

**RPR 48C. APPLICATION TO USE THERAPEUTIC IONIZING RADIATION
IN HUMAN RESEARCH STUDIES**

HUMAN USE SUBCOMMITTEE OF THE
RADIATION SAFETY COMMITTEE
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 deliver brachytherapy and/or teletherapy to humans; Clinical Radiation Use Application on file in Radiological Health Dept.

Check ONE of the following categories which applies to the therapeutic ionizing radiation to be used in this study:

___ **1** Teletherapy involving x-rays and/or electrons

___ **2** Brachytherapy, Radioisotope _____

PURPOSE OF STUDY (Include sufficient information to allow HUS to evaluate benefit/risk ratio):

DURATION OF STUDY _____

STUDY LOCATION:

Department (if different than dept. of P.I.) _____

Room number and building _____

Equipment to be used - type, manufacturer _____

Radiation Oncology Consultants (if applicable) _____

Person responsible for Radiation Safety and Calibration of equipment and date of last Radiation Safety Survey and Calibration _____

FOR EXTERNAL BEAM AND BRACHYTHERAPY

TYPE OF TREATMENT:

	Treatment name	Body area treated	Treatment volume	Tumor Dose
(1)	_____	_____	_____	_____
(2)	_____	_____	_____	_____

RADIATION DOSES (mrem) DELIVERED TO:

	Skin (entrance)	Gonads	(critical organ)	(critical organ)
(1)	_____	_____	_____	_____
(2)	_____	_____	_____	_____

For Radioactive Drug:

- ___ 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.

*For applications requiring RDRC and HUS review (drugs in category 3):

- 1. Pregnant females shall not be studied
- 2. A special summary must be sent to the FDA (if the study involves more than 30 subjects or involves subjects or involves subjects under age 18.

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 _____

Method to measure/verify activity administered _____

Route of administration _____ Number of administrations per subject _____

Radiation dose in mrem

Location

Total body
gonads
active blood-forming organs
lens of eye

_____ (critical organ)
_____ (critical organ)
_____ (critical organ)

† Total radiation dose for all therapy administrations per subject, if radioisotope is to be administered more than once per subject in this study.

Does the therapeutic dose require a diagnostic dose? If so, provide _____

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 _____

Method to measure/verify activity administered _____

Route of administration _____ Number of administrations per subject _____

Radiation dose in mrem

Location

Total body
gonads
active blood-forming organs
lens of eye

_____ (critical organ)
_____ (critical organ)
_____ (critical organ)

Give the method by which radiation dose was estimated, such as by calculation or by other method. Include references and/or calculations used to estimate the doses.

SUBJECTS TO BE STUDIED:

Age of subjects: Age 18 or over Under age 18

Number of males _____
Number of females _____
Total number of subjects _____

Subject groups excluded: _____

Methods to assure pregnant females are not studied or justification for including them in study:

Justification for subjects under age 18 _____

SUBJECTS' ADVERSE REACTIONS:

The principal investigator SHALL IMMEDIATELY report to the HUS and the IRB all adverse reactions associated with the use of therapeutic ionizing radiation 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 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 Department 1-6141)