IRB Policy 3: Roles and Responsibilities for the Protection of Human Research Participants -

Effective Date: April 6, 2023

I. Summary Policy

It is the policy of both the ETSU IRB and ETSU/VA IRB to protect the rights and welfare of human research participants through review of protocols to ensure compliance with applicable regulations, monitoring of research activities, and education of the research community. The IRB is responsible for reviewing research projects involving human subjects proposed by students at, or employees of, East Tennessee State University and employees or medical staff of the James H. Quillen Veterans Affairs Medical Center and for any institution for whom these services are provided by contractual agreement. In order to comply with applicable regulation and ensure the highest ethical standards when conducting human subject research, there must be commitment and involvement from various institutional components in addition to the research team. This policy specifies the roles and responsibilities of investigators and others when conducting or overseeing research involving human subjects.

II. Principal Investigator

The Principal Investigator (PI) initiates the research proposal, defines the protocol, controls the conduct of the research, and directly supervises all other research study staff or personnel involved in the research. The PI bears ultimate responsibility for the scientific, technical, and administrative aspects of the research study, even when tasks have been delegated to other research study staff. The PI must be qualified to conduct the research proposed through appropriate training, experience, and credentialing and must attest that adequate facilities, staffing and resources are available to conduct the research as proposed in accordance with applicable regulation, policy, and ethical standards.

To be eligible to serve as PI on a protocol submitted to ETSU IRB or ETSU/VA IRB, an individual must be directly affiliated with ETSU or the Quillen VAMC, as follows:

- A current member of the ETSU faculty and/or staff
- A current student enrolled at ETSU (undergraduate, graduate, resident, or postdoctoral fellow) with an active Faculty Mentor
- A current VA appointment to conduct VA research

The IRB is responsible for determining that the PI and research team are qualified to conduct the research as proposed and has the authority to impose additional eligibility requirements as deemed appropriate to protect the rights and welfare of the participants.

As a general condition for the approval of a research study, the IRB holds the principal investigator of the study responsible for the following:

1. Maintaining current contact information, education, compliance related education/certification and applicable experience documentation;
2. Accurately identifying research site and team members. Assuring all Investigators and study personnel complete initial and continuing education in human research protections to remain up-to-date on Federal regulations, ETSU policies and procedures, and compliance expectations. Assuring all study personnel complete conflict of interest disclosure forms, maintain documentation, and report any identified conflicts to the IRB.
3. Adherence to Federal regulations, state and local laws, Institutional policies, IRB policies and procedures regarding the safety and protection of human participants and Good Clinical Practice (GCP) guidelines (if applicable to the type of research).
4. Adherence to all Federal and ETSU policies regarding the responsible conduct of research as presented at https://www.etsu.edu/research/researchethics.php.
5. Ensuring the ETSU IRB and ETSU/VA IRB (registered and holding OHRP approved Federalwide Assurances (FWA) in compliance with the requirements of 45 CFR 46, 38 CFR 17, and 21 CFR Part 56) will be responsible for the initial and continuing review (as required) and approval of the research, unless reliance on an external IRB has been established in accordance with IRB Policy 21.
6. Reporting adverse events and unanticipated problems involving risk to participants and others to the IRB according to IRB policies and procedures, sponsors and appropriate Federal agencies as required.
7. For studies that require continuing review (see policy 11), assure continuing review applications are submitted in a timely manner so IRB review occurs prior to the expiration date. The Investigator acknowledges that the Federal regulations do not allow a grace period.
8. For studies that do not require continuing review, ensure administrative check-in forms are submitted in a timely manner prior to the assigned deadline.
9. Being aware of current literature in the field of study to assure participants are no longer placed at risk if additional risks have been identified or no benefit has been proven. The Investigator should build off previously conducted research to decrease the potential for participants to be needlessly placed at risk.
10. Acting as a liaison between the IRB and the sponsor to facilitate information sharing as appropriate.
11. Supervising the research process, ensuring that research is conducted in a manner which will minimize risks to subjects. Taking responsibility for ensuring study personnel are properly trained, qualified and have appropriate facilities and resources to conduct the research. Ensuring all students, faculty, associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments. Assuring adherence to the study protocol. Monitoring the informed consent process. Communicating regularly and effectively with their research staff. Responsible for protection of the safety and welfare of research participants.

