

**REVISED RADITION RISK WORDING FOR HUMAN RESEARCH
STUDIES INVOLVING IONIZING RADIATION
March 2019**

Dose Level	Dose Levels		Examples of Procedures
	Annual Effective Dose (E) mSv	mrem	
1	$E \leq 5$	$E \leq 500$	Multiple DXA scans; extremity x-rays; chest x-rays; < 3 x-rays of the abdomen, spine or pelvis; single CT of the head or neck.
2	$5 < E \leq 50$	$500 < E \leq 5,000$	Fluoroscopic procedures; 1-3 CT scans of the chest, abdomen and/or pelvis; 1-4 nuclear medicine scans; 1-3 PET/CT scans.
3	$50 < E \leq 100$	$5,000 < E \leq 10,000$	Complicated fluoroscopy procedures; >3 CT scans; >3 PET/CT scans.
4	$E > 100$	$E > 10,000$	Multiple CT or PET/CT scans (5 or more)
5	N/A	N/A	Radiation therapy.

The following language should be included in all informed consent statements involving ionizing radiation:

“If you have had radiation (like x-rays, CT or radiation therapy) before or you participated in a different study where you were exposed to radiation, please tell us now. We want to make certain that the probability of harm from the amount of radiation you will be exposed to in this study continues to be low when combined with the radiation you have received within the past year. If you are pregnant, you cannot take part in this research study. If you are able to have a baby, are not pregnant and wish to take part in this study, you will need to take a pregnancy test prior to enrollment. If you get pregnant while taking part in this study, or think you are pregnant, please tell _____ right away. You may not be able to continue this study if you become pregnant.”

Dose Level Wording

Dose Level 1: ($E \leq 500$ mrem)

The (**insert type of scan(s), e.g., PET, CT**) that you get in this study will expose you to low amounts of radiation. Every day, people are exposed to low levels of radiation that come from the natural environment and man-made radiation sources around them. This type of radiation is called “background radiation.” The amount of radiation you will get from the scans in this study is approximately, or less than, 1 years’ worth of background radiation. The probability of harm from participating in this study is low compared to other everyday risks. Certain diseases or conditions may affect your sensitivity to radiation. For more detailed information on the risks of radiation or if you wish to have a more detailed dose estimate, please ask your study doctor.

Dose Level 2: (500 < E ≤ 5,000 mrem)

The (**insert type of scan(s), e.g., PET, CT**) that you get in this study will expose you to radiation. Every day, people are exposed to low levels of radiation that come from the natural environment and man-made radiation sources around them. This type of radiation is called “background radiation.” The amount of radiation you will get from the scans in this study is approximately (**insert appropriate number 1-10**) years’ worth of background radiation. Most of the time, this amount of extra radiation is not harmful to you. However, scientists believe that being exposed to too much radiation can cause harmful side effects. Certain diseases or conditions may affect your sensitivity to radiation. For more detailed information on the risks of radiation or if you wish to have a more detailed dose estimate, please ask your study doctor.

Dose Level 3: (5000 < E ≤ 10,000 mrem)

The (**insert type of scan(s), e.g., PET, CT**) that you get in this study will expose you to radiation. Every day, people are exposed to low levels of radiation that come from the natural environment and man-made radiation sources around them. This type of radiation is called “background radiation.” The amount of radiation you will get from the scans in this study is approximately (**insert appropriate number 10-20**) years’ worth of background radiation. Scientists believe that being exposed to too much radiation can cause harmful side effects. This could include getting a cancer. We estimate that this could happen in about 1 out of every 1000 people who get a large amount of extra radiation. Certain diseases or conditions may affect your sensitivity to radiation. For more detailed information on the risks of radiation or if you wish to have a more detailed dose estimate, please ask your study doctor.

Dose Level 4: (E > 10,000 mrem)

The (**insert type of scan(s), e.g., PET, CT**) that you get in this study will expose you to significant amounts of radiation. Every day, people are exposed to low levels of radiation that come from the natural environment and man-made radiation sources around them. This type of radiation is called “background radiation.” The amount of radiation you will get from scans in this study is approximately more than 20 years’ worth of background radiation. Scientists believe that being exposed to this amount of radiation can cause an increase in your risk of getting cancer and/or leukemia. We estimate that this could happen in about 1 out of every 1000 people who get a large amount of extra radiation. Certain diseases or conditions may affect your sensitivity to radiation. For more detailed information on the risks of radiation or if you wish to have a more detailed dose estimate, please ask your study doctor.

Dose Level 5: (Therapy)

The radiation treatment that you get in this study will expose you to significant amounts of radiation. This radiation is intended to damage and kill certain cells and tissues. As a part of this process, healthy cells may also be damaged. Scientists believe that being exposed to this amount of radiation can cause an increase in your risk of getting cancer and/or leukemia. However, it may be 5-20 years before any effect occurs. Certain diseases or conditions may affect your sensitivity to radiation. For more detailed information on the risks of radiation or if you wish to have a more detailed dose estimate, please ask your study doctor. A table of possible side effects is provided below.

COMMON, SOME MAY BE SERIOUS

In 100 people receiving radiation therapy, 20 to 100 may have:

- Reddening, tanning, or peeling of the skin
- Mild pain
- Hair loss
- Tiredness
- Diarrhea, nausea
- Anemia, which may require transfusion
- Infection, especially when white blood cell count is low

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving radiation therapy, 4 to 20 may have:

- Thickening and numbness of the skin
- Sores or ulcers on the skin or near the cancer location
- Permanent hair loss
- Bleeding from the skin
- Sores in mouth which may cause difficulty swallowing

RARE, AND SERIOUS

In 100 people receiving radiation therapy, 3 or fewer may have:

- Damage to internal organs
- Abnormal opening in internal organs which may cause pain and bleeding