

INTRODUCTION

It is the policy of *East Tennessee State University (ETSU) and the James H. Quillen Veterans Affairs Medical Center (VAMC) at Mountain Home (Johnson City), Tennessee to comply with all applicable local, state, federal, and international regulations in the conduct of human subject research. Written procedures are required to document the management of assurances of compliance. In accordance with the Federal Policy on the Protection of Human Subjects (Department of Health and Human Services (DHHS) Title 45, Code of Federal Regulations (CFR), Part 46, Food and Drug Administration (FDA) Title 21 CFR Parts 50 and 56, 38 CFR 16), ETSU and the VAMC are jointly responsible for the protection of the rights and welfare of human subjects of research conducted by, or under the supervision of physicians, faculty, staff, or students. To conduct this responsibility effectively, the University maintains Institutional Review Boards (IRB) to review research protocols involving human subjects and to evaluate both risk and protection against risk for those subjects. It is the function of the IRBs to 1) determine and certify that all research projects conducted by ETSU or by the James H. Quillen VAMC, or by physicians, faculty, staff, or students of either institution, or for any institution for whom these services are provided by contractual agreement, conform to the regulations and policies set forth by the DHHS, Office for Human Research Protection (OHRP), the FDA, and other federal entities regarding the health, welfare, safety, rights, and privileges of human subjects; and 2) assist the investigator in complying with federal and state regulations.

*Two Boards have been constituted within the Human Research Protection Program (HRPP) at East Tennessee State University to operate within the regulatory requirements of 45 CFR 46.107. These boards address the needs of both the ETSU research community and that of the James H. Quillen Veterans Affairs Medical Center (VAMC). Institutional responsibility is clarified and applicable throughout this document as follows:

I. PARTICIPANTS

One Institutional Review Board (IRB) serves the academic campus of ETSU and is designated as the East Tennessee State University Campus IRB (ETSU IRB). Its members primarily hold terminal degrees such as the Ph.D. or Ed.D. degree and are drawn from the Colleges other than the Quillen College of Medicine. 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. Staff and community representatives and one M.D. are included in its membership. The expertise is primarily in the social and behavioral sciences and in educational research. The ETSU IRB reviews non-medical research conducted by or under the supervision of faculty, staff, or students of the institution. ETSU is responsible for the protection of the rights and welfare of human subjects engaged in the research activities reviewed for approval by this IRB.

The participating institutions in the second Board, designated as the Medical Campus ETSU/VA IRB, are East Tennessee State University and the James H. Quillen Veterans Affairs Medical Center. The second IRB serves the Quillen College of Medicine, the James H. Quillen VA Medical Center, and is also the IRB of record for Mountain States Health Alliance, a local hospital group. Its members are largely drawn from the Quillen College of Medicine and the James H. Quillen VAMC and hold either the M.D. or other doctoral degrees. Community members are included. Its expertise is in the medical sciences and clinical research. The Medical Campus East Tennessee State University/James H. Quillen Veterans Affairs Medical Center IRB (ETSU/VA IRB) reviews medical research conducted by or under the supervision of physicians, faculty, staff, or students of either/both institutions. Research protocols submitted under contractual agreements from physicians and/or staff employed by any Mountain States Health Alliance (MSHA) institution are additionally reviewed for approval by the ETSU/VA IRB. East Tennessee State University (ETSU) and the James H. Quillen Veterans Affairs Medical Center (VA) at Mountain Home (Johnson City), Tennessee, are jointly responsible for the protection of the rights and welfare of human subjects engaged in the research activities reviewed for approval by this IRB.

In order to facilitate communication and accomplish the mutual goal of protecting participants, leadership from these institutions meet on a quarterly basis, with more frequent meetings as needed.

The Institutional Review Board Administration, located on the campus of East Tennessee State University, serves as the official Human Research Protections Program (HRPP) provider for the James H. Quillen Veterans Affairs Medical Center (Refer to the Memorandum of Understanding). The HRPP is officially outlined and documented in the Policies and Procedures, the MOU, and the OHRP approved Federal-wide Assurance. All policies are reviewed by both institutions and updated as necessary by the IRB.

Whether a study is reviewed by one board or the other depends upon the type of research, not just the College in which the investigators hold an appointment.