12. Overseeing external performance sites, assuring adequate staff, resources, pharmacy practices and Federal assurances with appropriate IRB approvals.
13. Assuring the IRB protocol is reflected in the grant proposal for extramural or intramural support, and informing the IRB of any updates or modifications to the protocol prior to their implementation and in compliance with Federal and institutional regulations.
14. Assuring proper performance of the informed consent process. Retaining a copy of the signed and dated informed consent document in the study file and provides a copy to the research participant.
15. Promoting compliance and maintaining documents in accordance with Federal and state regulations, and sponsor and institutional policies and procedures regarding the safety and welfare of human participants. Making records available for inspection in accordance with 21 CFR 312.68.
16. Agreeing to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, to not make any changes in the research without written IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.
17. Reviewing and approving IRB applications, amendments and adverse events prior to their submission to the IRB, as documented by their signature on the IRB application. Submitting applicable reports in a timely manner or according to published deadlines.
18. Assuring participant privacy (relates to person) and confidentiality (relates to data) according to HIPAA guidelines, Institutional and IRB policies and procedures.
19. Conducting the study in accordance with the relevant, current protocol and to only make changes in a protocol after notifying the IRB, and if funded, the sponsor, except when necessary to protect the immediate safety of subjects.
20. Informing the OHRP, VA R&D, the ETSU or ETSU/VA IRB (as appropriate) at the time of research site or records audits conducted by study sponsor, monitor or other internal, external or regulatory entity, whether announced or unannounced, for-cause or not for-cause. The initial notification (auditors on site) will be followed by a copy of the written audit findings forwarded by the auditing body to the PI, within 30 days of the PI receiving the report. As available, a copy of the PI response, along with any corrective actions plans must additionally be forwarded.
21. Informing any subject, or any persons used as controls, procedures or other interventions being used for research purposes and ensuring requirements related to obtaining informed consent and IRB review and approval found are met.
22. Being responsive to IRB requests for information and notifications.
23. Notifying IRB in writing of completed study per policy and retention of study records for six years from the end of the calendar year in which the study is closed.
24. Notifying the IRB prior to separating from the university (i.e., graduation, leaving employment) to close active protocols or transfer oversight to another Investigator as appropriate.

Additionally, for VA studies:

25. Investigators are required to prepare and maintain adequate and accurate case histories. A case history is a record of all observations and other data pertinent to the investigation on each research subject. Case histories include the case report forms and supporting data including signed and dated consent forms, any medical records including, but are not limited to: progress notes of the physician, the individual's hospital chart(s), and nurses' notes. The case history for each individual must document that informed consent was obtained prior to participation in the study.
26. If the PI will not personally obtain consent, the researcher must formally and prospectively designate to another research team member the responsibility of obtaining consent.
27. Students and trainees (including residents, fellows, and VA employees), from schools with an academic affiliation agreement consistent with current VHA policy, may serve as researchers within a VA facility, or use data, or human biological specimens, that have been collected within VA for clinical, administrative or research purposes. A researcher sufficiently experienced in the area of the trainee's research interest must serve as PI or co-PI and is responsible for oversight of the research and the trainee.
28. Maintain a master list of enrolled subjects
29. If the investigator contracts with a firm (e.g., a survey research firm) to obtain consent from subjects, collect private individually identifiable information from human subjects, or be involved in activities that would institutionally engage the firm in human subjects research, ensure that the firm has its own IRB oversight of the activity and that the Privacy Officer (PO) has determined that there is appropriate authority to allow the disclosure of individual names and other information to the contracted firm;
30. If either the awardee of a clinical trial funded or supported by a Federal agency or department other than VA, or conducting a clinical trial funded or supported by a non-Federal agency or department (e.g., university, industry, nonprofit organization) or not funded, posting a copy of the IRB-approved informed consent form used to enroll subjects after the clinical trial is closed to recruitment and no later than 60 days after the last study visit by any subject as described in the IRB-approved protocol. For multi-site studies, it applies when all sites have closed subject recruitment. See Policy 13 for additional details.

Additionally, for studies with investigational drugs or devices,

31. (for investigational drug studies) Agree to inform any subject, patients, or any persons used as controls, that the drugs are being used for investigational purposes and ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and Institutional Review Board (IRB) review and approval in 21 CFR Part 56 are met. Agree to protect the rights, safety and welfare of the participants under their care.

32. If applicable, read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug and appropriately communicate those to the IRB and participants.
33. Administer the drug or device only to participants under their personal supervision or the supervision of a sub-investigator
34. Supply investigational drug or devices only to persons authorized to receive it under 21 CFR 312.61; 21 CFR 812.110.
35. Maintain adequate records of the disposition of the drug, including dates, quantity and use by participants. Device records must include records of receipt, use or disposition of a device including the type and quantity of a device, the receipt date, the batch number or code mark, names of all persons who received, used, or disposed of each device, records of returns, repairs or disposals.
36. Return unused supplies of the drug to the sponsor or otherwise provide for disposition of the unused drug according to regulations at 21 CFR 312.59; 21 CFR 312.62; 21 CFR 812.110.
37. Maintain adequate and accurate records recording all pertinent data including the obtaining of informed consent prior to study participation. Allow authorized persons to have access to, and copy and verify records or reports (21 CFR 312.62 and 21 CFR 812.145).
38. Maintain records to meet the standards of all applicable regulations, including federal guidance, institutional standards and sponsor requirements. FDA requires record retention for drug studies to be maintained for a period of 2 years following the date a marketing application is approved for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified (21 CFR 312.62). FDA requires record retention for device studies to be maintained for 2 years after the latter of the following two dates: termination of completion or when records are no longer required (21 CFR 812.140). ETSU policy requires retention of records for six years from the end of the calendar year in which the study has been closed. Sponsor requirements may vary.
39. Furnish reports to the sponsor of the drug, including report shortly after completion of their participation.
40. Promptly report to the sponsor any adverse effect that may reasonably be regarded as caused by, or probably caused by, the drug.
41. Provide sponsor with accurate disclosure statements as required at 21 CFR 312.64; 21 CFR 812.110; 21 CFR 54.4(b).
42. Assure that an IRB meeting the requirements of part 56 is responsible for initial and continuing approvals.
43. For investigational drug subject to the Controlled Substances Act, take all required security precautions.
44. Prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation.

Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. The case history for each individual shall document that informed consent was obtained prior to participation in the study.

III. Unaffiliated Investigators

Unaffiliated Investigators are any research study staff that are not employees, students, or agents of ETSU or the VAMC, or any institution for whom these services are provided by contractual agreement. Investigators and physicians in private practice settings who are not acting as employees or agents of the institutions under the approved Federalwide Assurances noted in this policy are subject to all of the usual human protection requirements and responsibilities. Such investigators must be under the direction or supervision of an affiliated Principal Investigator and will be required to sign an Unaffiliated Investigator Agreement (UIA), agreeing to comply with all educational requirements and to be bound by the human protection policies of the ETSU and ETSU/VA IRBs. A copy of the fully executed document will be returned to the investigator to be added to the research records. The original copy will be maintained in the IRB Administrative records, along with the curriculum vitae for the investigator.

IV. Co-investigator, Study Coordinator, and Research Staff

Appropriately qualified co-investigators and research study staff may perform tasks as delegated by the PI, but they do not accept primary responsibility for the research study. All individuals engaged in research must be identified on the IRB proposal and receive approval prior to performing research activities. The PI is responsible for training and delegating tasks to approved research study staff and must maintain appropriate documentation in the study record. All study personnel must complete initial and continuing education in human research protections to remain up-to-date on Federal regulations, ETSU (and VA if applicable) policies and procedures, and compliance expectations.

