

Should I be concerned about participating in medical research studies in which I will receive radiation?

It is important that you understand the potential risks. The risk estimates in this pamphlet are based on statistics for the average person and may vary from one person to another. Many other factors must also be considered. Ethnicity, diet, smoking, drinking alcohol, stress, genetics, and general health are all factors which will increase or reduce your risk of cancer.

The doses associated with research pose minimal risk. All activities have some element of risk. Flying in an airplane, smoking, drinking alcohol, talking on the phone while driving, and even crossing the street, are examples of everyday activities that carry some risk. However, we routinely accept the risk associated with these activities.

Who reviews these studies?

All human research studies involving radiation are reviewed by the NIH Institutional Review board (IRB), the NIH Radiation Safety Committee (RSC), and, for studies involving radioactive research drugs, the NIH Drug Research committee (RDRC). Each committee reviews the study for safety, effectiveness, scientific worth, social value, and other factors to ensure the volunteer's rights and safety are protected.

What is the benefit to me?

As a subject in a research study there may be no benefit to you from research radiation exposure. However, information gathered from your participation in the study may lead scientists to better diagnosis and treatment of certain diseases.

Mission Statement

The Division of Radiation Safety is a leader in radiation protection, specializing in radiation safety, regulatory compliance, and risk management for biomedical and clinical research efforts that directly support the NIH mission.

We are a diverse collection of professionals who maximize our unique talents and expertise to provide comprehensive services and innovative solutions to protect individuals, populations, and the environment from ionizing radiation.

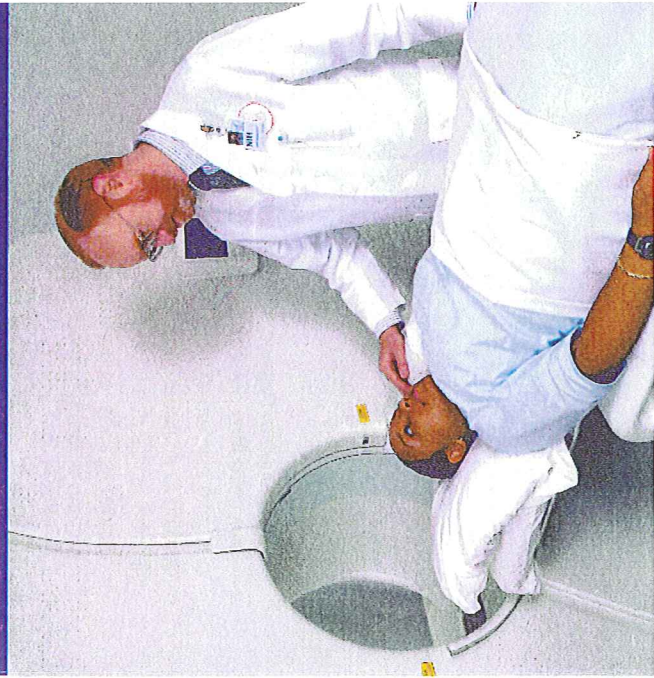
By conducting a successful radiation safety program, we proudly contribute to the advancement of science and medicine for the benefit of humanity

AN INTRODUCTION TO

Radiation

FOR NIH RESEARCH SUBJECTS

National Institutes of Health
Radiation Safety Committee
Division of Radiation Safety



Office of Research Services
National Institutes of Health
U.S. Department of Health and Human Services



Typical Radiation Doses

Source	Average Dose (REM)
Natural Radiation	
5 hour jet plane ride	0.003
Breathing Radon gas for 1 year Internal (our own body)	0.200 0.04/year
Consumer Products	
Building materials Tobacco products (Exposure to the lungs from 20 cigarettes/day)	0.004/year 5.3/year
Medical	
Chest X-ray	0.008
Mammogram	0.138
CT scan	2.5
Cancer treatment(dose to tumor)	5,000

When a person receives radiation as part of a research study at NIH, radiation exposure is limited by the U.S. Food and Drug Administration (FDA) and NIH policies to:

Exposed Location	Dose/ Single Test	Dose/ Year
Whole Body	3 REM	5 REM
Individual organ	5 REM	15 REM

Children (under age of 18) are limited to 1/10 of the adult limits. The limits apply only to research radiation exposure, not to therapeutic radiation administered for treatment of diseases (such as cancer).

What is the risk to me?

Risk from radiation exposure has been, and continues to be, closely studied by scientists and scientific committees. There is still some disagreement on the level of risk or the amount of potential harm from radiation. At high levels of exposure, scientists agree that radiation can cause cancer. At lower levels of exposure, most scientists believe the risk is very low or that there is no risk at all. Some studies have even shown beneficial effects from low level radiation exposure. There are still some who believe that any amount of radiation exposure can increase your chance of getting cancer.

The American Cancer Society estimates that about 25% of the population (1 in 4) will develop a fatal cancer in their lifetime. If you participate in an NIH research protocol, based on the current radiation dose guidelines, your lifetime chance of developing cancer is estimated to increase to 25.04%. If you have additional questions, you should meet with your physician and review the informed consent documents specific to your study.

The average American receives about 0.001 REM per day from natural background and medical radiation.

Are there limits for radiation exposure?

A person who is a radiation worker and receives radiation exposure on-the-job is allowed to receive 5 REM/year (occupational exposure). This limit is set by the Nuclear Regulatory Commission as a safe limit for occupational radiation exposure.

Radiation exposure received for medical or dental purposes is not job related and is not included in this limit. Physicians consider two things when ordering a medical procedure involving radiation exposure. The first is that the person needs the exposure to obtain medical information or for treatment. The second consideration is how to minimize radiation exposure from the test or treatment, and still achieve the desired result.

What are radiation and radioactivity?

As a result of your participation in clinical research you may be exposed to radiation or radioactive material. Radiation is energy in the form of atomic particles or highly energetic light-like entities known as photons. Radiation that has enough energy to affect the atoms and molecules in our bodies is called ionizing radiation. Ionizing radiation cannot be seen or felt.

Radioactive material is any material that contains radioactive atoms emitting ionizing radiation. The research in which you are participating may use radioactive material attached to chemical compounds to image parts of your body.

Radiation and radioactivity occur naturally in our environment. Radioactive materials, such as radium and radon, are found in soil, water, and air. All animals, plants, and humans contain small amounts of naturally occurring radioactive materials. We are also exposed to cosmic radiation from the sun and space, as well as radiation emitted from the building materials used in our homes.

Other sources of radiation exposure include x-rays and nuclear medicine studies. Some consumer products like smoke detectors and illuminated exit signs may also contain small amounts of radioactive material.

The standard unit used to measure radiation exposure to our bodies is called the REM (Roentgen Equivalent Man). The term is used to relate the biological effect to our body of different types of radiation.