For example, a study in exercise physiology would be reviewed by the Medical IRB if it involved evaluation of the effects of natural product ingestion on performance.

The Chair of either IRB may request that a study scheduled for review by their IRB be transferred to the other IRB if the other IRB may be the more appropriate one for review. However, all VA research must be reviewed by the ETSU/VA IRB.

Except where explicitly separated in the following sections, these Policies and Procedures apply to both IRBs and all non-affiliated investigators and sites using either IRB (including those sites for which services are provided through contractual agreement). Additionally, sites where ETSU employees and students conduct research may, by agreement, use either IRB.

II. PURPOSE

The purpose of the IRB is to ensure that humans involved in research at these Institutions are afforded protection as described in the revised version of the Belmont Report, the Declaration of Helsinki, the International Conference on Harmonisation (ICH) Guidelines as adopted by FDA, Good Clinical Practices (GCP), the Health Insurance Portability and Accountability Act of 1996 (HIPAA), all applicable Federal Regulations governing human subjects research, and the moral and ethical precepts of the Institutions.

The IRB shall have three major functions:

- 1) Assure the protection of human subjects involved in research or related activities;
- 2) Assure that East Tennessee State University and the James H. Quillen Veteran Affairs Medical Center fulfill their contractual and federally mandated obligations relative to the protection of human subjects; and
- 3) Maintain the policies and procedures for the protection of human subjects which are, at a minimum, in accord with applicable regulations of funding and regulatory agencies.

The primary concern of the IRB is the protection of the rights and welfare of human subjects in research [21 CFR 56.111(a)(1)-(5)(b)]. Toward that end, the IRB addresses: 1) identification of the risk; 2) evaluation of the risk (e.g., a determination of whether or not the risk/benefit ratio is acceptable/appropriate);

3) evaluation of procedures to minimize risk; 4) evaluation of the informed consent document which must adequately explain the risks and 5) privacy and confidentiality issues. All research involving human subjects at ETSU and the VA Medical Center must be submitted to the appropriate IRB for review.

The Belmont Report of April 18, 1979 contains the principles upon which the HRPP is based. These principles are:

- A. Respect
- B. Beneficence
- C. Justice

The principles of the Belmont Report are addressed in the IRB training and on the IRB website (www.etsu.edu/irb) as a reference, and shall be applied to the review and conduct of all human subject research.

III. FEDERAL-WIDE ASSURANCE (FWA) and BOARD REGISTRATION

The institutions function under assurances approved by the federal Office for Human Research Protections (OHRP) under the Secretary, Department of Health and Human Services as:

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| East Tennessee State University | FWA#00002703 |
| James H. Quillen Veteran Affairs Medical Center | FWA#00002117 |

The Institutional Review Boards (IRB), operating within these assurances, are registered and identified as:

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|---|----------------------|---------------|
| East Tennessee State University Campus Institutional Review Board (ETSU IRB) | Non-medical research | IRB #00000256 |
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| Medical Campus East Tennessee State University /James H. Quillen Veterans Affairs Institutional Review Board (ETSU/VA IRB) | Medical research | IRB#00002054 |
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IV. AUTHORITY

The policies governing the IRB are in accord with the Federal-wide Assurance

(FWA) numbers indicated above and filed with the Federal Office for Human Research Protections (OHRP).

No research that involves human subjects may be undertaken at East Tennessee State University or the James H. Quillen Veterans Affairs Medical Center, or other non-affiliated site(s) using either IRB, without the prior approval of the IRB. If research is disapproved by the IRB, or the IRB requires modifications, the disapproval or need for modifications cannot be overruled by any other authority.

ETSU

All individuals engaged in research that is sponsored by East Tennessee State University, conducted by or under the direction of any faculty, staff, or student or agent of ETSU in connection with his or her institutional responsibilities; conducted by or under the direction of any employee or agent of ETSU using any property or facility of ETSU; or involves the use of ETSU's non-public information to identify or contact human research participants or prospective participants must obtain ETSU or ETSU/VA IRB approval before beginning any research activities.

