

# Radiation Safety

Any protocol that involves the use of experimental radiotherapy at University of Washington (UW)\* or Seattle Cancer Care Alliance (SCCA) licensed facilities requires review by the Human Subjects Radiation Approval Committee (HSRAC). *IRB reciprocity agreements do not apply to the use of radiation and radioactive materials when used at a UW site.*

The HSRAC may issue Approvals for certain uses of radiation in human subjects. All investigators planning to do research on humans using any type of radiation (x-rays, nuclear medicine, radiation therapy, etc.) must apply for Approval to Use Radiation in Human Subjects.

\*UW-licensed facilities include the University of Washington Medical Center and Harborview Medical Center

## ▶ Radiation and Pregnancy

In the first trimester of development, the unborn fetus shows greater sensitivity to the effects of radiation. For this reason, the HSRAC strongly discourages (and usually does not allow) the entry of potentially pregnant persons into research protocols that involve exposure to radiation. To ensure non-pregnancy, female subjects of childbearing age should be given a serum or urine pregnancy test prior to exposure to any radiation.

The HSRAC understands that most clinical protocols do require pregnancy screening at some point prior to the initiation of treatment. Often, however, the protocol flow charts show that a pregnancy test is not scheduled until after other screening exams (some involving radiation exposure, such as chest x-rays and CT scans) have been completed. *The HSRAC considers that it is the responsibility of the investigator and his/her research team to ensure proper pregnancy testing prior to any screening exams that may involve exposure to radiation*

# Review Requirements

Any protocol that involves the use of experimental radiotherapy at University of Washington (UW)\* or Seattle Cancer Care Alliance (SCCA) licensed facilities requires review by the Human Subjects Radiation Approval Committee (HSRAC). *IRB reciprocity agreements do not apply to the use of radiation and radioactive materials when used at a UW site.*

\*UW-licensed facilities include the University of Washington Medical Center and Harborview Medical Center

HSRAC review is required in the following circumstances:

- HSRAC review is required for any radiation procedures performed during the study, either standard or experimental, that are required *solely for research purposes*. The reasonably foreseeable risks of these procedures must be described in the consent form.
- HSRAC review is required if the protocol design *dictates* the procedure provided to the subject. The reasonably foreseeable risks associated with that procedure must be described in the consent form.
- HSRAC review is required if the protocol design *restricts* the ability of the subject or the subject's care provider to choose the procedure or treatment (type or frequency) that the subject will receive. The reasonably foreseeable risks of these procedures must be described in the consent form.

## ▶ [Risks of Harm from Standard Care at the Human Subjects Division Web site](#)

## ▶ [Examples of Types of Clinical Trials That May Need Radiation Safety Review](#)

# Renewals

## RADIATION SAFETY RENEWALS

If your protocol is approved by the HSRAC, your Radiation Safety approval expires when your IRB approval expires. As long as enrolled subjects will be undergoing research radiographic procedures, you will need to keep your HSRAC approval current. The annual renewal application for both the HSRAC and the IRB should be submitted at the same time.

If renewal is required, use [HSRAC Form 2](#) entitled Renewal Application for Continued Approval to Use Radiation with Human Research Subjects. HSRAC renewal is not required for long-term follow-up or for data analysis.

# The Human Subjects Radiation Approval Committee

- The Human Subjects Radiation Approval Committee (HSRAC) is composed of 2 staff members, 1 is an employee of UW, the other is employed by SCCA. The remaining membership of the HSRAC is composed of volunteer representatives from the 2 radiation safety committees, UW and SCCA.
- Most studies involving the use of radiation in human subjects can be reviewed in an expedited manner, meaning that review and approval will be completed by 1 staff member and 1 volunteer HSRAC member. The staff member will be the one who is most appropriate for the location of the research. The volunteer HSRAC committee member reviewing the application will be chosen as appropriate to the study and committee membership.
- If studies cannot be appropriately reviewed expeditiously, they will be reviewed by the entire HSRAC, through a virtual meeting. A review summary will be prepared by the appropriate staff member, and then the entire study will be distributed electronically to every HSRAC member. Discussion and voting will occur by email.
- Only in very rare instances is it predicted that a study would need to proceed to the appropriate Radiation Safety Committee (RSC).
- The target for turn-around time, from receipt to final approval, is 2 weeks. It should be understood that some studies, e.g., those that need complex dosimetry calculations, may take much longer to review. The 2-week target will also not apply to applications that are considered to be inadequate upon receipt by the HSRAC.

