

UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER INSTITUTIONAL REVIEW BOARD	
AUTHORITY, MEMBERSHIP, AND PERMANENT POSITIONS	
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AUTHORITY, MEMBERSHIP, AND PERMANENT POSITIONS

I. PURPOSE

To document the authority, membership, and permanent positions for the University of Tennessee Health Science Center Institutional Review Board.

II. SCOPE

This SOP applies to UTHSC faculty, staff, students, residents, and fellows; to employees and agents of UTHSC-affiliated institutions Campbell Clinic, Le Bonheur Children’s Hospital, Methodist Healthcare - Memphis Hospitals, and Regional One Health; and to the IRB Chair, Vice Chair, IRB Director, IRB Associate Director, IRB administrative staff, and Board members.

Personnel responsible:

IRB administrative staff, IRB members, and investigators.

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 (45 CFR 46, 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.

University of Tennessee Health Science Center (UTHSC) established the University of Tennessee Health Science Center Institutional Review Board in 1972. The IRB has oversight authority for all research with human subjects conducted by anyone when acting as an employee or agent of UTHSC, including faculty, staff, students, residents, or fellows. Through Reliance Agreements (also called a Cooperative Agreements, IRB Authorization Agreements or Memorandums of Understanding), the IRB has oversight authority for human subjects research conducted at UTHSC-affiliated institutions (Campbell Clinic, Le Bonheur Children's Hospital, Methodist Healthcare - Memphis Hospitals, and Regional One Health) by their employees and agents.

In addition, the UTHSC IRB reviews non-research requests for the use of drugs, biologics, or devices under the federal regulations pertaining to Emergency Use, Compassionate Use/Treatment Use, and Humanitarian Use Devices (HUDs) conducted by anyone acting as an employee or agent of UTHSC or its affiliated institutions.

The IRB maintains reliance agreements with St. Jude Children's Research Hospital and University of Memphis; for further information, see SOP: UTHSC IRB Utilization of Local Reliance Agreements. The IRB also maintains a reliance agreement with the National Cancer Institute (NCI) CIRB program; for further information, see SOP: UTHSC IRB Utilization of the NCI CIRB. Anyone, when acting as an employee or agent of UTHSC, including faculty, staff, students, residents, or fellows, conducting human subjects research at a Veterans Affairs facility, including the VA Medical Center at Memphis, or a Department of Defense (DoD) facility, should obtain approval from the appropriate VA or DoD IRB and do not need to undertake any interactions with the UTHSC IRB. Finally, the IRB at its discretion may oversee research activities conducted by non-UTHSC personnel who are not covered by any of the aforementioned agreements.

The UTHSC IRB reports administratively to the UTHSC Vice Chancellor for Research via the Senior Associate Vice Chancellor for Research. The Board functions independently of all other administrative units and committees of the University.

UTHSC IRB is duly constituted and has written procedures in compliance with requirements defined in 45 CFR 46 and 21CFR 50 and 56. The mission of the UTHSC 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. UTHSC IRB has the authority to approve, require modifications in, and disapprove research protocols based on consideration of human subject protection, including the authority to:

- Require progress reports from the investigators and oversee the conduct of the study,
- Investigate complaints or reports of noncompliance or protocol deviations,
- Suspend or terminate approval(s) or place restrictions on a study,
- Evaluate the risk/benefit status of studies,
- Ensure the adequacy of the informed consent process and informed consent documentation,
- Manage potential conflicts of interest in the research, and
- 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:

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.

IV. DEFINITIONS

Employee or Agent. For purposes of this document, “employee” or “agent” refers to individuals who perform institutionally designated activities under the legal authority of the institution. Employees and agents can include staff, students, residents, fellows, contractors and volunteers, among others, regardless of whether these individuals are receiving compensation. The academic institution conducts research whenever and wherever its employees or agents engage in research in their capacity as employees or agents of the institution.

V. PROCEDURES

1. Authority of the IRB:

- a. The IRB has oversight authority for all research with human subjects conducted by anyone when acting as an employee or agent of UTHSC, including faculty, staff, students, residents, or fellows.
- b. Through IRB Reliance Agreements, the IRB has oversight authority for human subjects research conducted at UTHSC-affiliated institutions (Campbell Clinic, Le Bonheur Children’s Hospital, Methodist Healthcare- Memphis Hospitals, and Regional One Health) by their employees and agents.
- c. The UTHSC IRB reviews non-research requests for the use of drugs, biologics, or devices under the federal regulations pertaining to Emergency Use, Compassionate Use/Treatment Use, and Humanitarian Use Devices (HUDs) conducted by anyone acting as an employee or agent of UTHSC or its affiliated institutions.

