RADIATION SAFETY MANUAL

RESEARCH PROJECTS WITH NUCLEAR SUBSTANCES OR RADIATION EMITTING DEVICES INVOLVING HUMANS
No.: 00379
(Formerly ADM XII 105)

ISSUED BY: Radiation and Laser Safety Department

APPROVED BY: Senior Management Committee

CATEGORY: Radiation Safety

DATE OF APPROVAL: 2005/12/08
LAST REVISION DATE: 2018/01/30
IMPLEMENTATION DATE: 2010/02/03

POLICY STATEMENT:

In addition to The Ottawa Hospital Research Ethics Board (OHREB) review, all research projects and clinical trials at The Ottawa Hospital (TOH) and affiliated institutions, which involve nuclear substances (radioisotopes) or radiation emitting devices used on or in humans will require Radiation Safety (RS) assessment and approval.

NOTE: All research projects and clinical trials involving patients receiving radiation therapy at TOH Cancer Centre (TOHCC) will only require OHREB Approval. Should the OHREB require expert advice on exposures involved in these projects, it will be the research applicant’s responsibility to obtain this information by contacting a TOHCC medical physicist.

DEFINITION(S):

1. **Clinical Trial**: 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.

2. **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.
3. **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.

4. **OHREB**: Research Ethics Board

5. **RPO**: Radiation protection officer (radiologist)

6. **PERC**: Positron-Emitting Radiopharmaceuticals Committee

7. **R&LS**: Radiation & Laser Safety Department

8. **TOHRSC**: The Ottawa Hospital Radiation Safety Committee

**ALERTS**: N/A

**PROCEDURE:**

The approval of the research study will depend on the type of radiation used in the study.

The following categories of studies have different approval process:

1. Studies involving only the use of nuclear substances (radioisotopes).
2. Studies involving the use of radiation emitting devices (X-ray).

Details of the application process are outlined on the ‘Approval Flow Chart, accessible on the Radiation Safety and Health Physics Web site’.

The *Radiation Safety Form for Protocols Using Nuclear Substances and Radiation Emitting Devices (X-ray) Involving Humans* must be completed (later referred to as ‘Radiation Safety Form’).

Refer to the document *Contact Persons for Dosimetry Human Studies* for assistance with completion of the *Radiation Safety Form for Protocols Using Nuclear Substances and Radiation Emitting Devices (X-ray) Involving Humans* and the *Radiation Dosimetry References Human Studies*.

**Roles and Responsibilities of the Research Applicant**

1. Ensure the following documents are submitted with every application:
   i. Executive Summary
   ii. Complete protocol
   iii. Radiation Safety Form
iv. Department of Medical Imaging Impact Form (where applicable).


2. Make any changes or revisions to the Radiation Safety component of the protocol, when requested.

3. For industry sponsored or multicenter studies, enclose an application fee of $400.00 for the radiation safety assessment.

Roles and Responsibilities of the R&LS Department

1. Review all information on the radiation safety forms for protocols involving nuclear substances and correspond with the chair of TOHRSC.

2. Ensure the Radiation Safety Form is completed following approval by the OHRSC

3. Send approval status to research coordinator.

Role of the RPO

Coordinate the approval of the study as per the ‘approval flow chart’.

Role and Responsibility of The Ottawa Hospital Radiation Safety Committee

1. Review and evaluate doses to participants, workers and the general public according established references.

3. Review the risk statement and recommend changes to the risk statement form in line with CNSC and institutional criteria.

4. Request amendment to risk statement and radiation form to meet CNSC license and institutional criteria.

5. Approve the study.

Role and Responsibility of TOH REB

1. Provide the RSHP Department with monthly termination notices.

2. Ensure that all research projects with nuclear substances or radiation emitting devices involving human do not get OHREB approval until the Radiation Safety form has been signed by TOHRSC chair, RPO, or PERC Chair, as per Radiation Safety Form.

RELATED POLICIES / LEGISLATION:
1. CNSC Human Research Studies license
2. CNSC Diagnostic Nuclear Medicine license
3. INFO 0491 Guidelines for Research on Human Subjects Using Radionuclides
4. TOHRSC Terms of Reference
5. International Conference on Harmonization (ICH), Good Clinical Practice (GCP) Guidelines. Section 4.12, 4.13, 5.21, 5.22

REFERENCES: N/A

COMMENTS / SIGNIFICANT REVISIONS: N/A