

**Corporate Standard Operating Procedure**

**Approving Research Projects with Nuclear Substances or Radiation Emitting Devices Involving Humans**

### **Purpose Statement:** To outline the necessary steps to obtain approval from the Radiation Safety Committee for research projects using nuclear substances or radiation devices involving humans.

**Scope:**  All clinical research studies using radioactive materials or radiation devices where there are therapeutic uses or imaging studies above standard of care.

**Definitions:**

**Standard of Care:** Treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals. Also called best practice, standard of care, and standard therapy.

**Study:** Research protocol which recruits (usually large numbers of) subjects or participants, most often with known clinical conditions, to statistically assess the efficacy of an intervention.

**Clinical Investigation:** A systematic investigation, in humans, which seeks to establish facts, principles and develop generalizable knowledge in human physiology, as well as the pathophysiology of disease. It generally involves more intensive studies in fewer subjects than do clinical trials.

**Volunteer**: Any participant that takes part in a research study. To varying degrees, the study may impact the individual subject’s medical health directly, although the principal aim of research is to develop new knowledge. Volunteers may be recruited from the hospital patient population or from the general population. They may have specific clinical conditions or be healthy subjects.

**OHSN-REB:** Ottawa Health Science Network - Research Ethics Board

**Procedure:**

Provide specific details (step-by-step) on how to complete the procedure. If there are steps to be completed by different staff members, consider using a sub-headers or a table format.

1. **Completing the Diagnostic Radiation Safety Form**
2. The study coordinator is to complete the diagnostic radiation safety form prior to submitting the study details to the research ethics board (REB).
3. Only procedures that are above standard of care need to be considered for the dosimetry summary.
4. The form must be signed and dated by the principal investigator prior to submission to the Radiation Protection Officer or the Radiation & Laser Safety Office.
   1. **Studies involving only radiation emitting devices with exposures less than 50 mSv from non standard of care procedures**
5. Once completed, the study coordinator will submit the radiation safety form for diagnostic imaging procedures to the radiation protection officer (RPO) for review.
6. The RPO will review the protocol and radiation safety form and where applicable request amendments to the form or the study.
7. The study coordinator will incorporate the requested amendments or provide justification for not including them
8. Once the form has been satisfactorily completed, RPO will sign the appropriate section and provide the coordinator with a copy.
9. The study coordinator will proceed with submitting the study to the REB.
   1. **Studies involving radioactive materials and/or exposures more than 50 mSv from non standard of care procedures.**
10. Once completed, the study coordinator will submit the radiation safety form for diagnostic imaging procedures to the Radiation & Laser Safety Department.
11. The Radiation & Laser Safety Department will review the protocol and radiation safety form and where applicable request amendments to the form or the study.
12. The study coordinator will incorporate the requested amendments or provide justification for not including them.
13. Once the form has been completed the Radiation & Laser Safety Department will provide The Ottawa Hospital Radiation Safety Committee with a summary of the protocol and the expected exposure from non standard of care procedures.
14. The Ottawa Hospital Radiation Safety Committee will approve the research study or ask for clarifications or amendments to the radiation safety form or to the research protocol. The Radiation & Laser Safety Department will forward the amendments to the Study Coordinator.
15. Once the form has been satisfactorily completed the Chair of The Ottawa Hospital Radiation Safety Committee will sign the appropriate section and the Radiation & Laser Safety Department will provide the coordinator with a copy.
16. The study coordinator will proceed with submitting the study to the REB.
17. **Studies involving the therapeutic use of radioactive materials.**
18. The study coordinator is to complete the therapeutic radiation safety form prior to submitting the study details to the research ethics board (REB).
19. Only procedures that are above standard of care need to be considered for the dosimetry summary.
20. The form must be signed and dated by the principal investigator prior to submission to the Radiation Protection Officer or the Radiation & Laser Safety Office.
21. Once completed, the study coordinator will submit the radiation safety form for therapeutic procedures to the Radiation & Laser Safety Department.
22. The Radiation & Laser Safety Department will review the protocol and radiation safety form and where applicable request amendments to the form or the study.
23. The study coordinator will incorporate the requested amendments or provide justification for not including them.
24. Once the form has been completed the Radiation & Laser Safety Department will provide The Ottawa Hospital Radiation Safety Committee with a summary of the protocol and the expected exposure from non standard of care procedures.
25. The Ottawa Hospital Radiation Safety Committee will approve the research study or ask for clarifications or amendments to the radiation safety form or to the research protocol. The Radiation & Laser Safety Department will forward the amendments to the Study Coordinator.
26. Once the form has been satisfactorily completed the Chair of The Ottawa Hospital Radiation Safety Committee will sign the appropriate section and the Radiation & Laser Safety Department will provide the coordinator with a copy.
27. The study coordinator will proceed with submitting the study to the REB.
28. **Industry Sponsored Studies**
29. Research studies that are sponsored will be subject to a review fee.
30. The Radiation & Laser Safety Department will submit an invoice to the study coordinator.
31. The study coordinator will ensure the invoice is paid in a timely manner.
32. **Consent Form Language**
33. Where it is deemed appropriate, the Ottawa Hospital Radiation Safety Committee (OHRSC) will ask that any applicable risks will be included on the consent form. The OHRSC will specify the language.
34. The requested consent form language will be communicated to the study coordinator and the OHSN-REB by the Radiation & Laser Safety Department.

**Related Documents:**

1. OHRSC Terms of Reference

**Regulatory or Legislative Requirements:**

### CNSC Human Research Studies license

1. CNSC Diagnostic Nuclear Medicine license
2. INFO 0491 Guidelines for Research on Human Subjects Using Radionuclides
3. International Conference on Harmonization (ICH), Good Clinical Practice (GCP) Guidelines. Section 4.12, 4.13, 5.21, 5.22

**References:**

None

**Metadata for Policy Medical Only – will not appear on the document**

|  |  |  |
| --- | --- | --- |
| **Document #:** *<<i.e.: COR-ADM-I 100>>* | | **Created:** *<date initially developed>* |
| **Description:** | | |
| **Published on:** | | **Responsible Department:** |
| **Last Review date:** | **Version:** | **Effective date:** |
| **Summary of Changes:** | | |
| **Audience:** | | **Next Review Date** |
| **Author:** | | **Owner/Manager:** |
| **Approver:** | | **Committee:** |
| **Key Stakeholders/Reviewers for workflow:** | | |