

IRB Policy 2: Institutional Review Boards

Effective Date: October 2, 2023

I. Summary Policy

It is the policy of both the East Tennessee State University Campus Institutional Review Board (ETSU IRB) and the East Tennessee State University/Veterans Affairs Institutional Review Board (ETSU/VA IRB) that the composition of IRB Committees is in accordance with federal and other pertinent regulations. Each IRB will be appropriately constituted for the volume and types of research to be reviewed at ETSU. ETSU applies the same policies and procedures for protections for participants in non-DHHS funded research.

II. Membership

A. Summary Composition

The membership of each IRB will be based on the federal policy requirements as described in 45 CFR 46.107. The requirements for the composition of the IRB under the revised Common Rule vary slightly from the 1991 Common Rule. The composition of the ETSU and ETSU/VA IRB complies with both rules. Individuals from the Research and Sponsored Programs Office at ETSU or the Research Office at James H. Quillen VA Medical Center (JHQVAMC or VAMC) do not serve as voting members of either IRB. No members who are responsible for business development may serve as members of the IRB or carry out the day-to-day operations of the review process. Each IRB will be composed so that its membership does not lack diversity, including consideration of race, gender and cultural backgrounds, experience, expertise, and sensitivity to such issues as community attitudes, necessary to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

Each IRB is required to have a minimum of five members with varying backgrounds and expertise to provide thorough and complete review of research activities commonly conducted by ETSU and JHQVAMC. Each IRB includes at least one member whose primary concerns are in a scientific area and at least one member whose primary concerns are in non-scientific areas. Non-scientific primary concerns are those unambiguously in non-scientific areas, meaning little or no scientific or medical training or experience. Nurses, pharmacists, and other biomedical health professionals are not considered to have primary concerns in non-scientific areas. Each IRB includes at least one member who is not otherwise affiliated with the East Tennessee State University or the JHQVAMC (i.e., not a family member or spouse of an employee and not an active alumnus). Nonaffiliated members must attest in writing that neither they, nor any immediate

family member, are affiliated with ETSU or (for the ETSU/VA IRB) the VA affiliate covered under these assurances. The signed attestation (IRB Form 101; Member Info Sheet) will be maintained in the IRB membership records for a period of three years beyond the end of the term. The roster will include at least one member who represents the perspective of research participants, such as a former or current research participant. One member may satisfy more than one membership category.

Each IRB must be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. Each IRB is required to be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. Therefore, each IRB will include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, pregnant women, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

An IRB may, in its discretion, invite individuals (i.e., consultants) with competence in special areas to assist in the review of issues that require expertise beyond, or in addition to, that available on the IRB. These individuals may not vote with the IRB.

B. ETSU/VA IRB:

IRB members will be appointed by both the Vice Provost for Research of East Tennessee State University and the Director of the Veterans Affairs Medical Center upon recommendation of the HRPP Director and IRB Chair. The letter of appointment shall be affirmed with the signature of both the ETSU Vice Provost for Research and the VAMC Director.

The ETSU/VA IRB will have the following composition consistent with the terms of agreement between ETSU and the JHQVAMC. There will be six representatives from ETSU faculty and three from staff. There will be no less than three VA representatives who are a minimum 1/8th full-time employee equivalent, with two of the three VAMC representatives being members of the medical staff. At least one VA representative must have scientific expertise. There will be two representatives from the local community. The regulations at

38 CFR 16.107 require that the IRB have at least one member not otherwise affiliated with the VAMC.

R&D administrative officials including, but not limited to ACOS and AO, are prohibited from serving as voting members of the IRB. The VA RCO may not serve as a voting or nonvoting member of the IRB. The VA RCO will be invited to attend all meetings of the ETSU/VA IRB and will serve as a nonvoting consultant to the ETSU/VA IRB. Individuals working on without compensation appointments or those with intergovernmental appointment act appointments cannot be VA representatives. Facility Directors, their administrative staff, Chiefs of Staff, and other facility senior administrators and the VA non-profit corporation administrative staff may observe IRB meetings, but may not be voting or ex-officio, nonvoting members of the ETSU/VA IRB.

