

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

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 Chairperson, IRB members, and 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 reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, through periodic re-publication in the Federal Register.

Research activities with human subjects involving no more than minimal risk and involving one or more of the categories defined in the CFR 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.

The 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.

OHRP Guidance on the Use of Expedited Review Procedures located at
<http://www.hhs.gov/ohrp/humansubjects/guidance/exprev.htm>.

Current Expedited Review Categories located at
<http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>.

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:
 - a. The IRB Director or designee 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, the Chairman or other senior member of the IRB is assigned the responsibility for reviewing the application.
 - d. The assigned reviewer(s) will review the application and consent documents according to applicable ethical principles, federal regulations and local IRB policies, and will complete the reviewer's form.
2. If the reviewer approves the expedited Form 1 application:
 - a. The results of the protocol review will be summarized by an IRB analyst in a letter to the principal investigator.
 - 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.
3. If it is decided that the research cannot be approved on an expedited basis:
 - a. The investigator will be notified electronically of the determination.
 - b. IRB Director or designee will place the correspondence in the electronic IRB file for the study.
 - c. The application will be assigned full Board review status.
4. Revisions in previously approved research during the period prior to the approval expiration date may qualify for expedited review. Permissible expedited revisions include, but are not restricted to:
 - a. Amendments or modifications to a previously approved protocol/project descriptors that provide for a minor administrative or procedural change that does not alter or that decreases the risk to subjects.
 - b. Minor amendments or revisions to a previously approved consent form.

- c. Changes of 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.
 - d. Non-English translations of informed consent documents submitted after initial approval.
5. The IRB Director or designee will prepare any correspondence regarding the IRB's review and give to the Chairman or other senior IRB member who conducted the assessment for review and signature prior to transmission to the investigator.
6. The full board will be advised of all expedited application approvals at the next regularly scheduled meeting.
7. Documentation of IRB review and approval will be included in the IRB minutes.