

IRB Policy 2: IRB Boards

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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. ETSU applies the same policies and procedures for protections for participants in non-DHHS funded research.

II. Membership

A. Summary Composition

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.

The membership of each IRB will be based on the Federal policy requirements as described in 45 CFR 46.107. Individuals from the Research and Sponsored Programs Office at ETSU or the Research Office at James H. Quillen VA Medical Center do not serve as voting members of either IRB. No members who are responsible for business development may serve as members on the IRB or carry out the day-to-day operations of the review process.

Under the 1991 Common Rule, IRB Committees are required to have a minimum of five members each, with varying backgrounds and expertise to provide thorough and complete review of research activities commonly conducted by the Institution(s). Among the voting members the following constituencies will be represented: men and women, behavioral and social scientists, and non-scientists. Each IRB includes at least one member whose primary concerns are in the 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 institution and who is not part of the immediate family of a person who is affiliated with the institution.

The 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.

Under the 2018 Common Rule, the following requirements apply to the composition of the IRB:

Each 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 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. The 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. The 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, 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.

The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. The IRB shall include 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.

An IRB may, in its discretion, invite individuals 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. [§ .107]

B. ETSU/VA IRB:

According to the terms of agreement between East Tennessee State University and the James H. Quillen VA Medical Center, the ETSU/VA IRB will have the following composition. There shall be six (6) representatives from ETSU faculty. There shall be no less than 3 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. There shall be four (4) ETSU staff representatives. At least one VA representative must have scientific expertise. There shall be two (2) representatives from the local community.

The ETSU/VA IRB Committee must include at least one (1) member whose primary interests are in a scientific area, one (1) member whose primary interests are in a non-scientific area, and one (1) member who is not affiliated with East Tennessee State University or the James H. Quillen VA Medical Center (i.e., not a family member or spouse of an employee and not an active alumnus). The non-scientist and non-affiliated member may be the same individual. The roster will include at least one member who represents the perspective of research participants, such as a former or current research participant.

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 (IPA) appointments cannot be VA representatives. Facility Directors, their administrative staff, Chiefs of Staff, and other facility senior administrators and the VA non-profit corporation (NPC) administrative staff may observe IRB meetings, but may not be voting or ex-officio, nonvoting members of the ETSU/VA IRB.

IRB members will be appointed by both the President of East Tennessee State University and the Director of the Veterans Affairs Medical Center upon recommendation of the Provost/Vice President for Academic Affairs, the Vice President for Health Affairs and the Associate Chief of Staff for Research (VA). The letter of appointment shall be affirmed with the signature of both the President and the VAMC Director.

C. ETSU IRB:

The ETSU IRB members will be appointed by the President of East Tennessee State University upon recommendation of the Provost/Vice President for Academic Affairs, and/or the Vice President for Health Affairs. The letter of appointment shall be affirmed with the signature of the President. Per ETSU policy, the ETSU IRB will include at least nine voting faculty representatives as follows: one representative from the College of Business and Technology, one representative from the College of Clinical and Rehabilitative Health Sciences; one representative from the College of Nursing, one representative from the College of Public Health; one representing the humanities; one representing the social sciences within the College of Arts and Sciences; one representing the area of human development; one representing the areas of curriculum and instruction and educational leadership within the College of Education, and one representing the Faculty Senate. In addition, two ETSU Staff Representatives, 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. Research involving prisoners as participants must be reviewed by the ETSU IRB. One voting member of the ETSU IRB must hold the M.D. degree. The ETSU IRB Committee must include at least one member whose primary interests are in a scientific area, one member whose primary interests are in a non-scientific area and one member who is not affiliated with East Tennessee State University (i.e. not a family member or spouse of an employee and not an active alumnus). The non-scientist and non-affiliated member may be the same individual. The roster will include at least one member who represents the perspective of research participants, such as a former or current research participant.

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: The Assistant to the President for Legal Affairs at ETSU, the IRB Director, IRB Coordinator(s), and IRB Information Research Technician. Their terms shall be indefinite.

On the ETSU/VA IRB, the Administrative Officer (AO) of the Quillen VA Medical Center Research and Development Office will be appointed as a non-voting *ex officio* member for an indefinite term. In addition, for the approved term of service, the Director of Pharmacy Services at Johnson City Medical Center Hospital shall also serve as a non-voting member of the ETSU/VA IRB. The ETSU Privacy Officer and a Mountain States Health Alliance representative will also serve as *ex officio* members of the ETSU/VA IRB.

