

Criteria for Administrative Review of Human Use Protocols Involving Research Ionizing Radiation Procedures

All human use research protocols that involve one or more Research Ionizing Radiation Procedures must be approved by the Human Use Subcommittee (HUS) of the Joint Radiation Safety Committee (JRSC).

A “Research Ionizing Radiation Procedure” is defined as any procedure involving ionizing radiation that is only being performed because the individual is involved in the research study, including, but not limited to:

- Any procedure that is not clinically indicated
- Any procedure that is performed in addition to procedures that would be considered to be Standard of Care Ionizing Radiation Procedures or at more frequent intervals than would be performed under currently applicable standard of care
- Any procedure using an investigational radiologic source, radiopharmaceutical, radionuclide or ionizing radiation exposure setting or sequence
- Any Standard of Care Ionizing Radiation Procedure performed on a healthy individual in a research study.

“Investigational” is defined as either non-FDA approved or used in a manner that is not consistent with the current applicable standard of care.

A “Standard of Care Ionizing Radiation Procedure” is defined as any clinically indicated procedure involving ionizing radiation performed as part of clinical care that is standard in the general medical community and would be performed even if the individual were not involved in the research study.

A JRSC application involving a Research Ionizing Radiation Procedure **may be administratively reviewed** by the Chair of the HUS without review by the HUS **IF**:

1. No minor subjects are involved in the study; AND
2. The estimated effective dose of the ionizing radiation to a typical subject in the study is not more than 3 mSv in total over the course of the study; AND
3. No tissue reactions such as hair loss or skin injury are reasonably foreseen. A procedure with a dose to the skin of less than 3 Gy is not expected to result in a skin tissue reaction.

A “tissue reaction” (also referred to as a “deterministic effect”) is defined as injury to populations of cells, characterized by a threshold dose and by an increase in the severity of the reaction as the dose is increased further. For further clarification of tissue reactions, refer to International Commission on Radiological Protection Publication 118, available at <http://www.sciencedirect.com/science/article/pii/S014664531200024>

Amendments to a JRSC Application involving a Research Ionizing Radiation Procedure, whether the protocol was initially reviewed administratively or by the HUS, **may be administratively reviewed** by the Chair of the HUS without review by the HUS **UNLESS**:

1. Minor subjects are added to the study; OR
2. There is a change in the study protocol and/or the study's estimated dosimetry resulting in an estimated effective dose of ionizing radiation to a typical subject in the study of more than 3 mSv in total over the course of the study; OR
3. Tissue reactions such as hair loss or skin injury are reasonably foreseen;
OR
4. If the JRSC protocol was initially reviewed by the HUS, the number of subjects involved in the research ionizing radiation procedure is increased by more than 100% and the resulting number exceeds 30.

A principal investigator may make an initial recommendation as to whether an ionizing radiation procedure is considered a Standard of Care Ionizing Radiation Procedure or a Research Ionizing Radiation Procedure, but the final determination will be made by the IRB.



12/20/19