|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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** |
|  |  |  |  |