

JHM-IRB

Guidelines for Radiation Statements

When a participant in a research study is subjected to ionizing radiation exposure (other than that which is incidental for the standard medical management of the participant) the consent form must make a full disclosure of the exposure. Include in the risk section of your consent form the appropriate language from one of the three categories below.

Please note that effective dose values should be summed for all procedures involving radiation exposure. Make sure that values are expressed in the appropriate units (use rem, 1 rem = 1000mrem) in the consent form statement

For studies using < 0.3 rem

This research study includes exposure to radiation from x-rays or gamma rays. This radiation exposure is for research purposes only and is not part of your medical care. X-rays and gamma rays can damage cells, but at low doses, the body is usually able to repair these cells.

The radiation exposure that you will get in this research study is _____ rem (a rem is a unit of absorbed radiation). This is less than the 0.3 rem that the average person in the United States gets each year from natural sources like the sun, outer space, air, food, and soil. The risk from the radiation exposure in this research study is very small.

The radiation exposure described here is what you will get from this research study only. It does not include any exposure you may have received or will receive from other medical tests outside of this study that are a part of your medical care. If you have questions about the total amount of radiation you will be receiving, you should ask your doctor.

For studies using < 5.0 rem

This research study includes exposure to radiation from x-rays or gamma rays. This radiation exposure is for research purposes only and is not part of your medical care. X-rays and gamma rays from natural or medical sources can damage the genetic material (DNA) in your cells. At low doses, the body is usually able to repair the damage.

The radiation exposure that you will get in this research study is _____ rem (a rem is a unit of absorbed radiation). This is more than the 0.3 rem that the average person in the United States gets each year from natural sources like the sun, outer space, air, food and soil. It is less than the 5 rems of radiation that is allowed each year for people who are exposed to radiation in their jobs.

The radiation exposure described here is what you will get from this research study only. It does not include any exposure you may have received or will receive from other tests outside of this study that are a part of your medical care. If you have questions about the total amount of radiation you will be receiving, you should ask your doctor.

For studies using $\geq 5.0 - 15$ rem

This research study includes exposure to radiation from x-rays or gamma-rays. This radiation exposure is for research purposes only and is not part of your medical care. X-rays and gamma rays can damage the genetic material (DNA) in cells. At low doses, cells usually can repair this damage. There is some possibility that an incorrect repair may increase the risk of cancer in your lifetime. The normal lifetime risk of cancer is 25%. A radiation dose of 15 rems (a rem is a unit of radiation dose) would increase your lifetime risk to 25.6%.

The radiation exposure that you will get in this research study is _____ rem. To put that in context, the average person in the United States gets a radiation exposure of 0.3 rem per year from natural sources, like the sun, outer space, air, food and soil. People who work with radiation (for example, x-ray technologists) are allowed a maximum exposure of 5.0 rem each year. Although these levels of radiation are thought to cause an increased risk of cancer, studies in people who work with radiation have rarely shown a measurable increase in cancer risk.

The radiation exposure described here is what you will get from this research study only. It does not include any exposure you may have received or will receive from other tests outside of this study that are a part of your medical care. If you have questions about the total amount of radiation you will be receiving, you should ask your doctor.

If women capable of having children are included in the protocol, they must be informed that they cannot take part in the study if they are pregnant[†]. One of the following statements should be included in the consent form.

For research studies where pregnancy testing is NOT required, but can be requested.

“Pregnant women cannot take part in this study. If you are a woman capable of having children, you may take part in this study only if you are certain you are not pregnant. A pregnancy test will be performed at your request. If you become pregnant (or suspect pregnancy) before this study is completed, you must inform the study doctor.”

For research studies where pregnancy testing IS required.

“Pregnant women cannot take part in this study. If you are woman capable of having children, you must have a pregnancy test. The results of that test must be negative for you to continue in the study. If you become pregnant (or suspect pregnancy) before the study is completed, you must inform the study doctor.”

[†]Pregnant participants are typically excluded from protocols using ionizing radiation. However, conditions could exist where pregnant participants may be involved. If pregnant participants are recruited into a protocol using ionizing radiation, their involvement will be reviewed on a case by case basis.

**For assistance in dosimetry, contact:
Mhaderappa Mahesh, M.S., Ph.D., (410-955-5115),
Thomas Beck, Sc.D. (410-955-2684) or
Stanley Wadsworth, MS (410-955-3710).**

Johns Hopkins Medicine IRB 1-5
Request for Use of Ionizing Radiation in Human Research
(To be completed for all types of radiation exposure)

APP No:
PI Name:
TITLE

*Send this completed form and Application form to:
The Johns Hopkins Medicine IRB, Reed Hall, 1620 McElderry Street Suite B130
Return only those pages pertinent to the protocol; Dose tables are for investigators convenience only.*

I. Subject Population

| | Healthy Controls | Subjects with Disease |
|-------------------------------------|------------------|-----------------------|
| A. Number of Subjects | | |
| B. Age Range | | |
| C. Sex | | |
| D. Nature of Disease | | |
| E. Will pregnant women be excluded? | | |

II. Radioactive Materials

- A. Are Radioactive materials administered to research subjects in this protocol?
 Yes No (If **No** skip to Section III)
- B. Would the subjects receive this radioactivity whether or not they participate in this protocol?
 Yes No If **No**, attach *Worksheet for Radionuclide Radiation Exposure*.

