SOP 602I: Radiation Safety Office

1. POLICY

The Radiation Safety Office (RSO) shall review all human research that involves the use of ionizing radiation when the research is performed solely as part of the research and is not standard of care and shall provide its knowledge and expertise to the IRB.

Specific Policies

1.1 Committee Interaction

Following review of a research project, the Radiation Safety Office will provide written recommendations to the IRB. The IRB shall consider these recommendations when conducting its review.

RSO review should be conducted prior to IRB review. If time is a factor, however, the IRB will allow concurrent review by the IRB and the RSO. Final IRB approval of the project shall be contingent upon IRB receipt and review of the RSO written recommendations.

2. SCOPE

This SOP applies to human participant research that involves the use of ionizing radiation when the research is performed solely as part of the research and is not standard of care, as indicated by the investigator.

3. RESPONSIBILITY

3.1 The investigator is responsible for submitting human research projects that involve the use of ionizing radiation to the RSO and the IRB when such radiation is performed solely as part of the research and is not standard of care.

3.2 The IRB Administrator is responsible for obtaining the RSO written recommendations before submitting the research project to the IRB Chair or IRB designee for final IRB approval.

4. APPLICABLE REGULATIONS AND GUIDELINES

None

5. REFERENCES TO OTHER APPLICABLE SOPS

None

6. ATTACHMENTS

305-C Reviewer Checklist
602I-A Radiation Safety Approval Letter

7. PROCESS OVERVIEW

7.1 Submission Procedures

7.1.1 When an IRB submission involves the use of ionizing radiation performed solely as part of the research project (or as requested by the IRB or the RSO on a case-by-case basis) and not as standard of care, the investigator will indicate this on the IRB application and describe in the
informed consent document the risks to participants as a result of the exposure to ionizing radiation.

7.1.2 The investigator must also complete the Application for Human Use of Radiation or Radioactive Materials (available as a subform within the IRB electronic information system).

7.2 IRB Review Procedure

7.2.1 The IRB Administrator reviews the investigator’s submission documents for the use of ionizing radiation.

7.2.2 The IRB Administrator notifies the IRB reviewer that the submission will need to be reviewed by the convened IRB. The IRB Administrator will assign the RSO as an additional consultant/ad hoc reviewer on the file.

7.2.3 If the RSO letter is not available at the time of research project submission to the IRB, the research project can be reviewed by the convened IRB with notification to the IRB members that the RSO review results are pending.

7.2.4 The convened IRB reviews the RSO recommendations and suggested modifications to the protocol and/or consent documents.

7.2.5 If the RSO recommendations and suggested modifications qualify as minimal modifications, the IRB may request that the investigator revise the project according to both RSO and IRB requested stipulations. Once the investigator submits the IRB and RSO requested revisions, the IRB Chair or IRB designee reviews the revisions and, if the revisions are satisfactory, grants final IRB approval for the project through the expedited review process.

If the RSO recommends modifications that are more than minimal, the IRB may request that the PI submit revised protocol and consent documents, as applicable, and forward the modifications to the RSO for a subsequent review. If a second review by the RSO is requested by the IRB, the updated RSO recommendations and suggested modifications will be reviewed by the convened IRB to make a determination on the IRB submission.

7.3 RSO Review Procedure

7.3.1 The RSO will review the ionizing radiation component of the research project. If the RSO reviewer has questions, s/he may contact the investigator directly. If the RSO reviewer requires additional information or documentation, the investigator will receive notification of the RSO reviewer’s stipulations via the IRB’s electronic information system.

7.3.2 When the ionizing radiation component of the IRB submission review is completed, the RSO documents their recommendations and suggested modifications to the protocol or to the consent documents, as applicable, in the IRB’s electronic submission system for action by the IRB Chair or IRB designee.
NEXT ESTABLISHED REVIEW DATE: AUGUST 2016