# Sample Consent Form Language for Study-Related Radiation Exposure

**IMPORTANT NOTE:** The following guide contains risk statements that are based on your subject population and the level of exposure that can be expected *during one year of the study*. To view the risk statements, choose the study-appropriate link below.

# General Population

**Very low level of exposure (<0.1 mSv during one year of the study)**

## X-Rays

### Chest X-Ray (PA, one view only; patient is ambulatory, x-ray done in Radiology)

There are some risks from the chest x-ray used during your screening process. This x-ray will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from your x-ray will be about 0.02 mSv. The risk of harm from this amount of radiation is very low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.1]

### Head X-Rays (AP and lateral)

There are some risks from the x-rays of your head taken during your screening and follow-up appointments. These x-rays will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each set of x-rays (2 views) will be about 0.08 mSv. The risk of harm from this amount of radiation is very low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.5]

### X-Rays of Extremities (e.g., foot, arm, ankle, shoulder, leg, hand, wrist)

There are some risks from the x-rays of your \_\_\_\_\_ taken during your screening and follow-up appointments. These x-rays will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each set of x-rays (2 views) will be less than 0.1 mSv. The risk of harm from this amount of radiation is very low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.2]

## Dental X-Rays

### Dental X-Rays (Bitewing, periapical, and panoramic views, variable number and frequency)

There are some risks from the dental x-rays used during your treatment and follow-up. These x-rays will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The total radiation dose to your whole body from all of your x-rays will be less than 0.1 mSv. The risk of harm from this amount of radiation is very low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.2]

### Panoramic X-Ray (0.5-1.5 mSv skin entrance)

There are some risks from the x-ray taken during your exam. This x-ray will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and from the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from your x-ray will be less than 0.01 mSv. The risk of harm from this amount of radiation is very low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.0]

### Cephalometric X-Ray (0.5 mSv skin entrance)

There are some risks from the x-ray of your head taken during your exam. This x-ray will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from your x-ray will be less than 0.01 mSv. The risk of harm from this amount of radiation is very low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.0]

## DEXA

### DEXA (dual-energy x-ray absorptiometry, bone density measurements, hip, spine, and wrist)

There are some risks from the DEXA scans used to determine your bone density. These scans will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each of these scans will be about as follows:

- Hip: 0.03 mSv
- Spine: 0.04 mSv
- Wrist: 0.0001 mSv

The risk of harm from this amount of radiation is very low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.8]

### DEXA (single dual-energy x-ray absorptiometry, body composition measurement)

There are some risks from the DEXA scan you will undergo during this study. This scan will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from your DEXA scan will be about 0.001 mSv. The risk of harm from this amount of radiation is very low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.6]

### DEXA (multiple dual-energy x-ray absorptiometry, body composition measurement)

There are some risks from the DEXA scans you will undergo during this study. These scans will expose you to radiation. If you live in the US,

you receive about 3 millisieverts of radiation each year. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each of your DEXA scans will be about 0.001 mSv. The risk of harm from this amount of radiation is very low. If you have more procedures that expose you to radiation, this risk will go up.

