



Title:	Research Involving Radiation		
SOP Number:	4101	Effective Date:	September 9, 2019
Previous Version Dates:	June 2, 2019		

1 Research involving radiation

Studies involving the use of radiation, such as those requiring patients to be X-rayed, are not eligible for expedited review, even if all of the other procedures in the study have been deemed to pose no more than minimal risk.

Projects in which subjects are exposed to ionizing radiation must receive approval from the Radiation Safety Subcommittee (RSS) of UNC-Chapel Hill before final IRB approval can be granted. The Application for Human Use of Radiation in Research should be completed and approved by to the Radiation Safety Subcommittee prior to submitting to the IRB.

However, if subjects are 18 years and older and receiving five or fewer of the following views/scans, the RSS has determined that they represent no greater than minimal risk and therefore do not require review and approval by the RSS.

- DEXA scans
- Chest x-rays
- Planar x-rays of extremities (as defined by Nuclear Regulatory Commission) – hands, forearms, elbows, feet, knees, leg below the knees, and ankles)
- Dental x-rays

It is important to note that one procedure could have multiple views/scans (e.g., AP and Lat view for “chest x-ray”). The following statement must be included in the risk section of the consent form:

This research study involves exposure to radiation from (insert maximum number scans and type of procedure). Please note that this radiation exposure is not necessary for your medical care and is for research purposes only.

For comparison, the average person in the United States receives a radiation exposure of 0.3 rem (or 300 mrem) per year from natural background sources, such as from the sun, outer space, and from radioactive materials that are found naturally in the earth’s air and soil. The dose that you will receive from participation in this research study is less than amount you receive from these natural sources in one year.

The amount of radiation you will receive in this study has a minimal risk and is below the dose guideline established by The University of North Carolina Radiation Safety Committee for research subjects.

For studies that meet the criteria for approval by the Radioactive Drug Research Committee (RDRC), investigators should also submit a UNC RDRC Application. Such studies must be basic research and meet limits on pharmacological dose and radiation dose as specified in the [RDRC regulations](#) (21 CFR 361.1).