

INSTRUCTIONS FOR COMPLETING RAD. SAFETY FORM A-1a
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: If the PI is **not** the individual administering or supervising the administration of the radioactive material, the name of the physician supervising the administration of the radioactive material and/or the Radionuclide Use Permit code (available from the Permit Holder) should be listed here.
- 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-1a, 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. Radionuclide Administrations and Procedures Performed on Research Subjects

- Table 1: It may be necessary to contact the appropriate department (e.g. Nuclear Medicine or the Office of Research Imaging (ORI)) for assistance in completing Table 1. The required information is as follows:
 - Enter the elemental symbol and mass number for the radionuclide (e.g. F-18, Tc-99m, etc.)
 - Enter either the chemical form (e.g. MDP, FDG, etc.) or the procedure (e.g. bone scan, MUGA, etc.) in the second column. Inclusion of the chemical form is preferable.
 - Enter the typical amount of radioactivity in millicuries (mCi) that will be administered.
 - Enter the number of administrations of that particular radionuclide and chemical form that will be performed per year strictly for research purposes in the fourth column.
 - If the study will carry on for more than 1 year and additional administrations will be performed in successive years, the total number should be summed and listed in the fifth column. If the study has no clear termination date, place a “*” in column 5 and enter an explanation in item 3.
 - If the subjects will receive administrations of the same radionuclide and chemical form as part of their standard care (SOC) in addition to the administration for research, enter the appropriate numbers for each year and over the entire study in columns 6 and 7.
 - If subjects will receive a specific radionuclide and chemical form only for SOC, it should be listed in a separate line in the table with columns 3, 4, and 5 left blank. The numbers in columns 6 and 7 should be entered.

- Item #1: Check all facilities where radionuclides will be administered. 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 the administration of radioactive materials (e.g. performing an echocardiogram or a “MUGA” scan to evaluate cardiac function). 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 radioactive material administration option as opposed to the non-radioactive material option.
- Item #3: Self-explanatory.
- Table 2: In addition to the administration of radioactive materials to research subjects, some study protocols may require procedures (usually imaging) that involve exposing the subject to x-rays for either research or SOC. Examples include CT scans performed either separately or in conjunction with a PET/CT scan. The same basic instructions provided for the information in Table 1 apply to this table as well.
- Item #4: Check all locations where the machine-produced radiation procedures will be performed.
- Item #5: Self-explanatory.

III. 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-1a, 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.**

IV. Type of Human Use Research

- Item #1: This item generally applies to studies to be reviewed by the Radioactive Drug Research Committee (RDRC).
- Item #2: This item generally applies to clinical trials of radioactive drugs which are under IND. If that is the case, the IND number should be listed in Item #6 of this section.
- Item #3: Self-explanatory.
- Item #4: If this application is being submitted to amend an existing study that has already been reviewed and approved by a radiation safety committee, a check should be placed next to the committee that originally reviewed and approved the study. The IRB number should be listed in Item #6.
- Item #5: If none of the above apply, the type of human research should be listed here.
- Item #6: Self-explanatory and as listed above.

V. Information for the Formulation and Administration of Radionuclides

- Item #1: Radiolabeled drugs may be formulated and obtained from a variety of sources such as vendors, a clinical department, or the PI may formulate the radioactive drug. The source of the radiolabeled drug should be identified by checking the appropriate box along with any specific information (e.g. vendor, DMF number, etc.).
- Item #2: Identify the method of administration. If the radiolabeled drug will be administered orally, item #3 does not apply and can be skipped.
- Item #3: Radioactive material administered IV must be sterile and pyrogen-free. Select the appropriate box and provide information as requested.
- Item #4: Self-explanatory – usually a “dose calibrator”, “gamma counter”, or “liquid scintillation counter” (for beta emitting radionuclides) is utilized for determining the administered amount of radioactivity.
- Items #5 and #6: Self-explanatory.

VI. Information Required for Radioactive Drug Research Committee (RDRC) Review and Approval

- Item #1: This is generally the chemical form of the radioactively labeled product.
- Item #2: Self-explanatory.
- Item #3: This is the amount of the labeled product that will produce no biological affect or response.
- Item #4: Provide the reference(s) where the aforementioned information was obtained. References can be submitted with the study.
- Item #5: Self-explanatory.

VII. Radiation Dose Information

- Item #1: Provide the dose calculations associated with the administered radioactive material and include the source of those dose calculations.
- Item #2: If subjects receive exposure from machine-produced radiation for research purposes, provide the dose calculations and source of those dose calculations. Dose calculations for CT scans should be obtained from the Office of Research Imaging (ORI) or possibly the clinical department.
- Item #3: Self-explanatory.

VIII. Radionuclide Handling Precautions, Radioactive Waste Generation, and Personnel Involved in the Study

- This section only needs to be completed if the applicant will be preparing and administering the radioactive material to human subjects. If the preparation and administration is being performed under an existing Radionuclide Use Permit, this section does not need to be completed unless special handling or special requirements are involved in handling and/or disposal of radioactive waste.
- Item #1: Check all equipment that will be utilized to protect or measure radiation exposures or contamination to personnel involved in the handling and/or administration of the radioactive material.
- Item #2: Check all forms of radioactive waste that will be generated in conjunction with the study.
- Item #3: List all laboratories and/or areas where radioactive material will be used or stored and check the type of usage. If any of these areas are shared with other Radionuclide Use Permit holders, please list the building and room number along with the other Permit Holder’s name or PH code.

- Item #4: List all personnel involved in the preparation or administration of radioactive material and/or any individuals who might receive radiation exposure from the subjects in the study.
- Item #5: Self-explanatory.

IX. 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.
- 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.

X. Signature/Approval of Individual Authorized to Administer Radiation/Radioactive Material to Humans

- For human research studies where the applicant is not administering or supervising the administration of the radioactive material (i.e. that is being done under a Radionuclide Use Permit issued to a clinical department), the applicant must assure the physician administering or supervising the administration of the radioactive material is willing to do so. This assurance can be accomplished by either obtaining the supervising physician’s digital or hand-written signature as described above.
- 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 physician supervising the administration of the radioactive material has agreed to do so by checking the box and including his/her name and date.