2. IRB Chair(s) Responsibilities:

- a. The Chair(s) is a member of the IRB whose experience and expertise is documented in his/her CV. The Chair(s) is appointed by the UTHSC Vice Chancellor for Research or designee. The Chair(s) will serve a term of 3 years and may serve successive terms at the discretion of the Vice Chancellor for Research or designee. Removal of the Chair(s) may be accomplished by resignation in writing or by written notification of termination of the appointment by the Vice Chancellor for Research or designee.
- b. The Chair(s) will perform functions including, but not limited to the following:
 - i. Direct the proceedings of the full IRB committee. The position of Chair(s) is a voting position.
 - ii. Enforce UTHSC IRB policies and standards, as well as all applicable state and federal rules, regulations and statutes concerning human subject protection.

- iii. Oversee the review all protocols submitted to the committee, including new applications, continuations, and revisions, and communicate as necessary with all IRB subcommittees, consultants, auditors, and other reviewers so that all IRB issues are identified and resolved.
- iv. Review and make decisions about responses to administrative provisos for IRB approval, when necessary.
- v. Review and acknowledge emergency use requests.
- vi. Review and approve treatment use requests.
- c. The Vice Chancellor for Research or designee will evaluate the Chair(s) annually according to the following criteria:
 - i. Number of meetings attended and chaired out of total number of meetings;
 - ii. Completion of Collaborative Institutional Training Initiative (CITI) Initial Basic Training for IRB Members, Administrators, and Institutional Officials: Human Subjects Protections and Good Clinical Practices course, or the corresponding recertification testing course, every 3 years;
 - iii. Communicates effectively with investigators;
 - iv. Communicates effectively with organizational officials;
 - v. Knowledge regarding agenda items and preparedness to discuss issues that may be raised at the meetings;
 - vi. Knowledge of regulations and IRB policies pertinent to reviews conducted at meetings;
 - vii. Presents educational material in a way that is helpful in deliberations regarding specific applications;
 - viii. Provides adequate opportunity for Board members to contribute to deliberations regarding agenda items;
 - ix. Moderates deliberations regarding agenda items in an organized and efficient manner;
 - x. Adequately summarizes the key elements of proposed motions before voting by the Board;
 - xi. Conducts meeting agendas in a manner that is organized and efficient in the use of time;
 - xii. Knowledge of regulations and IRB policies pertinent to applications being reviewed by staff members; and
 - xiii. Carefully considers advice of staff members on issues related to both applications under review and the general operation of the IRB.

The evaluation performed by the Vice Chancellor or designee will be provided in writing. It will be based on information submitted by the Chair(s) regarding fulfillment of the above criteria. Pertinent information regarding fulfillment of criteria (ix)-(xv) will also be provided via an annual survey completed by IRB members, and pertinent information regarding fulfillment of criteria (xvi)-(xxii) will be provided via an annual survey completed by IRB staff. Areas needing improvement will be included in the annual objectives of the Chair(s) for the forthcoming year.

3. **IRB Director Responsibilities:**

- a. Serve as a voting member on the UTHSC IRB.
- b. Develop and implement IRB policy.
- c. 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.
- d. Develop and implement IRB policies and procedures regarding the HIPAA regulations, and train all IRB staff, members, and consultants on these requirements.
- e. Develop, implement, and update as necessary an orientation program for all new staff and IRB members.
- f. Seek out appropriate new members, consultants, ad hoc members, staff members and auditors.
- g. Advise the university administration, departments, investigators and compliance officials on IRB policies and procedures.
- h. Review all submissions with IRB staff for completeness and follow-up with other IRB administrative staff on any issues needing clarification prior to the IRB meeting and/or review of such submissions.
- i. 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.
- j. Create, maintain, and archive comprehensive documentation of IRB actions in a manner required by OHRP and FDA guidance including citation of specific regulatory categories under which determinations are made.
- k. Reviews outcome letters to assure that key regulatory issues are adequately addressed and negotiates satisfactory resolution of these issues in exchanges with section chairs, assigned reviewers, and investigators
- l. Plan departmental meetings to address questions regarding IRB review and policies.
- m. Triage research between IRB review categories (full board review, expedited review, exempt, HIPAA waivers).
- n. 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.
- o. Represent the IRB at professional, community and institutional meetings.
- p. Manage functions of all IRB administrative staff, including development and updating of job descriptions; assume responsibility for hiring, training, review, and termination of staff.
- q. Assist in reviewing serious adverse events, Safety Alerts, MedWatch, protocol deviations, unanticipated problems involving 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.
- r. Conduct review of proposals submitted for expedited review or exempt status.

