award costs, will be credited either as a cost reduction or cash refund, as appropriate, to the Federal Government. However, any interest actually paid or credited to a non-Federal entity incident to a refund of tax, interest, and penalty will be paid or credited to the Federal Government only to the extent that such interest accrued over the period during which the non-Federal entity has been reimbursed by the Federal Government for the taxes, interest, and penalties.
- (c) Value Added Tax (VAT) Foreign taxes charged for the purchase of goods or services that a non-Federal entity is legally required to pay in country is an allowable expense under Federal awards. Foreign tax refunds or applicable credits under Federal awards refer to receipts, or reduction of expenditures, which operate to offset or reduce expense items that are allocable to Federal awards as direct or indirect costs. To the extent that such credits accrued or received by the non-Federal entity relate to allowable cost, these costs must be credited to the Federal awarding agency either as costs or cash refunds. If the costs are credited back to the Federal award, the non-Federal entity may reduce the Federal share of costs by the amount of the foreign tax reimbursement, or where Federal award has not expired, use the foreign government tax refund for approved activities under the Federal award with prior approval of the Federal awarding agency.

#### **§ 200.471 Telecommunication costs and video surveillance costs.**

- (a) Costs incurred for telecommunications and video surveillance services or equipment such as phones, internet, video surveillance, cloud servers are allowable except for the following circumstances:
- (b) Obligating or expending covered telecommunications and video surveillance services or equipment or services as described in § 200.216 to:
- (1) Procure or obtain, extend or renew a contract to procure or obtain;
  - (2) Enter into a contract (or extend or renew a contract) to procure; or
  - (3) Obtain the equipment, services, or systems.

*[85 FR 49570, Aug. 13, 2020]*

#### **§ 200.472 Termination costs.**

Termination of a Federal award generally gives rise to the incurrence of costs, or the need for special treatment of costs, which would not have arisen had the Federal award not been terminated. Cost principles covering these items are set forth in this section. They are to be used in conjunction with the other provisions of this part in termination situations.

- (a) The cost of items reasonably usable on the non-Federal entity's other work must not be allowable unless the non-Federal entity submits evidence that it would not retain such items at cost without sustaining a loss. In deciding whether such items are reasonably usable on other work of the non-Federal entity, the Federal awarding agency should consider the non-Federal entity's plans and orders for current and scheduled activity. Contemporaneous purchases of common items by the non-Federal entity must be regarded as evidence that such items are reasonably usable on the non-Federal entity's other work. Any acceptance of common items as allocable to the terminated portion of the Federal award must be limited to the extent that the quantities of such items on hand, in transit, and on order are in excess of the reasonable quantitative requirements of other work.

- (b) If in a particular case, despite all reasonable efforts by the non-Federal entity, certain costs cannot be discontinued immediately after the effective date of termination, such costs are generally allowable within the limitations set forth in this part, except that any such costs continuing after termination due to the negligent or willful failure of the non-Federal entity to discontinue such costs must be unallowable.
- (c) Loss of useful value of special tooling, machinery, and equipment is generally allowable if:
  - (1) Such special tooling, special machinery, or equipment is not reasonably capable of use in the other work of the non-Federal entity,
  - (2) The interest of the Federal Government is protected by transfer of title or by other means deemed appropriate by the Federal awarding agency (see also § 200.313 (d)), and
  - (3) The loss of useful value for any one terminated Federal award is limited to that portion of the acquisition cost which bears the same ratio to the total acquisition cost as the terminated portion of the Federal award bears to the entire terminated Federal award and other Federal awards for which the special tooling, machinery, or equipment was acquired.
- (d) Rental costs under unexpired leases are generally allowable where clearly shown to have been reasonably necessary for the performance of the terminated Federal award less the residual value of such leases, if:
  - (1) The amount of such rental claimed does not exceed the reasonable use value of the property leased for the period of the Federal award and such further period as may be reasonable, and
  - (2) The non-Federal entity makes all reasonable efforts to terminate, assign, settle, or otherwise reduce the cost of such lease. There also may be included the cost of alterations of such leased property, provided such alterations were necessary for the performance of the Federal award, and of reasonable restoration required by the provisions of the lease.
- (e) Settlement expenses including the following are generally allowable:
  - (1) Accounting, legal, clerical, and similar costs reasonably necessary for:
    - (i) The preparation and presentation to the Federal awarding agency of settlement claims and supporting data with respect to the terminated portion of the Federal award, unless the termination is for cause (see subpart D, including §§ 200.339-200.343); and
    - (ii) The termination and settlement of subawards.
  - (2) Reasonable costs for the storage, transportation, protection, and disposition of property provided by the Federal Government or acquired or produced for the Federal award.
- (f) Claims under subawards, including the allocable portion of claims which are common to the Federal award and to other work of the non-Federal entity, are generally allowable. An appropriate share of the non-Federal entity's indirect costs may be allocated to the amount of settlements with contractors and/or subrecipients, provided that the amount allocated is otherwise consistent with the basic guidelines contained in § 200.414. The indirect costs so allocated must exclude the same and similar costs claimed directly or indirectly as settlement expenses.

*[78 FR 78608, Dec. 26, 2013. Redesignated and amended at 85 FR 49570, Aug. 13, 2020]*

### **§ 200.473 Training and education costs.**

The cost of training and education provided for employee development is allowable.

*[78 FR 78608, Dec. 26, 2013. Redesignated at 85 FR 49570, Aug. 13, 2020]*

### **§ 200.474 Transportation costs.**

Costs incurred for freight, express, cartage, postage, and other transportation services relating either to goods purchased, in process, or delivered, are allowable. When such costs can readily be identified with the items involved, they may be charged directly as transportation costs or added to the cost of such items. Where identification with the materials received cannot readily be made, inbound transportation cost may be charged to the appropriate indirect (F&A) cost accounts if the non-Federal entity follows a consistent, equitable procedure in this respect. Outbound freight, if reimbursable under the terms and conditions of the Federal award, should be treated as a direct cost.

[78 FR 78608, Dec. 26, 2013. Redesignated at 85 FR 49570, Aug. 13, 2020]

### § 200.475 Travel costs.

- (a) **General.** Travel costs are the expenses for transportation, lodging, subsistence, and related items incurred by employees who are in travel status on official business of the non-Federal entity. Such costs may be charged on an actual cost basis, on a per diem or mileage basis in lieu of actual costs incurred, or on a combination of the two, provided the method used is applied to an entire trip and not to selected days of the trip, and results in charges consistent with those normally allowed in like circumstances in the non-Federal entity's non-federally-funded activities and in accordance with non-Federal entity's written travel reimbursement policies. Notwithstanding the provisions of § 200.444, travel costs of officials covered by that section are allowable with the prior written approval of the Federal awarding agency or pass-through entity when they are specifically related to the Federal award.
- (b) **Lodging and subsistence.** Costs incurred by employees and officers for travel, including costs of lodging, other subsistence, and incidental expenses, must be considered reasonable and otherwise allowable only to the extent such costs do not exceed charges normally allowed by the non-Federal entity in its regular operations as the result of the non-Federal entity's written travel policy. In addition, if these costs are charged directly to the Federal award documentation must justify that:
- (1) Participation of the individual is necessary to the Federal award; and
  - (2) The costs are reasonable and consistent with non-Federal entity's established travel policy.
- (c)
- (1) Temporary dependent care costs (as dependent is defined in 26 U.S.C. 152) above and beyond regular dependent care that directly results from travel to conferences is allowable provided that:
    - (i) The costs are a direct result of the individual's travel for the Federal award;
    - (ii) The costs are consistent with the non-Federal entity's documented travel policy for all entity travel; and
    - (iii) Are only temporary during the travel period.
  - (2) Travel costs for dependents are unallowable, except for travel of duration of six months or more with prior approval of the Federal awarding agency. See also § 200.432.
- (d) In the absence of an acceptable, written non-Federal entity policy regarding travel costs, the rates and amounts established under 5 U.S.C. 5701-11, ("Travel and Subsistence Expenses; Mileage Allowances"), or by the Administrator of General Services, or by the President (or his or her designee) pursuant to any provisions of such subchapter must apply to travel under Federal awards (48 CFR 31.205-46(a)).
- (e) **Commercial air travel.**
- (1) Airfare costs in excess of the basic least expensive unrestricted accommodations class offered by commercial airlines are unallowable except when such accommodations would:
    - (i) Require circuitous routing;
    - (ii) Require travel during unreasonable hours;
    - (iii) Excessively prolong travel;
    - (iv) Result in additional costs that would offset the transportation savings; or
    - (v) Offer accommodations not reasonably adequate for the traveler's medical needs. The non-Federal entity must justify and document these conditions on a case-by-case basis in order for the use of first-class or business-class airfare to be allowable in such cases.
  - (2) Unless a pattern of avoidance is detected, the Federal Government will generally not question a non-Federal entity's determinations that customary standard airfare or other discount airfare is unavailable for specific trips if the non-Federal entity can demonstrate that such airfare was not available in the specific case.
- (f) **Air travel by other than commercial carrier.** Costs of travel by non-Federal entity-owned, -leased, or -chartered aircraft include the cost of lease, charter, operation (including personnel costs), maintenance, depreciation, insurance, and other related costs. The portion of such costs that exceeds the cost of airfare as provided for in paragraph (d) of this section, is unallowable.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75887, Dec. 19, 2014. Redesignated and amended at 85 FR 49570, Aug. 13, 2020]

## § 200.476 Trustees.

Travel and subsistence costs of trustees (or directors) at IHEs and nonprofit organizations are allowable. See also § 200.475.

[85 FR 49571, Aug. 13, 2020]

## Subpart F - Audit Requirements

### GENERAL

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#### § 200.500 Purpose.

This part sets forth standards for obtaining consistency and uniformity among Federal agencies for the audit of non-Federal entities expending Federal awards.

### AUDITS

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#### § 200.501 Audit requirements.

- (a) **Audit required.** A non-Federal entity that expends \$750,000 or more during the non-Federal entity's fiscal year in Federal awards must have a single or program-specific audit conducted for that year in accordance with the provisions of this part.
- (b) **Single audit.** A non-Federal entity that expends \$750,000 or more during the non-Federal entity's fiscal year in Federal awards must have a single audit conducted in accordance with § 200.514 except when it elects to have a program-specific audit conducted in accordance with paragraph (c) of this section.
- (c) **Program-specific audit election.** When an auditee expends Federal awards under only one Federal program (excluding R&D) and the Federal program's statutes, regulations, or the terms and conditions of the Federal award do not require a financial statement audit of the auditee, the auditee may elect to have a program-specific audit conducted in accordance with § 200.507. A program-specific audit may not be elected for R&D unless all of the Federal awards expended were received from the same Federal agency, or the same Federal agency and the same pass-through entity, and that Federal agency, or pass-through entity in the case of a subrecipient, approves in advance a program-specific audit.
- (d) **Exemption when Federal awards expended are less than \$750,000.** A non-Federal entity that expends less than \$750,000 during the non-Federal entity's fiscal year in Federal awards is exempt from Federal audit requirements for that year, except as noted in § 200.503, but records must be available for review or audit by appropriate officials of the Federal agency, pass-through entity, and Government Accountability Office (GAO).
- (e) **Federally Funded Research and Development Centers (FFRDC).** Management of an auditee that owns or operates a FFRDC may elect to treat the FFRDC as a separate entity for purposes of this part.
- (f) **Subrecipients and contractors.** An auditee may simultaneously be a recipient, a subrecipient, and a contractor. Federal awards expended as a recipient or a subrecipient are subject to audit under this part. The payments received for goods or services provided as a contractor are not Federal awards. Section § 200.331 sets forth the considerations in determining whether payments constitute a Federal award or a payment for goods or services provided as a contractor.
- (g) **Compliance responsibility for contractors.** In most cases, the auditee's compliance responsibility for contractors is only to ensure that the procurement, receipt, and payment for goods and services comply with Federal statutes, regulations, and the terms and conditions of Federal awards. Federal award compliance requirements normally do not pass through to contractors. However, the auditee is responsible for ensuring compliance for procurement transactions which are structured such that the contractor is responsible for program compliance or the contractor's records must be reviewed to determine program compliance. Also, when these procurement transactions relate to a major program, the scope of the audit must include determining whether these transactions are in compliance with Federal statutes, regulations, and the terms and conditions of Federal awards.
- (h) **For-profit subrecipient.** Since this part does not apply to for-profit subrecipients, the pass-through entity is responsible for establishing requirements, as necessary, to ensure compliance by for-profit subrecipients. The agreement with the for-profit subrecipient must describe applicable compliance requirements and the for-profit subrecipient's compliance

responsibility. Methods to ensure compliance for Federal awards made to for-profit subrecipients may include pre-award audits, monitoring during the agreement, and post-award audits. See also § 200.332.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75887, Dec. 19, 2014; 85 FR 49571, Aug. 13, 2020]

### § 200.502 Basis for determining Federal awards expended.

- (a) **Determining Federal awards expended.** The determination of when a Federal award is expended must be based on when the activity related to the Federal award occurs. Generally, the activity pertains to events that require the non-Federal entity to comply with Federal statutes, regulations, and the terms and conditions of Federal awards, such as: expenditure/expense transactions associated with awards including grants, cost-reimbursement contracts under the FAR, compacts with Indian Tribes, cooperative agreements, and direct appropriations; the disbursement of funds to subrecipients; the use of loan proceeds under loan and loan guarantee programs; the receipt of property; the receipt of surplus property; the receipt or use of program income; the distribution or use of food commodities; the disbursement of amounts entitling the non-Federal entity to an interest subsidy; and the period when insurance is in force.
- (b) **Loan and loan guarantees (loans).** Since the Federal Government is at risk for loans until the debt is repaid, the following guidelines must be used to calculate the value of Federal awards expended under loan programs, except as noted in paragraphs (c) and (d) of this section:
  - (1) Value of new loans made or received during the audit period; plus
  - (2) Beginning of the audit period balance of loans from previous years for which the Federal Government imposes continuing compliance requirements; plus
  - (3) Any interest subsidy, cash, or administrative cost allowance received.
- (c) **Loan and loan guarantees (loans) at IHEs.** When loans are made to students of an IHE but the IHE does not make the loans, then only the value of loans made during the audit period must be considered Federal awards expended in that audit period. The balance of loans for previous audit periods is not included as Federal awards expended because the lender accounts for the prior balances.
- (d) **Prior loan and loan guarantees (loans).** Loans, the proceeds of which were received and expended in prior years, are not considered Federal awards expended under this part when the Federal statutes, regulations, and the terms and conditions of Federal awards pertaining to such loans impose no continuing compliance requirements other than to repay the loans.
- (e) **Endowment funds.** The cumulative balance of Federal awards for endowment funds that are federally restricted are considered Federal awards expended in each audit period in which the funds are still restricted.
- (f) **Free rent.** Free rent received by itself is not considered a Federal award expended under this part. However, free rent received as part of a Federal award to carry out a Federal program must be included in determining Federal awards expended and subject to audit under this part.
- (g) **Valuing non-cash assistance.** Federal non-cash assistance, such as free rent, food commodities, donated property, or donated surplus property, must be valued at fair market value at the time of receipt or the assessed value provided by the Federal agency.
- (h) **Medicare.** Medicare payments to a non-Federal entity for providing patient care services to Medicare-eligible individuals are not considered Federal awards expended under this part.
- (i) **Medicaid.** Medicaid payments to a subrecipient for providing patient care services to Medicaid-eligible individuals are not considered Federal awards expended under this part unless a state requires the funds to be treated as Federal awards expended because reimbursement is on a cost-reimbursement basis.
- (j) **Certain loans provided by the National Credit Union Administration.** For purposes of this part, loans made from the National Credit Union Share Insurance Fund and the Central Liquidity Facility that are funded by contributions from insured non-Federal entities are not considered Federal awards expended.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75887, Dec. 19, 2014]

### § 200.503 Relation to other audit requirements.

- (a) An audit conducted in accordance with this part must be in lieu of any financial audit of Federal awards which a non-Federal entity is required to undergo under any other Federal statute or regulation. To the extent that such audit provides a Federal agency with the information it requires to carry out its responsibilities under Federal statute or regulation, a Federal agency must rely upon and use that information.
- (b) Notwithstanding subsection (a), a Federal agency, Inspector General, or GAO may conduct or arrange for additional audits which are necessary to carry out its responsibilities under Federal statute or regulation. The provisions of this part do not authorize any non-Federal entity to constrain, in any manner, such Federal agency from carrying out or arranging for such additional audits, except that the Federal agency must plan such audits to not be duplicative of other audits of Federal awards. Prior to commencing such an audit, the Federal agency or pass-through entity must review the FAC for recent audits submitted by the non-Federal entity, and to the extent such audits meet a Federal agency or pass-through entity's needs, the Federal agency or pass-through entity must rely upon and use such audits. Any additional audits must be planned and performed in such a way as to build upon work performed, including the audit documentation, sampling, and testing already performed, by other auditors.
- (c) The provisions of this part do not limit the authority of Federal agencies to conduct, or arrange for the conduct of, audits and evaluations of Federal awards, nor limit the authority of any Federal agency Inspector General or other Federal official. For example, requirements that may be applicable under the FAR or CAS and the terms and conditions of a cost-reimbursement contract may include additional applicable audits to be conducted or arranged for by Federal agencies.
- (d) **Federal agency to pay for additional audits.** A Federal agency that conducts or arranges for additional audits must, consistent with other applicable Federal statutes and regulations, arrange for funding the full cost of such additional audits.
- (e) **Request for a program to be audited as a major program.** A Federal awarding agency may request that an auditee have a particular Federal program audited as a major program in lieu of the Federal awarding agency conducting or arranging for the additional audits. To allow for planning, such requests should be made at least 180 calendar days prior to the end of the fiscal year to be audited. The auditee, after consultation with its auditor, should promptly respond to such a request by informing the Federal awarding agency whether the program would otherwise be audited as a major program using the risk-based audit approach described in § 200.518 and, if not, the estimated incremental cost. The Federal awarding agency must then promptly confirm to the auditee whether it wants the program audited as a major program. If the program is to be audited as a major program based upon this Federal awarding agency request, and the Federal awarding agency agrees to pay the full incremental costs, then the auditee must have the program audited as a major program. A pass-through entity may use the provisions of this paragraph for a subrecipient.

[78 FR 78608, Dec. 26, 2013, as amended at 85 FR 49570, Aug. 13, 2020]

### **§ 200.504 Frequency of audits.**

Except for the provisions for biennial audits provided in paragraphs (a) and (b) of this section, audits required by this part must be performed annually. Any biennial audit must cover both years within the biennial period.

- (a) A state, local government, or Indian tribe that is required by constitution or statute, in effect on January 1, 1987, to undergo its audits less frequently than annually, is permitted to undergo its audits pursuant to this part biennially. This requirement must still be in effect for the biennial period.
- (b) Any nonprofit organization that had biennial audits for all biennial periods ending between July 1, 1992, and January 1, 1995, is permitted to undergo its audits pursuant to this part biennially.

### **§ 200.505 Sanctions.**

In cases of continued inability or unwillingness to have an audit conducted in accordance with this part, Federal agencies and pass-through entities must take appropriate action as provided in § 200.339.

[85 FR 49571, Aug. 13, 2020]

### **§ 200.506 Audit costs.**

See § 200.425.

[85 FR 49571, Aug. 13, 2020]



**§ 200.507 Program-specific audits.**

- (a) **Program-specific audit guide available.** In some cases, a program-specific audit guide will be available to provide specific guidance to the auditor with respect to internal controls, compliance requirements, suggested audit procedures, and audit reporting requirements. A listing of current program-specific audit guides can be found in the compliance supplement, Part 8, Appendix VI, Program-Specific Audit Guides, which includes a website where a copy of the guide can be obtained. When a current program-specific audit guide is available, the auditor must follow GAGAS and the guide when performing a program-specific audit.
- (b) **Program-specific audit guide not available.**
- (1) When a current program-specific audit guide is not available, the auditee and auditor must have basically the same responsibilities for the Federal program as they would have for an audit of a major program in a single audit.
  - (2) The auditee must prepare the financial statement(s) for the Federal program that includes, at a minimum, a schedule of expenditures of Federal awards for the program and notes that describe the significant accounting policies used in preparing the schedule, a summary schedule of prior audit findings consistent with the requirements of § 200.511(b), and a corrective action plan consistent with the requirements of § 200.511(c).
  - (3) The auditor must:
    - (i) Perform an audit of the financial statement(s) for the Federal program in accordance with GAGAS;
    - (ii) Obtain an understanding of internal controls and perform tests of internal controls over the Federal program consistent with the requirements of § 200.514(c) for a major program;
    - (iii) Perform procedures to determine whether the auditee has complied with Federal statutes, regulations, and the terms and conditions of Federal awards that could have a direct and material effect on the Federal program consistent with the requirements of § 200.514(d) for a major program;
    - (iv) Follow up on prior audit findings, perform procedures to assess the reasonableness of the summary schedule of prior audit findings prepared by the auditee in accordance with the requirements of § 200.511, and report, as a current year audit finding, when the auditor concludes that the summary schedule of prior audit findings materially misrepresents the status of any prior audit finding; and
    - (v) Report any audit findings consistent with the requirements of § 200.516.
  - (4) The auditor's report(s) may be in the form of either combined or separate reports and may be organized differently from the manner presented in this section. The auditor's report(s) must state that the audit was conducted in accordance with this part and include the following:
    - (i) An opinion (or disclaimer of opinion) as to whether the financial statement(s) of the Federal program is presented fairly in all material respects in accordance with the stated accounting policies;
    - (ii) A report on internal control related to the Federal program, which must describe the scope of testing of internal control and the results of the tests;
    - (iii) A report on compliance which includes an opinion (or disclaimer of opinion) as to whether the auditee complied with laws, regulations, and the terms and conditions of Federal awards which could have a direct and material effect on the Federal program; and
    - (iv) A schedule of findings and questioned costs for the Federal program that includes a summary of the auditor's results relative to the Federal program in a format consistent with § 200.515(d)(1) and findings and questioned costs consistent with the requirements of § 200.515(d)(3).
- (c) **Report submission for program-specific audits.**
- (1) The audit must be completed and the reporting required by paragraph (c)(2) or (c)(3) of this section submitted within the earlier of 30 calendar days after receipt of the auditor's report(s), or nine months after the end of the audit period, unless a different period is specified in a program-specific audit guide. Unless restricted by Federal law or regulation, the auditee must make report copies available for public inspection. Auditees and auditors must ensure that their respective parts of the reporting package do not include protected personally identifiable information.
  - (2) When a program-specific audit guide is available, the auditee must electronically submit to the FAC the data collection form prepared in accordance with § 200.512(b), as applicable to a program-specific audit, and the reporting required by the program-specific audit guide.

- (3) When a program-specific audit guide is not available, the reporting package for a program-specific audit must consist of the financial statement(s) of the Federal program, a summary schedule of prior audit findings, and a corrective action plan as described in paragraph (b)(2) of this section, and the auditor's report(s) described in paragraph (b)(4) of this section. The data collection form prepared in accordance with § 200.512(b), as applicable to a program-specific audit, and one copy of this reporting package must be electronically submitted to the FAC.
- (d) **Other sections of this part may apply.** Program-specific audits are subject to:
- (1) 200.500 Purpose through 200.503 Relation to other audit requirements, paragraph (d);
  - (2) 200.504 Frequency of audits through 200.506 Audit costs;
  - (3) 200.508 Auditee responsibilities through 200.509 Auditor selection;
  - (4) 200.511 Audit findings follow-up;
  - (5) 200.512 Report submission, paragraphs (e) through (h);
  - (6) 200.513 Responsibilities;
  - (7) 200.516 Audit findings through 200.517 Audit documentation;
  - (8) 200.521 Management decision; and
  - (9) Other referenced provisions of this part unless contrary to the provisions of this section, a program-specific audit guide, or program statutes and regulations.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75887, Dec. 19, 2014; 85 FR 49571, Aug. 13, 2020]

## AUDITEES

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### § 200.508 Auditee responsibilities.

The auditee must:

- (a) Procure or otherwise arrange for the audit required by this part in accordance with § 200.509, and ensure it is properly performed and submitted when due in accordance with § 200.512.
- (b) Prepare appropriate financial statements, including the schedule of expenditures of Federal awards in accordance with § 200.510.
- (c) Promptly follow up and take corrective action on audit findings, including preparation of a summary schedule of prior audit findings and a corrective action plan in accordance with § 200.511(b) and (c), respectively.
- (d) Provide the auditor with access to personnel, accounts, books, records, supporting documentation, and other information as needed for the auditor to perform the audit required by this part.