C. ETSU IRB:

The ETSU IRB members will be appointed by the Vice Provost for Research of East Tennessee State University upon recommendation of the HRPP Director and IRB Chair. The letter of appointment shall be affirmed with the signature of the Vice Provost for Research.

The ETSU IRB will include at least six voting ETSU faculty representatives. In addition, two ETSU Staff representatives, one ETSU student representative, two representatives from the local community, and one prisoner or prisoner representative with appropriate background and experience will serve as voting members. The prisoner representative must have a close working knowledge, understanding and appreciation of prison conditions from the perspective of the prisoner.

D. Non-voting *Ex Officio* Members:

The following are designated as non-voting *ex officio* or administrative members on both boards by virtue of their position or area of expertise: ETSU Legal Counsel, the HRPP Director and IRB Coordinator(s). Their terms shall be indefinite.

The ETSU Privacy Officer and the Administrative Officer (AO) of the JHQVAMC Research and Development (R&D) Office will also serve as a non-voting *ex officio* member of the ETSU/VA IRB.

Unless the Chair of the VAMC Research and Development Committee (VA R&D) has been appointed by the VPR and the VAMC Director to serve as a regular voting member on the ETSU/VA IRB, the VA R&D Committee Chair will also be a non-voting *ex officio* member of the IRB. Their (*ex officio*) term shall run concurrently with the term of service on the VA R&D Committee.

Ex officio members, invited guests, and expert consultants do not have voting privileges.

E. Alternates:

Alternates are appointed by the same process and for the same length of time as IRB members. An alternate may substitute for the primary IRB member for an entire meeting or at any time during a meeting. Alternates and IRB members have equal responsibilities in terms of required education, service and time commitments, and participation. Alternates receive the same information that the regular members receive. Although the function of an alternate member is to replace a regular member who cannot participate in a meeting, alternates should rotate their attendance at meetings, so as to gain from their experience in serving on the IRB.

The areas of expertise of the alternates should match that of the regular members such that the federal policy requirements for membership as described in 45 CFR 46.107 are met if a regular member cannot attend an IRB meeting. The IRB roster will identify the primary member or members for whom each alternate may substitute. Additionally, the minutes will reflect when an alternate member is representing a regular member.

F. Community Members:

The federal regulations specify that there must be representation on the IRB that is sensitive to issues such as community attitudes. Community members (also called nonaffiliated members) provide valuable insight in analyzing the Informed Consent Document (ICD) for clarity and understandability. They are invaluable in discussions of risks and benefits and function as an effective link between the IRB, the investigator, and the community. The community member provides the perspective of the individual or subject.

G. Selection and Credentialing of IRB Membership:

The regulatory requirements regarding IRB membership as found in §46.107 apply. The IRB must have sufficient expertise and diversity to evaluate ethical issues involved in protocols presented for review and approval. Selection of potential IRB members is made based on recommendations from committee members, Service Chiefs, Department Chairs, and Deans. Committee member selection must be made with the goal of maintaining appropriate IRB diversity, expertise, and regulatory compliance.

Acting upon recommendations received, at minimum, a curriculum vita or résumé must be submitted along with a written affirmation of degrees, certificates earned, technical areas of expertise, etc. (IRB Form 101) for each IRB nominee. The IRB Chairs, HRPP Director, and for ETSU/VA IRB, the VA AO will review all documents submitted to identify those nominees exhibiting technical expertise or other pertinent qualifications to review the types of research commonly presented to these Boards. Supporting documentation for appointment recommendation will be shared with the VPR by the HRPP Director. Documents supporting final appointments to either Board, along with records of continuing education, will become a part of the permanent membership records maintained by the IRB support office. The configuration of the IRB membership will be reviewed, at least annually by the institutions, including the VA R&D Committee. Substantive changes will be reported to OHRP. For the ETSU/VA IRB, changes will be reported to the VA AO by the HRPP Director. The VAMC Director is responsible for reporting changes in rosters to ORO Central Office with a simultaneous copy to the appropriate ORO Research Officer.

