

Touro University Nevada **I**nstitutional **R**eview **B**oard (**IRB**)

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Henderson, NV 89014

702-777-8687

tun.irb@touro.edu

# Non-Exempt Human Subject Research IRB Application

# Expedited and Full Board Review

*Submit Addendum 1 with this application to be considered for expedited review.*

**Instructions**

* **Do NOT begin advertising or data collection prior to IRB approval**.
* Follow the instructions carefully to ensure that you answer the correct questions. Enter information in shaded text boxes.
* Please provide **complete information**, understanding that the IRB must know enough about the project and how human subjects are involved in order to complete a review.
* If an item is not applicable, indicate with ‘NA’.
* All materials must be **typed**; handwritten materials will be returned.
* To **eligible** for full board review in a particular month, all materials must be received electronically by the IRB Chair at tun.irb@wtouro.edu no less than 10 business days prior to the next meeting. IRB meetings are scheduled on the second Wednesday of each month.

**Study Title**:

**Level of Review Requested:**

[ ]  Expedited (***Complete Addendum 1 now and submit with your application***)

[ ]  Full Board

**Principal Investigator (PI) Contact Information**: The Principal Investigator (PI) must be TUN faculty, staff, or administration. He or she will be the study supervisor at TUN as well as the point of contact for all correspondence from the IRB. Students and visiting faculty may not serve as PI, but may be listed as co-investigators.

|  |  |
| --- | --- |
| Name: |   |
| Dept. or Professional workplace: |   |
| Position at TUN: |   |
| Phone: |   |
| Email: |   |

## SECTION 1. General Information

|  |
| --- |
| *Human Participants Training: TUN IRB* ***requires all personnel*** *involved in the research to complete CITI training in the ethical use of human participants in research. The principal investigator (PI) is responsible for the training and the documentation of the personnel listed on the application.* ***Re-training is required every three years****. For CITI training details, visit the TUN IRB web page.*  |

1. Human Participant Training Record (CITI –TUN) of Principal Investigator:

[ ]  PI’s CITI training is **current** and was **taken through TUN**. This statement will be administratively confirmed.

[ ]  PI’s CITI training was **not taken through TUN.** If so, **attach documentation** to confirm the PI’s training.

1. **Co-Investigator(s) (Co-PIs) Contact Information and Role in study***.* Include all persons who will be directly responsible for the study management, data collection, consent process, data analysis, transcription, participant recruitment, or follow up. If necessary, attach a list of additional Co-PIs*.* In the final column, check the box if the Co-PI has documentation of current CITI training through TUN. This will be administratively checked. **If the CO-PI has documentation of CITI training from a different institution, do not check the box and attach the documentation**.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Email** | **Position/Title** | **Role in the study** | **CITI training completed through TUN** |
|       |       |       |       | [ ]  |
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1. **Estimated duration of study**: *Starting date* **to** *Ending date*
2. [ ]  Yes [ ]  No Is this research supported in whole or in part by a grant or contract? If yes:

Funding Agency(s), Foundation, or Business:

PI on Grant/Contract:

Grant Title/Contract:

* 1. [ ]  Yes [ ]  No **Is your research a clinical trial?** A clinical trial is defined in federal regulations as, “a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.” If so, you are required to register on ‘ClinicalTrials.gov’ and provide evidence of registration with your application. A copy of your consent form must be posted after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by a research subject (45 CFR 46.46.116(h)(1-3)).
1. [ ]  Yes [ ]  No Does the research require another IRB’s review (US and International)? If yes:

 Name of the IRB:

 Federal Wide Assurance (FWA) number or equivalent number:

**(*NOTE:* *PI is responsible for securing approval and forwarding the documentation of approval to TUN IRB****).*

1. [ ]  Yes [ ]  No Is the proposed research study conducted at an outside (non-TUN) facility or entity (such

as hospitals, clinics, schools, school districts, factories, offices, etc..,)?

