

Radiation Safety Language for IRB Informed Consents

(Updated December 12, 2023)

Language For Use in Studies Submitted Through SLU IRB Or Central IRBs

Important Notes:

- If sponsor template contains risk language that is accurate it may be retained in place of SLU specific language. (If slight adjustment in submitted language is needed, that would be permissible.)
- All protocols involving radioactive materials must continue to be submitted to the RSC. The RSC will make the final determination whether the dose to the patient exceeds 5 mSv or not.
- Customized language may be used if the proposed template language is not sufficient for protocols involving higher doses (e.g., exceeding 50 mSv). (See D. Below)

A. Diagnostic Imaging Procedures (not involving fluoroscopy or radiation therapy):

Adults:

1. Estimate study specific radiation exposure using UCSD radiation calculator.

https://ehs.ucsd.edu/Radiation_Risk/request/home

Note: If institution or study specific estimates of effective radiation dose are available for a particular imaging procedure, provide that effective radiation dose estimate instead of using the UCSD calculator.

2. Consent language not required for study exposure \leq 5mSv.
3. *“During your participation in this research study, you will be exposed to radiation from “x” - insert study specific imaging studies. The total exposure from the study is approximately equivalent to “n” times the amount of natural radiation that you would be exposed to each year while living in the St. Louis area. Cumulative exposure from radiation may increase your risk of developing certain types of cancer in the future. The risk of cancer from the study related exposure alone is very low (5-20 mSv) or low (20-50 mSv).”*

Calculate "n" by determining study specific radiation exposure using the UCSD calculator in mSv. Then divide the total exposure level by 3. (St. Louis background exposure is 3 mSv or 300 mrem.)

Pediatric:

1. Calculate study specific radiation using the UCSD radiation calculator.

https://ehs.ucsd.edu/Radiation_Risk/request/home

Note: If institution or study specific estimates of effective radiation dose are available for a particular imaging procedure, provide that effective radiation dose estimate instead of using the UCSD calculator.

2. *“During your participation in this research study, you will be exposed to radiation from “x” - insert study specific imaging studies. The total exposure from the study is approximately equivalent to “n” times the amount of natural radiation that a person would be exposed to each year while living in the St. Louis area. Cumulative exposure from radiation may increase the risk of developing certain types of cancer in the future. While children are considered more sensitive to the potential effects of radiation compared to adults, the estimated additional lifetime risk of a child developing cancer from the study related radiation exposure alone is negligible (<1 mSv), very low (1-4 mSv) or low (5-10 mSv).”*

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Calculate "n" by determining study specific radiation exposure using the UCSD calculator in mSv. Then divide the total exposure level by 3 (St. Louis background exposure is 3mSv or 300 mrem.)

B. Fluoroscopy Risk Language - Adults

"The _____ procedure in this study uses fluoroscopy. Fluoroscopy has radiation doses that are usually higher than in common imaging like x-rays. This means these procedures are slightly more likely to increase the possibility you may get cancer later in life. Some fluoroscopy procedures can take a longer time and so use more radiation than others. These higher radiation doses could cause skin damage and hair loss in the area imaged."

C. Radiation Therapy Procedures:

1. **Radionuclide Therapy Language** (based on Cornell site, with edits): "The radionuclide therapy that you receive in this study from the administration of a radiopharmaceutical will expose you to a significant dose of radiation that is consistent with treatment for your disease. Harmful effects could include development of a second cancer, genetic changes, or other organ toxicities."
2. **Radiation Therapy (External Beam) Language:** "The external beam radiation therapy that you receive in this study will expose you to a significant dose of radiation that is consistent with treatment for your disease. Harmful effects could include development of a second cancer, genetic changes, or other organ toxicities."
3. **Radiation Therapy (Brachytherapy) Language:** "The brachytherapy radiation that you receive from the implant of radioactive sources in this study will expose you to a significant dose of radiation that is consistent with treatment for your disease. Harmful effects could include development of a second cancer, genetic changes, or other organ toxicities."

D. Procedures with Effective Dose Totals Exceeding 50 mSv:

IRB protocols involving imaging and other procedures with an effective dose total greater than 50 mSv may be submitted with the following risk statement; customized language may be substituted.

"During your participation in this research study, you will be exposed to radiation from "x" - insert study specific imaging studies. The total exposure from the study is approximately equivalent to "n" times the yearly radiation worker dose limit of 50mSv. Cumulative exposure from radiation may increase your risk of developing certain types of cancer in the future. The risk of cancer from the study related radiation exposure alone is moderate (50 mSv – 500 mSv)."

Calculate "n" by determining study specific radiation exposure using the UCSD calculator in mSv. Then divide the total exposure level by 50. (The dose limit for radiation workers is 50 mSv or 5,000 mrem per year.)