

**UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER  
INSTITUTIONAL REVIEW BOARD  
PROCEDURES FOR FULL BOARD REVIEW**

**I. PURPOSE**

This document outlines the required elements of Institutional Review Board (IRB) procedures concerning full board review of studies submitted to the University of Tennessee Health Science Center Institutional Review Board under Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR 46 and Food and Drug Administration (FDA) regulations at 21 CFR 50 and 56.

**II. SCOPE**

This SOP applies to all IRB administrative staff and board members.

**Personnel Responsible:**

IRB members and administrative staff

**III. BACKGROUND**

UTHSC IRB has the authority to perform the following functions under federal regulations for the protection of human subjects:

- Conduct initial and continuing review of any research activities involving use of a drug or device, or other medical, behavioral, psychosocial, or educational interventions involving human subjects
- Report findings and actions to the investigator and sponsor, as applicable
- Determine which studies need more than annual review
- Determine which studies need verification from sources other than the investigator that no material changes have occurred since previous IRB review
- Insure prompt reporting to the IRB of changes in research activities
- Insure that changes in previously approved human subject research are not initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subject
- Insure prompt reporting to the IRB of unanticipated problems involving risks to subjects or others, or any serious or continuing noncompliance with federal regulations or the requirements or determinations of the IRB
- Review and ensure the adequacy of the informed consent document and process
- Review and approve both HIPAA authorization language incorporated into the informed consent document and requests for waiver of the HIPAA authorization requirements
- Suspend or terminate the research or revoke approval of any study under its review.

Review of research occurs at convened meetings at which a majority of the voting members of the section are present, including at least one member whose concerns are non-scientific. Approval by UTHSC IRB does not constitute permission from the host institution to initiate research studies.

**In Accordance With:**

45 CFR 46.103(b)(4) and (5); 45 CFR 46.108(a); 45 CFR 46.111; 21 CFR 50, 56 OHRP Common Findings and Guidance; OHRP Guidelines for Formulating Written IRB Policies and Procedures; ORHP Guidance for Continuing Review.

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

**IV. PROCEDURES**

1. Submissions to UTHSC IRB:

- a. Submissions to the UTHSC IRB will be transmitted electronically via iMedRIS.
- b. The IRB Chairperson or designee will determine whether submissions qualify for full board review, expedited review, or exempt status. Full board review will be required for all studies that involve more than minimal risk or do not otherwise qualify for expedited review or exempt status.
- c. For new studies requiring full board review, the principal investigator will submit to the UTHSC IRB the following documents 21 days prior to the scheduled IRB meeting:
  - i. Form 1 application prepared according to the IRB instructions, including all required signatures,
  - ii. Study protocol (if applicable) including amendments,
  - iii. Informed consent document(s) prepared according to UTHSC IRB informed consent template,
  - iv. Grant application (if applicable),
  - v. Subject surveys or questionnaires (if applicable),
  - vi. Copy of all proposed advertisement(s) / recruitment materials, and
  - vii. Investigator's Drug Brochure and/or Package Insert(s) (if applicable)
- d. For renewals of previously approved studies requiring full board review, the principal investigator will submit to the UTHSC IRB the following documents:
  - i. Form 3 with all required signatures,
  - ii. The currently approved application and informed consent document(s),
  - iii. A list of any revisions to the study since the last renewal,
  - iv. Miscellaneous supporting documents including DSMB reports, adverse events, clinical or laboratory results, or articles published that have been reported to the IRB since the last continuation, and

- v. The master protocol and investigator's brochures (if applicable) may be attached, although the latter items are available to the reviewer in the electronic file for the study.
  - e. For revisions of previously approved studies requiring full board review, the principal investigator will submit to the UTHSC IRB the following documents:
    - i. Completed Form 2 application
    - ii. Complete copy of the original protocol (if applicable)
    - iii. Revised protocol (if applicable)
    - iv. Original Form 1 application
    - v. Revised Form 1 application (if applicable)
    - vi. Original informed consent document(s)
    - vii. Revised informed consent document(s)
    - viii. Sponsor correspondence (if applicable)
  - f. Revisions will qualify for expedited review only if there are only minor changes, corrections, or clarifications, such as minor changes in study staff, study procedures or the consent disclosure. If the PI is being changed, a letter from the new PI must be included stating he/she is aware of the change and is assuming responsibility for the study.
2. Document Distribution:
- All materials are placed on the agenda and available to all IRB members on the iMedRIS website at least 5 days prior to the IRB meeting. Preparation of the agenda is the responsibility of the Director or designee.
3. Review Process:
- a. Full Board review will be required of all new studies that involve more than minimal risk to human subjects or do not otherwise qualify for expedited or exempt review, as well as all continuations and revisions that do not qualify for expedited review.
  - b. Reviewers will be assigned as appropriate to the subject matter of the application. For all new studies requiring full board review, a primary and secondary reviewer will be assigned. For continuation and revision applications, there will be only one reviewer.
  - c. All applications for full board review are due in the iMedRIS system 21 days prior to the meeting at which they will be reviewed.
  - d. Applications and all supporting documents are distributed to reviewers after an initial review is conducted by the assigned IRB administrator, 19 days prior to the meeting of the full Board.
  - e. Reviewers must complete their review no more than 13 days prior to the Board meeting using the reviewer form available in the iMedRIS system.

