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 disproves 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 *radioactive drugs without New Drug Applications (NDA) filed with the FDA or without Investigational New Drug (IND) numbers issued by the FDA*.

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/chosen 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.

Human research studies involving radioactive drugs without a NDA filed with the FDA or without an IND number issued by the FDA must be reviewed in accordance with 21 CFR 361.1. **RDRC-HUS members** vote on each such application at Committee meetings.

All research applications for use of ionizing radiation sources in human research studies submitted to the **RDRC-HUS** also shall be submitted to, evaluated by, and approved or disapproved by the **Institutional Review Board (IRB)**. Human research studies involving ionizing radiation sources shall not begin until approval of the **IRB** and **RDRC-HUS** is obtained.

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

Food and Drug Administration, *Radioactive Drugs for Certain Research Uses*, 21 CFR 361.1.

International Commission on Radiological Protection:

Radiation Dose to Patients from Radiopharmaceuticals, ICRP Publication 53, 1987.

Mossman and Mills, *The Biological Basis for Radiation Protection Practice*, Chapter 17, 1992.

Robert's Rules of Order.

University of Utah, *Radiation Safety Manual and Procedures*, Radiation Procedures and Records.

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 _____

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 _____

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 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.

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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

(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

(1) _____ _____
(2) _____
(3)_____ _____

For Fluoroscopic exams:

Area to Be Examined	Approx. Entrance Exposure rate (r/min)	Average Time (minutes)

(1) _____
_____
(2) _____
_____
(3)_____

For Densitometric exams:

Area to Be Examined	Approx. Entrance Exposed per scan (mrem)	Number of exams

(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.*
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.

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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)

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