**For all research protocols involving the administration of radioactive materials for THERAPEUTIC purposes.**

**SECTION 1: GENERAL INFORMATION**

**Protocol Title:**

**Brief Description of Study:**

|  |  |  |  |
| --- | --- | --- | --- |
| Principal Investigator |  | Phone  |  |
| E-mail |  |
| Research Coordinator |  | Phone  |  |
| E-mail |  |
| Internal mailing address |  |

Expected number of study participants: \_\_\_\_\_\_\_

Expected start date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Expected End Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Campus where protocol will be conducted (check all that apply):**

|  |  |  |  |
| --- | --- | --- | --- |
| Civic | Heart Institute | General | Riverside |

**SECTION 2: THERAPEUTIC STUDIES**

Name of radiopharmaceutical (include radionuclide and chemical form):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Method/Route of Adminstration: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Activity to be administered to a single patient per treatment (MBq): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Number of treatments: \_\_\_\_\_\_\_\_\_\_\_\_\_

Is a license amendment required?

|  |  |
| --- | --- |
| Yes | No |

Will the patient be treated as an in-patient?

|  |  |
| --- | --- |
| Yes | No |

If treated as an outpatient, do they require care?

|  |  |
| --- | --- |
| Yes | No |

Have you attacjed all relevant radiopharmaceutical product information including dosimetry calculations, kinetics and biodistribution?

|  |  |
| --- | --- |
| Yes | No |

**SECTION 3: RADIATION EXPOSURE FROM TREATMENT**

**Patient Dosimetry Information - Radiopharmaceuticals**

**NOTE: Include all procedures that are above Standard of Care (including diagnostic studies)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Radiopharmaceutical** | **Activity Administered per treatment (MBq)** | **Number of Treatments** | **Effective Dose per scan (mSv)** | **Total Effective Dose (mSv)** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| Total Effective Dose from all Radiopharmaceuticals: |  |

**Patient Dosimetry Information - Radiation Emitting Devices**

**NOTE: Include all procedures that are above Standard of Care (including diagnostic studies)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Imaging Procedure** | **Number of Procedures** | **Effective Dose per Procedure (mSv)** | **Total Effective Dose (mSv)** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Total Effective Dose from all Procedures: |  |

**3B: ORGAN DOSIMETRY INFORMATION**

**NOTE: Include only the organs receiving the highest exposures**

|  |  |
| --- | --- |
| **Organ** | **Organ Dose (Gy)** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

List the risks to specific organs associated with the radiation exposure (where applicable):

**SECTION 6: SIGNATURES AUTHORIZATION**

**6A. Protocol Submission: Principal Investigator**

The signature below indicates the Principal Investigator has read and completed this form and will abide by the conditions for which approval was granted.

 **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_**

 **Name (Principal Investigator) Signature Date**

**6B. Protocol Approval: Radiation Safety Committee**

The signatures below indicates 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.

 **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_**

 **Name (Chair, Rad. Safety Committee) Signature Date**