Radiation Safety Committee Review Instructions:

Instructions for IRB Protocols Involving Ionizing Radiation Exposure to Human Subjects

AIM: The review by members of the Radiation Safety Committee (RSC) is required to provide the IRB with expert opinions of the appropriateness, safety, dosimetry and relative risks concerning the use of ionizing radiation in research protocols involving human subjects.

NOTE: RSC review is not generally required when the use of ionizing radiation involves routine therapeutic or diagnostic procedures and exposure levels on people for whom these procedures would be considered part of their standard of care for an existing or suspected medical condition. Additional scans or exposures for research, however, require review. MRI or ultrasound procedures do not currently require Radiation Safety Review.

COORDINATE: As early in the process as possible, it is recommended that the investigator consult an appropriate faculty member in Radiology or Radiation Oncology to clarify the appropriateness of the imaging or therapy techniques involved. The inclusion of such a faculty member on the project may be appropriate is some cases, especially when a non-routine technique is to be used.

Please follow the following steps to expedite the review by the RSC:

1. In the IRB Application Form, be sure to indicate the nature and number of additional procedures involving ionizing radiation. In the "**Risks**" section of the application and in the Consent Document indicate **the effective dose*** and risk information for the radiation used**. See the attached dose information sheet and sample statement** or contact Dr. Kent Ogden, Section Chief of Radiological Physics.

2. Share the project with Joseph Spadaro on IRBNet

- After evaluation (usually in 7-10 days), the RSC Chairperson will upload a letter in IRBNet summarizing recommendations of the RSC.
- Any questions regarding the review process may be directed to:
  J.A. Spadaro, Ph.D., Rm. 3119 IHP, phone: 464-6625, Fax: 464-6638, or
  spadaroj@upstate.edu
- For assistance with radiation dosimetry matters contact: Kent Ogden, PhD, Rm. 641 UH, phone: 464-5083, Fax: 464-5095, or ogdenk@upstate.edu

*The **effective radiation dose** takes into account the type of radiation, the size and anatomy of the region exposed and the radiation sensitivity of the organs/tissues exposed, and the equipment used. Some typical values are presented in the table below. More information on radiation doses and risks can be found at the following web site of the American College of Radiology:
http://www.radiologyinfo.org/en/safety/index.cfm?pg=sfty_xray

Radiation doses to 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 examinations[1].

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 (464- 5083) in Radiology before proceeding.**

This research study involves exposure to radiation, and you will receive --X--[2] mSv from the diagnostic tests[3]. 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.

[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 50 mrem is estimated to be no more than about 1 in 40,000.

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

[4] Note that 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. 25 mrem is about 1 month).