III. External Radiation

- A. Are research subjects exposed to external sources of ionizing radiation in this protocol?
 Yes (If **No** skip to Section IV)
- B. Would the subjects receive this radiation whether or not they participate in this protocol?
 Yes If **No**, attach *Worksheet for External Radiation Exposure*.

IV. Locations

Procedures involving radiation will be conducted at (check all that are appropriate):

- | | |
|--|---|
| <input type="checkbox"/> Nuclear Medicine (JHH or Bayview) | <input type="checkbox"/> MIRU (JHH) |
| <input type="checkbox"/> Radiation Oncology (JHH) | <input type="checkbox"/> Radiology (JHH or Bayview) |
| <input type="checkbox"/> Other (specify): | |

Worksheet for Radionuclide Radiation Exposure

APP NO:

TITLE

I. Radiopharmaceutical

| | Isotope A | Isotope B | Isotope C | Isotope D |
|---|-----------|-----------|-----------|-----------|
| A. Isotope (e.g. ^{99m}Tc) | | | | |
| B. millicuries per administration | | | | |
| C. Administrations per subject | | | | |
| D. Route of administration (e.g., IV, oral) | | | | |
| E. Chemical/physical form | | | | |
| F. Active ingredient (mg per administration) | | | | |

II. FDA status of radiopharmaceutical

| | Isotope A | Isotope B | Isotope C | Isotope D |
|--|-----------|-----------|-----------|-----------|
| A. Well established use | | | | |
| B. New Drug Application | | | | |
| C. Investigational New Drug Application (give IND No.) | | | | |
| D. Not FDA approved for intended use or route of administration | | | | |

III. Sterility and Pyrogenicity*

| | Isotope A | Isotope B | Isotope C | Isotope D |
|--|-----------|-----------|-----------|-----------|
| A. Is material supplied sterile? | | | | |
| B. Is material supplied pyrogen free? | | | | |

* If the material is not supplied in a sterile and non-pyrogenic form, attach a description of methods that will be used to assure sterility and non-pyrogenicity

IV. Radiation Dosimetry

- A. For standard radiopharmaceuticals administered by standard routes: List the product of effective dose equivalent per millicurie administered and the activity administered in millicuries for each isotope below. Effective doses per millicurie may be obtained from Table 1, the package insert, or another publication, multiply by activity administered. Doses shall be summed for the total number of administrations for each isotope.

| | Isotope A | Isotope B | Isotope C | Isotope D |
|------------------------|-----------|-----------|-----------|-----------|
| Effective Doses (mrem) | | | | |

- B. For non-standard radiopharmaceuticals or non standard routes of administration, specify isotope and list organ doses for total activity administered as follows:

| Organ | Isotope 1 _____ | | Isotope 2 _____ | | |
|--|----------------------------|-------------|---------------------|-------------|---------------------|
| | Weighting factor (W_i) | Dose (mrem) | Dose x W_i (mrem) | Dose (mrem) | Dose x W_i (mrem) |
| Gonads (mean of both sexes as appropriate) | .25 | | | | |
| Female Breast | .15 | | | | |
| Red Bone Marrow | .12 | | | | |
| Lungs | .12 | | | | |
| Thyroid | .03 | | | | |
| Bone Surfaces | .03 | | | | |
| Critical Organ* _____ | .06 | | | | |
| Other _____ | .06 | | | | |
| Other _____ | .06 | | | | |
| Other _____ | .06 | | | | |
| Other _____ | .06 | | | | |
| Effective Dose** | 1.00 | | | | |

* The organ with the highest radiation dose, other than listed organs. Refers to the four remaining organs with the highest doses (e.g., liver, kidneys, spleen, brain, thymus, adrenals, pancreas, stomach, small intestine, upper large intestine, and lower large intestine, but excluding skin and extremities).

** Sum products of doses and weighting factors to obtain Effective Dose.

Total Effective dose from all radionuclide procedures* rem

* Divide doses in mrem by 1000 to convert to rem, add result to that obtained from all external radiation procedures (if appropriate) and enter in blank on standard informed consent statement for radiation exposure.

Worksheet for External Radiation Exposure

I. Diagnostic X-Ray Procedures:

A. Procedures

| Procedure | Body region exposed* | Repetitions** |
|-----------|----------------------|---------------|
| | | |
| | | |
| | | |
| | | |
| | | |

*For example: trunk, upper abdomen, head, lower leg, etc.

**List number of times imaging procedure will be repeated for each study participant over duration of protocol.

B. Radiation Dose Effective doses (H_E) for some conventional radiographic procedures and for computed tomography in Tables, 2 and 3, respectively. If procedure is not listed, obtain a dose estimate from Radiology personnel or one of the consultants listed on page 1.

| Procedure | Effective Dose | Skin Entrance Dose* |
|-----------|----------------|---------------------|
| | | |
| | | |
| | | |
| | | |
| | | |

* List skin doses only if Effective Dose is not available.

II. Therapeutic Radiation Procedures: List target doses in rem (cSv):

| Procedure | Body Region | Dose/Fraction | # Fractions |
|---------------|-------------|---------------|-------------|
| Brachytherapy | | | |
| Teletherapy | | | |

Total Effective Dose from all external radiation procedures*: rem
(exclude therapeutic procedures).

* Divide doses in mrem by 1000 to convert to rem, add result to that obtained from radionuclide procedures (if appropriate) and enter in blank on standard informed consent statement for radiation exposure. (Do not sum skin entrance doses)