

**Collaborative Communication
Procedures for Research Involving
Radiation Exposure Between
Radiation Safety Entities and UIC
IRBs**

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POLICY:

- I. The UIC EHSO has a policy (*Radiation Safety: Human Subject Research Protocols*) that defines when research protocols involving human subjects require review by the EHSO prior to IRB review and approval. Protocols requiring review by EHSO include:
 - A. Research protocols involving radiation exposure for research purposes and that involve increased exposure for the subject versus standard of care due to additional procedures or more frequent procedures;
 - B. Research protocols that require review by the RDRC as they involve the use of a radioactive labeled drug as defined by the FDA;
 - C. Protocols involving greater than 100 mrem exposure per year and having an estimated effective equivalent dose below 25 rem per year whole body, 250 rem per year individual organs and tissues, and 75 rem per year eyes. These protocols require RSO review. These effective equivalent doses are for patient research subjects only. The Radiation Safety Office will not approve an effective equivalent dose greater than 5 rem/yr to any healthy human research subject;
 - D. Research protocols with an estimated effective equivalent dose above 25 rem per year whole body, above 250 rem per year individual organs and tissues or 75 rem per year eyes; and
 - E. Protocols involving the use of investigational medical devices emitting ionizing radiation (i.e., not having FDA approval).

- II. The JBVAMC RSO must review research protocols involving:
 - A. Any radiation exposure to healthy clinical research volunteers;
 - B. Uses of radiation sources that do not meet the criteria for “medically indicated” and are therefore regarded as “indicted for research;”
 - C. Administration of radioactive research drugs or radiopharmaceuticals that are not NDA approved by the FDA;
 - D. Use of radiopharmaceuticals that are NDA approved but are being used for off-label procedures;

- E. Administration of radioactive biologicals (e.g., monoclonal antibodies, insulin, penicillin, blood and blood products, vaccines, derivatives or natural substances, and extracts of living cells); and
 - F. Medical devices emitting ionizing radiation that have not received FDA approval.
- III. The EHSO and the JBVAMC RSO review provides the IRBs with a risk assessment and a determination regarding the research prior to IRB review and approval to ensure that the IRB has the information required in order to make the necessary determinations as required by the approval criteria outlined in the regulations [45 CFR 46.111 (a) (1)(2), 21 CFR 56.111 (a) (1) (2), 38 CFR 16.111 (a) (1) (2)].
- (1) Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purpose.
 - (2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
- IV. For protocols requiring EHSO and/or JBVAMC RSO review, approval notification from EHSO and/or JBVAMC RSO must be received prior to IRB review and approval. Typically, this approval should be obtained before IRB submission. If it is not, IRB review will not proceed until this is obtained.

PROCEDURE:

- I. Initial Review.
 - A. The investigator provides the research protocol and consent document, IRB application form, and any additional supporting documents required to the UIC EHSO and/or JBVAMC RSO for radiation safety review before submission to the IRB.
 - B. The submission is reviewed by the appropriate committee (i.e., RSO, Human Use Radiation Safety Subcommittee, or RDRC).
 - C. When it has been determined that radiation use is appropriate and safe and the consent document language adequately represents the radiation risks, a letter of determination, noting the full title of the research and the PI, is provided to the PI and copied to the OPRS Director. Based upon these letters, OPRS will maintain a log of all EHSO/JBVAMC RSO approved initial review submissions. The OPRS will also maintain a log of correspondence from the EHSO/JBVAMC RSO whereby it was determined the radiation use/exposure was not acceptable in the proposed research.
 - D. The EHSO/JBVAMC RSO approval letter should be included in the initial submission application to OPRS. If not included, the OPRS file copy (sent to the Director) may be used to supplement the investigator's application, but the PI will be notified of the omission for subsequent submissions.
 - E. The approval letter to the PI will note that additional review by the EHSO/JBVAMC RSO is required for any amendments that affect the radiation

exposure and also for the CR application. PIs must allow for the additional time required for this safety review (approximately ten business days).

F. EHSO/JBVAMC RSO is copied on the IRB approval letter, as applicable.

II. Amendment Review.

A. If a change is made to the research that involves an increase in radiation dose or a change in body exposure site, the amendment must be reviewed by the EHSO/JBVAMC RSO to evaluate the risks to subjects. The amendment may not be submitted to the IRB until the EHSO/JBVAMC RSO has reviewed the revisions to the research and/or consent document.

B. A letter of determination is provided to the PI and copied to the OPRS Director. OPRS will maintain a log of all amendments that have received EHSO/JBVAMC RSO approval.

C. Once the PI receives the EHSO/JBVAMC RSO review notification, the PI can then submit the amendment application for IRB review. IRB approval cannot be provided without EHSO/JBVAMC RSO review documentation included in the application materials. If not included, the OPRS file copy (sent to the Director) may be used to supplement the investigator's application, but the PI will be notified of the omission for subsequent submissions.

D. EHSO/JBVAMC RSO is copied on the amendment approval letter, as applicable.

III. Continuing Review.

A. Investigators must submit all applicable IRB submission materials and materials required by the EHSO/JBVAMC RSO policy for Continuing Review well in advance of the expiration of the approval of the research protocol (allow an additional ten days for EHSO/JBVAMC RSO review).

B. EHSO/JBVAMC RSO reviews the safety information provided in the Continuing Review application to ensure that no additional risks related to radiation exposure have been identified in the past approval period. If any revisions are required to the research based upon the EHSO/JBVAMC RSO review, the investigator is notified by EHSO/JBVAMC RSO in writing that an amendment is required and the OPRS Assistant Director for the IRB is copied on the determination letter. If changes are not required, the investigator is notified in writing that the CR is cleared to submit for IRB review and approval. The OPRS Director is copied on this communication. OPRS will maintain a log regarding EHSO/JBVAMC RSO Continuing Review approvals and requests for revisions.

C. If the Continuing Review is IRB approved, the EHSO/JBVAMC RSO is copied on the approval letter, as applicable.

IV. Protocol Deviations.

A. EHSO/JBVAMC RSO policy requires that "any deviation in participant radiation dose administration from the approved protocol must be reported in writing immediately to the RSO." According to UIC HSPP policy this would be an unanticipated problem that would require prompt reporting to the IRB using the *Event Requiring Prompt Reporting to the Institutional Review Board* form.

If the OPRS/IRB receives a report of an event that meets the reporting requirements within the EHSO/JBVAMC RSO policy, the EHSO/JBVAMC RSO will be notified promptly and will be copied regarding any IRB determinations.

REFERENCES:

[21 CFR 56.111\(a\) \(1\) \(2\)](#)

[38. CFR 16.111\(a\) \(1\) \(2\)](#)

[45 CFR 46.111\(a\) \(1\)\(2\)](#)

[VHA Handbook 1200.1, VHA Handbook 1200.05](#)