UNIVERSITY OF TENNESSEE COLLEGE OF MEDICINE CHATTANOOGA/ ERLANGER HEALTH SYSTEM INSTITUTIONAL REVIEW BOARD

AUTHORITY, MEMBERSHIP AND PERMANENT POSITIONS

I. PURPOSE

To document the authority, membership and permanent positions for the University of Tennessee College of Medicine Chattanooga/Erlanger Health System Institutional Review Board (UTCOMC IRB).

II. SCOPE

This SOP applies to the IRB Chair, Vice Chair, IRB administrator, and Board members.

Personnel Responsible
UTCOMC IRB administration and Board members

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 subjects research activities, regardless of whether the research is subject to federal regulations, must be guided by the ethical principles in The Belmont Report. 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 45 CFR 46, i.e., Subparts A, B, C, and D. For research that is not conducted or supported by any federal agency that has adopted the Common Rule, the University voluntarily applies the aforementioned laws and regulations, with the exception of communicating with federal departments or agency heads (such as reporting investigator noncompliance or requesting approval for prisoner research). 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 21 CFR 50 and 56. 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 UTHSC personnel conducting FDA-regulated studies must secure prior review and approval of the UTHSC IRB. Any studies approved under both the HHS and FDA regulations will be required to adhere to the more stringent regulations of each set where they differ.

The University of Tennessee Health Science Center (UTHSC) established the University of Tennessee Health Science Center Institutional Review Board in 1972. The UTCOMC IRB is linked to the UTHSC IRB by the Federal Wide Assurance. The IRB has oversight authority for all research with human subjects conducted by UTHSC faculty, staff, students, residents, or fellows and also has a MOU in place with Erlanger Health Systems as review board. The IRB maintains a cooperative agreement with the National Cancer Institute (CIRB program. The IRB at its discretion may oversee research activities conducted by non- UTCOMC personnel who are not covered by any of the aforementioned agreements.

The UTCOMC IRB reports administratively to the UTCOMC Dean, the EHS President, and also to the UTHSC Assistant Vice Chancellor for Research.

The Board functions independently of all other administrative units and committees of the University. UTCOMC IRB is duly constituted and has written procedures in compliance with requirements defined in 45 CFR 46 and 21 CFR Parts 50 and 56. The mission of the UTCOMC IRB is to ensure that research is conducted according to the ethical principles of the Belmont Report, all federal regulations when applicable, institutional policies, and state laws, and to ensure that the rights and welfare of human subjects are adequately protected. The UTCOMC 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 IRB approval prior to the initiation of an investigation and recruitment of subjects.
2. Require progress reports from the investigators and oversee the conduct of the study;
3. Investigate complaints or reports of noncompliance or protocol deviations;
4. Suspend or terminate approval(s) or place restrictions on a study;
5. Evaluate the risk/benefit status of studies;
6. Ensure the adequacy of the informed consent process and informed consent documentation;
7. Manage potential conflicts of interest in the research; and
8. 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.

Research that has been reviewed and approved by the UTCOMC IRB may be subject to review and disapproval by officials of EHS or UTCOMC, or any institution for which the UTCOMC IRB has agreed to serve as the IRB of record in accordance with an assurance filed with OHRP and a signed Memorandum of Understanding (MOU). However, those officials may not approve research that has

been disapproved by the IRB.

In accordance with:

For studies approved under the revised Common Rule:

45 CFR 46.108(a)(2), 107, 108(b), & 109

For studies approved under the Pre-2018 Common Rule:

45 CFR 46.103(b)(3), 107, and 109

For FDA-regulated studies:

21 CFR 56.107, 108(c), 109, & 115(a)(5)

OHRP Guidance on Written IRB Procedures

https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html

FDA Information Sheets: Frequently Asked Questions: IRB Membership

http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm#IRBMember

FDA Information Sheets: Frequently Asked Questions: IRB Procedures

http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm#IRBProcedures

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

DEFINITIONS

Human subject

For FDA Regulated research: 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)

Common Rule definition: Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Interaction includes communication or interpersonal contact between investigator and subject.

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Legally authorized Representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this policy, the following are deemed not to be research:

a. Scholarly and journalistic activities including the collection and use of information that focus directly on the specific individuals about whom the information is collected.
b. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
c. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
d. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Specific examples of activities not deemed research are provided at 45 CFR 46.102 (l)

Investigator-Initiated Research: Research conducted by a UTCOMC or EHS investigator who initiates and/or conducts a clinical investigation, alone or with others. The IRB may recommend that an independent data safety monitor review all reportable adverse events and that these reports are forwarded to the IRB in a timely manner.

IV. PROCEDURES

1. Authority of the IRB:

The IRB has oversight authority for all research with human subjects conducted by UTCOMC faculty, staff, students, residents, or fellows. In addition, the IRB has

oversight authority for human subjects research conducted at UTCOM-affiliated institutions (Erlanger Health System) by their employees and agents.