As a general condition for the approval of a research study, the IRB holds the study personnel responsible for the following:

1. Adherence to Federal regulations, state and local laws, Institutional policies, IRB policies and procedures regarding the safety and protection of human participants and Good Clinical Practice (GCP) guidelines (if applicable to the type of research).
2. Reporting adverse events and unanticipated problems involving risks to the participants and others to the IRB according to IRB policies and procedures, sponsors and appropriate Federal agencies as required.
3. Acting as a liaison between the IRB, the Investigator and the sponsor.

4. Promoting compliance and maintains documents in accordance with Federal and state regulations, and sponsor and institutional policies and procedures.
5. Assuring participant privacy and confidentiality according to HIPAA guidelines, Institutional and IRB policies and procedures.

V. Department Chair, Dean or VA Service Chief

The Department Chair, Dean, or VA Service Chief (for VA studies) are in the best position to evaluate the adequacy of resources and qualifications of researchers under their supervision. As such, for non-student led research, the Dean, Department Chair, or VA Service Chief must review the protocol submission and provide written attestation prior to IRB review and has the following responsibilities:

1. Promote compliance with Federal and state regulations, and sponsor and institutional policies and procedures regarding the safety and welfare of human participants involved in research studies initiated from their department.
2. Review and approve IRB applications prior to submission, as documented by their signature on the IRB application to assure the soundness of the research design, scientific and scholarly merit in relation to the departmental capacities, and adequate staff and resources to conduct the study.

VI. Faculty Mentor

When a student investigator is listed as the PI on the IRB submission, a full-time ETSU faculty or staff member must also be listed as the Faculty Mentor. Visiting faculty may not serve as primary Faculty Mentor. The IRB holds the Faculty Mentor(s) responsible for the overall management of an approved research protocol in conjunction with the student PI. Management of the research encompasses the ethical, administrative, fiscal, and applied elements of a project. The designated Faculty Mentor must sign the IRB submission to attest that the student investigator is qualified to perform the study as proposed, the study is scientifically sound, and there are adequate resources available to complete the project in the proposed timeline. In addition, the Faculty Mentor(s):

1. Agrees to meet with the student investigator on a regular basis to monitor study progress;
2. Agrees to be available, personally, to supervise the student investigator in solving problems, should problems arise during the course of the study;
3. Ensures the student PI and all study personnel have sufficient training and experience to conduct the research as proposed;
4. Reviews responsibilities of the Principal Investigator (Section II of this policy) with the student PI and accepts shared responsibility with student PI;
5. Collaborates with the student PI during preparation of the IRB submission to ensure the study proposal is scientifically sound, ethically appropriate, and in compliance with applicable regulations and policy;

6. Reviews the completed IRB submission form and all supporting documents, including the consent form(s), recruitment materials, and data collection form(s), and affirms the submission is complete, accurate, and ready for IRB review;
7. Ensures all research activities have IRB approval and other applicable approvals required by the institution(s) before human subjects are involved, and implements the research as approved by the IRB;
8. Reviews all proposed changes to the research with the student PI, collaborates to submit appropriate modification forms to the IRB, and trains research personnel on how to implement the modifications once IRB approval is obtained;
9. Assists the student PI with recordkeeping, project management, and research compliance for the duration of the project; and
10. Continues to be actively engaged and oversee the research for the duration of the project, and confirms the student PI has closed the study with IRB once completed.

