The Ottawa Hospital | L'Hôpital d'Ottawa

ADMINISTRATIVE POLICY AND PROCEDURE MANUAL
MANUEL DES POLITIQUES ET PROCÉDURES ADMINISTRATIVES

Research Projects with Nuclear Substances or Radiation Emitting Devices Involving HUMANS

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ISSUED BY / PRÉPARÉE PAR :
Radiation Safety & Health Physics Department
Radioprotection

APPROVED BY / APPROUVÉE PAR :
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1. POLICY

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. These will be reviewed against the appropriate established criteria.

These criteria could include: Canadian Nuclear Safety Commission (CNSC) Regulations, licenses and accepted guidelines on human studies; internal standards outlined by TOH Radiation Safety Committee (TOHRSC), and TOH Radiation Safety Manual (RSM).

Although research often involves patients treated according to the standard of care, the concern for Radiation Safety is the exposure experienced by subjects which is over and above the standard of care. Clinical research may, in general, be divided into clinical trials and clinical investigation.

> 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.

2. DEFINITIONS:

Clinical Trials: Research protocols which recruit (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.

REB: Research Ethics Board
RPO: Radiation Protection Officer (Radiologist)
PERC: Positron Emitting Radiopharmaceuticals Committee
RSHP: Radiation Safety & Health Physics Department
OHRSC: Ottawa Hospital Radiation Safety Committee

3. PROCEDURES:
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.

3.1 Studies involving only the use of nuclear substances (radioisotopes)
3.2 Studies involving the use of radiation emitting devices (X-Ray)
3.3 Studies involving the use of radiation emitting devices (X-ray) and radioisotopes.
3.4 Studies involving the use of positron emitters.

Details of the application process are illustrated on the 'Approval Flow Chart, accessible on the Radiation Safety & 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*.

Role and Responsibility of the Research Applicant

Ensure the following documents are submitted with every application:

1. Executive Summary
2. Complete protocol
3. The Radiation Safety Form
4. Financial Impact Form.

Forms are available on the OHREB web site at :
http://www.ohri.ca/ohreb/
or on the Radiation Safety & Health Physics Web site on Infonet at:
http://infonet/body_radiation.cfm?id=10347

5. Make any changes or revisions to the Radiation Safety component of the protocol, when requested.
6. For industry sponsored or multicenter studies, enclose an application fee of $300.00 for the radiation safety assessment.

Role and Responsibility of the RSHP Department

1. Review all information on the radiation safety forms for protocols involving nuclear substances and correspond with the chair of TOHRSC.
2. Send approval status to research applicant, research coordinator and REB on behalf of TOHRSC.

Role of the RPO or PERC Delegate

Coordinate the approval of the study as per the 'approval flow chart'.

Role and Responsibility of the DI Department

The role of DI Department will be as outlined in the DI procedure for research studies.

ROLE AND RESPONSIBILITY OF THE OTTAWA HOSPITAL RADIATION SAFETY COMMITTEE

1. Ensure all qualifying protocols (as per 'approval flow chart') are approved and supervised by a medical practitioner who is qualified to work with nuclear substances and radiation devices.

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

Effective Dose per Year	Project Assessment	Approval required
< 0.1 mSv	No radiological protection review necessary	Radiation Safety & Health Physics Department only
≥ 0.1 and <1 mSv	Minimal review	Radiation Safety & Health Physics Department only
≥ 1 and < 20 mSv	Maximal review	Ottawa Hospital Radiation Safety Committee or RPO
≥ 20 mSv	Maximal review (approve only under exceptional circumstances if involving healthy volunteers)	Nuclear Substances: Ottawa Hospital Radiation Safety Committee X-ray: RPO
≥ 50 mSv	Maximum review	X-Ray and Nuclear Substances: Ottawa Hospital Radiation Safety Committee

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.

6. Return to delegate or RSHP for distribution to research applicant and OHREB.

3.5 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.

4. RELATED POLICIES AND / OR LEGISLATIONS:

- CNSC Human Research Studies license
- CNSC Diagnostic Nuclear Medicine license
- INFO 0491Guidelines for Research on Human Subjects Using Radionuclides
- TOHRSC Terms of Reference 2007

International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. Section 4.12, 4.13, 5.21, 5.22
http://www.ich.org/UrlGrpServer.jser?@_ID=276&@_TEMPLATE=254

Health Canada Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials. Division 5. Canada Gazette Part II, Vol. 135, NO.13, June 7, 2001
http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/food_drug_reg_amend_1024_gcp_tc_e.html