Radiation / Radioisotope Guidelines

Research protocols involving the use of external sources of ionizing radiation or internally administered radioisotopes, require the approval of the Radiation Safety Office. A form for this purpose is included in the CCI/IRB Research Proposal Application. Upon receipt, the CCI Office will forward the protocol to the Radiation Safety Office for review and approval. CCI approval will only be granted upon approval of the Radiation Safety Office.

INFORMED CONSENT LANGUAGE:

For research involving radiation exposure to subjects, **all procedures, including those that would be performed forstandard clinical care, are to be included in the consent document in the 'Procedures' paragraph.**

For *procedures that are beyond what would normally beif standard clinical care (i.e. for research purposes only)*, language regarding exposure risk must be included in the consent document in the 'Risks' paragraph:

To calculate the 'effective radiation dose', use the following guidelines:

CT Chest Exam:	510 mrem
CT Abdomen Exam:	410 mrem
CT Head Exam:	240 mrem
Chest X-Ray:	Local Dose is 10-50 mrem
Bone Scan:	400 mrem
Cardiac Scan (Thallium):	720 mrem
Cardiac Scan (Technetium)	500 mrem
Gallium Scan:	1600 mrem
Mammogram:	500 mrem per breast

For repeated examinations with the same procedure, SUM the effective dose for each exposure to estimate the total dose. Once the effective dose has been determined, use one of the following four (4) paragraphs, and insert the appropriate language in the paragraph. DELETE the non-applicable paragraphs.

Option 1: To be used when the effective radiation dose is up to 1000 mrem.
This research study involves exposure to radiation from [*Insert name of the procedure to be performed*]. The amount of radiation you will receive from the (these) procedure(s) is [*Insert the radiation dose amount*] millirems. You may compare this to the amount of natural radiation you receive every year living in the New York City area, which is about 300 millirems. The risk to you from the radiation dose received from this procedure is too small to be detected.

Option 2: To be used when the radiation dose is between 1000 – 5000 mrem.
This research study involves exposure to radiation from [*Insert name of the procedure to be performed*]. The amount of radiation you will receive from the (these) procedure(s) is [*Insert the radiation dose amount*] millirems. You may compare this to the allowable radiation dose for radiation workers of 5000 millirems per year. There is a very small risk of developing cancer from this level of exposure.

Option 3: To be used when the radiation dose is over 5000 mrem.
This research study involves exposure to radiation from [*Insert name of the procedure to be performed*]. The amount of radiation you will receive from the (these) procedure(s) is [*Insert the radiation dose amount*] millirems. You may compare this to the allowable radiation dose for radiation workers of 5000 millirems per year. Your increased risk of developing cancer from exposure to this level of radiation is [*contact the Radiation Safety Office at 718-920-5012 for estimate and put that amount here*].

Option 4: To be used when multiple procedures are being performed.
This research study involves exposure to radiation from several different tests to be performed, namely: from [*Insert name of the procedure(s) to be performed*]. The amount of radiation you will receive from each of these procedures as follows:

[*List name of procedure 1 here*] ……. [*List how many millirems of radiation the test gives here*] millirems.
[*List name of procedure 2 here*] ……. [*List how many millirems of radiation the test gives here*] millirems.
[*List name of procedure 3 here*] ……. [*List how many millirems of radiation the test gives here*] millirems.
[*Continue listing procedures and millirem amounts until all are named.*]

Use the following paragraph if the total radiation dose for all of the procedures combined is no greater than 1000 mrem:
The cumulative total of the radiation dose for all of these procedures combined is [*Insertthe total radiation dose*] millirems. You may compare this to the amount of natural radiation you receive every year living in the New York City area, which is about 300 millirems. The risk from this radiation dose is too small to be detected.

Help Text: Use the following paragraph if the total radiation dose for all of the procedures combined is 1000 – 5000 mrem:
The cumulative total of the radiation dose for all of these procedures combined is [*Insertthe total radiation dose*] millirems. You may compare this to the allowable radiation dose for radiation workers of 5000 millirems per year. There is a very small risk of developing cancer from this level of exposure.

Help Text: Use the following paragraph if the total radiation dose for all of the procedures combined is OVER 5000 mrem:
The cumulative total of the radiation dose for all of these procedures combined is [*Insertthe total radiation dose*] millirems. You may compare this to the allowable radiation dose for radiation workers of 5000 millirems per year. Your increased risk of developing cancer from exposure to this level of radiation is [*contact the Radiation Safety Office at 718- 920-5012 for estimate and put that amount here*].