Touro University Nevada

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

874 American Pacific Dr.

Henderson, NV 89014

702-777-8687

tun.irb@tun.touro.edu

**Addendum 1: Expedited Categories and Determinations**

|  |  |
| --- | --- |
| **Study Title:** |  |

***Applicability***

* **Use this form if you have already checked whether your study qualifies as human subjects research, and that it does not qualify for exempt status. Use the Exemption Determination form to do so.**
* **Research activities can be reviewed by expedited review if they are (1) no more than minimal risk to human participants, and (2) completely encompassed by categories specified by federal law (45 CFR 46.110, 21 CFR 56.110). The activities listed should not be deemed to be of minimal risk simply because they are included on this list.**
* **The categories in this list apply regardless of the age of participants, except as noted.**
* **The expedited review procedure may not be used where participants and/or their responses would reasonably be placed at risk of criminal or civil liability or damage to their financial standing, employability, insurability, reputation, or otherwise stigmatize them. If so, reasonable and appropriate protections must be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.**
* **The expedited review procedure may not be used for classified research [[1]](#footnote-1)involving human participants.**
* **The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless to expedited and full IRB reviews.**

Answer Section 1, check the applicable research categories in Section 2 and submit with Non-Exempt Application.

**SECTION 1. Is the study more than minimal risk?**

1. Yes  No Does this research activity present more than minimal risk[[2]](#footnote-2) to the participants?

If **‘No’, continue to section 2.** If **‘Yes’,** your study does not meet expedited review criteria. **You don’t need** this addendum. Complete the application form for **non-exempt review**[[3]](#footnote-3)**.**

Indicate which of the following categories are applicable to your research by checking the boxes below.

**SECTION 2. Does the study fit within an expedited category or categories?**

* + - 1. **Clinical studies of drugs and medical devices** only when condition (a) **Or** (b) is met.
         1. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. **Note:** *Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.*
         2. Research on medical devices for which **one** of the two conditions apply (**check one or both**):

An investigational device exemption application (21 CFR Part 812) is not required.

The medical device is cleared or approved for marketing and the medical device is being used in accordance with its cleared or approved labeling.

1. **Collection of blood samples** by finger stick, heel stick, ear stick, or venipuncture if **one** of the two following conditions are met (**check one or both**):

From healthy, non -pregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week.

From other adults and children considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml total or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

1. **Prospective collection of biological specimens** for research purposes by noninvasive means.

**Examples including and not limited to:**

(a) Hair and nail clippings in a non-disfiguring manner

* 1. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction
  2. Permanent teeth if routine patient care indicates a need for extraction
  3. Excreta and external secretions (including sweat)
  4. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue
  5. Placenta removed at delivery
  6. Amniotic fluid obtained at the time of rupture of the membrane prior to or during lab
  7. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques
  8. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washing
  9. Sputum collected after saline mist nebulization.

1. **Collection of data through noninvasive procedures** (**not involving general anesthesia or sedation**) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (*Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications*.)

**Examples (and not limited to):**

(a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy;

(b) Weighing or testing sensory acuity;

(c) Magnetic resonance imaging;

(d) Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography;

(e) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(f) Vaginal swabs that do not go beyond the cervical os (opening of the cervix);

(g) Rectal swabs that do not go beyond the rectum; and

(h) Nasal swabs that do not go beyond the nares

1. **Research involving** materials (**data, documents, records, or specimens**) that have

been collected, or will be collected **solely for non research purposes** (such as medical treatment or diagnosis). For this category, addendum 9 is required. (*Note: Some research in this category may be exempt (exemption category 4) from the HHS regulations for the protection of human subjects: 45 CFR 46.101(b) (4). This listing refers only to research that is not exempt.)*

1. **Collection of data** from voice, video, digital, or image **recordings** made for **research purposes** other than transcription. (*Note: Some research in this category may be exempt (exemption category 3) from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)*
2. **Research on individual or group characteristics** or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing **survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies**. (*Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101 (b) (2) and (b) (3). This listing refers only to research that is not exempt.*)

1. Classified Research”: Research for which knowledge of methods and/or results are restricted to individuals who have U.S. government security clearances. [↑](#footnote-ref-1)
2. 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(i) [↑](#footnote-ref-2)
3. Applications that require full board review have the potential for more than minimal risks to subjects (physical, psychological or social) and/or those that have special populations consent considerations (research on Native Americans, prisoners, persons who are not legally competent, ethnic considerations). [↑](#footnote-ref-3)