EAST TENNESSEE STATE UNIVERSITY

Institutional Review Board for the Protection of Human Subjects

Policy Effective Date: Insert • **Policy Revised:** 10/03/2024
Procedures Effective Date: Insert • **Procedures Revised:** Insert

Policy Name: Institutional Review Board for the Protection of Human Subjects

Policy Purpose

This policy specifies the oversight responsibilities and authorities of the Institutional Review Boards (IRBs) for the protection of Human Subjects Research.

Applicability

This policy is applicable to all ETSU employees, agents of ETSU, students, residents, and trainees conducting Research activities with humans, human data, or human biospecimens, regardless of funding source or performance sites where the Research activities occur.

Responsible Official, Office, and Interpretation

The Vice Provost for Research (VPR) and Chief Research Officer and the Human Research Protection Program (HRPP) Office are responsible for the review and revision of this policy. For questions about this policy, please contact the HRPP Office. The Provost in consultation with the Office of University Counsel, has the final authority to interpret this policy.

Defined Terms

A defined term has a specific meaning within the context of this policy.

Federal-wide Assurance (FWA)

An assurance of compliance with the U.S. federal regulations for the protection of Human Subjects in Research. An FWA is required whenever an Institution becomes engaged in Human Subjects Research conducted or supported by any U.S. federal department or agency.

Human Subject

An individual, including that individual's data and biospecimens, who meets the definition of "Human Subject" in HHS, FDA, or other applicable regulatory requirements.

Institutional Official (IO)

The individual authorized to act for the institution and obligates the institution to the terms of the Federal-wide Assurance; also called Signatory Official.

Research

A systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses both basic and applied Research and includes all Research meeting the definition of "Research" in HHS regulations, "clinical investigation" in FDA regulations, or other applicable regulatory agencies' definitions. Activities that meet this definition constitute Research for the purposes of this policy, whether or not they are conducted or supported under a program that is considered Research for other purposes. For example, some demonstration and service programs may include Research activities.

Reliance Arrangement

A written agreement between the institution operating the IRB overseeing the Research and the institution conducting the Research, which documents respective authorities, roles, responsibilities, and communication between each institution and its investigators. Also called an IRB Authorization Agreement (IAA), Reliance Agreement, or MOU.

The Belmont Report

Developed by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1974 to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral Research involving Human Subjects and to develop guidelines which should be followed to assure that such Research is conducted in accordance with those principles.

Policy Name: Institutional Review Board for the Protection of Human Subjects

Policy

It is the policy of East Tennessee State University (ETSU) to foster a Research environment that promotes respect for the rights and welfare of Human Subjects in Research conducted by or under the auspices of the University. The oversight and conduct of human Research activities under the auspices of ETSU will conform to applicable federal and state laws and regulations, the principles of The Belmont Report, and requirements of the Institutional Review Boards (IRBs).

1. Assurance of Compliance.

1.1. Federal-wide Assurance.

ETSU holds a Federal-wide Assurance (FWA) from the Office for Human Research Protections (OHRP). Through its IRBs, ETSU will uphold its FWA to comply with the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule). ETSU chooses to limit this assurance to federally sponsored Research; however, the Common Rule, including its subparts, provides the practical basis for the review and approval for all Research at ETSU regardless of sponsorship or funding. ETSU will also uphold its FWA that all Research, regardless of the source of support, will be guided by the principles of The Belmont Report.

The ethical principles set forth in The Belmont Report are:

1.1.1.1. Respect for Persons. Recognition of personal dignity and autonomy of individuals and special protection of those with diminished autonomy;

1.1.1.2. Beneficence. Obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risk of harm; and

1.2. Justice.

Fairness in the distribution of Research benefits and burdens and appropriate subject selection

1.3. Regulatory Application.

ETSU will apply additional regulations such as, the U.S. Food and Drug Administration (FDA) regulations, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Family Educational Rights and Privacy Act (FERPA), and others, when applicable, to Research involving Human Subjects under review.

2. Institutional Official.

The Vice Provost for Research (VPR) is the authorized Institutional Official (IO) responsible for enforcement of this policy. The VPR is responsible for the oversight of Research and Research related regulatory compliance which includes the Human Research Protection Program. In this capacity, the IO may exercise administrative and operational authority to enforce policies to maintain strong and effective compliance for Research involving Human Subjects.

2.1. Responsibilities.

The IO has the following responsibilities:

2.1.1. Foster, supporting, and maintaining an organizational culture that supports the ethical conduct of Research involving Human Subjects and adherence to regulations and institutional policies and procedures;

2.1.2. Serving as the signatory authority as delegated by the ETSU President and verifying compliance with the terms of the FWA;

2.1.3. Serving as a knowledgeable point of contact for federal oversight agencies, external collaborators, affiliates, and internal administration for human Research protection and ethics;

2.1.4. Ensuring that the IRBs function independently by, among other mechanisms, being directly accessible to the IRB Chairs and members if they experience undue influence or if they have concerns about the function of the IRBs;

2.1.5. Ensuring compliance with institutional policies and all applicable regulations for the protection of Human Subjects;

2.1.6. Ensuring effective implementation of an educational plan for an IRB members, staff and investigators to ensure they are knowledgeable;

2.1.7. Providing support to the human Research protection program, by ensuring that it has sufficient staff and resources to fulfill its mission and obligations.

