INDIANA UNIVERSITY
OFFICE OF RESEARCH ADMINISTRATION
RADIATION SAFETY – INDIANAPOLIS

Rad. Safety Form A-1b
(Revised April, 2015)

APPLICATION FOR HUMAN USE RESEARCH INVOLVING MACHINE PRODUCED RADIATION

I. General Information

1. PI/Applicant:	2. Dept:	3. Email Address:	4. Phone #:

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 #:

9. Title and Any Identifying Numbers of Research Study:

10. Expected Start Date:	11. Expected Project Duration:	12. IRB No. (or type "Pending"):

II. Type of X-Ray Producing Device(s) Utilized (Check all that apply)

☐ Radiographic x-ray machine ☐ Fluoroscopic x-ray machine ☐ CT Scanner ☐ Dual photon x-ray absorptiometry
☐ Dental x-ray machine ☐ Accelerator ☐ 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):
☐ UH Radiology, ☐ WD Radiology, ☐ Riley Radiology, ☐ Methodist Radiology, ☐ 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? ☐ Yes ☐ No If "Yes" is checked, provide justification for using the procedure that involves the use of machine-produced ionizing radiation.

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:

V. Radiation Dose Information.

Please provide the following information regarding the machine-produced radiation for research purposes as listed in Sections II and III:

1. Detailed dose calculations are required for machine-produced radiation of subjects for research purposes (not SOC) listed in Table 1. The calculation method, references, and any assumptions associated with the radiation dose calculations should be provided. Assistance with dose calculations can be obtained from the Office of Research Imaging, the Radiation Safety Office, or possibly the clinical department administering performing the procedure.
   ☐ Dose calculations for machine-produced radiation are attached or,
   ☐ Dose calculations for machine-produced radiation are provided on page number(s) of the study protocol.
   ☐ I request the Radiation Safety Office provide dose calculations for the procedures listed in Table 1 (**only applies to radiographs, DXA scans, and/or fluoroscopic procedures**).
2. Insert any comments on this section here:

VI. Signature of Applicant

Digital Signature:_____ Date:_____
The applicant may insert a digital signature above. In lieu of a digital signature, by placing an "X" in the box below, the individual completing this form verifies that the information contained in this application has been shared with the applicant and the applicant is in full agreement with the contents of this application.
☐ I hereby verify that the contents of this application have been shared with the applicant and the applicant is in full agreement with the information contained herein.

Name of Individual Providing this Verification:_____Date:_____

Radiation Safety Office Use Only

Approved by:

☐ Radiation Safety Office (date):_____

☐ MPRSC Subcommittee (date):_____

☐ MPRSC (date):_____