University of Pittsburgh
Request for New Clinical Use of Drug or Device that Emits Ionizing Radiation

All new ionizing radiation-emitting drugs and devices intended for clinical use are required to be reviewed and approved by the Radiation Safety Committee (RSC) **in advance** of their purchase or related facility construction. RSC meetings are held quarterly, and a short presentation of the project may be required. **If completing this form manually, provide this completed form to radsafe@pitt.edu.** Once submitted, a member of the Radiation Safety Division will be in contact to complete Section 2 of this form. (Note: The RSC Executive Committee may grant full approval or require a presentation to the RSC.)

Applicable Regulations:

- 10 CFR 33.13c(3)(iii): The Radiation Safety Committee is required to review and approve all new usage of radioactive materials for Type A Broadscope Licensees.
- 10 CFR 35.24(f) requires a Radiation Safety Committee oversight for medical licensees in facilities that utilize two or more modalities.
- PA Code Title 25 Chapter 219.8 requires Radiation Safety Committee oversight for PA registrants of radiation-producing machines in facilities that utilize two or more modalities.

Definitions:
The Authorized User is the individual who authorized the implementation of the new use; who will oversee the implementation of the new use, including the development of appropriate radiation safety and use procedures; and who has the appropriate training and experience to perform these activities. The individual initiating this request does not need to be the Authorized User, but the Authorized User shall be available for completing Section 2, as needed.

Section 1: Contact and Project Information	
Contact Information: Name: _____ Phone Number: _____ Email: _____	Hospital and Department making the request: Responsible Authorized User(s):
Date of Form Submission:	Proposed Clinical Use Implementation Date:
Type of new use being requested: ☐ Radioactive Materials Type (diagnostic or therapy)/ Radiopharmaceutical(s): _____ ☐ Radiation-Producing Machines Type of Machine(s): _____	
Description and rationale for proposed new use(s):	

University of Pittsburgh
Request for New Clinical Use of Drug or Device that Emits Ionizing Radiation

Section 2: Radiation Safety Program Details
Instructions: A member of the Radiation Safety Division will be in touch to complete Section 2 with the requestor and/or Authorized User.
1. Will this new use require a new License, a License Amendment, or Registration with the Commonwealth of Pennsylvania? ☐ YES, New License ☐ YES, License Amendment ☐ YES, New Registration ☐ Yes, Change/Addition to Current Registration ☐ No Change
2. Does the University of Pittsburgh Radiation Safety Office currently provide oversight of this drug or radiation emitting device at another location? ☐ YES, Location(s): _____ ☐ NO
3. Describe the current or proposed training and experience requirements of the Authorized User and staff who will be involved in the clinical use of this proposed new use (also note if Applications training will be provided by a vendor):
4. Address the adequacy of the current or proposed facilities and equipment associated with the proposed new use:

University of Pittsburgh
Request for New Clinical Use of Drug or Device that Emits Ionizing Radiation

5. Will facility requirements associated with proposed new use require shielding evaluation(s) to be performed by the University of Pittsburgh Radiation Safety Office?

☐ YES

☐ NO

6. Will new equipment (e.g., dose calibrators, survey meters, software systems) need to be purchased and/or new construction completed in order to meet regulatory requirements or safety concerns associated with the proposed new use? If yes, provide details:

☐ NO

☐ YES

Details:

7. Will the proposed new use necessitate any changes to the applicable facility's policies and procedures governing radioactive waste disposal (e.g., amount, liquid disposal, gaseous effluents, long-lived rad waste)? If yes, provide details:

☐ NO

☐ YES

Details:

University of Pittsburgh
Request for New Clinical Use of Drug or Device that Emits Ionizing Radiation

8. Will the proposed new use necessitate additional or revised radiation dosimetry monitoring (e.g., whole body or extremity monitoring, neutron monitoring, bioassay monitoring) for involved staff? If yes, provide details:

☐ NO

☐ YES

Details:

9. Will this propose new use require any current equipment and/or locations to be retired and decommissioned? If yes, provide details:

☐ NO

☐ YES

Details:

10. Will this propose new use require any radiation safety or equipment surveys to be performed before initial use on humans?

☐ NO

☐ YES

11. What support will be needed to complete surveys referenced in Item #10?

☐ Vendor Applications training

☐ Trained Individual to operate the equipment

☐ Other: _____

University of Pittsburgh
Request for New Clinical Use of Drug or Device that Emits Ionizing Radiation

11. Attach a copy of the handling and/or operating procedures corresponding to this proposed new clinical use.

Section 3: Radiation Safety Committee Disposition

☐ Approved by RSC Executive Committee (with no further action necessary)

☐ Presentation to full RSC required; Date presentation to RSC was completed: _____

☐ Approved by full RSC (with no further action necessary)

☐ Approved by full RSC with the following stipulations: _____

_____

_____

☐ Denied by full RSC for the following reasons:_____

_____

_____

Section 4: RSC Executive Committee Signatures

The below signatures verify the approvals or denial as documented in Section 3.

	Signature	**Date**
Radiation Safety Officer:	_____	_____
Chairperson:	_____	_____
Vice Chairperson:	_____	_____
Management Representative:	_____	_____