RADIOACTIVE DRUG RESEARCH COMMITTEE
and
HUMAN USE SUBCOMMITTEE
of the Radiation Safety Committee

PURPOSE

This procedure defines the membership, authority, responsibilities, and operating rules of the University's Radioactive Drug Research Committee and Human Use Subcommittee of the Radiation Safety Committee.

POLICY

In accordance with Food and Drug Administration (FDA) regulations, the Radioactive Drug Research Committee (RDRC) is empowered and required to evaluate and to approve or disapprove all research and developmental uses of radioisotopes on or in humans. The RDRC also serves as the Human Use Subcommittee of the Radiation Safety Committee (HUS). As required by Utah Division of Radiation Control, the HUS evaluates and approves or disapproves all proposed uses of ionizing radiation sources on or in humans for investigational or non-routine clinical procedures. Review of an application for the use of ionizing radiation sources on or in human subjects is conducted by the RDRC and the HUS or by the HUS only after the adequacy of the facilities and qualifications of the investigator have been verified by the Radiation Safety Officer (RSO). Applications for the use of ionizing radiation sources in human research studies from the Veterans' Administration Medical Center (VAMC) also are reviewed by the University's RDRC-HUS.

RESPONSIBILITIES AND AUTHORITY

The RDRC and the HUS are responsible for the evaluation and approval or disapproval of applications involving investigational or non-routine clinical uses of FDA-approved radioactive drugs, radioactive drugs with IND numbers issued by the FDA, or any other ionizing radiation sources (x-ray, brachytherapy, etc.).

The HUS is responsible for the evaluation and approval or disapproval of applications involving investigational or non-routine clinical uses of FDA-approved radioactive drugs, radioactive drugs with IND numbers issued by the FDA, or any other ionizing radiation sources (x-ray, brachytherapy, etc.).

MEMBERSHIP

The RDRC-HUS must be composed of at least five individuals professionally qualified in the use of radiation in medicine and clinical research. The Committee must include the following three individuals: (i) A physician recognized as a specialist in nuclear medicine, (ii) a person qualified by training and experience to formulate radioactive drugs, and (iii) a person with special competence in radiation safety and radiation dosimetry. The Chairperson of the Radiation Safety Committee (RSC) and the RSO shall be ex-officio members.

The Committee members and chairperson are appointed by the University President for indefinite terms on the basis of professional qualifications. These appointees shall be individuals qualified in various disciplines pertinent to the field of radiology (e.g. nuclear medicine, internal medicine, clinical pathology, hematology, endocrinology, radiation therapy, radiation physics, radiation biophysics, health physics and radiopharmacy). Membership shall be sufficiently diverse to permit expert review of the technical and scientific aspects of proposals submitted to the RDRC-HUS.

Membership of the RDRC-HUS is reviewed at least annually and additions or replacements normally are appointed at the beginning of the Fourth Calendar Quarter.
Each RDRC shall be specifically approved by the Center for Drug Evaluation and Research, Division of Medical Imaging and Radiopharmaceutical Drug Products. Applications shall be submitted to the FDA, shall contain the names and qualifications of the Committee members, and shall contain a statement that the Committee agrees to comply with the requirements of 21 CFR 361.1. FDA approval is based upon assessment of the qualifications of the Committee members and the assurance that all necessary fields of expertise are covered. Approval of the RDRC remains effective unless and until the FDA withdraws such approval. Changes in membership and applications for new members shall be submitted to the FDA as soon as, or before, vacancies occur on the RDRC.

**REVIEW OF RESEARCH APPLICATIONS**

Application forms are submitted to the RDRC-HUS for use of radioactive drugs, diagnostic external radiation, and therapeutic ionizing radiation in human research studies (see attached forms). Each proposed research study must have a Responsible User (RU) who has a Clinical Radiation Use Application on file with the Radiological Health Department. The RU is not required to be the Principal Investigator (PI) of the research study, but is the individual responsible for ensuring safe use of ionizing radiation sources in the research study.

All applications, except for studies involving radioactive drugs without a NDA filed with the FDA or without an IND number issued by the FDA, are handled and approved or disapproved through the mail. All RDRC-HUS members must vote on each application within the allotted time. In the event the member does not vote due to absence during balloting period, his/her vote will be considered an abstention. On a protocol in which he/she is an investigator, a RDRC-HUS member shall abstain from voting.

