NCRP Report No. 185: Evaluating and Communicating Radiation Risks for Studies Involving Human Subjects: Guidance for Researchers and Institutional Review Boards

National Council on Radiation Protection and Measurements

NCRP Report No. 185, *Evaluating and Communicating Radiation Risks for Studies Involving Human Subjects: Guidance for Researchers and Institutional Review Boards*, is a unique, comprehensive document providing information integral to the development, evaluation and execution of research involving exposure of human subjects to ionizing radiation.

Researchers, Institutional Review Boards (IRBs) and medical practitioners can use this report to:

- **Design and evaluate research studies, and**
- **Better understand radiation risk communication and the requirements for establishing informed consent.**

Understanding how radiation interacts with the body is critical to the development and review of research protocols using radiation, and to communicating risks to potential research subjects. However, many researchers, physicians and institutional review board (IRB) members have limited backgrounds in radiation science.

In order to help researchers optimize radiation use in research protocols, IRBs to perform due diligence in review of those protocols, and to promote understanding of the potential short- and long-term health effects, this Report provides extensive information: historical and regulatory background, definitions, descriptions of medical imaging studies and procedures, and more than 500 reference sources.

This Report covers information necessary for research protocol development and evaluation, including:

- basic information on radiobiology, radiation protection, and metrics pertinent to radiation;
- regulatory requirements for the conduct and supervision of research;
- in-depth discussions on estimation of radiation dose and risk and the appropriate use of effective and absorbed dose;
- ethical principles relevant to human studies research involving radiation exposure, including those unique to vulnerable populations, including children; and
- the informed consent process and examples of language to assist in developing informed consent documents.

Purchase a copy of NCRP Report No. 185:
Evaluating and Communicating Radiation Risks for Studies Involving Human Subjects: Guidance for Researchers and Institutional Review Boards
https://ncrponline.org/shop/reports/report-no-185/

NCRP Report No. 185: Evaluating and Communicating Radiation Risks for Studies Involving Human Subjects: Guidance for Researchers and Institutional Review Boards

National Council on Radiation Protection and Measurements

Excerpt from Table 11.1—*Examples of plain language to simplify consent forms for clinical research studies using ionizing radiation*.

Original Language	Plain Language	Grade Level Change
A chest radiograph will be performed to rule out tuberculosis.	You will have a chest x ray to make sure you do not have tuberculosis.	9.5 → 4.9
A fluoroscopy-guided placement of the novel cardiac pacemaker will be performed for all subjects who participate in this protocol. There is a risk of transient erythema consequential to this procedure.	If you take part in this research, you will have a new kind of heart pacemaker placed in your chest. The doctor will use x rays to place the pacemaker. You may have temporary reddening of your skin by the x-ray beam (like sunburn).	13.4 → 5.6
The radiation dose you will receive from the chest computed tomography (CT) scan as a result of your participation in this study is 1 mSv, which is equal to 33 % of the annual natural background radiation exposure.	If you take part in this research, you will have a chest CT scan, which uses radiation. The radiation dose you will get is equal to about one-third of the natural radiation everyone gets in one year.	17.9 → 9.4
The risks of radiation therapy include epilation in the treatment field, dermal blistering or necrosis, and bone marrow depression, which may result in anemia, coagulopathy and opportunistic infections.	The radiation therapy you will have may cause hair loss and skin burns in the area being treated. It may also cause drops in your blood cell counts. As a result, you may experience fatigue, easy bruising, problems with stopping bleeding from cuts, and infections.	20.6 → 7.0