University of Colorado
Denver | Anschutz Medical Campus

RDRC USE ONLY

RDRC NUMBER _____

SECTION I: GENERAL INFORMATION

1. Title of Research Project:

You must attach the following documents in order for this application to be considered complete:

- If the study is to be reviewed by an IRB besides COMIRB, a copy of the protocol and consent form that were submitted.

For radioactive drugs manufactured at the Cyclotron:

- A copy of the label(s) to be used for the radioactive material and
- A copy of the batch records demonstrating successful manufacture of the materials to be used and the Radiopharmaceutical Oversight Committee (RPOC) approval letter

COMIRB Protocol Number: _____
HuCIR Protocol Number (if not submitted enter pending): _____

2. Principal Investigator Information

a. Principal Investigator Name:	**b. PI Title/Department:**
c. **PI Campus Address:**	
d. **PI Campus Phone:**	e. **PI E-mail:**

3. Authorized User Information

a. Authorized User (AU) Name *(if different than PI)*:	**b. AU Title/Department** *(if different than PI)*:
c. **AU Campus Address:**	
d. **AU Campus Phone:**	e. **AU E-mail:**

f. Has this AU been previously approved by the RDRC: _____

4. FDA RDRC requirements 21 CFR 361.1 *(General Notes: Approval of a protocol can only be obtained if a) the AU has been approved by HuCIR, and b) the radioactive drug is FDA approved)*

a. Does this study meet the criteria for RDRC review listed below? ☐ YES ☐ NO

(i) *This is basic research designed to study the metabolism of a radioactive drug or to gain information about human physiology, pathophysiology, or biochemistry.*

(ii) *This research is **not intended** for immediate therapeutic, diagnostic, or similar purposes*

(iii) *This research is **not intended** to determine the safety and effectiveness of the radioactive drug*

b. Type of Submission (Attach COMIRB protocol and Consent Form): ☐ 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

☐ Change in dose/exposure to radiopharmaceutical

☐ Change in research location

☐ Change in vendor supplying radiopharmaceutical

☐ Change in AU

☐ 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 COMIRB protocol, if appropriate. If there are different parts to the protocol with different radiation exposures, please review aims or purpose of all of them.

2. **For an Amendment:** Describe the Protocol Changes relevant to radiation exposure.

SECTION III: HUMAN SUBJECTS

1. **Total Number of Subjects approved by IRB to be consented** _____

2. **Total Number of Subjects to be administered the radioactive drug** _____

Does the total # of subjects exceed 30 in either #1 or #2 above? ☐ YES ☐ No

If Yes, please contact: the Committee Coordinator at RDRC@ucdenver.edu for information on the completion of an FDA 2915 special summary for inclusion with this RDRC submission.

a. If checked YES above, state reason for exceeding 30 subjects (this may include the study of multiple subpopulations related to age, sex or disease types):

3. **Subject Population(s):**

4. **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 and form at the RDRC website

e. Report any positive pregnancy test to RDRC@ucdenver.edu

5. **Adverse Event Reporting:**

Adverse events associated with the use of the radioactive drug or exposure to radiation in the research study must be reported to RDRC@ucdenver.edu immediately, but no later than 7 calendar days.

Please acknowledge that any adverse events related to use of the radioactive drug or exposure to radiation in the study will be reported to the RDRC immediately, but no later than 7 calendar days. (this reporting requirement is separate from COMIRB reporting requirement).

☐ YES ☐ No

Please see Adverse Events form at the RDRC website

SECTION IV: RADIATION SOURCES

1. Radioactive Drug List

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

2. Radioactive Drugs: Specific Information

A.	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.	If applicable, has the Radiopharmaceutical Oversight Committee (RPOC) approved this drug? (please include batch records, label, and a copy of the RPOC approval letter with this application)	☐ YES ☐ No ☐ Pending
e.	If radioactive drug will be obtained commercially, please provide a copy of the package insert.	☐ YES ☐ No

B.	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.	If applicable, has the Radiopharmaceutical Oversight Committee (RPOC) approved this drug? (please include batch records, label, and a copy of the RPOC approval letter with this application)	☐ 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.

Dosimetry entered into this section must match the dosimetry included in the COMIRB protocol, consent form(s), and FDA form 2915.

If changes in dosimetry or procedures are required, an amendment must be submitted to the RDRC.

SECTION VI: SIGNATURE PAGE

PI signature: _____

RDRC Chair signature: _____