**If yes**, Name (s) of the facility or entity:

***Attach a signed letter, contract, or agreement from the appropriate designee at the non-TUN facility.*** *The researcher has an obligation to ensure that the outside entity is aware of the proposed research study and has no objections (i.e. agrees to participate). In order to respect the sovereign governments, research to be conducted on Native American tribal lands will require a letter from the Tribal Council (or equivalent authorized signatory) to the TUN IRB acknowledging the research study and their willingness to allow the proposed research*.

1. [ ]  Yes [ ]  No Does the research require approval from other TUN compliance committees?

 (i.e., Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC), etc...)

**If yes,** PI has responsibility to seek approval from the other committees required for this research. Work cannot start until final approval is received from **all** appropriate committees.

## SECTION 2. Study Description

**Provide a brief summary of the proposed research.** Use lay language and avoid technical terms. IRB members not familiar with the area of research must understand the nature of the research. **The application will be returned without further review if summary is too technical.**

**Brief (500 words or less) summary of research study** which clearly indicates the **purpose, design, and procedures** that are planned. For projects involving multiple phases or complex designs, attach flow chart(s) describing the sequence of study procedures.

**What will each participant be asked to do** in his/her role as a participant? Be specific enough that an IRB member will be able to visualize the experience of a research participant.

## SECTION 3. Data Collection Methods

Check all method(s) to be used.

1. [ ]  Survey/Questionnaire

[ ]  Phone [ ]  In person [ ]  Internet [ ]  E-mail [ ]  Postal mail

[ ]  Other:

***If checked, submit copies (if applicable, translated versions) of data collection procedures and instruments.***

1. [ ]  Interview

 [ ]  One-on-one [ ]  Focus group  [ ]  Other:

***If checked, submit copies (if applicable, translated versions) of all data collection procedures and instruments.***

1. [ ]  Observation of Public Behavior

[ ]  Classroom [ ]  Public meetings [ ]  Other:

1. [ ]  Examination of Archived Data/Secondary or Records

 Briefly describe the source of the records, and the type of data that will be collected:

1. [ ]  Taste Evaluation

[ ]  Wine/alcohol [ ]  Non-wholesome food [ ]  Genetically altered food

***Studies involving wholesome foods can be determined exempt under Exemption 6 (see exempt determination form****).*

1. [ ]  Examination of Human Pathological or Diagnostic Tissue Specimens (ex: blood, bodily fluids…)
2. [ ]  Experimental (Unproven or Untested Procedures)

[ ]  Biomedical [ ]  Psychological [ ]  Other:

1. [ ]  Recordings

[ ]  Voice [ ]  Video [ ]  Digital [ ]  Image

***Some studies involving adults that include audiovisual data collection may be eligible for exempt status under Exemption 3 (see exempt determination form).***

 Purpose of the recordings: [ ]  Transcription [ ]  Other

**If ‘Other’, explain below**: (For example, for speech pattern analysis, archiving purposes, presentation at the meetings etc.)

*Note: For* ***greater than minimal risk studies****, a confidentiality agreement is required for transcription and translation of the recordings if the job is done by project personnel such as a student or research assistant, or by professionals hired to do the work. For* ***no more than minimal risk studies****, a confidentiality agreement should be considered on a case-by-case basis. If needed, complete* ***Addendum 10 and submit with the application.***

## SECTION 4. Confidentiality and Protection of Data

1. Does your research use any of the following ‘personal health information’ (PHI) identifiers? [ ]  Yes [ ]  No

If yes, check all that apply. Your research may require a consent process under of HIPAA (see section 11).

[ ]  Names [ ]  Account numbers

[ ]  Geographic subdivisions smaller than a State [ ]  Certificate/license numbers

[ ]  Elements of dates (except year) related to an individual [ ]  Vehicle identifiers

 [ ]  Device identifiers and serial number [ ]  Biometric identifiers

[ ]  Telephone numbers [ ]  Web URLs

[ ]  Fax numbers [ ]  Email addresses

[ ]  Social Security numbers [ ]  IP address numbers

[ ]  Medical record numbers [ ]  Full-face photos/images

[ ]  Health plan beneficiary numbers

[ ]  Any other unique identifying number (a value the researcher use to link data to an individual)

1. Will this research include any technologies or techniques (e.g., ‘Big data’ mining, genome sequencing) that could foreseeably generate identifiable private information or identifiable biospecimens from information that would otherwise be considered de-identified? [ ]  Yes [ ]  No

If so, explain what technique or technology will be used, generally what types of information will be input, and what type of information is anticipated output.

