

Radiation Safety Requirements for Human Research

There are two levels of human research involving use of radiation. Both levels require prior approval from the KUMC Radiation Safety Committee (RSC).

Level I: The use of radiation/radioactive materials is an FDA approved use, however, the subject will be receiving additional tests/scans/procedures that are for research purposes only. Examples of research procedures include x-rays, CT scans, radiation therapy, and nuclear medicine scans such as bone scans, MUGA, gastric emptying. [Studies that only employ dexta scans or a single screening chest x-ray have blanket RSC approval; additional RSC review is not required.]

Example: During the treatment of cancer the patient would routinely receive CT scans every 8 weeks for 6 months resulting in 3 CT scans. If this patient is enrolled in a research study in which the CT scans are done every month, the patient will be exposed to 3 additional CT scans for research purposes only. It is these 3 extra CT scans that require RSC review.

Level II: A PI wants to participate in a research study in which the use of radiation/radioactive materials is not FDA approved. In Level II, the use of the radiation/radioactive material is being researched.

Review of Level I Projects

Level I projects do not require a special form for RSC submission. PIs should submit the protocol, the draft consent form, and a cover letter that explains the difference between standard of care and the exposure to radiation that will occur for research purposes. The submission should be sent by email to Ruth Schukman-Dakotas, the Radiation Safety Officer.

Projects are reviewed by RSC on an individual basis. The risk associated with the radiation exposure differs by the type of procedure and the portion(s) of the body that will be exposed.

Review of Level II Projects

Level II submissions should include the Level I paperwork and a "Project Application to Use Radioactive Materials in Humans." Level II projects are evaluated for risks to subjects as well as the credentials (training and experience) of the PI.

All Projects

Submissions may be reviewed at monthly meetings of the RSC; alternately, submissions may be distributed to members, discussed and voted on electronically.

Human subjects research involving either Level I or Level II must have review and approval from the KUMC Radiation Safety Committee prior to implementation. The Human Subjects Committee does not grant final project approval until RSC approval is secured.

More information is available from the KUMC Radiation Safety Policies and Procedures posted at: <http://www2.kumc.edu/safety/labsafety/radsafety/>