 HUSC #:_____ (To be completed by HUSC Office)

University of Pittsburgh

APPLICATION FOR THE HUMAN RESEARCH USE OR EVALUATION OF PROCEDURES THAT EMIT IONIZING RADIATION

Date of Submission:

Protocol Title:

Principal Investigator:
Telephone #:
E-mail:

Authorized User[1]:
Telephone:
E-mail:

Summarize the Authorized User's training and experience related to the use of the research procedure that emits ionizing radiation:

[1]**An "authorized user" is a physician or dentist previously approved by the University's Radiation Safety Committee as possessing the appropriate qualifications for overseeing certain procedures that emit ionizing radiation. An appropriately qualified (i.e., for the experimental procedures specified in the proposed research study) "authorized user" must be involved in the research study as either the principal investigator or a listed co-investigator.**

1. This research protocol involves the following experimental procedure(s) that emit ionizing radiation:

___ the use or evaluation of a drug or procedure (e.g., medical device) that is not currently approved (i.e., for any clinical indication) by the FDA for commercial marketing.

IND #: _____ or [ ] Request for RDRC approval
IDE #: _____ (if applicable)

___ the evaluation (i.e., as addressed in the objectives or specific aims of the protocol) of a drug or device for an "experimental" indication or involving "experimental" procedures[2]

___ the use of a drug or device for an "experimental" indication or involving "experimental" procedures[2]

___ the receipt of a drug or procedure by individuals (e.g., healthy controls) who would not normally receive the drug or procedure in association with the diagnosis or treatment of a disease or condition

[2]**"Experimental" indications or procedures are those that are not consistent with standard clinical practice or the current FDA-approved product labeling.**

2. Number of Subjects: Indicate the proposed number of subjects who will undergo the research procedure(s) that emit ionizing radiation:

Number of Patients: _____[3]

0-17 years: ___ Yes[3] ___ No

Number of Normal Volunteers: _____[3]

0-17 years: ___ Yes[3] ___ No

[3]**A respective scientific justification must be provided in the research protocol for the inclusion of > 30 subjects and/or subjects < 18 years old.**

3. Summary of Experimental Procedures that Emit Ionizing Radiation:

   a. Radioactive Drugs (if applicable):
      - For each radioactive drug, indicate the amount of radioactivity (mCi) per single dosage, and the total number of dosages per Single Study[4] and per complete research protocol:

Radioactive Drug	mCi/Dosage	# Dosages/Single Study	# Dosages/Protocol

      - For each radioactive drug, address the source of the drug (e.g., manufacturer, PET facility, central nuclear pharmacy) and specify the governing document (i.e., FDA-approved product labeling, FDA-accepted IND application, RDRC-approved Drug Master File, research protocol) that defines the procedures that will be used for its preparation, quality control testing and labeling:

Radioactive Drug	Source	Governing Document

      - Attach a Radiation Dosimetry Table which addresses individual organ radiation doses (to include, at a minimum, gonads, bone marrow, lens of the eye [skin], critical organs, and ED) per single dosage of each radioactive drug, per total Single Study[4] (inclusive of all respective radioactive drug dosages), and per complete research protocol (inclusive of all radioactive drug dosages).

   b. Diagnostic Devices (if applicable):
      - For each diagnostic device, indicate the total number of exposures per Single Study[4] and per complete research protocol:

Device	# Exposures/Single Study	# Exposures/Protocol

      - For each diagnostic device, specify the skin entrance radiation dose and Effective Dose (ED):

Device	Skin Entrance Dose	ED

   c. Radiotherapy Procedures (if applicable): For each radiotherapy procedure, specify the total radiation dose and respective dose fractionation and treatment plan.

Radiotherapy Procedure	Total Radiation Dose	Dose Fractionation and Treatment Plan

[4]**A "Single Study" includes all procedures that emit ionizing radiation which are performed during a single study visit or session.**

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I certify that this information is correct: _____ _____

Principal Investigator Signature/Date Authorized User Signature/Date