**LOW RISK HUS SUBCOMMITTEE**

The Low Risk HUS Subcommittee consists of the chairperson, the representative of the Radiation Safety Officer or his designee, and at least one other member of the main committee. The third member can be rotated/choseh each time by expertise or availability with concurrence of the chairperson. One member of the subcommittee should have dosimetry training.

For the study application to go to this subcommittee, it must qualify as “low risk”. A low risk study includes diagnostic external radiation (i.e. chest x-ray, bone densitometry) with less than 500 mrem (skin entrance dose) total body dose for the study. A low risk study must not be a “Healing Arts” Screening.

If any member of the subcommittee has concerns about the application, that member can request another member review the application for ballot as well, or request that it go to full committee for review.

If questions or concerns cannot be adequately resolved for a member of the subcommittee, the application can be disapproved or sent to full committee at the discretion of the chairperson.

The outcome of these application reviews will be summarized with a brief description of the study and placed in the agenda notice for the next quarterly meeting. This allows the full committee to be apprized of actions taken. These would also be part of the concurrence review of the full list of applications approved for the quarter.

**ADVERSE REACTIONS IN SUBJECTS**

The PI shall immediately report to the IRB and the RDRC-HUS all adverse reactions associated with the use of the ionizing radiation sources in the human research study. In accordance with 21 CFR 361.1, all adverse reactions involving radioactive drugs without a NDA filed with the FDA or without an IND number issued by the FDA must be reported immediately to the FDA by the RDRC.

**MEETINGS, AGENDA, AND QUORUM**
The RDRC-HUS meets at least once each calendar quarter to review and act on applications for use of radiation sources in or on human subjects. These meetings shall be scheduled at least two weeks prior to RSC quarterly meetings. A recommended agenda for RDRC-HUS meetings is attached (p. 4). A quorum consisting of more than 50 percent of the RDRC-HUS's total membership must be present with appropriate representation of the required fields of specialization. Between meetings, decisions may be made by a majority of all voting members via mailed ballot. Parliamentary procedures shall be determined by Robert's Rules of Order.

RECORDS AND REPORTS

The RDRC-HUS Chairperson shall sign all applications, minutes, and reports of the Committee. Minutes shall be kept and shall include the numerical results of votes on protocols involving use in human subjects.

The RDRC-HUS reports to the RSC in writing at least once each calendar quarter. A recommended RDRC-HUS Activity Report is attached (p. 4). Approved minutes from RDRC-HUS meeting(s) held in the previous calendar quarter also are submitted to the RSC each calendar quarter.

The RDRC shall submit an annual report on or before January 31 of each year to the FDA. The annual report shall include the resumes and qualifications of the members of, and of any consultants to the RDRC, and a summary of information for each study involving radioactive drugs without a NDA filed with the FDA or an IND number issued by the FDA conducted during the preceding year. The format of this annual report must be in accordance with 21 CFR 361.1 (FDA Forms 2914 and 2915).

In accordance with 21 CFR 361.1, the RDRC also shall submit a special summary report (FDA Form 2915) to the FDA for each study involving radioactive drugs without a NDA filed with the FDA or an IND number issued by the FDA in which 30 or more subjects will be studied or in which subjects under age 18 will be studied. A special summary report shall be sent to the FDA immediately after RDRC approval of such a study.

FDA MONITORING OF THE RDRC

The FDA reviews periodically the RDRC. Monitoring is conducted through review of the annual reports, through review of minutes and full protocols for certain studies, and through on-site inspections.

GUIDELINES FOR USING (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.

REFERENCES


International Commission on Radiological Protection:


*Robert's Rules of Order*.


Utah Department of Environmental Quality, Division of Radiation Control, *Utah Radiation Control Rules*. 
RDRC-HUS STANDARD AGENDA

I. OPENING BUSINESS

A. Attendance and agenda
B. Approval of minutes
C. Announcements

II. OLD BUSINESS

III. REVIEW OF SUBMITTED PROTOCOLS

A. New applications since last meeting
B. RDRC protocols
C. Adverse reactions from approved protocols

IV. NEW BUSINESS

V. NEXT MEETING

STANDARD RDRC-HUS ACTIVITY REPORT

TO: Radiation Safety Committee
FROM: RDRC-HUS Chairman
SUBJECT: Quarterly Activity Report.

