

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

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# Form to Identify Human Subjects Research and Exempt Research

**Instructions**

* The TUN IRB will determine whether or not your research qualifies for exemption. **Do NOT begin advertising or data collection activities prior to the IRB determination.**
* Follow the instructions 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 make a determination. If an item is not applicable, please indicate with ‘NA’.
* All materials must be typed; handwritten materials will be returned.
* If TUN IRB determines that a study is exempt ([CFR 46.104](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html)), the regulatory requirements for informed consent do not apply. However, research that is exempt from federal regulations is not exempt from ethical standards as outlined in the [Belmont Report](https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf). This means, for example, that if potential subjects will be interviewed in a study that qualifies for exemption, they must be fully informed and free to choose whether to participate.

**Study Title**:

**Principal Investigator (PI) Contact Information**: Principal Investigator (PI) must be TUN faculty, staff, or administration, and 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: |   |

**Training Requirements for Investigators:** CITI training is **required for the PI** and **encouraged for all staff** **involved in exempt human subjects research**, with **r**e-training every three years. The PI is ultimately responsible to adequately train all staff in the protection of human participants in research.

[ ] 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.

## SECTION 1. It is Human Subjects Research by the Federal Definition?

*Answer the questions below:*

1. [ ] YES [ ] NO Will information and/or biospecimens be obtained through **interaction** (i.e., communication or interpersonal contact in any medium)or **interventions** (e.g., manipulation of people or their environment) **with living individuals**, directly or indirectly?

2. [ ] YES [ ] NO Will **identifiable private information** or **identifiable biospecimens** be **used, studied, analyzed or generated** during this study?

**If you answered “NO”** to questions 1 and 2 above, your research does not involve human participants and IRB review is not required. Skip to the information below question 7 for instructions on how to proceed.

**If you answered “YES”** to either question, continue.

1. [ ] YES [ ] NO **Does the proposed study focus directly (and solely) on the specific individuals about whom information is collected**? Examples include oral history, journalism, biography, literary criticism, legal research, or historical research.
2. [ ] YES [ ] NO Does the proposed work consist solely of **public health surveillance activities** that are conducted, supported, requested, ordered required, or authorized by a **public health authority**? Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products).
3. [ ] YES [ ] NO Is the proposed work the collection and analysis of information, biospecimens, or records by or for a **criminal justice agency for activities authorized by law or court order** solely for criminal justice or criminal investigative purposes?
4. [ ] YES [ ] NO Is the proposed work **authorized operational activities** (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions?

**If you answered “YES”** to any question (3-6) above, your research does not fall within the federal definition of human subjects research that requires IRB oversight. Skip to the information below question 7 for instructions on how to proceed.

**If you answered “NO”** to questions 3-6, skip to the next section (Section 2).

1. [ ] YES [ ] NO Is the study a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge?

**If you answer “YES” to question 7, your work is classified as human subjects research, so continue.**

**If “NO”, your study is not classified as research and IRB review is not required by federal law. You do not need to continue with this form, and you do not need to send it to the IRB unless you desire one of the following actions from the IRB:**

[ ]  Get a ‘not human subjects research’ letter from the IRB for documentation required by a funding agency, publishing/conference/education organization, or any other reason. Answer the questions in Section 3 ‘Study Description’ and return this form.

## SECTION 2. Does the study qualify for exempt status?

***Federal regulations specify that certain types of research can never be given exempt status. To determine if your study is exempt, answer the following screening questions.***

8. [ ]  YES [ ]  NO Are participants involved who may not be legally/mentally/cognitively competent?

9. [ ]  YES [ ]  NO Will blood/body fluids be drawn?

1. [ ] YES [ ] NO Is there a **funding agency, law, or government official** who has said you cannot consider this research exempt?
2. [ ] YES [ ] NO Does the proposed work include **prisoners by design**? Do not check YES if prisoners might be incidentally involved**.**

**If any answers to questions 8-11 are “YES”, your research is NOT exempt. Do not submit this form. You need to fill out the non-exempt application.**

**If all answers to questions 8-11 are “NO”, proceed to the checklist below.**

**Exemption Category Checklist. Indicate which exemption category(ies) apply to your research. All planned research activities must fit within an exemption category for the application to be determined exempt.**

[ ]  **Exemption Category 1**: Research… in **established or commonly accepted educational settings**…, which include **normal educational practices**, and are **not likely to adversely impact** students’ opportunity to learn or assessment of educators, such as research on assessing effectiveness of instructional strategies or techniques, curriculum, or classroom management methods.

[ ]  **Exemption Category 2**: Research that only includes interactions involving educational tests, surveys, interviews, or observation of public behavior (including visual/auditory recording) if **one or more** of the following criteria is met (check all that apply).

1. [ ]  Information is recorded so that **subjects cannot be identified** [NOTE: Allowed for research on children only if investigator did not directly participate in observed activities]
2. [ ]  Disclosure of responses would **not reasonably place anyone in danger of criminal or civil liability or be damaging to financial standing, employability, educational advancement, or reputation** [Allowed for research on children only if investigator did not directly participate in observed activities]
3. [ ]  Information is recorded in a way that **subjects can be identified**, but a **limited IRB review is completed**.[This exemption sub-category is NOT allowed for research on children]

[ ]  **Exemption Category 3**: Research involving **benign behavioral interventions** in conjunction with **collection of information verbally, in writing, or through audiovisual recording** if the **adult** subject **prospectively agrees** to the intervention and information collection and if **one or more** of the following criteria applies. ‘Benign’ is defined as brief, harmless, painless, not physically invasive, and not likely to have a lasting impact on subjects, physically or mentally. If deception is involved, the research will be exempt only if adult subjects prospectively agree to be involved in research in which he or she will be unaware of or misled regarding the purpose or nature of the research.

[NOT allowed for research on children]

**Check all that apply** (at least one required to be exempted using Exemption Category 3):

1. [ ]  Information is recorded so **subjects cannot be identified**
2. [ ]  Disclosure of the subjects’ **responses would not reasonably place anyone in danger of criminal or civil liability or be damaging to financial standing, employability, educational advancement, or reputation**
3. [ ]  Information is recorded in a way that **subjects can be identified**. **Limited IRB review is required for this sub-category.**

[ ]  **Exemption Category 4**: **Secondary research** (research using data collected for a purpose separate from the research project being proposed) using **identifiable private information or identifiable biospecimens** when **no consent is required**. **One or more** of the following must be true (check all that apply):

1. [ ] The identifiable information or biospecimens are **publicly availabainle**
2. [ ]  Information is recorded in a way that **subjects cannot easily be identified**, and the investigator agrees **not to contact subjects or attempt to re-identify subjects**
3. [ ]  The investigator’s **use of identifiable information is regulated under HIPAA under certain conditions (45 CFR parts 160 and 164)**
4. [ ]  Research is initiated on behalf of **a federal agency under certain conditions (45 CFR 46.104(d)(4))**

[ ]  **Exemption Category 5**: Research and demonstration projects that are **conducted or supported by a Federal department or agency**, or otherwise subject to the approval of department or agency heads, and that are **designed to study, evaluate, improve, or otherwise examine public benefit or service programs**. This category includes (1) procedures for obtaining benefits or services under those programs, (2) possible changes in or alternatives to those programs or procedures, or (3) possible changes in methods or levels of payment for benefits or services under those programs (e.g., internal studies by Federal employees, studies under contracts or consulting arrangements, cooperative agreements, or grants). Other rules apply (45 CFR 46.104(d)(5))

[ ]  **Exemption Category 6:** Taste and food quality evaluation and consumer acceptance studies, if **one or more** pertain (check all that apply):

1. [ ]  Wholesome foods without additives are consumed
2. [ ]  A food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by listed US governmental entities (FDA, EPA, FSIS of the USDA)

[ ]  **Exemption Category 7**: Storage or maintenance of **identifiable private information or identifiable biospecimens** for **potential secondary research** use when **broad consent** was obtained. **Limited IRB review is required**.

[ ]  **Exemption Category 8**: Secondary research involving the use of **identifiable private information or identifiable biospecimens**. **Limited IRB review is required to ensure that the proposed research is within the scope of the broad consent**. **All** of the following criteria must be met (check all that apply):

* [ ]  Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained.
* [ ]  Documentation of informed consent or waiver of informed consent was obtained.
* [ ]  The investigator does not return individual research results to subjects unless required to do so by law.

## SECTION 3. Study Description

Provide the following information in sufficient detail that the IRB can evaluate whether your study qualifies as HSR or for exemption and/or limited review.

**Estimated duration of study**: *Starting date* **to** *Ending date*

**Research Question and Hypothesis:**

**Participants (inclusion criteria and recruitment methods, if appropriate):**

**Procedures (describe interventions or interactions and data collection methods):**

**Data Confidentiality and Security during Collection, Analysis, and Storage:**

**Risks (include physical, psychological, social, legal, financial, etc.):**

**Benefits (to participants or to society):**

**Check the box and provide the information or complete the tasks immediately below if the following statements are true.**

[ ]  The research is supported in whole or in part by a grant or contract.

 Funding Agency(s), Foundation, or Business:

[ ]  This research will involve IRBs other than TUN IRB (US and International).

 If checked, please specify the other IRBs involved

[ ]  The proposed research study will be conducted at an outside (non-TUN) facility (such as hospitals, clinics, schools, school districts, factories, offices, etc.). The PI must ensure that the outside entity is aware of the proposed research study and has agreed to participate.

