## Request for Review of Expedited Category Research Project

**IRB Project # _____**
**(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 Chair (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 North Texas Regional IRB at 817-735-0409.

***Title of Research Activity:***

***Name of Principal Investigator (Faculty Member):***

***Department and Institution (UNTHSC or JPS):***

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

| ***Category 1:*** | **Check if applicable:** | **Check if applicable:** | **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. |
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| ☐ **Clinical studies of drugs and medical devices ONLY when condition (a) or (b) is met**: → | ☐ (a) Research on drugs for which an investigational new drug application is not required. | ☐ (b) Research on medical devices for which:<br>(i) an investigational device exemption application is NOT required **OR**<br>(ii) medical device is **cleared/ approved** for marketing and it is being used in accordance with its cleared/approved labeling. | |
| ***Category 2:*** | **Check applicable box:** | ☐ (b) 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.<br>**Contact IRB Staff for criteria** | **Indicate volume and frequency of blood draws.**<br>_____<br>_____<br>_____<br>_____ |
| ☐ **Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from:** → | ☐ (a) Healthy, non-pregnant adults who weigh at least 110 pounds.<br>**Contact IRB Staff for criteria** | | |
| ***Category 3:*** | **Check all that apply:** | ☐ Amniotic fluid obtained at the time of membrane rupture prior to or during labor<br>☐ 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]<br>☐ Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings | ☐ Hair and nail clippings in a non-disfiguring manner<br>☐ Sputum collected after saline mist nebulization<br>**If research does not include any of the given specimen collections, give a brief description:**<br>_____<br>_____<br>_____ |
| ☐ **Prospective collection of biological specimens for research purposes by noninvasive means.** → | ☐ Placenta removed at delivery<br>☐ Deciduous teeth taken during exfoliation or routine patient care<br>☐ Permanent teeth if routine patient care indicates a need for extraction<br>☐ Excreta and external secretions (including sweat)<br>☐ Uncannulated saliva | | |
| ***Category 4:*** | **Check all that apply:** | ☐ Magnetic resonance imaging (MRI)<br>☐ Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing (appropriate to age, weight, and health of the individual)<br>**If research procedures do not include any of the given procedures, please enclose a brief description:**<br>_____<br>_____<br>_____ | **NOTE:** *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.*<br>*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).* |
| ☐ **Collection of data through noninvasive procedures routinely done in clinical practice. Where medical devices are employed, they must be cleared/approved for marketing.** → | ☐ 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<br>☐ Weighing or testing sensory acuity<br>☐ Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography | | |

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| ***Category 5:***<br>☐ **Research involving materials (data, documents, records, or specimens) that:** → | **Check if applicable:**<br>☐ (a) Have already been collected for some **other purpose**, | **Check if applicable:**<br>☐ (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?**<br>☐ Yes ☐ No |
| ***Category 6:***<br>☐ **Collection of data from voice, video, digital, or image recordings made for research purposes** → | **Check all those applied for research study:**<br>☐ **Voice** ☐ **Video**<br>☐ **Digital** ☐ **Image** | **Will subjects be informed about the recordings?**<br>☐ Yes ☐ 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:***<br>☐ **Research where condition (a) or (b) is applicable:** → | **Check if applicable:**<br>☐ (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:**<br>☐ (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?**<br>☐ Yes ☐ 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) ☐ JPS employees ☐ Other: _____

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: _____

***If the IRB materials you submit fail to capture the most necessary information for a complete/thorough review, your project will not be reviewed. 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 PI's signature)
(2) Protocol Synopsis
(3) Conflict of Interest Form
(4) CITI Training Certificates

*If applicable:*

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

_____ _____

**Principal Investigator Signature** **Date**

**SUBMISSION:**

- Please submit all documents in IRBNet (www.irbnet.org) by creating a new account and then selecting "Create New Project" in the left-hand navigation bar. - Please note the following:

-THE PRINCIPAL INVESTIGATOR MUST HAVE FULL ACCESS TO THE IRBNET PROTOCOL PACKAGE IN ORDER FOR IT TO BE REVIEWED BY THE IRB.

- Please be sure to use a very descriptive file name for each document submitted as a pdf or word.doc file. Example: "MMSE scale" is much better than "Scale 1"…. "Recruiting flyer" is better than "Ad 1", and so forth.

- Refer to the "Read Me First" document located in IRBNet under "Forms and Templates" for more guidance.

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