



ENVIRONMENTAL HEALTH & SAFETY | RADIATION SAFETY

and

COMMITTEE ON IONIZING RADIATION

OFFICE OF THE ASSISTANT VICE CHANCELLOR FOR REGULATORY COMPLIANCE

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

Important: All EHS forms are posted to the Web as fillable PDFs. The Chrome browser is the only program which successfully enables opening, editing, and saving of these documents. It is essential that the Chrome browser be used to access all EHS forms.

This guidance pertains to the [RAM Application for Medical Research \(Human Use\)](#) (RSF-078) only.

Use RSF-078 to apply for authorization to use radioactive materials for human medical research. For non-research (clinical) use of radioactive material, contact Riad Safadi, Radiation Safety Officer, 303-724-0234 or riad.safadi@ucdenver.edu.

RSF-078 is distinct from, but may be submitted concurrently with, the Institutional Review Board (IRB) application. The IRB will not grant final approval without Committee on Ionizing Radiation (CIR) and, if applicable, Radioactive Drug Research Committee (RDRC) approval.

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

Save a copy of the form using a new file name. Complete all fields by tabbing through the entire document. If a field is not applicable, enter NA. Refer to the [Radiation Safety Manual](#) and the [Radioactive Waste Disposal Manual](#) for additional guidance.

Submit the completed application to radapphu@ucdenver.edu

Item III. Radiation Workers

List all individuals requiring unescorted access to the rooms entered in the application. All workers must complete the required radiation safety training before access is granted.

Item IV. Radioactive Material and Amounts

Accurate data is essential in order to demonstrate an acceptable level of knowledge of the isotope properties. Contact Riad Safadi, 4-0234, for assistance securing this information.

*The requested possession limit 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. A **possession limit** request exceeding twice the amount anticipated to be used in one year will require some explanation. (e.g., minimum amount of radioactivity available, half-life, or purchase economy).*

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 an IND number has or will be obtained from the FDA.

B. Dose scheme

Enter maximum activity and number of doses to be administered per subject.

C. Purpose of research study

Describe the scope of the study and its objectives. **Photocopies of materials not written by the applicant for this purpose (e.g., lab notes, published standard protocols, manufacturer's instructions) are unlikely to be found acceptable by committee reviewers, unless they are annotated in a way that reflects careful consideration.**

D. Dose preparation

The section is reviewed with particular rigor to assess the applicant's understanding of the study, its hazards, and its anticipated generation of waste. Special details must be provided for

- Uses subject to concern about radioactivity in volatile forms, notably tritiated water and acetate, radioiodines and sulfur-labeled amino acids;
- Any handling step which may cause dispersal into air, including centrifugation, sonication, homogenization, or opening sealed vessels of radioactive liquids; and
- Any step involving infectious material.

Item VII. Exposure Control and Monitoring

Personal dosimetry service is available through Environmental Health & Safety. Conditions requiring the use of personal dosimetry devices are found in section 3.4.4.4 of the [Radiation Safety Manual](#).

All requirements found in sections 3.4.3, 3.4.4, and 3.4.5 of the [Radiation Safety Manual](#) must be addressed, if applicable. Avoid clearly inappropriate references, such as specifying shielding for tritium, etc. Consult Riad Safadi, 303-724-0234, for guidance regarding appropriate precautions for a given application.

Item VIII. Radiation Monitoring

A. Portable survey instrument

Applicant must possess an appropriate portable survey instrument if any radionuclide other than H-3 will be used. Refer to the [Radiation Safety Manual](#), section 3.4.3.1.

D. Frequency of contamination surveys

Surveys must include wipe testing for removable radioactive contamination. Documented surveys must be performed as noted in Appendix XV of the [Radiation Safety Manual](#).

Item IX. Radioactive Waste Handling and Disposal

Radioactive waste disposal service is provided free of charge by EHS to all investigators whose grants are funded at the on-campus ICR rate.