

**Radiation Safety: Human Subject Research Protocols**

Page 1 of 5

10/25/07

**1.0 PURPOSES**

- 1.1 To recognize that a procedure utilizing radiation with an exposure normally accepted as “standard patient care” is considered “for research application” when performed more frequently.
- 1.2 To identify human subject research activities which require Radiation Safety Officer review and approval.
- 1.3 To identify human subject research activities which require Human Use Radiation Safety Subcommittee review and approval.
- 1.4 To establish the process for Principal Investigators to obtain review and approval on initial application to the IRB and on follow-up reapprovals.
- 1.5 To define a communication and notification process among committees, Radiation Safety, and the Principal Investigators.

**2.0 SCOPE**

- 2.1 This policy applies to all UIC research projects utilizing radiation exposures to human subjects.

**3.0 AUTHORITY**

- 3.1 420 Illinois Compiled Statutes 40/1 Title 32 Radiation Protection Act of 1990. <http://www.ilga.gov/legislation/ilcs/ilcs2.asp?ChapterID=37>
- 3.2 The General Rules Concerning University Organization and Procedure, Article V, Section 1 (a) University of Illinois
- 3.3 U.S. Food and Drug Administration 21 CFR 361.1.  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=361.1>

**4.0 DEFINITIONS**

- 4.1 **As Low As Reasonably Achievable (ALARA)** - a program designed to keep exposures to workers and the public as low as reasonably achievable.
- 4.2 **Human Use Radiation Safety Subcommittee** - oversees the prudent use of radioactive materials, sealed sources and machine produced radiation for patient diagnosis and treatment.
- 4.3 **Institutional Review Board (IRB)** - has jurisdiction over research when that research involves the use of human subjects, or identifiable private

**Radiation Safety: Human Subject Research Protocols**

Page 2 of 5

10/25/07

data or tissues derived from human subjects, and the institution is “engaged” in the research by the nature of the research activities:

- 4.4 **Principal Investigator (PI)** - a faculty member or guest member, who is assigned laboratory space in order to conduct research, and who is requesting UIC IRB approval to conduct that research.
- 4.5 **Radioactive Drug Research Committee (Subcommittee) (RDRC)** - oversees the safe use of radioactive materials for human research protocols.
- 4.6 **Radiation Safety Officer (RSO)** - responsible for implementing the UIC radiation protection program and ensuring that radiation safety activities are being performed in accordance with license-defined procedures and regulatory requirements.
- 4.7 **Research Subject** - FDA regulations define **human research subject** as an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

**5.0 PROCEDURE**

- 5.1 Proposed research protocol radiation exposure review requirements
  - 5.1.1 No Review: Estimated effective equivalent doses below 100 mrem per year, a limit set by the Nuclear Regulatory Commission for “general public” exposure.
  - 5.1.2 RSO Review: Estimated effective equivalent doses below 25 rem per year whole body, 250 rem per year individual organs and tissues, and 75 rem per year eyes. These effective equivalent doses are for patient research subjects only. **The Radiation Safety Office will not approve an effective equivalent dose greater than 5 rem/yr to any healthy human research subject.**
  - 5.1.3 Human Use Radiation Safety Subcommittee Review: Estimated effective equivalent doses above 25 rem per year whole body, above 250 rem per year individual organs and tissues or 75 rem per year eyes. Also, use of medical devices emitting ionizing radiation that do not have FDA approval.
  - 5.1.4 Radiation Safety Radioactive Drug Research Subcommittee: Administration of radioactive research drugs or

**Radiation Safety: Human Subject Research Protocols**

Page 3 of 5

10/25/07

radiopharmaceuticals that are not New Drug Application (NDA) approved by the FDA or that have NDA approval but are being used for off-label procedures.

5.1.5 RSO and Biosafety Officer (BSO) Review: Administration of radioactive biologicals including blood and blood products, living cell extracts, insulin, antibodies and vaccines)

5.1.6 RSO and Institutional Biosafety Committee (IBC): Administration of radioactive recombinant DNA products or radioactive infectious agents.