VII. VA Privacy (PO) and Information System Security (ISSO) Officers

For VA Studies, the VA facility PO and ISSO are responsible for:

1. Ensuring that the proposed research complies with all applicable local, VA, and other Federal requirements for privacy and confidentiality, and for information security, by identifying and addressing potential concerns about proposed research studies.
2. Reviewing the proposed study protocol, study specific privacy and security information, and any other relevant materials submitted with the IRB application.
3. Identifying deficiencies in the provisions for privacy and confidentiality or information security, respectively, of the proposed research, and making recommendations to the investigator and/or the IRB of options available to correct the deficiencies.
4. Following up with the investigator and/or the IRB, in a timely manner, to ensure the proposed research is in compliance with relevant privacy and confidentiality and information security requirements, respectively, before the investigator initiates the study
5. Conducting a final review after the IRB has approved the study to ensure no further changes impact the privacy and security requirements of this study.

VIII. Institutional Official

The Institutional Official (IO) is the individual authorized to act for the institution and obligates the institution to the terms of the Federalwide Assurance. The IO makes appointments to the IRB, in consultation with the HRPP Director and IRB Chair(s), or may elect not to renew an appointment for members not contributing effectively, or as needed for sufficient composition of the IRB.

The IO is responsible for:

1. Designating one or more IRBs to conduct independent review of research conducted at or on behalf of the institution;
2. Providing sufficient resources, space, and staff to support the IRB's functions and maintain the integrity of the Human Research Protection Program;
3. Making available training and educational opportunities for the IRB, HRPP, and investigators;
4. Establishing and maintaining an institutional culture of respect for human participants;
5. Ensuring effective institution-wide communication and guidance on human participants research;
6. Serving as a knowledgeable point of contact for federal oversight agencies, external collaborators, and internal administration;
7. Ensuring certification of IRB approval of research to the appropriate federal agency, as required; and
8. Delegating authority or responsibilities to the IRB and HRPP staff to ensure regulatory and institutional oversight of research involving human participants.

IX. Human Research Protection Program Staff

The IRB shall be supported by an adequate number of staff personnel; generally, one staff member per 300 active studies. At a minimum this staff shall include the Director, IRB Coordinator, and support staff provided by East Tennessee State University and the James H. Quillen Veterans Affairs Medical Center. Human Research Protection Program (HRPP) staff are designated by the Institutional Official to oversee and manage the IRB operations, including working in collaboration with the committee to develop and maintain appropriate policy, procedures, processes, and records for research activities involving human participants.

The HRPP Staff responsibilities include the following:

1. Checking all IRB protocol submissions for completeness and contents of the elements of proper informed consent as required by IRB policy prior to forwarding for IRB review;
2. Confirming the requirements for compliance education have been achieved by all investigators prior to issuance of study approvals;
3. Promoting communication among investigators, department heads, the IO, IRBs, and external partners to maintain a high level of awareness regarding ethical conduct of research;
4. Informing investigators of the status of IRB review, documenting review decisions, and notifying investigators in writing of IRB determinations;
5. Facilitating IRB meetings and preparing all meeting materials in a timely fashion;

6. Determining the appropriateness of collaborative and cooperative research arrangements and ensuring required agreements are documented in writing in accordance with IRB policy and federal guidance;
7. Ensuring IRB records are maintained per federal regulations and university policy and that records are accessible, upon request, to authorized persons;
8. Ensuring prompt reporting to the IRB, appropriate institutional officials, OHRP, sponsoring agencies, and other appropriate offices or committees of unanticipated problems involving risks to subjects or others, serious and/or continuing noncompliance with regulation or IRB determinations, and suspension or termination of IRB approval for research;
9. Facilitating training and continuing education for IRB Chairs and members;
10. Monitoring changes in Federal, state, and local laws, regulations, and guidance, as well as accreditation standards, related to the protection of human subjects in research and incorporating changes into IRB policies, procedures, and processes in a timely manner;
11. Providing educational support in human subjects research to faculty, staff and students through attending orientations, presenting to research classes, and offering workshops; and
12. Ensuring appropriate oversight and quality assurance mechanisms are implemented to ensure compliance of IRB determinations.

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October 2, 2008, revisied November 11, 2009, revised January 27, 2011, revised April 2, 2012, revised February 8, 2013, revised February 9, 2015, revised May 5, 2016, revised April 2, 2018, revised January 24, 2019, revised October 8, 2019