[78 FR 78608, Dec. 26, 2013, as amended at 85 FR 49572, Aug. 13, 2020]

### § 200.509 Auditor selection.

- (a) **Auditor procurement.** In procuring audit services, the auditee must follow the procurement standards prescribed by the Procurement Standards in §§ 200.317 through 200.327 of subpart D of this part or the FAR (48 CFR part 42), as applicable. In requesting proposals for audit services, the objectives and scope of the audit must be made clear and the non-Federal entity must request a copy of the audit organization's peer review report which the auditor is required to provide under GAGAS. Factors to be considered in evaluating each proposal for audit services include the responsiveness to the request for proposal, relevant experience, availability of staff with professional qualifications and technical abilities, the results of peer and external quality control reviews, and price. Whenever possible, the auditee must make positive efforts to utilize small businesses, minority-owned firms, and women's business enterprises, in procuring audit services as stated in § 200.321, or the FAR (48 CFR part 42), as applicable.
- (b) **Restriction on auditor preparing indirect cost proposals.** An auditor who prepares the indirect cost proposal or cost allocation plan may not also be selected to perform the audit required by this part when the indirect costs recovered by the auditee during the prior year exceeded \$1 million. This restriction applies to the base year used in the preparation of the indirect cost proposal or cost allocation plan and any subsequent years in which the resulting indirect cost agreement or cost allocation plan is used to recover costs.

- (c) **Use of Federal auditors.** Federal auditors may perform all or part of the work required under this part if they comply fully with the requirements of this part.

[78 FR 78608, Dec. 26, 2013, as amended at 85 FR 49572, Aug. 13, 2020; 86 FR 10440, Feb. 22, 2021]

### § 200.510 Financial statements.

- (a) **Financial statements.** The auditee must prepare financial statements that reflect its financial position, results of operations or changes in net assets, and, where appropriate, cash flows for the fiscal year audited. The financial statements must be for the same organizational unit and fiscal year that is chosen to meet the requirements of this part. However, non-Federal entity-wide financial statements may also include departments, agencies, and other organizational units that have separate audits in accordance with § 200.514(a) and prepare separate financial statements.
- (b) **Schedule of expenditures of Federal awards.** The auditee must also prepare a schedule of expenditures of Federal awards for the period covered by the auditee's financial statements which must include the total Federal awards expended as determined in accordance with § 200.502. While not required, the auditee may choose to provide information requested by Federal awarding agencies and pass-through entities to make the schedule easier to use. For example, when a Federal program has multiple Federal award years, the auditee may list the amount of Federal awards expended for each Federal award year separately. At a minimum, the schedule must:
- (1) List individual Federal programs by Federal agency. For a cluster of programs, provide the cluster name, list individual Federal programs within the cluster of programs, and provide the applicable Federal agency name. For R&D, total Federal awards expended must be shown either by individual Federal award or by Federal agency and major subdivision within the Federal agency. For example, the National Institutes of Health is a major subdivision in the Department of Health and Human Services.
  - (2) For Federal awards received as a subrecipient, the name of the pass-through entity and identifying number assigned by the pass-through entity must be included.
  - (3) Provide total Federal awards expended for each individual Federal program and the Assistance Listings Number or other identifying number when the Assistance Listings information is not available. For a cluster of programs also provide the total for the cluster.
  - (4) Include the total amount provided to subrecipients from each Federal program.
  - (5) For loan or loan guarantee programs described in § 200.502(b), identify in the notes to the schedule the balances outstanding at the end of the audit period. This is in addition to including the total Federal awards expended for loan or loan guarantee programs in the schedule.
  - (6) Include notes that describe that significant accounting policies used in preparing the schedule, and note whether or not the auditee elected to use the 10% de minimis cost rate as covered in § 200.414.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75887, Dec. 19, 2014; 85 FR 49572, Aug. 13, 2020]

### § 200.511 Audit findings follow-up.

- (a) **General.** The auditee is responsible for follow-up and corrective action on all audit findings. As part of this responsibility, the auditee must prepare a summary schedule of prior audit findings. The auditee must also prepare a corrective action plan for current year audit findings. The summary schedule of prior audit findings and the corrective action plan must include the reference numbers the auditor assigns to audit findings under § 200.516(c). Since the summary schedule may include audit findings from multiple years, it must include the fiscal year in which the finding initially occurred. The corrective action plan and summary schedule of prior audit findings must include findings relating to the financial statements which are required to be reported in accordance with GAGAS.
- (b) **Summary schedule of prior audit findings.** The summary schedule of prior audit findings must report the status of all audit findings included in the prior audit's schedule of findings and questioned costs. The summary schedule must also include audit findings reported in the prior audit's summary schedule of prior audit findings except audit findings listed as corrected in accordance with paragraph (b)(1) of this section, or no longer valid or not warranting further action in accordance with paragraph (b)(3) of this section.
- (1) When audit findings were fully corrected, the summary schedule need only list the audit findings and state that corrective action was taken.

- (2) When audit findings were not corrected or were only partially corrected, the summary schedule must describe the reasons for the finding's recurrence and planned corrective action, and any partial corrective action taken. When corrective action taken is significantly different from corrective action previously reported in a corrective action plan or in the Federal agency's or pass-through entity's management decision, the summary schedule must provide an explanation.
- (3) When the auditee believes the audit findings are no longer valid or do not warrant further action, the reasons for this position must be described in the summary schedule. A valid reason for considering an audit finding as not warranting further action is that all of the following have occurred:
  - (i) Two years have passed since the audit report in which the finding occurred was submitted to the FAC;
  - (ii) The Federal agency or pass-through entity is not currently following up with the auditee on the audit finding; and
  - (iii) A management decision was not issued.
- (c) **Corrective action plan.** At the completion of the audit, the auditee must prepare, in a document separate from the auditor's findings described in § 200.516, a corrective action plan to address each audit finding included in the current year auditor's reports. The corrective action plan must provide the name(s) of the contact person(s) responsible for corrective action, the corrective action planned, and the anticipated completion date. If the auditee does not agree with the audit findings or believes corrective action is not required, then the corrective action plan must include an explanation and specific reasons.

[78 FR 78608, Dec. 26, 2013, as amended at 85 FR 49572, Aug. 13, 2020]

## § 200.512 Report submission.

- (a) **General.**
  - (1) The audit must be completed and the data collection form described in paragraph (b) of this section and reporting package described in paragraph (c) of this section must be submitted within the earlier of 30 calendar days after receipt of the auditor's report(s), or nine months after the end of the audit period. If the due date falls on a Saturday, Sunday, or Federal holiday, the reporting package is due the next business day.
  - (2) Unless restricted by Federal statutes or regulations, the auditee must make copies available for public inspection. Auditees and auditors must ensure that their respective parts of the reporting package do not include protected personally identifiable information.
- (b) **Data collection.** The FAC is the repository of record for subpart F of this part reporting packages and the data collection form. All Federal agencies, pass-through entities and others interested in a reporting package and data collection form must obtain it by accessing the FAC.
  - (1) The auditee must submit required data elements described in Appendix X to Part 200, which state whether the audit was completed in accordance with this part and provides information about the auditee, its Federal programs, and the results of the audit. The data must include information available from the audit required by this part that is necessary for Federal agencies to use the audit to ensure integrity for Federal programs. The data elements and format must be approved by OMB, available from the FAC, and include collections of information from the reporting package described in paragraph (c) of this section. A senior level representative of the auditee (e.g., state controller, director of finance, chief executive officer, or chief financial officer) must sign a statement to be included as part of the data collection that says that the auditee complied with the requirements of this part, the data were prepared in accordance with this part (and the instructions accompanying the form), the reporting package does not include protected personally identifiable information, the information included in its entirety is accurate and complete, and that the FAC is authorized to make the reporting package and the form publicly available on a website.
  - (2) **Exception for Indian Tribes and Tribal Organizations.** An auditee that is an Indian tribe or a tribal organization (as defined in the Indian Self-Determination, Education and Assistance Act (ISDEAA), 25 U.S.C. 450b(l)) may opt not to authorize the FAC to make the reporting package publicly available on a Web site, by excluding the authorization for the FAC publication in the statement described in paragraph (b)(1) of this section. If this option is exercised, the auditee becomes responsible for submitting the reporting package directly to any pass-through entities through which it has received a Federal award and to pass-through entities for which the summary schedule of prior audit findings reported the status of any findings related to Federal awards that the pass-through entity provided. Unless restricted by Federal statute or regulation, if the auditee opts not to authorize publication, it must make copies of the reporting package available for public inspection.

- (3) Using the information included in the reporting package described in paragraph (c) of this section, the auditor must complete the applicable data elements of the data collection form. The auditor must sign a statement to be included as part of the data collection form that indicates, at a minimum, the source of the information included in the form, the auditor's responsibility for the information, that the form is not a substitute for the reporting package described in paragraph (c) of this section, and that the content of the form is limited to the collection of information prescribed by OMB.
- (c) **Reporting package.** The reporting package must include the:
- (1) Financial statements and schedule of expenditures of Federal awards discussed in § 200.510(a) and (b), respectively;
  - (2) Summary schedule of prior audit findings discussed in § 200.511(b);
  - (3) Auditor's report(s) discussed in § 200.515; and
  - (4) Corrective action plan discussed in § 200.511(c).
- (d) **Submission to FAC.** The auditee must electronically submit to the FAC the data collection form described in paragraph (b) of this section and the reporting package described in paragraph (c) of this section.
- (e) **Requests for management letters issued by the auditor.** In response to requests by a Federal agency or pass-through entity, auditees must submit a copy of any management letters issued by the auditor.
- (f) **Report retention requirements.** Auditees must keep one copy of the data collection form described in paragraph (b) of this section and one copy of the reporting package described in paragraph (c) of this section on file for three years from the date of submission to the FAC.
- (g) **FAC responsibilities.** The FAC must make available the reporting packages received in accordance with paragraph (c) of this section and § 200.507(c) to the public, except for Indian tribes exercising the option in (b)(2) of this section, and maintain a data base of completed audits, provide appropriate information to Federal agencies, and follow up with known auditees that have not submitted the required data collection forms and reporting packages.
- (h) **Electronic filing.** Nothing in this part must preclude electronic submissions to the FAC in such manner as may be approved by OMB.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75887, Dec. 19, 2014; 85 FR 49573, Aug. 13, 2020]

## FEDERAL AGENCIES

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### § 200.513 Responsibilities.

- (a)
- (1) **Cognizant agency for audit responsibilities.** A non-Federal entity expending more than \$50 million a year in Federal awards must have a cognizant agency for audit. The designated cognizant agency for audit must be the Federal awarding agency that provides the predominant amount of funding directly (direct funding) (as listed on the Schedule of expenditures of Federal awards, see § 200.510(b)) to a non-Federal entity unless OMB designates a specific cognizant agency for audit. When the direct funding represents less than 25 percent of the total expenditures (as direct and subawards) by the non-Federal entity, then the Federal agency with the predominant amount of total funding is the designated cognizant agency for audit.
  - (2) To provide for continuity of cognizance, the determination of the predominant amount of direct funding must be based upon direct Federal awards expended in the non-Federal entity's fiscal years ending in 2019, and every fifth year thereafter.
  - (3) Notwithstanding the manner in which audit cognizance is determined, a Federal awarding agency with cognizance for an auditee may reassign cognizance to another Federal awarding agency that provides substantial funding and agrees to be the cognizant agency for audit. Within 30 calendar days after any reassignment, both the old and the new cognizant agency for audit must provide notice of the change to the FAC, the auditee, and, if known, the auditor. The cognizant agency for audit must:
    - (i) Provide technical audit advice and liaison assistance to auditees and auditors.
    - (ii) Obtain or conduct quality control reviews on selected audits made by non-Federal auditors, and provide the results to other interested organizations. Cooperate and provide support to the Federal agency designated by OMB to lead a governmentwide project to determine the quality of single audits by providing a reliable

estimate of the extent that single audits conform to applicable requirements, standards, and procedures; and to make recommendations to address noted audit quality issues, including recommendations for any changes to applicable requirements, standards and procedures indicated by the results of the project. The governmentwide project can rely on the current and on-going quality control review work performed by the agencies, State auditors, and professional audit associations. This governmentwide audit quality project must be performed once every 6 years (or at such other interval as determined by OMB), and the results must be public.

- (iii) Promptly inform other affected Federal agencies and appropriate Federal law enforcement officials of any direct reporting by the auditee or its auditor required by GAGAS or statutes and regulations.
  - (iv) Advise the community of independent auditors of any noteworthy or important factual trends related to the quality of audits stemming from quality control reviews. Significant problems or quality issues consistently identified through quality control reviews of audit reports must be referred to appropriate state licensing agencies and professional bodies.
  - (v) Advise the auditor, Federal awarding agencies, and, where appropriate, the auditee of any deficiencies found in the audits when the deficiencies require corrective action by the auditor. When advised of deficiencies, the auditee must work with the auditor to take corrective action. If corrective action is not taken, the cognizant agency for audit must notify the auditor, the auditee, and applicable Federal awarding agencies and pass-through entities of the facts and make recommendations for follow-up action. Major inadequacies or repetitive substandard performance by auditors must be referred to appropriate state licensing agencies and professional bodies for disciplinary action.
  - (vi) Coordinate, to the extent practical, audits or reviews made by or for Federal agencies that are in addition to the audits made pursuant to this part, so that the additional audits or reviews build upon rather than duplicate audits performed in accordance with this part.
  - (vii) Coordinate a management decision for cross-cutting audit findings (see in § 200.1 of this part) that affect the Federal programs of more than one agency when requested by any Federal awarding agency whose awards are included in the audit finding of the auditee.
  - (viii) Coordinate the audit work and reporting responsibilities among auditors to achieve the most cost-effective audit.
  - (ix) Provide advice to auditees as to how to handle changes in fiscal years.
- (b) **Oversight agency for audit responsibilities.** An auditee who does not have a designated cognizant agency for audit will be under the general oversight of the Federal agency determined in accordance with § 200.1 *oversight agency for audit*. A Federal agency with oversight for an auditee may reassign oversight to another Federal agency that agrees to be the oversight agency for audit. Within 30 calendar days after any reassignment, both the old and the new oversight agency for audit must provide notice of the change to the FAC, the auditee, and, if known, the auditor. The oversight agency for audit:
- (1) Must provide technical advice to auditees and auditors as requested.
  - (2) May assume all or some of the responsibilities normally performed by a cognizant agency for audit.
- (c) **Federal awarding agency responsibilities.** The Federal awarding agency must perform the following for the Federal awards it makes (See also the requirements of § 200.211):
- (1) Ensure that audits are completed and reports are received in a timely manner and in accordance with the requirements of this part.
  - (2) Provide technical advice and counsel to auditees and auditors as requested.
  - (3) Follow-up on audit findings to ensure that the recipient takes appropriate and timely corrective action. As part of audit follow-up, the Federal awarding agency must:
    - (i) Issue a management decision as prescribed in § 200.521;
    - (ii) Monitor the recipient taking appropriate and timely corrective action;
    - (iii) Use cooperative audit resolution mechanisms (see the definition of *cooperative audit resolution* in § 200.1 of this part) to improve Federal program outcomes through better audit resolution, follow-up, and corrective action; and

- (iv) Develop a baseline, metrics, and targets to track, over time, the effectiveness of the Federal agency's process to follow-up on audit findings and on the effectiveness of Single Audits in improving non-Federal entity accountability and their use by Federal awarding agencies in making award decisions.
- (4) Provide OMB annual updates to the compliance supplement and work with OMB to ensure that the compliance supplement focuses the auditor to test the compliance requirements most likely to cause improper payments, fraud, waste, abuse or generate audit finding for which the Federal awarding agency will take sanctions.
- (5) Provide OMB with the name of a single audit accountable official from among the senior policy officials of the Federal awarding agency who must be:
  - (i) Responsible for ensuring that the agency fulfills all the requirements of paragraph (c) of this section and effectively uses the single audit process to reduce improper payments and improve Federal program outcomes.
  - (ii) Held accountable to improve the effectiveness of the single audit process based upon metrics as described in paragraph (c)(3)(iv) of this section.
  - (iii) Responsible for designating the Federal agency's key management single audit liaison.
- (6) Provide OMB with the name of a key management single audit liaison who must:
  - (i) Serve as the Federal awarding agency's management point of contact for the single audit process both within and outside the Federal Government.
  - (ii) Promote interagency coordination, consistency, and sharing in areas such as coordinating audit follow-up; identifying higher-risk non-Federal entities; providing input on single audit and follow-up policy; enhancing the utility of the FAC; and studying ways to use single audit results to improve Federal award accountability and best practices.
  - (iii) Oversee training for the Federal awarding agency's program management personnel related to the single audit process.
  - (iv) Promote the Federal awarding agency's use of cooperative audit resolution mechanisms.
  - (v) Coordinate the Federal awarding agency's activities to ensure appropriate and timely follow-up and corrective action on audit findings.
  - (vi) Organize the Federal cognizant agency for audit's follow-up on cross-cutting audit findings that affect the Federal programs of more than one Federal awarding agency.
  - (vii) Ensure the Federal awarding agency provides annual updates of the compliance supplement to OMB.
  - (viii) Support the Federal awarding agency's single audit accountable official's mission.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75887, Dec. 19, 2014; 85 FR 49573, Aug. 13, 2020]

## AUDITORS

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### § 200.514 Scope of audit.

- (a) **General.** The audit must be conducted in accordance with GAGAS. The audit must cover the entire operations of the auditee, or, at the option of the auditee, such audit must include a series of audits that cover departments, agencies, and other organizational units that expended or otherwise administered Federal awards during such audit period, provided that each such audit must encompass the financial statements and schedule of expenditures of Federal awards for each such department, agency, and other organizational unit, which must be considered to be a non-Federal entity. The financial statements and schedule of expenditures of Federal awards must be for the same audit period.
- (b) **Financial statements.** The auditor must determine whether the financial statements of the auditee are presented fairly in all material respects in accordance with generally accepted accounting principles. The auditor must also determine whether the schedule of expenditures of Federal awards is stated fairly in all material respects in relation to the auditee's financial statements as a whole.
- (c) **Internal control.**

- (1) The compliance supplement provides guidance on internal controls over Federal programs based upon the guidance in Standards for Internal Control in the Federal Government issued by the Comptroller General of the United States and the Internal Control - Integrated Framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).
  - (2) In addition to the requirements of GAGAS, the auditor must perform procedures to obtain an understanding of internal control over Federal programs sufficient to plan the audit to support a low assessed level of control risk of noncompliance for major programs.
  - (3) Except as provided in paragraph (c)(4) of this section, the auditor must:
    - (i) Plan the testing of internal control over compliance for major programs to support a low assessed level of control risk for the assertions relevant to the compliance requirements for each major program; and
    - (ii) Perform testing of internal control as planned in paragraph (c)(3)(i) of this section.
  - (4) When internal control over some or all of the compliance requirements for a major program are likely to be ineffective in preventing or detecting noncompliance, the planning and performing of testing described in paragraph (c)(3) of this section are not required for those compliance requirements. However, the auditor must report a significant deficiency or material weakness in accordance with § 200.516, assess the related control risk at the maximum, and consider whether additional compliance tests are required because of ineffective internal control.
- (d) **Compliance.**
- (1) In addition to the requirements of GAGAS, the auditor must determine whether the auditee has complied with Federal statutes, regulations, and the terms and conditions of Federal awards that may have a direct and material effect on each of its major programs.
  - (2) The principal compliance requirements applicable to most Federal programs and the compliance requirements of the largest Federal programs are included in the compliance supplement.
  - (3) For the compliance requirements related to Federal programs contained in the compliance supplement, an audit of these compliance requirements will meet the requirements of this part. Where there have been changes to the compliance requirements and the changes are not reflected in the compliance supplement, the auditor must determine the current compliance requirements and modify the audit procedures accordingly. For those Federal programs not covered in the compliance supplement, the auditor must follow the compliance supplement's guidance for programs not included in the supplement.
  - (4) When internal control over some or all of the compliance requirements for a major program are likely to be ineffective in preventing or detecting noncompliance, the planning and performing of testing described in paragraph (c)(3) of this section are not required for those compliance requirements. However, the auditor must report a significant deficiency or material weakness in accordance with § 200.516, assess the related control risk at the
- (e) **Audit follow-up.** The auditor must follow-up on prior audit findings, perform procedures to assess the reasonableness of the summary schedule of prior audit findings prepared by the auditee in accordance with § 200.511(b), and report, as a current year audit finding, when the auditor concludes that the summary schedule of prior audit findings materially misrepresents the status of any prior audit finding. The auditor must perform audit follow-up procedures regardless of whether a prior audit finding relates to a major program in the current year.
- (f) **Data collection form.** As required in § 200.512(b)(3), the auditor must complete and sign specified sections of the data collection form.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75887, Dec. 19, 2014; 85 FR 49574, Aug. 13, 2020; 86 FR 10440, Feb. 22, 2021]

### § 200.515 Audit reporting.

The auditor's report(s) may be in the form of either combined or separate reports and may be organized differently from the manner presented in this section. The auditor's report(s) must state that the audit was conducted in accordance with this part and include the following:

- (a) **Financial statements.** The auditor must determine and provide an opinion (or disclaimer of opinion) whether the financial statements of the auditee are presented fairly in all material respects in accordance with generally accepted accounting principles (or a special purpose framework such as cash, modified cash, or regulatory as required by state law). The auditor must also decide whether the schedule of expenditures of Federal awards is stated fairly in all material respects in relation to the auditee's financial statements as a whole.



- (b) A report on internal control over financial reporting and compliance with provisions of laws, regulations, contracts, and award agreements, noncompliance with which could have a material effect on the financial statements. This report must describe the scope of testing of internal control and compliance and the results of the tests, and, where applicable, it will refer to the separate schedule of findings and questioned costs described in paragraph (d) of this section.
- (c) A report on compliance for each major program and a report on internal control over compliance. This report must describe the scope of testing of internal control over compliance, include an opinion or disclaimer of opinion as to whether the auditee complied with Federal statutes, regulations, and the terms and conditions of Federal awards which could have a direct and material effect on each major program and refer to the separate schedule of findings and questioned costs described in paragraph (d) of this section.
- (d) A schedule of findings and questioned costs which must include the following three components:
  - (1) A summary of the auditor's results, which must include:
    - (i) The type of report the auditor issued on whether the financial statements audited were prepared in accordance with GAAP (i.e., unmodified opinion, qualified opinion, adverse opinion, or disclaimer of opinion);
    - (ii) Where applicable, a statement about whether significant deficiencies or material weaknesses in internal control were disclosed by the audit of the financial statements;
    - (iii) A statement as to whether the audit disclosed any noncompliance that is material to the financial statements of the auditee;
    - (iv) Where applicable, a statement about whether significant deficiencies or material weaknesses in internal control over major programs were disclosed by the audit;
    - (v) The type of report the auditor issued on compliance for major programs (i.e., unmodified opinion, qualified opinion, adverse opinion, or disclaimer of opinion);
    - (vi) A statement as to whether the audit disclosed any audit findings that the auditor is required to report under § 200.516(a);
    - (vii) An identification of major programs by listing each individual major program; however, in the case of a cluster of programs, only the cluster name as shown on the Schedule of Expenditures of Federal Awards is required;
    - (viii) The dollar threshold used to distinguish between Type A and Type B programs, as described in § 200.518(b)(1) or (3) when a recalculation of the Type A threshold is required for large loan or loan guarantees; and
    - (ix) A statement as to whether the auditee qualified as a low-risk auditee under § 200.520.
  - (2) Findings relating to the financial statements which are required to be reported in accordance with GAGAS.
  - (3) Findings and questioned costs for Federal awards which must include audit findings as defined in § 200.516(a).
    - (i) Audit findings (e.g., internal control findings, compliance findings, questioned costs, or fraud) that relate to the same issue must be presented as a single audit finding. Where practical, audit findings should be organized by Federal agency or pass-through entity.
    - (ii) Audit findings that relate to both the financial statements and Federal awards, as reported under paragraphs (d)(2) and (d)(3) of this section, respectively, must be reported in both sections of the schedule. However, the reporting in one section of the schedule may be in summary form with a reference to a detailed reporting in the other section of the schedule.
- (e) Nothing in this part precludes combining of the audit reporting required by this section with the reporting required by § 200.512(b) when allowed by GAGAS and appendix X to this part.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75887, Dec. 19, 2014; 85 FR 49574, Aug. 13, 2020]

## § 200.516 Audit findings.

- (a) **Audit findings reported.** The auditor must report the following as audit findings in a schedule of findings and questioned costs:
  - (1) Significant deficiencies and material weaknesses in internal control over major programs and significant instances of abuse relating to major programs. The auditor's determination of whether a deficiency in internal control is a significant deficiency or a material weakness for the purpose of reporting an audit finding is in relation to a type of compliance requirement for a major program identified in the Compliance Supplement.

- (2) Material noncompliance with the provisions of Federal statutes, regulations, or the terms and conditions of Federal awards related to a major program. The auditor's determination of whether a noncompliance with the provisions of Federal statutes, regulations, or the terms and conditions of Federal awards is material for the purpose of reporting an audit finding is in relation to a type of compliance requirement for a major program identified in the compliance supplement.
  - (3) Known questioned costs that are greater than \$25,000 for a type of compliance requirement for a major program. Known questioned costs are those specifically identified by the auditor. In evaluating the effect of questioned costs on the opinion on compliance, the auditor considers the best estimate of total costs questioned (likely questioned costs), not just the questioned costs specifically identified (known questioned costs). The auditor must also report known questioned costs when likely questioned costs are greater than \$25,000 for a type of compliance requirement for a major program. In reporting questioned costs, the auditor must include information to provide proper perspective for judging the prevalence and consequences of the questioned costs.
  - (4) Known questioned costs that are greater than \$25,000 for a Federal program which is not audited as a major program. Except for audit follow-up, the auditor is not required under this part to perform audit procedures for such a Federal program; therefore, the auditor will normally not find questioned costs for a program that is not audited as a major program. However, if the auditor does become aware of questioned costs for a Federal program that is not audited as a major program (e.g., as part of audit follow-up or other audit procedures) and the known questioned costs are greater than \$25,000, then the auditor must report this as an audit finding.
  - (5) The circumstances concerning why the auditor's report on compliance for each major program is other than an unmodified opinion, unless such circumstances are otherwise reported as audit findings in the schedule of findings and questioned costs for Federal awards.
  - (6) Known or likely fraud affecting a Federal award, unless such fraud is otherwise reported as an audit finding in the schedule of findings and questioned costs for Federal awards. This paragraph does not require the auditor to report publicly information which could compromise investigative or legal proceedings or to make an additional reporting when the auditor confirms that the fraud was reported outside the auditor's reports under the direct reporting requirements of GAGAS.
  - (7) Instances where the results of audit follow-up procedures disclosed that the summary schedule of prior audit findings prepared by the auditee in accordance with § 200.511(b) materially misrepresents the status of any prior audit finding.
- (b) **Audit finding detail and clarity.** Audit findings must be presented in sufficient detail and clarity for the auditee to prepare a corrective action plan and take corrective action, and for Federal agencies and pass-through entities to arrive at a management decision. The following specific information must be included, as applicable, in audit findings:
- (1) Federal program and specific Federal award identification including the Assistance Listings title and number, Federal award identification number and year, name of Federal agency, and name of the applicable pass-through entity. When information, such as the Assistance Listings title and number or Federal award identification number, is not available, the auditor must provide the best information available to describe the Federal award.
  - (2) The criteria or specific requirement upon which the audit finding is based, including the Federal statutes, regulations, or the terms and conditions of the Federal awards. Criteria generally identify the required or desired state or expectation with respect to the program or operation. Criteria provide a context for evaluating evidence and understanding findings.
  - (3) The condition found, including facts that support the deficiency identified in the audit finding.
  - (4) A statement of cause that identifies the reason or explanation for the condition or the factors responsible for the difference between the situation that exists (condition) and the required or desired state (criteria), which may also serve as a basis for recommendations for corrective action.
  - (5) The possible asserted effect to provide sufficient information to the auditee and Federal agency, or pass-through entity in the case of a subrecipient, to permit them to determine the cause and effect to facilitate prompt and proper corrective action. A statement of the effect or potential effect should provide a clear, logical link to establish the impact or potential impact of the difference between the condition and the criteria.
  - (6) Identification of questioned costs and how they were computed. Known questioned costs must be identified by applicable Assistance Listings number(s) and applicable Federal award identification number(s).
  - (7) Information to provide proper perspective for judging the prevalence and consequences of the audit findings, such as whether the audit findings represent an isolated instance or a systemic problem. Where appropriate, instances identified must be related to the universe and the number of cases examined and be quantified in terms of dollar

value. The auditor should report whether the sampling was a statistically valid sample.

- (8) Identification of whether the audit finding was a repeat of a finding in the immediately prior audit and if so any applicable prior year audit finding numbers.
  - (9) Recommendations to prevent future occurrences of the deficiency identified in the audit finding.
  - (10) Views of responsible officials of the auditee.
- (c) **Reference numbers.** Each audit finding in the schedule of findings and questioned costs must include a reference number in the format meeting the requirements of the data collection form submission required by § 200.512(b) to allow for easy referencing of the audit findings during follow-up.

[78 FR 78608, Dec. 26, 2013, as amended at 85 FR 49574, Aug. 13, 2020]

### § 200.517 Audit documentation.

- (a) **Retention of audit documentation.** The auditor must retain audit documentation and reports for a minimum of three years after the date of issuance of the auditor's report(s) to the auditee, unless the auditor is notified in writing by the cognizant agency for audit, oversight agency for audit, cognizant agency for indirect costs, or pass-through entity to extend the retention period. When the auditor is aware that the Federal agency, pass-through entity, or auditee is contesting an audit finding, the auditor must contact the parties contesting the audit finding for guidance prior to destruction of the audit documentation and reports.
- (b) **Access to audit documentation.** Audit documentation must be made available upon request to the cognizant or oversight agency for audit or its designee, cognizant agency for indirect cost, a Federal agency, or GAO at the completion of the audit, as part of a quality review, to resolve audit findings, or to carry out oversight responsibilities consistent with the purposes of this part. Access to audit documentation includes the right of Federal agencies to obtain copies of audit documentation, as is reasonable and necessary.

### § 200.518 Major program determination.

- (a) **General.** The auditor must use a risk-based approach to determine which Federal programs are major programs. This risk-based approach must include consideration of: current and prior audit experience, oversight by Federal agencies and pass-through entities, and the inherent risk of the Federal program. The process in paragraphs (b) through (h) of this section must be followed.
- (b) **Step one.**
  - (1) The auditor must identify the larger Federal programs, which must be labeled Type A programs. Type A programs are defined as Federal programs with Federal awards expended during the audit period exceeding the levels outlined in the table in this paragraph (b)(1):

Total Federal awards expended	Type A/B threshold
Equal to or exceed \$750,000 but less than or equal to \$25 million	\$750,000.
Exceed \$25 million but less than or equal to \$100 million	Total Federal awards expended times .03.
Exceed \$100 million but less than or equal to \$1 billion	\$3 million.
Exceed \$1 billion but less than or equal to \$10 billion	Total Federal awards expended times .003.
Exceed \$10 billion but less than or equal to \$20 billion	\$30 million.
Exceed \$20 billion	Total Federal awards expended times .0015.

- (2) Federal programs not labeled Type A under paragraph (b)(1) of this section must be labeled Type B programs.
  - (3) The inclusion of large loan and loan guarantees (loans) must not result in the exclusion of other programs as Type A programs. When a Federal program providing loans exceeds four times the largest non-loan program it is considered a large loan program, and the auditor must consider this Federal program as a Type A program and exclude its values in determining other Type A programs. This recalculation of the Type A program is performed after removing the total of all large loan programs. For the purposes of this paragraph a program is only considered to be a Federal program providing loans if the value of Federal awards expended for loans within the program comprises fifty percent or more of the total Federal awards expended for the program. A cluster of programs is treated as one program and the value of Federal awards expended under a loan program is determined as described in § 200.502.
  - (4) For biennial audits permitted under § 200.504, the determination of Type A and Type B programs must be based upon the Federal awards expended during the two-year period.
- (c) **Step two.**
- (1) The auditor must identify Type A programs which are low-risk. In making this determination, the auditor must consider whether the requirements in § 200.519(c), the results of audit follow-up, or any changes in personnel or systems affecting the program indicate significantly increased risk and preclude the program from being low risk. For a Type A program to be considered low-risk, it must have been audited as a major program in at least one of the two most recent audit periods (in the most recent audit period in the case of a biennial audit), and, in the most recent audit period, the program must have not had:
    - (i) Internal control deficiencies which were identified as material weaknesses in the auditor's report on internal control for major programs as required under § 200.515(c);
    - (ii) A modified opinion on the program in the auditor's report on major programs as required under § 200.515(c);  
or
    - (iii) Known or likely questioned costs that exceed five percent of the total Federal awards expended for the program.
  - (2) Notwithstanding paragraph (c)(1) of this section, OMB may approve a Federal awarding agency's request that a Type A program may not be considered low risk for a certain recipient. For example, it may be necessary for a large Type A program to be audited as a major program each year at a particular recipient to allow the Federal awarding agency to comply with 31 U.S.C. 3515. The Federal awarding agency must notify the recipient and, if known, the auditor of OMB's approval at least 180 calendar days prior to the end of the fiscal year to be audited.
- (d) **Step three.**
- (1) The auditor must identify Type B programs which are high-risk using professional judgment and the criteria in § 200.519. However, the auditor is not required to identify more high-risk Type B programs than at least one fourth the number of low-risk Type A programs identified as low-risk under Step 2 (paragraph (c) of this section). Except for known material weakness in internal control or compliance problems as discussed in § 200.519(b)(1) and (2) and (c)(1), a single criterion in risk would seldom cause a Type B program to be considered high-risk. When identifying which Type B programs to risk assess, the auditor is encouraged to use an approach which provides an opportunity for different high-risk Type B programs to be audited as major over a period of time.
  - (2) The auditor is not expected to perform risk assessments on relatively small Federal programs. Therefore, the auditor is only required to perform risk assessments on Type B programs that exceed twenty-five percent (0.25) of the Type A threshold determined in Step 1 (paragraph (b) of this section).
- (e) **Step four.** At a minimum, the auditor must audit all of the following as major programs:
- (1) All Type A programs not identified as low risk under step two (paragraph (c)(1) of this section).
  - (2) All Type B programs identified as high-risk under step three (paragraph (d) of this section).
  - (3) Such additional programs as may be necessary to comply with the percentage of coverage rule discussed in paragraph (f) of this section. This may require the auditor to audit more programs as major programs than the number of Type A programs.
- (f) **Percentage of coverage rule.** If the auditee meets the criteria in § 200.520, the auditor need only audit the major programs identified in Step 4 (paragraphs (e)(1) and (2) of this section) and such additional Federal programs with Federal awards expended that, in aggregate, all major programs encompass at least 20 percent (0.20) of total Federal

awards expended. Otherwise, the auditor must audit the major programs identified in Step 4 (paragraphs (e)(1) and (2) of this section) and such additional Federal programs with Federal awards expended that, in aggregate, all major programs encompass at least 40 percent (0.40) of total Federal awards expended.

- (g) **Documentation of risk.** The auditor must include in the audit documentation the risk analysis process used in determining major programs.
- (h) **Auditor's judgment.** When the major program determination was performed and documented in accordance with this Subpart, the auditor's judgment in applying the risk-based approach to determine major programs must be presumed correct. Challenges by Federal agencies and pass-through entities must only be for clearly improper use of the requirements in this part. However, Federal agencies and pass-through entities may provide auditors guidance about the risk of a particular Federal program and the auditor must consider this guidance in determining major programs in audits not yet completed.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75887, Dec. 19, 2014; 85 FR 49574, Aug. 13, 2020]

### § 200.519 Criteria for Federal program risk.

- (a) **General.** The auditor's determination should be based on an overall evaluation of the risk of noncompliance occurring that could be material to the Federal program. The auditor must consider criteria, such as described in paragraphs (b), (c), and (d) of this section, to identify risk in Federal programs. Also, as part of the risk analysis, the auditor may wish to discuss a particular Federal program with auditee management and the Federal agency or pass-through entity.
- (b) **Current and prior audit experience.**
  - (1) Weaknesses in internal control over Federal programs would indicate higher risk. Consideration should be given to the control environment over Federal programs and such factors as the expectation of management's adherence to Federal statutes, regulations, and the terms and conditions of Federal awards and the competence and experience of personnel who administer the Federal programs.
    - (i) A Federal program administered under multiple internal control structures may have higher risk. When assessing risk in a large single audit, the auditor must consider whether weaknesses are isolated in a single operating unit (e.g., one college campus) or pervasive throughout the entity.
    - (ii) When significant parts of a Federal program are passed through to subrecipients, a weak system for monitoring subrecipients would indicate higher risk.
  - (2) Prior audit findings would indicate higher risk, particularly when the situations identified in the audit findings could have a significant impact on a Federal program or have not been corrected.
  - (3) Federal programs not recently audited as major programs may be of higher risk than Federal programs recently audited as major programs without audit findings.
- (c) **Oversight exercised by Federal agencies and pass-through entities.**
  - (1) Oversight exercised by Federal agencies or pass-through entities could be used to assess risk. For example, recent monitoring or other reviews performed by an oversight entity that disclosed no significant problems would indicate lower risk, whereas monitoring that disclosed significant problems would indicate higher risk.
  - (2) Federal agencies, with the concurrence of OMB, may identify Federal programs that are higher risk. OMB will provide this identification in the compliance supplement.
- (d) **Inherent risk of the Federal program.**
  - (1) The nature of a Federal program may indicate risk. Consideration should be given to the complexity of the program and the extent to which the Federal program contracts for goods and services. For example, Federal programs that disburse funds through third-party contracts or have eligibility criteria may be of higher risk. Federal programs primarily involving staff payroll costs may have high risk for noncompliance with requirements of § 200.430, but otherwise be at low risk.
  - (2) The phase of a Federal program in its life cycle at the Federal agency may indicate risk. For example, a new Federal program with new or interim regulations may have higher risk than an established program with time-tested regulations. Also, significant changes in Federal programs, statutes, regulations, or the terms and conditions of Federal awards may increase risk.

- (3) The phase of a Federal program in its life cycle at the auditee may indicate risk. For example, during the first and last years that an auditee participates in a Federal program, the risk may be higher due to start-up or closeout of program activities and staff.
- (4) Type B programs with larger Federal awards expended would be of higher risk than programs with substantially smaller Federal awards expended.

[78 FR 78608, Dec. 26, 2013, as amended at 85 FR 49575, Aug. 13, 2020]

### § 200.520 Criteria for a low-risk auditee.

An auditee that meets all of the following conditions for each of the preceding two audit periods must qualify as a low-risk auditee and be eligible for reduced audit coverage in accordance with § 200.518.

- (a) Single audits were performed on an annual basis in accordance with the provisions of this Subpart, including submitting the data collection form and the reporting package to the FAC within the timeframe specified in § 200.512. A non-Federal entity that has biennial audits does not qualify as a low-risk auditee.
- (b) The auditor's opinion on whether the financial statements were prepared in accordance with GAAP, or a basis of accounting required by state law, and the auditor's in relation to opinion on the schedule of expenditures of Federal awards were unmodified.
- (c) There were no deficiencies in internal control which were identified as material weaknesses under the requirements of GAGAS.
- (d) The auditor did not report a substantial doubt about the auditee's ability to continue as a going concern.
- (e) None of the Federal programs had audit findings from any of the following in either of the preceding two audit periods in which they were classified as Type A programs:
  - (1) Internal control deficiencies that were identified as material weaknesses in the auditor's report on internal control for major programs as required under § 200.515(c);
  - (2) A modified opinion on a major program in the auditor's report on major programs as required under § 200.515(c); or
  - (3) Known or likely questioned costs that exceeded five percent of the total Federal awards expended for a Type A program during the audit period.

[78 FR 78608, Dec. 26, 2013, as amended at 85 FR 49575, Aug. 13, 2020]

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## MANAGEMENT DECISIONS

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### § 200.521 Management decision.

- (a) **General.** The management decision must clearly state whether or not the audit finding is sustained, the reasons for the decision, and the expected auditee action to repay disallowed costs, make financial adjustments, or take other action. If the auditee has not completed corrective action, a timetable for follow-up should be given. Prior to issuing the management decision, the Federal agency or pass-through entity may request additional information or documentation from the auditee, including a request for auditor assurance related to the documentation, as a way of mitigating disallowed costs. The management decision should describe any appeal process available to the auditee. While not required, the Federal agency or pass-through entity may also issue a management decision on findings relating to the financial statements which are required to be reported in accordance with GAGAS.
- (b) **Federal agency.** As provided in § 200.513(a)(3)(vii), the cognizant agency for audit must be responsible for coordinating a management decision for audit findings that affect the programs of more than one Federal agency. As provided in § 200.513(c)(3)(i), a Federal awarding agency is responsible for issuing a management decision for findings that relate to Federal awards it makes to non-Federal entities.
- (c) **Pass-through entity.** As provided in § 200.332(d), the pass-through entity must be responsible for issuing a management decision for audit findings that relate to Federal awards it makes to subrecipients.
- (d) **Time requirements.** The Federal awarding agency or pass-through entity responsible for issuing a management decision must do so within six months of acceptance of the audit report by the FAC. The auditee must initiate and proceed with corrective action as rapidly as possible and corrective action should begin no later than upon receipt of the audit report.

- (e) **Reference numbers.** Management decisions must include the reference numbers the auditor assigned to each audit finding in accordance with § 200.516(c).

[78 FR 78608, Dec. 26, 2013, as amended at 85 FR 49575, Aug. 13, 2020]

## **Appendix I to Part 200 - Full Text of Notice of Funding Opportunity**

The full text of the notice of funding opportunity is organized in sections. The required format outlined in this appendix indicates immediately following the title of each section whether that section is required in every announcement or is a Federal awarding agency option. The format is designed so that similar types of information will appear in the same sections in announcements of different Federal funding opportunities. Toward that end, there is text in each of the following sections to describe the types of information that a Federal awarding agency would include in that section of an actual announcement.

A Federal awarding agency that wishes to include information that the format does not specifically discuss may address that subject in whatever section(s) is most appropriate. For example, if a Federal awarding agency chooses to address performance goals in the announcement, it might do so in the funding opportunity description, the application content, or the reporting requirements.

Similarly, when this format calls for a type of information to be in a particular section, a Federal awarding agency wishing to address that subject in other sections may elect to repeat the information in those sections or use cross references between the sections (there should be hyperlinks for cross-references in any electronic versions of the announcement). For example, a Federal awarding agency may want to include Section A information about the types of non-Federal entities who are eligible to apply. The format specifies a standard location for that information in Section C.1 but does not preclude repeating the information in Section A or creating a cross reference between Section A and C.1, as long as a potential applicant can find the information quickly and easily from the standard location.

The sections of the full text of the announcement are described in the following paragraphs.

### **A. Program Description - Required**

This section contains the full program description of the funding opportunity. It may be as long as needed to adequately communicate to potential applicants the areas in which funding may be provided. It describes the Federal awarding agency's funding priorities or the technical or focus areas in which the Federal awarding agency intends to provide assistance. As appropriate, it may include any program history (e.g., whether this is a new program or a new or changed area of program emphasis). This section must include program goals and objectives, a reference to the relevant Assistance Listings, a description of how the award will contribute to the achievement of the program's goals and objectives, and the expected performance goals, indicators, targets, baseline data, data collection, and other outcomes such Federal awarding agency expects to achieve, and may include examples of successful projects that have been funded previously. This section also may include other information the Federal awarding agency deems necessary, and must at a minimum include citations for authorizing statutes and regulations for the funding opportunity.

### **B. Federal Award Information - Required**

This section provides sufficient information to help an applicant make an informed decision about whether to submit a proposal. Relevant information could include the total amount of funding that the Federal awarding agency expects to award through the announcement; the expected performance indicators, targets, baseline data, and data collection; the anticipated number of Federal awards; the expected amounts of individual Federal awards (which may be a range); the amount of funding per Federal award, on average, experienced in previous years; and the anticipated start dates and periods of performance for new Federal awards. This section also should address whether applications for renewal or supplementation of existing projects are eligible to compete with applications for new Federal awards.

This section also must indicate the type(s) of assistance instrument (e.g., grant, cooperative agreement) that may be awarded if applications are successful. If cooperative agreements may be awarded, this section either should describe the "substantial involvement" that the Federal awarding agency expects to have or should reference where the potential applicant can find that information (e.g., in the funding opportunity description in Section A. or Federal award administration information in Section D. If procurement contracts also may be awarded, this must be stated.

### **C. Eligibility Information**

This section addresses the considerations or factors that determine applicant or application eligibility. This includes the eligibility of particular types of applicant organizations, any factors affecting the eligibility of the principal investigator or project director, and any criteria that make particular projects ineligible. Federal agencies should make clear whether an applicant's failure to meet an eligibility criterion by the time of an application deadline will result in the Federal awarding agency returning the application without review or, even though an application may be reviewed, will preclude the Federal awarding agency from making a Federal award. Key elements to be addressed are:

1. *Eligible Applicants - Required.* Announcements must clearly identify the types of entities that are eligible to apply. If there are no restrictions on eligibility, this section may simply indicate that all potential applicants are eligible. If there are restrictions on eligibility, it is important to be clear about the specific types of entities that are eligible, not just the types that are ineligible. For example, if the program is limited to nonprofit organizations subject to 26 U.S.C. 501(c)(3) of the tax code (26 U.S.C. 501(c)(3)), the announcement should say so. Similarly, it is better to state explicitly that Native American tribal organizations are eligible than to assume that they can unambiguously infer that from a statement that nonprofit organizations may apply. Eligibility also can be expressed by exception, (e.g., open to all types of domestic applicants other than individuals). This section should refer to any portion of Section D specifying documentation that must be submitted to support an eligibility determination (e.g., proof of 501(c)(3) status as determined by the Internal Revenue Service or an authorizing tribal resolution). To the extent that any funding restriction in Section D.6 could affect the eligibility of an applicant or project, the announcement must either restate that restriction in this section or provide a cross-reference to its description in Section D.6.

2. *Cost Sharing or Matching - Required.* Announcements must state whether there is required cost sharing, matching, or cost participation without which an application would be ineligible (if cost sharing is not required, the announcement must explicitly say so). Required cost sharing may be a certain percentage or amount, or may be in the form of contributions of specified items or activities (e.g., provision of equipment). It is important that the announcement be clear about any restrictions on the types of cost (e.g., in-kind contributions) that are acceptable as cost sharing. Cost sharing as an eligibility criterion includes requirements based in statute or regulation, as described in § 200.306 of this Part. This section should refer to the appropriate portion(s) of section D, stating any pre-award requirements for submission of letters or other documentation to verify commitments to meet cost-sharing requirements if a Federal award is made.

3. *Other - Required, if applicable.* If there are other eligibility criteria (i.e., criteria that have the effect of making an application or project ineligible for Federal awards, whether referred to as "responsiveness" criteria, "go-no go" criteria, "threshold" criteria, or in other ways), must be clearly stated and must include a reference to the regulation of requirement that describes the restriction, as applicable. For example, if entities that have been found to be in violation of a particular Federal statute are ineligible, it is important to say so. This section must also state any limit on the number of applications an applicant may submit under the announcement and make clear whether the limitation is on the submitting organization, individual investigator/program director, or both. This section should also address any eligibility criteria for beneficiaries or for program participants other than Federal award recipients.

## D. Application and Submission Information

1. *Address to Request Application Package - Required.* Potential applicants must be told how to get application forms, kits, or other materials needed to apply (if this announcement contains everything needed, this section need only say so). An Internet address where the materials can be accessed is acceptable. However, since high-speed Internet access is not yet universally available for downloading documents, and applicants may have additional accessibility requirements, there also should be a way for potential applicants to request paper copies of materials, such as a U.S. Postal Service mailing address, telephone or FAX number, Telephone Device for the Deaf (TDD), Text Telephone (TTY) number, and/or Federal Information Relay Service (FIRS) number.

2. *Content and Form of Application Submission - Required.* This section must identify the required content of an application and the forms or formats that an applicant must use to submit it. If any requirements are stated elsewhere because they are general requirements that apply to multiple programs or funding opportunities, this section should refer to where those requirements may be found. This section also should include required forms or formats as part of the announcement or state where the applicant may obtain them.

This section should specifically address content and form or format requirements for:

i. Pre-applications, letters of intent, or white papers required or encouraged (see Section D.4), including any limitations on the number of pages or other formatting requirements similar to those for full applications.



- ii. The application as a whole. For all submissions, this would include any limitations on the number of pages, font size and typeface, margins, paper size, number of copies, and sequence or assembly requirements. If electronic submission is permitted or required, this could include special requirements for formatting or signatures.
- iii. Component pieces of the application (e.g., if all copies of the application must bear original signatures on the face page or the program narrative may not exceed 10 pages). This includes any pieces that may be submitted separately by third parties (e.g., references or letters confirming commitments from third parties that will be contributing a portion of any required cost sharing).
- iv. Information that successful applicants must submit after notification of intent to make a Federal award, but prior to a Federal award. This could include evidence of compliance with requirements relating to human subjects or information needed to comply with the National Environmental Policy Act (NEPA) (42 U.S.C. 4321-4370h).

3. *Unique entity identifier and System for Award Management (SAM) - Required.* This paragraph must state clearly that each applicant (unless the applicant is an individual or Federal awarding agency that is excepted from those requirements under 2 CFR 25.110(b) or (c), or has an exception approved by the Federal awarding agency under 2 CFR 25.110(d)) is required to: (i) Be registered in SAM before submitting its application; (ii) Provide a valid unique entity identifier in its application; and (iii) Continue to maintain an active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by a Federal awarding agency. It also must state that the Federal awarding agency may not make a Federal award to an applicant until the applicant has complied with all applicable unique entity identifier and SAM requirements and, if an applicant has not fully complied with the requirements by the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant.

4. *Submission Dates and Times - Required.* Announcements must identify due dates and times for all submissions. This includes not only the full applications but also any preliminary submissions (e.g., letters of intent, white papers, or pre-applications). It also includes any other submissions of information before Federal award that are separate from the full application. If the funding opportunity is a general announcement that is open for a period of time with no specific due dates for applications, this section should say so. Note that the information on dates that is included in this section also must appear with other overview information in a location preceding the full text of the announcement (see § 200.204 of this part).

5. *Intergovernmental Review - Required, if applicable.* If the funding opportunity is subject to Executive Order 12372, "Intergovernmental Review of Federal Programs," the notice must say so and applicants must contact their state's Single Point of Contact (SPOC) to find out about and comply with the state's process under Executive Order 12372, it may be useful to inform potential applicants that the names and addresses of the SPOCs are listed in the Office of Management and Budget's website.

6. *Funding Restrictions - Required.* Notices must include information on funding restrictions in order to allow an applicant to develop an application and budget consistent with program requirements. Examples are whether construction is an allowable activity, if there are any limitations on direct costs such as foreign travel or equipment purchases, and if there are any limits on indirect costs (or facilities and administrative costs). Applicants must be advised if Federal awards will not allow reimbursement of pre-Federal award costs.

7. *Other Submission Requirements - Required.* This section must address any other submission requirements not included in the other paragraphs of this section. This might include the format of submission, i.e., paper or electronic, for each type of required submission. Applicants should not be required to submit in more than one format and this section should indicate whether they may choose whether to submit applications in hard copy or electronically, may submit only in hard copy, or may submit only electronically.

This section also must indicate where applications (and any pre-applications) must be submitted if sent by postal mail, electronic means, or hand-delivery. For postal mail submission, this must include the name of an office, official, individual or function (e.g., application receipt center) and a complete mailing address. For electronic submission, this must include the URL or email address; whether a password(s) is required; whether particular software or other electronic capabilities are required; what to do in the event of system problems and a point of contact who will be available in the event the applicant experiences technical difficulties.<sup>[1]</sup>

## E. Application Review Information

1. *Criteria - Required.* This section must address the criteria that the Federal awarding agency will use to evaluate applications. This includes the merit and other review criteria that evaluators will use to judge applications, including any statutory, regulatory, or other preferences (e.g., minority status or Native American tribal preferences) that will be applied in the review process. These criteria are distinct from eligibility criteria that are addressed before an application is accepted for review and any program policy

or other factors that are applied during the selection process, after the review process is completed. The intent is to make the application process transparent so applicants can make informed decisions when preparing their applications to maximize fairness of the process. The announcement should clearly describe all criteria, including any sub-criteria. If criteria vary in importance, the announcement should specify the relative percentages, weights, or other means used to distinguish among them. For statutory, regulatory, or other preferences, the announcement should provide a detailed explanation of those preferences with an explicit indication of their effect (e.g., whether they result in additional points being assigned).

If an applicant's proposed cost sharing will be considered in the review process (as opposed to being an eligibility criterion described in Section C.2), the announcement must specifically address how it will be considered (e.g., to assign a certain number of additional points to applicants who offer cost sharing, or to break ties among applications with equivalent scores after evaluation against all other factors). If cost sharing will not be considered in the evaluation, the announcement should say so, so that there is no ambiguity for potential applicants. Vague statements that cost sharing is encouraged, without clarification as to what that means, are unhelpful to applicants. It also is important that the announcement be clear about any restrictions on the types of cost (e.g., in-kind contributions) that are acceptable as cost sharing.

**2. Review and Selection Process - Required.** This section may vary in the level of detail provided. The announcement must list any program policy or other factors or elements, other than merit criteria, that the selecting official may use in selecting applications for Federal award (e.g., geographical dispersion, program balance, or diversity). The Federal awarding agency may also include other appropriate details. For example, this section may indicate who is responsible for evaluation against the merit criteria (e.g., peers external to the Federal awarding agency or Federal awarding agency personnel) and/or who makes the final selections for Federal awards. If there is a multi-phase review process (e.g., an external panel advising internal Federal awarding agency personnel who make final recommendations to the deciding official), the announcement may describe the phases. It also may include: the number of people on an evaluation panel and how it operates, the way reviewers are selected, reviewer qualifications, and the way that conflicts of interest are avoided. With respect to electronic methods for providing information about funding opportunities or accepting applicants' submissions of information, each Federal awarding agency is responsible for compliance with Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d).

In addition, if the Federal awarding agency permits applicants to nominate suggested reviewers of their applications or suggest those they feel may be inappropriate due to a conflict of interest, that information should be included in this section.

**3.** For any Federal award under a notice of funding opportunity, if the Federal awarding agency anticipates that the total Federal share will be greater than the simplified acquisition threshold on any Federal award under a notice of funding opportunity may include, over the period of performance, this section must also inform applicants:

- i. That the Federal awarding agency, prior to making a Federal award with a total amount of Federal share greater than the simplified acquisition threshold, is required to review and consider any information about the applicant that is in the designated integrity and performance system accessible through SAM (currently FAPIIS) (see 41 U.S.C. 2313);
- ii. That an applicant, at its option, may review information in the designated integrity and performance systems accessible through SAM and comment on any information about itself that a Federal awarding agency previously entered and is currently in the designated integrity and performance system accessible through SAM;
- iii. That the Federal awarding agency will consider any comments by the applicant, in addition to the other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in § 200.206.

**4. Anticipated Announcement and Federal Award Dates - Optional.** This section is intended to provide applicants with information they can use for planning purposes. If there is a single application deadline followed by the simultaneous review of all applications, the Federal awarding agency can include in this section information about the anticipated dates for announcing or notifying successful and unsuccessful applicants and for having Federal awards in place. If applications are received and evaluated on a "rolling" basis at different times during an extended period, it may be appropriate to give applicants an estimate of the time needed to process an application and notify the applicant of the Federal awarding agency's decision.

## F. Federal Award Administration Information

**1. Federal Award Notices - Required.** This section must address what a successful applicant can expect to receive following selection. If the Federal awarding agency's practice is to provide a separate notice stating that an application has been selected before it actually makes the Federal award, this section would be the place to indicate that the letter is not an authorization to begin performance (to the extent that it allows charging to Federal awards of pre-award costs at the non-Federal entity's own risk).

This section should indicate that the notice of Federal award signed by the grants officer (or equivalent) is the authorizing document, and whether it is provided through postal mail or by electronic means and to whom. It also may address the timing, form, and content of notifications to unsuccessful applicants. See also § 200.211.

**2. Administrative and National Policy Requirements - Required**. This section must identify the usual administrative and national policy requirements the Federal awarding agency's Federal awards may include. Providing this information lets a potential applicant identify any requirements with which it would have difficulty complying if its application is successful. In those cases, early notification about the requirements allows the potential applicant to decide not to apply or to take needed actions before receiving the Federal award. The announcement need not include all of the terms and conditions of the Federal award, but may refer to a document (with information about how to obtain it) or Internet site where applicants can see the terms and conditions. If this funding opportunity will lead to Federal awards with some special terms and conditions that differ from the Federal awarding agency's usual (sometimes called "general") terms and conditions, this section should highlight those special terms and conditions. Doing so will alert applicants that have received Federal awards from the Federal awarding agency previously and might not otherwise expect different terms and conditions. For the same reason, the announcement should inform potential applicants about special requirements that could apply to particular Federal awards after the review of applications and other information, based on the particular circumstances of the effort to be supported (e.g., if human subjects were to be involved or if some situations may justify special terms on intellectual property, data sharing or security requirements).

**3. Reporting - Required**. This section must include general information about the type (e.g., financial or performance), frequency, and means of submission (paper or electronic) of post-Federal award reporting requirements. Highlight any special reporting requirements for Federal awards under this funding opportunity that differ (e.g., by report type, frequency, form/format, or circumstances for use) from what the Federal awarding agency's Federal awards usually require. Federal awarding agencies must also describe in this section all relevant requirements such as those at 2 CFR 180.335 and 180.350.

If the Federal share of any Federal award may include more than \$500,000 over the period of performance, this section must inform potential applicants about the post award reporting requirements reflected in appendix XII to this part.

## **G. Federal Awarding Agency Contact(s) - Required**

The announcement must give potential applicants a point(s) of contact for answering questions or helping with problems while the funding opportunity is open. The intent of this requirement is to be as helpful as possible to potential applicants, so the Federal awarding agency should consider approaches such as giving:

- i. Points of contact who may be reached in multiple ways (e.g., by telephone, FAX, and/or email, as well as regular mail).
- ii. A fax or email address that multiple people access, so that someone will respond even if others are unexpectedly absent during critical periods.
- iii. Different contacts for distinct kinds of help (e.g., one for questions of programmatic content and a second for administrative questions).

## **H. Other Information - Optional**

This section may include any additional information that will assist a potential applicant. For example, the section might:

- i. Indicate whether this is a new program or a one-time initiative.
- ii. Mention related programs or other upcoming or ongoing Federal awarding agency funding opportunities for similar activities.
- iii. Include current Internet addresses for Federal awarding agency Web sites that may be useful to an applicant in understanding the program.
- iv. Alert applicants to the need to identify proprietary information and inform them about the way the Federal awarding agency will handle it.
- v. Include certain routine notices to applicants (e.g., that the Federal Government is not obligated to make any Federal award as a result of the announcement or that only grants officers can bind the Federal Government to the expenditure of funds).

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**FOOTNOTES - APPENDIX I TO PART 200**

[<sup>1</sup>] With respect to electronic methods for providing information about funding opportunities or accepting applicants' submissions of information, each Federal awarding agency is responsible for compliance with Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d).

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**Appendix II to Part 200 - Contract Provisions for Non-Federal Entity Contracts Under Federal Awards**

In addition to other provisions required by the Federal agency or non-Federal entity, all contracts made by the non-Federal entity under the Federal award must contain provisions covering the following, as applicable.

(A) Contracts for more than the simplified acquisition threshold, which is the inflation adjusted amount determined by the Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (Councils) as authorized by 41 U.S.C. 1908, must address administrative, contractual, or legal remedies in instances where contractors violate or breach contract terms, and provide for such sanctions and penalties as appropriate.

(B) All contracts in excess of \$10,000 must address termination for cause and for convenience by the non-Federal entity including the manner by which it will be effected and the basis for settlement.

(C) Equal Employment Opportunity. Except as otherwise provided under 41 CFR Part 60, all contracts that meet the definition of "federally assisted construction contract" in 41 CFR Part 60-1.3 must include the equal opportunity clause provided under 41 CFR 60-1.4(b), in accordance with Executive Order 11246, "Equal Employment Opportunity" (30 FR 12319, 12935, 3 CFR Part, 1964-1965 Comp., p. 339), as amended by Executive Order 11375, "Amending Executive Order 11246 Relating to Equal Employment Opportunity," and implementing regulations at 41 CFR part 60, "Office of Federal Contract Compliance Programs, Equal Employment Opportunity, Department of Labor."

(D) Davis-Bacon Act, as amended (40 U.S.C. 3141-3148). When required by Federal program legislation, all prime construction contracts in excess of \$2,000 awarded by non-Federal entities must include a provision for compliance with the Davis-Bacon Act (40 U.S.C. 3141-3144, and 3146-3148) as supplemented by Department of Labor regulations (29 CFR Part 5, "Labor Standards Provisions Applicable to Contracts Covering Federally Financed and Assisted Construction"). In accordance with the statute, contractors must be required to pay wages to laborers and mechanics at a rate not less than the prevailing wages specified in a wage determination made by the Secretary of Labor. In addition, contractors must be required to pay wages not less than once a week. The non-Federal entity must place a copy of the current prevailing wage determination issued by the Department of Labor in each solicitation. The decision to award a contract or subcontract must be conditioned upon the acceptance of the wage determination. The non-Federal entity must report all suspected or reported violations to the Federal awarding agency. The contracts must also include a provision for compliance with the Copeland "Anti-Kickback" Act (40 U.S.C. 3145), as supplemented by Department of Labor regulations (29 CFR Part 3, "Contractors and Subcontractors on Public Building or Public Work Financed in Whole or in Part by Loans or Grants from the United States"). The Act provides that each contractor or subrecipient must be prohibited from inducing, by any means, any person employed in the construction, completion, or repair of public work, to give up any part of the compensation to which he or she is otherwise entitled. The non-Federal entity must report all suspected or reported violations to the Federal awarding agency.

(E) Contract Work Hours and Safety Standards Act (40 U.S.C. 3701-3708). Where applicable, all contracts awarded by the non-Federal entity in excess of \$100,000 that involve the employment of mechanics or laborers must include a provision for compliance with 40 U.S.C. 3702 and 3704, as supplemented by Department of Labor regulations (29 CFR Part 5). Under 40 U.S.C. 3702 of the Act, each contractor must be required to compute the wages of every mechanic and laborer on the basis of a standard work week of 40 hours. Work in excess of the standard work week is permissible provided that the worker is compensated at a rate of not less than one and a half times the basic rate of pay for all hours worked in excess of 40 hours in the work week. The requirements of 40 U.S.C. 3704 are applicable to construction work and provide that no laborer or mechanic must be required to work in surroundings or under working conditions which are unsanitary, hazardous or dangerous. These requirements do not apply to the purchases of supplies or materials or articles ordinarily available on the open market, or contracts for transportation or transmission of intelligence.

(F) Rights to Inventions Made Under a Contract or Agreement. If the Federal award meets the definition of "funding agreement" under 37 CFR § 401.2 (a) and the recipient or subrecipient wishes to enter into a contract with a small business firm or nonprofit organization regarding the substitution of parties, assignment or performance of experimental, developmental, or research work

under that "funding agreement," the recipient or subrecipient must comply with the requirements of 37 CFR Part 401, "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts and Cooperative Agreements," and any implementing regulations issued by the awarding agency.

(G) Clean Air Act (42 U.S.C. 7401-7671q.) and the Federal Water Pollution Control Act (33 U.S.C. 1251-1387), as amended - Contracts and subgrants of amounts in excess of \$150,000 must contain a provision that requires the non-Federal award to agree to comply with all applicable standards, orders or regulations issued pursuant to the Clean Air Act (42 U.S.C. 7401-7671q) and the Federal Water Pollution Control Act as amended (33 U.S.C. 1251-1387). Violations must be reported to the Federal awarding agency and the Regional Office of the Environmental Protection Agency (EPA).

(H) Debarment and Suspension (Executive Orders 12549 and 12689) - A contract award (see 2 CFR 180.220) must not be made to parties listed on the governmentwide exclusions in the System for Award Management (SAM), in accordance with the OMB guidelines at 2 CFR 180 that implement Executive Orders 12549 (3 CFR part 1986 Comp., p. 189) and 12689 (3 CFR part 1989 Comp., p. 235), "Debarment and Suspension." SAM Exclusions contains the names of parties debarred, suspended, or otherwise excluded by agencies, as well as parties declared ineligible under statutory or regulatory authority other than Executive Order 12549.

(I) Byrd Anti-Lobbying Amendment (31 U.S.C. 1352) - Contractors that apply or bid for an award exceeding \$100,000 must file the required certification. Each tier certifies to the tier above that it will not and has not used Federal appropriated funds to pay any person or organization for influencing or attempting to influence an officer or employee of any agency, a member of Congress, officer or employee of Congress, or an employee of a member of Congress in connection with obtaining any Federal contract, grant or any other award covered by 31 U.S.C. 1352. Each tier must also disclose any lobbying with non-Federal funds that takes place in connection with obtaining any Federal award. Such disclosures are forwarded from tier to tier up to the non-Federal award.

(J) See § 200.323.

(K) See § 200.216.

(L) See § 200.322.

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75888, Dec. 19, 2014; 85 FR 49577, Aug. 13, 2020]

## **Appendix III to Part 200 - Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Institutions of Higher Education (IHEs)**

### **A. General**

This appendix provides criteria for identifying and computing indirect (or indirect (F&A)) rates at IHEs (institutions). Indirect (F&A) costs are those that are incurred for common or joint objectives and therefore cannot be identified readily and specifically with a particular sponsored project, an instructional activity, or any other institutional activity. See subsection B.1 for a discussion of the components of indirect (F&A) costs.

### **1. Major Functions of an Institution**

Refers to instruction, organized research, other sponsored activities and other institutional activities as defined in this section:

a. *Instruction* means the teaching and training activities of an institution. Except for research training as provided in subsection b, this term includes all teaching and training activities, whether they are offered for credits toward a degree or certificate or on a non-credit basis, and whether they are offered through regular academic departments or separate divisions, such as a summer school division or an extension division. Also considered part of this major function are departmental research, and, where agreed to, university research.

- (1) ***Sponsored instruction and training*** means specific instructional or training activity established by grant, contract, or cooperative agreement. For purposes of the cost principles, this activity may be considered a major function even though an institution's accounting treatment may include it in the instruction function.
- (2) ***Departmental research*** means research, development and scholarly activities that are not organized research and, consequently, are not separately budgeted and accounted for. Departmental research, for purposes of this document, is not considered as a major function, but as a part of the instruction function of the institution.

- (3) Only mandatory cost sharing or cost sharing specifically committed in the project budget must be included in the organized research base for computing the indirect (F&A) cost rate or reflected in any allocation of indirect costs. Salary costs above statutory limits are not considered cost sharing.

b. *Organized research* means all research and development activities of an institution that are separately budgeted and accounted for. It includes:

- (1) **Sponsored research** means all research and development activities that are sponsored by Federal and non-Federal agencies and organizations. This term includes activities involving the training of individuals in research techniques (commonly called research training) where such activities utilize the same facilities as other research and development activities and where such activities are not included in the instruction function.
- (2) **University research** means all research and development activities that are separately budgeted and accounted for by the institution under an internal application of institutional funds. University research, for purposes of this document, must be combined with sponsored research under the function of organized research.

c. *Other sponsored activities* means programs and projects financed by Federal and non-Federal agencies and organizations which involve the performance of work other than instruction and organized research. Examples of such programs and projects are health service projects and community service programs. However, when any of these activities are undertaken by the institution without outside support, they may be classified as other institutional activities.

d. *Other institutional activities* means all activities of an institution except for instruction, departmental research, organized research, and other sponsored activities, as defined in this section; indirect (F&A) cost activities identified in this Appendix paragraph B, Identification and assignment of indirect (F&A) costs; and specialized services facilities described in § 200.468 of this part.

## 2. Criteria for Distribution

a. *Base period.* A base period for distribution of indirect (F&A) costs is the period during which the costs are incurred. The base period normally should coincide with the fiscal year established by the institution, but in any event the base period should be so selected as to avoid inequities in the distribution of costs.

b. *Need for cost groupings.* The overall objective of the indirect (F&A) cost allocation process is to distribute the indirect (F&A) costs described in Section B, Identification and assignment of indirect (F&A) costs, to the major functions of the institution in proportions reasonably consistent with the nature and extent of their use of the institution's resources. In order to achieve this objective, it may be necessary to provide for selective distribution by establishing separate groupings of cost within one or more of the indirect (F&A) cost categories referred to in subsection B.1. In general, the cost groupings established within a category should constitute, in each case, a pool of those items of expense that are considered to be of like nature in terms of their relative contribution to (or degree of remoteness from) the particular cost objectives to which distribution is appropriate. Cost groupings should be established considering the general guides provided in subsection c of this section. Each such pool or cost grouping should then be distributed individually to the related cost objectives, using the distribution base or method most appropriate in light of the guidelines set forth in subsection d of this section.

c. *General considerations on cost groupings.* The extent to which separate cost groupings and selective distribution would be appropriate at an institution is a matter of judgment to be determined on a case-by-case basis. Typical situations which may warrant the establishment of two or more separate cost groupings (based on account classification or analysis) within an indirect (F&A) cost category include but are not limited to the following:

- (1) If certain items or categories of expense relate solely to one of the major functions of the institution or to less than all functions, such expenses should be set aside as a separate cost grouping for direct assignment or selective allocation in accordance with the guides provided in subsections b and d.
- (2) If any types of expense ordinarily treated as general administration or departmental administration are charged to Federal awards as direct costs, expenses applicable to other activities of the institution when incurred for the same purposes in like circumstances must, through separate cost groupings, be excluded from the indirect (F&A) costs allocable to those Federal awards and included in the direct cost of other activities for cost allocation purposes.
- (3) If it is determined that certain expenses are for the support of a service unit or facility whose output is susceptible of measurement on a workload or other quantitative basis, such expenses should be set aside as a separate cost grouping for distribution on such basis to organized research, instructional, and other activities at the institution or within the department.

- (4) If activities provide their own purchasing, personnel administration, building maintenance or similar service, the distribution of general administration and general expenses, or operation and maintenance expenses to such activities should be accomplished through cost groupings which include only that portion of central indirect (F&A) costs (such as for overall management) which are properly allocable to such activities.
- (5) If the institution elects to treat fringe benefits as indirect (F&A) charges, such costs should be set aside as a separate cost grouping for selective distribution to related cost objectives.
- (6) The number of separate cost groupings within a category should be held within practical limits, after taking into consideration the materiality of the amounts involved and the degree of precision attainable through less selective methods of distribution.

d. Selection of distribution method.

- (1) Actual conditions must be taken into account in selecting the method or base to be used in distributing individual cost groupings. The essential consideration in selecting a base is that it be the one best suited for assigning the pool of costs to cost objectives in accordance with benefits derived; with a traceable cause-and-effect relationship; or with logic and reason, where neither benefit nor a cause-and-effect relationship is determinable.
- (2) If a cost grouping can be identified directly with the cost objective benefitted, it should be assigned to that cost objective.
- (3) If the expenses in a cost grouping are more general in nature, the distribution may be based on a cost analysis study which results in an equitable distribution of the costs. Such cost analysis studies may take into consideration weighting factors, population, or space occupied if appropriate. Cost analysis studies, however, must (a) be appropriately documented in sufficient detail for subsequent review by the cognizant agency for indirect costs, (b) distribute the costs to the related cost objectives in accordance with the relative benefits derived, (c) be statistically sound, (d) be performed specifically at the institution at which the results are to be used, and (e) be reviewed periodically, but not less frequently than rate negotiations, updated if necessary, and used consistently. Any assumptions made in the study must be stated and explained. The use of cost analysis studies and periodic changes in the method of cost distribution must be fully justified.
- (4) If a cost analysis study is not performed, or if the study does not result in an equitable distribution of the costs, the distribution must be made in accordance with the appropriate base cited in Section B, unless one of the following conditions is met:

(a) It can be demonstrated that the use of a different base would result in a more equitable allocation of the costs, or that a more readily available base would not increase the costs charged to Federal awards, or

(b) The institution qualifies for, and elects to use, the simplified method for computing indirect (F&A) cost rates described in Section D.

- (5) Notwithstanding subsection (3), effective July 1, 1998, a cost analysis or base other than that in Section B must not be used to distribute utility or student services costs. Instead, subsection B.4.c, may be used in the recovery of utility costs.

e. Order of distribution.

- (1) Indirect (F&A) costs are the broad categories of costs discussed in Section B.1.
- (2) Depreciation, interest expenses, operation and maintenance expenses, and general administrative and general expenses should be allocated in that order to the remaining indirect (F&A) cost categories as well as to the major functions and specialized service facilities of the institution. Other cost categories may be allocated in the order determined to be most appropriate by the institutions. When cross allocation of costs is made as provided in subsection (3), this order of allocation does not apply.
- (3) Normally an indirect (F&A) cost category will be considered closed once it has been allocated to other cost objectives, and costs may not be subsequently allocated to it. However, a cross allocation of costs between two or more indirect (F&A) cost categories may be used if such allocation will result in a more equitable allocation of costs. If a cross allocation is used, an appropriate modification to the composition of the indirect (F&A) cost categories described in Section B is required.

## B. Identification and Assignment of Indirect (F&A) Costs

## 1. Definition of Facilities and Administration

See § 200.414 which provides the basis for these indirect cost requirements.

