HUMAN USE SUBCOMMITTEE
Radiation Safety Committee

PURPOSE

This procedure defines the membership, authority, responsibilities, and operating rules of the University's Human Use Subcommittee of the Radiation Safety Committee for use of ionizing radiation in investigational or non-routine clinical procedures.

POLICY

As required by the **Utah Division of Radiation Control,** the **Human Use Subcommittee** (**HUS)** evaluates and approves or disapproves all proposed uses of ionizing radiation sources on or in human subjects for investigational or non-routine clinical procedures. Review of an application for the use of ionizing radiation sources on or in human subjects are conducted 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 Affairs Medical Center (VAMC), Shriners Hospitals for Children** and **Primary Children's Medical Center** in support of the **University of Utah Institutional Review Board (IRB)** which provides reviews for these entities also are reviewed by the University's **HUS**.

RESPONSIBILITIES AND AUTHORITY

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

The **HUS** 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 **HUS**.

There may be more members in order to populate more than one review panel to accommodate larger numbers of applications and to cover members who may not be available. Each review panel must meet the standards above unless the applications are low risk studies and must meet quarterly.

Membership of the **HUS** is reviewed at least annually and additions or replacements normally are appointed at the beginning of the fourth calendar quarter.

REVIEW OF RESEARCH APPLICATIONS

Research application forms are submitted to the **HUS** for use of radioactive drugs, diagnostic external radiation, and therapeutic ionizing radiation in human research studies through the **IRB**'s web based system (ERICA). 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. If the radiation is standard of care and the participant would receive it whether or not they are in the study, an RU and radiation dosimetry is not required. Instructions for obtaining and submitting the radiation related information needed is provided in a web link to assure that the latest versions of information on dosimetry and consent language are available.

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 online through the ERICA system (erica.research.utah.edu). The procedures for Amendments are handled through email requests. All **HUS** members assigned to review a protocol must vote within the allotted time. In the event the member does not vote due to absence during the balloting period, his/her vote will be considered an abstention. On a protocol in which he/she is a PI, the **HUS** member shall abstain from voting.

LOW RISK HUS SUBCOMMITTEE

The Low Risk HUS Subcommittee consists of three members of the HUS. One member should have dosimetry training.

For the study application to qualify as Alow risk@, it must include diagnostic external radiation (i.e. chest x-ray, bone densitometry) with less than 500 mrem effective dose equivalent for the study. A low risk study must not be a AHealing 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 HUS agenda for the next quarterly meeting. This allows the full committee to be apprised of actions taken. These would also be part of the concurrence review of the full list of applications approved at the quarterly meeting.

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

ADVERSE REACTIONS IN SUBJECTS

The **PI** shall **immediately** report to the **IRB** and the **HUS** all adverse reactions associated with the use of the ionizing radiation sources in the human research study.

MEETINGS, AGENDA, AND QUORUM

The **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 are scheduled at least two weeks prior to the RSC quarterly meetings. A recommended agenda for **HUS** meetings is included in this RPR. A quorum consisting of more than 50 percent of the **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* e-mailed or mailed ballot. Parliamentary procedures shall be determined by *Robert's Rules of Order*.

RECORDS AND REPORTS

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

The **HUS** reports to the **RSC** in writing at least once each calendar quarter. A recommended standard **HUS** Activity Report is included in this RPR. Approved minutes from **HUS** meeting(s) held in the previous calendar quarter also are submitted to the RSC each calendar quarter.

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 Human Use Subcommittee of the Radiation Safety Committee (HUS) wishes to emphasize, that 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 **HUS** has set some specific guidelines for PIs 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 18 years, the whole body dose must be below 1 mSv (100 mrem) 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. 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. 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 106, 2008.

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*.

HUS STANDARD AGENDA

I. OPENING BUSINESS

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

II. OLD BUSINESS

A. Quarterly update of the annual status of protocols

III. REVIEW OF SUBMITTED PROTOCOLS

A. New applications since last meeting
B. New applications reviewed by the low risk sub-commitee
C. List of review requests for exemptions
D. RDRC proposals
E. Adverse reactions from approved protocols

IV. NEW BUSINESS

V. NEXT MEETING

STANDARD HUS ACTIVITY REPORT

TO: Radiation Safety Committee

FROM: 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 _____ to_____.

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

1. Research Application #, IRB # PI surname(s), RU surname(s): *Title of Application* Approval date: