|  |  |
| --- | --- |
| **RSM-8** |  **Application for Investigational Human Use of Radioactive Material** |
|  |  |
| **Name:** |  |  |  |  |  |
|  | (Last) |  | (First) |  | (Middle) |
| **Title:** |  | **OSU Kerberos ID:**  |  |
|  |  | **(name.#)** | (Name.#) |
| **OSU ID#:** |  | **Date of Birth:** |  |
| **Department:** |  | **Division:** |  |
| **Address:** |  |
| **Email:** |  |
| **Phone:** |  | **After Hours Contact:** |  |
|  |  |
| [ ]  | New Application |
| [ ]  | Amendment to Permit Number: |  |  |
|  |  |
| **1. Requested Use(s) and Radionuclide(s)** |
|[ ]  3701:1-58-32 | Use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required. |
|[ ]  3701:1-58-34 | Use of unsealed radioactive material for imaging and localization studies for which a written directive is not required. |
|[ ]  3701:1-58-37 | Use of unsealed radioactive material for which a written directive is required. |
| [ ]  | 3701:1-58-43 | Use of manual brachytherapy sources |
|[ ]  3701:1-58-53 | Use of sealed sources for diagnosis |
|[ ]  3701:1-58-55 | Use of teletherapy units, remote afterloader units (HDR), and gamma stereotactic radiosurgery units |
|[ ]  3701:1-58-72 | Other medical uses of radioactive material or radiation from radioactive material: |
|  |  | Description: |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Radionuclide(s)** |  | **Form (Chemical / Physical)** |  | **Maximum Activity per Order (mCi)** |  | **Maximum Possession****(mCi)** |
| 1. |  |  |  |  |  |  |  |
| 2. |  |  |  |  |  |  |  |
| 3. |  |  |  |  |  |  |  |
| 4. |  |  |  |  |  |  |  |
| 5. |  |  |  |  |  |  |  |

**2. Location of Use (Check all that Apply):**

|  |  |  |  |
| --- | --- | --- | --- |
| University Hospitals: |[ ]  Nuclear Medicine |[ ]  Nuclear Pharmacy |[ ]  Radiology / VIR |
|  |[ ]  Patient Room |[ ]  Surgery |[ ]  Other: |  |
| The James Cancer Hospital: |[ ]  Nuclear Medicine |[ ]  Radiation Oncology |[ ]  Radiology / VIR |
|  |[ ]  Patient Room |[ ]  Surgery |[ ]  Other: |  |
| The Ross Heart Hospital: |[ ]  Nuclear Medicine |[ ]  Cath Labs |[ ]  Radiology |
|  |[ ]  Patient Room |[ ]  Surgery |[ ]  Other: |  |
| University Hospital East: |[ ]  Nuclear Medicine |[ ]  Cath Labs |[ ]  Radiology / VIR |
|  |[ ]  Patient Room |[ ]  Surgery |[ ]  Other: |  |
| The James Breast Center: |[ ]  Radiation Oncology |[ ]  Radiology/Mammo |[ ]  Other: |  |
| Other |[ ]   |[ ]   |[ ]   |

**3. Radioactive Material Use:**

|  |
| --- |
| Attach approval from the Human Subjects Radiation Committee and include the IND Number or approval by authorized RDRC. |
| IND Number: |  |  |  |
| Will use involve the release of individuals containing unsealed radioactive materials and/or sealed source implants containing radioactive material? |
|  |[ ]  No |[ ]  Yes |  |
| Will use require a fume hood? |
|  |[ ]  No |[ ]  Yes | If yes, Location: |  |
| Storage Location: |
|  | Building: |  | Room Number: |  |
| Storage Method: |
|  |[ ]  Refrigerator |[ ]  Freezer |[ ]  Ambient |[ ]  Other: |  |
| Radioactive Waste Disposal Method: |
|  |[ ]  Decay-in-Storage |[ ]  Other: |  |
|  |  |  |  |  |  |
|  |  | Waste Location: |  |

**4. Personnel**

|  |
| --- |
|[ ]  All department/division trained Radioactive Material workers are considered potential workers under this application and my responsibility for their supervision is the same as on my clinical human-use authorization. |
|[ ]  Personnel under this application are limited to: |
|  | 1. |  | 6. |  |
|  | 2. |  | 7. |  |
|  | 3. |  | 8. |  |
|  | 4. |  | 9. |  |
|  | 5. |  | 10. |  |

**5. Methods / Procedures / References**

Attach a description of the methods and procedures to be used under this authorization and/or applicable publications.

**6. Supervisor’s Acknowledgment of Responsibility:**

This application is for investigational human-use of radioactive material. Administration of radioactive material in or on humans shall only be performed by or under the supervision of a physician as defined in OAC 3701:1-38-01, specifically, *"a person licensed pursuant to Chapter 4731 of the Ohio Revised Code to practice medicine or surgery or osteopathic medicine or surgery.”*

1. Insuring all user under your supervision has received radiation safety training;
2. Insuring all users of radioactive material participate in required on the job, site / use specific training prior to beginning work;
3. Insuring a commitment to the philosophy to keep radiation exposures **A**s **L**ow **A**s **R**easonably **A**chievable (ALARA);
4. Insuring every user under your supervision has been instructed in, or have read, OAC Chapter 3701:1-38, OAC 3701:1-58, the *Radiation Safety Standards for The Ohio State University,* and the contents of this permit;
5. Notifying Radiation Safety immediately of any new individuals who require the approval for the use of radioactive materials;
6. Insuring the procedures and precautions as outlined in this permit are followed;
7. Maintaining postings of the Ohio Department of Health’s “Notice to Employees” and other appropriate caution signs, labels and signals as required by OAC 3701:1-38 and 3701:1-58.

In addition to the above, I certify the radioactive material usage will be limited to specific protocols approved by the applicable IRB and reviewed/approved by the IRB/URSC all procedures will have IND approval or Radioactive Drug Research Committee (RDRC) approval. I understand each specific human-use protocol must be approved by the IRB/URSC and that my responsibility is the same as for clinical human-use. Moreover, I agree to abide by these regulations, by all statements, precautions, and procedures presented in this application; and by any conditions added by the IRB/URSC during its review. Radiation Safety will forward such conditions to me, in writing.

|  |
| --- |
| **I have read the above requirements, understand them, and will abide by them.**  |
|  |  |  |  |  |
| Applicant’s Name (Typed or Printed) |  | Applicant’s Signature |  | Date |
|  |  |  |  |  |
| Department/Division Chair (Typed or Printed) |  | Department/Division Chair Signature |  | Date |

|  |
| --- |
| **For Radiation Safety Use Only** |
| **PI Number** | **Date Received** | **RSS Approval / Date** | **URSC Approval / Date** |
|  |  |  |  |