Consistent documentation of the following will be required from each member of the IRB at initial appointment and as significant changes occur, and will be made available as appropriate, upon request, during conditions of audit:

- ❑ Completed IRB Form 101: Member Information Sheet
- ❑ Current curriculum vitae or résumé
- ❑ Participation in the required training and New Member Orientation within the first 30-days of appointment
- ❑ Current education in the conduct of human subject research, as required by IRB Policy 1
- ❑ Current Volunteer Agreement in accordance with University policy

In addition, the IRB maintains documentation of participation in continuing education opportunities made available throughout the year.

H. Length of Appointment:

The term of appointment to the IRB for voting members and alternates shall be three (3) years, with the exception of student members, who shall serve terms of 1-3 years as their program duration allows. Members may be re-appointed to additional terms at the discretion of the Vice Provost for Research, and for the ETSU/VA IRB, the VAMC Director.

VA representatives to the ETSU/VA IRB are appointed for a period of three years and may be re-appointed to a new three-year term without lapse in service at the end of each term.

I. Attendance:

Attendance at the meetings of the IRB is crucial. Members are expected to attend no less than 50% of the convened IRB meetings annually. If a voting member has been unable to attend at least 50% of the meetings of the IRB during one year, the issue will be referred to the IRB Chair for remediation. If determined necessary by the IRB Chair, the member will be relieved of their position on the IRB, through written notification. For VA representatives, the VAMC Director must additionally sign the written notification. A new voting member will be appointed to the vacant position, selected from the pool of alternates or identified through solicitation of the Department Chairs, Deans, or appropriate other individual.

For VA representatives of the ETSU/VA IRB, the VAMC Director is responsible for suspending or terminating the IRB membership of any individuals who are not fulfilling their member responsibilities or obligations.

J. Frequency of Meetings:

The medical IRB will meet monthly. The campus IRB will meet every month during the academic year, with additional meetings scheduled if issues or studies that require full board deliberation are received. Additional meetings may be called at the discretion of the IRB Chair. Additionally, meetings may be canceled at the discretion of the IRB Chair.

K. Chair and Vice Chair:

Both the Chair and the Vice Chair play a leadership role in establishing and implementing IRB policy. As primary representatives of IRB decisions, the IRB Chair shares authority over all IRB policy and procedures in collaboration with the institutional official and the HRPP Director. The Chair should be willing to represent the institutions in discussions with federal authorities and should review all protocols presented to the full committee. The Chair/Vice-Chair is encouraged to communicate with other reviewers so that important IRB issues are resolved or identified before the convened meeting. The Chair directs the proceedings and discussion of the convened meeting and is a voting member with full privileges except in instances of declared conflict of interest. The Chairs and Vice Chairs should have an in-depth understanding of the ethical issues,

state law, institutional policy, and federal research regulations applicable to the types of studies reviewed by the IRB.

The Chairs and Vice Chairs are credentialed and appointed as indicated above (see Section G). In addition, they should have familiarity in conducting meetings of this type, interpersonal skills, leadership, and a background and reputation that cultivates respect from the IRB membership, the administration, and local researchers. Their profession should mirror the focus of the Board (recommended MD for the ETSU/VA IRB, PhD [social or behavioral scientist] for the ETSU IRB).

In the Chair's absence, the Vice Chair will have signatory authority and shall act in all matters concerning the functions of the IRB.

In the absence of both the Chair and the Vice Chair, the IRB may appoint a temporary acting chair with the approval of the VPR for the ETSU IRB and both the VPR and the ACOS/R for the ETSU/VA IRB. At the time of the scheduled meeting, the following criteria must exist for the acting chair: 1) served three or more years on the IRB, and 2) must have demonstrated understanding of human subject research regulations and local policy.