- s. Implement, track, review and coordinate IRB communication regarding continuing review.
- t. Monitor and manage conflict of interest reports of investigators, key study personnel, and IRB staff per IRB policies and procedures.
- u. Implement, manage, and communicate reports of any IRB subcommittees.
- v. 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.
- w. Develop and maintain information and resources for the IRB website.
- x. Review submissions and prepare written correspondence with investigators, sponsors or the FDA concerning any submissions for emergency use or compassionate use.
- y. Conduct ethical and technical review of IRB applications meeting requirements for review by the full convened IRB to determine whether the applications are sufficiently well prepared to be placed on a meeting agenda
- z. Schedule IRB agendas for weekly meetings and assigns appropriate reviewers
- aa. Oversee the review of all protocols submitted to the full convened IRB including new applications, continuations, and revisions, and communicates as necessary with all compliance committees, consultants, IRB Chairs, auditors, and other reviewers so that all IRB issues are identified and resolved
- bb. Prepare each IRB section Chair regarding prominent regulatory issues that can be expected to arise regarding specific studies, based on initial assessments and assigned reviewer comments
- cc. Review audit reports of clinical sites for compliance with IRB policies and procedures, as well as other applicable laws and regulations
- dd. Maintain and update IRB information concerning federal regulations, guidelines, information sheets, applicable state and local laws and institutional policies regarding human subject research.
- ee. Assume responsibility for the files of the IRB, whether electronic or paper, including archiving, tracking, storage, retrieval, QA and security.
- ff. Coordinate, prepare appropriate paperwork, and maintain any correspondence concerning applications for and updates of the IRB Assurance(s).
- gg. Promote and support staff certification.

4. **IRB Associate Director Responsibilities:**

- a. Serve as a voting member on the UTHSC IRB.
- b. Administer and assist with the implementation of IRB policies and Procedures (SOPs) that comply with federal regulations, guidance documents, and state laws.
- c. Develop and manage departmental organizational and operational policies.
- d. Monitor IRB staff, IRB members, faculty, and research staff for adherence with IRB SOPs.
- e. Develop and provide training, guidance, and assistance to IRB staff.

- f. Develop and conducts individual and departmental training programs regarding the IRB electronic system and the IRB process.
- g. Develop, coordinate, and present topics for the quarterly IRB training sessions, *IRB Insights* – training program for researchers to learn more about human subject research protections and the IRB electronic process.
- h. Provides regulatory, ethical and method advice to research staff (investigators/coordinators) engaged in research involving human subjects to assure compliance with federal, state and university policies and regulations.
- i. Consult with investigators/coordinators regarding the ongoing IRB review required to assure compliance with federal and state regulations, and university and IRB policies and procedures.
- j. Collaborate with core users of the electronic system to develop and implement enhancements.
- k. Coordinate with Electronic Research Administration regarding maintenance and updates to iMedRIS.
- l. Review IRB submissions for regulatory compliance and provides feedback to the investigators/coordinators.
- m. Analyze and facilitate the review and approval of non-research requests for the use of drugs, biologics or devices under federal regulations pertaining to Emergency Use, Compassionate Use/Treatment Use, and Humanitarian Use Devices.
- n. Act as liaison with faculty and research coordinators, providing technical assistance and guidance on human research participation protection.
- o. Represent the IRB in coordinating human subjects research efforts with other departments on campus, and with campus administration.
- p. Triage applications for level of review and direct work assignments to appropriate department staff.
- q. Responsible for training, supervising, reviewing the work of IRB staff, and establishes work priorities and deadlines.
- r. Assist Director in interviewing, selection, performance evaluation, promotion and disciplinary action of IRB staff.
- s. Direct administrative staff concerning department guidelines, regulatory or policy changes.
- t. Supervise the work of IRB staff by monitoring their progress and providing timely feedback in their performance.
- u. Provide regulatory information and advises the IRB staff responsible for screening and reviewing submissions to the IRB.
- v. Oversee IRB staff in the development of communications to investigators/coordinators regarding IRB decisions.
- w. Evaluate the IRB review process on an on-going basis and implement changes as needed.
- x. Assist in review of audit report of clinical sites for compliance with IRB policies and procedures, as well as other laws and regulations.
- y. Receive and triage complaints from research subjects and researchers.