*If these procedures are conducted at the General Clinical Research Center, you may want to add the following paragraph, if the extra scans are being conducted as part of the GCRC procedures:*

At some point during the study, we might ask you to have an extra scan. We will use the extra scan to make sure that we are doing the scans right. Having the additional scan is up to you. Not having the second scan will not impact your participation in the research study. Please ask the staff if you have any questions or if you do not understand why we are asking you to have an additional scan. [Grade 6.0]

#### ▶ **DEXA (dual-energy x-ray absorptiometry, bone density and body composition measurements)**

There are some risks from the DEXA scans you will undergo during this study. These scans will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each of these scans will be about as follows:

- Hip: 0.03 mSv
- Spine: 0.04 mSv
- Wrist: 0.0001 mSv
- Whole-body: 0.001 mSv

The risk of harm from this amount of radiation is very low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 7.5]

#### ▶ **Nuclear Medicine - GFR Scan**

I-125 Iothalamate Glomerular Filtration-Rate (GFR) Scan

There are some risks from the GFR scan you will undergo in the Nuclear Medicine Clinic. This scan will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from your GFR scan will be less than 0.01 mSv. The risk of harm from this amount of radiation is very low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.3]

### **Low Level of Exposure (0.1-10 mSv during one year of the study)**

#### ▶ **X-rays**

##### ▶ **Chest X-Rays (PA and lateral views; patient is ambulatory, x-rays done in Radiology)**

There are some risks from the chest x-rays (2 views) used during your screening process. These x-rays will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each set of x-rays will be about 0.1 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 5.9]

##### ▶ **Chest X-Rays (AP, one view only; patient is non-ambulatory, x-ray done in the Emergency Room, in the ICU, in the patient's room, etc.)**

There are some risks from the chest x-ray taken during your initial exam. This x-ray will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from your x-ray will be about 0.1 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.1]

##### ▶ **Chest X-Rays (AP only, variable number for treatment of ARDS patients)**

There are some risks from the chest x-rays used to monitor your status. These x-rays will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each of your x-rays will be about 0.1 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 5.9]

##### ▶ **Chest X-Rays and X-Rays of Extremities (hands and feet)**

There are some risks from the x-rays taken during your screening and follow-up appointments. These x-rays will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each set of chest x-rays will be about 0.1 mSv. The radiation dose to your whole body from each set of x-rays of your hands and feet will be less than 0.01 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.4]

##### ▶ **X-Rays of the Neck (variable number, more than 1)**

There are some risks from the x-rays of your neck taken to help with your diagnosis and to follow your treatment. These x-rays will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each x-ray of your neck will be about 0.2 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.2]

##### ▶ **X-Rays of the Neck (each set includes 6 views: AP, lateral, flexion-extension, and lateral bending)**

There are some risks from the x-rays of your neck taken to help with your diagnosis and to follow your recovery. These x-rays will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each set of x-rays of your neck (6 views) will be about 1 mSv. The risk of harm from this amount of radiation is low. If you have more

procedures that expose you to radiation, this risk will go up. [Grade 6.4]

#### ▶ **X-Rays of the Torso (spine, shoulders, abdomen, hips, pelvis)**

There are some risks from the x-rays of your \_\_\_\_\_ taken during your screening and follow-up appointments. These x-rays will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each set of x-rays (\_\_\_ views) will be about \_\_\_\_ mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.1]

#### ▶ **X-Rays of the Hip and Arm or Leg**

There are some risks from the x-rays used to diagnose your injury. These x-rays will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each set of x-rays of your hip (2 views) will be about 1.4 mSv. The dose from an x-ray of your arm or your leg will be about 0.001 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 5.9]

#### ▶ **Mammography**

(screening mammogram at study entry and/or for monitoring during a study)

There are some risks from your mammograms. These mammograms use x-rays and will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each mammogram (2-4 views) will be about 0.4 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.5]

#### ▶ **Dental X-Rays**

Bitewing, Periapical, and Panoramic Views (variable number and frequency)

There are some risks from the dental x-rays used during your treatment and follow-up. These x-rays will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The total radiation dose to your whole body from all of your x-rays will be about 0.15 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.3]

#### ▶ **DEXA**

DEXA (repeated dual-energy x-ray absorptiometry, bone density and body composition measurements)

There are some risks from the DEXA scans you will undergo during this study. These scans will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each of these scans will be about as follows:

- Hip: 0.03 mSv
- Spine: 0.04 mSv
- Wrist: 0.0001 mSv
- Whole-body: 0.001 mSv

The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 7.5]

#### ▶ **CT Scans**

##### ▶ **Body Composition (single-slice abdominal CT scan)**

There are some risks from your abdominal CT scan. This scan will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The total radiation dose to your whole body from this scan will be about 0.3 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.1]

##### ▶ **CT Scan (one scan of the head)**

There are some risks from the CT scan of your head. This scan will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The total radiation dose to your whole body from this scan will be about 2 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 5.4]

##### ▶ **CT Scans (more than 1 scan of the head, no more than 5 scans in one year)**

There are some risks from the CT scans of your head. These scans will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The total radiation dose to your whole body from each scan will be about 2 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 5.4]

##### ▶ **Head CT Scan (treatment planning for a radiotherapy study)**

There are some risks from the head CT scan used to plan your treatment. This scan will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each head CT scan will be about 2 mSv. The risk of harm from this amount of radiation is low. It is much smaller than the risks of your treatment. You may need to have other x-rays or scans for your care. Your doctors will explain the risks of the other x-rays or scans. [Grade 4.6]

##### ▶ **CT Scans of Brain (treatment planning, possible monitoring of health/tumor status)**

There are some risks from the CT scans used to plan your treatment and that may be used to monitor your health and tumor status. These scans will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each CT scan of your brain will be about 2 mSv. The risk of harm from this amount of radiation is low. It is much smaller than the risks of your treatment. You may need to have other x-rays or scans for your care. Your doctors will explain the risks of the other x-rays or scans. [Grade 5.0]

### ▶ **CT Scans (head and neck)**

There are some risks from the CT scan of your head and neck. This scan will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The total radiation dose to your whole body from your scan will be about 5 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 5.4]

### ▶ **CT Scan (one scan of the thymus)**

There are some risks from the CT scan of your thymus. This scan will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The total radiation dose to your whole body from this scan will be about 6 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 5.6]

### ▶ **CT Scans (high resolution for coronary valve imaging, and for scoring coronary calcification)**

There are some risks from the CT scans taken to check the condition of your valve and heart. These scans will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from your CT scans will be about 5 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 5.9]

### ▶ **CT Scans (single high resolution chest CT)**

There are some risks from the HRCT scans used to monitor your health during your treatment. This scan will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each of your HRCT scans will be about 9 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.0]

## ▶ **Catheter Placement**

(PA chest x-ray and fluoroscopy, chest and upper arm, 1-2 minutes)

There are some risks from the placement of your catheter. This placement will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from your catheter placement will be about 0.9 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.7]

## ▶ **Pacemaker Implant**

Chest X-Rays and Fluoroscopy (dual lead pacemaker implant, chest, 30 min)

There are some risks from the x-rays required for the implantation of your pacemaker. These x-rays will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each of these will be about as follows:

- Chest x-rays (2 views): 0.1 mSv
- Fluoroscopy: 6 mSv

The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.2]

## ▶ **Lumbar Puncture for Spinal Tap**

Lumbar Puncture for Spinal Tap (fluoroscopic guidance)

There are some risks from the x-rays required during your lumbar puncture. These x-rays will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. If you are a man, the radiation dose to your whole body during your lumbar puncture will be about 1.3 mSv. If you are a woman, your exposure will be about 2.8 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.4]

## ▶ **Right Heart Catheterization**

There are some risks from the x-rays required during your heart catheterization. These x-rays will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body during your heart catheterization will be about 2 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.8]

## ▶ **Peripheral Angiography**

Peripheral Angiography (fluoroscopy of the lower leg)

There are some risks from the diagnostic and follow-up angiograms required for your treatment. These exams will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body during your exams will be about 1.3 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.9]

## ▶ **Diagnostic Cholangiography**

Diagnostic Cholangiography (Endoscopic retrograde cholangiopancreatography, or ERCP)

There are some risks if x-rays are used during your cholangiography. These x-rays will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body during your cholangiogram will be about 4 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.4]

