

RPR 48A. APPLICATION TO USE RADIOACTIVE MATERIALS IN HUMAN SUBJECTS

(Use one form per research protocol and per radioisotope)

RADIOACTIVE DRUG RESEARCH COMMITTEE (RDRC)
and/or HUMAN USE SUBCOMMITTEE (HUS)
UNIVERSITY OF UTAH HEALTH SCIENCES CENTER
SALT LAKE CITY, UT 84132

APPLICATION NUMBER _____

IRB NUMBER _____

DATE _____

TITLE OF APPLICATION: _____

PRINCIPAL INVESTIGATOR _____

DEPARTMENT ADDRESS & PHONE _____

RESPONSIBLE USER* _____

* authorized by Radiation Safety Committee to use radioisotopes on or in humans; Clinical Radiation Use Application on file in Radiological Health Dept.

RADIONUCLIDE _____ **Chemical & physical form** _____

Methods for assuring drug sterility and apyrogenicity _____

Check ONE of the following categories which applies to the radioactive drug to be used in this study:

- 1** FDA-approved drug
- 2** FDA-approved investigational new drug, IND number _____
- 3** Drug without new drug application (NDA) filed with or IND issued by FDA

Drugs in category 1 or 2 are reviewed by the Human Use Subcommittee of the Radiation Safety Committee.
Drugs in category 3 are reviewed by the Radioactive Drug Research Committee and the Human Use Subcommittee.

PURPOSE OF STUDY _____

DURATION OF STUDY _____

PROCEDURES TO BE USED _____

Location in which radioactive drug is to be stored _____

Maximum activity on hand _____

Location in which studies are to be performed _____

Activity to be administered per subject _____

SUBJECTS' ADVERSE REACTIONS:

The principal investigator is required to IMMEDIATELY report to the RDRC-HUS and the IRB all adverse reactions associated with the use of the radioactive drug in the research study.

Signature: _____
Principal Investigator (PI) Responsible User (If other than PI)

Guidelines for Using Normal (Healthy) Volunteers in Radiation-Related Studies

The principal investigator(s) should be familiar with the general guidelines stated in the Office of Human Research Protections (OHRP), "Institutional Review Board Guidebook" relative to the involvement of students, employees, and normal volunteers in research. The Radioactive Drug Research Committee and Human Use Subcommittee of the Radiation Safety Committee (RDRC-HUS) wishes to emphasize, that your proposed research using ionizing radiation should maximize the possible benefits (i.e. increase the knowledge base) and minimize the radiation risks involved through participation. It should be emphasized further, that participation is voluntary and does not involve large monetary payments, student credit etc. as inducements to participation.

In addition, the RDRC/HUS has set down some specific guidelines for investigators to follow:

1. Adults (18 Years and older): The annual maximum occupational limit for radiation workers will be invoked. That is, the whole body dose delivered to the healthy adult volunteer will not exceed 50 mSv (5 rem) per year for the study.
2. Children (Below Age 18 years): In the case of volunteers below the age of 18y, the whole body dose must be below 1 mSv. (100mrem) per year for the study.
3. The protocol must outline specifically the reason(s) for using healthy volunteers and the expected outcomes relative to knowledge gained. *This justification will play a crucial role in determining whether their inclusion will be approved.*
4. The Consent Form will include the following:
 - A. If there is no potential therapeutic benefit from participation, that fact should be clearly stated.
 - B. The participant may be subject to additional exposure to ionizing radiation from diagnostic tests (dental x-rays, chest x-rays, etc.) related to their personal health

- during the time period they are involved in the study.
- C. That the participant attests to the fact that they have not participated in any previous research studies involving the use of ionizing radiation (either radioisotopes or diagnostic x-rays) during the past 12 months.
 - D. Further, that the participant should not volunteer for other research studies involving the use of ionizing radiation within 12 months of completing the current study.

PROTOCOL APPROVAL PROCESS:

(1) THE ORIGINAL and 10 copies of this application must be provided to the Chair of the RDRC-HUS. The name and address of the current RDRC-HUS Chair can be obtained by telephoning the Radiological Health Department (581-6141).

(2) PLEASE INCLUDE 10 copies of the research proposal with literature citations or animal study data, the informed consent form* and the application being submitted to the Institutional Review Board (IRB) including the IRB Summary.

(3) Allow at least two weeks for RDRC-HUS review of the application.

(4) Approval of IRB also must be obtained.

*Note: Review the consent form for clear information regarding the reason for the use of the radiation and risks associated with its use. (for questions, contact the Radiological Health Dept, 581-6141).