UNIVERSITY OF TENNESSEE GRADUATE SCHOOL OF MEDICINE
INSTITUTIONAL REVIEW BOARD
IRB EXPEDITED REVIEW

I. PURPOSE

To document the procedures used by University of Tennessee Graduate School of Medicine Institutional Review Board (UTGSM IRB) to review and evaluate research projects submitted for expedited review.

II. SCOPE

This SOP applies to the IRB Chairperson, IRB members, IRB Director or designee.

Personnel Responsible:

IRB Chairperson, IRB members, IRB Director or designee.

III. BACKGROUND

The Department of Health and Human Services and the Food and Drug Administration have established, and published in the Federal Register, a list of categories of research that may be approved by the IRB through the expedited review process. The list will be amended, as appropriate, through periodic updates in the Federal Register.

Research Categories that Qualify for Expedited Review

1. 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. (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.)
   b. Research on medical devices for which:
      (i) An investigational device exemption application 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.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   a. 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
   b. from other adults and children[2], 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.

3. Prospective collection of biological specimens for research purposes by noninvasive means.
   Examples:
   a. hair and nail clippings in a non-disfiguring 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.

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 (MRI);
   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.
5. 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).
6. Collection of data from voice, video, digital, or image recordings made for research purposes.

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. (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.)
8. Continuing review of research previously approved by the convened IRB as follows:
   a. 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
   b. where no subjects have been enrolled and no additional risks have been identified; or
   c. where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Research activities with human subjects involving no more than minimal risk and involving one or more of the categories defined above may qualify for expedited review. In addition, minor changes in previously approved research during the period (of less than one year) for which approval is authorized may qualify for expedited review.

Reviewers may exercise all the authority of the IRB except to disapprove the research. The reviewer may decide that the application does not meet expedited review requirements or that the application needs to undergo review by the full Board for other specific reasons.

The Department of Health and Human Services and Food and Drug Administration may restrict, suspend, or terminate an institution's or IRB's use of the expedited review procedure when necessary to protect the rights or welfare of subjects.

In Accordance With:

21 CFR 56.110; 45 CFR 46.110; OHRP Guidelines for Formulating Written IRB Policies and Procedures, 2011; OHRP Guidance on Continuing Review, 2010.

FDA Guidance for Institutional Review Boards and Clinical Investigators 1998 Update located at
https://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm#IRBProcedures

OHRP Guidance located at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html

Compliance with this policy also requires compliance with state or local laws or regulations that provide additional protections for human subjects.

IV. PROCEDURES

1. Upon receipt of a protocol for determination of expedited review, the following procedures will be utilized:
   i. The Director in consultation with the Chairperson will determine whether the application qualifies for expedited review.
   ii. If determined to be expeditable, the IRB administrative staff will assign an IRB number and pre-review the application for completeness and accuracy.
   iii. The Chairperson or designee is assigned the responsibility for reviewing the application.
   v. The assigned reviewer will review the application and consent documents according to applicable ethical principles and federal regulation.

2. If the reviewer approves the expedited application,
   i. The results of the protocol review will be summarized in a letter to the principal investigator.
   ii. The original will be sent to the investigator through iMedRIS.

3 If it is decided that the research may not be approved using the expedited review process, the investigator will be notified of the determination.

4. Revisions in previously expedited approved research during the period of less than one year can qualify for expedited review. Such revisions include, but are not restricted to:
   i. Amendments or modifications to a previously approved protocol/project descriptors that provide for a minor administrative or procedural change that does not alter the risk to subjects.
   ii. Minor amendments or revisions to a previously approved consent form.
   iii. Changing the investigator who will conduct a previously approved (within one year) study protocol, provided such individual has standing as a faculty member, resident or fellow, and is otherwise qualified to conduct the study.
   iv. Non-English translations of informed consent documents submitted after initial approval.

5. The IRB Director or designee will prepare any correspondence for the investigator regarding the IRB's review.

6. The full board will be advised of all expedited application approvals at a convened meeting.

7. Documentation of IRB review and approval will be included in IRB minutes.