- z. Attend weekly IRB meetings and ensure that the minutes of the meetings are documented in compliance with federal regulations.
- aa. Review all submissions prior to IRB meetings to identify regulatory issues as well as institutional policy issues and make recommendations to IRB Analysts. These include DHHS, FDA, and HIPAA research-related regulations and policies, as well as requirements of UTHSC and affiliated institutions.
- bb. Monitor items on meeting agenda that require follow-up to assure that necessary actions are taken.
- cc. Attend meetings for IRB professionals and Leads AAHRPP accreditation effort including advising staff who assist with the effort, which involves: conducting the initial self-evaluation process; revising IRB policies and procedures; the creation and compilation of the Step 1 and Step 2 AAHRPP accreditation applications; responding to any AAHRPP concerns; creation of the training curriculum and education tools; training persons that make up UTHSC's HRPP (Human Research Protection Program); coordinating the site visit; and upon receiving accreditation status, overseeing the maintenance of accreditation status including various required activities and reports.
- dd. Oversee invoicing, receivable, and manage all IRB accounts receivable and accounts payable.
- ee. Develop and maintain information and resources for the IRB website.

5. **Senior Regulatory Specialist:**

- a. Analyze research protocol submissions to assure that protocol procedures and the consent process are structured in a manner that meets the requirements of federal, state, and institutional regulations and policies governing human research and privacy, and where appropriate, grant approval and makes recommendations.
- b. Reconcile proposals for funding with approved IRB applications.
- c. Communicate concerns to research staff (investigators and/or coordinators) with the goal of resolving pertinent issues and approve administrative and procedural modifications.
- d. Oversee and coordinate the preparation of new applications qualifying for expedited review and new applications qualifying for review by the full convened IRB and ensures that all relevant documents are provided to the IRB members and that the new applications are ready for review by the Board.
- e. Attend all IRB meetings in order to explain to members regulatory issues regarding study applications and to clarify their recommendations for change.
- f. Review and facilitate approval for non-research requests for the use of drugs, biologics or devices under federal regulations pertaining to Emergency Use, Compassionate Use/Treatment Use, and Humanitarian Use Devices.
- g. Provide guidance regarding policies and procedures to faculty, staff, and student researchers and research/study coordinators.
- h. Provide recommendations and assist with the design, testing and management of the IRB electronic system, iMedRIS.
- i. Collaborate with department core users to enhance current electronic system.

- j. Develop training courses, presentations and materials for board members, researchers and research/study coordinators regarding the IRB electronic system and the IRB process.
- k. Serve as a Board member to each section of the IRB and perform related job duties in the absence of the Director.

6. **Regulatory Specialist Responsibilities:**

- a. Analyze research protocol submissions to assure that protocol procedures and the consent process are structured in a manner that meets the requirements of federal, state, and institutional regulations and policies governing human research and privacy, and where appropriate, grant approval and makes recommendations.
- b. Reconcile proposals for funding with approved IRB applications.
- c. Communicate concerns to research staff (investigators and/or coordinators) with the goal of resolving pertinent issues and approve administrative and procedural modifications.
- d. Oversee and coordinate the preparation of new applications qualifying for expedited review and new applications qualifying for review by the full convened IRB and ensure that all relevant documents are provided to the IRB members and that the new applications are ready for review by the Board.
- e. Attend all IRB meetings in order to explain to members regulatory issues regarding study applications and to clarify their recommendations for change.
- f. Review and facilitate approval for non-research requests for the use of drugs, biologics or devices under federal regulations pertaining to Emergency Use, Compassionate Use/Treatment Use, and Humanitarian Use Devices.
- g. Provide guidance regarding policies and procedures to faculty, staff, and student researchers and research/study coordinators.
- h. Provide recommendations and assist with the design, testing and management of the IRB electronic system, iMedRIS.
- i. Collaborate with department core users to enhance current electronic system.
- j. Develop training courses, presentations and materials for board members, researchers and research/study coordinators regarding the IRB electronic system and the IRB process.

