INDIANA UNIVERSITY
OFFICE OF RESEARCH ADMINISTRATION
RADIATION SAFETY – INDIANAPOLIS

APPLICATION TO USE RADIOACTIVE MATERIALS IN HUMANS FOR RESEARCH PURPOSES

I. General Information

1. PI/Applicant:	2. Dept:	3. Email Address:	4. Phone #:

5. Physician or Permit Code Under Which Radioactive Material Will Be Administered:

6. Individual Completing This Application (if different from above):	7. E-mail Address:	8. Phone #:

9. Title and Any Identifying Numbers of Research Study:

10. Expected Start Date:	11. Expected Project Duration:	12. IRB No. (or type "Pending"):

II. Radionuclide Administrations and Procedures Performed on Research Subjects

Table 1 – Radionuclide Administrations

Nuclide(s)	Chemical Form or Procedure	mCi per Admin.	# of Admin/yr for Research	# of Total Admin for Research	# of Admin/yr for SOC*	# of Total Admin for SOC

1. The radionuclides listed above will be administered at (check all that apply):
☐UH Nuc. Med. ☐Eskenazi Nuc. Med. ☐Riley Nuc. Med. ☐IUSCC PET ☐Methodist Nuc. Med./PET
☐Goodman Hall PET ☐Other (list):

2. Does the study protocol allow for alternative procedures that do **not** require the administration of radioactive materials for research purposes? ☐Yes ☐No If "Yes" is checked, provide justification for using the procedure that involves the administration of radioactive material.

3. Provide any comments regarding the information supplied in Table 1 here:

Table 2 – Machine Produced Radiation Procedures

Procedure Description	# per Yr for Research	# Over Entire Study for Research	# per yr for SOC	# Over Entire Study for SOC

4. The machine produced radiation procedures will be performed at the following locations (C heck all that apply):

☐UH Radiology ☐Eskenazi Radiology ☐Riley Radiology ☐IUSCC PET ☐Methodist Radiology/PET
☐Goodman Hall PET ☐Other (list):

5. Provide any comments regarding the information supplied in Table 2 here:

III. General Information Required for All Human Use Research Studies

1. Provide a brief description of the research project including the rationale for utilizing radioactive materials:

2. Provide the following information regarding the research subjects:
   a. Total number of subjects for the entire study:
   b. Total number subjects under 18 years of age, if any:
   c. Women of child-bearing age will be included in the study: ☐Yes ☐No
   d. Are any of these subjects "normal" volunteers?: ☐Yes ☐No
   e. Provide any specific information regarding the research subjects in this study that may be relevant with respect to the radiation safety review of this study:

3. A copy of some information required by the IRB can either be submitted with this form or the Radiation Safety Office can obtain that information directly from the KC-IRB website. Please indicate where the documents below are located:
   a. Lay Study Summary & Research Design questionnaire: ☐Attached ☐Available on KC-IRB website
   b. Risks, Benefits, Protections Questionnaire: ☐Attached ☐Available on KC-IRB website
   c. Informed Consent Statement: ☐Attached ☐Available on KC-IRB website
   d. Research Study Protocol: ☐Attached ☐Available on KC-IRB website

4. Insert any comments on this section here:

IV. Type of Human Use Research (Check One):

1. ☐ The radioactive material in this study is being used to obtain basic information on metabolism, human physiology, pathophysiology, or biochemistry, but not intended for immediate therapeutic, diagnostic, or similar purposes or to determine the safety and effectiveness of the drug in humans for such purposes.
2. ☐ This research study is a "clinical trial" of the radioactive material/drug.
3. ☐ The radioactive material in this study is a standard diagnostic test specifically performed in support of a clinical research protocol.
4. ☐ This is an amendment to a human use research study which has been approved by:
a. ☐ the Radioactive Drug Research Committee
b. ☐ the Radionuclide Radiation Safety Committee
5. ☐ Other (describe):
6. Insert any additional comments on this section here:

V. Information for the Formulation and Administration of Radionuclides

The information in this section should be completed by an individual from a department or office who is knowledgeable of such information.

