

## RESEARCH INVOLVING RADIATION

### 1. Overview

Radiation exposure beyond that received in routine and/or non-research clinical care procedures may pose special risks to research participants. The use of radiation for research purposes must be reviewed and approved by the Human Subject Radiation Committee, a subcommittee of the OSU Radiation Safety Committee, in addition to the IRB before research (or changes to research) may be initiated.

### 2. Definitions

**Effective Dose/Effective Dose Equivalent:** A quantity that compares (on a common scale) the overall health effects of radiation, taking into account the absorbed dose of radiation received by a tissue or organ and the tissue/organ's sensitivity, type of radiation, and potential for the radiation to cause biologic damage (i.e., some types of radiation are more damaging than others when the dose is equal). The effective dose is measured in rems or sieverts.

**Human Subject Radiation Committee (HSRC):** A subcommittee of The Ohio State University Radiation Safety Committee responsible for the review and approval of the research use of radiation in research involving human subjects. *Note: The Medical Use Subcommittee of the University Radiation Safety Committee serves as the Human Subject Radiation Committee.*

**Ionizing Radiation:** Any radiation capable of displacing electrons from atoms or molecules, thereby producing ions. Examples include alpha, beta, gamma, and X-rays. High doses of ionizing radiation may produce severe skin or tissue damage.

**Nuclear Regulatory Commission:** Independent government agency established by the Energy Reorganization Act of 1974 to regulate civilian use of nuclear materials.

**Radiation Exposure:** In health physics, the quantity used to indicate the amount of ionization in air produced by X-ray or gamma radiation while conducting radiologic procedures.

**Radiologic (Radiological) Procedure:** Any procedure involving radiation (e.g., X-ray) or a radioactive agent (e.g., radionuclide used in a nuclear medicine study).

**Dosimetrist:** Individual with special training in radiation safety and in the accurate determination of radiation dosages.

### 3. General Information

- A. The Human Subject Radiation Committee evaluates the “research use” of radiation in human subjects research. Such uses include the following:
- Radiologic procedures that are administered solely for experimental or research purposes (i.e., would not otherwise be administered)
  - Standard of care procedures that are being altered as part of research
  - Radiologic procedures that are administered in addition to those that the participant would receive as part of standard medical care (i.e., “extra”).
- B. The HSRC does not routinely review research involving radiologic exams or procedures that would also have been administered for non-research purposes (i.e., performed as part of standard medical care). However, the IRBs may request HSRC review (or re-review) for any proposed study involving radiation.
- C. Research activities for proposed research requiring HSRC review may not begin until both HSRC and IRB approvals have been granted. HSRC approval of the research use of radiation must be obtained prior to IRB review as described below (see “HSRC Review and Approval”).

#### **4. Authority**

The authority, structure, and functions of the Human Subject Radiation Committee are specified in the agreement between the State of Ohio, Nuclear Regulatory Commission, and Ohio Department of Health.

#### **5. Committee Composition**

The Human Subject Radiation Committee is comprised by a minimum of five individuals qualified in various disciplines pertinent to the fields of radiology, radiologic sciences, nuclear medicine, and radiation oncology. The HSRC also includes an individual(s) with special training in radiation safety and radiation dosimetry.

#### **6. HSRC Review and Approval**

Research involving radiation is reviewed based on the effective dose equivalent for all proposed radiologic procedures and the proposed participant population. A dosimetrist will assist in determining the effective dose and the type of review required. *Appendix V* of the *Initial Review of Human Subjects Research* application form must be completed for IRB and HSRC review of new studies involving the research use of radiation and amendments to ongoing studies that involve changes to currently approved radiation doses or procedures.

##### **6.1 Types of Review**

- A. **Administrative Review** may be performed when the effective dose equivalent for all proposed radiologic procedures is 100 millirem (mrem) or less. Administrative review will be performed by a dosimetrist or another member of the HSRC with appropriate expertise. Studies may be referred to the expedited review process at the administrative reviewer's discretion.
- B. **Expedited (Subcommittee) Review** may be performed when the effective dose equivalent for all proposed radiologic procedures is greater than 100 mrem, but not greater than 3 rem (3000 mrem). One or more HSRC members with appropriate expertise will perform expedited review. Studies may be referred to the convened HSRC for full Committee review at the expedited reviewer's discretion.
- C. **Full (Convened) Review** is conducted by the HSRC for research involving any of the following:
- An effective dose equivalent for all proposed radiologic procedures (including repeat exposures) of greater than 3 rem
  - Children
  - Pregnant women
  - Healthy volunteers.

## 6.2 Approval Procedures

The HSRC may approve, require modifications before approving, or disapprove the proposed research use of radiation in human subjects research.

The HSRC will consider the following guidelines to approve proposed radiologic procedures:

- Radiation exposure is necessary and justified by the anticipated benefit to participants (if any) and the importance of the information sought
- The research subsequently meets the requirements for approval by an IRB
- Any additional relevant aspects of the study are appropriate, such as qualifications and training of investigators, location of procedure(s), procedures to ensure participant safety, etc.

## 7. Informed Consent

Informed consent is to be obtained from each participant or legally authorized representative (unless the requirement for consent is waived by the IRB). A description of the radiologic procedure(s) must be included in the consent process and document in accordance with OSU HRPP policies [[Informed Consent Process and the Elements of Informed Consent](#)] and [[Documentation of the Informed Consent Process](#)].

Radiation risk language based on radiation exposure estimated by the dose calculator (described below) must also be included.

## 8. Dose Calculations and Risk Language

Radiation exposures for proposed radiologic procedures are to be calculated using the dose calculator made available by [Duke University Radiation Safety Committee](#). Dosimetry calculations should be entered into the appropriate sections of *Appendix V* and a copy of the calculations provided with the appendix. Risk language appropriate to the radiation exposure will also be provided and must be included in the informed consent process and document (described above). Assistance with dose calculations can be obtained by contacting the Office of Environmental Health and Safety at 614-292-1284.

## 9. Additional Review Considerations

- A. Changes to previously approved radiologic procedures or the addition of new procedures meeting the criteria for HSRC review described above (see “General Information”) must be resubmitted to the HSRC for approval. The type of review will be determined based on the effective dose equivalent for all proposed radiologic procedures and the proposed participant population. Following HSRC approval, all such changes must also be approved by the IRB prior to initiation.
- B. Adverse events and unanticipated problems involving risks to subjects or others that involve the research use of radiation will be reviewed by the HSRC and IRB. For more information on event reporting, see OSU HRPP policy [[Event Reporting – Unanticipated Problems Involving Risks to Subjects or Others, Adverse Events, and Other Problems](#)].
- C. Continuing review of the research use of radiation by the HSRC is not required. However, the research is subject to the continuing review requirements of the OSU IRBs as described by OSU HRPP policies [[Review of Research by the Convened IRB](#)] and [[Expedited Review Procedures](#)].

## 10. Applicable Regulations/Guidance

21 CFR 50, 21 CFR 56, 45 CFR 46, Medical Use of RAM ODH OAC [3701:1-58](#), Radiation Generating Equipment OAC [3701:1-66](#), Radioactive Materials-Irradiators [3701:1-52](#)