UNIVERSITY OF TENNESSEE GRADUATE SCHOOL OF MEDICINE
INSTITUTIONAL REVIEW BOARD
AUTHORITY, MEMBERSHIP AND PERMANENT POSITIONS

I. PURPOSE

To document the authority, membership and permanent positions for the University of Tennessee Graduate School of Medicine Institutional Review Board (UTGSM IRB)

II. SCOPE

This SOP applies to the IRB Chairperson, IRB Assistant Director, IRB administrative staff and Board members.

Personnel Responsible:

UTGSM IRB administration and members of the UTGSM IRB

III. BACKGROUND

Any institution engaged in human subjects research that is supported or conducted by any department or agency of the federal government which has adopted the Federal Policy for the Protection of Human Subjects, known as the Common Rule (45CFR46, Subpart A), is required to establish a Federal Wide Assurance (FWA) with the Office for Human Research Protections of the Department of Health and Human Services (HHS). Under the terms of the Assurance, all of the institution's human subject's research activities, regardless of whether the research is subject to federal regulations, must be guided by the ethical principles in The Belmont Report (Appendix 01) and other appropriate ethical standards recognized by federal departments and agencies that have adopted the Common Rule. In addition, all human subjects research undertaken by the institution that is conducted or supported by any federal agency which has adopted the Common Rule must comply with the terms of the latter, as well as any additional human subjects regulations and policies of the federal agency which conducts or supports the research, and any other applicable federal, state, local, or institutional laws, regulations and policies. For research that is conducted or supported by HHS, the institution must also comply with all subparts of the HHS regulations at 45CFR46, i.e., Subparts A, B, C, and D (Appendix 02). For research that is not conducted or supported by any federal agency that has adopted the Common Rule, the University is voluntarily committed by the terms of its FWA to apply all aforementioned laws and regulations. The Common Rule includes the requirement that each institution to which the Rule applies must establish an Institutional Review Board (IRB) to oversee the application of relevant ethical principles and federal regulations in the conduct of human research.

A similar requirement for IRB review derives from regulations of the Food and Drug Administration (FDA). For all clinical investigations using articles regulated under sections 505(i), 507(d), and 520(g) of the Food, Drug and Cosmetic Act, FDA regulations require IRB review and the informed consent of subjects as specified at 21CFR56 and 50 (Appendix 03). In

addition, under the revision of the investigational new drug (IND) application regulations of March 19, 1987, the same regulatory requirements apply to studies involving marketed drugs exempt from the IND requirements. Similar conditions are included in the investigational device (IDE) regulations addressing abbreviated requirements for certain categories of device investigations. Although FDA regulations for the protection of human subjects do not require institutions conducting FDA-regulated human research to have their own IRB, local IRB policy requires that any UTGSM personnel conducting FDA-regulated studies must secure prior review and approval of the UTGSM IRB.

University of Tennessee Health Science Center (UTHSC) established the University of Tennessee Health Science Center Institutional Review Board in 1972. To better serve the needs of researchers at the Graduate School of Medicine, the UTHSC established the UTGSM IRB (previously referred to as UTGSM IRB 03; now referred to as UTGSM IRB 05) in 1989.

The UTGSM IRB maintains a cooperative agreement with University Health System (UHS), a private not for profit entity which operates University of Tennessee Memorial Hospital in Knoxville, TN. Representatives from that organization are included as ad hoc members of the IRB. The UTGSM IRB also maintains a cooperative agreement with the National Cancer Institute CIRB program. Finally, the IRB, at its discretion, may oversee research activities conducted by non-UTGSM personnel as well.

The UTGSM IRB reports administratively to the Dean of the UTGSM who reports to the UTHSC Vice Chancellor for Research. The Board functions independently of all other administrative units and committees of the University.

The UTGSM IRB is duly constituted and has written procedures in compliance with requirements defined in 21 CFR Parts 50 and 56, 45 CFR 46 and ICH Guidelines relating to Good Clinical Practice. The mission of the UTGSM is to ensure that research is conducted according to the ethical principles of the Belmont Report and the Declaration of Helsinki, all federal regulations and international guidelines, institutional policies, and state laws, and to ensure that the rights and welfare of human subjects are adequately protected. The UTGSM IRB has the authority to approve, require modifications in, and disapprove research protocols based on consideration of human subject protection, including the authority to:

1. Require progress reports from the investigators and oversee the conduct of the study,
2. Investigate complaints or reports of noncompliance or protocol deviations,
3. Suspend or terminate approval(s) or place restrictions on a study,
4. Evaluate the risk / benefit status of studies,
5. Ensure the adequacy of the informed consent process and informed consent documentation,
6. Refer potential conflicts of interest in the research to the appropriate institutional body, and
7. Ensure that the research has in place adequate mechanisms to protect human subjects, including the auditing of sites and monitoring of the informed consent process by using third party monitors.

