West Virginia University Hospitals
Radioactive Drug Research Committee (WVUH-RDRC)
Application to Involve Human Subjects in
Biomedical Research that includes use of
Radioactive Drugs not covered under an IND
(2019-1)

RDRC USE ONLY **RDRC COMMITTEE NUMBER: _____**

SECTION I: GENERAL INFORMATION

Title of Research Project:	
Principal Investigator:	**Title/Department:**
Campus Address:	
Campus Phone:	**E-mail:**
Authorized User (AU):	
Campus Address:	
Campus Phone :	**E-mail**
Has this Authorized User been previously approved by the RDRC: _____	

General Notes: Approval of a protocol can only be obtained if b) the AU has been approved by HUC and RSC, and b) the radioactive drugs have been approved.

1. Does this study meet the Criteria for RDRC review listed below?

a. Basic research designed to study: the metabolism of a radioactive drug or to gain information about human physiology, pathophysiology, or biochemistry.
b. This research is **not intended** for immediate therapeutic, diagnostic, or similar purposes
c. This research is **not intended** to determine the safety and effectiveness of the radioactive drug.

☐ YES ☐ NO

2. **Type of Submission:** ☐ Initial ☐ Amendment

If Amendment, specify type and highlight amendment in sections below:

☐ Change in the number of subjects in current study cohort(s)
☐ Addition of a new aim with a new study cohort
☐ Increase in the number of injections of previously approved radiopharmaceuticals
☐ Addition of a new radiopharmaceutical
☐ Change in PI/AU
☐ Change in dose/exposure to radiopharmaceutical
☐ Change in research location
☐ Change in vendor supplying radiopharmaceutical
☐ Addition of imaging studies that expose the research subjects to radiation
☐ Other: _____

SECTION II: STUDY METHODOLOGY

1. **Statement of Purpose:** State the scientific aim(s) of the study, specifically involving radiation exposure. Cross-reference HIC protocol, if appropriate. If there are different parts to the protocol with different radiation exposures (e.g., one part with 2 tracer injections and one part with 3 tracer injections), please identify these parts individually.

2. **For an Amendment:** Describe the Protocol Changes relevant to radiation exposure. Highlight in the sections below changes in the relevant parts

SECTION III: HUMAN SUBJECTS

1. **Total Number of Subjects**：_____

Does the total # of subjects exceed 30 for any given subject population? ☐ YES ☐No

If Yes, please contact: Stephen Root (sroot@hsc.wvu.edu) for information on the completion of an FDA 2915 special summary for inclusion with this RDRC submission.

   a. **State reason for exceeding 30 subjects** (this may include the study of multiple subpopulations related to age, sex or disease types):

2. **Subject Population(s):**
   a. **Does the subject population include subjects under 18 years of age?** ☐ YES ☐No

If Yes, please contact: Stephen Root (sroot@hsc.wvu.edu) for information on the completion of an FDA 2915 special summary for inclusion with this RDRC submission.

State reason for including subjects under 18 years of age:

   b. Description of subject population(s):

3. Pregnancy

a. Are women of child-bearing potential included in this study? ☐ YES ☐ No
b. If Yes, will pregnancy testing be performed? ☐ YES ☐ No
c. If Yes, at what time points will pregnancy testing be performed?

☐ Screening Type of Test: ☐ Serum ☐ Urine

☐ Prior to Each Administration of Radioactivity Type of Test: ☐ Serum ☐ Urine

☐ Other: _____ Type of Test: ☐ Serum ☐ Urine

d. If item b. above is checked "No", will all women of child-bearing potential be required to state in writing that they are not pregnant ☐ YES ☐ No
Please see policy from the RDRC

4. Adverse Event Reporting:

Adverse effects associated with the use of the radioactive drug in the research study immediately report to *Stephen Root (sroot@hsc.wvu.edu)*

Please acknowledge that adverse reactions will be reported to the RDRC immediately.
☐ YES ☐ No

SECTION IV: RADIATION SOURCES

1. Radioactive Drug List

#	Radioactive Drug	Supplier	Location of Use
1			
2			
3			
4			
5			

2. Radioactive Drugs: Specific Information

Detailed information on the radioactive drugs is included in the CMC package and DMF, provided as part of review of the

1.	**Radioactive Drug Name:**	
a.	Route of Administration	☐ I.V. ☐ P.O. ☐ Other _____
b.	Maximum Mass Dose of non-radioactive drug administered per subject (µg)	
c.	Maximum Radioactivity per Dose (mCi)	
d.	Has the RDRC approved this drug?	☐ YES ☐ No ☐ Pending
e.	If radioactive drug will be obtained commercially, please provide a copy of the package insert.	☐ YES ☐ No

2.	**Radioactive Drug Name:**	
a.	Route of Administration	☐ I.V. ☐ P.O. ☐ Other _____
b.	Maximum Mass Dose of non-radioactive drug administered per subject (µg)	
c.	Maximum Radioactivity per Dose (mCi)	
d.	Has the RDRC approved this drug?	☐ YES ☐ No ☐ Pending
e.	If radioactive drug will be obtained commercially, please provide a copy of the package insert.	☐ YES ☐ No

3.	**Radioactive Drug Name:**	
a.	Route of Administration	☐ I.V. ☐ P.O. ☐ Other _____
b.	Maximum Mass Dose of non-radioactive drug administered per subject (µg)	
c.	Maximum Radioactivity per Dose (mCi)	
d.	Has the RDRC approved this drug?	☐ YES ☐ No ☐ Pending
e.	If radioactive drug will be obtained commercially, please provide a copy of the package insert.	☐ YES ☐ No

SECTION V: DOSIMETRY

1. Radiation absorbed dose. Provide the maximum dose commitment to the whole body and each organ specified in 21 CFR 361.1(b)(3)(i), that was received by a representative subject and the calculations or references that were used to estimate these maximum dose commitments. Include the dose contribution of both the administered radionuclide(s) and any X-ray procedures associated with the study. If the study elicits data on the uptake or excretion of the radioactive drug pertinent to the estimation of dose commitment, report the mean value and range of values. For each subject provide (if determined at this stage):

(a) Age, sex, and approximate weight.

(b) Total activity of each radionuclide administered for each radioactive drug used in the study. Report each X-ray procedure used in conjunction with the study.

(c) If the subject has participated in other radioactive drug research studies, report the name of the radioactive drug used in these other studies, the date of administration, and the total activity of each radionuclide administered. If any X-ray procedures were used, identify the x-ray procedure(s) and include an estimate of the absorbed radiation doses.

(d) If more than one administration of a radioactive drug per subject, cumulative radiation dose and dose commitment, expressed as whole body, active blood-forming organs, lens of the eye, gonads, and other organ doses from the administered radionuclides.

SECTION VI: SIGNATURE PAGE

PI signature: _____ Date: _____

RDRC Chair signature: _____ Date: _____