The IRB must review all human subject research if one or more of the following apply:

1. The research is sponsored by ETSU
2. The research is conducted by or under the direction of any employee, faculty, staff, student, or agent of ETSU in connection with his or her institutional responsibilities
3. The research is conducted by or under the direction of any employee or agent of ETSU using any of ETSU's property or facilities
4. The research involves the release of non-public, information maintained by ETSU to identify or contact prospective participants or participants
5. The research involves the use of non-public information that is subject to HIPAA or FERPA maintained by ETSU to identify or contact prospective participants or participants
6. ETSU is the recipient of a direct federal award to conduct human subject research, even where all activities involving humans are carried out by a subcontractor or collaborator
7. ETSU or ETSU/VA IRB is the IRB of record by contract or MOU

Approval by the VA Research & Development (R&D) Committee is additionally required for any VA research ((defined as research that is conducted by VA investigators (serving on compensated, WOC, or IPA appointments) while on VA time). For VA studies, the Facility Director, Research and Development Committee and ORD can disapprove research. Future references in policies to "VA studies" refer to studies that meet this criteria at the James H. Quillen VAMC.

The following steps are taken to ensure that research involving human participants does not commence until the research has received all approvals required by the organization.

1. Education of researchers:
 - a. The Vice Provost for Research and Sponsored Programs (VPR) and other relevant personnel attends the annual New Faculty Orientation, and emphasizes the required approvals to incoming faculty.
 - b. The IRB Chair or other IRB representative attends and/or provides information for the “Thesis and Dissertation Boot Camp” and emphasizes the required approvals to graduate students preparing to initiate the thesis or dissertation process.
 - c. The Vice Provost for Research and Sponsored Programs (VPR) or designee attends and/or provides information for the Graduate Student Orientation and emphasizes the required approvals to new graduate students.
 - d. If a contract checklist has not been completed on an initial study submission that has an associated contract, the IRB Coordinator enters a “hold approval contract ” event on the protocol home page and ensures that the PI knows that IRB approval is held pending completion of this requirement.
 - e. If required site permissions, Department of Education attestations, etc, are missing at the time of an initial submission to the IRB, the IRB Coordinator enters a “hold approval” event on the protocol home page and ensures that the PI knows IRB approval is held pending completion of relevant requirements.
 - f. When new protocol submission xforms complete the administrative IRB review process and are accepted into the electronic system, a notice is sent to PIs stating that the application has been received, and informing them that “THIS DOES NOT CONSTITUTE AN APPROVAL BY THE ETSU OR ETSU/VA IRB, but you may log in to IRBManager and view the review process.”
 - g. As part of individualized training for the electronic system, researchers are educated about how to view the stage of their submission and clearly know where their new study is in the review process. Individual steps display with a “yes” or “no”, informing them if that particular step has been completed or is still pending.
 - h. When approval is issued for a new protocol submission, PIs receive an email notice that informs them that their new protocol submission has been approved by the IRB and tells them to log in to view and obtain their approval letter and associated documents. The notice also tells

them: PLEASE NOTE: If your study is a MSHA study, you must obtain MSHA approval as well before initiating the study.

- i. For VA new studies, when IRB review is complete, PIs are notified that their new protocol submission has been approved by the IRB, and are informed, "However, your study still requires approval by the VA R&D Committee."
2. Other steps taken include:
 - j. For VA studies, approval letters are posted as "internal only" attachments (viewable only to IRB member and staff) until R&D approval is obtained. When the VA Administrative Officer issues the VA approvals, the IRB Coordinator is notified via email and releases the IRB approval and stamped approved ICD to the PI.
 - k. When research is funded by ETSU, IRB approval letters for initial review and continuing review are copied to the Office of Research and Sponsored Programs Administration.
 - l. The Office of Research and Sponsored Programs Pre-Award Account Number Request Authorization requires that, if applicable, appropriate proofs of compliance (i.e, IRB, radiation, biosafety) accompany the form.
 - m. Conduction of a non-exempt human subject research project without IRB approval is investigated under the IRB Non-Compliance Policy.

Any signatory Institution may deny a research project approved by the IRB, including projects exempted by the IRB Chair. No office of any of the participating Institutions may approve a research activity that has been disapproved by the IRB.