***A summary of this information must be included in your Informed Consent document.***

1. The methods of protecting data should be appropriate to the risk posed to research subjects by a data breach. For example, de-identified data pose virtually no risk to participants and can be largely unprotected. At the other extreme, data sets that link individuals to facts or opinions that could affect the individual’s standing insurability, employment, or civil or criminal liability, such as diagnosis of an STD, genetic data showing high risk for a debilitating disease, or history involving law-breaking, would need the maximum level of protection available to offset the risk associated with the data.

**Method(s) of protection and location of data storage: (Check all that apply)**

1. [ ]  Locked Office (not private)

[ ]  Locked Cabinet

[ ]  Coded to a Master List - If checked, answer the following

 i. Will the master list be kept separate from the data? [ ]  Yes [ ]  No

ii. Will the master list be available to any member of the research team? [ ]  Yes [ ]  No

[ ]  Restricted Computer

[ ]  Password Protected

[ ]  Locked Private Office

[ ]  Locked Non-Private Office

[ ]  Encrypted Data

[ ]  Fire Wall System

[ ]  Other:

1. Location(s) of data:
2. When and how will all research materials be destroyed, including voice/video/digital/image? (*TUN guidelines require all research materials [consent forms, surveys etc...] to be kept for a minimum of three years after completion of the study. Many professional organizations or publishing institutions require data be kept a longer period)*

## SECTION 5. Human Subject Population

1. Approximate number of subjects to be enrolled (**Answer for each subject group.**):
2. Identify subjects that will be recruited. Submit additional materials as required.
3. Age of Participants:

|  |  |
| --- | --- |
| **Age** | **Consent/Permission /Assent forms Required** |
| [ ]  0-7 years | Parental Permission Form  |
| [ ]  4-7 years | Parental Permission Form and Child's Assent |
| [ ]  8-17 years | Parental Permission Form and Child's Written Assent |
| [ ]  18 & over | Written Consent |

1. A vulnerable person is one who is “vulnerable to coercion and undue influence, in recognition that coercion or undue influence refers to the ability to make an informed decision about participating in research” (HHS 2017). Vulnerable populations should therefore only be included in research for which their group directly benefits, and they may require extra protections or consent procedures.

|  |
| --- |
| [ ]  Neonates/Fetuses |
| [ ]  Children (ages 0-18)1 |
| [ ]  Prisoners2 |
| [ ]  Pregnant women |
| [ ]  Decisionally impaired |
| [ ]  HIV/AIDS patients |
| [ ]  Crime victims |
| [ ]  Substance abusers |
| [ ]  Non-English speaking |
| [ ]  Terminally ill |
| [ ]  Institutionalized individuals |
| [ ]  Other:  |

**1** If you are conducting research with children, complete ***Addendum 2*** and submit with the application.

**2** If you are conducting research with prisoners **by design**, complete ***Addendum 3*** and submit with the application.

1. Describe and justify your **inclusion criteria**.
2. Briefly describe and explain your **exclusion criteria**:

## SECTION 6. Human Subject Recruitment

1. Recruitment/advertising methods. Check all that apply and **attach all materials that will be used.**

[ ]  Person to person solicitation

[ ]  Phone

[ ]  Postal mail

[ ]  E-mail

[ ]  Poster

[ ]  Media (TV, newspaper, radio, Web site)

[ ]  Other:

[ ]  None

1. How will potential subjects be identified and approached (**Answer for each subject group**)?

**Explain in detail:**

1. Who will obtain consent/assent and when will that be done (**Answer for each subject group**)?

**Explain in detail:**

1. What steps have been taken to prevent potential coercion or undue influence in recruiting subjects and obtaining consent or assent?

