

INSTRUCTIONS FOR COMPLETING RAD. SAFETY FORM A-1b
APPLICATION TO USE RADIOACTIVE MATERIALS IN HUMANS
FOR RESEARCH PURPOSES

I. General Information

- Item #s 1 through 4: General contact information for the Principal Investigator (PI)/Applicant. **The PI listed here should be the same individual that is listed as the PI in the IRB submission.**
- Item #5: Exposing research subjects to machine-produced radiation must be performed under the aegis of a physician. If the PI/Applicant is not a physician, please provide the name of a physician (perhaps a co-investigator) that will supervise the use of machine-produced radiation.
- Items #s 6 through 8: General contact information for the individual completing this form if not the PI.
- Item #9: List the title of the research study **exactly as listed on the IRB submission** here. Identifying numbers not part of the title may be listed in addition to the title.
- Item #s 10 and 11: List expected start date and expected project duration. An end date may be listed in item #11, rather than the project duration.
- Item #12: List the IRB number that has been assigned to this study. If the IRB application has not been submitted or is being submitted concurrently with the Rad. Safety Form A-1b, insert “Pending” in this box. **Unless extenuating circumstances exist, radiation safety review of the application will not start until the IRB application has been submitted.**

II. Type of X-Ray Producing Device(s) Utilized

- The applicant should indicate all ionizing radiation (x-ray) producing devices that will be utilized for imaging or other purposes on the research subjects
- It should be noted that “MRI” or “ultrasound” devices do not produce ionizing radiation and research studies involving only those imaging devices do not require review and approval by the Radiation Safety Office or a radiation safety committee.

III. Description of Radiation Use

- Table 1:
 - Procedure Description Column: Enter the specific type of x-ray procedure to be performed. For radiographs, this should include the actual views rather than a general description. For example, “chest x-rays” or “DXA scans” are not definitive enough. “PA chest x-rays”, “LAT chest x-rays”, “DXA scans of the spine”, or “DXA scans of the whole body” provide the appropriate level of detail. Each view should be entered as a separate line in the table.
 - Enter the number of the listed procedure that will be performed per year strictly for research purposes in the third column.
 - If the same procedure will also be performed for the subjects’ standard care (SOC), enter the number of the listed procedure that will be performed for that purpose in the fourth column. For example, a subject might have 2 chest CT scans performed strictly for research purposes and 2 chest CT scans performed as part of their standard care in one year (i.e. the study protocol requires 2 additional chest CT scans be performed strictly for research). Thus a “2” should be entered in column 2 and a “2” would be entered in column 4.

- If the study spans a time frame of over one year and the research and SOC procedures are done in the following years, the numbers for both should be summed and enter in columns 3 and 5. In some cases even for studies that span over multiple years, the procedures performed for research purposes and/or SOC might only be performed in the first year. In that case, the numbers “per year” and “over the entire study” would be the same for the respective columns.
- Some studies may not have an actual termination date – they may continue as long as the subject remains in the study. In that case, columns 3 and 5 may be left blank or an asterisk could be entered in those columns with an explanation provided in item #3 of this section of the form.
- Item #1: Check all facilities where machine-produced radiation procedures will be performed. If there is a facility not specifically listed, check “Other” and provide the name of the facility.
- Item #2: Some research studies specify options for certain types of procedures that do not involve exposure to ionizing radiation (e.g. performing an MRI scan rather than a CT scan). If such an option is not included in the study protocol, simply check “No”. However, if such options are provided in the study protocol, check “Yes” and provide justification for utilizing the ionizing radiation option as opposed to the non-ionizing radiation option.
- Item #3: Self-explanatory.
- Table 2: In addition to the use of machine-produced radiation, some study protocols may require procedures (usually imaging) that involve administration of radioactive material as part of the subjects’ SOC. The same basic instructions provided for the information in Table 1 apply to this table as well. If any of administrations of radioactive material are for research purposes, Rad. Safety Form A-1a should be used rather than this form.
- Item #4: Check all locations where the machine-produced radiation procedures will be performed.
- Item #5: Self-explanatory.

IV. General Information Required for All Human Use Research Studies

- Item #1: Self-explanatory
- Item #2a. through 2e.: Self-explanatory
- Item #3a through 3d: Some of the information required by the IRB is also needed for radiation safety review. That information can either be submitted directly to the Radiation Safety Office (RSO) along with the completed Rad. Safety Form A-1b, or the RSO has the ability to download that information directly from the KC-IRB website. Simply check the appropriate boxes regarding the provision of that information.
- Item #4: Self-explanatory. **If the study is being reviewed by an external IRB, please indicate that in item 4 and attach documentation of the application to the external IRB. Note that neither the Informed Consent Statement nor the study protocol for studies being reviewed by an external IRB are generally submitted to KC-IRB. Those two documents should be submitted to the Radiation Safety Office along with this completed application.**

V. Radiation Dose Information

- Item #1: The annual and total effective doses over the course of the study from the x-ray procedures performed for research must be estimated and/or calculated. Radiation dose information may be obtained from the following sources:
 - Radiographic procedures and DXA scans: Radiation Safety Office or the Office of Research Imaging (ORI),
 - CT scans: ORI
 - Fluoroscopy procedures: Radiation Safety Office

- The research study protocol may provide dosimetry information for any of the aforementioned procedures.

The appropriate boxes in Item #1 should be checked to indicate the source of the radiation dose information and any calculations should be appended to the application.

- Item #2: Any comments or references for the dose calculations should be indicated here.

VI. Signature/Approval of Applicant

- The applicant may insert a “digital” signature and date to indicate his/her agreement with the information provided in the application or a copy of the signature page with the applicant’s hand-written signature can be obtained and submitted to the Radiation Safety Office.
- If the application is completed by another individual (e.g. a Research Coordinator) on the applicant’s behalf, that individual should verify (by checking the box) that the information has indeed been shared with the applicant and sign and date that verification. Including the applicant in the emailed application is recommended.