Name (s) of the facility or entity:

[ ]  The research requires approval from other TUN compliance committees (i.e., Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC), etc...)

Work cannot start until final approval is received from **all** appropriate committees.

## SECTION 4. Justification of Proposed Exemption Category

**Justify how your study qualifies for exemption by addressing the critical elements (listed below) for the relevant exemption category/categories**

**Exemption category 1**: Focus on setting, educational practices, and likelihood of affecting students’ opportunity to learn or assessment of educators who provide the instruction.

**Exemption category 2**: Explain how at least one criterion is met. If criterion 3, limited review is required (attach form). Attach the test, survey, etc., instrument if one is to be used.

**Exemption category 3**: Focus on subject age, prospective agreement, the type of information collected, the nature of the intervention, whether deception is used and approved, and explain how at least one criterion is met. If criterion 3, limited review is required (attach form). Attach the test, survey, etc., instrument if one is to be used.

**Exemption category 4:** Explain how at least one of the criteria will be met, being specific about where the data will come from and why the criterion applies.

**Exemption category 5:** Explain and provide documentation of the Federal department or agency which approved the work, and how the program being studied provides public benefit or service.

**Exemption category 6:** Document that the food meets one of the two criteria listed, being specific about which one is used.

**Exemption category 7:** Document how the broad consent will be or has been obtained and how the information or samples will be stored. Requires limited review (attach form).

**Exemption category 8:** Document how the informed consent and broad consent were obtained or waived, and if information will be returned to subjects. Requires limited review (attach form).

**Identify the exemption category(ies) number** thatyou believe applies to the project:

**Justify the use of the exemption category using the criteria above**:

[ ] Limited review is required for this project to be exempt (Exemption Categories 2iii, 3iii, 7, 8).

## SECTION 5. Conflicts of Interest

The Touro University Nevada Institutional Review Board (IRB) requires that each **protocol** submitted to the IRB for review must be accompanied by a COI Disclosure Statement for **each person involved in the conduct, design or reporting of research involving human subjects** in the covered study. This IRB Conflict of Interest Statement is independent of any additional forms that may need to be disclosed to other units within the University. See the TUN IRB manual for the entire Conflict of Interest policy. The PI should fill out the form below, and additional forms for co-PIs can be obtained on the TUN IRB web page.

**CONFLICT OF INTEREST STATEMENT**

Name of Person (Investigator/Key Personnel) completing this statement:

Check all boxes that apply to you or any member of your immediate family (spouse, children, parent, in-laws, and siblings) in regards to the study in this IRB application:

[ ]  I/We own equity in the company (stock ownership equal to or greater than 5%, Stock Options, Real Estate, or other ownership interest in any amount) whose drug, procedure, technique, device, or software I am testing.

[ ]  The company holds patent rights to inventions created by me or a member of my family.

[ ]  I/We hold(s) a position of senior management officer or director of the company whose drug, procedure, technique, device, or software I am testing.

[ ]  I/we am/are a scientific advisor or consultant to the company and I/we receive honoraria exceeding $5,000 annually.

[ ]  I/we are aware that if a device, technique, software, or procedure involved in the research is marketed, I/we will get royalty income or other income from the sale of the product.

[ ]  Any other financial interest that may appear to conflict with the protection of subjects or which should be disclosed to subjects in order to secure informed consent.

If you checked any boxes, please explain and provide additional information as needed for the IRB to consider the risks related to your conflict of interest.

[ ]  I have no conflict of interest to disclose.

My signature below is my representation that I have **accurately represented any conflict 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**.

**Signature**:

**Checklist for Submission of Materials:**

[ ]  Completed application

[ ]  Limited review form (if required)

[ ]  Documentation of PI’s CITI training if not completed through an account with Touro University Nevada

[ ]  Signature

[ ]  If claiming exemptions 7 or 8, an electronic copy of the broad and/or study consent/assent forms and solicitations

[ ]  Other supporting documentation, such as instruments to be used for exemption categories 2 or 3.

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

**How to Submit:**

***All submissions (application and the supporting materials) should be emailed to*** [***tun.irb@tun.touro.edu***](file:///%5C%5Cnv1nas01%5CUSERS%24%5CTricia.Catalino%5CMy%20Documents%5CIRB%5CIRB%20Forms%5Ctun.irb%40tun.touro.edu)***.***

***Subject line: ‘Exempt Application’ plus a word or two that describes your study. If someone else (example: student, Co-PI or staff) is submitting the application on behalf of 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 [ ] PI has CITI training [ ] Research registration form submitted

**Review Status Assigned:**

[ ] Not HSR [ ] Exempt [ ] Non-Regulatory Review

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.