Form OHR-32 (Rev. 10/9/24)

Jefferson
HOME OF SIDNEY KIMMEL MEDICAL COLLEGE

HUMAN SUBJECTS RESEARCH APPLICATION
FOR STUDIES INVOLVING IONIZING RADIATION (X-RAY OR RADIOACTIVE MATERIAL)

JEFFERSON OFFICE OF HUMAN RESEARCH PROTECTION

Instructions: List each type of radiation to be used in the study. The Form OHR-32 is not required if all radiation types fall within the standard of care (SOC), that is, the type, form, amount, or indication is not investigational, and patients would undergo the procedures involving radiation as part of their normal care whether they are enrolled in your study or not. If one or more radiation types or its use is not SOC, complete this form and attach the Investigator's Brochure, Study Protocol, and IND Letter. Email to the Radiation Safety Officer (RSO) at catherine.anderko@jefferson.edu.

1. **iRIS ID Number:** **Sponsor:**
2. **Study Title:**
3. **Principal Investigator**: **Department:**
4. **Research Coordinator:**
5. **Brief Summary of Study Purpose**:
6. **Radiation Type(s) to be Used** (use the instructions and table that follow):

Radiation Type(s): 1) CT 2) Radiography 3) Fluoroscopy 4) Accelerator* 5) Radioactive Material (RAM) - List radioisotope & chemical form such as Ga-68 Dotatate, F-18 FDG etc. and complete the table in Section 9.
Procedure: List the name of the procedure using radiation (PET scan, CT Abdomen/Pelvis, Barium Enema etc.).
Total #: Enter how many times the procedure involving radiation will be performed per subject during the study.
SOC or RES: If all types and uses of radiation are SOC, do not complete OHR-32. If 1 or more are not SOC, list each type and enter SOC or RES.
Timepoints: If RES, enter the timing of procedures during the course of the research study. Leave blank if SOC.
Radiation Dose: If RES, enter the estimated radiation dose for 1 procedure (in units of mSv or mGy) as provided by the study sponsor, qualified expert, or literature. Leave blank if SOC.

Radiation Type	Procedure Involving Radiation	Total # Procedures/Subject During Study	SOC or RESEARCH (RES)	Timepoints:	Radiation Dose per procedure (mSv or mGy)

*Provide dose/fraction, # fractions, total dose to deliver, and target site in Section 10

7. **Nature of Study** (which of the following statements best characterizes your research study - check all that apply):

a. ☐ A drug is labeled with a radioactive material in order to evaluate and measure metabolic pathways, distribution, localization, or biochemistry of the drug in the body.

b. ☐ Study is designed to evaluate the safety & effectiveness of an investigational radioactive drug or x-ray device.

c. ☐ FDA-approved imaging protocols (CT, Fluoro, etc.) are being used to assess the efficacy of a non-radioactive drug, article, or process that is the subject of the research.

d. ☐ FDA-approved radioactive drugs, imaging equipment, or therapeutic devices are being used off-label, to diagnose or treat conditions not listed in the prescribing information, or using amounts of radiation or quantities of radioactive material outside of the approved range of use or SOC.

8. **Subject Data**:

Research Subjects to Enroll: Children Excluded: No Pregnant Individuals Excluded: No

List Additional Exclusions:

Length of Study: Years Informed Consent has clear radiation risk language: No

9. **Radioactive Material Details** (complete only for investigational radioactive drugs that are not SOC):

Name of test article/drug:	
Manufacturer:	
IND# and IND Holder:	
Dosage (mCi) per procedure:	
Total # of administrations and frequency:	
Administration location (Department, Bldg, Room #):	
Physician overseeing administration:	

10. Optional Notes (provide any additional detail to assist the RSO and Radiation Safety Committee (RSC) in their review):

11. Principal Investigator (PI) Attestation:

☐ I certify that all ionizing radiation sources to be used in this study have been evaluated by a qualified clinical expert and accurately characterized as standard of care (SOC) use or research (RES) use.

☐ I certify the study will be conducted in accordance with 45 CFR Part 46 on the Protection of Human Subjects, 25 PA Code Chapter 221.15, Good Clinical Practice Guidelines (GCP), and any applicable TJU/TJUH policies.

☐ I attest that the information provided herein is true and correct:

Print (Last, First): Signature and Date:

FOR RADIATION SAFETY OFFICE USE ONLY:

Date Received: RSO Approve/Disapprove Date: Initials:
RSC Approve/Disapprove Date (vote, recusals): PI Letter Send Date:
Comments:

Total Effective Dose Equivalent (TEDE): Risk Level and Consent Language (NIH):

- < 1 mSv = exempt from RSC approval; RSO may approve
- < 3 mSv = minimal risk; use brief consent language
- 3-50 mSv = low risk; extend consent language
- > 50 mSv = moderate but acceptable risk (ICF may include organ dose and extended language)