

# **IRB PROTOCOLS REQUIRING RADIATION SAFETY COMMITTEE (RSC) REVIEW**

## **Instructions for IRB Departmental Coordinators and IRB Office Staff (Revised: October 3, 2019)**

*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. For IRB protocols involving non-standard of care use of radioactive materials which require submission to RSO/RSC, per IRB Guidelines, the proposed radiation risk language will either be drafted by IRB staff or drafted by the research team and then verified by IRB staff at the time of IRB submission, prior to submission for RSC review. Studies using a central IRB may be submitted to the SLU RSC and IRB offices at the same time, however, the study will not be allowed to be submitted to a central IRB until the RSC has completed its review.
2. Each submission to RSO/RSC should be made by sending an email, with all relevant documents attached electronically, to:  
Kevin Ferguson ([kevin.ferguson@slu.edu](mailto:kevin.ferguson@slu.edu)); with copy to: Mark Haenchen ([mark.haenchen@slu.edu](mailto:mark.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 or Central IRB Submission Authorization Form
  - b. Draft SLU IRB Informed Consent (Consistent with SLU IRB requirements)
  - c. Study Sponsor Protocol
  - d. 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. ***SLU IRB Ionizing Radiation Risk Informed Consent Template Language should be utilized, inclusive of radiation effective dose estimates (from Duke website and 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](#)

***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 (usually Duke website).***
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.