

Guidelines for IRB Protocols Involving the Use of Ionizing Radiation

The Radiation Safety Committee (RSC) is charged by Federal and State regulatory agencies to oversee the use of ionizing radiation at VCU/MCVH. Sources of ionizing radiation include both radioactive materials and radiation-producing devices. Examples of uses of these sources include (but are not limited to) chest x-rays, DEXA scans, CT scans, fluoroscopy, and nuclear medicine procedures. **Use of ionizing radiation in human research in any manner that does not directly benefit the patient/subject must be approved by the RSC.**

To comply with FDA and DHHS guidelines and regulations, the Institutional Review Board (IRB) must assure that the patient/subject enrolled in an investigational study is adequately informed about risk. Since the use of ionizing radiation in humans is associated with health risks in proportion to the amount of radiation received, it is the responsibility of the Principal Investigator (PI) to inform the IRB of any ionizing radiation procedures employed in the study. Additionally, the PI will be required to identify those ionizing radiation procedures that are beyond routine standard of care and for research purposes only (i.e., procedures that **do not** directly benefit the patient/subject). **Note: the PI and the IRB will be ultimately responsible for determining whether a procedure is for the direct benefit of the patient.** If the protocol includes procedures of this type, prior RSC approval is necessary before the protocol can be submitted to the IRB. The PI, or designee, shall contact the Radiation Safety Officer (RSO) or his designee and supply the necessary information about the ionizing radiation procedure(s). The anticipated whole body effective dose equivalent (EDE) will be calculated from this information and an appropriate risk statement developed by the RSO for inclusion into the informed consent document. The EDE and other pertinent information will be used by the PI to complete an RSC application form to be reviewed for approval by the RSC Executive Committee (10 working day turnaround). Protocols received by the IRB without prior RSC approval (and proper consent form risk statement) will be not evaluated until RSC approval is obtained.

Inclusions to Summary and/or Cover Sheet

The cover sheet or summary sheet of the IRB protocol application should include three Y/N check boxes to provide a quick means of determining whether the study patients/subjects are exposed to ionizing radiation and whether or not the PI has complied with the instructions stated above. The first box would identify if **any** ionizing radiation procedure(s) will be included in the study; the second box would indicate if there will be procedure(s) that are **not** for the direct benefit of the patient/subject; and the third box would indicate if RSO approval has been obtained. In addition, a space for listing the ionizing radiation procedure(s) that are not for the direct benefit of the patient/subject should be included on this form (see attached example for inclusions to cover sheet).

Informed Consent Information for Ionizing Radiation Procedures

1. The investigator or Radiation Safety will calculate the anticipated whole body effective dose equivalent (EDE) from all procedures involving ionizing radiation that are not for the direct clinical benefit of the patient.
2. The calculated dose will be expressed as a fraction or percentage of the annual permissible occupational exposure level for the whole body.
3. The informed consent will include a statement of the relationship of the anticipated dose to the annual permissible occupational whole body exposure level of 5 rem (i.e., 1/10, 1/3, 2X, etc.).
4. To assist the subject in understanding the meaning of “permissible occupational exposure levels” the following statement will be included in the appropriate section of the consent form: “The National Council on Radiation Protection and Measurements has set permissible occupational radiation exposure limits for many radiologists, technologists, and scientists who work with radiation and are exposed nearly every day. These limits are defined as the dose of radiation that, in light of present knowledge, is not expected to cause appreciable bodily injury to a person at any time during his/her lifetime. The risk of this amount of occupational exposure to radiation is, thus, considered to be very small and less than that associated with normal everyday activities. The radiation dose mentioned is what you receive from the research component of this study only and does not include any exposure you may have received or will receive in the future from other tests.” (See attached example for sample risk statement).

Sample Risk Statement

In the sample protocol, the patient will receive a nuclear medicine MUGA scan. The approximate EDE for this procedure is 475 mrem. The following information should be included in the appropriate section of the informed consent:

“As a participant in this study you will receive extra radiation exposure from studies that are for research purposes only (not for your direct clinical benefit). Your radiation dose from this procedure is approximately one-tenth (1/10) [alternatively, approximately 10%] of the annual permissible occupational exposure level for radiation workers. The National Council on Radiation Protection and Measurements has set permissible occupational radiation exposure limits for many radiologists, technologists, and scientists who work with radiation and are exposed nearly every day. These limits are defined as the dose of radiation that, in light of present knowledge, is not expected to cause appreciable bodily injury to a person at any time during his/her lifetime. The risk of this amount of occupational exposure to radiation is, thus, considered to be very small and less than that associated with normal everyday activities. The radiation dose mentioned is what you receive from the research component of this study only and does not include any exposure you may have received or will receive in the future from other tests. “