## ▶ **PET Scans**

### ▶ **PET Scan (one F-18-FDG scan)**

There are some risks from the PET scan used to monitor your response to treatment. This scan will expose you to radiation. If you live in the

US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from your PET scan will be about 6 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 5.8]

▶ **PET Scans (no more than two optional F-18-FDG scans in one year, primary review by CHRMC IRB)**

There are some risks from the optional research PET scans used to monitor your tumor status and the results of your treatment. These scans will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” This is the same amount of radiation as that from 30 sets of chest x-rays. It is also the same amount that you would get in 100 airplane trips from New York to Seattle. A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each of your PET scans will be about 6 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.3]

▶ **PET or PET/CT Scans (research only, chest is region of interest, F-18 FLT & F-18 FDG, possible CT attenuation)**

There are some risks from the research PET scans used to image your tumors. These scans will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each of your PET scans will range from about 3.4 to 7.4 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.0]

▶ **PET Scans (research only, one 0-15-water and one 0-15-oxygen scan of the brain)**

There are some risks from the research PET scans used to see how much oxygen is reaching your brain. These scans will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and from the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each set of your PET scans will be about 4.4 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 5.9]

▶ **Radiolabeled Platelets**

Radiolabeled Platelets (20 µCi Cr-51, 15 µCi In-111)

There are some risks from the radioactive substances mixed with your platelets. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used for measuring doses of radiation. The radiation dose to your whole body from your Cr-51 transfusion will be about 0.11 mSv. The dose from each of your In-111 transfusions will be about 0.17 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 7.1]

▶ **MUGA Scan**

MUGA Scan (multiple gated acquisition, gated blood pool, radionuclide ventriculography, is used for determination of the left ventricle ejection fraction, or LVEF)

There are some risks from the MUGA scan (if required) used to monitor the status of your heart. This scan will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from your MUGA scan will be about 8 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.2]

▶ **Miscellaneous combination of scans**

▶ **Spine X-Rays and DEXA (repeated DEXA, bone density and body composition measurements)**

There are some risks from the x-rays and DEXA scans you will undergo during this study. These scans will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each of these x-rays or scans will be about follows:

- Lateral-lumbar spine x-ray: 1 mSv
- Lateral-thoracic spine x-ray: 1.5 mSv
- DEXA scan of hip: 0.03 mSv
- DEXA scan of spine: 0.04 mSv
- DEXA scan of wrist: 0.0001 mSv
- DEXA scan of whole-body: 0.001 mSv

The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 5.9]

▶ **X-Rays and Bone Scan (metastatic cancer, x-rays of spine and hip, bone scan)**

There are some risks from the bone scan and the x-rays of your spine and hips taken to check for the extent of your bone disease. These scans and x-rays will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from your bone scan will be about 4 mSv. Your dose from each set of x-rays (7 views) will be about 4 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 5.3]

▶ **Chest X-Rays and CT Scans (one set of chest films and chest CT to confirm eligibility & diagnosis)**

There are some risks from the chest x-rays and CT scans used to confirm your eligibility and diagnosis. These x-rays and scans will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each of these x-rays or scans will be about as follows:

- Chest x-rays (2 views): 0.1 mSv
- CT scan of the chest: 7 mSv

The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 5.9]

#### ▶ **Chest X-Rays and Fluoroscopy (dual-lead pacemaker implant, chest, 30 min)**

There are some risks from the x-rays required for the implantation of your pacemaker. These x-rays will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each of these will be about as follows:

- Chest x-rays (2 views): 0.1 mSv
- Fluoroscopy: 5.8 mSv

The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.3]

#### ▶ **X-Rays and CT Scan of the Neck (each set of x-rays includes 6 views: AP, lateral, flexion-extension, and lateral bending)**

There are some risks from the CT scan and the x-rays of your neck. They will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each set of x-rays of your neck (6 views) will be about 1 mSv. The dose from your CT scan can vary from about 1.5 to 5.5 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 5.5]

