

**UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER
INSTITUTIONAL REVIEW BOARD
IRB EXPEDITED REVIEW OF NEW STUDIES**

I. PURPOSE

To document the procedures used by University of Tennessee Health Science Center Institutional Review Board to review and evaluate submissions under expedited review procedures.

II. SCOPE

This SOP applies to the IRB administrative staff, Board members, and investigators.

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 reviewed by the IRB through an expedited review procedure. Research activities with human subjects involving no more than minimal risk and involving only one or more of the categories of qualifying procedures may qualify for expedited review. The list will be amended, as appropriate, through periodic re-publication in the Federal Register.

A Chairman or other senior member of the IRB may conduct an expedited review of a study. The reviewer 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.

Conditions for IRB Use of Expedited Review

<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm118099.htm>

Expedited Review: Categories of Research that may be Reviewed Through an Expedited Review Procedure

<http://www.hhs.gov/ohrp/policy/expedited98.html>

Guidance on Expedited Review Procedures

<http://www.hhs.gov/ohrp/policy/exprev.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. Investigators must submit the initial Expedited application via the Form 1 Application within iMedRIS with appropriate signature(s) and with all the appropriate attachments such as,
 - a. protocol;
 - b. surveys, questionnaires, data collection instruments;
 - c. package insert;
 - d. informed consent document.
2. Upon receipt of the Form 1 Application, the following procedures will be utilized:
 - a. The IRB Director or other qualified IRB administrative staff member will assign an IRB number to the application.
 - b. The Form 1 application is forwarded to the electronic queue of an IRB analyst for determination of whether the application qualifies for expedited review.
 - c. If the study qualifies for expedited review, a Chair or other experienced reviewer designated by the Director is assigned the responsibility for reviewing the application. No IRB member will participate in the expedited review of research in which the member has a conflict of interest.

- d. If Methodist Le Bonheur Healthcare is included as a research site, a representative from Methodist Le Bonheur Healthcare Research Administration will be assigned as a secondary reviewer.
 - e. The assigned reviewer(s) will review the application, study documents (if any), and consent documents according to applicable ethical principles, federal regulations and local IRB policies, and will complete the reviewer's form within iMedRIS.
 - f. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited review procedure set forth in 45 CFR 46.108(b).
3. Based on the review of the information submitted, the IRB will take one of the following actions:
 - a. Approve the expedited application without provisos;
 - b. Approve the expedited application pending response to administrative provisos;
 - c. Defer approval of the application pending resolution of substantive conditions requiring further review; or
 - d. The application will be re-assigned exempt or full board review status.
4. If the reviewer approves the expedited Form 1 application:
 - a. The results of the protocol review will be summarized by an IRB Regulatory Specialist, IRB Administrator or other qualified IRB administrative staff person in a letter to the principal investigator. The approval letter will include the approval period for the study.
 - b. A copy of the correspondence will be placed in the electronic IRB file for the study.
 - c. The letter will be mailed electronically to the investigator, the study contact(s), and the appropriate Research Administrative Specialist (RAS) (if applicable).
5. If an application is approved pending response to administrative provisos, the assigned IRB analyst will collate the comments of the reviewer(s) and administrative staff and send them to the investigator, study contact(s), and RAS (if appropriate) in a letter via iMedRIS. The investigator must respond to the proviso letter within 60 days from the time the letter is issued. If the investigator misses the deadline, the IRB will consider the study inactive and reactivation may require re-submission of the original application for review.

6. If an application is deferred, the assigned IRB analyst will collate the comments of the reviewer(s) and administrative staff and send them to the investigator, study contact(s), and RAS (if appropriate) in a letter via iMedRIS. Subsequent review and approval by a Chair or other experienced reviewer designated by the Director will be required.
7. 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 following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
8. The categories in this list apply regardless of the age of subjects, except as noted.
9. The expedited review procedure will not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
10. The expedited review procedure will not be used for classified research involving human subjects.
11. Categories of research that qualify for expedited review are:
 - 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 (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.)
 - b. 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.

- 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, 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 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.

- 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.

- 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). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects previously found at 45 CFR 46.101(b)(4) which is now found at [45 CFR 46.104\(d\)\(4\)](#) under the revised Common Rule. This listing refers only to research that is not exempt.)
- 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 previously found at 45 CFR 46.101(b)(2) and (b)(3) which is now found at [45 CFR 46.104\(d\)\(2\)](#) and (d)(3) under the revised Common Rule. This listing refers only to research that is not exempt.)
- 8) For information regarding the expedited review procedure for continuing review, see SOP: Continuing Review of Research.
- 9) Research for which limited IRB review is a condition of exemption.
12. For information regarding the expedited review procedure for revisions, see SOP: Revisions in Approved Studies.
13. A copy of all correspondence concerning the expedited review will be retained in the IRB files for the study.

14. Documentation of IRB review and approval, approval pending response to administrative provisos, and deferrals will be placed on the electronic meeting agenda and sent electronically to Board members before the Board meeting each applicable week when the agenda is finalized. Also included will be the satisfaction by the investigator of conditions for IRB approval of research reviewed under an expedited review procedure, including the date when an IRB Chair, Director, Regulatory Specialist, IRB Administrator, other qualified IRB administrative staff person, or other designated IRB senior member determines that all conditions of IRB approval have been satisfied, the date when initial approval becomes effective, and the date by which continuing review must occur.
15. A copy of the finalized agenda is provided to the Vice Chancellor for Research in fulfillment of the regulatory requirement to communicate the IRB's findings and actions to the institution in writing (previously found at 45 CFR 103(a)(4)(i), now found at 45 CFR 46.108(a)(3)(i) in the revised Common Rule).