7. **IRB Reliance Manager Responsibilities:**

- a. Responsible for managing the reliance process and relationships between the UTHSC IRB and outside/external IRBs, including institutional and commercial IRBs; this includes reliance relationships in which UTHSC IRB participates as reviewing and relying IRB.
- b. Working with the IRB Director and Associate Director to develop policies, guidelines, and procedures related to the reliance agreement process.
- c. Serve as key liaison between the UTHSC IRB, researchers, clinical study sites, and external organizations and IRBs regarding IRB reliance issues.

- d. Work with the Office of Sponsored Programs to address legal and institutional requirements related to reliance agreements and the reliance process.
- e. 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.
- f. Provide back-up support for IRB Administrators by completing 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.

8. IRB Reliance Liaison Responsibilities:

- a. Works with IRB Reliance Managers to determine eligibility for authorization/reliance agreement and communicate reliance determinations to researchers.
- b. Works with IRB Reliance Managers to ensure that all UTHSC institutional requirements for human subjects' research, and ancillary reviews such as IBC and radiation safety committee reviews, are completed and relevant information provided to reviewing IRB, when UTHSC is the relying IRB.
- c. Interprets and applies federal and state regulations, and institutional policies, relevant to human research and privacy. These include DHHS, FDA, and HIPAA research related regulations and policies as well as requirements of UTHSC and other institutions covered by the UTHSC IRB.
- d. Communicates concerns to research staff (investigators and/or coordinators) with the goal of resolving pertinent issues.
- e. Works with IRB Reliance Managers to determine when reliance agreements should be submitted to the Office of Sponsored Programs through Cayuse SP.
- f. Submits post-approval documents from the reviewing IRB including but not limited to continuations/renewals, amendments/modifications, unanticipated problems, etc.

9. IRB Administrator Responsibilities:

- a. Interpret and apply federal and state regulations and policies, and institutional policies relevant to human research and privacy. These include DHHS, FDA, and HIPAA research related regulations and policies, as well as requirements of UTHSC and other institutions covered by the UTHSC IRB.
- b. 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.
- c. Complete reviews of applications that qualify for exempt and not human subject research (NHSR) status.
- d. Communicate concerns to research staff (investigators and/or coordinators) with the goal of resolving pertinent issues and approve administrative and procedural modifications.

- e. Maintain IRB renewal system including administrative closures/terminations and generate appropriate reports.

10. IRB Compliance Advisor Responsibilities:

- a. Determine if investigators are accurately applying relevant federal and state laws, regulations, and institutional policies and guidelines to ongoing clinical research.
- b. Conduct random/routine, informed consent, for cause, training and investigator-initiated study audits of IRB approved projects.
- c. Review investigator records, dental/medical records, and IRB records.
- d. Monitor ongoing research to ensure adherence of study procedures as described in the most recently approved versions of the study protocol and informed consent document.
- e. Observe the consent process and interview investigators, staff and subjects.
- f. Ensure the timely reporting of adverse events or other unanticipated problems and address specific concerns identified by the IRB Chair or Director.
- g. Prepare reports of audit findings.
- h. Correspond and follow up with investigators regarding audit findings
- i. Update and maintain audit files.
- j. Conduct general audits of the IRB as requested by the Chair(s), Director, or Associate Director.
- k. Develop customer satisfaction and needs assessment instruments and analyzing the results in order to identify educational needs of the University's researchers and client institutions regarding regulatory requirements and navigation of IRB application forms and processes.
- l. Develop and implement training programs and materials to meet identified educational needs.
- m. Responsible for analyzing research proposed research activities involving human subjects by using independent judgment in interpreting and applying relevant federal and state laws, regulations and institutional policies and guidelines, and where appropriate, grant approval for the Institutional Review Board.

11. Administrative Research Specialist Responsibilities:

- a. Provide administrative assistance to the IRB Chair(s), IRB Director, IRB Associate Director, and IRB Board members.
- b. Assist investigators and research/study coordinators with electronic submissions for review by the IRB.
- c. Generate approval documents regarding advertising for research studies.
- d. Generate approval documents for unanticipated events, IND Safety Reports and MedWatch reports.
- e. Process termination reports.
- f. Invoice and assist with management of IRB accounts receivable and payable.