Following is the Quarterly Activity Report of the Radioactive Drug Research Committee and Human Use Subcommittee of the Radiation Safety Committee for the period of 199 through 199.

The following research applications have been received, reviewed, and approved:

(1) Research Application #: PI & RU surname(s): Title of Application was reviewed with # approvals, # disapprovals, and # abstentions.
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

TITLEx 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 pyrogenicity ___________________________________

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 ______________________________________________
Method to measure/verify activity administered

Route of administration Number of administrations per subject

<table>
<thead>
<tr>
<th>Radiation dose in mrem†</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>total body</td>
</tr>
<tr>
<td></td>
<td>gonads</td>
</tr>
<tr>
<td></td>
<td>active blood-forming organs</td>
</tr>
<tr>
<td></td>
<td>lens of eye</td>
</tr>
<tr>
<td></td>
<td>(critical organ)</td>
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<td></td>
<td>(critical organ)</td>
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<tr>
<td></td>
<td>(critical organ)</td>
</tr>
</tbody>
</table>

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

SUBJECT TO BE STUDIED:

Age of subjects: _ Age 18 or over _ Under age 18∗

Number of males
Number of females
Total number of subjects∗

Will Healthy Volunteers be Used? 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∗

____________________________________________________________

*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 under age 18.

Give the method by which radiation dose was estimated, such as by calculation, by in vivo measurements, by uptake excretion, or by other method. Include the references and/or calculations used to estimate the doses.
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.)
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:

<table>
<thead>
<tr>
<th>Area to be Examined</th>
<th>Exam type (gen radiographic, spot film, etc.) and ave. technique</th>
<th>Approx. Entrance Exposure per frame or film (mrem)</th>
<th>Number of films or frames</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2)</td>
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<td></td>
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<tr>
<td>(3)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For CT scans:

<table>
<thead>
<tr>
<th>Area to be Examined</th>
<th>Enhanced/Unenhanced</th>
<th>Resolution of slices technique Mhs kvp, slice thickness</th>
<th>Dose/Slice</th>
<th>Number of Scan</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1)</td>
<td></td>
<td></td>
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<td></td>
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<tr>
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<td>(3)</td>
<td></td>
<td></td>
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</tbody>
</table>

For Fluoroscopic exams:

<table>
<thead>
<tr>
<th>Area to Be Examined</th>
<th>Approx. Entrance Exposure rate (r/min)</th>
<th>Average Time (minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1)</td>
<td></td>
<td></td>
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<tr>
<td>(2)</td>
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<tr>
<td>(3)</td>
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</tbody>
</table>

For Densitometric exams:

<table>
<thead>
<tr>
<th>Area to Be Examined</th>
<th>Approx. Entrance Exposed per scan (mrem)</th>
<th>Number of exams</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1)</td>
<td></td>
<td></td>
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<tr>
<td>(2)</td>
<td></td>
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<tr>
<td>(3)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**RADIATION DOSES (mrem) DELIVERED TO:**

<table>
<thead>
<tr>
<th>Tissue</th>
<th>Radiographic</th>
<th>CT Scans</th>
<th>Fluoroscopic study</th>
<th>Densitometric study</th>
<th>Total dose per study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Entrance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lungs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active Bone Marrow</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thyroid</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Trunk Tissue</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breasts</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gonads</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Critical Organ (specify)</td>
<td></td>
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</tbody>
</table>

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.
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 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:
   a) 5 copies, if it is a low radiation dose potential, this means diagnostic external radiation, machine producted, ie, chest x-ray, bone densitometry, less than 500 mrem total dose for study and it is not a “Healing Arts” Screening.
   b) 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.
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:

<table>
<thead>
<tr>
<th>Treatment name</th>
<th>Body area treated</th>
<th>Treatment volume</th>
<th>Tumor Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2)</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

RADIATION DOSES (mrem) DELIVERED TO:

<table>
<thead>
<tr>
<th>Skin (entrance)</th>
<th>Gonads</th>
<th>(critical organ)</th>
<th>(critical organ)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>(2)</td>
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</tbody>
</table>

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 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 ______

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<thead>
<tr>
<th>Radiation dose in mrem</th>
<th>Location</th>
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<td>Total body</td>
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<tr>
<td></td>
<td>gonads</td>
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<td></td>
<td>active blood-forming organs</td>
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<td></td>
<td>lens of eye</td>
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† 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 ______
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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)