RADIATION SAFETY SUBCOMMITTEE
USE OF RADIATION IN HUMAN SUBJECT RESEARCH
(HSR SUBCOMMITTEE)
Approved May 2005

Policies and Procedures

1.1 Purpose of the Radiation Safety Subcommittee for Use of Radiation in Human Subject Research

The Radiation Safety Subcommittee for Use of Radiation in Human Subject Research (HSR) Subcommittee is responsible assisting the Institutional Review Board (IRB) in its review of human subject research involving the use of radioisotopes or radioactive drugs (as defined in 21 USC 310.3(n)) in humans or any exposure of human subjects to radiation, other than use and exposures that are a routine aspect of the patient's on-going care and treatment. The Subcommittee shall review and approve the use of radiation and/or radiation generating equipment to confirm the amount and type of radiation exposure and determine whether such exposure is an acceptable risk. A copy of the Subcommittee's approval shall be provided to the IRB prior to the IRB's review of the project.

1.2 Activities Requiring HSR Subcommittee Review

Any use of radioisotopes, radioactive drugs in humans or exposure of human subjects to radiation as part of any systematic investigation, including research development, testing, and evaluation (research) that involves human subjects must receive approval from the Subcommittee prior to IRB review of the research project.

1.3 Selection and Composition of the HSR Subcommittee

The Subcommittee is composed of at least three standing members of the Radiation Safety Committee and includes at least one member who is a medical physicist.

1.4 HSR Subcommittee Meetings

The Subcommittee meets on the second and fourth Thursday of each month, except that during the months of November and December, it meets only on the first Thursday of the month. The schedule of regular Subcommittee meetings is available on the web at www.creighton.edu/researchcompliance/Radiation_Safety. All materials for Subcommittee review must be received by the Radiation Safety Office (Room 117, Criss I) **at least 10 days** prior to the meeting at which the information will be reviewed.

1.4.1 Quorum

A majority of members must be available (in person or by telephone) to conduct business of the Subcommittee. The final approval of an application will require a vote of at least two members.

1.5 Submission Requirements and Review Process

1.5.1 HSR Subcommittee Applications

There are three different types of Applications depending on the type of radiation involved and the age of the human subjects.

- **Application for Human Radioactive Drug Research – Drug without an NDA or IND (RSO-11)**: Use RSO 11 when radioactive drugs are proposed to be used in the absence of a valid NDA or IND regardless of the subject's age.

- **Application for Use of Radiation in Research Involving Human Subjects (RSO-12):** Use RSO 12 when radioactive materials or radiation generating equipment will be used.

- **Application for Use of Diagnostic X-rays in Subjects 19 years or Older (RSO-13):** Use RSO 13 when only diagnostic X-rays (including DEXA) will be used in research involving only subjects who are 19 years or older. If any subject will be less than 19 years of age, then use RSO 12.

1.5.2 Authorized User Requirement

Any application involving the use of radioisotopes in human subject research must identify a Creighton Authorized User. Studies that only involve the use of radiation generating equipment do not require an Authorized User.

1.5.3 Exposure Limitations

1.5.3.1 Adult Study Subjects (19 years or older)

The study limit for radiation exposure shall not be more than 30,000uSv per adult subject (19 years or older) per study. No adult subject shall be exposed to more than 50,000uSv per year for all studies. It is the Investigator's responsibility to ensure that no adult subject is exposed to more than 30,000uSv per study and no more than 50,000uSv per year for all studies during that year. The Radiation Safety HSR shall not approve any study where the radiation exposure to adult subjects enrolled in the study will exceed 30,000uSv.

1.5.3.2 Minor Subjects (Less than 19 years of age)

The study limit for radiation exposure shall not be more than 3,000uSv per minor subject per study. No minor subject shall be exposed to more than 5,000uSv per year for all studies. It is the Investigator's responsibility to ensure that no minor subject is exposed to more than 3,000uSv per study and no more than 5,000uSv per year for all studies during that year. The Radiation Safety HSR shall not approve any study where the radiation exposure to minor subjects enrolled in the study will exceed 3,000uSv.

1.5.4 Submission Requirements

Once you have determined the type of application(s) that is required for your project, submit the following information to the Radiation Safety Office at least 10 days prior to the next regularly scheduled Subcommittee meeting:

- Original and three (3) copies of the applicable Application
- Four copies of the protocol study design
- Four copies of the informed consent
- Four copies of the assent (if any subjects are less than 19 years of age).

1.5.5 Review Process

After you have submitted your Application(s) your submission will be reviewed by the Subcommittee at its next regularly scheduled meeting that is 10 days or more from the date of the submission. The Subcommittee will take one of the following actions:

- Approved
- Approved pending modifications
- Denied

You will be notified in writing of the determination. If you are asked to make changes, allow one week for the Subcommittee to respond once you have submitted the requested changes.

1.5.6 Informed Consent Language – Exposure to Radiation

The informed consent language should sufficiently describe the amount of radiation exposure in comparison to other exposures that are common to the subject (e.g. background radiation, number of transatlantic flights). Attachment "A" is a listing of effective dose equivalent (EDE) for common procedures that have been conducted at Creighton as part of a research protocol. The EDEs listed in Attachment "A" may vary

depending on the equipment. If you have any questions regarding the exposure or effective dose equivalent for any radioactive exposure during a study, contact Stan Jaeger at 449-4197 or ssj007@cox.net for further guidance. Attachment "A" is subject to change, so it is your responsibility to make sure you are using the most current information. The following are examples of acceptable radiation exposure language in the informed consent.

EXAMPLES OF ACCEPTABLE INFORMED CONSENT FOR RADIATION EXPOSURE:

Example 1: A lateral spine X-ray will be performed on the first visit. You will be exposed to approximately 1,300 uSv of radiation, which is less than one-half of the normal background radiation you are exposed in a year.

Example 2: You will undergo a DEXA scan of your entire body, which will expose you to 20 uSv of radiation. Your radiation exposure due to the DEXA scan is the same amount you would receive during a 2 hour airplane flight and is less than normal background radiation you are exposed to on a yearly basis.

Example 3: During this study, you will have a CT of the abdomen performed on the 6th visit. You will be exposed to approximately 10,000 uSv of radiation as a result of the abdomen CT. This exposure is one-third of the radiation exposure allowed by the federal government for human subjects.

Contact the Radiation Safety Office (280-5570) if you have any questions on how to complete the application or the informed consent language regarding exposure to radiation.

Attachment “A”

PROCEDURE DOSES

PROCEDURE (Single, unless otherwise stated)	**EFFECTIVE DOSE EQUIVALENT (EDE) uSv**
X-ray, Chest AP	20
X-ray, Chest LAT	40
X-ray, Skull LAT	70
X-ray, Femur	8
X-ray, Hand/Radius	1
X-ray, T-spine AP	500
X-ray, T-spine LAT	700
X-ray, L-spine AP	700
X-ray, L-spine LAT	1,300
DEXA, each	2.4
DEXA, whole body	20
QCT, Body	60
QCT, Radius	20
CT, head	2,000
CT abdomen	10,000
CT chest	8,000

COMPARISON EXPOSURES
(You may use other comparisons as acceptable to the HSR)

Flight	**10uSv/hour**
Background	**3,600/year**
Study Limit	**30,000/year**