## 2. Depreciation

a. The expenses under this heading are the portion of the costs of the institution's buildings, capital improvements to land and buildings, and equipment which are computed in accordance with § 200.436.

b. In the absence of the alternatives provided for in Section A.2.d, the expenses included in this category must be allocated in the following manner:

- (1) Depreciation on buildings used exclusively in the conduct of a single function, and on capital improvements and equipment used in such buildings, must be assigned to that function.
- (2) Depreciation on buildings used for more than one function, and on capital improvements and equipment used in such buildings, must be allocated to the individual functions performed in each building on the basis of usable square feet of space, excluding common areas such as hallways, stairwells, and rest rooms.
- (3) Depreciation on buildings, capital improvements and equipment related to space (e.g., individual rooms, laboratories) used jointly by more than one function (as determined by the users of the space) must be treated as follows. The cost of each jointly used unit of space must be allocated to benefitting functions on the basis of:

(a) The employee full-time equivalents (FTEs) or salaries and wages of those individual functions benefitting from the use of that space; or

(b) Institution-wide employee FTEs or salaries and wages applicable to the benefitting major functions (see Section A.1) of the institution.

- (4) Depreciation on certain capital improvements to land, such as paved parking areas, fences, sidewalks, and the like, not included in the cost of buildings, must be allocated to user categories of students and employees on a full-time equivalent basis. The amount allocated to the student category must be assigned to the instruction function of the institution. The amount allocated to the employee category must be further allocated to the major functions of the institution in proportion to the salaries and wages of all employees applicable to those functions.

## 3. Interest

Interest on debt associated with certain buildings, equipment and capital improvements, as defined in § 200.449, must be classified as an expenditure under the category Facilities. These costs must be allocated in the same manner as the depreciation on the buildings, equipment and capital improvements to which the interest relates.

## 4. Operation and Maintenance Expenses

a. The expenses under this heading are those that have been incurred for the administration, supervision, operation, maintenance, preservation, and protection of the institution's physical plant. They include expenses normally incurred for such items as janitorial and utility services; repairs and ordinary or normal alterations of buildings, furniture and equipment; care of grounds; maintenance and operation of buildings and other plant facilities; security; earthquake and disaster preparedness; environmental safety; hazardous waste disposal; property, liability and all other insurance relating to property; space and capital leasing; facility planning and management; and central receiving. The operation and maintenance expense category should also include its allocable share of fringe benefit costs, depreciation, and interest costs.

b. In the absence of the alternatives provided for in Section A.2.d, the expenses included in this category must be allocated in the same manner as described in subsection 2.b for depreciation.

c. A utility cost adjustment of up to 1.3 percentage points may be included in the negotiated indirect cost rate of the IHE for organized research, per the computation alternatives in paragraphs (c)(1) and (2) of this section:



- (1) Where space is devoted to a single function and metering allows unambiguous measurement of usage related to that space, costs must be assigned to the function located in that space.
- (2) Where space is allocated to different functions and metering does not allow unambiguous measurement of usage by function, costs must be allocated as follows:
  - (i) Utilities costs should be apportioned to functions in the same manner as depreciation, based on the calculated difference between the site or building actual square footage for monitored research laboratory space (site, building, floor, or room), and a separate calculation prepared by the IHE using the "effective square footage" described in subsection (c)(2)(ii) of this section.
  - (ii) "Effective square footage" allocated to research laboratory space must be calculated as the actual square footage times the relative energy utilization index (REUI) posted on the OMB Web site at the time of a rate determination.

A. This index is the ratio of a laboratory energy use index (lab EUI) to the corresponding index for overall average college or university space (college EUI).

B. In July 2012, values for these two indices (taken respectively from the Lawrence Berkeley Laboratory "Labs for the 21st Century" benchmarking tool and the US Department of Energy "Buildings Energy Databook" and were 310 kBtu/sq ft-yr. and 155 kBtu/sq ft-yr., so that the adjustment ratio is 2.0 by this methodology. To retain currency, OMB will adjust the EUI numbers from time to time (no more often than annually nor less often than every 5 years), using reliable and publicly disclosed data. Current values of both the EUIs and the REUI will be posted on the OMB website.

## 5. General Administration and General Expenses

a. The expenses under this heading are those that have been incurred for the general executive and administrative offices of educational institutions and other expenses of a general character which do not relate solely to any major function of the institution; *i.e.*, solely to (1) instruction, (2) organized research, (3) other sponsored activities, or (4) other institutional activities. The general administration and general expense category should also include its allocable share of fringe benefit costs, operation and maintenance expense, depreciation, and interest costs. Examples of general administration and general expenses include: Those expenses incurred by administrative offices that serve the entire university system of which the institution is a part; central offices of the institution such as the President's or Chancellor's office, the offices for institution-wide financial management, business services, budget and planning, personnel management, and safety and risk management; the office of the General Counsel; and the operations of the central administrative management information systems. General administration and general expenses must not include expenses incurred within non-university-wide deans' offices, academic departments, organized research units, or similar organizational units. (See subsection 6.)

b. In the absence of the alternatives provided for in Section A.2.d, the expenses included in this category must be grouped first according to common major functions of the institution to which they render services or provide benefits. The aggregate expenses of each group must then be allocated to serviced or benefitted functions on the modified total cost basis. Modified total costs consist of the same elements as those in Section C.2. When an activity included in this indirect (F&A) cost category provides a service or product to another institution or organization, an appropriate adjustment must be made to either the expenses or the basis of allocation or both, to assure a proper allocation of costs.

## 6. Departmental Administration Expenses

a. The expenses under this heading are those that have been incurred for administrative and supporting services that benefit common or joint departmental activities or objectives in academic deans' offices, academic departments and divisions, and organized research units. Organized research units include such units as institutes, study centers, and research centers. Departmental administration expenses are subject to the following limitations.

- (1) Academic deans' offices. Salaries and operating expenses are limited to those attributable to administrative functions.
- (2) Academic departments:

(a) Salaries and fringe benefits attributable to the administrative work (including bid and proposal preparation) of faculty (including department heads) and other professional personnel conducting research and/or instruction, must be allowed at a rate of 3.6 percent of modified total direct costs. This category does not include professional business or professional administrative officers.

This allowance must be added to the computation of the indirect (F&A) cost rate for major functions in Section C; the expenses covered by the allowance must be excluded from the departmental administration cost pool. No documentation is required to support this allowance.

(b) Other administrative and supporting expenses incurred within academic departments are allowable provided they are treated consistently in like circumstances. This would include expenses such as the salaries of secretarial and clerical staffs, the salaries of administrative officers and assistants, travel, office supplies, stockrooms, and the like.

- (3) Other fringe benefit costs applicable to the salaries and wages included in subsections (1) and (2) are allowable, as well as an appropriate share of general administration and general expenses, operation and maintenance expenses, and depreciation.
- (4) Federal agencies may authorize reimbursement of additional costs for department heads and faculty only in exceptional cases where an institution can demonstrate undue hardship or detriment to project performance.

b. The following guidelines apply to the determination of departmental administrative costs as direct or indirect (F&A) costs.

- (1) In developing the departmental administration cost pool, special care should be exercised to ensure that costs incurred for the same purpose in like circumstances are treated consistently as either direct or indirect (F&A) costs. For example, salaries of technical staff, laboratory supplies (e.g., chemicals), telephone toll charges, animals, animal care costs, computer costs, travel costs, and specialized shop costs must be treated as direct costs wherever identifiable to a particular cost objective. Direct charging of these costs may be accomplished through specific identification of individual costs to benefitting cost objectives, or through recharge centers or specialized service facilities, as appropriate under the circumstances. See §§ 200.413(c) and 200.468.
- (2) Items such as office supplies, postage, local telephone costs, and memberships must normally be treated as indirect (F&A) costs.

c. In the absence of the alternatives provided for in Section A.2.d, the expenses included in this category must be allocated as follows:

- (1) The administrative expenses of the dean's office of each college and school must be allocated to the academic departments within that college or school on the modified total cost basis.
- (2) The administrative expenses of each academic department, and the department's share of the expenses allocated in subsection (1) must be allocated to the appropriate functions of the department on the modified total cost basis.

## 7. Sponsored Projects Administration

a. The expenses under this heading are limited to those incurred by a separate organization(s) established primarily to administer sponsored projects, including such functions as grant and contract administration (Federal and non-Federal), special security, purchasing, personnel, administration, and editing and publishing of research and other reports. They include the salaries and expenses of the head of such organization, assistants, and immediate staff, together with the salaries and expenses of personnel engaged in supporting activities maintained by the organization, such as stock rooms, print shops, and the like. This category also includes an allocable share of fringe benefit costs, general administration and general expenses, operation and maintenance expenses, and depreciation. Appropriate adjustments will be made for services provided to other functions or organizations.

b. In the absence of the alternatives provided for in Section A.2.d, the expenses included in this category must be allocated to the major functions of the institution under which the sponsored projects are conducted on the basis of the modified total cost of sponsored projects.

c. An appropriate adjustment must be made to eliminate any duplicate charges to Federal awards when this category includes similar or identical activities as those included in the general administration and general expense category or other indirect (F&A) cost items, such as accounting, procurement, or personnel administration.

## 8. Library Expenses

a. The expenses under this heading are those that have been incurred for the operation of the library, including the cost of books and library materials purchased for the library, less any items of library income that qualify as applicable credits under § 200.406. The library expense category should also include the fringe benefits applicable to the salaries and wages included therein, an

appropriate share of general administration and general expense, operation and maintenance expense, and depreciation. Costs incurred in the purchases of rare books (museum-type books) with no value to Federal awards should not be allocated to them.

b. In the absence of the alternatives provided for in Section A.2.d, the expenses included in this category must be allocated first on the basis of primary categories of users, including students, professional employees, and other users.

- (1) The student category must consist of full-time equivalent students enrolled at the institution, regardless of whether they earn credits toward a degree or certificate.
- (2) The professional employee category must consist of all faculty members and other professional employees of the institution, on a full-time equivalent basis. This category may also include post-doctorate fellows and graduate students.
- (3) The other users category must consist of a reasonable factor as determined by institutional records to account for all other users of library facilities.

c. Amount allocated in paragraph b of this section must be assigned further as follows:

- (1) The amount in the student category must be assigned to the instruction function of the institution.
- (2) The amount in the professional employee category must be assigned to the major functions of the institution in proportion to the salaries and wages of all faculty members and other professional employees applicable to those functions.
- (3) The amount in the other users category must be assigned to the other institutional activities function of the institution.

## 9. Student Administration and Services

a. The expenses under this heading are those that have been incurred for the administration of student affairs and for services to students, including expenses of such activities as deans of students, admissions, registrar, counseling and placement services, student advisers, student health and infirmary services, catalogs, and commencements and convocations. The salaries of members of the academic staff whose responsibilities to the institution require administrative work that benefits sponsored projects may also be included to the extent that the portion charged to student administration is determined in accordance with subpart E of this Part. This expense category also includes the fringe benefit costs applicable to the salaries and wages included therein, an appropriate share of general administration and general expenses, operation and maintenance, interest expense, and depreciation.

b. In the absence of the alternatives provided for in Section A.2.d, the expenses in this category must be allocated to the instruction function, and subsequently to Federal awards in that function.

## 10. Offset for Indirect (F&A) Expenses Otherwise Provided for by the Federal Government

a. The items to be accumulated under this heading are the reimbursements and other payments from the Federal Government which are made to the institution to support solely, specifically, and directly, in whole or in part, any of the administrative or service activities described in subsections 2 through 9.

b. The items in this group must be treated as a credit to the affected individual indirect (F&A) cost category before that category is allocated to benefitting functions.

## C. Determination and Application of Indirect (F&A) Cost Rate or Rates

### 1. Indirect (F&A) Cost Pools

a. (1) Subject to subsection b, the separate categories of indirect (F&A) costs allocated to each major function of the institution as prescribed in Section B, must be aggregated and treated as a common pool for that function. The amount in each pool must be divided by the distribution base described in subsection 2 to arrive at a single indirect (F&A) cost rate for each function.

(2) The rate for each function is used to distribute indirect (F&A) costs to individual Federal awards of that function. Since a common pool is established for each major function of the institution, a separate indirect (F&A) cost rate would be established for each of the major functions described in Section A.1 under which Federal awards are carried out.

- (3) Each institution's indirect (F&A) cost rate process must be appropriately designed to ensure that Federal sponsors do not in any way subsidize the indirect (F&A) costs of other sponsors, specifically activities sponsored by industry and foreign governments. Accordingly, each allocation method used to identify and allocate the indirect (F&A) cost pools, as described in Sections A.2 and B.2 through B.9, must contain the full amount of the institution's modified total costs or other appropriate units of measurement used to make the computations. In addition, the final rate distribution base (as defined in subsection 2) for each major function (organized research, instruction, etc., as described in Section A.1 functions of an institution) must contain all the programs or activities which utilize the indirect (F&A) costs allocated to that major function. At the time an indirect (F&A) cost proposal is submitted to a cognizant agency for indirect costs, each institution must describe the process it uses to ensure that Federal funds are not used to subsidize industry and foreign government funded programs.

## 2. The Distribution Basis

Indirect (F&A) costs must be distributed to applicable Federal awards and other benefitting activities within each major function (see section A.1) on the basis of modified total direct costs (MTDC), consisting of all salaries and wages, fringe benefits, materials and supplies, services, travel, and up to the first \$25,000 of each subaward (regardless of the period covered by the subaward). MTDC is defined in § 200.1. For this purpose, an indirect (F&A) cost rate should be determined for each of the separate indirect (F&A) cost pools developed pursuant to subsection 1. The rate in each case should be stated as the percentage which the amount of the particular indirect (F&A) cost pool is of the modified total direct costs identified with such pool.

## 3. Negotiated Lump Sum for Indirect (F&A) Costs

A negotiated fixed amount in lieu of indirect (F&A) costs may be appropriate for self-contained, off-campus, or primarily subcontracted activities where the benefits derived from an institution's indirect (F&A) services cannot be readily determined. Such negotiated indirect (F&A) costs will be treated as an offset before allocation to instruction, organized research, other sponsored activities, and other institutional activities. The base on which such remaining expenses are allocated should be appropriately adjusted.

## 4. Predetermined Rates for Indirect (F&A) Costs

Public Law 87-638 (76 Stat. 437) as amended (41 U.S.C. 4708) authorizes the use of predetermined rates in determining the "indirect costs" (indirect (F&A) costs) applicable under research agreements with educational institutions. The stated objectives of the law are to simplify the administration of cost-type research and development contracts (including grants) with educational institutions, to facilitate the preparation of their budgets, and to permit more expeditious closeout of such contracts when the work is completed. In view of the potential advantages offered by this procedure, negotiation of predetermined rates for indirect (F&A) costs for a period of two to four years should be the norm in those situations where the cost experience and other pertinent facts available are deemed sufficient to enable the parties involved to reach an informed judgment as to the probable level of indirect (F&A) costs during the ensuing accounting periods.

## 5. Negotiated Fixed Rates and Carry-Forward Provisions

When a fixed rate is negotiated in advance for a fiscal year (or other time period), the over- or under-recovery for that year may be included as an adjustment to the indirect (F&A) cost for the next rate negotiation. When the rate is negotiated before the carry-forward adjustment is determined, the carry-forward amount may be applied to the next subsequent rate negotiation. When such adjustments are to be made, each fixed rate negotiated in advance for a given period will be computed by applying the expected indirect (F&A) costs allocable to Federal awards for the forecast period plus or minus the carry-forward adjustment (over- or under-recovery) from the prior period, to the forecast distribution base. Unrecovered amounts under lump-sum agreements or cost-sharing provisions of prior years must not be carried forward for consideration in the new rate negotiation. There must, however, be an advance understanding in each case between the institution and the cognizant agency for indirect costs as to whether these differences will be considered in the rate negotiation rather than making the determination after the differences are known. Further, institutions electing to use this carry-forward provision may not subsequently change without prior approval of the cognizant

agency for indirect costs. In the event that an institution returns to a post-determined rate, any over- or under-recovery during the period in which negotiated fixed rates and carry-forward provisions were followed will be included in the subsequent post-determined rates. Where multiple rates are used, the same procedure will be applicable for determining each rate.

## 6. Provisional and Final Rates for Indirect (F&A) Costs

Where the cognizant agency for indirect costs determines that cost experience and other pertinent facts do not justify the use of predetermined rates, or a fixed rate with a carry-forward, or if the parties cannot agree on an equitable rate, a provisional rate must be established. To prevent substantial overpayment or underpayment, the provisional rate may be adjusted by the cognizant agency for indirect costs during the institution's fiscal year. Predetermined or fixed rates may replace provisional rates at any time prior to the close of the institution's fiscal year. If a provisional rate is not replaced by a predetermined or fixed rate prior to the end of the institution's fiscal year, a final rate will be established and upward or downward adjustments will be made based on the actual allowable costs incurred for the period involved.

## 7. Fixed Rates for the Life of the Sponsored Agreement

a. Except as provided in paragraph (c)(1) of § 200.414, Federal agencies must use the negotiated rates in effect at the time of the initial award throughout the life of the Federal award. Award levels for Federal awards may not be adjusted in future years as a result of changes in negotiated rates. "Negotiated rates" per the rate agreement include final, fixed, and predetermined rates and exclude provisional rates. "Life" for the purpose of this subsection means each competitive segment of a project. A competitive segment is a period of years approved by the Federal awarding agency at the time of the Federal award. If negotiated rate agreements do not extend through the life of the Federal award at the time of the initial award, then the negotiated rate for the last year of the Federal award must be extended through the end of the life of the Federal award.

b. Except as provided in § 200.414, when an educational institution does not have a negotiated rate with the Federal Government at the time of an award (because the educational institution is a new recipient or the parties cannot reach agreement on a rate), the provisional rate used at the time of the award must be adjusted once a rate is negotiated and approved by the cognizant agency for indirect costs.

## 8. Limitation on Reimbursement of Administrative Costs

a. Notwithstanding the provisions of subsection C.1.a, the administrative costs charged to Federal awards awarded or amended (including continuation and renewal awards) with effective dates beginning on or after the start of the institution's first fiscal year which begins on or after October 1, 1991, must be limited to 26% of modified total direct costs (as defined in subsection 2) for the total of General Administration and General Expenses, Departmental Administration, Sponsored Projects Administration, and Student Administration and Services (including their allocable share of depreciation, interest costs, operation and maintenance expenses, and fringe benefits costs, as provided by Section B, and all other types of expenditures not listed specifically under one of the subcategories of facilities in Section B.

b. Institutions should not change their accounting or cost allocation methods if the effect is to change the charging of a particular type of cost from F&A to direct, or to reclassify costs, or increase allocations from the administrative pools identified in paragraph B.1 of this Appendix to the other F&A cost pools or fringe benefits. Cognizant agencies for indirect cost are authorized to allow changes where an institution's charging practices are at variance with acceptable practices followed by a substantial majority of other institutions.

## 9. Alternative Method for Administrative Costs

a. Notwithstanding the provisions of subsection C.1.a, an institution may elect to claim a fixed allowance for the "Administration" portion of indirect (F&A) costs. The allowance could be either 24% of modified total direct costs or a percentage equal to 95% of the most recently negotiated fixed or predetermined rate for the cost pools included under "Administration" as defined in Section B.1, whichever is less. Under this alternative, no cost proposal need be prepared for the "Administration" portion of the indirect (F&A) cost rate nor is further identification or documentation of these costs required (see subsection c). Where a negotiated indirect (F&A) cost agreement includes this alternative, an institution must make no further charges for the expenditure categories described in Section B.5, Section B.6, Section B.7, and Section B.9.

b. In negotiations of rates for subsequent periods, an institution that has elected the option of subsection a may continue to exercise it at the same rate without further identification or documentation of costs.

c. If an institution elects to accept a threshold rate as defined in subsection a of this section, it is not required to perform a detailed analysis of its administrative costs. However, in order to compute the facilities components of its indirect (F&A) cost rate, the institution must reconcile its indirect (F&A) cost proposal to its financial statements and make appropriate adjustments and reclassifications to identify the costs of each major function as defined in Section A.1, as well as to identify and allocate the facilities components. Administrative costs that are not identified as such by the institution's accounting system (such as those incurred in academic departments) will be classified as instructional costs for purposes of reconciling indirect (F&A) cost proposals to financial statements and allocating facilities costs.

## 10. Individual Rate Components

In order to provide mutually agreed-upon information for management purposes, each indirect (F&A) cost rate negotiation or determination must include development of a rate for each indirect (F&A) cost pool as well as the overall indirect (F&A) cost rate.

## 11. Negotiation and Approval of Indirect (F&A) Rate

a. Cognizant agency for indirect costs is defined in Subpart A.

- (1) Cost negotiation cognizance is assigned to the Department of Health and Human Services (HHS) or the Department of Defense's Office of Naval Research (DOD), normally depending on which of the two agencies (HHS or DOD) provides more funds directly to the educational institution for the most recent three years. Information on funding must be derived from relevant data gathered by the National Science Foundation. In cases where neither HHS nor DOD provides Federal funding directly to an educational institution, the cognizant agency for indirect costs assignment must default to HHS. Notwithstanding the method for cognizance determination described in this section, other arrangements for cognizance of a particular educational institution may also be based in part on the types of research performed at the educational institution and must be decided based on mutual agreement between HHS and DOD. Where a non-Federal entity only receives funds as a subrecipient, see § 200.332.
- (2) After cognizance is established, it must continue for a five-year period.

b. Acceptance of rates. See § 200.414.

c. Correcting deficiencies. The cognizant agency for indirect costs must negotiate changes needed to correct systems deficiencies relating to accountability for Federal awards. Cognizant agencies for indirect costs must address the concerns of other affected agencies, as appropriate, and must negotiate special rates for Federal agencies that are required to limit recovery of indirect costs by statute.

d. Resolving questioned costs. The cognizant agency for indirect costs must conduct any necessary negotiations with an educational institution regarding amounts questioned by audit that are due the Federal Government related to costs covered by a negotiated agreement.

e. Reimbursement. Reimbursement to cognizant agencies for indirect costs for work performed under this Part may be made by reimbursement billing under the Economy Act, 31 U.S.C. 1535.

f. Procedure for establishing facilities and administrative rates must be established by one of the following methods:

- (1) Formal negotiation. The cognizant agency for indirect costs is responsible for negotiating and approving rates for an educational institution on behalf of all Federal agencies. Federal awarding agencies that do not have cognizance for indirect costs must notify the cognizant agency for indirect costs of specific concerns (i.e., a need to establish special cost rates) which could affect the negotiation process. The cognizant agency for indirect costs must address the concerns of all interested agencies, as appropriate. A pre-negotiation conference may be scheduled among all interested agencies, if necessary. The cognizant agency for indirect costs must then arrange a negotiation conference with the educational institution.
- (2) Other than formal negotiation. The cognizant agency for indirect costs and educational institution may reach an agreement on rates without a formal negotiation conference; for example, through correspondence or use of the simplified method described in this section D of this Appendix.

g. Formalizing determinations and agreements. The cognizant agency for indirect costs must formalize all determinations or agreements reached with an educational institution and provide copies to other agencies having an interest. Determinations should include a description of any adjustments, the actual amount, both dollar and percentage adjusted, and the reason for making adjustments.

h. Disputes and disagreements. Where the cognizant agency for indirect costs is unable to reach agreement with an educational institution with regard to rates or audit resolution, the appeal system of the cognizant agency for indirect costs must be followed for resolution of the disagreement.

## 12. Standard Format for Submission

For facilities and administrative (indirect (F&A)) rate proposals, educational institutions must use the standard format, shown in section E of this appendix, to submit their indirect (F&A) rate proposal to the cognizant agency for indirect costs. The cognizant agency for indirect costs may, on an institution-by-institution basis, grant exceptions from all or portions of Part II of the standard format requirement. This requirement does not apply to educational institutions that use the simplified method for calculating indirect (F&A) rates, as described in Section D of this Appendix.

As provided in section C.10 of this appendix, each F&A cost rate negotiation or determination must include development of a rate for each F&A cost pool as well as the overall F&A rate.

## D. Simplified Method for Small Institutions

### 1. General

a. Where the total direct cost of work covered by this Part at an institution does not exceed \$10 million in a fiscal year, the simplified procedure described in subsections 2 or 3 may be used in determining allowable indirect (F&A) costs. Under this simplified procedure, the institution's most recent annual financial report and immediately available supporting information must be utilized as a basis for determining the indirect (F&A) cost rate applicable to all Federal awards. The institution may use either the salaries and wages (see subsection 2) or modified total direct costs (see subsection 3) as the distribution basis.

b. The simplified procedure should not be used where it produces results which appear inequitable to the Federal Government or the institution. In any such case, indirect (F&A) costs should be determined through use of the regular procedure.

