

Radiation Risk Calculator and Consent Form Language for Radiation Risk

Columbia's Radiation Safety Office has recently developed a **Radiation Dose Calculator** <http://radio-sea.cpmc.columbia.edu:5025/#/> (must be within VPN) to estimate radiation doses for patients and health care providers involved in research studies. These values are based on published data and locally obtained data at Columbia University. Radiation safety **language for use in Informed Consent** has also been developed to facilitate discussion with research subjects regarding their risks associated with ionizing radiation.

Categories of Radiation Exposure

The Human Use Subcommittee of the Joint Radiation Safety Committee suggests the use of the following three categories for radiation exposure disclosure in consent form language:

Minimal Risk (<3mSv):

For effective doses under 3 mSv, the risk can be described as "minimal" and the consent form language is rather brief. Provide a numeric value for the effective dose.

Consent form language:

This research study involves exposure to radiation. This radiation exposure is not required for your medical care and is for research purposes only. The radiation exposure is necessary to obtain the research information desired. The total amount of radiation that you may receive in this study is approximately X mSv, which is less than that is typically received from natural sources of radiation in a year. At these very low levels, scientists are uncertain as to the actual risk and there may be no risk at all.

Low Risk (3 mSv to 100 mSv):

For effective doses between 3 mSv and 100 mSv, the risk can be described as "low" and slightly more consent form language is recommended. Provide a numeric value for the effective dose and a numeric estimated risk of future cancer incidence. Doses to individual organs should be discussed if dose from administered radiopharmaceuticals to any individual organ is greater than 1 Sv.

Consent form language:

This research study involves exposure to radiation. This radiation exposure is not required for your medical care and is for research purposes only. The radiation exposure is necessary to obtain the research information desired. The total amount of radiation that you may receive in this study is approximately XX mSv. The additional cancer risk from this research study is estimated to be up to Z%. At these low levels, scientists are uncertain as to the actual risk and there may be no risk at all.

Acceptable Risk (> 100 mSv)

For effective doses above 100 mSv, the risk can be described as "acceptable" and more extensive consent form language should be provided. Provide a numeric value for the effective dose and a numeric estimated risk of future cancer incidence. Doses to individual organs must be discussed

if the dose from administered radiopharmaceuticals to any individual organ is greater than 1 Sv. Use of the effective dose concept may not be appropriate for therapeutic application of radiation, and special risk language should be developed for this on a case-by-case basis.

Consent form language:

This research study involves exposure to radiation. This radiation exposure is not required for your medical care and is for research purposes only. The total amount of radiation that you may receive in this study is approximately XXX mSv. The additional cancer risk from this research study is estimated to be up to ZZ%. The Human Use Subcommittee of the Joint Radiation Safety Committee has approved the use of radiation in this research study. Please tell the research team if you have taken part in other research studies or have recently received any medical care involving radiation.

Additional consent form language for studies with a potential for tissue reactions:

In addition, the procedures involving radiation in this research study might increase the possibility of skin injury, hair loss and/or cataracts.

SKIN (Peak Skin Dose > 3 Gy):

Skin injuries seldom occur and are usually limited to a small area of reddening of the skin surface that was irradiated. They rarely result in an ulcer.

HAIR (Only if skin information is also given; may not be necessary if target area does not have much hair):

If hair loss occurs, it is usually temporary, but could be permanent.

EYES (lens dose > 0.5 Gy to either or both eyes):

Cataracts occur rarely and appear many years after the exposure of the eyes to large doses of radiation.

Risk Calculations for Low and Acceptable Risk Radiation Exposure:

With respect to the % risk calculation for dose levels exceeding 3 mSv, for studies involving only adults, the youngest subject who could be enrolled in the study should be used to calculate risk.

The risk to a female subject should be used unless the study is limited to only males. For all pediatric subjects, we recommend using the risk to a 10-year old female subject unless the study is directed at younger children, in which case an appropriate age should be used.

As a reminder, investigators who wish to enroll subjects in research that results in the exposure to or absorption of ionizing radiation for research purposes are required to obtain written approvals from the Human Use Subcommittee of the Joint Radiation Safety Committee (**JRSC**) or, in certain cases, the University's Radioactive Drug Research Committee (**RDRC**).

Should you have any questions about the Radiation Dose Calculator or the radiation risk consent form language, please contact Dr. Weintraub at jw750@cumc.columbia.edu, 212 305-7132.