**Explain in detail:**

1. Describe (and provide) any screening tools/procedures (**Answer for each subject group**):

**Explain in detail:**

1. Will subjects be compensated? (*If participants are paid by a TUN check; this requires the participants' social security number.)*

[ ]  Yes [ ]  No

**If yes,**

1. What is the compensation (e.g. extra credit, money, gift certificate, etc.), how much will the subject be offered, and how will they receive it?

**Explain in detail:**

1. When will the participants be compensated?

[ ]  Before the study [ ]  Installments during the study [ ]  Withdraw/complete the study

## SECTION 7. Informed Consent/Parental Permission/Assent Process

[ ]  I would like to **obtain information or biospecimens for screening, recruiting, or determining eligibility of prospective subjects without the informed consent** of the prospective subject or legally authorized representative. *One of the following must be true to allow you to do this (45CFR46.116(g)).* *Check all that apply.*

 [ ]  You will obtain the information through oral or written communication with the prospective

subject or a legally authorized representative.

 [ ]  You will obtain the identifiable private information or identifiable biospecimens by accessing

records or stored identifiable biospecimens (i.e., not by creating new information).

*If you checked at least one box above*, **explain how you will maintain the privacy and confidentiality of the information**, bearing in mind that measures taken must be proportional to the risks involved to subjects in the case of a data breach.

If the data are in a HIPAA-covered entity, attach **Addendum 7**.

*Indicate how each population (check all that apply) will gain consent in your study,* and **attach appropriate forms to this application.** A list of required elements of informed consent (Example of Consent Forms), and addenda are available on the TUN IRB web page.

|  |  |  |
| --- | --- | --- |
| [ ]  Adult(s) [ ]  Children[ ]  Parent(s) [ ]  Guardian(s)[ ]  Vulnerable Pop. | [ ]  Written Consent | A consent, assent, or permission form that contains all of the required elements of informed consent. |
| [ ]  Adult(s) [ ]  Children[ ]  Parent(s) [ ]  Guardian(s)[ ]  Vulnerable Pop. | [ ]  Alteration of Informed Consent process  | Requesting IRB approval for waiver of some or all of the elements of informed consent, assent, or permission (i.e. medical record review, deception research, or collection of biological specimens).**If checked,** complete ***Addendum 4*** and submit with the application. |
| [ ]  Adult(s) [ ]  Children[ ]  Parent(s) [ ]  Guardian(s)[ ]  Vulnerable Pop. | [ ]  Waiver of Documentation of Informed Consent | Requesting IRB approval for waiver of the requirement for documentation of informed consent, assent, or permission (i.e. telephone survey or mailed survey, internet research, or certain international research).**If checked,** complete ***Addendum 5*** and submit with the application. |
| [ ]  Adult(s) [ ]  Children[ ]  Parent(s) [ ]  Guardian(s)[ ]  Vulnerable Pop. | [ ]  Waiver of Informed Consent Process | Requesting IRB approval for waiver of the requirement for the informed consent, assent, or permission process (i.e. medical record review, deception research, or collection of biological specimens).**If checked,** complete ***Addendum 6*** and submit with the application. |

## SECTION 8. Risk and Benefit Assessment

1. Potential risks to participants: **(Check all that apply)**

[ ]  Invasion of privacy to the subject or family

[ ]  Breach of confidentiality

[ ]  Physical harm or discomfort

[ ]  Psychological/emotional discomfort or distress

[ ]  Psychological effect that is more than discomfort or distress

[ ]  Social stigmatization

[ ]  Economic (e.g., employment, insurability)

[ ]  Legal

[ ]  Any study related activity which subjects might consider sensitive, offensive, threatening, or degrading?

[ ]  Withholding standard care and procedures

[ ]  Significant time or inconvenience

[ ]  Other:

1. Does the study pose risk to individuals other than the participants?

[ ]  YES [ ]  NO **If yes, explain in detail:**

1. How will you minimize the potential risks in order to protect subjects' rights and welfare?

**Explain in detail:**

1. In the event that any of these potential risks are realized, how will it be handled (e.g. compensation, counseling, etc.)?

**Explain in detail:**

1. Is it possible that you will discover a subject's previously unknown physical or psychological condition (e.g. disease, depression, suicidal ideation, genetic predisposition, etc.) as a result of your procedures?

