

Guidance Document for Preparing Studies for Human Use Subcommittee Review

1. Identify within your study all procedures that will use ionizing radiation including the types of studies and their frequency.
2. Evaluate whether or not the radiation procedures are standard of care. To determine this, ask the question: “Would this subject (or patient) receive these procedures at this point in time if they were not enrolled in this study?”
 - a. If the answer is yes, the procedure is likely to be standard of care and the application can proceed with an “Exemption” from the RDRC-HUS committee. When you submit a study you designate for “Exemption”, the application is screened by a physician on the committee and the committee chair.

Note: If procedures that involve radiation are considered standard of care, the radiation risks should not be described in the consent document and there must be a clear statement that the patient would receive that diagnostic scan or radiation therapy regardless of whether or not they join the study.

- b. If the answer is no, the application must be reviewed by the RDRC-HUS committee. The application must include dosimetry, sufficient justification of the radiation exposures and a risk statement that is consistent with the amount of radiation that the research subject will or might receive for the procedures that are not standard of care.

For Diagnostic procedures:

- i. For **external** diagnostic radiation sources at the University of Utah facilities (i.e. x-rays, CT, DEXA) use this dosimetry calculator: <http://medicine.utah.edu/radiology/medical-physics/dose-information.php>

If the study you need is not available or if you have questions, contact the diagnostic medical physicist, Peter Jenkins (peter.jenkins@hsc.utah.edu), Department of Radiology. To determine the Responsible User that will need to approve the proposed radiation procedures, look at the table in this guidance. If you still need help, contact health physicist, Mary Handy at mary@rso.utah.edu or chair Scott Miller at scott.miller@hsc.utah.edu.

- ii. If these procedures are not going to be performed at the University of Utah, a Responsible User (RU) from that institution, listed in the table below, should be contacted so they can confirm that they will review and approve the submission. The appropriate radiation dosimetry should be obtained from that facility as well.
 - iii. For **internal** radiation sources (i.e. PET scans, PET/CT scans, MUGAs and all other nuclear medicine studies) contact the Director of Nuclear Medicine, Dr. John Hoffman, via his administrative officer, Neha Kataria (Neha.Kataria@hci.utah.edu) for dosimetry calculations.
 - iv. Examples of radiation risk language can be found at the end of this document.

For Therapy using Radiation:

- i. For internal radiation sources (i.e. I-131 therapy and other injected therapeutic radiopharmaceuticals) contact the Director of Nuclear Medicine, Dr. John Hoffman, via his administrative officer, Neha Kataria (Neha.Kataria@hci.utah.edu) for dosimetry calculations.
- ii. For external therapy radiation sources, such as accelerator radiation therapy, contact the Radiation Oncologist who is participating in the study to direct you to the therapy medical physicist who would provide the radiation dosimetry.
- iii. For brachytherapy radiation sources, contact the Radiation Oncologist who is participating in the study to provide the radiation dosimetry.

For combinations of diagnostic procedures and/or multiple Responsible Users, provide a summary of all the radiation and include the total radiation dosimetry in the informed consent. For assistance with the language for the informed consent, contact Mary Handy at mary@rso.utah.edu.

3. Submission procedure:

- a. Prior to entering your application into ERICA, your identified RU(s) should have approved the diagnostic or therapeutic procedures. This approval can be sent via email.
- b. After the RU has approved, but before you upload to ERICA, we recommend that you send a complete copy of the application materials to Mary Handy at the Radiological Health Department (mary@rso.utah.edu) for a pre-review.
- c. After the pre-review and corrections and changes have been made, if necessary, the application can be submitted into the ERICA system.

4. Contact information for questions and concerns:

- a. Mary Handy, Health Physicist, Radiological Health Department at mary@rso.utah.edu
- b. Karen Langley, Radiation Safety Officer and Director, Radiological Health Department at karen@rso.utah.edu
- c. Scott Miller, Department of Radiology and Chair, Radioactive Drug Research Committee and Human Use Subcommittee (RDRC-HUS) of the Radiation Safety Committee at scott.miller@hsc.utah.edu

