OHR-32 **Rev. 8/24/22**

HUMAN SUBJECTS RESEARCH APPLICATION INVOLVING EXPOSURE TO X-RAY OR RADIOACTIVE MATERIAL

OFFICE OF RADIATION SAFETY

Instructions: Complete this form with PI signature. As applicable, attach the Investigator's Brochure, Clinical Study Protocol, Consent Language Plan, Package Insert, and IND Letter or equivalent product information for investigational agents. Email to the TJU Radiation Safety Officer (RSO) at catherine.anderko@jefferson.edu.

1. **PROTOCOL NUMBER and SPONSOR:**
2. **PROTOCOL TITLE:**
3. **LAY SUMMARY**:
4. **PRINCIPAL INVESTIGATOR** (PI):
5. **RESEARCH COORDINATOR(S)**:
6. **IONIZING RADIATION TO BE USED:** (note SOC or RES; Request radiation dose estimate from RSO or Physicist as needed)

List each radiation source (ie. CT, PET, radiographic study, radioisotope)	Name of Study using radiation	Frequency	SOC or RES	Radiation Dose (EDE) in mSv if RES	TEDE (mSv)

7. **NATURE OF RESEARCH STUDY**:

   a. ☐ Research involves radioactive drugs to obtain information on the metabolism (kinetics, distribution, and localization) of the radioactive drug or regarding human physiology, pathophysiology, or biochemistry

   b. ☐ Research to study safety and effectiveness of a radioactive drug or radiation producing device

   c. ☐ Research uses of FDA-approved clinical radiation methods to assess a non-radiation article under study.

   d. ☐ Research to study the efficacy of a study article or regimen when used in conjunction with SOC clinical therapeutic or diagnostic radiation procedures that the patient would receive regardless of enrollment in the study as SOC. *(If outside of SOC, check 4.C above).*

8. **SUBJECT DATA**:

   Enrollment # : Term of Study: Children Subjects: Y N Pregnant Subjects: Y N

   List All Subject Exclusion(s):

9. **IF RADIOACTIVE MATERIAL (RAM) WILL BE USED, PROVIDE ADDITIONAL DETAIL**:

Name of test article/drug: Manufacturer: FDA Approved for Marketing?

IND#: IND Holder: Dosage (mCi):

Number of administrations: Interval between administrations:

Administration Location (Department, Bldg, Room #):

Physician Authorized User to Administer RAM:

Provide additional information to assist with review (radiation safety plan, informed consent detail, patient safety etc.):

☐ I authorize that the radiation types to be used in this protocol are SOC and being used in methods that are SOC (A qualified physician specializing in the specific area of medical practice shall print name, sign, and date). **Check here if RES:** ☐

☐ I certify that the information provided is true and correct.

☐ This study will be conducted in accordance with the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), and Thomas Jefferson University research policies.

Print: **Sign**: Date:

END OF APPLICATION

FOR RADIATION SAFETY USE ONLY:

Date Received: RSO Approve/Disapprove Date: RSO Initials:

RSC Approve/Disapprove Date (vote, recusals): PI Letter Send Date:

Comments:

RSO Signature: Date:

TEDE: Suggested Risk Level and Consent Language (NIH):

- < 1 mSv = exempt from further approval; RSO may approve
- < 3 mSv = minimal risk; brief consent language only needed
- 3-50 mSv = low risk (extend consent language)
- > 50 mSv = moderate but acceptable risk (consent to include organ dose with extended language)