- g. Verify record of certification of the CITI Initial Basic Training for Clinical Researchers and Study Teams: Human Subject Protections and Good Clinical Practices course in the protection of human research subjects for all faculty and staff involved in human subjects research at the University and affiliated institutions, or the corresponding recertification testing course, every 3 years. New UTHSC/affiliate investigators/researchers', or non-UTHSC/non-affiliate investigators/researchers', human subjects training can be reviewed for reciprocity.
- h. Verifies completion of annual IRB Confidentiality Acknowledgment and Conflict of Interest Disclosure for IRB members.
- i. Create and maintain training files for all IRB staff, members, and consultants.
- j. Oversees catering for IRB meetings.
- k. Schedule use of the electronic conference room for Research Administration.

12. **Board Membership:**

- a. UTHSC 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 Director or Associate Director of the IRB.
- 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. UTHSC 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. The maximum number of section members is thirty. Alternate members are used to maintain a working quorum of the IRB.
- d. Insofar as the UTHSC IRB 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. In addition, at least one of these individuals will be present at the meeting where a study involving this population will be reviewed, *or* consultation will be obtained from this individual before the meeting (with the exception of the prisoner representative, who must attend the meeting and may not simply provide consultation).
- e. Membership will include one or more individuals who represents the perspective of research participants, such as a former or current research participant or a research participant advocate.
- f. UTHSC IRB will not consist entirely of members of one profession.
- g. UTHSC IRB 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).
- h. All prospective applicants will be evaluated for potential membership (full or alternate member) based on the following:
 - i. Evidence of education and training (as documented in his/her CV or resume),
 - ii. Community service and/or length of residence in the community (as documented in his/her CV or resume),
 - iii. Specific needs of the IRB, and
 - iv. Willingness and time to serve his/her term.
 - i. 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, and
 - viii. Members representing research administration at the Regional One Health, Le Bonheur Children's Hospital, and Methodist Healthcare.
 - j. All stipulations for full membership apply to the Chair(s), Director, Associate Director, and Senior Regulatory Specialist.
 - k. All members will sign a Confidentiality Acknowledgement and Conflict of Interest Disclosure Statement that will be maintained on file.
 - l. Prospective applicants for Board membership submit to the IRB Director or designee supporting documents, including a current CV or resume and a copy of any professional license (if applicable to their application).
 - m. IRB members are appointed by the Vice Chancellor for Research or designee for an initial 3-year term, and may be reappointed for successive terms at the discretion of the Vice Chancellor or designee.
 - n. Annually (and at any other time deemed necessary), the Director will evaluate each Board member according to the following criteria:
 - i. Number of meetings attended (and chaired if applicable) out of total number of meetings;
 - ii. Availability to perform reviews as needed;
 - iii. Timeliness of reviews;
 - iv. Reviews are thoughtful and thorough;
 - v. Contributes in a meaningful way to deliberations during meetings;

- vi. Completion of CITI Initial Basic Training for IRB Members, Administrators, and Institutional Officials: Human Subjects Protections and Good Clinical Practices course, or the corresponding recertification testing course, every 3 years;
 - vii. Participation in educational sessions regarding the federal regulations/IRB policies; and
 - viii. Ability to work well with IRB staff in addressing issues regarding studies assigned for his/her review.
- o. Feedback will be provided in writing to each member. Where a Board member serves more than one role, such as also serving as a Chair, he/she will be evaluated according to both sets of criteria. Membership will be adjusted based on this periodic review; i.e., if a member receives a poor evaluation and does not adjust his/her performance as an IRB member accordingly, he/she will be removed from the Board by letter within 3 months.
 - p. Upon notification of a member's appointment, the IRB Administrative Research Specialist will prepare a letter of appointment for the member and provide it to the Vice Chancellor for Research or designee for signature.
 - q. Once signed by the Vice Chancellor for Research or designee, the IRB Administrative Research Specialist will forward the original letter to the member and file a copy with the IRB files.
 - r. The new member's name will be added to the IRB Roster. A copy of the new roster will be sent to OHRP for filing and posted on the IRB website.
 - s. The new member will review the training documents on the IRB website.
 - t. The IRB administrative staff will schedule the new member for orientation and training in the use of the iMedRIS electronic IRB system.