[ ]  YES [ ]  NO

**If yes,** what would they be and how will you handle these situations? **Explain in detail:**

1. Describe the expected benefits of this project *(NOTE:* ***compensation is not considered a benefit****)*:
2. To the individual subjects:

**Explain in detail:**

1. To society:

**Explain in detail:**

1. Explain how, in your assessment, benefits of this study outweigh the risks. (e.g. risk/benefit ratio)

1. Indicate which of the categories listed below accurately describes the specific potential risk level for the study:

[ ]  Not greater than minimal risk (“Minimal risk” means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.) 45 CFR 46.102(j)

[ ]  Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects

[ ]  Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition

[ ]  Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects

## SECTION 9. Research Involving Potential Reportable Activity

1. To the best of your knowledge, will the project involve the potential discovery of child abuse?

[ ]  Yes [ ]  No

**If yes,** there are legal obligations to disclose to the proper authorities certain information about reportable activities obtained during research.  ***This obligation and intended course of action must be communicated to the participants in the consent form.***

## SECTION 10. Research Involving Deception

**Note: Some research involving adults can include deception and be determined exempt suing Exemption 3. See the Exempt Determination Form for details.**

1. [ ]  Yes [ ]  No Will any information be purposely withheld from the participants or will they be given any misinformation?

**If yes,** this will require alteration of informed consent process. Complete ***Addendum 4*** and submit along with the application.

1. Why is the deception necessary?

**Explain in detail:**

1. How and when will the subjects be debriefed after the project? **Attach debriefing script.**

**Explain in detail:**

## SECTION 11. Research Involving Health Insurance Portability and Accountability Act (HIPAA)

Address the following questions regarding the use of protected health information:

1. [ ]  Yes [ ]  No Will health information be obtained from a covered entity[[1]](#footnote-1) (a health care provider who bills health insurers e.g., TUN Clinic, CADD, hospitals)?
2. [ ]  Yes [ ]  No Does the research involve the provision of healthcare in a covered entity, such as TUN health services?
3. [ ]  Yes [ ]  No If the study involves the provision of healthcare, will a health insurer or billing agency be contacted for billing or eligibility?
4. [ ]  Yes [ ]  No Does the research involve the use or creation of protected health information?

If **no** to all the questions above you are **not** subject to HIPAA**.**

If **yes** to any of the questions abovecomplete ***Addendum 7*** and submit wi**t**h the application.

## SECTION 12. Research Involving Investigational Drugs, Devices, Alcohol, Blood, Tissue, Bodily Fluids or other Biological Specimens

1. [ ]  Yes [ ]  No Will any investigational new drug (IND) be used?

If yes, complete ***Addendum 8*** and attach it to the application.

1. [ ]  Yes [ ]  No Will any other drugs be used?

If yes, complete ***Addendum 8*** and attach it to the application.

1. [ ]  Yes [ ]  No Is a **device**, defined as a health care product that does not achieve its primary

intended purposes by chemical action or by being metabolized, a focus of the study?

**If yes**, complete ***Addendum 8*** and attach it to the application.

1. [ ]  Yes [ ]  No Will alcohol be ingested by the subjects?

**If yes**, describe what type and how it will be administered:

1. [ ]  Yes [ ]  No Will blood, tissue, bodily fluids, or other biological specimens be collected?

If yes, complete ***Addendum 9*** and submit with the application.

**Note: if you are using blood, tissue, bodily fluids or other biological specimens, you may also need to seek Institutional Biosafety Approval** (T**U**N.Institutional.Biosafety.Officer@touro.edu) **before you begin the research.**

1. [ ]  Yes [ ]  No Will any of the blood, tissue, bodily fluids, or other biological specimens be used for genetic testing?
2. Do your studies involve the analysis of genes known to be implicated in the disorder(s), syndrome(s) or condition(s) you are studying? If so, what genes will you be studying?
3. Alternatively, do your studies involve finding the gene(s) that may cause the condition or genetic markers that co segregate with this condition?
4. Please confirm that the samples will not be used for any purpose other than to study genes related to the diseases discussed in the application and the consent form.

