

Request for Review of Expedited Category Research Project

IRB # _____ (Staff Use Only)

Research activities that (1) present **no more than minimal risk** to human subjects and (2) involve **only** procedures listed in one or more of the categories below in Section One may be reviewed by the IRB through the expedited review procedure. *Minimal risk means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

If you believe that your research falls into one of the following categories, please indicate which category or categories you believe is or are appropriate. The IRB Chairperson (or designee) will review your research to determine if expedited review is warranted and if approval can be granted. If you have any questions, you may contact the OPHS Office at 817-735-0409.

Title of Research Activity:

Name of Principal Investigator (Faculty Member):

Department/Program:

Categories Eligible for Expedited Review: (You can check more than one category, as needed.)

Category 1: <input type="checkbox"/> Clinical studies of drugs and medical devices ONLY when condition (a) or (b) is met: _____ →	Check if applicable: <input type="checkbox"/> (a) Research on drugs for which an investigational new drug application is not required.	Check if applicable: <input type="checkbox"/> (b) Research on medical devices for which: (i) an investigational device exemption application is NOT required OR (ii) medical device is cleared/ approved for marketing and it is being used in accordance with its cleared/approved labeling.	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.
Category 2: <input type="checkbox"/> Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from: _____ →	Check applicable box: <input type="checkbox"/> (a) Healthy, non-pregnant adults who weigh at least 110 pounds. Contact OPHS Staff for criteria	<input type="checkbox"/> (b) Other adults and <u>children*</u> , 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. Contact OPHS Staff for criteria	Indicate volume and frequency of blood draws. _____ _____ _____
Category 3: <input type="checkbox"/> Prospective collection of biological specimens for research purposes by noninvasive means. _____ →	Check all that apply: <input type="checkbox"/> Placenta removed at delivery <input type="checkbox"/> Deciduous teeth taken during exfoliation or routine patient care <input type="checkbox"/> Permanent teeth if routine patient care indicates a need for extraction <input type="checkbox"/> Excreta and external secretions (including sweat) <input type="checkbox"/> Uncannulated saliva	<input type="checkbox"/> Amniotic fluid obtained at the time of membrane rupture prior to or during labor <input type="checkbox"/> Supra- and subgingival dental plaque and calculus. [Collection is not more invasive than routine prophylactic teeth scaling and it is done according to accepted techniques] <input type="checkbox"/> Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings	<input type="checkbox"/> Hair and nail clippings in a non-disfiguring manner <input type="checkbox"/> Sputum collected after saline mist nebulization If research does not include any of the given specimen collections, give a brief description: _____ _____
Category 4: <input type="checkbox"/> Collection of data through noninvasive procedures routinely done in clinical practice. Where medical devices are employed, they must be cleared/approved for marketing. _____ →	Check all that apply: <input type="checkbox"/> Physical sensors applied to the body surface or at a distance AND do not involve input of significant amounts of energy into the subject or an invasion of subject's privacy <input type="checkbox"/> Weighing or testing sensory acuity <input type="checkbox"/> Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography	<input type="checkbox"/> Magnetic resonance imaging (MRI) <input type="checkbox"/> Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing (appropriate to age, weight, and health of the individual) If research procedures do not include any of the given procedures, please enclose a brief description: _____ _____	NOTE: <i>Studies intended to evaluate the safety and effectiveness of a medical device are NOT eligible for expedited review, including studies of cleared medical devices for new indications.</i> <i>To qualify for this subcategory, the study CANNOT involve general anesthesia, sedation or procedures with X-rays or microwaves (such as CT/CAT Scan, etc).</i>

