A Guide to the Process for Applying for An Authorization to Administer Radiation For Research With Humans

The Application For Authorization to Administer Radiation For Research With Humans is designed to obtain information about the amount of radiation human research subjects will receive from participating in research studies authorized by the University of Maryland, Baltimore. Risks associated with exposure to ionizing radiation cannot be adequately assessed without knowing the type and quantity of radiation administered as well as the target organ(s) involved.

Background

The University's Radiation Safety Committee (RSC) is responsible for regulating and controlling the use of radioactive materials at UMB through a license issued to the University from the Maryland Department of the Environment. This Committee is also charged with the control of exposure from radiation producing devices at UMB. Under this structure, the authority of this committee covers, UMB, UMBC, UMMS, COMB, and UMBI. Unlike the Institutional Review Board (IRB), the RSC does not have the authority to approve or regulate activities at other institutions, e.g., the VA. In situations involving research at other sites, the RSC can act as a technical consultant to the IRB.

NOTE: All proposals involving human subjects must have written approval by the IRB. In order to receive this approval, a full submission to IRB of the proposal is required. Additional information can be obtained from the Office for Research Subjects. Their website, http://medshool.umaryland.edu/ors/smORS.html, provides detailed instructions for submitting protocols to the IRB

What procedures are required to be reported/reviewed?

The RSC has two standing subcommittees, the Human Use/Radioactive Drug Research Committee (HU/RDRS) and the Basic Research Subcommittee (BRS). The HU/RDRS has established a three-tier classification scheme for research involving the administration of radiation to human subjects.

Tier 1 These are protocols where the exposure of subjects to ionizing radiation is required as part of their routine medical care and is not necessitated by the research. Tier 1 research would not require completion of the application or review by the HU/RDRS.

For example, research where a population of subjects has been shown to qualify for inclusion or exclusion in a study based on the results of radiation procedures conducted as part of their medical care would qualify as Tier 1 since the dose was not necessitated by the research. However, research, which proposes to "screen" subjects using a radiation procedure, e.g., chest x-ray, to determine if they qualify for inclusion or exclusion in a study would not qualify as routine medical care.

Tier 2 These are proposals where exposure of subjects to ionizing radiation is required as part of the research, there is no direct medical benefit to the patients, and the total radiation dose to the subjects is within the accepted dose limits established by the University's RSC. If the criterion is met, the application can receive "Expedited Review" by the HU/RDRS.

Tier 3 These are proposals, which do not qualify as either Tier 1 or Tier 2. These studies include procedures where, either the projected dose(s) exceed(s) the accepted limits or the procedure is investigational, e.g., a radioactive research drug. Tier 3 research proposals must be reviewed by the full HU/RDRS.

How do we obtain the application and what does it entail?

Application materials (The Application For Authorization to Administer Radiation For Research With Humans, dose guidelines and consent form recommendations) will be provided to investigators via the website, www.ehs.umaryland.edu, or by contacting the Radiation Safety Office.

The application form is divided into two parts. The first part is the body of the application which seeks information about the applicant, the title and purpose of the research project, radiation procedures that are part of the research, the subject population, information regarding informed consent and the total dose a subject would receive from participating in the research. The second part contains individual forms to describe each type of radiation procedure that will be administered: x-ray, nuclear medicine, radioactive research drugs and others. It is expected that the individual or department that will actually perform the procedure since they will have the required dose information will complete the second part(s) of the application. The second part also includes a Radiation Exposure Work Sheet that is to be used to report the subject dose from each type of procedure to be performed. The dose recorded on the individual work sheets will be summarized and reported in the body of the application under Item 6.

There are two (2) handouts that accompany the application form. A Summary of Radiation Dose Guidelines and Limits Applicable to Human Subjects in Research Studies handout addresses the exposure limits applicable to human research subjects adopted by the University's Human Use/Radioactive Drug Research Subcommittee from the International Commission on Radiation Protection (ICRP), the U.S. Nuclear Regulatory Commission, FDA and others.

The Radiation Aspects Of Informed Consent Statements For Clinical Research Projects In Which Radiation Exposure Is For Research Purpose And Not For The Medical Benefit Of The Subject (Patients And Normals) handout is intended to assist the applicant in preparing a consent statement that is clear, accurate and comprehensible. Statements of comparable risk such as "X miles of travel in the family car" or "X % of the casual dose" are not sufficient. The recommended wording or a version thereof should state what the dose to the subject is expected to be and compare that dose to recognized acceptable limits.

What are the exposure limits or standards that will be used to evaluate proposals?

The dose limits used by the HU/RDRS have been taken from the various regulatory agencies and standard setting bodies, which deal with radiation and human effects. Further, the HU/RDRS subscribes to the NRC's "As Low As Reasonably Achievable" (ALARA) principle which seeks to minimize radiation exposure whenever possible. In most cases the HU/RDRS uses these limits as guidelines when evaluating proposals. However, unless specifically prohibited by regulations, the HU/RDRS may approve any exposure level that can be justified by the value of the research.

What constraints can/will be placed on research from this view?

The HU/RDRS has the authority and the responsibility to disapprove or modify any University of Maryland sponsored research, which poses an unreasonable risk to the human subjects involved. This may involve limiting the type or number of radiation procedures or recommending alternative ones. In the case of fluoroscopic procedures where the dose to subjects can vary dramatically depending on the subject and/or the clinician performing the procedure, the applicant will be required to record the actual exposure parameters and report this information to the HU/RDRS annually.

In reviewing protocols, the total radiation dose to the research subject will be taken into consideration. For example, if a research proposal involves both medical exposure and additional exposure for the research, the total radiation expose to the subject will be taken into consideration, not just the research part.

Where and how do I submit the application?

Pre-review

The Application For Authorization To Administer Radiation for Research With Humans must be returned to the Radiation Safety Office, located at the EHS building, 714 W. Lombard Street. The Radiation Safety Officer will review and assign initial classification, i.e., Tier. Preliminary comments will be added and the draft returned to the applicant, if necessary.

Formal Review

Tier 2 proposals will receive expedited review by the Radiation Safety Officer and the Chairperson of the HU/RDRS. The actions taken in expedited review are subject to confirmation by the full HU/RDRS.

Tier 3 proposals will be distributed to the full HU/RDRS for review and action. The actions of the HU/RDRS will be communicated in writing to the IRB and the applicant.

Approvals will normally be for a period of up to one year with an expiration date set to coincide with those set by the IRB. Applications for renewal or continuation will be handled in the same manner with the additional requirement for certain studies, e.g., fluoroscopic and radioactive research drugs, to report the exposure received by subjects participating in the research during the preceding year. In these cases, the exposure dose information is necessary to determine if the projected doses were accurate and the exposure doses were within acceptable limits.