UNIVERSITY OF TENNESSEE GRADUATE SCHOOL OF MEDICINE
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 Graduate School of Medicine Institutional Review Board (GSM IRB) 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

GSM 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 of research studies by GSM IRB is not in itself a commitment or approval by the institution(s) where the research involves the use of the institution's facilities or personnel.

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 Guidance on Written IRB Procedures located at http://www.hhs.gov/ohrp/policy/irbgd107.html

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

IV. PROCEDURES

Review by IRB

A. All studies must be submitted electronically in iMedRIS by the IRB deadline dates published on the IRB website.. IRB Schedule A pre-review will be conducted by the IRB staff.. Revisions may be requested by the IRB staff during pre-review. Submissions not corrected and submitted to the IRB in a timely manner will not be placed on that month's agenda for review.

B. The IRB Director in consultation with the Chair will determine whether submissions qualify for full board review, expedited review, or exempt status. The full board will be required to review 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 GSM IRB the following documents as listed in the table below:
   i. Study protocol, including amendments,
   ii. GSM IRB Form 1, including all required signatures,
   iii. Informed consent document prepared according to UTGSM 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)
   viii. Fee for IRB review unless a waiver of fee is granted. Fee Payment Policy

Cooperative Group Studies or Commercially Sponsored Studies	Locally Written Protocols
• IRB Application • Consent document	• IRB Application • Final Consent document

Cooperative Group Studies or Commercially Sponsored Studies	Locally Written Protocols
• Subject surveys, diaries, questionnaires etc. • Advertising • Study Budget • Copy of current OID (Outside	• Subject surveys, diaries, questionnaires etc. • Advertising • Study budget • Final Protocol
Interest Disclosure form) • Most recent version of Final Protocol and all amendments • Investigator's Brochure or package insert • Grant Application	• Investigator's Brochure or package inserts • Grant application

D. For revisions of previously approved studies requiring full board review, the principal investigator will submit to the GSM IRB the following:
   i. An Amendment Form with all required signatures Revised sponsor protocol, where applicable (changes highlighted)
   ii. Summary of Revision Revised informed consent (with changes tracked & highlighted)
   iii. Revised clean informed consent document

3. Document Distribution: The following materials are sent to the Board members through iMedRIS:
   A. New Applications:
      i. All Board members are provided the following materials:
         a. Completed IRB Application including Collaboration Forms if applicable
         b. Protocol
         c. Investigator's brochure or package insert (if applicable)
         d. Informed consent document
         e. Data collection forms – questionnaires, surveys, and other instruments used in the study to collect information.
         f. Study Budget
         g. Advertisements, solicitations, recruitment tools (if applicable)
         h. Grant application (if applicable)
   B. Continuation Applications:
      i. All Board members are provided the following materials:
         a. Completed Continuing Review Form with all attachments (Appendix 12)

b. Protocol and/or project descriptors
c. Current informed consent form

C. Revision Applications:
i. All Board members are provided the following materials:
a. Completed Amendment Form
b. Revised protocol with changes highlighted
c. Summary of changes
d. Revised informed consent with changes highlighted
e. Clean copy of consent with changes included
f. Sponsor correspondence

4. Review Process:
A. Focused attention will be placed on studies involving:
- Vulnerable populations that warrant additional protections
- Use of placebo controls
- Challenge studies
- Radiation exposure
- Deviations from standards of care
- Significant risk studies

B. 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.
C. All IRB members will review the project descriptors, protocol / protocol amendment(s), and the proposed consent form, the investigator's credentials, investigational site information, any proposed recruitment procedures, and written information to be provided to subjects.
D. Information such as the Investigator's Brochure, package inserts, advertisements, grant applications and other supporting documents will be available to the reviewers
E. Reviewers will be defined as appropriate to the subject matter of the application. A copy of the reviewer's written comments and / or recommendations will be included as part of the IRB minutes.
F. The assigned reviewers will conduct a detailed review of the research study and may discuss any unanswered questions with the sponsor, PI, or consultants before the full board meeting. At the full board meeting, the reviewers must present a synopsis of their review, any significant issues, and their recommendation to the IRB. The reviewer will provide a written summary of the review in in iMedRIS.
G. Continuation (renewal) applications will be reviewed by the Chairman or an assigned primary reviewer who will conduct a detailed review of the progress of the research and discuss any unanswered questions with the sponsor, PI, or consultants before the full board meeting. 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.
H. For revisions of studies requiring full board review, a primary reviewer (the original reviewer when feasible) will conduct a detailed review of the proposed revisions and discuss any unanswered questions with the sponsor, PI, or consultants before the full board meeting. 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. The reviewer will provide a written summary of the review in iMedRIS

I. Adverse event reports may be reviewed by the full Board or by a subcommittee of the IRB Chairperson. All adverse event reports will be placed on the meeting agenda and forwarded to the full committee.

J. All members voting on a protocol will be free of conflicting interests with respect to the protocol, institution, or sponsor involved, and any member having a conflicting 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.

K. Action items will be reviewed first to ensure that potential loss of quorum does not delay any agenda items requiring review and vote.

L. Review of unanticipated problems involving risks to subjects or others or of 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.

M. Decisions are made independently for each research proposal submitted. Refer to SOP # IRB 004, "Criteria for Approval."

N. 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; approval pending satisfaction of full board provisos; deferral of approval; 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, or materials on behalf of the IRB under an expedited review procedure. Approval pending satisfaction of full board provisos or deferral will apply to applications in which the IRB does not stipulate specific revisions, but which require the investigator to address substantive issues raised in the IRB deliberations. In both the latter cases, subsequent review and approval by the full Board is required.

O. 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.

P. When a nonscientist member is not present, the IRB may not take further action until a nonscientist is present.

5. Minutes will be completed for each meeting per SOP # ADM 013.