Unless the Chair of the Quillen VA Medical Center Research and Development Committee (VA R&D) has been appointed by the President of East Tennessee State University 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:

A pool of alternates may be selected for the IRB upon approval of the Provost/Vice President for Academic Affairs, the Vice-President for Health Affairs, and (for the ETSU/VA IRB) the Director of the James H. Quillen Veterans Affairs Medical Center. Alternate members will have full voting authority only in the absence of

the regular member. They are designated to replace regular members at meetings that the latter cannot attend. Their length of service will be the same as the term of the voting member. 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. Although the function of an alternate member is to replace a regular member who cannot attend a meeting, alternates should rotate their attendance at meetings, so as to gain from their experience in serving on the IRB. Meeting minutes must document when an alternate member replaces a voting member. Alternates may be recommended by the Chair for election to vacant, un-expired terms and three year terms for which they qualify on the regular committee.

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. Alternates receive the same information that the regular members receive.

F. Community Members:

45 CFR 46.107 specifies that there must be representation on the IRB that is sensitive to issues such as community attitudes. The community member serves as a consumer representative and as the ethical conscience of the Board. Community 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. Their success reinforces and strengthens public trust in research. The community member provides the perspective of the individual or subject. The regulations at 38 CFR 16.107 require that the IRB have at least one member not otherwise affiliated with the VAMC. Community members must attest in writing that neither they, nor any family member, are affiliated with ETSU or (for the ETSU/VA IRB) the VA affiliate covered under these assurances (IRB Membership Certificate 101-Addendum 101a). The signed attestation will be maintained in the Office for the Protection of Human Research Subjects (OPHRS) membership records for a period of three years beyond the end of the term.

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. (form 101) for each IRB nominee. The IRB Chairs, 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 forwarded to the Vice Provost for Research (VPR) by the Director. The VPR will forward the final selection of nominees to the Provost/Vice President for Academic Affairs, the Vice President for Health Affairs, and (for ETSU/VA IRB) the Associate Chief of Staff for Research. Documents supporting final appointments to either Board, along with records of continuing education, will become a part of the permanent membership records maintained by OPHRS. The configuration of the IRB membership will be reviewed, at least annually by the institutions, including the VA Research and Development Committee. Substantive changes will be reported to OHRP. For the ETSU/VA IRB, changes will be reported to the VA AO by the OPHRS Director. The Medical Center 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 annually, and will be made available as appropriate, upon request, during conditions of audit:

- ❑ Completed Membership Certificate (IRB Form 101)
- ❑ Current curriculum vitae
- ❑ Attendance at 60% (at minimum) of the regularly scheduled IRB meetings, or [the members] contact with the ETSU Office for the Protection of Human Research Subjects (OPHRS) to inform the staff of potential absence, and [the members] contact with the alternate member assigned to them in order to have the alternate attend in their stead;
- ❑ Participation in the required training and New Member Orientation within the first 30-days of appointment;
- ❑ Documentation of current institutional certification (as appropriate) in compliance education in the conduct of human subject research (please refer to education 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. Members may be reappointed to additional terms at the discretion of the University President, and for the ETSU/VA IRB, the VA 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. To insure quorum, in the event the regular member cannot attend, it is the responsibility of the member to contact their appointed alternate member to attend in their stead. Notification of the change should additionally be forwarded to OPHRS. If a voting member has been unable to attend at least 60% of the meetings of the IRB during one year, and has not contacted their alternate member to attend in their stead (to guarantee quorum), the member will be relieved of their position on the IRB, through written notification, over the signatures of the IRB Chair and the OPHRS Director. For ETSU/VA IRB members, the medical center 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.

For ETSU/VA IRB, the medical center 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 Chair of the IRB.

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 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. Additionally, neither the Chair nor the Vice Chair may review for approval research studies submitted for exempt or expedited review from their respective departments or divisions (for larger departments). These individuals 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 encourage 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, 2) current certification in human subject research compliance education.

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 either Board.

M. Liability:

The Institutions acknowledge that their respective employee and community 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: IRB Member, Consultant, and IRB Staff Conflicting Interest for criteria.

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

The requirements regarding conflict of interest under the revised Common Rule vary very slightly from the 1991 Common Rule. The policy of the ETSU and ETSU/VA IRB complies with both rules.

Under the 1991 Common Rule, no IRB member may participate in the IRB's initial or continuing review of a project in which a member has a conflict of interest, except to provide information requested by the IRB. IRB members with a conflict of interest leave the meeting room during the deliberation and vote, and their departure is noted in the minutes.

