

**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, board members, and investigators.

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:

For studies approved under the revised Common Rule:
45 CFR 46.108(a)(3) and (4); 45 CFR 46.111;

For studies approved under the Pre-2018 Common Rule:
[45 CFR 46.103\(b\)\(4\) and \(5\)](#)

For FDA-regulated studies:
21 CFR 50, 56

OHRP Guidance on Written IRB Procedures located at
<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/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. **Submissions to UTHSC IRB:**
 - a. Submissions to the UTHSC IRB will be transmitted electronically via iMedRIS.
 - b. An IRB Chair 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,
 - vii. Investigator's Drug Brochure and/or Package Insert(s) (if applicable),
 - viii. For HHS-supported multicenter clinical trials, the complete HHS-approved protocol, and
 - ix. For HHS-supported multicenter clinical trials, the HHS-approved sample informed consent document.
- d. For renewals of previously approved studies requiring full board review, see SOP: UTHSC IRB Continuing Review
 - e. For revisions of previously approved studies requiring full board review, see SOP: UTHSC IRB Revisions in Approved Studies.

2. Document Distribution:

All materials are placed on the agenda and available to all IRB members on the iMedRIS website 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.
- c. All applications for full board review are usually 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 analyst, 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 analyst collates the comments of the reviewers and administrative staff and sends them to the investigator, study contact(s),

- and Research Administrative Specialist (RAS) (if appropriate) via iMedRIS as pre-review recommendations prior to the meeting.
- g. The principal investigator must respond to questions and recommendations using the PI Response Form the Friday or Monday prior to the meeting, if possible.
 - h. The application is finalized on the agenda and is available to all board members, along with the PI Response Form and all supporting documentation 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 departure of the investigator, 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, see SOP: UTHSC IRB Continuing Review of Research.
 - k. For **revisions** of studies requiring full board review, see SOP: UTHSC IRB Revisions in Approved Studies.
 - l. **Adverse event reports** may be reviewed by the full Board, a subcommittee of the IRB, a Chair or designee. Reports of unanticipated problems that are submitted for studies that occur at Methodist Le Bonheur Healthcare facilities will also be forwarded to a Board member from Methodist Healthcare – Memphis Hospitals or Le Bonheur Children’s Hospital to conduct an administrative review. All adverse event reports submitted as reportable will be placed on the meeting agenda, which will be finalized prior to the meeting but can be viewed by the full committee at any time prior to 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 deliberating and voting on a protocol must be free of conflicts of interest, and any member having a conflict of interest shall disqualify himself/herself in a given review. IRB members who have a conflict of interest will leave the meeting room at the time indicated by a Chair for deliberation and voting. For more information on conflicts of interest, see SOP: UTHSC IRB Conflicts of Interest.
 - n. Action items will be reviewed first to ensure that potential loss of quorum does not delay any agenda items requiring review and vote. Quorum is calculated as 50% of the members on the corresponding section’s roster, plus one. For example, if there are 12 members total serving on that section of the Board, a quorum would be present if 7 members were in attendance (and none had to recuse themselves for that 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 a Chair or designee (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 conditions 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. An IRB Chair, Director, IRB analyst will review the responsive materials from the investigator required by the IRB, and determine whether the provisos stipulated by the IRB have been satisfied. Deferral of approval pending satisfaction of full board conditions 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. If a quorum fails during a meeting, then 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. The minutes will include the following items:
- a. Attendance of members at the meeting;
 - b. Pre-review recommendations for changes in applications provided to the investigator prior to the meeting;
 - c. Separate deliberations, actions and votes by the convened IRB for each protocol undergoing initial review, continuing review, or revision;
 - d. The vote on all IRB actions including the number of members voting for, against, and abstaining recorded in a manner that documents the continued existence of a quorum, with the votes recorded using the following format:

- Total = 15, Vote: For-14, Opposed-0, Abstained-1; When an IRB member is recused because of a conflict of interest, he/she will not be counted towards quorum, and the votes will be recorded using the following format: Total = 14, Vote: For-14, Opposed-0, Abstained-0 ([Name] was not present for the deliberation or vote as he/she has a [conflict of interest briefly described]).
- e. Conditions of approval or reasons for deferral for each action taken by the IRB;
5. The findings of the IRB regarding full board applications, including administrative provisos or reasons for deferral, are transmitted to the investigator, study contact, and RAS (if appropriate) via iMedRIS.
 6. The following items 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:
 - a. Unanticipated problems submitted to the IRB as reportable events, including adverse events, as well as protocol deviations, DSMB reports and other safety reports received;
 - b. Informational items for IRB members regarding the satisfaction by the investigator of conditions for IRB approval of research reviewed at a convened meeting or for research reviewed under an expedited review procedure, including the date when an IRB Chair, Director, IRB Analyst, 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.
 - c. Additional Informational items for IRB members regarding administrative actions of the Board, including all new exempt applications and revisions to exempt applications reviewed, as well as all expedited new applications, expedited continuations and expedited revisions reviewed, recruitment materials reviewed, miscellaneous documents reviewed, audits completed, and reports of termination.
 7. The Vice Chancellor for Research is notified of the actions of the IRB by transmission of the approved minutes of the meetings and finalized agenda 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).