1. The labeled drug will be formulated in accordance with the following procedure:
☐ Labeled drug is provided or formulated by a vendor (list vendor):
☐ RDRC Drug Master File Procedure (list DMF reference number):
☐ Labeled drug is formulated in accordance with a procedure provided by the vendor.
☐ Formulation procedure attached, or
☐ Formulation procedure reference (e.g. provide page number or section from research protocol):
2. Route of administration of the radioactive material: ☐ Parenteral ☐ Oral (Skip to item 4) ☐ Other (specify):
3. Radioactive material administered for parenteral use must be sterile and pyrogen free. How is sterility and pyrogenicity determined (check one or more of the following)? ☐ Provided in sterile and pyrogen free form by vendor listed above in Item V.1 ☐ Sterility and pyrogenicity testing is performed using a standard protocol from a clinical department. Provide the protocol name or reference number: ☐ Sterility and pyrogenicity testing performed using the attached protocol (include protocol as separate attachment to this application) ☐ Other method to assure sterility & control pyrogenicity (describe or attach description):
4. Describe the method to measure and/or calculate the amount of radioactive material being administered to each subject:
5. If the labeled drug will be formulated and utilized under an IND, provide the IND number and the individual, vendor, or facility that holds the IND:
6. Insert any additional comments on this section here:

VI. Information Required for Radioactive Drug Research Committee (RDRC) Review and Approval - *This section should be completed only if item 1 or item 4a of Section IV was checked.*

Pharmacological Information. The amount of active ingredient or combination of active ingredients to which the radioactive material is labeled shall be known not to cause any clinically detectable pharmacological effect. If the same active ingredients (exclusive of the radionuclide) are to be administered simultaneously (e.g., under an IND or NDA), the total amount of active ingredients including the radionuclide shall be known not to exceed the dose limitations applicable to the separate administration of the active ingredients excluding the radionuclide.

1. Name of active ingredient:
2. Maximum mass dose of active ingredient (μg or mg) administered per single dose to subject: ☐μg or ☐mg
3. No-observed-effect-level (NOEL) mass dose: ☐μg or ☐mg
4. Provide the reference(s) (e.g., published literature or other valid human studies) for items 1, 2, and 3:
5. Insert any additional comments on this section here:

VII. Radiation Dose Information

Please provide the following information regarding the radioactive material administered and machine-produced radiation for research purposes as listed in Section II:

1. Detailed dose calculations are required for radionuclides administered for research purposes (not SOC) listed in Table 1. The calculation method, any biological distribution data, references, and any assumptions associated with the radiation dose calculations should be provided. Assistance with dose calculations can be obtained from the Office of Research Imaging, the Radiation Safety Office, or possibly the clinical department administering the radionuclide. ☐ Dose calculations for radionuclides are attached. or ☐ Dose calculations for administered radionuclides are provided on page number(s) of the study protocol.
2. Dose calculations should also be provided for diagnostic x-ray procedures listed in Table 2 that are performed for research (not SOC) purposes. The same information as outlined above should be included for these calculations as well. If radiation doses vary among groups of subjects (e.g., control subjects versus non-control subjects) include dose calculations for a representative subject from each group. Once again, assistance with dose calculations from diagnostic x-ray procedures can be obtained from the sources listed above in item 1. ☐ Dose calculations for machine-produced radiation are attached or, ☐ Dose calculations for machine-produced radiation are provided on page number(s) of the study protocol. ☐ I request the Radiation Safety Office provide dose calculations for the procedures listed in Table 2 (**only applies to radiographs, DXA scans, and/or fluoroscopic procedures**).
3. Insert any additional comments on this section here:

VIII. Radionuclide Handling Precautions, Radioactive Waste Generation, and Personnel Involved in the Study

Completion of this page is <u>NOT</u> required if all radioactive materials are to be handled under an existing Radionuclide Use Permit AND there are no changes to that permit resulting from the inclusion of this research study.