In Accordance With:

45 CFR 46.107(a - d); 21 CFR 56.107(a - d); FDA Information Sheets - IRB Membership; IRB Guidebook; OHRP Common Findings and Guidance; OHRP Guidance on Written Procedures, 7/11/02.

FDA Guidance for Institutional Review Boards and Clinical Investigators 1998 Update located at
http://www.fda.gov/scienceresearch/specialtopics/runningclinicaltrials/guidancesinformationsheetsandnotices/ucm113709.htm

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

DEFINITIONS

Human subject
Human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. 21 CFR 50.3 (d) (FDA)

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains
(1) Data through intervention or interaction with the individual or
(2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. 45 CRF 46.102 (f)

Research
Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. 45 CRF 46.102 (d).

A single case study for presentation at a meeting generally does not qualify as research.

IV. PROCEDURES

1. **The IRB Chairperson:** The Chairperson is a member of the IRB whose experience and expertise is documented in his/her CV. The Chairperson is appointed by the UT GSM Assistant Dean for Research. The Chairperson will serve a term of three years and may serve successive terms at the discretion of the Assistant Dean for Research. Removal of the Chairperson may be accomplished by resignation in writing or by written notification of termination of the appointment by the Assistant Dean for Research.
   The Chairperson will perform functions including, but not limited to the following:
   a. Direct the proceedings of the full IRB committee. The position of Chair is a voting position.
   b. Establish and enforce UTGSM policies and standards, as well as all applicable state and federal rules, regulations and statutes concerning human subject protection. As a primary representative of IRB decisions, the Chair has authority over all IRB policies and procedures.
   c. Represent the IRB in discussions with other segments of the organization.
   d. Review all protocols presented to the committee and communicate as necessary with all IRB subcommittees, consultants, auditors, and other reviewers so that all IRB issues are identified and resolved.
   e. Review and make decisions about responses to administrative provisos for IRB approval.
   f. Conduct review of proposals submitted for expedited review or exempt status. This task may be shared with other senior members of the IRB, depending on expertise.
   g. Review all reports of adverse events, safety reports, DSMB reports, protocol deviation reports, continuing review reports, reports of unanticipated problems or unexpected risks to subjects and / or others, and reports of complaints or noncompliance.
   h. Enforce corrective actions for violations.
   i. Exercise oversight authority for all professional and administrative functions of the IRB.
   j. Assist the IRB Director in drafting letters and other communications from the IRB to researchers, sponsors and regulatory authorities or agencies concerning IRB decisions. The Chair will review and sign correspondence in a timely manner.
   k. Interact with investigators, coordinators, sponsors, institutional officials, subjects, and auditors regarding ethical questions, questions of IRB policy / oversight and human subject protections.
   l. Assist in preparing any reports and recommendations as may be mandated or required.
   m. Report to the IRB, sponsor, investigator, University officials, OHRP and FDA as required for the following events:
      i. Any unanticipated problems involving risks to subjects or others;
      ii. Any serious or continued noncompliance with the regulations or protocol requirements;
      iii. Any serious or continued noncompliance with the policies of the IRB;

iv. Any suspensions or terminations of IRB approval.

n. Direct audits of clinical sites for compliance with IRB policies and procedures, as well as other applicable laws and regulations.

2. **IRB Director or designee:**

a. File and update Federal Wide Assurance (FWA) with OHRP.
b. File and update IRB Registration with OHRP.
c. Update and maintain the iMedRIS electronic system.
d. With IRB staff, train Board members, investigators and study teams on iMedRIS
e. Develop and implement IRB policy.
f. Develop standard operating procedures (SOPs) and update current SOPs (at least annually), and direct training of all staff, IRB members, consultants and auditors regarding applicable laws and regulations for the protection of human subjects.
g. Develop and implement IRB policies and procedures regarding the HIPAA regulations, and train all IRB staff, members, and consultants on these requirements.
h. Develop, implement, and update as necessary an orientation program for all new staff and IRB members. Create and maintain training files for all IRB staff, members, and consultants.
i. Under the direction of the Chairperson, seek out appropriate new members, consultants, ad hoc members, staff members and auditors.
j. Develop, update and oversee the IRB investigator-training program on the conduct of human research according to ethical and regulatory requirements
k. Advise the university administration, departments, investigators and compliance officials on IRB policies and procedures
l. Serve as a contact person for communications regarding IRB deliberations, review, and actions; oversee preparation and signature of correspondence from the IRB regarding these deliberations, reviews, and actions.
m. Create, maintain, and archive comprehensive IRB minutes and documents concerning IRB functions and meetings.
n. Plan departmental meetings to address questions regarding IRB review and policies
o. Triage research between IRB review categories along with the Chair (full board review, expedited review, exempt, HIPAA waivers).
p. Serve as contact person and liaison for audits from sponsors, OHRP or FDA; develop, update and implement procedures for managing and responding to these types of audits.
q. Represent the IRB at professional, community and institutional meetings
r. Serves as an Alternate Member of the IRB. Reviews and approves Exempt applications and other reviews as designated by the IRB Chair.

