



APPLICATION FOR HUMAN USE RESEARCH INVOLVING MACHINE PRODUCED RADIATION

I. General Information

1. PI/Applicant:	2. Dept:	3. Email Address:	4. Phone #:
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5. Physician supervising the use of machine-produced radiation on subjects (if different from above):

6. Individual Completing This Application (if different from above):	7. E-mail Address:	8. Phone #:
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9. Title and Any Identifying Numbers of Research Study:

10. Expected Start Date:	11. Expected Project Duration:	12. IRB No. (or type "Pending"):
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II. Type of X-Ray Producing Device(s) Utilized (Check all that apply)

<input type="checkbox"/> Radiographic x-ray machine	<input type="checkbox"/> Fluoroscopic x-ray machine	<input type="checkbox"/> CT Scanner	<input type="checkbox"/> Dual photon x-ray absorptiometry
<input type="checkbox"/> Dental x-ray machine	<input type="checkbox"/> Accelerator	<input type="checkbox"/> Other (specify):	

III. Description of Radiation Use

Table 1 – Machine Produced Radiation Procedures

Procedure Description	# per Yr for Research	# Over Entire Study for Research	# per yr for SOC	# Over Entire Study for SOC

1. The machine produced radiation procedures will be performed at the following locations (check all that apply): <input type="checkbox"/> UH Radiology, <input type="checkbox"/> WD Radiology, <input type="checkbox"/> Riley Radiology, <input type="checkbox"/> Methodist Radiology, <input type="checkbox"/> Other (list):

2. Does the study protocol allow for alternative procedures that do not require the use of machine-produced ionizing radiation for research purposes? <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" is checked, provide justification for using the procedure that involves the use of machine-produced ionizing radiation.
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3. Provide any comments regarding the information supplied in Table 1 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 in Table 1.

In some cases, radioactive materials may be administered to the subjects as part of their “standard of care (SOC).” Please complete Table 2 for all SOC procedures involving the administration of radioactive materials. **Note: If radioactive materials are administered to the subject for research purposes, Rad. Safety Form A-1a should be completed rather than this form.**

Table 2 – SOC Radionuclide Administrations

Nuclide(s)	Chemical Form or Procedure	# Admin. Per Year	# Admin. Entire Study

4. The radionuclides listed above will be administered at (check all that apply):

- UH Nuc. Med.
 WD Nuc. Med.
 Riley Nuc. Med.
 IUSCC PET
 Goodman Hall PET
 Methodist Nuc. Med./PET
 Other (list):

5. Provide any comments regarding the information supplied in Table 2 here:

IV. General Information Required for All Human Use Research Studies

1. Provide a brief description of the research project including the rationale for utilizing machine-produced radiation:

2. Provide the following information regarding the research subjects:

- a. Total number of subjects for the entire study:
- b. Total number subjects under 18 years of age, if any:
- c. Women of child-bearing age will be included in the study: Yes No
- d. Are any of these subjects “normal” volunteers?: Yes No
- e. Provide any specific information regarding the research subjects in this study that may be relevant with respect to the radiation safety review of this study:

3. A copy of some information required by the IRB can either be submitted with this form or the Radiation Safety Office can obtain that information directly from the KC-IRB website. Please indicate where the documents below are located:

- a. Lay Study Summary & Research Design questionnaire: Attached Available on KC-IRB website
- b. Risks, Benefits, Protections Questionnaire: Attached Available on KC-IRB website
- c. Informed Consent Statement: Attached Available on KC-IRB website
- d. Research Study Protocol: Attached Available on KC-IRB website

4. Insert any comments on this section here:

