The Ottawa Hospital | L'Hôpital d'Ottawa

RADIATION SAFETY FORM for:

Protocols Using Nuclear Substances and Radiation Emitting Devices (X-Ray) Involving Humans

Section 1: GENERAL INFORMATION

Protocol Title: (***Type in the full PROTOCOL TITLE and copy paste in the footer***)

Protocol #: _____
Description of Study:_____ **(*Enclose summary*)**

Principal Investigator: _____ Phone: Email:
Internal Mailing Address: _____
Research Coordinator: _____ Phone: Email:

Number of recruits required: _____ Start Date: _____ End Date: _____

Campus and Department where protocol will be conducted:
Civic ☐ Heart Institute: ☐ General ☐ Riverside: ☐

Please complete only the sections of this form that pertain to the research protocol being submitted to the REB for approval.

This study involves:

a) X-Ray: ☐ *Complete Section 2*
b) Radioisotopes (Nuclear Substances): ☐ *Complete Section 3*
c) X-Ray and Radioisotopes: ☐ ***Complete Section 2 AND 3***
E.g.: PET/CT or SPECT/CT

Note: Positron Emitting Radiopharmaceuticals (PET Tracers): ☐
send application copy for** Positron Emitters Review Committee (**PERC) review.

Pregnant women and children under the age of 12 will be excluded from this research study: ☐ YES ☐ NO

This protocol involves the use of x-ray or nuclear substances above what would be needed for routine standard of care: ☐ *YES* ☐ NO

Section 2: RADIATION EMITTING DEVICES (X-RAY)

Radiation Emitting Device (X-ray) Exam eg.: *CT, general X-ray*	**Number of Exams**	**Dose per Exam**	**Total Effective Dose (mSv)**
Total Effective Dose for all Exams:			**mSv**

Reference used: See OREB Web site: http://www.ohri.ca/OHREB/forms.htm

Does this protocol meet with routine standard of care*:* ☐ *YES* ☐ *NO*

For assistance with dose calculations, please contact the designated person at the campus where the study is conducted:See table of contacts below.

Estimated dose to third party (i.e. x-ray technologist) as a result of exposure (if applicable): _____ mSv

Section 3: NUCLEAR SUBSTANCES

This protocol involves nuclear substances to be used on or in a human research recruit for the purpose of assessing, assuring and or im proving the recruit's personal medical health:

☐ *YES* ☐ *NO*

Radioisotope used:_____ Maximum Amount in Possession: :_____

Storage Location:_____

Available Instrument(s) to perform Contamination Monitoring: _____

Radioactive Waste Disposal Procedure: _____

A: RECRUIT DOSIMETRY INFORMATION

Radioisotopes (Nuclear Substances)	**Activity administered per scan/ study**	**Number of scans /studies**	**Effective Dose per scan/ study (mSv)**	**Total effective dose (mSv)**	**Critical Organ (mGy)** if dose > 50 mSv
Total Effective Dose from all exams:			**mSv**		

For assistance with dose calculations, please contact the designated person at the campus where the study is conducted:See table of contacts below.

References used to derive dosimetry estimates:_____

_____

Enclose additional information which is essential to verify dose calculations:_____

_____

(i.e. radiopharmaceutical kinetics and biodistribution).

B: THIRD PARTY DOSIMETRY INFORMATION

Name and location of Department where radioisotope will be administered	
Has radiation safety training been received	
Approximate time with recruit per visit	
Approximate distance from recruit per visit	
Total Estimated dose to third party for duration of protocol	

Section 4: TOTAL RECRUIT DOSE

DOSE CONTRIBUTIONS	mSv
Dose from Radiation Emitting Device (X-Ray):	
Dose from Radioisotopes (Nuclear substances):	
Total Dose for protocol (round up to nearest decimal):	**_____ mSv**

Section 5: RISK STATEMENT

Risk statement from radiation must be stated in the consent form. Use the appropriate risk statement below for the appropriate dose rate.
Calculate the number of years living in Ontario (natural background exposure) equivalent to this total dose using this formula:

years of equivalent natural background exposure= $\frac{\text{Total dose for protocol}}{\text{2.7 mSv/year}}$

Note:
2.7 mSv is the exposure from natural background while living in Ontario for 1 year (12 months)
Health Canada; ***http://www.hc-sc.gc.ca/ed-ud/event-incident/radiolog/info/radiation-ion-eng.php***

If dose is above 50 mSv, then calculate the percentage of the average natural lifetime exposure in Ontario using this formula:

% of additional average natural lifetime exposure in Ontario= $\frac{\text{Total dose for protocol}}{\text{218 mSv lifetime exposure}}$

Note:
According to Statistics Canada, the average life expectancy of Ontarian is 80.7 years, therefore the average natural lifetime exposure is 2.7 mSv x 80.7 years = 218 mSv.
Life expectancy, abridged life table, at birth and at age 65, by sex, Canada provinces and territories, annual (years) (CANSIM Table 102-0511).
Ottawa, Statistics Canada, 2008

Under 0.05 mSv: No radiological protection review required.

Greater or equal than 0.05 and under 2.7 mSv

*"The additional amount of radiation you will receive from participating in this research study is about the same amount a person would receive naturally, while living in Ontario for _____months. The risk is considered to be **negligible**."*

Greater or equal than 2.7 mSv and under 20 mSv

*"The additional amount of radiation you will receive from participating in this research study is about the same amount a person would receive naturally, while living in Ontario for _____years. The risk is considered to be **minimal** and there are no expected consequences associated with this exposure."*

Greater or equal than 20 mSv and under or equal to 50 mSv

*"The additional amount of radiation you will receive from participating in this research study is about the same amount a person would receive naturally, while living in Ontario for _____years. The overall risk is considered to be **acceptable** and there are no expected consequences associated with this exposure."*

Above 50 mSv

"The *additional* amount of radiation you will receive from participating in this research study is approximately ____% of the average natural lifetime exposure in Ontario. The overall risk is considered to be **acceptable** and there are no expected consequences associated with this exposure. "Doses to individual organs are listed and can be discussed with your physician." *

*NOTE: The underlined statement above applies only to nuclear medicine studies where nuclear substances are administered.

Section 6: SIGNATURES AUTHORIZATION

Depending on the radiation types used in the protocol, one, two, or all of the approvals below may be required as specified.

A) Protocol Approval : Radiation Emitting Devices (X-Ray)

The signatures below indicate the Investigator has read and completed this form and that the Ottawa Hospital Radiation Protection Officer (RPO) has reviewed the Radiation Safety component of the Protocol referred to above and that the Protocol can proceed for final approval by OHREB.

Principal Investigator:

Name: _____

Signature: _____ **Date:** _____

Radiation Protection Officer (RPO)

Name: _____

Signature: _____ **Date:** _____

B) Radioisotopes (Nuclear Substances) AND studies where total radiation exposure equal or greater than 50 mSv

The signatures below indicate the Investigator has read and completed this form and that the Ottawa Hospital Radiation Safety Committee has reviewed the Radiation Safety component of the Protocol referred to above and that the Protocol can proceed for final approval by OHREB.

Principal Investigator:

Name: _____

Signature: _____ **Date:** _____

Chair, The Ottawa Hospital Radiation Safety Committee:

Name: Dr. Laurent Dinh

Signature: _____ **Date:** _____

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C) Positron Emitting Radiopharmaceuticals (PET Tracers) if applicable

For the use of:
Positron Emitting Radiopharmaceuticals Committee (PERC)

The above referenced protocol meets the following criteria for research:

- ☐ **Clinical Research –** *Complete HC_3011 and submit this protocol to Health Canada. A No Objection letter is required for HREB approval.*
- ☐ **Basic Research –** *A submission to Health Canada is not required.*

This protocol has been reviewed and meets the following criteria for Basic Research:

- ☐ The PER(s) are not used primarily for immediate therapeutic or diagnostic purposes.
- ☐ The amount of ingredients or combination of active ingredients within the PER(s) is known not to cause any clinically detectable pharmacological effect in humans and has a demonstrated safety profile.
- ☐ Total study radiation dose < 20 mSv/year per subject
- ☐ Quality of PERs: PER(s) used in the study are fully characterized and meet the required chemical, pharmaceutical, radiochemical and radionuclide standards of identity, strength, quality, purity and impurities. The quality is reproducible.

Please note the following:

1. **Protocol amendments that change previously approved PER research studies must be reviewed by the PERC.**
2. **Records for all information related to the research study is recorded, handled and stored in a way that allows its complete and accurate reporting as well as its interpretation and verification. All records related to PERs research must be stored for 25 years.**
3. **All adverse events related to the use of PERs must be reported to PERC.**
4. **A copy of HREB approval must be forwarded to the attention of the PERC secretariat.**

Principal Investigator:

Name: _____

Signature: _____ **Date:** _____

Chair, Basic Research Positron Emitting Radiopharmaceuticals Committee:

Name: Dr. Robert deKemp

Signature: _____ **Date:** _____