

TEMPLATE C *(Total effective dose > 5 rem)*

This research study involves exposure to radiation from *(insert type of procedure or procedures)*. Please note that this radiation exposure is **not** necessary for your medical care and is for research purposes only. The total amount of radiation you will receive in this study is from *(insert maximum number)* injections (scans or repetitions) of *(insert quantity of radioactive material, in units of millicuries; or type of x-ray procedure)*. The NIH Radiation Safety Committee¹ has reviewed the use of radiation in this research study and has approved this use as involving acceptable risk and necessary to obtain the research information desired.

Using the standard way of describing radiation dose, from participating in this study, you will receive a total of *XX* rem to your *(insert highest-dosed organ)*, *XX* rem to your *(2nd highest-dosed organ)*, and *XX* rem to your *(3rd highest-dosed organ)*. All other organs will receive smaller amounts of radiation. The amount of radiation received in this study exceeds the dose guideline established by the NIH Radiation Safety Committee for research subjects. The guideline is an effective dose of 5 rem (or 5,000 mrem) received per year².

(Include discussion about possible acute and chronic organ effects of radiation therapy, specific to study and subject population).

If you would like more information about radiation and examples of exposure levels from other sources, please ask the investigator for a copy of the pamphlet called, *An Introduction to Radiation for NIH Research Subjects*.

Please tell your doctor if you have taken part in other research studies or received any medical care at the NIH or other places/hospitals that used radiation. This way we can make sure that you will not receive too much radiation. Consider x-rays taken in radiology departments, cardiac catheterization, and fluoroscopy as well as nuclear medicine scans in which radioactive materials were injected into your body.

If you are pregnant or breast feeding, you will not be permitted to participate in this research study. It is best to avoid radiation exposure to unborn or nursing children since they are more sensitive to radiation than adults.