2.2. Authority.

The IO is authorized to:

2.2.1. Establish IRBs and appoint IRB members with sufficient knowledge and expertise to review Research;

2.2.2. Take appropriate action to investigate and resolve attempts to unduly influence or compromise the independence of the IRBs;

2.2.3. Adopt and enforce standard operating procedures, including those dealing with conflicts of interest, to govern the review, conduct and oversight of human Research activities at ETSU;

2.2.4. Serve as the university's designee to enter into agreements documenting IRBs reliance or other necessary agreements to govern the conduct of Research;

2.2.5. Suspend or terminate Research including disapproving a protocol or Research activity approved by the IRBs;

2.2.6. Take actions necessary to ensure the protection of Human Subjects, integrity of the Research enterprise and HRPP, authority of the IRBs, proper conduct of Research, and compliance with applicable requirements; and

2.2.7. Prohibit or place limitations on Research privileges, disallow or restrict use of data, require investigators to undergo training, appoint persons to monitor ongoing Research, and other appropriate actions. Such actions will be reported to the applicable IRB, when appropriate.

3. Institutional Review Boards.

To conduct its responsibility effectively, ETSU will create and authorize IRBs to review Research protocols involving Human Subjects. Each IRB is an autonomous administrative body established to protect the rights and welfare of Human Subjects Research through documented adherence to established ethical standards, applicable regulations and laws, and University policies.

3.1. Jurisdiction of the IRBs.

The IRBs have jurisdiction over all Human Subject Research conducted under the auspices of ETSU, regardless of funding or performance site, including, but not limited to Research:

3.1.1. Sponsored by ETSU or its affiliates;

3.1.2. Conducted by or under the direction of any employee or agent (including students, residents, and trainees) in connection with their institutional responsibilities or with significant use of ETSU resources;

3.1.3. Involving the use of non-public information or materials maintained by ETSU or ETSU Health to identify, contact, or study Human Subjects;

3.1.4. When ETSU is the direct recipient of a federal award involving the conduct of Research involving Human Subjects; and/or

3.1.5. Where an ETSU IRB has agreed to serve as IRB of record through established Reliance Arrangements.

3.2. Membership.

IRB members shall be appointed by the IO. In addition to membership requirements stipulated by federal regulations, the membership of each IRB shall be chosen to credibly represent the varying perspectives of subjects, investigators, and society at large with appropriate expertise to review Research under its authority. In appropriate circumstances, the IRB shall solicit consultation or advice from others who are especially qualified to represent the views of a particular subject population or to provide expertise in addition to that available on the IRB. These additional individuals shall not vote with the IRB.

3.3. Conflict of Interest.

To conduct its responsibility effectively, ETSU will create and authorize IRBs to review Research protocols involving Human Subjects. Each IRB is an autonomous administrative body established to protect the rights and welfare of Human Subjects Research through documented adherence to established ethical standards, applicable regulations and laws, and University policies.

IRB members shall not participate in the review or approval of projects in which they are involved or have a conflicting interest, except to provide information requested by the IRB.

3.4. Authorities of the IRBs.

The IRBs have the following duties and authorities to:

3.4.1.1. Enforce regulatory requirements, university policies, and SOPs;

3.4.1.2. Determine when activities require IRB review;

3.4.1.3. Determine when Research qualifies for exempt status, and to conduct limited IRB review when applicable;

3.4.1.4. Approve, require modifications to secure approval, or disapprove Human Subject Research activities;

3.4.1.5. Require informed consent be obtained and documented in accordance with regulatory and policy requirements and may require that information, in addition to that specifically mentioned in the regulations, be given to participants when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects, support participant autonomy, or enhance their decision-making ability;

3.4.1.6. Waive or alter the requirements of informed consent and/or HIPAA authorization, as applicable, if specific criteria have been satisfied as specified in regulatory and policy requirements;

3.4.1.7. Conduct substantive continuing review of Research at intervals appropriate to the degree of risk of the Research and for protection of Human Subjects, but not less than once per year unless continuing review is not required under applicable regulation and/or policy;

3.4.1.8. Observe, or have a third party observe, the consent process;

3.4.1.9. Observe, or have a third party observe, the conduct of the Research;

3.4.1.10. Suspend or terminate approval of Research activities not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to Human Subjects;

3.4.1.11. Receive, evaluate, and conduct reviews concerning reports of subject complaints, adverse events, unanticipated problems, non-compliance, and other applicable matters that affect the approval of the Research or the safety of study participants;

3.4.1.12. Determine appropriate corrective and preventive actions, including but not limited to, whether data or specimens gathered without IRB approval or in association with harm to subjects or IRB noncompliance may be published or used for Research purposes;

3.4.1.13. Report to appropriate ETSU, affiliate, and government officials any findings and corrective actions for unanticipated problems involving risks to subjects or others, noncompliance, and suspension or termination of IRB approval of Research; and

3.4.1.14. The IRB may delegate one or more of its duties and authority to qualified staff of the HRPP Office upon approval of the IO.

