

Research Radiation Risk Language Template

- This language must be included in the consent form if the study involves *research related* radiation risk.
- Dosage calculation and exposure comparison information must be included.
- This language applies to *all studies, including those reviewed by an external IRB (i.e. Advarra/WIRB)
***Exception** – Unable to adjust language in studies reviewed by NCI-CIRB
- The Research Radiation dosage and any deviation to this language must be reviewed and approved by the Research Radiation Consultant through ancillary review in myResearch.

Risks to Radiation Exposure from Medical Imaging Studies

This study involves exposure to radiation from one or more medical imaging studies. Please note that this radiation exposure is NOT necessary for your medical care and is for research purposes only.

In this study, you will receive radiation exposure from [insert type and number of procedures]. The estimated radiation dose for each [insert procedure] scan is [_____] mrem (short for millirem, which is a unit of radiation dose). The total radiation dose from these research procedures is no more than [_____] mrem. This radiation exposure is what you will receive from this research study only, and does not include any exposure you may have received or will receive from other diagnostic or therapeutic procedures that are part of your medical care. If you have questions about the total amount of radiation you will be receiving, you should ask your study doctor.

To help you understand how much radiation you will be exposed to by being in this study, we will compare it to natural radiation in the world in which we live that is coming from the sun, space, air, food and soil. The average person in the United States receives approximately 300 mrem each year from this natural radiation. A single chest x-ray can give a dose of up to 10 mrem. A single chest CT scan can vary widely (approximately 200-1200 mrem) depending on many factors, including your size and the machine used. Finally, the yearly radiation dose limit for radiation workers in the United States is 5,000 mrem.

The natural risk for a person to develop a fatal cancer during his/her lifetime is about 1 out of 4 (or 25%). The **additional** risk for developing a fatal cancer specifically from radiation is about 0.04% per 1,000 mrem. This means that if you are exposed to 1000 mrem of radiation, your chance of developing cancer goes up .04%, to 25.04% (2000 mrem will increase your chance to 25.08%, and so on). **This change in risk is statistically very small and is generally regarded as insignificant.** The amount of radiation received in this study is within FDA guidelines for exposure to research subjects.

If you have questions about the radiation you will be exposed to in this study, contact the Radiation Safety Officer of Stony Brook University at 631-632-6410.

Additional information regarding imaging scans using radiation, including other dose comparisons, can be found at these websites: *Health Physics Society*: <http://hps.org/publicinformation/>
<http://hps.org/publicinformation/>

and

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Society of Nuclear Medicine:

<http://www.snmmi.org/ClinicalPractice/doseTool.aspx?ItemNumber=11216&navItemNumber=11218>