

## Radiation Risk Language for Consent Form

### 1.0 Studies Without Normal Cohorts

Informed consent forms (ICF) for studies without normal cohorts reviewed by the RSC must have the following language in the Radiation Risk section. Please select the appropriate excerpt(s) from the quotation marks that apply to your protocol:

*“Tests included in this study (enter non-SOC studies here) are employed routinely in the care of patients with medical conditions. They involve radiation exposure, and that exposure is increased the more often such tests are done. Radiation exposure at certain doses can potentially cause cancer. Any possible increase in cancer risk associated with participation in this study is within acceptable limits for human research subjects.”*

### 2.0 Studies With Normal Cohorts

Informed consent forms (ICF) for studies with normal cohorts reviewed by the RSC must have the following language in the Radiation Risk section. Please select the appropriate excerpt(s) from the quotation marks that apply to your protocol:

*“Tests included in this study (enter non-SOC studies here) are employed routinely in the care of patients with medical conditions. They involve radiation exposure, and that exposure is increased the more often such tests are done. Radiation exposure at certain doses can potentially cause cancer. Any possible increase in cancer risk associated with participation in this study is within acceptable limits for human research subjects who might not benefit from participating.”*

### 3.0 Studies That Employ Fluoroscopy

Informed consent forms (ICF) for studies reviewed by the RSC that employ fluoroscopy must also have the following language in the Radiation Risk section:

*“This study involves the use of fluoroscopy (x-rays) during the procedure. Potential radiation risks to you from fluoroscopy may include:*

- *Skin rashes, which on rare occasions may result in tissue breakdown and possibly severe ulcers.*
- *Hair loss may occur, which can be temporary or permanent.*

*The likelihood of either of these occurring depends on the difficulty of the procedure and whether you are sensitive to radiation due to previous procedures, disease, or genetic conditions.*

*We will advise you or your family if we use substantial amounts of radiation during the case. If this happens, you will be given written instructions stating that you are expected to have a family member check you for any of the above-mentioned signs of skin damage or hair loss.”*

### 4.0 Studies That Employ Therapeutic Radionuclide Treatments

Informed consent forms (ICF) for studies reviewed by the RSC that employ radionuclide therapies must also have the following language in the Radiation Risk section:

*“The radionuclide therapy that you receive in this study will expose you to a significant dose of radiation that is consistent with treatment for your disease. Harmful effects could include development of cancer, genetic changes, or other organ toxicities.”*