5.1.7 Exposure levels of 1/10 of the above levels will apply to protocol reviews for minors under the age of eighteen.

5.1.8 (Intentionally Blank)

5.2 Radiation Dosimetry

5.2.1 The research protocol must include an estimate of the radiation dose that will be received by research subjects, including total effective dose equivalent (TEDE) and specific organ exposures, and the reference(s) utilized.

5.2.2 The following websites may be helpful for establishing these estimates:

<http://www.doseinfo-radar.com/RADARDoseRiskCalc.html>

[http://www.safety.duke.edu/RadSafety/consents/irbcf\\_esp/adults/default.asp](http://www.safety.duke.edu/RadSafety/consents/irbcf_esp/adults/default.asp)

5.2.3 If these websites do not provide the necessary information, the PI should contact the RSO for additional resources.

5.2.4 (Intentionally Blank)

5.3 Review Process

5.3.1 The investigator must provide the following to the Radiation Safety Section of the Environmental Health and Safety Office prior to submission to the Institutional Review Board:

- The complete protocol
- The application form and associated documents
- The proposed consent form
- The calculated level of exposure/dose
- An optional Radiation Dose Supplement form

**Radiation Safety: Human Subject Research Protocols**

Page 4 of 5

10/25/07

- 5.3.2 The RSO or designated Radiation Safety Subcommittee will review the submission to ensure that the intended exposure, frequency and amount of an administered dose, is kept to a minimum required to achieve the objectives of the research protocol (ALARA).
- 5.3.3 The RSO or designated Radiation Safety Subcommittee will review the submitted proposed consent form for accurate disclosure statements that include:
- That the radiation dose would be received even if the participant was not in the study *or*,
  - That the radiation dose is not medically indicated but is to be administered solely for research purposes, *and*
  - That a statement is included that pregnant women may not participate in research involving radiation exposure and that a determination will be made of the pregnancy status of female participants of childbearing years.
  - That in cases involving radiation therapy, the appropriate special risk language has been developed on a case-specific basis.
- 5.3.4 The RSO or designated Radiation Safety Subcommittee will review the submission to verify that potential participants will be screened for other radiation exposure to ensure that the total radiation dose from all studies is considered when calculating risks and are kept ALARA.
- 5.3.5 Assuming the submission materials are complete, a response time is estimated to be ten business days.
- 5.3.6 In cases involving radiation therapy, special risk language should be developed on a case-specific basis.
- 5.3.7 (Intentionally Blank)
- 5.4 Follow Up Process
- 5.4.1 A new review and approval are required when a project amendment proposes an increase in radiation dose or a change in body exposure site.
- 5.4.2 A follow up review is required annually via submission of the IRB continuing review application to the Radiation Safety Section.
- 5.4.3 (Intentionally Blank)

**Radiation Safety: Human Subject Research Protocols**  
10/25/07

**6.0 Reports and Recordkeeping**

- 6.1 The RSO or designee will complete an internal review checklist from data provided in the review submission materials. This form will be used by the RSO or the designated Radiation Safety Subcommittee along with the submission materials to perform the review.
- 6.2 The RSO must sign all approvals, denials, requests for modifications and other associated documents.
- 6.3 A copy of all project documents will be maintained in the EHSO Radiation Safety Section office.
- 6.4 A record of the project and status will be entered into the Radiation Safety Section database.
- 6.5 All documents will be made available to federal and state regulatory agencies when required for compliance inspection and other validation purposes.
- 6.6 Any deviation in participant radiation dose administration from the approved protocol must be reported in writing immediately to the RSO.
- 6.7 (Intentionally Blank)

**7.0 APPROVALS**

_____	_____
Chairperson, Main Radiation Safety Committee	Date
_____	_____
UIC Radiation Safety Officer	Date
_____	_____
Director of Environmental Health & Safety	Date