- f. The assigned IRB administrator collates the comments of the reviewers and administrative staff in the PI Response Form. This form is transmitted to the principal investigator within iMedRIS 9 days prior to the meeting.
- g. The principal investigator must respond to questions and provisos using the PI Response Form within 5 days prior to the meeting.
- h. The application is finalized on the agenda and becomes available to all board members, along with the PI Response Form and all supporting documentation 5 days prior to the meeting.
- i. For new applications, a synopsis of the study is presented by the principal investigator or a co-investigator at the meeting of the full Board, and questions and comments are fielded from members of the Board. Following the presentation, the primary and secondary reviewers must present their assessment of any significant issues and make their recommendation to the IRB.
- j. For review of continuation applications, a primary reviewer will conduct a detailed review of the progress of the research prior to the full board meeting according to the procedures and schedule used for new applications. At the meeting of the full Board, the reviewer will present a synopsis of the progress of the research, any significant issues, and his/her recommendation to the IRB.
- k. For revisions of studies requiring full board review, a primary reviewer will conduct a detailed review of the proposed revisions and discuss any unanswered questions with the sponsor, PI, or consultants prior to the full board meeting according to the procedures and schedule used for new applications. At the meeting of the full Board, the reviewer will present a synopsis of the revisions, any significant issues, and his/her recommendation to the IRB.
- l. Adverse event reports may be reviewed by the full Board, a subcommittee of the IRB, the Chairperson or designee. All adverse event reports will be placed on the meeting agenda, which will be finalized 5 days prior to the meeting but can be viewed by the full committee at any time within 21 days before the meeting. Discussion of adverse event reports will occur if there are reasonable grounds for revision of the risk/benefit assessment, changes in study procedures or alteration of the informed consent disclosure.
- m. All members voting on a protocol must be free of conflicts of interest with respect to the protocol, institution, or sponsor involved, and any member having a conflict of interest in a given protocol, institution, or sponsor, shall disqualify himself/herself in a given review. IRB members who are investigators, sub-investigators or have a conflict of interest will leave the meeting room at the time indicated by the Chairperson for discussion, deliberation and voting.
- n. Action items will be reviewed first to ensure that potential loss of quorum does not delay any agenda items requiring review and vote.
- o. Review of unanticipated problems (other than adverse events) involving risks to subjects or others, or serious or continuing noncompliance will be first reviewed by the Chairperson (upon receipt of information/report) and will be then discussed at the next full Board meeting. Any discussion/action decided upon will be documented in the minutes for that meeting and communicated to the investigator/

- sponsor/FDA or other regulatory authority as required by federal regulations in writing within 48 hours.
- p. The expedited review process is an alternative to a convened meeting and may be used for those activities listed in the federal regulations as eligible for expedited review.
  - q. Decisions are made independently for each research proposal submitted.
  - r. The following actions, determined by majority vote of the quorum present, may be taken on any application: approval without provisos; approval pending satisfaction of administrative provisos; deferral of approval pending satisfaction of provisos requiring further review by the full board; or disapproval. Approval pending satisfaction of administrative provisos will only occur when the convened IRB stipulates specific revisions requiring simple concurrence by the investigator; the Chair or other designated senior IRB member may subsequently approve the revised research protocol, consent form, or other materials on behalf of the IRB under an administrative review procedure. Deferral of approval pending satisfaction of full board provisos will apply to applications for which the IRB requires the investigator to address substantive issues raised in the IRB deliberations. In the latter case, subsequent review and approval by the full Board is required.
  - s. Should a quorum fail during a meeting, the IRB may not take further action until a quorum is restored. Loss of quorum can occur due to early departure of members, absence of a nonscientist, or loss of eligibility to vote of members with conflicts of interest.
  - t. When a nonscientist member is not present, the IRB may not take further action until a nonscientist is present.
4. Minutes will be completed for each meeting.