**Hardin-Simmons University Institutional Review Board**

**Expedited Review Application**

Instructions: Complete the Application and send as an email attachment to [IRB@hsutx.edu](mailto:IRB@hsutx.edu). Include all appendix materials, including but not limited to consent forms, surveys, documentation of training, solicitation materials, and Vulnerable Populations Consideration Form (if applicable), and the *signed* Investigator Assurance form.

**Section I- Project and Researcher Information**

Title of Proposed Project:

Principal Investigator:

Role: HSU Faculty

Non-HSU Faculty

HSU graduate student (Faculty Advisor MUST be identified)

HSU undergraduate student (Faculty Advisor MUST be identified)

Phone:       Email:

Institution (if not HSU):       Department:

Faculty Advisor (if applicable):       Department:

Phone:       Email:

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| --- | --- | --- |
| Co-Investigators | Department/Affiliation | Date Completed Ethics Training |
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This project will be conducted On Campus Off Campus

If off campus, please indicate where:

Do you have permission to conduct the study at this site?  Yes No

Person of Contact at Off-campus site:       Phone:

Will this site require their own IRB approval or will they accept approval from the HSU IRB?

Yes  No

Is this project being funded by an outside agency? Yes No

If yes, please indicate which agency:

**Section II- Categories of Research for Expedited Review**

Research activities that may be reviewed through an Expedited Review must not present more than a minimal risk to human subjects. The expedited review procedure may not be sued where identification of the subjects and/or their responses would reasonably place them a risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable protections are implemented.

Please select the category of research that applies to your research:

**Category 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.
2. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling

**Category 2**- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

1. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, 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; or
2. from other adults and children [[2]](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html" \l "footnote2), 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 subjects, the amount drawn may

not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

**Category 3-** Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) 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; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) 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; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

**Category 4**- 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: (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.

**Category 5**- Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

**Category 6**- Collection of data from voice, video, digital, or image recordings made for research purposes

**Category 7**- 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. (Some research in this category may be exempt; this listing refers only to research that is not exempt).

**Category 8**- Continuing review of research previously approved by the convened IRB as follows:

1. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
2. where no subjects have been enrolled and no additional risks have been identified; or
3. where the remaining research activities are limited to data analysis.

**Section III- Research Proposal**

Please answer the following with sufficient detail so that reviewers will be able to determine the exemption that applies.

1. State the specific purpose of your research study.
2. Describe the need for your research study.
3. Describe how subjects will be recruited for your study.
   1. Will your research include any of the following special populations that require additional considerations? (Check those that apply)

Children

Pregnant Women or Fetuses

Neonates

Decisionally Impaired

Prisoners

Students

If checked, then complete the Vulnerable Populations Considerations form.

* 1. Will participants be compensated?  Yes No

If yes, please describe the compensation:

* 1. Will participants be screened prior to consent?  Yes No

If yes, please describe the screening criteria, any information that will ber recorded, and how the information will be managed if the prospective subject declines participation or withdraws.

* 1. Do you expect to enroll anyone whose first language is not English or who is not fluent in English?  Yes  No

If yes, then please note that a translated informed consent form may be required depending on your target population.

1. Explain your experimental methods in a step-bey-step manner. Provide as appendices examples of surveys, photos, illustrations, etc. that will aid the IRB members.
   1. Will you be using private information that is protected by HIPAA or FERPA?

Yes No

If yes, then please attach the HIPAA/ FERPA form.

1. Describe the alternative treatment the experimental or control groups may receive.
2. Describe how the data will be analyzed using quantitative or qualitative analysis techniques.
   1. How will the date be coded?
   2. Where will the data be stored?
   3. When will the data be destroyed:
   4. What is your estimated sample size?
3. Will data be shared with anyone outside of the research team (ex. statistician, consultant)?

Yes No

If yes, please describe which data will be shared, whether it is identifiable or de-identified, or a limited data set. Describe how the data will be transferred.

**Section IV – Risk Assessment**

1. List the potential physical risks associated with participation in this study and check the estimated likelihood

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| --- | --- | --- | --- |
| Potential Physical Risk |  |  |  |
|  | Likely | Less likely | Rare |
|  | Likely | Less likely | Rare |
|  | Likely | Less likely | Rare |
|  | Likely | Less likely | Rare |
|  | Likely | Less likely | Rare |

1. Describe how these potential physical risks will be minimized.
2. List the potential **minimal** pychological risks associated with participation in this study and check the estimated likelihood

|  |  |  |  |
| --- | --- | --- | --- |
| Potential Psychological Risk |  |  |  |
|  | Likely | Less likely | Rare |
|  | Likely | Less likely | Rare |
|  | Likely | Less likely | Rare |
|  | Likely | Less likely | Rare |
|  | Likely | Less likely | Rare |

1. Describe how these potential **minimal** psychological risks will be minimized.
2. What are the benefits of the study:
   1. To the participants:
   2. To broader knowledge and society:

**Section V- Conflicts of Interest**

Does anyone associated with the research team have a conflict of interest?  Yes  No

If yes, please identify the team member, the conflict, and plans to manage the conflict?

**APPENDICES**

Attach all necessary documents in support of your application.

*Signed* Investigator Assurance form (required)

Research training for ALL research team members (required)

Vulnerable Populations Considerations Form

Informed Consent Form

HIPAA/FERPA Form

Surveys

Other (please specify):