

IRB APPENDIX P - RADIATION
REV. FEBRUARY 2019

Complete this form to request inclusion of procedures involving radiation (e.g., x-rays, CT scans, fluoroscopy, nuclear medicine studies, etc.) in the proposed research.

Include only those exams/procedures that are to be administered for research purposes (i.e., not being performed as standard medical care).

Resources are available at [RADAR Medical Procedure Radiation Dose Calculator and Consent Language Generator](#) and [Effective Doses in Radiology and Diagnostic Nuclear Medicine: A Catalog](#). For further assistance, contact ORI.

Include the radiation risk language generated by using the dose calculator on applicable consent, assent, and/or parental permission forms prior to review.

Principal Investigator:

Project Short Title:

1. Provide the location where the radiologic procedure(s) will be performed:

Name of Institution/Department Administering Procedure(s)	Address (street, city and state, or country)
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>

2. Specify the age(s) of participants who will receive radiation exposure.

3. Provide the total number of participants (receiving radiation exposure) for whom you are seeking approval.

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4. Specify the participant population(s) to be included (check all that apply):

- Children
- Healthy Volunteers
- Pregnant Women *Provide an estimate of the radiation exposure to the fetus:*
- Women of childbearing potential
- Other(s) not listed above - Please specify:

5. Indicate the type of pregnancy testing that will be used to exclude pregnant women.

A serum pregnancy test must be used if the study involves greater than 100 mrem or the ovaries are in the radiation field.

- Serum BHCG test
- Other pregnancy testing - Please specify and provide justification:

6. Describe exams/procedures involving radiation and justification for each exposure. Indicate for each research participant the number of procedures administered per year and the total number of procedures for all years of the participant's exposure. **Include only exams/procedures that are administered for research purposes (i.e., not being performed as standard medical care).**

Exam/Procedure(s)	Justification for Radiation Exposure	Number of Procedures/Year	Total Number of Procedures/Participant

7. Complete **a** through **d** below to describe the radiation dose administered to participants for research purposes. **Attach a copy of dose calculations (i.e., printout from online [dose calculator](#), including recommended consent language)**
NOTE: 100 mrem = 1 mSv

N/A

a. Nuclear Medicine Procedures Per Year

Physician responsible for administration of nuclear medicine procedures:

Radionuclide and chemical form:

Name/description of procedure:

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Activity per administration (Bq, mCi):

Maximum number of administrations per participant per year:

Effective dose (mrem or mSv):

b. X-Ray Procedures Per Year

N/A

(For DEXA scans, specify unit (Lunar DPX-L, Lunar EXPERT, or Lunar PRODIGY) and type of scan (bone density or whole body composition)).

Name/description of procedure:

Effective dose (mrem or mSv):

c. Total Effective Dose Per Year

(Sum of all nuclear medicine and x-ray procedures for research purposes per year)

Effective dose (mrem or mSv):

d. Total Effective Dose for All Years of the Study

(Sum of all procedures performed for research purposes for all years)

Effective dose (mrem or mSv):