2. The IRB Chair

The Chair is a member of the IRB whose experience and expertise is documented in his/her CV. The Chair is appointed by the UTCOMC Dean with approval of the UTHSC Vice Chancellor for Research. The Chair will serve a term of three years and may serve successive terms at the discretion of the Dean of the UTCOMC and the UTHSC Vice Chancellor for Research. Removal of the Chair may be accomplished by resignation in writing or by written notification of termination of the appointment by the Vice Chancellor for Research. The Chair will perform functions including, but not limited to the following:

a. Direct the proceedings of the full IRB. The position of Chair is a voting position.

b. Establish and enforce the UTCOMC IRB 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 Board 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 as delegated by the Chair, depending on expertise.

g. Review all reports of adverse events, safety reports, data safety monitoring board 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. Distribute investigators' applications and review packets

k. Assist the IRB 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.

l. Interact with investigators, coordinators, sponsors, institutional

officials, subjects, and auditors regarding ethical questions, questions of IRB policy, IRB oversight, and human subject protections.

m. Assist in preparing any reports and recommendations as may be mandated or required.

n. Report to the IRB, sponsor, 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; and

iv. Any suspensions or terminations of IRB approval.

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

2. **The IRB Vice Chair**

The Vice Chair is a member of the IRB whose experience and expertise is documented in his/her CV. The Vice Chair is selected from the membership of the IRB. The Vice Chair is appointed on the advice of the Chair by the UTCOMC Dean with approval by the UTHSC Vice Chancellor for Research. The Vice Chair will perform functions including, but not limited to the following:

a. Execute all duties and responsibilities of the Chair in the latter's absence; and

b. Assist the Chair in the performance of his/her duties.

3. **The IRB Administrator (and staff)**

The IRB Administrator is expected to maintain files in a manner that represents a complete history of all IRB actions related to review and approval of a protocol, including continuing reviews, amendments, and adverse event reports for at least three (3) years. For all applications

that are approved and research initiated, the IRB Office must retain all records regarding that research for at least three years after completion of the research.

All records must be accessible for inspection and copying by authorized representatives of the sponsoring department or agency at reasonable times and in a reasonable manner.

The IRB Administrator will perform functions including, but not limited to the following:

a. Develop and implement IRB policy;
b. 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;
c. Develop and implement IRB policies and procedures regarding HIPAA regulations, and train all IRB staff, members, and consultants on these requirements;
d. Develop, implement, and update as necessary an orientation program for all new staff and IRB members;
e. Create and maintain training files for all IRB staff, members and consultants;
f. Under the direction of the Chair, seek out appropriate new members, consultants, ad hoc members, staff members and auditors;
g. Develop, update and oversee the IRB investigator- training program on the conduct of human research according to ethical and regulatory requirements;
h. Advise the university and EHS administration, departments, investigators, and compliance officials on IRB policies and procedures;
i. Complete comprehensive reviews of post-approval applications, including expedited revisions, expedited and full Board continuations, and other miscellaneous submissions, identify regulatory issues as well as institutional policy issues, and make recommendations
j. Facilitate the review of research protocol submission under IRB reliance agreements, e.g., Advarra, the National Cancer Institute (NCI) Central Institutional Review Board (CIRB), the National Marrow Donor Program, and St. Jude Children's Research Hospital.
k. Serve as a contact person for communications regarding IRB deliberations, review, and actions; oversee preparation and signatures of correspondence from IRB regarding these deliberations, review, and actions.
l. Create, maintain, and archive comprehensive IRB minutes and documents concerning IRB functions and meetings.
m. Assist the chair to distribute investigators' applications and review packets;
n. Triage research between IRB review categories along with the Chair (full board review, expedited review, exempt, HIPAA

waivers);

o. 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;

p. Assist the Chair in reviewing serious adverse events, safety alerts, DSMB reports, protocol deviations, unexpected problems or unanticipated risks to subjects or others, injury to subjects, complaints or reports of noncompliance; coordinate appropriate follow-up as needed by the IRB or Research Compliance Office; initiate and coordinate implementation of any policies and/or procedures related to such reports;

q. Implement, track, review and coordinate IRB communication regarding continuing review;

r. Monitor and manage conflict of interest reports per IRB policies and procedures;

s. Implement, manage, and communicate reports of any IRB subcommittees and the Scientific Review Committee;

t. Coordinate IRB meetings, including preparing of the agenda, assignment of review responsibilities, distribution of materials, and notification of relevant parties regarding time and place;

u. Update, and maintain the IRB website;

v. Review submissions and prepare written correspondence with investigators, sponsors, or the FDA concerning any submissions for emergency use or compassionate use;

w. Invoice, receive and manage all IRB accounts receivable and accounts payable;

x. Maintain and update IRB information concerning federal regulations, guidelines, information sheets, applicable state and local laws and institutional policies regarding human subject research;

y. Assume responsibility for the files of the IRB, whether electronic or paper, including archiving, tracking, storage, retrieval, QA and security;

z. Coordinate, prepare appropriate paperwork, and maintain any correspondence concerning applications for and updates of the IRB Assurance(s).

aa. Complete comprehensive reviews of post-approval applications, including expedited revisions, expedited and full Board continuations, and other miscellaneous submissions, identify regulatory issues as well as institutional policy issues, and make recommendations.

bb. Complete reviews of applications that qualify for QI and not human subject research (NHSR) status as well as final closure reports

cc. Facilitate the review of research protocol submission under IRB reliance agreements, e.g., Advarra, WCG, Sterling, the National Cancer Institute (NCI) Central Institutional Review Board (CIRB),.