#### ▶ **Head CT Scan and Lumbar Puncture for Spinal Tap (fluoroscopic guidance)**

The CT scan of your head, if you have one, will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The total radiation dose to your whole body from this scan will be about 2 mSv. If you need to have x-rays to guide your lumbar puncture, these will also expose you to radiation. If you are a man, the radiation dose to your whole body during your lumbar puncture will be about 1.3 mSv. If you are a woman, your exposure will be about 2.8 mSv. The risk of harm from this amount of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 6.6]

#### ▶ **CT Scans and PET Scans (research only, F-18 FDG PET, GE Advance scanner only)**

There are some risks from the CT and PET scans that you will undergo in this research study. These scans will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure doses of radiation. The radiation dose to your whole body from each of these scans will be about as follows:

- F-18 FDG PET scan: 6 mSv
- Orbital CT scan: 0.6 mSv

The risk of harm from these amounts of radiation is low. If you have more procedures that expose you to radiation, this risk will go up. [Grade 5.9]

### **High level of Exposure (>10 mSv during one year of the study)**

#### ▶ **CT scans only**

There are some risks from the CT scan used to determine the extent of your injuries. This scan will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure radiation dose. Your CT scan will include your head, your entire spine, and your torso. The radiation dose to your whole body from your CT scan will be about 12 to 43 mSv. The usual lifetime risk of getting cancer is 42%. For every 10 mSv you receive, your risk will increase 0.1%. If you have more procedures that expose you to radiation, your risk will go up. You may need to have other x-rays or scans for your care. Your doctors will explain the risks of the other x-rays or scans. [Grade 5.6]

#### ▶ **Cerebral angiography**

There are some risks from the angiogram and angioplasty required for your treatment. These procedures will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure radiation dose. The radiation dose to your whole body during your exam and treatment will be about 7 to 19 mSv. The usual lifetime risk of getting cancer is 42%. For every 10 mSv you receive, your risk will increase 0.1%. If you have more procedures that expose you to radiation, your risk will go up. You may need to have other x-rays or scans for your care. Your doctors will explain the risks of the other x-rays or scans. [Grade 6.3]

#### ▶ **CT angiography**

CT Angiography (research only, cardiology)

There are some risks from the diagnostic CT scan required for this research study. This scan will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure radiation dose. The radiation dose to your whole body from your CT scan will be about 4 to 17 mSv. The usual lifetime risk of getting cancer is 42%. For every 10 mSv you receive, your risk will increase 0.1%. If you have more procedures that expose you to radiation, your risk will go up. You may need to have other x-rays or scans for your care. Your doctors will explain the risks of the other x-rays or scans. [Grade 5.8]

#### ▶ **PET Scans**

F-18 FDG PET/CT Scans of Arteries (low dose attenuation, neck chest only, limited field of view)

There are some risks from the research PET/CT scans that will be used to look at the condition of your arteries. These scans will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure radiation dose. The radiation dose to your whole body from each of your PET/CT scans will be about 8.2 to 9.1 mSv. The usual lifetime risk of getting cancer is 42%. For every 10 mSv you receive, your risk will increase 0.1%. If you have more procedures that expose you to radiation, your risk will go up. You may need to have other x-rays or scans for your care. Your doctors will explain the risks

of the other x-rays or scans. [Grade 5.9]

### ▶ **Combination of scans and angiography**

Combination of Scans (conducted primarily in Cardiology)

There are some risks from the x-rays and scans used to diagnose your health and your heart condition and for your treatment. These scans and x-rays will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure radiation dose. The radiation dose to your whole body from each of your procedures will be about as follows:

- Chest x-rays (2 views): 0.1 mSv
- CT scan of the brain: 2 mSv
- CT angiography: 15-30 mSv
- Heart catheterization: 2 mSv
- Diagnostic angiography: 4 mSv
- Interventional angiography: 10 mSv