### 2. Simplified Procedure - Salaries and Wages Base

a. Establish the total amount of salaries and wages paid to all employees of the institution.

b. Establish an indirect (F&A) cost pool consisting of the expenditures (exclusive of capital items and other costs specifically identified as unallowable) which customarily are classified under the following titles or their equivalents:

- (1) General administration and general expenses (exclusive of costs of student administration and services, student activities, student aid, and scholarships).
- (2) Operation and maintenance of physical plant and depreciation (after appropriate adjustment for costs applicable to other institutional activities).
- (3) Library.
- (4) Department administration expenses, which will be computed as 20 percent of the salaries and expenses of deans and heads of departments.

In those cases where expenditures classified under subsection (1) have previously been allocated to other institutional activities, they may be included in the indirect (F&A) cost pool. The total amount of salaries and wages included in the indirect (F&A) cost pool must be separately identified.

c. Establish a salary and wage distribution base, determined by deducting from the total of salaries and wages as established in subsection a from the amount of salaries and wages included under subsection b.

d. Establish the indirect (F&A) cost rate, determined by dividing the amount in the indirect (F&A) cost pool, subsection b, by the amount of the distribution base, subsection c.

e. Apply the indirect (F&A) cost rate to direct salaries and wages for individual agreements to determine the amount of indirect (F&A) costs allocable to such agreements.

### 3. Simplified Procedure - Modified Total Direct Cost Base

a. Establish the total costs incurred by the institution for the base period.

b. Establish an indirect (F&A) cost pool consisting of the expenditures (exclusive of capital items and other costs specifically identified as unallowable) which customarily are classified under the following titles or their equivalents:

- (1) General administration and general expenses (exclusive of costs of student administration and services, student activities, student aid, and scholarships).
- (2) Operation and maintenance of physical plant and depreciation (after appropriate adjustment for costs applicable to other institutional activities).
- (3) Library.
- (4) Department administration expenses, which will be computed as 20 percent of the salaries and expenses of deans and heads of departments. In those cases where expenditures classified under subsection (1) have previously been allocated to other institutional activities, they may be included in the indirect (F&A) cost pool. The modified total direct costs amount included in the indirect (F&A) cost pool must be separately identified.

c. Establish a modified total direct cost distribution base, as defined in Section C.2, The distribution basis, that consists of all institution's direct functions.

d. Establish the indirect (F&A) cost rate, determined by dividing the amount in the indirect (F&A) cost pool, subsection b, by the amount of the distribution base, subsection c.

e. Apply the indirect (F&A) cost rate to the modified total direct costs for individual agreements to determine the amount of indirect (F&A) costs allocable to such agreements.

## E. Documentation Requirements

The standard format for documentation requirements for indirect (indirect (F&A)) rate proposals for claiming costs under the regular method is available on the OMB website.

## F. Certification

### 1. Certification of Charges

To assure that expenditures for Federal awards are proper and in accordance with the agreement documents and approved project budgets, the annual and/or final fiscal reports or vouchers requesting payment under the agreements will include a certification, signed by an authorized official of the university, which reads "By signing this report, I certify to the best of my knowledge and belief that the report is true, complete, and accurate, and the expenditures, disbursements and cash receipts are for the purposes and intent set forth in the award documents. I am aware that any false, fictitious, or fraudulent information, or the omission of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims or otherwise. (U.S. Code, Title 18, Section 1001 and Title 31, Sections 3729-3733 and 3801-3812)".

### 2. Certification of Indirect (F&A) Costs

a. *Policy.* Cognizant agencies must not accept a proposed indirect cost rate unless such costs have been certified by the educational institution using the Certificate of indirect (F&A) Costs set forth in subsection F.2.c



b. The certificate must be signed on behalf of the institution by the chief financial officer or an individual designated by an individual at a level no lower than vice president or chief financial officer.

An indirect (F&A) cost rate is not binding upon the Federal Government if the most recent required proposal from the institution has not been certified. Where it is necessary to establish indirect (F&A) cost rates, and the institution has not submitted a certified proposal for establishing such rates in accordance with the requirements of this section, the Federal Government must unilaterally establish such rates. Such rates may be based upon audited historical data or such other data that have been furnished to the cognizant agency for indirect costs and for which it can be demonstrated that all unallowable costs have been excluded. When indirect (F&A) cost rates are unilaterally established by the Federal Government because of failure of the institution to submit a certified proposal for establishing such rates in accordance with this section, the rates established will be set at a level low enough to ensure that potentially unallowable costs will not be reimbursed.

c. *Certificate*. The certificate required by this section must be in the following form:

### **Certificate of Indirect (F&A) Costs**

This is to certify that to the best of my knowledge and belief:

- (1) I have reviewed the indirect (F&A) cost proposal submitted herewith;
- (2) All costs included in this proposal [identify date] to establish billing or final indirect (F&A) costs rate for [identify period covered by rate] are allowable in accordance with the requirements of the Federal agreement(s) to which they apply and with the cost principles applicable to those agreements.
- (3) This proposal does not include any costs which are unallowable under subpart E of this part such as (without limitation): Public relations costs, contributions and donations, entertainment costs, fines and penalties, lobbying costs, and defense of fraud proceedings; and
- (4) All costs included in this proposal are properly allocable to Federal agreements on the basis of a beneficial or causal relationship between the expenses incurred and the agreements to which they are allocated in accordance with applicable requirements.

I declare that the foregoing is true and correct.

Institution of Higher Education:

Signature: \_\_\_\_\_

Name of Official: \_\_\_\_\_

Title: \_\_\_\_\_

Date of Execution: \_\_\_\_\_

[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75888, Dec. 19, 2014; 80 FR 54409, Sept. 10, 2015; 85 FR 49577, Aug. 13, 2020]

## **Appendix IV to Part 200 - Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Nonprofit Organizations**

### **A. General**

1. Indirect costs are those that have been incurred for common or joint objectives and cannot be readily identified with a particular final cost objective. Direct cost of minor amounts may be treated as indirect costs under the conditions described in § 200.413(d). After direct costs have been determined and assigned directly to awards or other work as appropriate, indirect costs are those remaining to be allocated to benefitting cost objectives. A cost may not be allocated to a Federal award as an indirect cost if any other cost incurred for the same purpose, in like circumstances, has been assigned to a Federal award as a direct cost.

2. "Major nonprofit organizations" are defined in paragraph (a) of § 200.414. See indirect cost rate reporting requirements in sections B.2.e and B.3.g of this Appendix.

## B. Allocation of Indirect Costs and Determination of Indirect Cost Rates

### 1. General

- a. If a nonprofit organization has only one major function, or where all its major functions benefit from its indirect costs to approximately the same degree, the allocation of indirect costs and the computation of an indirect cost rate may be accomplished through simplified allocation procedures, as described in section B.2 of this Appendix.
- b. If an organization has several major functions which benefit from its indirect costs in varying degrees, allocation of indirect costs may require the accumulation of such costs into separate cost groupings which then are allocated individually to benefitting functions by means of a base which best measures the relative degree of benefit. The indirect costs allocated to each function are then distributed to individual Federal awards and other activities included in that function by means of an indirect cost rate(s).
- c. The determination of what constitutes an organization's major functions will depend on its purpose in being; the types of services it renders to the public, its clients, and its members; and the amount of effort it devotes to such activities as fundraising, public information and membership activities.
- d. Specific methods for allocating indirect costs and computing indirect cost rates along with the conditions under which each method should be used are described in section B.2 through B.5 of this Appendix.
- e. The base period for the allocation of indirect costs is the period in which such costs are incurred and accumulated for allocation to work performed in that period. The base period normally should coincide with the organization's fiscal year but, in any event, must be so selected as to avoid inequities in the allocation of the costs.

### 2. Simplified Allocation Method

- a. Where an organization's major functions benefit from its indirect costs to approximately the same degree, the allocation of indirect costs may be accomplished by (i) separating the organization's total costs for the base period as either direct or indirect, and (ii) dividing the total allowable indirect costs (net of applicable credits) by an equitable distribution base. The result of this process is an indirect cost rate which is used to distribute indirect costs to individual Federal awards. The rate should be expressed as the percentage which the total amount of allowable indirect costs bears to the base selected. This method should also be used where an organization has only one major function encompassing a number of individual projects or activities, and may be used where the level of Federal awards to an organization is relatively small.
- b. Both the direct costs and the indirect costs must exclude capital expenditures and unallowable costs. However, unallowable costs which represent activities must be included in the direct costs under the conditions described in § 200.413(e).
- c. The distribution base may be total direct costs (excluding capital expenditures and other distorting items, such as subawards for \$25,000 or more), direct salaries and wages, or other base which results in an equitable distribution. The distribution base must exclude participant support costs as defined in § 200.1.
- d. Except where a special rate(s) is required in accordance with section B.5 of this Appendix, the indirect cost rate developed under the above principles is applicable to all Federal awards of the organization. If a special rate(s) is required, appropriate modifications must be made in order to develop the special rate(s).
- e. For an organization that receives more than \$10 million in direct Federal funding in a fiscal year, a breakout of the indirect cost component into two broad categories, Facilities and Administration as defined in paragraph (a) of § 200.414, is required. The rate in each case must be stated as the percentage which the amount of the particular indirect cost category (*i.e.*, Facilities or Administration) is of the distribution base identified with that category.

### 3. Multiple Allocation Base Method

- a. General. Where an organization's indirect costs benefit its major functions in varying degrees, indirect costs must be accumulated into separate cost groupings, as described in subparagraph b. Each grouping must then be allocated individually to benefitting functions by means of a base which best measures the relative benefits. The default allocation bases by cost pool are described in section B.3.c of this Appendix.

b. Identification of indirect costs. Cost groupings must be established so as to permit the allocation of each grouping on the basis of benefits provided to the major functions. Each grouping must constitute a pool of expenses that are of like character in terms of functions they benefit and in terms of the allocation base which best measures the relative benefits provided to each function. The groupings are classified within the two broad categories: "Facilities" and "Administration," as described in section A.3 of this Appendix. The indirect cost pools are defined as follows:

- (1) Depreciation. The expenses under this heading are the portion of the costs of the organization's buildings, capital improvements to land and buildings, and equipment which are computed in accordance with § 200.436.
- (2) Interest. Interest on debt associated with certain buildings, equipment and capital improvements are computed in accordance with § 200.449.
- (3) Operation and maintenance expenses. The expenses under this heading are those that have been incurred for the administration, operation, maintenance, preservation, and protection of the organization's physical plant. They include expenses normally incurred for such items as: janitorial and utility services; repairs and ordinary or normal alterations of buildings, furniture and equipment; care of grounds; maintenance and operation of buildings and other plant facilities; security; earthquake and disaster preparedness; environmental safety; hazardous waste disposal; property, liability and other insurance relating to property; space and capital leasing; facility planning and management; and central receiving. The operation and maintenance expenses category must also include its allocable share of fringe benefit costs, depreciation, and interest costs.
- (4) General administration and general expenses. The expenses under this heading are those that have been incurred for the overall general executive and administrative offices of the organization and other expenses of a general nature which do not relate solely to any major function of the organization. This category must also include its allocable share of fringe benefit costs, operation and maintenance expense, depreciation, and interest costs. Examples of this category include central offices, such as the director's office, the office of finance, business services, budget and planning, personnel, safety and risk management, general counsel, management information systems, and library costs.

In developing this cost pool, special care should be exercised to ensure that costs incurred for the same purpose in like circumstances are treated consistently as either direct or indirect costs. For example, salaries of technical staff, project supplies, project publication, telephone toll charges, computer costs, travel costs, and specialized services costs must be treated as direct costs wherever identifiable to a particular program. The salaries and wages of administrative and pooled clerical staff should normally be treated as indirect costs. Direct charging of these costs may be appropriate as described in § 200.413. Items such as office supplies, postage, local telephone costs, periodicals and memberships should normally be treated as indirect costs.

c. Allocation bases. Actual conditions must be taken into account in selecting the base to be used in allocating the expenses in each grouping to benefitting functions. The essential consideration in selecting a method or a base is that it is the one best suited for assigning the pool of costs to cost objectives in accordance with benefits derived; a traceable cause and effect relationship; or logic and reason, where neither the cause nor the effect of the relationship is determinable. When an allocation can be made by assignment of a cost grouping directly to the function benefitting, the allocation must be made in that manner. When the expenses in a cost grouping are more general in nature, the allocation must be made through the use of a selected base which produces results that are equitable to both the Federal Government and the organization. The distribution must be made in accordance with the bases described herein unless it can be demonstrated that the use of a different base would result in a more equitable allocation of the costs, or that a more readily available base would not increase the costs charged to Federal awards. The results of special cost studies (such as an engineering utility study) must not be used to determine and allocate the indirect costs to Federal awards.

- (1) Depreciation. Depreciation expenses must be allocated in the following manner:

(a) Depreciation on buildings used exclusively in the conduct of a single function, and on capital improvements and equipment used in such buildings, must be assigned to that function.

(b) Depreciation on buildings used for more than one function, and on capital improvements and equipment used in such buildings, must be allocated to the individual functions performed in each building on the basis of usable square feet of space, excluding common areas, such as hallways, stairwells, and restrooms.

(c) Depreciation on buildings, capital improvements and equipment related space (e.g., individual rooms, and laboratories) used jointly by more than one function (as determined by the users of the space) must be treated as follows. The cost of each jointly used unit of space must be allocated to the benefitting functions on the basis of:

- (i) the employees and other users on a full-time equivalent (FTE) basis or salaries and wages of those individual functions benefitting from the use of that space; or

- (ii) organization-wide employee FTEs or salaries and wages applicable to the benefitting functions of the organization.

(d) Depreciation on certain capital improvements to land, such as paved parking areas, fences, sidewalks, and the like, not included in the cost of buildings, must be allocated to user categories on a FTE basis and distributed to major functions in proportion to the salaries and wages of all employees applicable to the functions.

- (2) Interest. Interest costs must be allocated in the same manner as the depreciation on the buildings, equipment and capital equipment to which the interest relates.
- (3) Operation and maintenance expenses. Operation and maintenance expenses must be allocated in the same manner as the depreciation.
- (4) General administration and general expenses. General administration and general expenses must be allocated to benefitting functions based on modified total costs (MTC). The MTC is the modified total direct costs (MTDC), as described in § 200.1, plus the allocated indirect cost proportion. The expenses included in this category could be grouped first according to major functions of the organization to which they render services or provide benefits. The aggregate expenses of each group must then be allocated to benefitting functions based on MTC.

d. Order of distribution.

- (1) Indirect cost categories consisting of depreciation, interest, operation and maintenance, and general administration and general expenses must be allocated in that order to the remaining indirect cost categories as well as to the major functions of the organization. Other cost categories should be allocated in the order determined to be most appropriate by the organization. This order of allocation does not apply if cross allocation of costs is made as provided in section B.3.d.2 of this Appendix.
- (2) Normally, an indirect cost category will be considered closed once it has been allocated to other cost objectives, and costs must not be subsequently allocated to it. However, a cross allocation of costs between two or more indirect costs categories could be used if such allocation will result in a more equitable allocation of costs. If a cross allocation is used, an appropriate modification to the composition of the indirect cost categories is required.

e. Application of indirect cost rate or rates. Except where a special indirect cost rate(s) is required in accordance with section B.5 of this Appendix, the separate groupings of indirect costs allocated to each major function must be aggregated and treated as a common pool for that function. The costs in the common pool must then be distributed to individual Federal awards included in that function by use of a single indirect cost rate.

f. Distribution basis. Indirect costs must be distributed to applicable Federal awards and other benefitting activities within each major function on the basis of MTDC (see definition in § 200.1).

g. Individual Rate Components. An indirect cost rate must be determined for each separate indirect cost pool developed. The rate in each case must be stated as the percentage which the amount of the particular indirect cost pool is of the distribution base identified with that pool. Each indirect cost rate negotiation or determination agreement must include development of the rate for each indirect cost pool as well as the overall indirect cost rate. The indirect cost pools must be classified within two broad categories: "Facilities" and "Administration," as described in § 200.414(a).

#### 4. Direct Allocation Method

a. Some nonprofit organizations treat all costs as direct costs except general administration and general expenses. These organizations generally separate their costs into three basic categories: (i) General administration and general expenses, (ii) fundraising, and (iii) other direct functions (including projects performed under Federal awards). Joint costs, such as depreciation, rental costs, operation and maintenance of facilities, telephone expenses, and the like are prorated individually as direct costs to each category and to each Federal award or other activity using a base most appropriate to the particular cost being prorated.

b. This method is acceptable, provided each joint cost is prorated using a base which accurately measures the benefits provided to each Federal award or other activity. The bases must be established in accordance with reasonable criteria and be supported by current data. This method is compatible with the Standards of Accounting and Financial Reporting for Voluntary Health and Welfare Organizations issued jointly by the National Health Council, Inc., the National Assembly of Voluntary Health and Social Welfare Organizations, and the United Way of America.

c. Under this method, indirect costs consist exclusively of general administration and general expenses. In all other respects, the organization's indirect cost rates must be computed in the same manner as that described in section B.2 of this Appendix.

## 5. Special Indirect Cost Rates

In some instances, a single indirect cost rate for all activities of an organization or for each major function of the organization may not be appropriate, since it would not take into account those different factors which may substantially affect the indirect costs applicable to a particular segment of work. For this purpose, a particular segment of work may be that performed under a single Federal award or it may consist of work under a group of Federal awards performed in a common environment. These factors may include the physical location of the work, the level of administrative support required, the nature of the facilities or other resources employed, the scientific disciplines or technical skills involved, the organizational arrangements used, or any combination thereof. When a particular segment of work is performed in an environment which appears to generate a significantly different level of indirect costs, provisions should be made for a separate indirect cost pool applicable to such work. The separate indirect cost pool should be developed during the course of the regular allocation process, and the separate indirect cost rate resulting therefrom should be used, provided it is determined that (i) the rate differs significantly from that which would have been obtained under sections B.2, B.3, and B.4 of this Appendix, and (ii) the volume of work to which the rate would apply is material.

## C. Negotiation and Approval of Indirect Cost Rates

### 1. Definitions

As used in this section, the following terms have the meanings set forth in this section:

a. *Cognizant agency for indirect costs* means the Federal agency responsible for negotiating and approving indirect cost rates for a nonprofit organization on behalf of all Federal agencies.

b. *Predetermined rate* means an indirect cost rate, applicable to a specified current or future period, usually the organization's fiscal year. The rate is based on an estimate of the costs to be incurred during the period. A predetermined rate is not subject to adjustment.

c. *Fixed rate* means an indirect cost rate which has the same characteristics as a predetermined rate, except that the difference between the estimated costs and the actual costs of the period covered by the rate is carried forward as an adjustment to the rate computation of a subsequent period.

d. *Final rate* means an indirect cost rate applicable to a specified past period which is based on the actual costs of the period. A final rate is not subject to adjustment.

e. *Provisional rate or billing rate* means a temporary indirect cost rate applicable to a specified period which is used for funding, interim reimbursement, and reporting indirect costs on Federal awards pending the establishment of a final rate for the period.

f. *Indirect cost proposal* means the documentation prepared by an organization to substantiate its claim for the reimbursement of indirect costs. This proposal provides the basis for the review and negotiation leading to the establishment of an organization's indirect cost rate.

g. *Cost objective* means a function, organizational subdivision, contract, Federal award, or other work unit for which cost data are desired and for which provision is made to accumulate and measure the cost of processes, projects, jobs and capitalized projects.

### 2. Negotiation and Approval of Rates

a. Unless different arrangements are agreed to by the Federal agencies concerned, the Federal agency with the largest dollar value of Federal awards directly funded to an organization will be designated as the cognizant agency for indirect costs for the negotiation and approval of the indirect cost rates and, where necessary, other rates such as fringe benefit and computer charge-out rates. Once an agency is assigned cognizance for a particular nonprofit organization, the assignment will not be changed unless there is a shift in the dollar volume of the Federal awards directly funded to the organization for at least three years. All concerned Federal agencies must be given the opportunity to participate in the negotiation process but, after a rate has been agreed upon, it will be accepted by all Federal agencies. When a Federal agency has reason to believe that special operating

factors affecting its Federal awards necessitate special indirect cost rates in accordance with section B.5 of this Appendix, it will, prior to the time the rates are negotiated, notify the cognizant agency for indirect costs. (See also § 200.414.) If the nonprofit does not receive any funding from any Federal agency, the pass-through entity is responsible for the negotiation of the indirect cost rates in accordance with § 200.332(a)(4).

b. Except as otherwise provided in § 200.414(f), a nonprofit organization which has not previously established an indirect cost rate with a Federal agency must submit its initial indirect cost proposal immediately after the organization is advised that a Federal award will be made and, in no event, later than three months after the effective date of the Federal award.

c. Unless approved by the cognizant agency for indirect costs in accordance with § 200.414(g), organizations that have previously established indirect cost rates must submit a new indirect cost proposal to the cognizant agency for indirect costs within six months after the close of each fiscal year.

d. A predetermined rate may be negotiated for use on Federal awards where there is reasonable assurance, based on past experience and reliable projection of the organization's costs, that the rate is not likely to exceed a rate based on the organization's actual costs.

e. Fixed rates may be negotiated where predetermined rates are not considered appropriate. A fixed rate, however, must not be negotiated if (i) all or a substantial portion of the organization's Federal awards are expected to expire before the carry-forward adjustment can be made; (ii) the mix of Federal and non-Federal work at the organization is too erratic to permit an equitable carry-forward adjustment; or (iii) the organization's operations fluctuate significantly from year to year.

f. Provisional and final rates must be negotiated where neither predetermined nor fixed rates are appropriate. Predetermined or fixed rates may replace provisional rates at any time prior to the close of the organization's fiscal year. If that event does not occur, a final rate will be established and upward or downward adjustments will be made based on the actual allowable costs incurred for the period involved.

g. The results of each negotiation must be formalized in a written agreement between the cognizant agency for indirect costs and the nonprofit organization. The cognizant agency for indirect costs must make available copies of the agreement to all concerned Federal agencies.

h. If a dispute arises in a negotiation of an indirect cost rate between the cognizant agency for indirect costs and the nonprofit organization, the dispute must be resolved in accordance with the appeals procedures of the cognizant agency for indirect costs.

i. To the extent that problems are encountered among the Federal agencies in connection with the negotiation and approval process, OMB will lend assistance as required to resolve such problems in a timely manner.

#### **D. Certification of Indirect (F&A) Costs**

- (1) Required Certification. No proposal to establish indirect (F&A) cost rates must be acceptable unless such costs have been certified by the nonprofit organization using the Certificate of Indirect (F&A) Costs set forth in section j. of this appendix. The certificate must be signed on behalf of the organization by an individual at a level no lower than vice president or chief financial officer for the organization.
- (2) Each indirect cost rate proposal must be accompanied by a certification in the following form:

#### **Certificate of Indirect (F&A) Costs**

This is to certify that to the best of my knowledge and belief:

- (1) I have reviewed the indirect (F&A) cost proposal submitted herewith;
- (2) All costs included in this proposal [identify date] to establish billing or final indirect (F&A) costs rate for [identify period covered by rate] are allowable in accordance with the requirements of the Federal awards to which they apply and with subpart E of this part.
- (3) This proposal does not include any costs which are unallowable under subpart E of this part such as (without limitation): Public relations costs, contributions and donations, entertainment costs, fines and penalties, lobbying costs, and defense of fraud proceedings; and

- (4) All costs included in this proposal are properly allocable to Federal awards on the basis of a beneficial or causal relationship between the expenses incurred and the Federal awards to which they are allocated in accordance with applicable requirements.

I declare that the foregoing is true and correct.

Nonprofit Organization: \_\_\_\_\_

Signature: \_\_\_\_\_

Name of Official: \_\_\_\_\_

Title: \_\_\_\_\_

Date of Execution: \_\_\_\_\_

[78 FR 78608, Dec. 26, 2013, as amended at 80 FR 54410, Sept. 10, 2015; 85 FR 49579, Aug. 13, 2020]

## **Appendix V to Part 200 - State/Local Governmentwide Central Service Cost Allocation Plans**

### **A. General**

1. Most governmental units provide certain services, such as motor pools, computer centers, purchasing, accounting, etc., to operating agencies on a centralized basis. Since federally-supported awards are performed within the individual operating agencies, there needs to be a process whereby these central service costs can be identified and assigned to benefitted activities on a reasonable and consistent basis. The central service cost allocation plan provides that process. All costs and other data used to distribute the costs included in the plan should be supported by formal accounting and other records that will support the propriety of the costs assigned to Federal awards.

2. Guidelines and illustrations of central service cost allocation plans are provided in a brochure published by the Department of Health and Human Services entitled "A Guide for State, Local and Indian Tribal Governments: Cost Principles and Procedures for Developing Cost Allocation Plans and Indirect Cost Rates for Agreements with the Federal Government." A copy of this brochure may be obtained from the HHS Cost Allocation Services or at their website.