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4. The IRB Membership

UTCOMC IRB membership is a privilege and a responsibility granted by invitation to scientific and non-scientific members of the academic and local community by the Chair and IRB Administrator.

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.

UTCOMC IRB sections shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution .

Board functions shall include (but are not limited to):

a. UTCOMC IRB 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 board members is thirty. Alternate members are allowed to maintain a working quorum of the IRB.

b. Insofar as the UTCOMC IRB reviews research that involves vulnerable categories of subjects, such as children, prisoners, pregnant women, physically or mentally disabled persons, membership will include one or more individuals who are knowledgeable and experienced in working with those vulnerable subjects.

c. The UTCOMC IRB will not consist entirely of members of one profession.

d. UTCOMC IRB will include at least one member whose primary concerns are in the scientific area (examples: physicians, nurses, pharmacists, 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).

e. All prospective applicants will be evaluated for potential membership (full or alternate) or as an ad hoc consultant (or non-voting member) based on the following:

   i. Evidence of education and training (as documented by CV);

ii. Community service and/or length of residence in the community;
iii. Specific needs of the IRB; and
iv. Willingness and time to serve.

f. 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. Representatives of special populations, such as a prisoner representative

g. All stipulations for full membership apply to the Chair and Vice Chair.

h. All members will sign a confidentiality agreement that will be maintained in the IRB file.

i Prospective applicants for Board members submit supporting documents, including a CV or resume and a copy of any professional license (if applicable to their application) to the IRB Administrator.

i. The IRB Administrator will forward the supporting documents of all prospective members to the Chairperson for review

j. IRB members are appointed by the Dean for an initial three- year term, and may be reappointed for successive terms at the discretion of the Dean

k. 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 Dean for signature.

l. Once signed by the Dean, the IRB Director will forward the original letter to the member and file a copy with the IRB files.

m. The new member's name will be added to the IRB Roster. The Director will update the IRB Registration with OHRP.

n. The IRB administrative staff will schedule the new member for orientation and will send a copy of the IRB policies andprocedures to the new member.

O All new members will be required to complete the CITI Tutorial for IRBs.

5. Alternate Members

Each IRB member may have an alternate member appointed to serve in the absence of the member. Alternate members may serve as an alternate for more than one member only if the alternate has comparable experience, expertise, background, professional competence and knowledge as the primary IRB members whom the alternate would replace.
Alternate members are appointed in accordance with guidelines in Section 4 above. Alternate members may attend any IRB meeting, but may not vote if the principal IRB member is present.

6. Ad Hoc/Consultant Members

When reviewing research that involves children, prisoners, pregnant women, physically or mentally disabled persons, or other category of subjects deemed vulnerable by the IRB (eg, students, elderly, employees of the site or institution, members of specific culturally 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. Ad hoc members are appointed in accordance with guidelines in Section 4 above. The ad hoc member will attend the IRB meetings to participate in the discussion of proposed research but at no time will be allowed to vote. The ad hoc member may provide the IRB comments in writing prior to the meeting.

7. Non-Voting Members

UTCOMC IRB 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 IRB membership.
The purpose of non-voting members is to advise the IRB on specific questions and at no time will be allowed to vote.

8. Membership Roster

A roster of IRB members and alternates is created and maintained by the IRB Administrator. The roster will identify members by:

a. Name
b. Earned degrees
c. Experience, qualifications, specialty (board certification, licenses, IRB certification)
d. Designation as principal, alternate member, ad hoc, or non-voting member
e. Scientific or non-scientific designation
f. Employment or relationship to IRB or other members
g. Hospital or institutional affiliation

The membership roster is reviewed annually by the IRB administrator and Chair to assure appropriate membership and diversity as outlined in 21 CFR 56 and 45 CFR 46. The checklist for IRB membership is used for the documentation of this review and assurance.

9. Attendance

Members are expected to attend all scheduled meetings in order to maintain their appointment to the Board. The IRB Administrator will maintain a log of attendance with cumulative attendance on a calendar year basis for review by the IRB Chair.

The Chair may ask for the resignation of the member if deemed appropriate.

10. Removal of Members and Vacancies

A member, alternate, ad hoc or non-voting member may be removed with or without cause from the IRB by the action of the Vice Chancellor for Research and the UTCOMC Dean on the recommendation of the Chair. Six consecutive absences or a pattern of non-attendance are grounds for dismissal. The Chair or Vice Chair may resign with a one-month notice. A member may resign from the IRB by submitting a letter or resignation to the Chair.

Vacancies shall be filled by the appointment process described in Section 4 above.

11. Quorum

The UTCOMC will conduct business only when a quorum of members is present. The quorum is a simple majority of members, but must include one non-scientific and one non-affiliated or "community" member (this may be the same person). The IRB Administrator will note any loss of quorum in the minutes