1. Contamination/Exposure Precautions - Specify the precautions and procedures below which will be taken during the use of radioactive material to prevent contamination/unnecessary exposure. Indicate on additional pages if more specific procedures or items are used (e.g., rooms containing charcoal-filtered hoods). **NOTE: A Rad. Safety Form A-5, "*Request for Personnel Monitoring Service*" must be completed when personnel monitoring is required (refer to the Radiation Safety Procedures Manual). In addition, an account number must be provided for personnel monitoring billing.**

☐Disposable gloves, ☐Absorbent paper, ☐Spill trays, ☐Tongs, ☐Charcoal-filtered hoods, ☐Fume hood
☐Survey instrument, ☐Whole body/ring badges, ☐Shielding (describe):

2. Waste - Indicate the types of radioactive waste below that will be produced. Solid and liquid waste containers are provided by the RSO. If you wish to use your own containers, they must be approved by this office. Specify on additional pages any special conditions (e.g., need for shielding) necessitated by the radwaste.

☐dry solid, ☐scintillation vials with biodegradable fluids, ☐scintillation vials with organic fluids, ☐aqueous liquids
☐organic liquids, ☐insoluble liquids, ☐animal carcasses, ☐infectious*, ☐other (describe):

***Infectious radioactive waste (e.g., waste containing blood and/or blood-borne pathogens), must be properly treated prior to disposal.**

3. Labs - List all laboratories (building and room #) in which radioactive material will be used and/or stored along with the use of the lab. **A Rad. Safety Form A-4, "*Application for Facility Approval for Radionuclide Usage,*" must be completed for each lab**. Specify how the radioactive material will be secured from unauthorized removal (e.g., by locking unattended labs).

Table 3 – Locations of Radioactive Material Use

Building	Rm #	Lab Work	Storage	Count Rm	Other (describe)

4. Personnel - List all personnel who will be handling radioactive material under this permit. **A Rad. Safety Form A-3, "*Authorization to Use Radioactive Material*," must be completed by each individual (including the applicant)**. A current copy of the applicant's *curriculum vitae* must also be attached.

Table 4 – Personnel Handling Radioactive Materials

Name	Name

5. Insert any additional comments on this section here:

IX. Signature/Approval of Applicant

Digital Signature:_____ Date:_____
The applicant may insert a digital signature above. In lieu of a digital signature, by placing an "X" in the box below, the individual completing this form verifies that the information contained in this application has been shared with the applicant and the applicant is in full agreement with the contents of this application.
☐ I hereby verify that the contents of this application have been shared with the applicant and the applicant is in full agreement with the information contained herein.

Name of Individual Providing this Verification:_____ Date:_____

X. Signature/Approval of Individual Authorized to Administer Radiation/Radioactive Material to Humans *(only required if the applicant is not supervising such administrations)*

Digital Signature of Authorized User/Physician*:_____ Date:_____
The physician supervising the administration of radiation and/or radioactive materials for the purposes stated in this application may insert a digital signature above. In lieu of a digital signature, by placing an "X" in the box below, the individual completing this form verifies that the Authorized User/Physician or an Authorized User/Physician under the Permit Code listed in Item I.5. of this application has agreed to supervise the administration of radioactive materials/radiation for research purposes as described in this application.
☐ I hereby verify that the contents of this application have been shared with the Authorized User/Physician or an Authorized User/Physician under the Permit Code listed in Item I.5. of this application and that individual has agreed to supervise the administration of radioactive materials/radiation for research purposes as described in this application.

Name of Individual Providing this Verification:_____ Date:_____

RADIATION SAFETY OFFICE USE ONLY

Preliminarily Approved by RRSC (if applicable) on (date):_____

Approved by: ☐ Radionuclide Radiation Safety Committee on (date):_____

☐ Radioactive Drug Research Committee on (date):_____