## SECTION 13. Investigator’s Responsibilities and Assurances

Indicate that you have read and will comply with each statement by checking the boxes.

1. [ ]  I certify that the information provided in this application, and in all attachments, is complete and correct.
2. [ ]  I understand that I have ultimate responsibility for the protection of the rights and welfare of human participants, the conduct of this study, and the ethical performance of this research.
3. [ ]  I agree to comply with all TUN policies and procedures, the terms of its Federal Wide Assurance, and all applicable federal, state, and local laws regarding the protection of human participants in research.
4. [ ]  I certify that
* The project will be performed by qualified personnel according to the TUN IRB-approved application.
* The equipment, facilities, and procedures to be used in this research meet recognized standards for safety.
* No change will be made to the human subjects protocol or consent form (s) until approved by the TUN IRB.
* Legally effective informed consent or assent will be obtained from human subjects as required and documented using the IRB approved consent form, unless waived by the IRB.
* Unanticipated problems, adverse events, and new information that may affect the risk– benefit assessment for this research will be reported to the TUN IRB Office (702-777-8687; tun.irb@touro.edu) and to my Department Chair/Director/Dean.
* I am familiar with the latest edition of the *TUN IRB Manual* and I will adhere to the policies and procedures explained therein.
* Student and co-investigators on this project have received adequate training and are knowledgeable about the regulations and policies governing this research.
* I agree to ensure adequate supervision of all research project personnel and to meet with the investigator(s), if different from myself, on a regular basis to monitor study progress.
1. [ ]  I further certify that the proposed research has not yet been done, is not currently underway, and will not begin until IRB approval has been obtained.

My signature below is my representation that I have accurately represented any conflicts of interest that has the potential to adversely affect subjects in this study. I acknowledge that I am required to notify the IRB within 10 business days if a change in my disclosure status occurs. I also attest that all materials submitted are true to the best of my knowledge.

PI Name:

Signature (electronic signature allowed):

Date:

**Checklist for Submission Materials:**

[ ]  A signed electronic copy of the application

[ ]  An electronic copy of the consent/assent form

[ ]  For PI or co-PIs who did not complete CITI training at TUN, an electronic copy of the CITI training certification verification sheet.

[ ]  Electronic copies of all required addenda for your research protocol.

[ ]  Other supporting documentation, such as surveys or instruments.

[ ]  Additional conflict of interest forms for personnel who are directly involved in the treatment or evaluation of research subjects.

***Submit by email to*** [***tun.irb@touro.edu***](file:///%5C%5Cnv1nas01%5CUSERS%24%5CTricia.Catalino%5CMy%20Documents%5CIRB%5CIRB%20Forms%5Ctun.irb%40tun.touro.edu)***. Subject line: ‘IRB Application’ and a few words that identify the proposed study. If someone else (example: student, Co-PI or staff) is submitting the application on behalf of the PI, the submission should be copied to the PI****.*

**NOTE: FAILURE TO COMPLY WITH THE REQUIRED INFORMATION WILL RESULT IN DELAY OF REVIEW AND APPROVAL FOR RESEARCH PROJECTS**

 **IRB Use Only**

IRB application No: TUNIRB

Date of Submission:

[ ] PI is affiliated with TUN [ ] Personnel have CITI training [ ] Research registration form submitted

**Review Status Assigned (provide justification if expedited application promoted to full board review):**

[ ] Expedited [ ] Full Board [ ] Determined Exempt [ ] Determined not HSR

Determined by: Enter here Date of determination:

These assurances are acceptable and this project has adequate protections for participants. This project has been properly reviewed and filed and is in compliance with federal and state law, and University regulation.

1. The Administrative Simplification standards adopted by Health and Human Services (HHS) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) apply to any entity that is

	* a health care provider that conducts certain transactions in electronic form (called here a "covered health care provider").
	* a health care clearinghouse.
	* a health plan.An entity that is one or more of these types of entities is referred to as a "covered entity" in the Administrative Simplification regulations. [↑](#footnote-ref-1)