APPLICATION FOR ANCILLARY APPROVAL OF HUMAN USE RESEARCH INVOLVING IONIZING RADIATION

Part A. General Information

Complete this form only if you intend to use ionizing radiation outside the standard of care. If you require assistance in completing this form, contact the Radiation Safety Officer at (706)721-9826 or RADIATIONSAFETYOFFICE@augusta.edu. If the radiation procedure itself is experimental, contact the Radiation Safety Officer for guidance.

I. General Information

Principal Investigator: _____ Phone: _____

Email Address: _____ Dept: _____

Campus Mailing Address: _____

Individual Completing this Application (if different from above): _____ Phone: _____

Email Address: _____

Title and Any Identifying Numbers of Research Study:

_____

Expected Start Date: _____ Expected Project Duration: _____

IRB Number: _____ OR Pending ☐

II. Information Required for All Human Use Research Studies

1. Provide the following information:

Total number of subjects per study: _____ Total number of subjects under 18: _____

Are women of child-bearing age included in the study? ◯ YES ◯ NO

Are any of these subjects "normal" volunteers? ◯ YES ◯ NO

Provide any specific information regarding the research subjects that may be relevant with respect to the radiation safety review of this study:

2. Attach copies of the research protocol and all informed consent documents associated with this research.

Part B. X-rays

Complete Part B only if you are intending to use x-rays on humans in your study. If you are not using x-rays, check the "N/A" box and skip to Part C.

☐ N/A

III. X-ray Producing Device(s) (Check all that apply):

☐ Radiographic (plain film) ☐ Fluoroscopic ☐ CT Scanner

☐ DEXA ☐ Dental

☐ Other (specify): _____

The x-ray procedures will be performed at the following location (Check all that apply):

☐ AU Health Radiology ☐ GPI ☐ Dental School

☐ Other (specify): _____

IV. Description of Radiation Use:

In Table 1, list each type of radiation procedure (e.g. PA chest x-ray, LAT lumbar spine x-ray, periapical dental x-ray, chest CT scan, whole body DEXA scan, etc.) and the number of each type of procedure a representative subject will undergo over the course of the study. It is important to differentiate between x-ray procedures received for the subject's "**Standard of Care (SOC)**" (i.e. x-rays received regardless of participation in this study) and additional x-rays received as a direct result of participation in this study (i.e. for research purposes only). Make separate entries for research and SOC procedures.

Check one of the following:

◯ Patient dose calculations are attached

◯ I request the Radiation Safety Office provide the patient doses

Table 1. X-ray Procedures

Diagnostic X-ray Procedure Name:	Research OR SOC ?	How many?	Patient dose per procedure (mrem)

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Provide any comments regarding the information supplied above here:

If the number or type x-ray procedures vary among groups of subjects (e.g. control subjects versus non-control subjects), a separate line entry should be provided for a representative subject from each group on Table 1.

Part C. Radioactive Material Use (Nuclear Medicine)

Complete Part C only if you are intending to use radioactive materials in humans in support of this research protocol. If you are not using diagnostic radioactive materials, check the "N/A" box and skip to Part D.

☐ N/A

V. Description of Radionuclide Use:

In Table 2, list each type of radionuclide procedure (e.g. name of nuclear medicine scan, PET-CT scan) and the number of each type of procedure a representative subject will undergo over the course of the study. It is important to differentiate between radionuclide procedures received for the subject's "**Standard of Care (SOC)**" (i.e. received regardless of participation in this study) and additional procedures received as a direct result of participation in this study (i.e. for research purposes only). Make separate entries for research and SOC procedures.

Check one of the following:

◯ Patient dose calculations are attached

◯ I request that the Radiation Safety Office provide the patient doses

Table 2. Radionuclide Procedures

Isotope:	Name of Procedure:	mCi:	Research OR SOC?	How many?	Dose per procedure (mrem):

Isotope:	Name of Procedure:	mCi:	Research OR SOC?	How many?	Dose per procedure (mrem):

Isotope:	Name of Procedure:	mCi:	Research OR SOC?	How many?	Dose per procedure (mrem):

The radionuclide procedures will be performed at the following location (check all that apply):

☐ AU Health Nuclear Medicine

☐ Other (specify):

If the number or type of radionuclide procedures vary among groups of subjects (e.g. control subjects versus non-control subjects) a separate line entry should be provided for a representative subject from each group in Table 2.

Provide any comments regarding the information supplied above here:

Part D. Therapeutic Radiation

Complete Part D only if your research protocol involves therapeutic radiation exposure to research subjects. If you are not using therapeutic radiation, check the "N/A" box and skip to Part E.

☐ N/A

VI. What form of therapeutic radiation will you use (check boxes that apply)?

☐ **Radiopharmaceutical therapy**

Radioisotope:	Radiopharmaceutical:	Quantity (mCi):	Method of delivery:

Anatomical site or target:	Research OR SOC?	Prescribed radiation dose (cGy):

☐ **External beam therapy (LINAC)**

Anatomical site or target:	Prescribed radiation dose (cGy):	Research OR SOC?

☐ **Gamma Knife Radiosurgery**

Anatomical site or target: | Prescribed radiation dose (cGy): | Research OR SOC?

☐ **Low dose rate brachytherapy**

Radioisotope: | Anatomical site or target: | Prescribed radiation dose (cGy): | Research OR SOC?

☐ **High dose rate brachytherapy**

Anatomical site or target: | Prescribed radiation dose (cGy): | Research OR SOC?

The therapeutic radiation will be delivered at:

◯ AU Health ◯ Radiation Therapy Center ◯ University Hospital

◯ Other (specify):

Provide any comments regarding the information supplied above here:

Part E. Signature and Submittal

VII. Signature of Applicant (not required for electronic submission by Principal Investigator).

Signature | Date:

If this electronic application and supplementary information are submitted to the Radiation Safety Office as email attachments **from the applicant,** a written signature is not required. If this application is submitted by someone other than the applicant, the applicant should be copied on the email submission or the applicant may send a separate email to the Radiation Safety Office (radiationsafetyoffice@augusta.edu)indicating the applicant's approval of the submitted information.