### **B. Definitions**

1. *Agency or operating agency* means an organizational unit or sub-division within a governmental unit that is responsible for the performance or administration of Federal awards or activities of the governmental unit.

2. *Allocated central services* means central services that benefit operating agencies but are not billed to the agencies on a fee-for-service or similar basis. These costs are allocated to benefitted agencies on some reasonable basis. Examples of such services might include general accounting, personnel administration, purchasing, etc.

3. *Billed central services* means central services that are billed to benefitted agencies or programs on an individual fee-for-service or similar basis. Typical examples of billed central services include computer services, transportation services, insurance, and fringe benefits.

4. *Cognizant agency for indirect costs* is defined in § 200.1. The determination of cognizant agency for indirect costs for states and local governments is described in section F.1.

5. *Major local government* means local government that receives more than \$100 million in direct Federal awards subject to this Part.

### **C. Scope of the Central Service Cost Allocation Plans**

The central service cost allocation plan will include all central service costs that will be claimed (either as a billed or an allocated cost) under Federal awards and will be documented as described in section E. omitted from the plan will not be reimbursed.

## D. Submission Requirements

1. Each state will submit a plan to the Department of Health and Human Services for each year in which it claims central service costs under Federal awards. The plan should include (a) a projection of the next year's allocated central service cost (based either on actual costs for the most recently completed year or the budget projection for the coming year), and (b) a reconciliation of actual allocated central service costs to the estimated costs used for either the most recently completed year or the year immediately preceding the most recently completed year.
2. Each major local government is also required to submit a plan to its cognizant agency for indirect costs annually.
3. All other local governments claiming central service costs must develop a plan in accordance with the requirements described in this Part and maintain the plan and related supporting documentation for audit. These local governments are not required to submit their plans for Federal approval unless they are specifically requested to do so by the cognizant agency for indirect costs. Where a local government only receives funds as a subrecipient, the pass-through entity will be responsible for monitoring the subrecipient's plan.
4. All central service cost allocation plans will be prepared and, when required, submitted within six months prior to the beginning of each of the governmental unit's fiscal years in which it proposes to claim central service costs. Extensions may be granted by the cognizant agency for indirect costs on a case-by-case basis.

## E. Documentation Requirements for Submitted Plans

The documentation requirements described in this section may be modified, expanded, or reduced by the cognizant agency for indirect costs on a case-by-case basis. For example, the requirements may be reduced for those central services which have little or no impact on Federal awards. Conversely, if a review of a plan indicates that certain additional information is needed, and will likely be needed in future years, it may be routinely requested in future plan submissions. Items marked with an asterisk (\*) should be submitted only once; subsequent plans should merely indicate any changes since the last plan.

### 1. General

All proposed plans must be accompanied by the following: an organization chart sufficiently detailed to show operations including the central service activities of the state/local government whether or not they are shown as benefitting from central service functions; a copy of the Comprehensive Annual Financial Report (or a copy of the Executive Budget if budgeted costs are being proposed) to support the allowable costs of each central service activity included in the plan; and, a certification (see subsection 4.) that the plan was prepared in accordance with this Part, contains only allowable costs, and was prepared in a manner that treated similar costs consistently among the various Federal awards and between Federal and non-Federal awards/activities.

### 2. Allocated Central Services

For each allocated central service\*, the plan must also include the following: a brief description of the service, an identification of the unit rendering the service and the operating agencies receiving the service, the items of expense included in the cost of the service, the method used to distribute the cost of the service to benefitted agencies, and a summary schedule showing the allocation of each service to the specific benefitted agencies. If any self-insurance funds or fringe benefits costs are treated as allocated (rather than billed) central services, documentation discussed in subsections 3.b. and c. must also be included.

### 3. Billed Services

a. *General.* The information described in this section must be provided for all billed central services, including internal service funds, self-insurance funds, and fringe benefit funds.

b. Internal service funds.

- (1) For each internal service fund or similar activity with an operating budget of \$5 million or more, the plan must include: A brief description of each service; a balance sheet for each fund based on individual accounts contained in the governmental unit's accounting system; a revenue/expenses statement, with revenues broken out by source, e.g., regular billings, interest earned, etc.; a listing of all non-operating transfers (as defined by GAAP) into and out of the fund; a



description of the procedures (methodology) used to charge the costs of each service to users, including how billing rates are determined; a schedule of current rates; and, a schedule comparing total revenues (including imputed revenues) generated by the service to the allowable costs of the service, as determined under this part, with an explanation of how variances will be handled.

- (2) Revenues must consist of all revenues generated by the service, including unbilled and uncollected revenues. If some users were not billed for the services (or were not billed at the full rate for that class of users), a schedule showing the full imputed revenues associated with these users must be provided. Expenses must be broken out by object cost categories (e.g., salaries, supplies, etc.).

c. *Self-insurance funds.* For each self-insurance fund, the plan must include: the fund balance sheet; a statement of revenue and expenses including a summary of billings and claims paid by agency; a listing of all non-operating transfers into and out of the fund; the type(s) of risk(s) covered by the fund (e.g., automobile liability, workers' compensation, etc.); an explanation of how the level of fund contributions are determined, including a copy of the current actuarial report (with the actuarial assumptions used) if the contributions are determined on an actuarial basis; and, a description of the procedures used to charge or allocate fund contributions to benefitted activities. Reserve levels in excess of claims (1) submitted and adjudicated but not paid, (2) submitted but not adjudicated, and (3) incurred but not submitted must be identified and explained.

d. *Fringe benefits.* For fringe benefit costs, the plan must include: a listing of fringe benefits provided to covered employees, and the overall annual cost of each type of benefit; current fringe benefit policies; and procedures used to charge or allocate the costs of the benefits to benefitted activities. In addition, for pension and post-retirement health insurance plans, the following information must be provided: the governmental unit's funding policies, e.g., legislative bills, trust agreements, or state-mandated contribution rules, if different from actuarially determined rates; the pension plan's costs accrued for the year; the amount funded, and date(s) of funding; a copy of the current actuarial report (including the actuarial assumptions); the plan trustee's report; and, a schedule from the activity showing the value of the interest cost associated with late funding.

## 4. Required Certification

Each central service cost allocation plan will be accompanied by a certification in the following form:

### CERTIFICATE OF COST ALLOCATION PLAN

This is to certify that I have reviewed the cost allocation plan submitted herewith and to the best of my knowledge and belief:

- (1) All costs included in this proposal [identify date] to establish cost allocations or billings for [identify period covered by plan] are allowable in accordance with the requirements of this Part and the Federal award(s) to which they apply. Unallowable costs have been adjusted for in allocating costs as indicated in the cost allocation plan.
- (2) All costs included in this proposal are properly allocable to Federal awards on the basis of a beneficial or causal relationship between the expenses incurred and the Federal awards to which they are allocated in accordance with applicable requirements. Further, the same costs that have been treated as indirect costs have not been claimed as direct costs. Similar types of costs have been accounted for consistently.

I declare that the foregoing is true and correct.

Governmental Unit: \_\_\_\_\_

Signature: \_\_\_\_\_

Name of Official: \_\_\_\_\_

Title: \_\_\_\_\_

Date of Execution: \_\_\_\_\_

## F. Negotiation and Approval of Central Service Plans

## 1. Federal Cognizant Agency for Indirect Costs Assignments for Cost Negotiation

In general, unless different arrangements are agreed to by the concerned Federal agencies, for central service cost allocation plans, the cognizant agency responsible for review and approval is the Federal agency with the largest dollar value of total Federal awards with a governmental unit. For indirect cost rates and departmental indirect cost allocation plans, the cognizant agency is the Federal agency with the largest dollar value of direct Federal awards with a governmental unit or component, as appropriate. Once designated as the cognizant agency for indirect costs, the Federal agency must remain so for a period of five years. In addition, the following Federal agencies continue to be responsible for the indicated governmental entities:

*Department of Health and Human Services* - Public assistance and state-wide cost allocation plans for all states (including the District of Columbia and Puerto Rico), state and local hospitals, libraries and health districts.

*Department of the Interior* - Indian tribal governments, territorial governments, and state and local park and recreational districts.

*Department of Labor* - State and local labor departments.

*Department of Education* - School districts and state and local education agencies.

*Department of Agriculture* - State and local agriculture departments.

*Department of Transportation* - State and local airport and port authorities and transit districts.

*Department of Commerce* - State and local economic development districts.

*Department of Housing and Urban Development* - State and local housing and development districts.

*Environmental Protection Agency* - State and local water and sewer districts.

## 2. Review

All proposed central service cost allocation plans that are required to be submitted will be reviewed, negotiated, and approved by the cognizant agency for indirect costs on a timely basis. The cognizant agency for indirect costs will review the proposal within six months of receipt of the proposal and either negotiate/approve the proposal or advise the governmental unit of the additional documentation needed to support/evaluate the proposed plan or the changes required to make the proposal acceptable. Once an agreement with the governmental unit has been reached, the agreement will be accepted and used by all Federal agencies, unless prohibited or limited by statute. Where a Federal awarding agency has reason to believe that special operating factors affecting its Federal awards necessitate special consideration, the funding agency will, prior to the time the plans are negotiated, notify the cognizant agency for indirect costs.

## 3. Agreement

The results of each negotiation must be formalized in a written agreement between the cognizant agency for indirect costs and the governmental unit. This agreement will be subject to re-opening if the agreement is subsequently found to violate a statute or the information upon which the plan was negotiated is later found to be materially incomplete or inaccurate. The results of the negotiation must be made available to all Federal agencies for their use.

## 4. Adjustments

Negotiated cost allocation plans based on a proposal later found to have included costs that: (a) are unallowable (i) as specified by law or regulation, (ii) as identified in subpart F, General Provisions for selected Items of Cost of this Part, or (iii) by the terms and conditions of Federal awards, or (b) are unallowable because they are clearly not allocable to Federal awards, must be adjusted, or a refund must be made at the option of the cognizant agency for indirect costs, including earned or imputed interest from the date of transfer and debt interest, if applicable, chargeable in accordance with applicable Federal cognizant agency for indirect costs regulations. Adjustments or cash refunds may include, at the option of the cognizant agency for indirect costs, earned or imputed

interest from the date of expenditure and delinquent debt interest, if applicable, chargeable in accordance with applicable cognizant agency claims collection regulations. These adjustments or refunds are designed to correct the plans and do not constitute a reopening of the negotiation.

## **G. Other Policies**

### **1. Billed Central Service Activities**

Each billed central service activity must separately account for all revenues (including imputed revenues) generated by the service, expenses incurred to furnish the service, and profit/loss.

### **2. Working Capital Reserves**

Internal service funds are dependent upon a reasonable level of working capital reserve to operate from one billing cycle to the next. Charges by an internal service activity to provide for the establishment and maintenance of a reasonable level of working capital reserve, in addition to the full recovery of costs, are allowable. A working capital reserve as part of retained earnings of up to 60 calendar days cash expenses for normal operating purposes is considered reasonable. A working capital reserve exceeding 60 calendar days may be approved by the cognizant agency for indirect costs in exceptional cases.

### **3. Carry-Forward Adjustments of Allocated Central Service Costs**

Allocated central service costs are usually negotiated and approved for a future fiscal year on a "fixed with carry-forward" basis. Under this procedure, the fixed amounts for the future year covered by agreement are not subject to adjustment for that year. However, when the actual costs of the year involved become known, the differences between the fixed amounts previously approved and the actual costs will be carried forward and used as an adjustment to the fixed amounts established for a later year. This "carry-forward" procedure applies to all central services whose costs were fixed in the approved plan. However, a carry-forward adjustment is not permitted, for a central service activity that was not included in the approved plan, or for unallowable costs that must be reimbursed immediately.

### **4. Adjustments of Billed Central Services**

Billing rates used to charge Federal awards must be based on the estimated costs of providing the services, including an estimate of the allocable central service costs. A comparison of the revenue generated by each billed service (including total revenues whether or not billed or collected) to the actual allowable costs of the service will be made at least annually, and an adjustment will be made for the difference between the revenue and the allowable costs. These adjustments will be made through one of the following adjustment methods: (a) a cash refund including earned or imputed interest from the date of transfer and debt interest, if applicable, chargeable in accordance with applicable Federal cognizant agency for indirect costs regulations to the Federal Government for the Federal share of the adjustment, (b) credits to the amounts charged to the individual programs, (c) adjustments to future billing rates, or (d) adjustments to allocated central service costs. Adjustments to allocated central services will not be permitted where the total amount of the adjustment for a particular service (Federal share and non-Federal) share exceeds \$500,000. Adjustment methods may include, at the option of the cognizant agency, earned or imputed interest from the date of expenditure and delinquent debt interest, if applicable, chargeable in accordance with applicable cognizant agency claims collection regulations.

### **5. Records Retention**

All central service cost allocation plans and related documentation used as a basis for claiming costs under Federal awards must be retained for audit in accordance with the records retention requirements contained in subpart D of this part.

### **6. Appeals**

If a dispute arises in the negotiation of a plan between the cognizant agency for indirect costs and the governmental unit, the dispute must be resolved in accordance with the appeals procedures of the cognizant agency for indirect costs.

## 7. OMB Assistance

To the extent that problems are encountered among the Federal agencies or governmental units in connection with the negotiation and approval process, OMB will lend assistance, as required, to resolve such problems in a timely manner.

[78 FR 78608, Dec. 26, 2013, as amended at 80 FR 54410, Sept. 10, 2015; 85 FR 49581, Aug. 13, 2020]

### Appendix VI to Part 200 - Public Assistance Cost Allocation Plans

#### A. General

Federally-financed programs administered by state public assistance agencies are funded predominately by the Department of Health and Human Services (HHS). In support of its stewardship requirements, HHS has published requirements for the development, documentation, submission, negotiation, and approval of public assistance cost allocation plans in Subpart E of 45 CFR Part 95. All administrative costs (direct and indirect) are normally charged to Federal awards by implementing the public assistance cost allocation plan. This Appendix extends these requirements to all Federal awarding agencies whose programs are administered by a state public assistance agency. Major federally-financed programs typically administered by state public assistance agencies include: Temporary Aid to Needy Families (TANF), Medicaid, Food Stamps, Child Support Enforcement, Adoption Assistance and Foster Care, and Social Services Block Grant.

#### B. Definitions

1. *State public assistance agency* means a state agency administering or supervising the administration of one or more public assistance programs operated by the state as identified in Subpart E of 45 CFR Part 95. For the purpose of this Appendix, these programs include all programs administered by the state public assistance agency.
2. *State public assistance agency costs* means all costs incurred by, or allocable to, the state public assistance agency, except expenditures for financial assistance, medical contractor payments, food stamps, and payments for services and goods provided directly to program recipients.

#### C. Policy

State public assistance agencies will develop, document and implement, and the Federal Government will review, negotiate, and approve, public assistance cost allocation plans in accordance with Subpart E of 45 CFR Part 95. The plan will include all programs administered by the state public assistance agency. Where a letter of approval or disapproval is transmitted to a state public assistance agency in accordance with Subpart E, the letter will apply to all Federal agencies and programs. The remaining sections of this Appendix (except for the requirement for certification) summarize the provisions of Subpart E of 45 CFR Part 95.

#### D. Submission, Documentation, and Approval of Public Assistance Cost Allocation Plans

1. State public assistance agencies are required to promptly submit amendments to the cost allocation plan to HHS for review and approval.
2. Under the coordination process outlined in section E, affected Federal agencies will review all new plans and plan amendments and provide comments, as appropriate, to HHS. The effective date of the plan or plan amendment will be the first day of the calendar quarter following the event that required the amendment, unless another date is specifically approved by HHS. HHS, as the cognizant agency for indirect costs acting on behalf of all affected Federal agencies, will, as necessary, conduct negotiations with the state public assistance agency and will inform the state agency of the action taken on the plan or plan amendment.

#### E. Review of Implementation of Approved Plans

1. Since public assistance cost allocation plans are of a narrative nature, the review during the plan approval process consists of evaluating the appropriateness of the proposed groupings of costs (cost centers) and the related allocation bases. As such, the Federal Government needs some assurance that the cost allocation plan has been implemented as approved. This is

accomplished by reviews by the Federal awarding agencies, single audits, or audits conducted by the cognizant agency for indirect costs.

2. Where inappropriate charges affecting more than one Federal awarding agency are identified, the cognizant HHS cost negotiation office will be advised and will take the lead in resolving the issue(s) as provided for in Subpart E of 45 CFR Part 95.
3. If a dispute arises in the negotiation of a plan or from a disallowance involving two or more Federal awarding agencies, the dispute must be resolved in accordance with the appeals procedures set out in 45 CFR Part 16. Disputes involving only one Federal awarding agency will be resolved in accordance with the Federal awarding agency's appeal process.
4. To the extent that problems are encountered among the Federal awarding agencies or governmental units in connection with the negotiation and approval process, the Office of Management and Budget will lend assistance, as required, to resolve such problems in a timely manner.

## F. Unallowable Costs

Claims developed under approved cost allocation plans will be based on allowable costs as identified in this Part. Where unallowable costs have been claimed and reimbursed, they will be refunded to the program that reimbursed the unallowable cost using one of the following methods: (a) a cash refund, (b) offset to a subsequent claim, or (c) credits to the amounts charged to individual Federal awards. Cash refunds, offsets, and credits may include at the option of the cognizant agency for indirect cost, earned or imputed interest from the date of expenditure and delinquent debt interest, if applicable, chargeable in accordance with applicable cognizant agency for indirect cost claims collection regulations.

[78 FR 78608, Dec. 26, 2013, as amended at 85 FR 49581, Aug. 13, 2020]

## Appendix VII to Part 200 - States and Local Government and Indian Tribe Indirect Cost Proposals

### A. General

1. Indirect costs are those that have been incurred for common or joint purposes. These costs benefit more than one cost objective and cannot be readily identified with a particular final cost objective without effort disproportionate to the results achieved. After direct costs have been determined and assigned directly to Federal awards and other activities as appropriate, indirect costs are those remaining to be allocated to benefitted cost objectives. A cost may not be allocated to a Federal award as an indirect cost if any other cost incurred for the same purpose, in like circumstances, has been assigned to a Federal award as a direct cost.
2. Indirect costs include (a) the indirect costs originating in each department or agency of the governmental unit carrying out Federal awards and (b) the costs of central governmental services distributed through the central service cost allocation plan (as described in Appendix V to this part) and not otherwise treated as direct costs.
3. Indirect costs are normally charged to Federal awards by the use of an indirect cost rate. A separate indirect cost rate(s) is usually necessary for each department or agency of the governmental unit claiming indirect costs under Federal awards. Guidelines and illustrations of indirect cost proposals are provided in a brochure published by the Department of Health and Human Services entitled "A Guide for States and Local Government Agencies: Cost Principles and Procedures for Establishing Cost Allocation Plans and Indirect Cost Rates for Grants and Contracts with the Federal Government." A copy of this brochure may be obtained from HHS Cost Allocation Services or at their website.
4. Because of the diverse characteristics and accounting practices of governmental units, the types of costs which may be classified as indirect costs cannot be specified in all situations. However, typical examples of indirect costs may include certain state/local-wide central service costs, general administration of the non-Federal entity accounting and personnel services performed within the non-Federal entity, depreciation on buildings and equipment, the costs of operating and maintaining facilities.
5. This Appendix does not apply to state public assistance agencies. These agencies should refer instead to Appendix VI to this part.

### B. Definitions

1. *Base* means the accumulated direct costs (normally either total direct salaries and wages or total direct costs exclusive of any extraordinary or distorting expenditures) used to distribute indirect costs to individual Federal awards. The direct cost base selected should result in each Federal award bearing a fair share of the indirect costs in reasonable relation to the benefits received from the costs.

2. *Base period* for the allocation of indirect costs is the period in which such costs are incurred and accumulated for allocation to activities performed in that period. The base period normally should coincide with the governmental unit's fiscal year, but in any event, must be so selected as to avoid inequities in the allocation of costs.

3. *Cognizant agency for indirect costs* means the Federal agency responsible for reviewing and approving the governmental unit's indirect cost rate(s) on the behalf of the Federal Government. The cognizant agency for indirect costs assignment is described in Appendix V, section F.

4. *Final rate* means an indirect cost rate applicable to a specified past period which is based on the actual allowable costs of the period. A final audited rate is not subject to adjustment.

5. *Fixed rate* means an indirect cost rate which has the same characteristics as a predetermined rate, except that the difference between the estimated costs and the actual, allowable costs of the period covered by the rate is carried forward as an adjustment to the rate computation of a subsequent period.

6. *Indirect cost pool* is the accumulated costs that jointly benefit two or more programs or other cost objectives.

7. *Indirect cost rate* is a device for determining in a reasonable manner the proportion of indirect costs each program should bear. It is the ratio (expressed as a percentage) of the indirect costs to a direct cost base.

8. *Indirect cost rate proposal* means the documentation prepared by a governmental unit or subdivision thereof to substantiate its request for the establishment of an indirect cost rate.

9. *Predetermined rate* means an indirect cost rate, applicable to a specified current or future period, usually the governmental unit's fiscal year. This rate is based on an estimate of the costs to be incurred during the period. Except under very unusual circumstances, a predetermined rate is not subject to adjustment. (Because of legal constraints, predetermined rates are not permitted for Federal contracts; they may, however, be used for grants or cooperative agreements.) Predetermined rates may not be used by governmental units that have not submitted and negotiated the rate with the cognizant agency for indirect costs. In view of the potential advantages offered by this procedure, negotiation of predetermined rates for indirect costs for a period of two to four years should be the norm in those situations where the cost experience and other pertinent facts available are deemed sufficient to enable the parties involved to reach an informed judgment as to the probable level of indirect costs during the ensuing accounting periods.

10. *Provisional rate* means a temporary indirect cost rate applicable to a specified period which is used for funding, interim reimbursement, and reporting indirect costs on Federal awards pending the establishment of a "final" rate for that period.

## C. Allocation of Indirect Costs and Determination of Indirect Cost Rates

### 1. General

a. Where a governmental unit's department or agency has only one major function, or where all its major functions benefit from the indirect costs to approximately the same degree, the allocation of indirect costs and the computation of an indirect cost rate may be accomplished through simplified allocation procedures as described in subsection 2.

b. Where a governmental unit's department or agency has several major functions which benefit from its indirect costs in varying degrees, the allocation of indirect costs may require the accumulation of such costs into separate cost groupings which then are allocated individually to benefitted functions by means of a base which best measures the relative degree of benefit. The indirect costs allocated to each function are then distributed to individual Federal awards and other activities included in that function by means of an indirect cost rate(s).

c. Specific methods for allocating indirect costs and computing indirect cost rates along with the conditions under which each method should be used are described in subsections 2, 3 and 4.

## 2. Simplified Method

- a. Where a non-Federal entity's major functions benefit from its indirect costs to approximately the same degree, the allocation of indirect costs may be accomplished by (1) classifying the non-Federal entity's total costs for the base period as either direct or indirect, and (2) dividing the total allowable indirect costs (net of applicable credits) by an equitable distribution base. The result of this process is an indirect cost rate which is used to distribute indirect costs to individual Federal awards. The rate should be expressed as the percentage which the total amount of allowable indirect costs bears to the base selected. This method should also be used where a governmental unit's department or agency has only one major function encompassing a number of individual projects or activities, and may be used where the level of Federal awards to that department or agency is relatively small.
- b. Both the direct costs and the indirect costs must exclude capital expenditures and unallowable costs. However, unallowable costs must be included in the direct costs if they represent activities to which indirect costs are properly allocable.
- c. The distribution base may be (1) total direct costs (excluding capital expenditures and other distorting items, such as pass-through funds, subcontracts in excess of \$25,000, participant support costs, etc.), (2) direct salaries and wages, or (3) another base which results in an equitable distribution.