L. Compensation:

The Chairs will receive a small stipend in support of their efforts in the review of human subject research. Members of the IRB will not be compensated for their service on neither Board.

M. Liability:

The Institutions acknowledge that their respective employee and nonaffiliated members of the IRB are covered under the liability programs of the Institutions for their participation in the actions of the IRB.

N. Conflict of Interest:

Any member who has an interest in or association with a proposed research project may not act as a voting member for that project. The member may remain in the board room to provide information requested by the committee, but may not be present during the deliberation or vote. Refer to IRB Policy 17b for criteria. The requirements regarding conflict of interest under the revised Common Rule vary slightly from the 1991 Common Rule. The policy of the ETSU and ETSU/VA IRB complies with both rules.

IRB members should identify any potential conflicts with items on the agenda at the beginning of the meeting.

III. Quorum

A quorum will consist of a majority (more than 1/2) of the voting members of the IRB, including one member whose primary concerns are in the non-scientific area, as is required by 45 CFR 46.108. In addition, for the ETSU/VA IRB, at least one voting VA representative must be present for VA research to be considered. If research involving an FDA-regulated article is being reviewed, a licensed physician must be included in the quorum.

In order for research to be approved, it must receive the approval of a majority of those members present at the meeting. If at any time during the meeting the quorum fails (i.e., loss of majority through recusal of members with conflicting interests, early departures, or absence of a non-scientific member), further votes cannot be taken unless the quorum is restored. The recording of the vote will denote the number of votes for, opposed, and abstained. If the only non-scientist representative must leave the meeting for brief period, the IRB will take no further actions or votes until the non-scientist returns to the meeting.

Board members are contacted per email approximately 7-10 days prior to the scheduled meeting date and asked to confirm their planned attendance to ensure appropriate notification of alternates. A quorum worksheet is completed by the IRB Staff or Chair to determine and document whether the IRB meeting is appropriately convened.

IV. Review of the IRB

The ETSU Human Research Protection Program maintains a Quality Assurance Program as detailed in IRB Policy 24, which includes review and evaluation of the IRB. The HRPP Director, or designee, regularly reviews metrics for each IRB and works closely with the VPR and IRB Chair to ensure each IRB operates efficiently and consistently, provides timely review, and maintains compliance.

Attendance of the members will be monitored by the HRPP Director or designee. Any issues related to poor attendance or participation will be discussed with the IRB Chair to determine whether action is necessary. Attendance reports will be sent to the members' responsible department chairs or center/institute director at their request.

The IRB membership and composition are reviewed on an annual basis by the

IRB Performance Group for compliance with University policy and applicable regulations. In addition, the VA R&D Committee reviews the membership and composition of the ETSU/VA IRB on an annual basis. Findings and any recommended adjustments are shared with the IRB Chair, HRPP Director, and VPR.

IRB members, including the Chairs and Vice-Chairs, complete a Performance Self-Evaluation on an annual basis. The form will include metrics on attendance and volume of IRB assignments for the member to review. Members send the completed evaluation to IRB staff. The HRPP Director reviews the completed forms with the IRB Chair for identification of needed continuing education topics and to determine if the member's term should continue.

References:

45 CFR § 46.107, 108(b), 304

21 CFR § 56.107

38 CFR § 16.107

OHRP Compliance Activities: Common Findings and Guidance, July 10, 2002

VHA Directive 1200.05(3)

Memorandum of Understanding, ETSU and James H. Quillen VAMC

FDA Information Sheets: Frequently Asked Questions: IRB Membership

Revision History:

April 16, 2008, revised June 11, 2010, revised 1/27/11, revised 5/28/13, revised February 9, 2015, revised March 3/3/15, revised 10/15/15, revised February 17, 2016, revised April 2, 2018, revised Feb 7, 2019, revised April 30, 2019, revised March 27, 2020, October 22, 2020