3.5. Prospective Review.

IRB review and approval must be obtained prior to initiating any Research-related activities, including recruitment and screening of prospective participants, and no Research may commence until all required institutional approvals are obtained. The applicable IRB may withhold approval until appropriate ancillary reviews, contracts or agreements, education and training, or other required documentation is provided.

Research that commences without prior to receiving an IRB's approval must cease and be immediately reported to the appropriate IRB. The IRB and/or the IO will determine the consequences for commencing Research involving Human Subjects without IRB approval.

IRBs shall not grant retroactive approval for Research already conducted.

3.5.1. IRB Oversight.

All IRB-approved Research studies are subject to ongoing review as deemed appropriate by the IRB, which may include periodic administrative review, compliance reviews, and other appropriate post-approval monitoring in coordination with the HRPP.

IRB approval must be maintained for the duration of the human Research activities. If approval by an IRB lapses or is revoked, all Research activity must stop immediately, unless it is documented by the investigator to be in the best interest of already enrolled subjects to continue their participation for health and safety reasons and such continuation is approved by the IRB. Such decisions must be reported to the IRB promptly. Ultimately, the IRB has the final determination whether subjects should continue and the plan to do so.

3.5.2. Coordination with other Committees or Officials.

The IRBs consult and coordinate with other ETSU committees and officials for advice on policies and practices but functions independently from them. Input from other committees or officials is solely advisory in nature, and no other committee or official is authorized to make determinations about Human Subject

Research activities or appropriate protections, and investigators must abide by the IRB-approved protocol.

Research that has been reviewed and approved by an IRB may also be subject to review and approval by ETSU officials or other committees for reasons other than protection of Human Subjects or IRB compliance. However, those officials or committees shall not approve Research if it has been disapproved by an IRB, or shall not overturn other determinations of the IRB made in accordance with this policy and applicable SOPs. Restrictions or disapproval by other officials or committees shall be reported to the IRB.

If a Human Subjects Research project is part of an application for extramurally funded Research, it must be reviewed and approved by the IRB prior to initiating any Human Subject Research activities or expenditure of related funds.

4. Adoption of Standard Operating Procedures (SOPs).

The IO and IRBs shall develop, adopt, and publish written standard operating procedures (SOPs) that must be followed when Human Subject Research activities are conducted. These procedures shall serve as the governing procedures for the conduct and review of all Human Subject Research conducted under the auspices of ETSU and shall be available on the IRBs website. All Research approved by an IRB must follow these SOPs.

Procedures

The process by which the standard operating procedures (SOPs) are reviewed, approved, and revised is as follows:

The HRPP Director and VPR are responsible for the development, refinement, and approval of IRB SOPs. The IRB Chairs will actively participate in this process by providing recommendations and feedback, ensuring that SOPs reflect the needs and priorities of the research community. The IRBs may request new SOPs, suggest changes, or provide other feedback, and the IRBs will review from time to time the content and adoption of these SOPs at a convened meeting. SOPs will be reviewed and evaluated at routine intervals during semi-annual performance meetings with the HRPP staff, IRB Chairs, and the VPR. A summary of the meeting is provided to the ETSU IRBs. Approval and effective dates

will be documented on the SOPs, which are publicly available on the ETSU IRB webpage (www.etsu.edu/irb). To support effective application of these policies and SOPs, IRB members will receive ongoing training and education.

Policy Name: Institutional Review Board for the Protection of Human Subjects

Applicable Forms and Websites

www.etsu.edu/irb

Authority and Revisions

Authority: TCA § 49-8-203 et seq.; 45 CFR 46 (The Common Rule); 21 CFR 50 (FDA – Informed Consent/ Protection of Human Subjects); 42 CFR 50, Subpart F (Promoting Objectivity in Research); 21 CFR Part 54 (FDA – Financial Disclosure by Clinical Investigators); 21 CFR 56 (FDA – Institutional Review Boards); 21 CFR 312 (FDA – Investigational Drugs); 21 CFR 361 (FDA – Radioactive Drugs for Research Purposes); 21 CFR 600 (FDA – Biologics); 21 CFR 812 (FDA – Investigational Devices); 21 CFR 814 (FDA – Humanitarian Use Devices); 45 CFR 160, 164 (HIPAA)

Previous Policy: N/A

The ETSU Board of Trustees is charged with policy making pursuant to TCA § 49-8-203, et seq. On March 24, 2017, the Board delegated its authority to ETSU's President to establish certain policies and procedures for educational program and other operations of the University, including this policy. The delegation of authority and required process for revision to this policy can be found on the Policy Development and Rule Making Policy webpage.

To suggest a revision to this policy, please contact the responsible official indicated in this policy. Before a substantive change to the policy section may take effect, the requested changes must be: (1) approved by the responsible office; (2) reviewed by the Office of University Counsel for legal sufficiency; (3) posted for public comment; (4) approved by either Academic Council or University Council; and (5) approved by ETSU's President.