Criteria for Administrative Review:

All human-use research protocols during which the subjects will be exposed to ionizing radiation need to be approved by the JRSC or RDRC, even if the radiation exposure is the current standard of care (SOC) for the relevant patients. A protocol may be administratively reviewed by the Chair of the Human Use Subcommittee (or, in the case of a potential conflict of interest, his/her designee) without review by the Subcommittee, if:

1. No minor subjects are involved in the study, AND
2. The estimated effective dose of research ionizing radiation (i.e. in addition to the radiation exposure from “standard of care” treatment) to a typical subject in the study is either zero or not more than 1mSv in total over the course of the study, AND
3. No tissue reactions such as hair loss or skin injury are reasonably foreseen. Procedures with dose to the skin of less than 3 Gy are not expected to result in skin tissue reactions.

Research ionizing radiation is defined as those procedures that are required by the study protocol but would not be performed in the absence of the research. Screening procedures that are included in the protocol and would not be performed in the absence of research are considered research. SOC procedures that are performed at increased frequency per the research protocol are considered research. If true SOC procedures can be identified, these can be excluded from those counted as research. Add-on components performed in the same session as a SOC procedure are considered research, however the baseline procedure is not research.

A tissue reaction is defined as injury in populations of cells, characterized by a threshold dose and an increase in the severity of the reaction as the dose is increased further. Tissue reactions are also referred to as deterministic effects. For further clarification of tissue reactions, refer to International Commission on Radiological Protection Publication 118, available at [http://www.sciencedirect.com/science/article/pii/S0146645312000024](http://www.sciencedirect.com/science/article/pii/S0146645312000024).

Amendments to protocols are expected of investigators whenever the typical radiation dose is likely to change. Amendments may be approved by the Chair of the Human Use Subcommittee without review by the Committee UNLESS

1. There is a change in the study protocol and/or the study’s estimated dosimetry resulting in an increase in any reported radiation dosimetric quantity by at least 10%; OR
2. There is a change in the study protocol and/or the study’s estimated dosimetry resulting in an increase in the effective dose of ionizing radiation received for research purposes to a typical subject in the study of at least 1mSv in total over the course of the study; OR
3. Minors are added to the study; OR
4. Tissue reactions such as hair loss or skin injury were observed or are potentially foreseen.