## 3. Multiple Allocation Base Method

- a. Where a non-Federal entity's indirect costs benefit its major functions in varying degrees, such costs must be accumulated into separate cost groupings. Each grouping must then be allocated individually to benefitted functions by means of a base which best measures the relative benefits.
- b. The cost groupings should be established so as to permit the allocation of each grouping on the basis of benefits provided to the major functions. Each grouping should constitute a pool of expenses that are of like character in terms of the functions they benefit and in terms of the allocation base which best measures the relative benefits provided to each function. The number of separate groupings should be held within practical limits, taking into consideration the materiality of the amounts involved and the degree of precision needed.
- c. Actual conditions must be taken into account in selecting the base to be used in allocating the expenses in each grouping to benefitted functions. When an allocation can be made by assignment of a cost grouping directly to the function benefitted, the allocation must be made in that manner. When the expenses in a grouping are more general in nature, the allocation should be made through the use of a selected base which produces results that are equitable to both the Federal Government and the governmental unit. In general, any cost element or related factor associated with the governmental unit's activities is potentially adaptable for use as an allocation base provided that: (1) it can readily be expressed in terms of dollars or other quantitative measures (total direct costs, direct salaries and wages, staff hours applied, square feet used, hours of usage, number of documents processed, population served, and the like), and (2) it is common to the benefitted functions during the base period.
- d. Except where a special indirect cost rate(s) is required in accordance with paragraph (C)(4) of this Appendix, the separate groupings of indirect costs allocated to each major function must be aggregated and treated as a common pool for that function. The costs in the common pool must then be distributed to individual Federal awards included in that function by use of a single indirect cost rate.
- e. The distribution base used in computing the indirect cost rate for each function may be (1) total direct costs (excluding capital expenditures and other distorting items such as pass-through funds, subawards in excess of \$25,000, participant support costs, etc.), (2) direct salaries and wages, or (3) another base which results in an equitable distribution. An indirect cost rate should be developed for each separate indirect cost pool developed. The rate in each case should be stated as the percentage relationship between the particular indirect cost pool and the distribution base identified with that pool.

## 4. Special Indirect Cost Rates

- a. In some instances, a single indirect cost rate for all activities of a non-Federal entity or for each major function of the agency may not be appropriate. It may not take into account those different factors which may substantially affect the indirect costs applicable to a particular program or group of programs. The factors may include the physical location of the work, the level of administrative support required, the nature of the facilities or other resources employed, the organizational arrangements used, or any combination thereof. When a particular Federal award is carried out in an environment which appears to generate a significantly different level of indirect costs, provisions should be made for a separate indirect cost pool applicable to that Federal award. The separate indirect cost pool should be developed during the course of the regular allocation process, and the separate

indirect cost rate resulting therefrom should be used, provided that: (1) The rate differs significantly from the rate which would have been developed under paragraphs (C)(2) and (C)(3) of this Appendix, and (2) the Federal award to which the rate would apply is material in amount.

b. Where Federal statutes restrict the reimbursement of certain indirect costs, it may be necessary to develop a special rate for the affected Federal award. Where a "restricted rate" is required, the same procedure for developing a non-restricted rate will be used except for the additional step of the elimination from the indirect cost pool those costs for which the law prohibits reimbursement.

## **D. Submission and Documentation of Proposals**

### **1. Submission of Indirect Cost Rate Proposals**

a. All departments or agencies of the governmental unit desiring to claim indirect costs under Federal awards must prepare an indirect cost rate proposal and related documentation to support those costs. The proposal and related documentation must be retained for audit in accordance with the records retention requirements contained in § 200.334.

b. A governmental department or agency unit that receives more than \$35 million in direct Federal funding must submit its indirect cost rate proposal to its cognizant agency for indirect costs. Other governmental department or agency must develop an indirect cost proposal in accordance with the requirements of this Part and maintain the proposal and related supporting documentation for audit. These governmental departments or agencies are not required to submit their proposals unless they are specifically requested to do so by the cognizant agency for indirect costs. Where a non-Federal entity only receives funds as a subrecipient, the pass-through entity will be responsible for negotiating and/or monitoring the subrecipient's indirect costs.

c. Each Indian tribal government desiring reimbursement of indirect costs must submit its indirect cost proposal to the Department of the Interior (its cognizant agency for indirect costs).

d. Indirect cost proposals must be developed (and, when required, submitted) within six months after the close of the governmental unit's fiscal year, unless an exception is approved by the cognizant agency for indirect costs. If the proposed central service cost allocation plan for the same period has not been approved by that time, the indirect cost proposal may be prepared including an amount for central services that is based on the latest federally-approved central service cost allocation plan. The difference between these central service amounts and the amounts ultimately approved will be compensated for by an adjustment in a subsequent period.

### **2. Documentation of Proposals**

The following must be included with each indirect cost proposal:

a. The rates proposed, including subsidiary work sheets and other relevant data, cross referenced and reconciled to the financial data noted in subsection b. Allocated central service costs will be supported by the summary table included in the approved central service cost allocation plan. This summary table is not required to be submitted with the indirect cost proposal if the central service cost allocation plan for the same fiscal year has been approved by the cognizant agency for indirect costs and is available to the funding agency.

b. A copy of the financial data (financial statements, comprehensive annual financial report, executive budgets, accounting reports, etc.) upon which the rate is based. Adjustments resulting from the use of unaudited data will be recognized, where appropriate, by the Federal cognizant agency for indirect costs in a subsequent proposal.

c. The approximate amount of direct base costs incurred under Federal awards. These costs should be broken out between salaries and wages and other direct costs.

d. A chart showing the organizational structure of the agency during the period for which the proposal applies, along with a functional statement(s) noting the duties and/or responsibilities of all units that comprise the agency. (Once this is submitted, only revisions need be submitted with subsequent proposals.)

### **3. Required certification.**



Each indirect cost rate proposal must be accompanied by a certification in the following form:

## Certificate of Indirect Costs

This is to certify that I have reviewed the indirect cost rate proposal submitted herewith and to the best of my knowledge and belief:

- (1) All costs included in this proposal [identify date] to establish billing or final indirect costs rates for [identify period covered by rate] are allowable in accordance with the requirements of the Federal award(s) to which they apply and the provisions of this Part. Unallowable costs have been adjusted for in allocating costs as indicated in the indirect cost proposal
- (2) All costs included in this proposal are properly allocable to Federal awards on the basis of a beneficial or causal relationship between the expenses incurred and the agreements to which they are allocated in accordance with applicable requirements. Further, the same costs that have been treated as indirect costs have not been claimed as direct costs. Similar types of costs have been accounted for consistently and the Federal Government will be notified of any accounting changes that would affect the predetermined rate.

I declare that the foregoing is true and correct.

Governmental Unit: \_\_\_\_\_

Signature: \_\_\_\_\_

Name of Official: \_\_\_\_\_

Title: \_\_\_\_\_

Date of Execution: \_\_\_\_\_

## E. Negotiation and Approval of Rates

1. Indirect cost rates will be reviewed, negotiated, and approved by the cognizant agency on a timely basis. Once a rate has been agreed upon, it will be accepted and used by all Federal agencies unless prohibited or limited by statute. Where a Federal awarding agency has reason to believe that special operating factors affecting its Federal awards necessitate special indirect cost rates, the funding agency will, prior to the time the rates are negotiated, notify the cognizant agency for indirect costs.

2. The use of predetermined rates, if allowed, is encouraged where the cognizant agency for indirect costs has reasonable assurance based on past experience and reliable projection of the non-Federal entity's costs, that the rate is not likely to exceed a rate based on actual costs. Long-term agreements utilizing predetermined rates extending over two or more years are encouraged, where appropriate.

3. The results of each negotiation must be formalized in a written agreement between the cognizant agency for indirect costs and the governmental unit. This agreement will be subject to re-opening if the agreement is subsequently found to violate a statute, or the information upon which the plan was negotiated is later found to be materially incomplete or inaccurate. The agreed upon rates must be made available to all Federal agencies for their use.

4. Refunds must be made if proposals are later found to have included costs that (a) are unallowable (i) as specified by law or regulation, (ii) as identified in § 200.420, or (iii) by the terms and conditions of Federal awards, or (b) are unallowable because they are clearly not allocable to Federal awards. These adjustments or refunds will be made regardless of the type of rate negotiated (predetermined, final, fixed, or provisional).

## F. Other Policies

### 1. Fringe Benefit Rates

If overall fringe benefit rates are not approved for the governmental unit as part of the central service cost allocation plan, these rates will be reviewed, negotiated and approved for individual recipient agencies during the indirect cost negotiation process. In these cases, a proposed fringe benefit rate computation should accompany the indirect cost proposal. If fringe benefit rates are not used at the recipient agency level (i.e., the agency specifically identifies fringe benefit costs to individual employees), the governmental unit should so advise the cognizant agency for indirect costs.

## 2. Billed Services Provided by the Recipient Agency

In some cases, governmental departments or agencies (components of the governmental unit) provide and bill for services similar to those covered by central service cost allocation plans (e.g., computer centers). Where this occurs, the governmental departments or agencies (components of the governmental unit) should be guided by the requirements in Appendix V relating to the development of billing rates and documentation requirements, and should advise the cognizant agency for indirect costs of any billed services. Reviews of these types of services (including reviews of costing/billing methodology, profits or losses, etc.) will be made on a case-by-case basis as warranted by the circumstances involved.

## 3. Indirect Cost Allocations Not Using Rates

In certain situations, governmental departments or agencies (components of the governmental unit), because of the nature of their Federal awards, may be required to develop a cost allocation plan that distributes indirect (and, in some cases, direct) costs to the specific funding sources. In these cases, a narrative cost allocation methodology should be developed, documented, maintained for audit, or submitted, as appropriate, to the cognizant agency for indirect costs for review, negotiation, and approval.

## 4. Appeals

If a dispute arises in a negotiation of an indirect cost rate (or other rate) between the cognizant agency for indirect costs and the governmental unit, the dispute must be resolved in accordance with the appeals procedures of the cognizant agency for indirect costs.

## 5. Collection of Unallowable Costs and Erroneous Payments

Costs specifically identified as unallowable and charged to Federal awards either directly or indirectly will be refunded (including interest chargeable in accordance with applicable Federal cognizant agency for indirect costs regulations).

## 6. OMB Assistance

To the extent that problems are encountered among the Federal agencies or governmental units in connection with the negotiation and approval process, OMB will lend assistance, as required, to resolve such problems in a timely manner.

*[78 FR 78608, Dec. 26, 2013, as amended at 79 FR 75889, Dec. 19, 2014; 85 FR 49581, Aug. 13, 2020]*

### **Appendix VIII to Part 200 - Nonprofit Organizations Exempted From Subpart E of Part 200**

1. Advance Technology Institute (ATI), Charleston, South Carolina
2. Aerospace Corporation, El Segundo, California
3. American Institutes of Research (AIR), Washington, DC
4. Argonne National Laboratory, Chicago, Illinois
5. Atomic Casualty Commission, Washington, DC
6. Battelle Memorial Institute, Headquartered in Columbus, Ohio
7. Brookhaven National Laboratory, Upton, New York

8. Charles Stark Draper Laboratory, Incorporated, Cambridge, Massachusetts
9. CNA Corporation (CNAC), Alexandria, Virginia
10. Environmental Institute of Michigan, Ann Arbor, Michigan
11. Georgia Institute of Technology/Georgia Tech Applied Research Corporation/Georgia Tech Research Institute, Atlanta, Georgia
12. Hanford Environmental Health Foundation, Richland, Washington
13. IIT Research Institute, Chicago, Illinois
14. Institute of Gas Technology, Chicago, Illinois
15. Institute for Defense Analysis, Alexandria, Virginia
16. LMI, McLean, Virginia
17. Mitre Corporation, Bedford, Massachusetts
18. Noblis, Inc., Falls Church, Virginia
19. National Radiological Astronomy Observatory, Green Bank, West Virginia
20. National Renewable Energy Laboratory, Golden, Colorado
21. Oak Ridge Associated Universities, Oak Ridge, Tennessee
22. Rand Corporation, Santa Monica, California
23. Research Triangle Institute, Research Triangle Park, North Carolina
24. Riverside Research Institute, New York, New York
25. South Carolina Research Authority (SCRA), Charleston, South Carolina
26. Southern Research Institute, Birmingham, Alabama
27. Southwest Research Institute, San Antonio, Texas
28. SRI International, Menlo Park, California
29. Syracuse Research Corporation, Syracuse, New York
30. Universities Research Association, Incorporated (National Acceleration Lab), Argonne, Illinois
31. Urban Institute, Washington DC
32. Nonprofit insurance companies, such as Blue Cross and Blue Shield Organizations
33. Other nonprofit organizations as negotiated with Federal awarding agencies

*[78 FR 78608, Dec. 26, 2013, as amended at 85 FR 49582, Aug. 13, 2020]*

### **Appendix IX to Part 200 - Hospital Cost Principles**

Until such time as revised guidance is proposed and implemented for hospitals, the existing principles located at 45 CFR part 75 Appendix IX, entitled "Principles for Determining Cost Applicable to Research and Development Under Grants and Contracts with Hospitals," remain in effect.

[86 FR 10440, Feb. 22, 2021]

## **Appendix X to Part 200 - Data Collection Form (Form SF-SAC)**

The Data Collection Form SF-SAC is available on the FAC Web site.

## **Appendix XI to Part 200 - Compliance Supplement**

The compliance supplement is available on the OMB website.

[85 FR 49582, Aug. 13, 2020]

## **Appendix XII to Part 200 - Award Term and Condition for Recipient Integrity and Performance Matters**

### **A. Reporting of Matters Related to Recipient Integrity and Performance**

#### **1. General Reporting Requirement**

If the total value of your currently active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds \$10,000,000 for any period of time during the period of performance of this Federal award, then you as the recipient during that period of time must maintain the currency of information reported to the System for Award Management (SAM) that is made available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)) about civil, criminal, or administrative proceedings described in paragraph 2 of this award term and condition. This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available.

#### **2. Proceedings About Which You Must Report**

Submit the information required about each proceeding that:

- a. Is in connection with the award or performance of a grant, cooperative agreement, or procurement contract from the Federal Government;
- b. Reached its final disposition during the most recent five-year period; and
- c. Is one of the following:
  - (1) A criminal proceeding that resulted in a conviction, as defined in paragraph 5 of this award term and condition;
  - (2) A civil proceeding that resulted in a finding of fault and liability and payment of a monetary fine, penalty, reimbursement, restitution, or damages of \$5,000 or more;
  - (3) An administrative proceeding, as defined in paragraph 5. of this award term and condition, that resulted in a finding of fault and liability and your payment of either a monetary fine or penalty of \$5,000 or more or reimbursement, restitution, or damages in excess of \$100,000; or
  - (4) Any other criminal, civil, or administrative proceeding if:
    - (i) It could have led to an outcome described in paragraph 2.c.(1), (2), or (3) of this award term and condition;
    - (ii) It had a different disposition arrived at by consent or compromise with an acknowledgment of fault on your part; and
    - (iii) The requirement in this award term and condition to disclose information about the proceeding does not conflict with applicable laws and regulations.

#### **3. Reporting Procedures**

Enter in the SAM Entity Management area the information that SAM requires about each proceeding described in paragraph 2 of this award term and condition. You do not need to submit the information a second time under assistance awards that you received if you already provided the information through SAM because you were required to do so under Federal procurement contracts that you were awarded.

#### 4. Reporting Frequency

During any period of time when you are subject to the requirement in paragraph 1 of this award term and condition, you must report proceedings information through SAM for the most recent five year period, either to report new information about any proceeding(s) that you have not reported previously or affirm that there is no new information to report. Recipients that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10,000,000 must disclose semiannually any information about the criminal, civil, and administrative proceedings.

#### 5. Definitions

For purposes of this award term and condition:

a. Administrative proceeding means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (e.g., Securities and Exchange Commission Administrative proceedings, Civilian Board of Contract Appeals proceedings, and Armed Services Board of Contract Appeals proceedings). This includes proceedings at the Federal and State level but only in connection with performance of a Federal contract or grant. It does not include audits, site visits, corrective plans, or inspection of deliverables.


b. Conviction, for purposes of this award term and condition, means a judgment or conviction of a criminal offense by any court of competent jurisdiction, whether entered upon a verdict or a plea, and includes a conviction entered upon a plea of nolo contendere.

c. Total value of currently active grants, cooperative agreements, and procurement contracts includes -

- (1) Only the Federal share of the funding under any Federal award with a recipient cost share or match; and
- (2) The value of all expected funding increments under a Federal award and options, even if not yet exercised.

B. [Reserved]

*[80 FR 43310, July 22, 2015, as amended at 85 FR 49582, Aug. 13, 2020]*

<b>Policy:</b> Sponsored Project Awards Closeout Policy	<b>Effective Date:</b> April 1, 2019	<b>Policy Version:</b> 1.0	<b>Policy Status:</b> FINAL
<b>Chief Financial Officer</b> 		<b>Date:</b> March 27, 2019	

**1. PURPOSE**

The purpose of this policy is to provide guidance on the requirements for closeout of all sponsored program awards.

**2. APPLICABILITY**

This Policy is applicable to all campuses of the Touro College and University System except New York Medical College (hereinafter “Touro”) that are the recipients of and responsible for managing sponsored program awards.

**3. DEFINITIONS**

**3.1 Closeout** - The process by which a sponsor and Touro determine that all applicable work and reporting required under the terms of an award have been completed. This refers both to Touro’s internal closeout requirements and to sponsor requirements detailed in an award.

**3.2 Office of Sponsored Programs (“OSP”):** Touro has three separate OSPs, located at Touro College, Touro University (California) and Touro University Nevada.

**3.3 Principal Investigator/Project Director (“PI/PD”):** The individual at Touro primarily responsible for and in charge of a sponsored project. The PI/PD normally is a member of the faculty, but in some instances may be a staff member or student depending upon the nature of the sponsored program and award.

**3.4 Sponsored Project Awards:** Projects and/or other activities that are originated and conducted by PI/PDs, and which are supported by restricted funds awarded by an external sponsor.

**4. Policy**

This policy aims to ensure compliance with 2 CFR 200 – Uniform Administrative Requirements, Cost Principles, and Audit Requirements for federal awards (or previously issued and applicable Office of Management and Budget Circulars), compliance with requirements of other government and non-government sponsors, and Touro institutional requirements related to closeouts of sponsored program awards.

**5. Procedures for Implementation**

5.1 On a timely basis, the PI/PD and the relevant school/department administrator should identify a project expiring within 90 days. The PI/PD should focus on appropriate steps for the orderly termination of project-related activities and production of non-financial reporting requirements (technical, inventions, etc.). The PI/PD and the school/department

administrator should ensure that all project costs either have been appropriately incurred and charged or are appropriately in process to be charged in a timely manner. As the project nears termination, it is important to review all costs and remove those that are *unallowable or incorrect* preferably prior to expiration of the award performance period but no later than 30 days thereafter to ensure timely financial reporting and/or invoicing.

Listed below are the responsibilities for sponsored award final closeout by area:

#### **5.1.1 PI/PD Responsibilities**

- The PI/PD is responsible for overseeing orderly close-out of an award, including meeting all sponsor and Touro requirements, such as signing off on or preparing and submitting all final reports, particularly those related to project technical matters.
- The PI/PD works closely with the school/department administrator, OSP, the Office of the Controller, and other Touro central offices as may be appropriate to fulfill those responsibilities and to assist Touro in carrying out its institutional responsibilities to the sponsor.

#### **5.1.2 OSP Responsibilities**

- Works closely with the PI/PD, school/department administrator, and Controller's Office (and/or other central administrative offices as may be appropriate to interpret award close-out requirements).
- Works closely with the award sponsor as may be required.
- Submits, or coordinates submission of non-financial final reports requiring institutional sign-off.

#### **5.1.3 Controller Responsibilities**

- The grants accountant works with the PI/PD and school/department administrator to clear any open cost items remaining on a project (expenditure account) after the final report/invoice has been completed, i.e., pending expense adjustments, encumbrance balance release, transfer of surplus or deficit.
- The grants accountant confirms that pending adjustments have posted to the project, as reflected in the College's general ledger. The only pending items allowed at the time of closeout are outstanding payments.
- These duties may be coordinated with other central office post-award administrators at the relevant campus.

#### **5.1.4 School/Department Responsibilities**

- Notify Human Resources of any account change for future costs such as salary or fringe.
- Process or follow-up on outstanding reasonable, allowable and allocable project costs so they are charged in a timely manner and meet financial reporting obligations, including subaward/subcontract outstanding invoices.
- Promptly transfer all unallowable or incorrect charges and clear out over-expenditure costs.

### **5.2 Charges Incurred after Award End- Date**

In accordance with sponsor-imposed limits, it is acceptable to process payments for costs that were incurred prior to the end of the project/award but posted to the project after the

termination date but before the reporting deadline (e.g., 90 days for Federal). Such costs must be posted prior to financial reporting deadline prescribed by the sponsor. Any charges posted after the termination date will need to be explained and justified for allowability.

Examples of common “after awarded date” charges include:

- Payroll expenses
- Copy services costs
- Other service center charges
- Subaward/subcontract costs

### **5.3 Resolving Deficits: Cost Overruns and Uncollectible Accounts Receivable**

Deficits on sponsored program awards are to be avoided through timely expenditure account reconciliations during the life of a project. In rare circumstances, cumulative legitimate expenses associated with project activities may exceed the amount awarded by the sponsor (i.e., over-expenditures); with approval of the school dean and/or department chair, these over-expenditures may be considered voluntary uncommitted cost sharing, which must be absorbed internally by Touro via timely cost transfers to a school/department org (expenditure account). This is particularly true if there are uncollectible accounts receivable from the sponsor, whereby final expenditures will exceed the revenue available.

It is the school/department’s responsibility to transfer any such overexpenditure no later than 90 days after the termination date.

### **5.4 Unallowable and Unallocable Costs**

Touro may not request reimbursement or payment from the awarding sponsor for unreasonable, unallowable or unallocable costs. If audited, such costs may give the appearance of inadequate financial controls at, and inappropriate stewardship of sponsored funds by, Touro.

Potential unreasonable/unallowable/unallocable costs may include:

- Projects costs that are strictly prohibited by the sponsor or require sponsor or internal delegated prior approval prior to acquisition/being incurred for which such approval was not secured.
- Restricted purchases without proper authorization from the sponsor and/or Touro, e.g., office equipment.
- Costs incurred after the award terminates.

### **5.5 Fixed-Price Agreements**

Occasionally, fixed-price agreements are entered into with sponsoring agencies by Touro and permit Touro to retain the unexpended (cash) balance at project expiration. These funds are managed and distributed in accordance with Touro’s Fixed-Price Contract Close-Out Procedure.

### **5.6 Technical and Other Reports (Non-Financial)**

Requirements for non-financial reports vary by sponsor, both the types of reports and the deadlines for their submission. For federal awards, these reports generally are due within 90 days of the award end date.



Some of these non-financial reports are submitted by the PI/PD and some require sign-off/submission by OSP (or potentially another central administration office as directed or coordinated by OSP). It is essential that the PI/PD, school/department administrator, and OSP administrator review and adhere to the sponsor requirements. Examples of non-technical reports include:

- Final Technical Report – prepared and submitted by the PI/PD
- Final Report of Inventions – prepared by the Principal Investigator and generally submitted by the PI (or, in some circumstances, by a central administration office)
- Final Inventory of Equipment – generally prepared in coordination with the school/department administrator and submitted either by that individual or by a central administration office.

### **5.7 Transfer or Termination of Sponsored Research**

When a PI/PD is leaving Touro and plans to transfer or terminate a sponsored award, close coordination with the sponsor and adhering to sponsor guidelines are essential to effect a timely and efficient outcome.

#### **a) *Transfer of Sponsored Research to Another Institution***

- a. The PI/PD notifies OSP of the intent to seek transfer of the award to another institution.
- b. The PI/PD and school/department estimates any unliquidated expenditures and future unobligated balance up to the proposed termination date and provides that information to OSP, the Controller's Office and the sponsor.
- c. OSP submits the required proposal to the sponsor for relinquishing the award; generally, this includes a progress report of work accomplished at Touro. This proposal must be coordinated with the "new" proposal submitted by the institution to which the PI/PD will be moving
- d. On receiving transfer approval from the sponsor, the PI/PD terminates the activity on the project and Touro liquidates all financial commitments outstanding on the project.
- e. Transfer of property and data, or any reports required, are done in accordance with Touro and sponsor requirements.
- f. After all financial commitments have been liquidated, a final financial report will be prepared and transmitted to the sponsor. Any residual funds remaining in the sponsored project generally will be returned to the sponsor, unless directed otherwise by the sponsor or if the award is a fixed-price contract.

#### **b) *Terminating the Project***

When a PI/PD permanently departs Touro and is unable to transfer the project to another institution, the following steps must be taken.

- a. The PI/PD, with appropriate clearances from the school/department, submits to OSP a justification for the termination of the award. The PI and school/department, estimates any unliquidated expenditures and future unobligated balance up to the proposed termination date and provides that information to OSP and the sponsor as appropriate.
  - i. OSP submits the proposal to the sponsor for terminating the award;
  - ii. On receiving the termination notice from the sponsor, the PI /PD terminates the activity on the project, and the Controller's Office liquidates all financial commitments outstanding on the project;

- iii. After all financial commitments have been liquidated, a final financial report will be prepared and transmitted to the sponsor. Any residual funds remaining in the sponsored project generally will be returned to the sponsor, unless directed otherwise by the sponsor or if the award is a fixed-price contract.
- b. All final non-financial reporting obligations also must be met as part of this process.