IRB Policy 23: Special Requirements
Revision Date: May 15, 2007, revised January 27, 2011, revised May 1, 2012, revised February 9, 2015

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. 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.
C. **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.

D. **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.

E. **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.

F. **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.