ENVIRONMENTAL HEALTH AND SAFETY | RADIATION SAFETY

Instructions for Completing the RAM Application for Medical Research (Human Use)

- This application is distinct from the Institutional Review Board (IRB) application. This application may be submitted concurrently with the IRB application. The IRB will not grant final approval without CIR and, if applicable, RDRC approvals.

- This form is used to apply for an authorization to use radioactive material for human research use. For non-research use of radioactive material (clinical), please contact Riad Safadi at (303) 724-0234 or Riad.Safadi@ucdenver.edu.

- Copy the file to your computer saving it with a new name. The document contains fields for the user to enter the requested information. Press the "Tab" key to move through the document fields. If a field is not applicable, enter "N/A" into the field. Please refer to the *UCD Radiation Safety Manual* and *UCD Radioactive Waste Disposal Manual* when completing the application.

- Email the completed application to EHS for preliminary review at RadAppHU@ucdenver.edu.

- EHS will email back a formal pre-review of comments and questions regarding each individual application.

- The Principal Investigator (PI) or Co-Investigator (Co-PI) must fulfill the training and experience requirements outlined in Section V of the application form. The "Authorized User" is a legal term defined in CDPHE Part 7 Regulations. The PI or Co-PI must meet the strict requirements for an "Authorized User".

These instructions pertain to the RAM Application For Medical Research (RSF-078) document only.

ENVIRONMENTAL HEALTH AND SAFETY | RADIATION SAFETY

Certain items on the **Radioactive Materials Application for Medical Research (RSF-078)** require special attention to minimize delays in resolving comments by Committee reviewers. The following notes are keyed by number to respective items on the application form.

ITEM I. PI Information

Either the Principal Investigator (PI) or Co-Investigator must fulfill the Training and Experience outlined in Part V.

ITEM II. Location of Use

Enter all buildings and room numbers where you plan to use radioactive materials. If you plan on using a fume hood or a biosafety cabinet, please list room number and biosafety cabinet identifying information.

ITEM III. Radiation Workers

List everyone who will require unescorted access to the rooms listed in Item II above. All workers must complete the required radiation safety training before they are granted access.

ITEM IV. Radioactive Material and Amounts

Entry of correct nuclear data is essential for convincing the CIR of your knowledge of the isotope's properties. If the information is not readily available to you contact the EHS at 4-0234.

Requested possession limits should show a reasonable and logical progression from the activity per research subject to the possession and yearly limits. The relationship should be reasonable in light of the proposed number of subjects per month. ***Possession limit*** *requests exceeding twice the amount anticipated to be used in one month will require some explanation as to why.* ***Annual limit*** *requests exceeding twice the amount anticipated to be used in one year will require some explanation as to why. If other considerations intervene (minimum amount of radioactivity available, half-life, or economically available from the vendor, etc.) please explain.*

ITEM V. Principal Investigator Training and Experience

The Committee will review the qualifications of Principal Investigators. Section A. should list any current authorizations. The Committee cannot issue final approval unless the PI or Co-PI meets the training and experience listed in this section.

ITEM VI. Plan of Investigation

A. Study Classification

Check the RDRC box if the study meets the RDRC Basic human research criteria outlined in 21CFR361.1.

Check the IND box if you already have an IND number or plan on obtaining a number directly from the FDA.

B. Dose Scheme

Enter maximum or range of activity and number of doses administered per subject.

C. Brief description of the purpose of the research study

Describe the scope of the study and its objectives. **Please be advised that photocopies of materials that were not written by the applicant for this purpose (lab notes, published standard protocols, manufacturers' instructions), are likely to generate a very adverse reaction from Committee reviewers unless they are annotated in a way that reflects careful consideration.**

D. Dose Preparation

Describe the chemical and physical handling steps involved in preparing the dose, along with any radiation safety precautions that will be observed in preparing and transporting the dose. Reviewers look at this section with particular rigor in order to assess the applicant's understanding of the study, its hazards, and its generation of waste materials. Note that special details must be provided for:

- transport and delivery of the RAM
- uses that are subject to concern about radioactivity in volatile forms (notably tritiated water and acetate, radioiodines and sulfur-labeled amino acids),
- any handling step that may cause dispersal into air as an aerosol, including procedures such as centrifugation, sonication, homogenization, and opening sealed vessels of radioactive liquids, and
- any step involving infectious material

ITEM VII. Exposure Control and Monitoring

Personal dosimetry (TLD badge) service is available through the Environmental Health and Safety office. Conditions requiring personal dosimetry devices are found in section 3.4.4.4 of the *UCD Radiation Safety Manual*.

Methods used to protect personnel should include means of contamination control (including but not necessarily limited to surveys, gloves and other protective apparel, absorbent paper and radioactive materials marking tape on benches), and use of fume hoods when appropriate. Shielding and consideration of storage locations for stock and bulk waste materials should also be specified when appropriate (sizable quantities of gamma or high-energy beta emitters). **All of the requirements in sections 3.4.3, 3.4.4, and 3.4.5 of the *UCD Radiation Safety Manual* should be addressed to the extent that they apply.** Take care to avoid clearly inappropriate references, such as specifying shielding for tritium, etc. When in doubt about appropriate precautions for a given application, consult EHS.

ITEM VIII. Radiation Monitoring

Possession of portable survey instrument - If your application is for any radionuclide other than H-3, the Committee will require you to **POSSESS** an appropriate portable survey instrument, usually a thin-window GM, for ongoing survey uses, such as frequent checks of hands and lab coats for contamination, surveying locations of spills, etc. Refer to the *UCD Radiation Safety Manual*, section 3.4.3.1.

Frequency of surveys - Surveys should include wipe testing for removable radioactive contamination. Documented surveys must be performed in accordance with the requirements published in appendix XV of the Radiation Safety Manual.

ITEM IX. Radioactive Waste Handling and Disposal

All radioactive waste disposal services are provided free of charge by EHS to all investigators whose grants are funded at the on-campus ICR rate. List the waste forms that the experiment will generate (solids, liquids, scintillation vials, animals, etc.) in Table D. For each waste form that requires disinfecting, a brief explanation of the method used to disinfect the waste must be included in Section C comments.

- For any RAM contaminated organic solvent wastes or other mixed (radioactive and hazardous) wastes, the chemical nature of the waste should be clearly stated.

- For any experiment that involves human tissue or bodily fluids including blood, serum, or plasma; or pathogenic microorganisms, all radioactive wastes containing such materials *or having been in contact with such materials* may require disinfecting before being picked up by EHS.