

PRINCIPAL INVESTIGATOR

Name _____ Title: _____
Last First M.I.

Phone: _____ Fax: _____ Email: _____

Study/Project Title _____

Application Status: initial renewal of RUA# _____ CHR Approval # (if available) _____

Brief Description of the intent of this research _____

ISOTOPE USERS

Principal Isotope User (for studies where the Principle Investigator will not be handling radioactive materials and/or the study will be done in collaboration with another Investigator who will be responsible for the use of radioactive materials.)

Name _____ Faculty Title _____

UA# _____ Box _____ Phone () _____

List all individuals who will be handling radioactive materials under this study.

First	Last	MI	Title	Phone	Email	RSO Use Trained Y / N

Are there any instructions for non-users? Yes No Not Applicable If yes, attach a copy.

APPROVAL SOUGHT BY APPLICANT

Please check the appropriate box(es). Attach CHR application where relevant or required.

- Routine Clinical Use** (non-IND/NDA radiopharmaceutical (RP) with extensive track record and known efficacy. No CHR required).
- Clinical Research** (Use of an IND/NDA RP where there is no known efficacy or direct patient benefit. CHR required.)
- New NDA Therapy RP** (RUA required for radiation protection. No CHR required)
- Manufacturer Sponsored Investigational New Drug (IND)** **Physician Sponsored Investigational New Drug (IND)**
 Manufacturer: _____ IND #: _____
- Radioactive Drug Research Committee (RDRC)**
 - a) Drug content / administration: _____ (mg), (ug) or equivalent
 - b) Pharmacological threshold (if any): _____
 - c) Radiation dose to volunteers (see instructions for details)

RADIONUCLIDE TO BE USED

Radionuclide	
Purchase Amount (mCi)	
Possession Limit (mCi)	
Activity / Administration (mCi)	
Number of Administrations / Subject	
RP final form *	
Route of Administration	
Excretory Pathway (e.g. urine)	

* Must meet USP requirements. Please provide the following information on your Quality Control Program:

Test	Frequency	Method
Chemical Purity		
Sterility		
Apyrogenicity		
Radionuclide Purity		
Radiochemical Purity		



SUBJECT SELECTION

	Male	Female	Minor
Age Range			
Total Number of Subjects			
Source of Patients			
Total Number of Controls			
Source of Controls			

* Total number of subjects not broken up by age or sex: _____

Will pregnant subjects be included? Yes No
If no, is pregnancy testing required? Yes No

RADIONUCLIDE USE AREAS

Campus / Site	Building	Room #	Room Use (e.g. labeling, storage)	Shielding (Check all that apply)					
				Pb Bricks	Pb Metal Foil	Shielded Waste Storage Area	Fume Hood	Biosafety Cabinet	Glovebox

INSTRUMENTATION

Radiopharmaceutical Assay: What instrument(s) will be used to assay the activity prior to administration?

Type of instrument (e.g. dose calibrator): _____

Manufacturer: _____ Model _____ Serial Number: _____

Attach instrument's SOP and the latest constancy results.

Contamination Survey: List instrument(s) that will be used to monitor for potential radioactive contamination.

Type of instrument (survey meter and probe type): _____

Make: _____ Model _____ Serial Number: _____

1) Do the dose calculations include contributions from radionuclide contaminants? _____

2) Please include dosimetry calculations, biokinetic data, and any reference source used for the calculations. _____

3) State the model upon which the dose calculations are based (e.g. MIRD). _____

RADIATION DOSIMETRY

Dose estimates in (mrem) (EDE in mrem)	Absorbed Dose per Single Administration	Total Dose per Organ per Year (sum resulting from radioactive drug administration & other sources)
Whole Body (EDE) *		
Lens of the eye *		
Gonads *		
Critical Organ #1 _____		
Critical Organ #2 _____		
Marrow *		

* Required for RDRC approval.

Will the subject(s) receive other radiological procedures as part of this research? Yes No
If yes, indicate any exams and the expected absorbed dose for the exam.

Exam	Absorbed Dose	Whole Body or Organ
	rads	rads
	rads	rads

SIGNATURES

The applicant certifies that all users will be in accordance with the University and Campus regulations.

 Signature of the Applicant Date _____

If this study is done in collaboration with Nuclear Medicine Section or a Principal Isotope User:

 Signature of the Chief of Nuclear Medicine or Principal Isotope User

Recharge Number _____ Recharge Contact _____ Phone _____

Do not write below this line - for committee use only.

CHR Approval Number _____
 Approval Date _____ Expiration Date _____

Radioactive use Authorization Number _____
 Expiration Date: _____ Approval Date _____

Radiation Safety Committee Chair _____ Date _____
 Radiation Safety Officer _____ Date _____
 Radioactive Drug Research Committee Chair _____ Date _____

OEHS Use Only

Date Received _____ Reviewed by _____

Comments _____