

**RPR 48B. APPLICATION TO USE DIAGNOSTIC EXTERNAL  
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 diagnostic external radiation (x-ray or I-125) to humans; Clinical Radiation Use Application on file in Radiological Health Dept.

**Check ONE of the following categories which applies to the diagnostic external radiation to be used in this study:**

- \_\_\_ **1** X-rays  
\_\_\_ **2** Gamma rays from machine containing radioactive source,  
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** \_\_\_\_\_  
\_\_\_\_\_

**Diagnostic Radiology Consultants** (if applicable) \_\_\_\_\_  
\_\_\_\_\_

**Person responsible for Radiation Safety and Calibration of equipment and date of last Radiation Safety Survey and Calibration** \_\_\_\_\_  
\_\_\_\_\_

**FOR ALL EXAMS (i.e., radiographic, fluoroscopic, densitometric, etc.):**

**For Radiographic exams:**

Area to be Examined	Exam type (gen radiographic, spot film, etc.) and ave. technique	Approx. Entrance Exposure per frame or film (mrem)	Number of films or frames
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(1) \_\_\_\_\_  
 (2) \_\_\_\_\_  
 (3) \_\_\_\_\_

**For CT scans:**

Area to be Examined	Enhanced/Unenhanced	Resolution of slices technique Mhs kvp, slice thickness	Dose/Slice	Number of Scan
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(1) \_\_\_\_\_  
 (2) \_\_\_\_\_  
 (3) \_\_\_\_\_

**For Fluoroscopic exams:**

Area to Be Examined	Approx. Entrance Exposure rate (r/min)	Average Time (minutes)
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(1) \_\_\_\_\_  
 (2) \_\_\_\_\_  
 (3) \_\_\_\_\_

**For Densitometric exams:**

Area to Be Examined	Approx. Entrance Exposed per scan (mrem)	Number of exams
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(1) \_\_\_\_\_  
 (2) \_\_\_\_\_  
 (3) \_\_\_\_\_

**RADIATION DOSES (mrem) DELIVERED TO:**

Tissue	Radiographic	CT Scans	Fluoroscopic study	Densitometric	Total dose per study
Skin Entrance	_____	_____	_____	_____	_____
Lungs	_____	_____	_____	_____	_____
Active Bone Marrow	_____	_____	_____	_____	_____
Thyroid	_____	_____	_____	_____	_____
Trunk Tissue	_____	_____	_____	_____	_____
Breasts	_____	_____	_____	_____	_____
Gonads	_____	_____	_____	_____	_____
Critical Organ (specify)	_____	_____	_____	_____	_____

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 \_\_\_\_\_

Will asymptomatic subjects be included? \_\_\_\_\_

Will healthy volunteers be included? Yes  No

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 is required to IMMEDIATELY report to the HUS and to the IRB all adverse reactions associated with the use of diagnostic external radiation in a 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.*
- d) 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 application and copies, the number of which designated by the risk category below, must be provided to the Chair of the RDRC-HUS. The same number of 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 must accompany the copies of the applications:

- e) 5 copies, if it is a low radiation dose potential, this means diagnostic external radiation, machine produced, ie, chest x-ray, bone densitometry, less than 500 mrem total dose for study and it is not a "Healing Arts" Screening.
- f) 10 copies, if it not in the low risk category stated in (a) above.

The name and address of the current RDRC-HUS Chair can be obtained by telephoning the Radiological Health Department (581-6141). If you have any questions about the number of copies, contact Radiological Health Department (581-6141).

- 2) Allow at least two weeks for the RDRC-HUS review of the application.
- 3) Approval of IRB must also be obtained.