

IRB Policy 23: Special Requirements

Revision Date: May 15, 2007, revised January 27, 2011, revised May 1, 2012, revised February 9, 2015, revised April 2, 2018, revised October 22, 2020

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) that all human research projects are reviewed to comply with applicable local, state, federal, and international regulations and ethical standards in the conduct of human subject research. While the ETSU IRBs are responsible for the protection of the rights and welfare of human subjects of research, commitment to human research protections is a shared responsibility among many group or offices across the institution(s). Additional committees or other responsible officials may also need to provide review, oversight, or approval depending on the nature of particular protocol proposals. This policy summarizes additional procedures or special requirements for certain types of research.

II. Special Requirements

A. Veterans Affairs Medical Center

If the research project is VA research (defined as research that is conducted by VA investigators serving on compensated, WOC, or IPA appointments while on VA time), approval by the VA Research and Development Committee (R&D) is needed in addition to ETSU/VA IRB approval. Investigators must be sure to indicate on the New Protocol Submission xform that the VAMC is to be involved. The VA Administrative Officer may be contacted for assistance with VA R&D approvals.

B. VA Without Compensation Appointment (WOC)

A WOC appointment must be completed for any non-VA personnel working on a research protocol at the JHQVAMC. This authorization includes but is not limited to access to patients, equipment, laboratories, and medical records. The WOC appointment must be approved by the VA Medical Center Director in an appointment letter which delineates the term of the appointment.

C. Biohazards

The ETSU Institutional BioSafety and Chemical Safety Committee (IBC) is responsible for developing institutional biosafety policies and for reviewing and approving research and teaching activities that use biohazards, recombinant

DNA and ensuring that protocols conform with the proper guidelines associated with the handling of toxic/hazardous chemicals as defined by the Occupational Health and Safety Administration and/or determined by the ETSU IBC.

New protocol submission xforms will be forwarded to the Vice Provost for Research (VPR) for review if the investigator indicates that the study involves:

- a. shipping specimens
- b. transporting of specimens (e.g., from collection site to ETSU, in any area of public access, or in between building on campus)
- c. collection of specimens in non-clinical setting
- d. administration of live vaccine(s)
- e. exposure of researcher(s) or participants to toxic or hazardous chemicals (as defined by ETSU Biosafety) during procedures done for research purposes
- f. administration of vaccines using recombinant nucleic acid

The VPR will review the submission and confirm the presence of one or more of the above criteria. The VPR will document his determination of the presence or absence of the criteria. If the VPR determines that one or more of the criteria are present, the VPR also determines if IBC review is needed. If the VPR anticipates that the IBC review may require changes that may affect the IRB review, the VPR will indicate that IBC review must be obtained prior to IRB review. Otherwise, IRB review will proceed concurrently with IBC review, and final IRB approval will be held until IBC approval is obtained. As part of their review, IBC is responsible for checking for biosafety training for study personnel. The VPR Office forwards the IBC approval letter for the project to the IRB Coordinator. The IRB Coordinator files the approval letter in the study file, and IRB approval is communicated in writing to the investigator.

For VA research, VA Subcommittee on Research Safety (SRS) approval is required. The IRB approval letter to the PI specifies that additional approvals (VA R&D and VA SRS) must be obtained prior to study initiation.

When the study involves blood draws, the investigator must indicate this on the new protocol submission xform and indicate who will perform the blood draws. All study staff who will perform blood draws must complete appropriate bloodborne pathogen training, which must be verified by the IBC if the study requires their review or by IRB staff if IBC review is not required. In addition, study staff who will perform the blood draw must either be a licensed or certified health care provider where this procedure falls within the scope of their practice, or have certification or other written documentation of appropriate phlebotomy training.

D. Radioisotope use in Humans

If radioisotopes are involved in the proposed project, additional approval for their use in humans is required. Investigators must indicate on the New Protocol Submission xform whether the study includes radioisotopes. The IRB Coordinator reviews the New Protocol Submission xform for identification of any study involving radioactive materials. If the study involves radioactive materials, the IRB Coordinator creates a “Hold Approval” Event in IRBManager and notes the need for verification of approvals related to radiation safety as outlined below.

For studies conducted at ETSU, the investigator must contact the ETSU Office of Radiation Safety for consultation and assistance with institutional requirements. If required, Radiation Safety Sub-Committee approval may be obtained before, during, or after submission to the IRB. Final IRB approval, however, is contingent upon approval of the Radiation Safety Sub-Committee. If the study is approved by the IRB prior to Radiation Safety Sub-Committee approval, final IRB approval is not issued until receipt of approval letter from the Radiation Safety Sub-Committee (as well as completion of any other required modifications). The Investigator is responsible for providing the Radiation Safety Sub-Committee approval letter to the IRB Coordinator. The IRB Coordinator files the approval letter in the study file, and IRB approval is communicated in writing to the investigator.

If the work is performed at the VA, then the VA SRS approval is required. The VA Radiation Safety Officer must additionally be contacted for assistance with their requirements. The IRB approval letter to the PI specifies that additional approvals (VA R&D and VA SRS) must be obtained prior to study initiation.

If the work is performed at Mountain States Health Alliance, approval from MSHA is required as documented by approval signature of the MSHA Radiation Safety Officer or, for radiation oncology Studies, the MSHA Medical Director for Radiation Oncology.

E. Radiation Safety

All ETSU (non-VA, non-MSHA) protocols involving radiation producing equipment other than the exceptions listed below must be referred to the ETSU Director of Radiation Safety. Examples include, but are not limited to, any use of an investigational radiation device, investigational radiopharmaceutical or investigational implant/seed, investigational contrast medium with radiation imaging where the imaging itself is the subject of the investigation, and non-standard of care CT or PET scans.

Exceptions to this process are:

- a. routine standard of care xrays
- b. routine standard of care diagnostic nuclear medicine tests
- c. standard of care radiation therapy for cancer

The IRB Chair will review the new protocol submission xform and determine if Radiation Safety review is needed for a study that involves radiation. This is in addition to the already required review for studies that have radionuclide administration. If input from Radiation Safety is needed, the Director of Radiation Safety will review the radiation aspects of the study and provide comments to the IRB regarding the radiation amount. Additionally, the IRB Chair or convened IRB has the discretion to request a consult with the Director of Radiation Safety or other appropriate consultant for any study.

For VA research, VA Subcommittee on Research Safety (SRS) approval is required. The IRB approval letter to the PI specifies that additional approvals (VA R&D and VA SRS) must be obtained prior to study initiation. If input from the VA Research Biosafety Subcommittee is needed, the Subcommittee, or designee, will review the radiation aspects of the study and provide comments to the IRB regarding the radiation amount.

F. Other ETSU Departments:

If other departmental resources are required, i.e., counseling services from ETSU Counseling Center, a letter of support from the department will generally be required to ensure the protocol has appropriate resources to conduct the proposed study before final IRB approval is issued. The IRB Coordinator verifies that all letters of support are present before issuing final IRB approval documentation to the investigator.