The usual lifetime risk of getting cancer is 42%. For every 10 mSv you receive, your risk will increase 0.1%. If you have more procedures that expose you to radiation, your risk will go up. You may need to have other x-rays or scans for your care. Your doctors will explain the risks of the other x-rays or scans. Exposure during treatment may sometimes be much greater. Much of the radiation will be to local areas of the skin. If procedures take longer than expected, it is possible that injury to the skin can occur. Symptoms of injury to the skin may take time to develop. If you notice hair loss or redness of the skin, inform your doctor or a member of the research team at once. [Grade 7.3]

## Subjects Being Treated for Cancer

 **High Level of Exposure (total radiation exposure during one year of the study >10 mSv)**

 **When all scans are required by the research protocol**

- ▶ **CT Scans (chest, abdomen, pelvis)**
- ▶ **F-18 FDG PET Scans (repeated at least 3 times during the study)**
- ▶ **Combination of Scans**

**When some (not all) scans are required by the research protocol**

- ▶ **CT Scans (research only, chest, abdomen, pelvis)**
- ▶ **PET Scans**
- ▶ **Combination of Scans**

## Subjects Undergoing Radiotherapy

### ▶ **CT Scans of Brain (treatment planning, possible monitoring of health/tumor status)**

There are some risks from the CT scans used to plan your treatment and that may possibly be used to watch your health and tumor status. These scans will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure radiation dose. The radiation dose to your whole body from each CT scan of your brain will be about 2 mSv. The risk of harm from this amount of radiation is low. It is much smaller than the risks of your treatment. You may need to have other x-rays or scans for your care. Your doctors will explain the risks of the other x-rays or scans. [Grade 4.9]

### ▶ **CT Scans (head/neck/chest, monitor health/tumor status and for treatment planning)**

There are some risks from the CT scans used to watch your health and tumor status and to plan your treatment. These scans will expose you to radiation. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure radiation dose. The radiation dose to your whole body from each of your scans will be about as follows:

- CT scan of the head and neck: 5 mSv
- CT scan of the chest: 7 mSv

The risk of harm from this amount of radiation is much smaller than the risks of your treatment. You may need to have other x-rays or scans for your care. Your doctors will explain the risks of the other x-rays or scans. [Grade 4.6]

### ▶ **General Statement for Clinical Scans Conducted During a Radiotherapy Protocol**

There are some risks from the scans used to watch your health and tumor status and to plan your treatment. These scans will expose you to radiation. The radiation dose to your whole body from each of your scans will be much lower than the dose from your radiotherapy. The risk of harm from the extra radiation from your scans is low. It is much smaller than the risks of your treatment. [Grade 5.5]

## Subjects Undergoing Fluoroscopy

Possible High Risk from Fluoroscopy Exposure (total radiation exposure during one year of the study >10 mSv)

- ▶ **Coronary Angiography (randomized to PCI or chest x-ray and surgery)**
- ▶ **Coronary Angiography and Intervention**

- ▶ **Fluoroscopy (dual-lead pacemaker implant, chest, 30 min)**
- ▶ **Fluoroscopy (general risk statement to be added to the primary risk statement for all studies with potential for high fluoroscopy exposure, >750 mSv to skin)**

## Possible Pregnancy

(this language is to be used in the Procedures section of the consent form)

(If *any* radiographic procedures are being used)

The radiation from x-rays and scans may be harmful to a fetus. If you are a woman who could become pregnant, you must have a pregnancy test done before your x-rays and/or scans. If you are pregnant, you may not take part in this study. If you will be sexually active, you must use a method to prevent pregnancy during this study. This applies to men and women. [Grade 5.6]

(If *radionuclides* are being used)

The radiation from Cr-51 or In-111 may be harmful to a fetus. If you are a woman who could become pregnant, you must have a pregnancy test done before your transfusions. If you are pregnant, you may not take part in this study. If you will be sexually active, you must use a method to prevent pregnancy during this study. This applies to men and women. [Grade 6.3]

## Process Flow Diagram

Would you like to know more about what happens with the Radiation Safety Review at a glance?

- **Radiation Safety Review Process**  



The document icon will take you to the printable version of the process diagram.