V. Policies

IRB Chairs and the Office for the Protection of Human Research Subjects (OPHRS) Director review the policies and procedures at least every 36 months. The OPHRS Director revises the policies and procedures and forwards the revisions to the Vice Provost for Research (VPR) for his review and approval. After the VPR approval, the revised policies are distributed to IRB members for review and approval at the subsequent meeting of each committee. These policies will be published and provided to all members of the IRB, all investigators at the Institutions, and other interested individuals upon request. Initially, researchers are made aware of the IRB's policies and procedures concerning reporting and continuing review requirements through training. Additionally, investigators are notified in the IRB letter of approval of the requirement to report changes and unanticipated problems in research activities. The IRB's written policies and procedures pertaining to continuing review and

reporting requirements, as well as the appropriate forms, are available on-line to ensure that all individuals involved in research activities understand their obligations.

The OPHRS Director will review informational websites (e.g., FDA, OHRP) for new regulations, guidance, and evolving ethical and scientific issues on a monthly basis. When the revised Common Rule goes into effect, ETSU IRB policies will be updated to revise definition of "private identifiable information" and "identifiable biospecimen" at least every four years, or when updated in the Federal Register per §____.102(e)(7)

The VA Administrative Officer forwards pertinent new changes in VA regulations to the OPHRS Director. The ETSU Assistant to the President for Legal Affairs will forward new information, including new laws or regulations that may affect the Human Research Protection Program, to the OPHRS Director. In addition, if a discrepancy between federal or national law and other applicable laws is identified, input from ETSU Legal Affairs will be obtained.

The OPHRS Director disseminates pertinent information to IRB Chairs, IRB Staff, and IRB members, as appropriate.

When policies are revised or new information affecting the HRPP is obtained, the updated information will be posted on the IRB web site, www.etsu.edu. The home page of the web site is utilized as a focal point for news items.

In addition, the policy revisions will be presented in an IRB newsletter, which will be posted on the IRB website, www.etsu.edu. The newsletter will be forwarded to the VA AO for VA distribution.

If additional education is deemed beneficial, as in the case of complex new forms or policy, issues relevant to participant safety, or multiple requests for information or assistance, the following steps will be implemented:

- a) brochures or flyers explaining the revision will be created and distributed to each ETSU department, and to the VA AO
- b) OPHRS Director or IRB Coordinators will schedule and present educational seminars to explain the change
- c) OPHRS Director will post additional information on the IRB website, such as Powerpoint presentation, and/or detailed instructions

VI. Resources

The resources allocated to the HRPP are maintained and reviewed as follows:

- a. The Vice Provost for Research (VPR) and the HRPP Director meet routinely on a weekly basis. If any urgent issues regarding resources, including

- personnel or space needs, are identified during these meetings, the VPR discusses those issues with the Provost and/or the ETSU President.
- b. In addition, the VPR is involved annually in budget negotiations for the HRPP with the Provost as well as the Dean of the Quillen College of Medicine. The VPR seeks the input of the HRPP Director to identify any needs before the budget meetings. The VPR and the HRPP Director also review the needs of the program before contract negotiation with affiliates.
 - c. Benchmarks of IRB review time and numbers of studies are reviewed at the meetings of the IRB Performance Group. If timelines are not being met, an evaluation of resources, including staff sufficiency, number of studies per board and adequacy of space and technology, is conducted by the IRB Performance Group.
 - d. The Vice Provost for Research and the HRPP Director meet on an annual basis to review resource allocation and to establish goals for the next year. The review will include an evaluation of the resources needed for the HRPP, including, but not limited to, the following items:
 1. Total budget
 2. Space allocation, including meeting space
 3. Personnel, adequacy of FTE
 4. Access/involvement of legal counsel
 5. Review/management of conflict of interest disclosures
 6. Quality improvement plan
 7. Community outreach
 8. HRPP education program
 9. IRBs

The results of the review are provided to the next meeting of the IRB Performance Group.

Any action items derived from the review, as determined by the VPR and/or the IRB Performance Group, are discussed with the President at the next bi-annual meeting.

VII. Policy Application

ETSU applies the same policies used to comply with DHHS regulations to all (non-FDA) research. When applicable, such as when required in state or local laws, tribal laws, and foreign laws, additional protections beyond those in DHHS regulations are applied (see applicable IRB policies).

References:

21 CFR 56.111

45 CFR 46

MOU

ETSU FWA

VA FWA

Belmont Report