13. **Alternate Members:**

- a. Each IRB member may have an alternate member appointed to serve in the absence of the member.
- b. Alternate members may serve as an alternate for more than one member. With respect to the capacity in which the primary IRB member serves, each alternate member has the same experience, expertise, background, professional competence and knowledge (as documented in his/her CV or resume) comparable to the primary IRB members whom the alternate would replace.
- c. The alternate members are appointed in accordance with item #11.
- d. Alternate members may attend any IRB meetings, but may not vote if the principal IRB member for whom that member is an alternate is present.
- e. Before each 3-year re-appointment (and at any other time deemed necessary), the Director will evaluate each alternate Board member according to the criteria listed above for the Board member evaluation. Feedback will be provided in writing and will only otherwise be provided to the IRB staff for purposes of providing education. Aggregate information about knowledge of regulations/IRB policies will be used to create Board member trainings to be provided at Board meetings. Membership will be adjusted based on this periodic review; i.e., if a member receives a poor

evaluation and does not adjust his/her performance as an IRB member accordingly, he/she will be removed from the Board by letter within 3 months.

14. Use of Consultants:

- a. UTHSC IRB may, at its discretion, call upon individuals with competence in special areas of knowledge, including medicine, institutional policies, vulnerable populations, 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 consultation is to advise the IRB on specific questions. The consultant may provide the IRB comments in writing prior to the IRB meeting. The consultant may also attend the IRB meetings and contribute to the deliberations regarding specific applications. However, the consultant may not vote on any actionable items.

15. 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 Member or Alternate Member,
 - v. Scientific / non-scientific designation,
 - vi. Employment by or relationship to the IRB or other members, and
 - vii. Affiliation with UTHSC.
- b. The membership roster is reviewed at least annually by the IRB Director or designee to assure appropriate membership and diversity as outlined in the 21 CFR 56 and 45 CFR 46.
- c. Current and archived IRB membership rosters will be posted on the IRB website.
- d. Changes to the IRB membership rosters will be submitted to OHRP within 90 days of the change.
- e. IRB membership roster will be renewed with OHRP every 3 years from the date of acceptance by OHRP.

16. Attendance:

Members are expected to attend all of the scheduled meetings of their assigned section 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 by the IRB Director and Associate Director.

- b. The Director or Associate may contact members who miss 6 consecutive meetings to determine the action to be taken.
- c. The Director or Associate Director may ask for the resignation of the member if deemed necessary.

17. Removal of Members / Vacancies:

A member or alternate member may be removed, with or without cause, from the IRB:

- a. By the action of the Vice Chancellor for Research or designee, on the recommendation of the Chair.
- b. Automatically, if the member's misses 6 consecutive meeting or has a pattern of non-attendance.
- c. The Chair(s) may resign with a one-month notice.
- d. A member may resign from the IRB by submitting a letter of resignation to the Director or Associate Director.
- e. Vacancies in the membership shall be filled by the appointment process described in #11.

18. Quorum:

UTHSC IRB will conduct all business only when a quorum of members is present.

- a. The quorum is a simple majority of members of the specific section of the board that is meeting, but must include one non-scientific member and one non-affiliated or "community" member.
- b. The IRB Director or designee will note in the minutes any loss of quorum.

19. Evaluation of IRB Staff:

- a. All IRB staff will be evaluated annually by the Director or the Associate Director according to the following criteria:
 - i. Efficiency and timeliness in the processing of workload;
 - ii. Satisfactory performance of duties as listed above per position;
 - iii. Completion of CITI Initial Basic Training for IRB Members, Administrators, and Institutional Officials: Human Subjects Protections and Good Clinical Practices course, or the corresponding recertification testing course, every 3 years;
 - iv. Attendance at educational sessions;
 - v. Attainment and maintenance of certification (CIM/CIP as applicable);
 - vi. Quality of pre-reviews before meetings (as applicable);
 - vii. Knowledge of regulations;
 - viii. Communication with Chair(s), Director, and supervisor(s);
 - ix. Communication with investigators and research staff; and
 - x. Ability to help investigators with iMedRIS and with answering recommendations/provisos.

Feedback will be provided face-to-face and in writing. Where a staff member serves more than one role, such as also serving as a Board member, he/she will be evaluated according to both sets of criteria. The results will be incorporated in the University's annual performance review for each staff member. Aggregate information about knowledge of regulations/IRB policies will be used to create staff training programs.