

August 19, 2021

RE: Revisions to the Radiation Dose Disclosure in Consent Forms

Dear Colleagues:

Categories of Radiation Exposure

The Human Use Subcommittee of the Joint Radiation Safety Committee has made minor revisions to the following three categories for radiation exposure disclosure in consent form language effective August 19, 2021:

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 includes exposure to radiation that is for research purposes only. Therefore, your total radiation exposure is more than what is required for your medical care alone. This extra radiation exposure is necessary to obtain the research information desired. The amount of additional 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. Note: The risk estimate is based on the subjects in the study population who are most sensitive to radiation exposure.

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 includes exposure to radiation that is for research purposes only. Therefore, your total radiation exposure is more than what is required for your medical care alone. This extra radiation exposure is necessary to obtain the research information desired. The amount of additional radiation that you may receive in this study is approximately XX mSv. The cancer risk from this additional radiation 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. Note: The risk estimate is based on the subjects in the study population who are most sensitive to radiation exposure.

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 includes exposure to radiation that is for research purposes only. Therefore, your total radiation exposure is more than what is required for your medical care alone. This extra radiation exposure is necessary to obtain the research information desired. The amount of additional radiation that you may receive in this study is approximately XXX mSv. The cancer risk from this additional radiation 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 using radiation or have recently received any medical care involving radiation. Note: The risk estimate is based on the subjects in the study population who are most sensitive to radiation exposure.

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.

Please do not hesitate to reach out to me if you have any questions or concerns.

Mikhail Doubrovin, M.D., Ph.D.
Chairman, Human Use Subcommittee of the Joint Radiation Safety Committee