

Radiation Risk Language in JHSPH Consent Forms

Introduction

When a participant in a research study is subjected to ionizing radiation exposure (other than that which is incidental for the standard medical management of the participant) the consent form must make a full disclosure of that exposure. The language below is required in the consent form for any research protocol involving ionizing radiation. There are two choices for the language, depending on whether the radiation risk is minimal risk or greater-than-minimal risk. The maximum radiation dose that still constitutes minimal risk is the dose from a standard chest x-ray (10 mrem).

The average risk per rem, in adults independent of sex, is 0.1% per rem for getting cancer, and 0.05% per rem for dying of cancer. These risk coefficients should be used in the greater-than-minimal risk language below in conveying risk to subjects.

For minimal risk studies, no risk estimation is required in the consent form. This is because the risks from one standard chest x-ray are low: 10 mrem x 0.0001% = 0.001% (1-in-100,000) risk of getting cancer from one chest x-ray, and 10 mrem x 0.00005% = 0.0005% (5-in-1,000,000) risk of dying from cancer from one chest x-ray.

Minimal Risk Verbiage

In this study, you will be exposed to a small amount of radiation called "ionizing radiation," which is like x-rays. Studies have shown that getting a lot of radiation at one time or getting many small doses over time may cause cancer. The risk of getting cancer from the one small radiation dose in this study is very small.

Tell us now if you have been in other research studies where you had ionizing radiation. Also tell us if you have been exposed to radiation in other ways, like on your job or in radiation therapy.

What if you are pregnant? *If you are pregnant or nursing, you cannot be in this research study because the radiation may harm your baby.*

Greater-than-minimal-risk Verbiage

*In this study, you will be exposed to radiation called "ionizing radiation," which is like x-rays. The amount of radiation you will get in the study is **XXX** mrem. (A "mrem" is how we measure radiation dose.) In comparison, one regular chest x-ray would give you 10 mrem. The natural radiation we are exposed to all the time – like from the sun – gives you about 300 mrem each year.*

Neither chest x-rays nor background radiation have been found to harm most healthy adults. The main potential risk from exposure to radiation is cancer. This could appear decades from now. The risk of getting cancer from radiation depends

on how much radiation you are exposed to. The risk of getting cancer from the radiation given in this study is thought to be about **[insert risk estimate here]**, and the risk of dying from cancer from that radiation is **[insert risk estimate here]**. In comparison, 4 out of every 10 people will get cancer in our lifetime. And, 2 out of every 10 of us will die from cancer.

Tell us now if you have been in other research studies where you had ionizing radiation. Also tell us if you have been exposed to radiation in other ways, like on your job or in radiation therapy.

What if you are pregnant? If you are pregnant or nursing, you cannot be in this research study because the radiation may harm your baby. If you are nursing a baby, please tell your doctor. If you are able to have a baby and are not pregnant now, and you want to be in this study, we will give you a free pregnancy test. If you join in this study, you should use contraception to keep from getting pregnant while you are in the study. If you get pregnant while you are in this study, or if you think you are pregnant, please tell the study doctor right away.