

IRB PROTOCOLS REQUIRING RADIATION SAFETY COMMITTEE (RSC) REVIEW

Instructions for IRB Departmental Coordinators and IRB Office Staff (Revised: January 5, 2016)

Adherence to these instructions and guidelines in the submission of quality applications will help to assure RSC full approval, with minimal follow-up necessary and decreased turnaround time.

1. **IRB protocols involving radioactive materials must be submitted to the RSO/RSC first, prior to submission to the IRB. (Please Note: The IRB will return protocols to investigators who do not comply with this requirement.)**
2. **Each submission should be made by sending an email, with all relevant documents attached electronically, to:**
Kevin Ferguson (fergusk2@slu.edu); with copy to: Mark Haenchen (haenchen@slu.edu)
3. **All emails must include the IRB No. and Investigator Name in the subject line of the email.**
4. **The following documents must be included as electronic attachments, preferably to a single email (Important to facilitate forwarding to RSC Membership):**
 - a. Draft SLU eIRB Protocol Application
 - b. Draft SLU IRB Informed Consent (Consistent with SLU IRB requirements)
 - c. Electronic copy of printout of radiation effective dose calculation from Duke University website
 - d. Study Sponsor Protocol
 - e. In some cases, additional documents, e.g. Investigator's Brochure, etc. may be required. Please note: the HIPAA document is not required or needed for RSC review.
5. **Guidelines for Assuring Expedient RSC Review and Approval of IRB Protocols:**
 - a. ***Specify the IRB No. on each document.***
 - b. ***Complete Section 4 of SLU IRB Protocol Application, in its entirety.***
 - i. Be sure to answer all questions accurately, and completely.
 - ii. Specify the procedures and anatomical location (e.g. CT Head, CT Abdomen, Chest X-Ray, Cardiac Cath, PET-CT Whole Body, fluoroscopic guidance, etc.)
 - iii. Specify the number of times that each procedure will be conducted throughout entire study.
 - iv. Clearly differentiate the procedures that are research vs. standard of care (i.e. the procedures the patient is undergoing only due to participation in the study). Not doing so will likely result in delay of final approval.
 - c. ***Utilize the SLU model radiation risk statements, inclusive of radiation effective dose estimates (from Duke website or other sources), adapting to the specifics of the protocol you are submitting.***
 - [SLU IRB Ionizing Radiation Risk Informed Consent Template Language](#)
 - [Adult radiation dose estimates on the Duke website](#)
 - [Pediatric radiation dose estimates on the Duke website](#)

Applicants must include the appropriate radiation risk statements in:

 - *“Section 9: Risks” of the SLU eIRB protocol and*
 - *“Section 4: What are the Risks?” of the SLU Informed Consent*
 - d. ***Cite the reference(s) for the radiation effective dose estimates.***
6. **Please provide the timeline needed for approval in the initial email (e.g. pending IRB deadlines, pending study sponsor deadlines). Note: Generally, the RSC meets monthly to accommodate timely IRB application review. Expedited requests can be considered on a case-by-case basis.**