Guidelines for IRB Protocols Involving the Use of Ionizing Radiation
Virginia Commonwealth University
EHS-SRM/Radiation Safety Section

The Radiation Safety Committee (RSC) is charged by State and Federal regulatory agencies to oversee the use of ionizing radiation at VCU/VCUHS. 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 and is not considered normal standard of care must be approved by the RSC.**

To comply with FDA and DHHS guidelines and regulations, the Institutional Review Board (IRB) must assure that the research subject/patient 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/subject.** 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 (ED) will be calculated from this information and an appropriate risk statement developed by the RSO for inclusion into the informed consent document. The ED and other pertinent information will be used by the PI to complete an RSC application form to be reviewed for approval by the Radiation Safety 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.

VCU IRB Initial Review Submission Form

Section 7 ("Project Detail") of the VCU IRB initial review submission form includes Questions 7-A, 7-B, and 7-C to provide a quick means of determining whether the research subject/patient is exposed to ionizing radiation and whether or not the PI has complied with the instructions stated above. Question 7-A identifies if the project involves the use of any procedure(s) that expose the research subject/patient to ionizing radiation. Question 7-B asks if these procedures are for the direct clinical benefit of the research subject/patient. If so, the PI is instructed to check "YES" and no further information is required. If the procedures are of research interest and will not affect the clinical management of the research subject/patient, the PI is instructed to check "NO" and proceed to Question 7-C, which asks if Radiation Safety Committee approval has been obtained. Information for contacting Radiation Safety is supplied.

Informed Consent Information for Ionizing Radiation Procedures

1. The investigator or the Clinical Radiation Safety Office will calculate the anticipated whole body effective dose (ED) from all procedures involving ionizing radiation that are not for the direct clinical benefit of the research subject/patient and not considered normal standard of care.

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 below for sample risk statement)

5. For risk statements involving therapeutic procedures, the risk statement described in 2, 3, & 4 above is not suitable since the magnitude of the radiation exposure from these procedures is not adequately addressed. In order to put the risk of the additional radiation exposure into perspective with the research subject's/patient's therapeutic dose, the following risk statement must be used when the research subject/patient is receiving a therapeutic radiation dose and additional ionizing radiation research procedures:

   "You will receive extra radiation dose from _____ (list additional studies resulting in radiation exposure that are not for the direct clinical benefit of the patient or considered normal standard of care). The extra radiation dose from participating in this study is _____% of the treatment effective (?) dose you will receive for the treatment of your cancer (inserted calculated percentage of total therapeutic effective dose). The radiation dose mentioned is what you will 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.

   Radiation Oncology is responsible for performing the calculations for these percentages.

Sample Risk Statement

In the sample protocol, the patient will receive a nuclear medicine MUGA scan. The approximate effective dose 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. "

Which Radiation Safety Committee Application form should be used?

All application forms are available at https://srm.vcu.edu/forms/. The ionizing radiation procedure to be performed will determine which application form to submit to the Radiation Safety Committee.

1. For studies involving clinically approved procedures (e.g., procedures routinely performed in Radiology or Nuclear medicine - chest x-rays, CT's, MUGA scans), use the "Application for Clinically Approved Procedures."

2. For studies involving the use of radioactive material that is for research purposes only and not performed clinically, use the "Application for the *In-Vivo* Use of Radioactive Materials."

3. For studies involving the use of radiation-producing devices that are for research purposes only and not performed on a routine basis, use the "Application for the Human Use of Radiation-Producing Devices."

All forms are available for download in Microsoft Word. Contact the Radiation Safety section at 828-9131 if there are any questions about which form to use.