

Touro University Nevada Institutional Review Board (IRB)

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**Limited Review Application**

**Instructions**

* Complete the following **only** if you require a limited IRB review, which means you already filled out the exemption determination form and your research is one of the following (check one or more, as applicable):
	+ [ ]  **Exemption Category 2**: Research that only includes interactions involving educational tests, surveys, interviews, or observation of public behavior (including visual/auditory recording) if 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 information is recorded in a way that subjects can be identified. Limited IRB review is required for this sub-category.
	+ [ ]  **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.
* If an item is not applicable, please indicate with ‘NA’.
* All materials must be typed; handwritten materials will be returned.
* Enter information in shaded text boxes. Please provide complete information, understanding that the IRB must know enough about the project to understand how the data are kept.

**Study Title**:

**Limited Review**

**All exemption categories:**

1. Explain how you will protect the information or biospecimens from data breaches. As applicable, include information about the following:
	1. De-identification of the data or specimens (including ease of re-identification):
	2. Use of the information or specimens (where, how much, by whom):
	3. Retention period for the information or specimens, and how will 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/publication of the study, and many publications require five years.
	4. Security controls in place to protect the integrity and confidentiality of the information or specimens (e.g., locked office, locked cabinet, restricted area, use of master list separate from data, restricted computer, password protected, encrypted firewall, etc.):
	5. Potential risk of harm to individuals if information is lost, stolen, compromised, or otherwise misused:
2. **IF** the study involves any individuals from vulnerable populations, such as children, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, what **additional safeguards** have been included in the study to protect the rights and welfare of these subjects?

1. Exemption Categories 7 or 8 only: Check the box to affirm, and answer or perform the following:
	1. [ ]  **Attach to your application a copy of the broad consent form** which was or will be used to gain consent.
	2. [ ]  Broad consent was or will be obtained from all subjects in this proposed study.
		1. Describe how broad consent was obtained (who approached and assisted potential subjects):

* 1. [ ]  I will use the IRB-approved consent form and maintain records for all consent responses. I understand that **the IRB may request an inspection of these materials** at any time during the study.
	2. Explain how the subjects were or will be **recruited** to seek broad consent (mail, telephone, email).

* + 1. [ ]  **Attach a copy of the solicitation**.
1. **IF you are claiming exemption under Exemption Category 8, answer or perform the following**:
	1. [ ]  If the primary study consent form and solicitation were separate from the broad consent form and solicitation, attach the primary study consent form and solicitation to your application.
	2. [ ]  Primary study consent was or will be obtained from all subjects in this proposed study.
	3. Briefly explain how your study fits within the scope of the broad consent.
	4. [ ]  YES [ ]  NO Is there anything in your study which may be shocking to of fundamentally inconsistent with prevailing community attitudes among the population that provided broad consent? If yes, please explain.
	5. [ ]  YES [ ]  NO Do you plan to return individual results to any participants in the study?
		1. If yes, you are only eligible for exemption if you are legally required to return the results. If you answered yes, explain and provide appropriate documentation if you cite legal obligation.

 **IRB Use Only**

IRB application No: TUNIRB

Date of Submission:

**Limited review:**

[ ] Approved (expedited) [ ] Approved (full board) [ ] Not approved (full board)

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.