Category 5:	Check if applicable: <input type="checkbox"/> (a) Have already been collected for some other purpose ,	Check if applicable: <input type="checkbox"/> (b) Will be collected for non-research purposes (such as medical treatment or diagnosis)	Does the research protocol fit under this category and is condition (a) or (b) met? <input type="checkbox"/> Yes <input type="checkbox"/> No
Category 6:	Check all those applied for research study: <input type="checkbox"/> Voice <input type="checkbox"/> Video <input type="checkbox"/> Digital <input type="checkbox"/> Image	Will subjects be informed about the recordings? <input type="checkbox"/> Yes <input type="checkbox"/> No	Include in the protocol a detailed description of how, when and what extent subjects will be recorded. In addition, describe data storage and confidentiality of the recorded data.
Category 7:	Check if applicable: <input type="checkbox"/> (a) Individual or group characteristics or behavior (research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior)	Check if applicable: <input type="checkbox"/> (b) Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.	Does the research protocol fit under this category? <input type="checkbox"/> Yes <input type="checkbox"/> No

Recall: 'Children' in (b) above is defined in the HHS regulations as "persons who have not attained the legal age for consent for treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted" [45 CFR 46.402(a)]. In Texas, this is typically under 18 years old.

Does the study involve storage or banking of human specimens or identifiable private information for use in future studies?
Yes No

Does the study involve genetic testing or DNA/RNA extraction? Yes No

If any of the answers to the above questions are yes, please ensure that this information is discussed in the informed consent form (if applicable).

Maximum number of subjects recruited for participation: _____ Age range of the subjects recruited: _____

Will this study include any of the following subject pools?

- Pregnant Women Cognitively Impaired Prisoners Genetics Military Personnel
 Minors (<18) UNTHSC employees Fetuses UNTHSC students Patients
 Economically Disadvantaged (homeless, evacuees)

How will you recruit and correspond with subjects for this study?

- Telephone (please submit telephone script with your submission) Referrals
 Advertising (newspaper, email, Daily News, website, brochure, radio, etc.) Other

Will subjects be compensated for their participation? Yes No

Document payment schedule in the protocol synopsis, and if applicable, the informed consent.

Will any of the following instruments or methods be used? **Check all that apply. Include copies of these materials with your submission:**

- Interview (attach script/guide) Surveys/Questionnaires
 Standardized (published) tests or assessments Focus Group (attach guide)

Does the study involve (**check all that apply**):

- Painful or aversive stimuli False Feedback Emotional Stress
 Withholding of critical information Deception False Information

List all OTHER KEY PERSONNEL associated with this project (co-investigators, study coordinator, study physician, etc.)

Is there a **STUDENT INVESTIGATOR** associated with this project? Yes No

Name of student investigator: _____

Email address of student investigator: _____ Contact number of student investigator: _____

Role/ Responsibilities: _____

CO-INVESTIGATOR:

Name & Degree: _____ Department: _____

Role/ Responsibilities: _____

CO-INVESTIGATOR:

Name & Degree: _____ Department: _____

Role/ Responsibilities: _____

STUDY COORDINATOR:

Name & Degree: _____ Department: _____

Role/ Responsibilities: _____

When submitting your Expedited research to the OPHS Office, please submit 2 complete packets with the following information contained within EACH packet.

If the IRB materials you submit fail to capture the most necessary information for a complete/thorough review, or if the application packet is incomplete, your IRB materials will be sent immediately back to you. Please ensure that the following information is submitted in each packet for a more streamlined "speedy" review of your research project. In addition, please keep in mind that the review process takes time, and research may not be initiated until the application has been approved.

- (1) IRB Application Form (with original PI signature on one copy)
- (2) Protocol Synopsis
- (3) Informed Consent Form (if applicable)
- (4) Conflict of Interest Form
- (5) CITI Training Certificates

If applicable:

- (6) Grant Application
- (7) Recruitment Materials (flyers, emails, advertisements, etc.)
- (8) Surveys/Questionnaires
- (9) Telephone scripts/oral scripts
- (10) Assent Forms/Parental Permission Forms
- (11) Research Agreements
- (12) Letters of permission/cooperation, and/or approvals from other IRBs

Principal Investigator Signature

Date