IRB Policy 23: Special Requirements
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I. Special Requirements

Radioisotope use in Humans:

The IRB Coordinator reviews the proposal, including checking 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.

A. If radioisotopes are involved in the proposed project, additional approval for their use in humans is required. For studies conducted at ETSU, the PI must contact the Director of Radiation Safety by calling (423-439-5640). Radiation Safety Sub-Committee approval may be obtained before, during, or after application 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 the obtaining of Radiation Safety Sub-Committee approval, the approval is an "approval pending modifications." The 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 Director of Radiation Safety forwards the approval letter for the project from the Radiation Safety Sub-Committee to the IRB Coordinator. The IRB Coordinator files the approval letter in the study file. Final IRB approval is then issued.

If the work is performed at the VA, then the VA Research Biosafety Sub-committee approval is required. The Radiation Safety Officer must additionally be contacted at 423-926-1171 ext 7836. The IRB approval letter to the PI specifies that additional approvals (VA R &D and VA Research Bio-safety Subcommittee) 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.

B. Biohazards

The ETSU Institutional Bio Safety 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.

For ETSU studies, new protocol submission (NPS) xforms will be forwarded to the Vice Provost for Research for review if the researcher 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 Vice Provost for Research (VPR) will review the NPS 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, IBC review is needed. If the VPR anticipates that the IBC review may require changes that may affect the IRB review (e.g., changes affecting the protocol or information provided on the NPS), the VPR will indicate that IBC review must be obtained prior to IRB review. Otherwise, IRB review will proceed 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's office forwards the IBC approval letter for the project to the IRB Coordinator. The IRB Coordinator attaches the IBC approval letter in IRBmanager, and processes as indicated (e.g., as requested change).

If the work is performed at the VA, 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 Research Bio-safety Subcommittee) must be obtained prior to study initiation.

In addition, when the study involves blood draws, the IRB requirement is that the study staff who will be drawing the blood 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. In addition, an initial IRB approval will not be issued unless bloodborne pathogen training has been verified for study staff who are drawing blood (by the IBC if the study requires their review or by IRB staff if IBC review is not required).

C. Radiation

The IRB Chair will indicate on the NPS if Radiation Safety input 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 (see criteria below), the Director of Radiation Safety will review the radiation aspects of the study and provide comments to the IRB regarding the radiation amount.

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

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

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.

If the work is performed at the VA, 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 Subcommittee on Research Safety (SRS)) must be obtained prior to study initiation. If input from the VA Research Biosafety Subcommittee is needed (see criteria above), the Subcommittee, or appropriate representative, will review the radiation aspects of the study and provide comments to the IRB regarding the radiation amount.

D. Use of "test articles": The use of new drugs and/or devices in an investigation usually requires approval form the U.S. Food and Drug Administration in addition to IRB approval (21 CFR 312). Refer to full review policy for information about required Investigational New Drug (IND) numbers and Device Policy for information about Investigational Device Exemption (IDE) numbers.

E. 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 by calling 423-926-1171 ext 2859.

F Intellectual Property and Invention Disclosure: The VA Technology Transfer Program (TTP) has the mission of serving the American public by translating the results of worthy discoveries made by the employees of VA (including Work without Compensation- WOC status) into practice. This requires a program that rigorously evaluates all inventions, educates inventors concerning their rights and obligations, obtains patents, and assists in the commercialization of new products. Investigators engaged in these activities should refer to the VA Investigator Handbook.

G. Without Compensation Appointment (WOC): A WOC appointment must be completed for any non-VA personnel working on a research protocol at the Veterans Affairs Medical Center. This authorization includes but is not limited to access to patients, equipment, laboratories, and medical records. The WOC form (OF 612 and OF306) must be completed and submitted to the VA R&D Office before initiation of the study. Appointments are valid for one year

H. Other Departments: If other departmental resources are required, i.e, counseling services from ETSU Counseling Center, a letter of support from the department will be required before final approval is issued. The IRB Coordinator checks protocol at submission and flags the chart by creating a “Hold Approval” event in IRBManager if a departmental support letter is required.