

RSC Guidance: Radiation dose information and sample risk statement for subjects involved in research studies.

If a subject is exposed to additional radiation exposure from a diagnostic examination or **treatment (i.e., not part of standard care), or if a normal volunteer is to be exposed to any radiation**, this issue needs to be addressed in the corresponding informed consent form. Subjects need to be informed that they will receive additional radiation exposure by participating in the research study

Three key questions that need to be addressed are: (1) Is the exposure necessary; (2) Has the radiation exposure been minimized; (3) How much radiation will the subject receive, and what is the magnitude of the risk from this extra radiation.

Many common radiological examinations expose the individual to very small doses of radiation. The table below shows a number of common, adult low dose radiological examinations¹.

Diagnostic x-ray exam	Description	Effective dose*
Extremity radiograph	Any extremity (elbow, forearm, knee, etc.)	< 0.01 mSv (1 mrem)
DEXA study	AP lumbar spine + hip	0.015 mSv (1.5 mrem)
Chest (PA view)	Performed with grid (i.e., not portable)	0.02 mSv (2 mrem)
Chest (lateral view)	Performed with grid (i.e., not portable)	0.05 mSv (5 mrem)
Mammogram	Two views of each breast (four films)	0.2 mSv (20 mrem)
Skull (AP view)	Single film	0.1 mSv (10 mrem)
Skull (Lateral view)	Single film	0.05 mSv (5 mrem)
Abdomen (AP view)	Single film	0.3 mSv (30 mrem)

***Note that an effective dose of 0.01 mSv (1 mrem) is equivalent to ~1 day of natural background**

If your **adult subject** is to have this type of simple low dose examination, you can use the following paragraph in the **"Risks" section of the** informed consent document. **For infants or children, or any other question, please contact Dr Kent Ogden at ogdenk@upstate.edu (464-5083) in Radiology before proceeding.**

This research study involves exposure to radiation, and you will receive --X--² mSv from the diagnostic tests³. This is equal to the radiation Americans receive in --Y--⁴ days from natural background radiation, such as naturally occurring radioactivity in the soil, air, etc. Any risk from this small amount of radiation is too small to be measured directly, and is generally small when compared to other every day risks.

Some examinations, such as CT and nuclear medicine, expose patients to much higher levels than those listed in the Table above. To obtain a definitive estimate of the **subject** dose, as well as a more detailed paragraph for inclusion in the informed consent form, please contact Dr. Ogden. For procedural or general questions you may contact the Radiation Safety Committee chair, Kerry Greene-Donnelly at GreeneK@upstate.edu or 464-6928.

¹ Any radiological examination or treatment that results in a patient effective dose of less than 50 mrem is deemed to be "low dose"; the corresponding risk of a fatal cancer from 0.5 mSv (50 mrem) is estimated to be no more than about 1 in 40,000.

² milli-Sieverts (mSv) or micro-Sieverts (micro-Sv) are now the preferred units.

³ Please insert a comprehensible **list and number** of the diagnostic tests **or treatments** (chest x-ray, extremity x-ray etc.).

⁴ Note that 0.01 mSv (1 mrem) is approximately equal to 1 day of natural background; the time should be rounded to the nearest day, week or month; e.g. ~0.3 mSv (~30 mrem) is about 1 month of natural background.

⁴ Note that 0.01 mSv (1 mrem) is approximately equal to 1 day of natural background; the time should be rounded to the nearest day, week or month; e.g. ~ 0.3 mSv (~30 mrem) is about 1 month of natural background exposure.