TUN
Biosafety Manual

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Approved by the IBC on August 26, 2020

Table of Contents

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

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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.

<u>Prevention:</u> 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

Class	Material	Extinguisher
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 disinfected 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

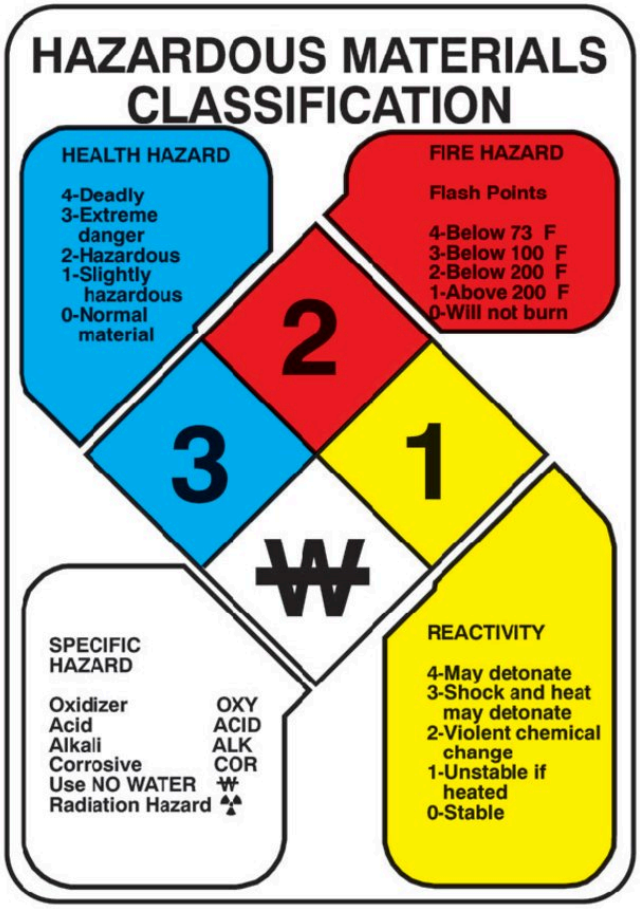
- Disposable personal protective equipment used in clinical or biomedical labs that are NOT contaminated with any of the biological wastes listed in category 1 above
- Unused medical devices
- Items contaminated with blood from animals not known to or expected to, contain pathogens
  The material should 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.

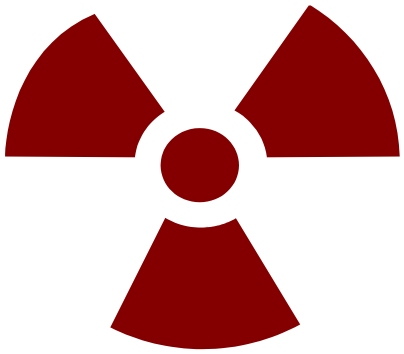

HAZARDOUS MATERIALS CLASSIFICATION
HEALTH HAZARD
4-Deadly
3-Extreme danger
2-Hazardous
1-Slightly hazardous
0-Normal material
FIRE HAZARD
Flash Points
4-Below 73 F
3-Below 100 F
2-Below 200 F
1-Above 200 F
0-Will not burn
2
3
1
W
SPECIFIC HAZARD
Oxidizer OXY
Acid ACID
Alkali ALK
Corrosive COR
Use NO WATER W
Radiation Hazard
REACTIVITY
4-May detonate
3-Shock and heat may detonate
2-Violent chemical change
1-Unstable if heated
0-Stable

2. Global Harmonized System Pictograms

3. Warning Symbols

Biohazard Warning Symbol

Radiation Warning Symbol



4. Laboratory Waste Disposal

Laboratory Material	**Infectious Waste/Sharps (Red Bag, Cardboard Box, Or Sharps Container)**
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	Yes
Plastic	
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

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

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.

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 Group1 (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

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, secreta, 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) (12 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 trainer.

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-sheathe 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

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.

Table 1: Employees at risk

Job classification	Task or exposure
Example: Phlebotomist	Example: Collect human clinical samples

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

Table 2: Employees who may be at risk

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 (Reconstructed1918 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 glycines)*
Ralstonia solanacearum race 3, biovar 2
Rathayibacter toxicus
Sclerophthora rayssiae var zeae
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

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/ft3) 60 m, 37 C, 30% hum VB, LV, NLV, MYC, BS
Paraformaldehyde+ (0.3 to 0.6g/ft3.) 4 hrs. <23 C, >60% hum VB, LV, NLV, MYC, BS

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.

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, benchtops). 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 aterrimus

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 lichemiformis 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 aterrimus
Bacillus brevis
Bacillus cereus
Bacillus globigii
Bacillus licheniformis
Bacillus megaterium
Bacillus natto
Bacillus niger
Bacillus pumilus
Bacillus sphaericus
Bacillus stearothermophilis
Bacillus subtilis
Bacillus thuringiensis
Clostridium acetobutylicum
Lactobacillus casei
Listeria grayi
Listeria monocytogenes
Listeria murrayi
Pediococcus acidilactici
Pediococcus damnosus
Pediococcus pentosaceus
Staphylococcus aureus
Staphylcoccus 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 salivarious
Streptococcus sanguis
Streptococcus sobrinus
Streptococcus thermophylus

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

PART I – REPORT TYPE
1. This is to report: ☐ A) Chemical material spill ☐ B) Biological material spill
PART II – GENERAL INCIDENT INFORMATION
2. Date and Time of Incident: **3.** Location of incident: **4.** Description of Spilled Hazardous Material: **5.** Size of spill: **6.** Person responsible:
PART III – DESCRIPTION OF EVENTS
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.)
PART VI – RECOMMENDATIONS/ACTIONS TAKEN TO PREVENT RECURRENCE
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.)
PART V – REPORTER'S CONTACT INFORMATION
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

Vladimir Bondarenko, PhD
Fax: 702.777.1799 874 American Pacific Drive Henderson, NV 89014

Appendix H Pest Management

Touro University Nevada	Page No. 1 of 5	Number:
	Effective Date: 6/6/2019	
POLICY & PROCEDURE MANUAL	Required Review: Annual	
	Reviewed:	
Policy [X] Procedure [ ]	Revised:	
Title: Integrated Pest Management Plan	Responsible Position: Director of EHS	
	Approval Requirements: 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/bmbl4/bmbl4toc.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.pdf http://www.pacifica.com/NitrileGlovesChemicalResistance-BarrierGuide.pdf

Office of Biosafety Administration
http://www4.od.nih.gov/oba/rac/Guidance/LentiVirus_Containment/index.htm