Table of Responsible Users and the facilities or equipment under their Authorization				
Responsible User (RU)	Phone	E-mail	Department, (equipment or specific location)	Address
Frederick Welt	(801) 213-4060	fred.welt@hsc.utah.edu	Cardiovascular Medicine	Huntsman Cancer Hospital
Timothy Beals	585-5400	timothy.beals@hsc.utah.edu	Orthopedics	590 Wakara Dr.
David Gaffney	581-8793	david.gaffney@hci.utah.edu	Radiation Oncology	Huntsman Cancer Hospital
Ying Hitchcock	581-8793	ying.hitchcock@hci.utah.edu	Radiation Oncology	Huntsman Cancer Hospital
John Hoffman	587-4064	john.hoffman@hci.utah.edu	Nuclear Medicine	Huntsman Cancer Hospital
Kristine Kokeny	581-8793	kristine.kokeny@hci.utah.edu	Radiation Oncology	Huntsman Cancer Hospital
Kathryn Morton	585-9068	kathryn.morton@hsc.utah.edu	Redwood Clinic	Radiology, 1A 71 SOM
Kathleen Murray	596-3600	kmurray@shrinenet.org	Shriner's Hospital	Shriners Hospitals for Children
Shane Lloyd	581-8793	shane.lloyd@hci.utah.edu	Radiation Oncology	Huntsman Cancer Hospital
Mary Murray	587-3905	mary.murray@hsc.utah.edu	Pediatric (DEXA)	Center for Clinical and Translational Science (CCTSC)
Ryan O'Hara	581-7553	ryan.ohara@hsc.utah.edu	Radiology, Interventional	Radiology, 1A 71 SOM
Matthew Peterson	581-3834	c.matthew.peterson@hsc.utah.edu	OB/GYN (DEXA)	2B200 SOM
Matthew Poppe	581-8793	matthew.poppe@hci.utah.edu	Radiation Oncology	Huntsman Cancer Hospital
Chris Davidson	(801) 584-1207	Hans.davidson@va.gov	VAMC	George E. Wahlen VA Medical Center
Dennis Shrieve	581-8793	dennis.shrieve@hci.utah.edu	Radiation Oncology	Huntsman Cancer Hospital
Edwin Stevens	581-8699	sstevens@hsc.utah.edu	Hospital General Radiology	Radiology, 1A 71 SOM
Alan Stotts	662-5622	alan.stotts@hsc.utah.edu	Orthopedics	PCMC Ste 4550
Jonathan Tward	581-8793	jonathan.tward@hci.utah.edu	Radiation Oncology	Huntsman Cancer Hospital
William Winters	662-1900	william.Winters@imail.org	Primary Children Medical Center	PCMC Dept Medical Imaging

5. Examples of Radiation Risk Language:

a. For doses up to 1 rem:

This research study involves (*list nonstandard of care scans*). These scans are not standard of care and you are receiving them only because you are enrolled in this research study. These procedures will expose you to radiation. The risk from this radiation exposure is considered to be small and comparable to other every day risks. To give you an idea of how much radiation you will receive, we will compare this radiation to the radiation that you receive from natural sources. Everyone receives a small amount of unavoidable radiation every day. Some of this radiation comes from space while some comes from radiation that is naturally occurring in water, soil, rocks and minerals found in plants and animals. The excess radiation that you will be exposed to in this research study is equivalent to about (*x days; 1 mrem = 1 day*) days of natural background radiation. This amount does not include any radiation exposures that you may receive from other types of tests.

b. For doses from 1-5 rem:

This research study involves exposure to radiation from (*list nonstandard of care scans*). These scans are being done for the research study and are not considered part of your standard care. The risk from this radiation exposure is considered to be small and comparable to other every day risks. This amount does not include any radiation exposures that you may receive from other types of tests.

ADD APPROPRIATE TABLE FROM BELOW

c. For doses greater than 5 rem:

This research study involves exposure to radiation from (*list nonstandard of care scans*). These scans are being done for the research study and are not considered part of your standard care. This does not include any radiation exposures that you may receive from other types of tests. A potential health problem caused by radiation exposure is a very small chance of cancer later in life. The excess cancer risk from this radiation is estimated to be about 1 in (XXX). Approximately 45 people out of 100 will develop cancer sometime in their life.

ADD APPROPRIATE TABLE FROM BELOW

d. For pediatric studies:

Choose the appropriate paragraph above but add these sentences (the >5 rem language already incorporates the idea of the first sentence): *Radiation exposure has the potential to lead to cancer later in life. The exact risk is not known, but the risk is believed to be 2-5 times higher in children than in adults exposed to the same radiation dose.*

e. For one type of scan:

If you are enrolled in this study, the excess radiation you will receive is about the same as a uniform whole-body dose of:	The amount of radiation that is considered safe for a radiation worker (e.g. doctor, nurse, scientist, etc.) to receive in one year:
rem	5 rem

**A “rem” is a unit of radiation dose.

f. For multiple scan types:

If you are enrolled in this study, the excess radiation you will receive is about the same as a uniform whole-body dose of:	The amount of radiation that is considered safe for a radiation worker (e.g. doctor, nurse, scientist, etc.) to receive in one year:
** rem for the ** scan + ** rem for the ** scan = about ** total rem	5 rem

**A “rem” is a unit of radiation dose.