The globe icon will take you to an interactive version of the process diagram.

## Forms, Documents & Policies

The completed radiation safety package for a new study should include:

- **Protocol (or Literature Review )**
- **Consent Form(s)**
- **IRB Application (UW-IRB, CC-IRB, WIRB, or other as appropriate)**
- **Human Subjects Radiation Approval Committee (HSRAC) Application**

For **annual renewals**, use the HSRAC 2 form, entitled Renewal Application for Continued Approval to Use Radiation with Human Research Subjects.

Submission of hard-copy documents through campus mail is preferred. Electronic submission of all documents will be accepted, view [contacts](#) for complete contact information. *If documents are submitted electronically, each document name must start with the last name of the Faculty Principal Investigator.*

## Best Practices for Completing the HSRAC Application Form

- Submit the HSRAC application and the appropriate (UW/WIRB/Cancer Consortium) IRB application concurrently, not consecutively. The HSRAC Form 1 (or Form 2 for renewals) should be submitted to the [UW Radiation Safety Office](#). The IRB application and consent form submitted with the HSRAC application can be "pending" review, rather than approved. *Note: When WIRB or the CC-IRB is the IRB of record, be sure to complete your UW/WIRB or UW/CC-IRB cover sheet. The UW Human Subjects Division will forward an approved copy of the UW/WIRB or UW/CC-IRB cover sheet to the HSRAC.*
- Include all of the requested information. Commonly omitted items include the PI's credentials, e.g., "MD, Board Certified," and/or his/her date of birth (DOB).
- Use the same study title that you used on the IRB application.
- Include the consent form, either *pending* review or *approved* by the IRB.
- When writing the consent form, explain all procedures that involve the use of radiation and the risks associated with such use. Distinguish between radiographic procedures that will be required for clinical care, vs. those that will be required for research purposes. The HSRAC staff will help you prepare the risk statement according to current guidelines. Click here for examples of [Consent Form Radiation Risk Statements](#). Use these risk statements as guidelines only -- they are revised regularly.
- Obtain the signature of the department chair, dean, or director. This individual shall acknowledge that the proposed activity has received intramural review and approval of the feasibility and scientific merit of the proposal and the qualifications of the investigators.

Studies qualified for expedited review include:

- Common radiation therapy on adult patients.
- Standard clinical procedures associated with the care of adult patients.
- "Generic studies" on adult patients done by an investigator when similar studies have been previously approved by the UW RSC, SCCA RSC, or HSRAC.
- Annual review of previously approved studies without changes.

Studies that usually require full HSRAC review include:

- Studies involving children (subjects <18 years old).
- Studies involving normal subjects.
- Studies involving nonstandard procedures.

Call the HSRAC for advice about the review of protocol amendments. Methods for submission of amendments will vary, depending upon the complexity of the amendment.

# HSRAC Submission Checklist

PI \_\_\_\_\_

Study \_\_\_\_\_

- Determine if HSRAC review is appropriate for your trial. Read through this section and/or contact the Radiation Safety Office for further information to help you make this determination.  
Date \_\_\_\_/\_\_\_\_/\_\_\_\_
- Complete all applicable sections of the Human Subjects Radiation Approval Committee (HSRAC) Form.  
Date \_\_\_\_/\_\_\_\_/\_\_\_\_
- Submit the following documents to the HSRAC Program Coordinator, Box 354400  
Date \_\_\_\_/\_\_\_\_/\_\_\_\_
  - HSRAC Form
  - Protocol (or Literature Review)
  - Consent Forms
  - IRB Application (UW-IRB, CC-IRB, WIRB)
- Respond to HSRAC staff questions (before your application is reviewed by the Committee HSRAC staff may have some questions about it).  
Date \_\_\_\_/\_\_\_\_/\_\_\_\_
- Respond to HSRAC questions (if any).  
Date \_\_\_\_/\_\_\_\_/\_\_\_\_
- Receive HSRAC approval.  
Date \_\_\_\_/\_\_\_\_/\_\_\_\_



[Printable Checklist](#)