s. Manage functions of all IRB administrative staff, including development and updating of job descriptions; assume responsibility for hiring, training, review, and termination of staff.
t. Assist the Chair in reviewing serious adverse events, Safety Alerts, protocol deviations, unexpected problems or unanticipated risks to subjects or others, injury to subjects, complaints or reports of noncompliance; coordinate appropriate follow-up needed by the IRB; initiate and coordinate implementation of any policies and / or procedures related to such reports.
u. Implement, track, review and coordinate IRB communication regarding continuing review.
v. Monitor and manage conflict of interest reports of investigators and IRB staff per IRB policies and procedures
w. Implement, manage, and communicate reports of any IRB subcommittees.
x. Along with IRB staff, coordinate all IRB meetings, including preparation of the agenda, assignment of review responsibilities, distribution of materials, and notification of relevant parties regarding time and place.
y. Create, update and maintain the IRB website.
z. Review submissions and prepare written correspondence with investigators, sponsors or the FDA concerning any submissions for emergency use or compassionate use.
aa. Invoice, receive and manage all IRB accounts receivable and accounts payable.
bb. Maintain and update IRB information concerning federal regulations, guidelines, information sheets, applicable state and local laws and institutional policies regarding human subject research.
cc. Assume responsibility for the files of the IRB, whether electronic or paper, including archiving, tracking, storage, retrieval, QA and security.
dd. Coordinate, prepare appropriate paperwork, and maintain any correspondence concerning applications for and updates of the IRB Assurance(s).
ee. Promote and support staff certification.
ff. Reviews and acknowledges Case Reports and Not Human Subject Research submissions.

3. Board Membership

a. UTGSM membership is a privilege and a responsibility granted by invitation to scientific and non-scientific members of the academic and local community.
b. Members will be sufficiently qualified through their experience, expertise and diversity, including consideration of race, gender, cultural attitudes and sensitivity to community attitudes, to ascertain the acceptability of proposed research in terms of institutional commitments, federal regulations, applicable law, and standards of professional conduct and to promote respect for the Board's advice and counsel in safeguarding the rights and welfare of human subjects.

c. UTGSM shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The maximum number of members is thirty. Alternate members are used to maintain a working quorum of the IRB.
d. Insofar as the UTGSM reviews research that involves vulnerable categories of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, membership will include one or more individuals who are knowledgeable and experienced in working with those vulnerable subjects.
e. UTGSM will not consist entirely of members of one profession.
f. UTGSM will include at least one member whose primary concerns are in the scientific area (examples: physicians, nurses, pharmacists, and dentists); at least one member whose primary concerns are in nonscientific areas (examples: lawyers, clergy, administrators, ethicists); and at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution (sometimes called a community member).
g. All prospective applicants will be evaluated for potential membership (full or alternate) or as an ad hoc / consultant/ex officio member based on the following:
    i. Evidence of education and training (as documented in his/her CV),
    ii. Community service and/or length of residence in the community,
    iii. Specific needs of the IRB,
    iv. Willingness and time to serve his/her term, and
    v. Other criteria as determined by the IRB Chairperson.
h. Membership may include, but is not limited to:
    i. Ethicists,
    ii. Members of the legal profession,
    iii. Clergy,
    iv. Members of the medical and other health care professions,
    v. Other scientists or non-scientists to provide the necessary expertise to evaluate the research proposals and the informed consent process,
    vi. Lay persons representing the values and attitudes of the community from which research subjects are drawn,
    vii. Specialty needs of the board, such as a prisoner representative, and
    viii. Non-voting members representing research administration at UHS.
i. All stipulations for full membership apply to the Chairperson.
j. All members will sign a Confidentiality Agreement that will be maintained on file (Appendix 04).
k. Prospective applicants for Board membership submit to the IRB Director supporting documents, including a current CV or resume and a copy of any professional license (if applicable to their application).
l. The IRB Director will forward the supporting documents of all prospective members to the Chairperson for review.
m. An Introductory Training Course will be scheduled for all new members.
n. IRB members are appointed by the Assistant Dean for Research for an initial three-year term, and may be reappointed for successive terms at the discretion of the Assistant Dean.
o. Upon notification of a member's appointment, the IRB Director or designee will

prepare a letter of appointment for the member and provide it to the Assistant Dean for signature.

p. Once signed by the Assistant Dean for Research, the IRB Director will forward the original letter to the member and file a copy with the IRB files.
q. The new member's name will be added to the IRB Roster. The Director will update the IRB Registration with OHRP.
r. The IRB administrative staff will schedule the new member for orientation and will send a copy of the IRB policies and procedures to the new member.

4. **Alternate Members:** Alternate scientific members will serve in the absence of a Primary scientific member. Alternate non-scientific members will serve in the absence of a Primary non-scientific member. Alternate members are appointed in accordance with item 3.
    a. Alternate members may attend any IRB meeting,
    b. Alternate members may not vote if the principal IRB members for whom that member is an alternate is not present.

5. **Ad Hoc / Consultant Members:** When reviewing research that involves children, prisoners, pregnant women, handicapped or mentally disabled persons, or other category of subjects deemed vulnerable by the IRB (students, elderly, employees of the site or institution, members of specific cultural groups or minorities), consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects, when such individuals are not otherwise represented on the board. In addition, the membership may invite individuals with competence in special areas to serve on an ad hoc basis to assist in the review of studies requiring expertise beyond that of the members.
    a. The membership of an ad hoc member will be established in accordance with #4 above.
    b. The ad hoc member may attend the IRB meetings for discussion purposes.
    c. The ad hoc member may provide the IRB comments in writing prior to the IRB meeting.
    d. At no time will an ad hoc member have voting power.

6. **Ex Officio Members:** UTGSM may, at its discretion, call upon individuals with competence in special areas or knowledge of institutional policies, community attitudes and state laws pertaining to research to assist in the review of issues requiring expertise beyond or in addition to that available in the membership of the IRB. The purpose of *ex officio* members is to advise the IRB on specific questions. At no time will an *ex officio* member have voting power.

7. **Membership Roster:**

a. A roster of IRB members and alternates is created and maintained by the IRB Director or designee. The roster will identify members by:
    i. Name,
    ii. Earned degrees,

iii. Experience, qualifications, specialty (board certification, licenses, IRB certification),
iv. Designation as Principal, Alternate Member, Ad Hoc or Ex Officio Member,
v. Scientific / non-scientific designation,
vi. Employment by or relationship to the IRB or other members, and
vii. Hospital or institutional affiliation.

b. The membership roster is reviewed at least annually by the IRB Director or designee and the Chairperson to assure appropriate membership and diversity as outlined in the 21 CFR 56 and 45 CFR 46.

8. **Attendance:** Members are expected to attend all of the scheduled meetings annually in order to maintain their appointment to the Board.

a. The IRB Director or designee will maintain a log of attendance with cumulative attendance on a calendar year basis for review with the IRB Chairperson at each meeting.
b. The Chairperson will contact members who miss 6 consecutive meetings to determine the action to be taken.
c. The Chairperson may ask for the resignation of the member if deemed necessary.

9. **Removal of Members / Vacancies:** A member, alternate, ad hoc or *ex officio* member may be removed, with or without cause, from the IRB:

a. By the action of the Vice Chancellor for Research, on the recommendation of the Chairperson.
b. Automatically, if the member's misses 6 consecutive meeting or has a pattern of non-attendance.
c. The Chairperson may resign with a one-month notice.
d. A member may resign from the IRB by submitting a letter of resignation to the Chairperson.
e. Vacancies in the membership shall be filled by the appointment process described in #3.

10. **Quorum:** UTGSM will conduct all business only when a quorum of members is present.

a. The quorum is a simple majority of members but must include one non-scientific member.
b. The IRB Director or designee will note in the minutes any loss of quorum.

11. **Tennessee Claims Commission Act of 1984:** IRB members who are employed by the University fulfill their administrative and institutional service responsibilities to the University, in part, by serving on an IRB. Accordingly, the University will defend IRB members in the event of a legal dispute relating to the actions of the committee, unless the acts or omissions were willful, malicious, criminal, or done for personal gain.

Registered Volunteers are those persons who are not employed by the University but provide service to the University by serving on an IRB. Registered Volunteers receive the same civil immunity from liability as does an employee of the University under the Act.