INDIANA UNIVERSITY
PUBLIC SAFETY
Environmental Health and Safety

APPLICATION TO USE RADIOACTIVE MATERIALS IN HUMANS FOR RESEARCH PURPOSES

RSO Form A-1a
(Rev. June 2023)

I. General Information

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

5. Supervising Nuclear Medicine Physician or Radionuclide Use Permit Code:

6. Individual completing application (if different from above):	7. Email Address:	8. Phone #:

9. Title of Study:

10. Expected Start Date:	11. Expected Duration:	12. IRB No. (or enter "Pending"):	13. Will this study be any of the following: □ CIRB □ WIRB □ IU as Reviewing IRB

II. Radionuclide Administrations and Procedures Performed on Research Subjects

Table 1 - Radionuclide Administrations - Non-recurring/Non-periodic Scans (e.g., screening, early discontinuation, etc.)

Nuclide	Chemical Form or Procedure	mCi per Admin.	# of Admin/yr (Research)	# of Admin/yr (SOC*)	SoC Scans used for Research?†	Notes (e.g., Screening is research, if SOC out of window, etc.)
					□ Y / □ N	
					□ Y / □ N	
					□ Y / □ N	
					□ Y / □ N	

Table 2 - Radionuclide Administrations - Recurring/Periodic Scans

Nuclide	Chemical Form or Procedure	mCi per Admin.	# of Admin/yr (Research)	# of Admin/yr (SoC*)	SoC Scans used for Research?†	Notes
					□ Y / □ N	
					□ Y / □ N	
					□ Y / □ N	
					□ Y / □ N	

Table 3 - All Machine Produced Radiation Procedures

Procedure Description	# of Admin/yr (Research)	# of Admin/yr (SoC*)	SoC Scans used for Research?†	Notes
			□ Y / □ N	
			□ Y / □ N	
			□ Y / □ N	
			□ Y / □ N	
			□ Y / □ N	

* SoC = Standard of Care. Standard of Care determination should be based on usual clinical care for patients in the same population as study subjects. While reimbursement can provide some indication of SoC status, a reimbursable study does not necessarily qualify as SoC. In lieu of other guidance, SoC determination should be in-line with National Comprehensive Cancer Network (NCCN) guidelines (https://www.nccn.org/professionals/physician_gls/default.aspx)

14. (†) If SOC scans alone are not adequate for research use, please provide details and justification (e.g., improper time-points for data collection, alteration to standard scan protocols, etc.):

15. The procedures above will be performed at (check all that apply):

□ University Nuc. Med. □ Methodist Nuc. Med./PET □ Eskenazi Nuc. Med./PET □ Goodman Hall PET

□ Simon Cancer Center PET □ R2/Walther Hall PET □ Riley Nuc. Med. □ Other: _____

16. Does the study protocol allow for alternative procedures that do **not** require the administration of radioactive materials for research purposes (e.g., ECHO instead of MUGA, etc.)? □ Y □ N If "Y" is checked, provide justification for using the procedure requiring radioactive material. If the study allows both options, but only one will be used, please indicate so here.

17. Provide a schedule of all scans and any comments regarding scans or administrations:

III. General Information Required for All Human Use Research Studies

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

19. 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:	□ Y / □ N
d. Pregnant subjects will be excluded from the study:	□ Y / □ N
e. Are any of these subjects "normal" volunteers?:	□ Y / □ N

20. Insert any additional comments here:

IV. Type of Human Use Research

21. This study is the following (check one):

a. An amendment to an existing human use research study approved by:

- □ i. the Radionuclide Radiation Safety Committee
- □ ii. The Radioactvie Drug Research Committee

b. A new study utilizing:

- □ i. standard diagnsotic radioactive drugs that are FDA-approved
- □ ii. investigative radioactive drugs under an IND or as part of a clinical trial‡
- □ iii. Investigative radioactive materials for conducting basic science research (RDRC)‡

‡ For studies utilizing INDs or that are regulated by the RDRC, submit additional information as outlined in sections VI and VII.

V. Radiation Dosimetry and Radiation Risk Statements for Informed Consent

All studies should be submitted to the Office of Research Imaging (ori@iupui.edu) for dosimtery calculations prior to submission to the Radiation Safety Office.

The Radionuclide Radiation Safety Committee has developed standardized radiation risk wording to be included within Informed Consent Statements. The risk statements vary with the annual amount of radiation dose received as part of research (irrespective of SOC dose). Risk wording is provided in Appendix A to this form. Risk language should be used verbatim, unless a change is required by the study sponsor or outside reviewing IRB.

VI. Additional Information for IND or NDA based Studies

22. 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:

Note: Please include the Investigator's Brochure along with any IND or NDA based study.

VII. Additional Information for RDRC Studies

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.

23. Name of active ingredient:

24. Maximum mass dose of active ingredient (µg or mg) administered per single dose to subject: □ µg -or- □ mg

25. No-observed-effect-level (NOEL) mass dose: □ µg -or- □ mg

26. Provide the reference(s) (e.g., published literature or other valid human studies) for items 23-25:

27. 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 (list vendor):
- □ 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)

VIII. 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:	

Digital Signature of AU/Physician:		Date:	

(Only required if the applicant is not supervising administration of radioactive material to humans) 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 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 and that individual has agreed to supervise the administration of radioactive materials/radiation for research purposes as described in this application.