Under the 2018 Common Rule, no IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

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. Meetings are not conducted by videoconference or teleconference.

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, 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.

If a quorum should fail during a meeting, (i.e., loss of majority through recusal of members with conflicting interests, early departures, or absence of a non-scientific member), the IRB will not take any further actions unless a quorum can be restored.

When reviewing a protocol involving children, the IRB will ensure that appropriate pediatric expertise is available to review the specific research activities. Non-voting consultants may be invited to assist with the review if additional expertise is needed.

When reviewing a protocol in which a prisoner is a subject,

- A majority of the IRB (exclusive of prisoner members or prisoner advocates) must have no association with the prison(s) involved, apart from their membership on the IRB;
- At least one IRB member present at the meeting shall be a prisoner, or a prisoner advocate /representative with appropriate background and experience to serve in that capacity. PRISONER/PRISONER REPRESENTATIVE MUST BE PRESENT AS VOTING MEMBER for the review of any studies (including initial review, continuing review, modification, or report of unanticipated problems involving risks to participants and others) that involve prisoners.

For VAMC research that involves mentally disabled persons or persons with impaired decision-making capacity, IRB membership must include at least one member who is an expert in the area of the research.

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.

Under the 1991 Common Rule, when reviewing studies with other vulnerable populations, including pregnant women, fetuses, neonates, handicapped persons, and cognitively impaired, the IRB will request review by expert consultant, as needed. If the IRB regularly reviews research involving a vulnerable category of subjects, one or more individuals who are knowledgeable about and experienced

in working with these subjects should be included as IRB members (refer to policy on vulnerable subjects for more details).

Under the 2018 Common Rule, if the IRB regularly reviews a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration will be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

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 Coordinator, Director, or Chair to determine and document whether the IRB meeting is appropriately convened.

When reviewing research funded by the National Institute on Disability and Rehabilitation Research that purposely requires inclusion of children with disabilities or individual with mental disabilities as research participants, the IRB must include at least one person primarily concerned with the welfare of these participants.

IV. Review of the IRB

The Office for the Protection of Human Research Subjects (OPHRS) will be audited by the East Tennessee State University Department of Internal Audit, at least once every five years. This department's function is guided by the *Institute of Internal Auditor's Statement of Responsibilities, Code of Conduct*, and the *Standards for the Professional Practice of Internal Auditing*. The audit includes evaluation of the adequacy of internal controls, and the level of compliance with institutional policies in addition to government laws and regulations.

The audit report will be forwarded as follows:

East Tennessee State Audit Office (ETSU), Office of the President, Provost for Academic Affairs, Vice Provost for Research, VP for Health Affairs, Director (OPHRS), VAMC Office of the Director, Associate Chief of Staff for Research, Veterans Health Administration Office of Research Oversight, VISN 9.

The OPHRS is additionally audited by external entities, which may include but are not limited to, the FDA, OHRP, ORO, Association for the Accreditation of Human Research Protection Programs, Inc. (AHRPP), and Mountain States Health Alliance Corporate Compliance and Auditing Services. When these

audits occur, a copy of the audit outcome, along with associated responses, will be forwarded to the ETSU Office of Internal Audit.

The IRB membership and composition is reviewed on an annual basis by the ETSU Office of Internal Audit. In addition, the VA Research and Development Committee review the membership and composition of the ETSU/VA IRB on an annual basis. Findings and any recommended adjustments are forwarded to the IRB Chair, Director, and the Vice Provost for Research.

IRB members, including the Chairs and Vice-Chairs, complete a Performance Self-Evaluation (Form 114) on an annual basis each April. Members forward the completed Form 114 to IRB staff. OPHRS Director reviews the completed forms for identification of continuing education topics.

IRB Staff are evaluated each March. The eValuation Form is completed by the Director for performance evaluation of IRB Coordinators and the IRB Information Research Technician and by the Vice-Provost for Research for evaluation of the OPHRS Director. The evaluation is discussed with the employee emphasizing strong and weak points in job performance. Mutual goals are set for the employee to reach before the next performance evaluation.

References:

45 CFR § 46.107

45 CFR § 46.304

38 CFR 16.107

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

45CFR 46.108(b)

21 CFR § 56.107

VHA Directive 1200.05

Memo of Understanding, ETSU and James H. Quillen VAMC

FDA Information Sheets: Frequently Asked Questions: IRB Membership

VHA Handbook 1058.01, June 15, 2015