Radiation Risk Language for Consent Form

**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, select the appropriate from within the parenthesis 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 exposure to radiation, 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.”

**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, select the appropriate from within the parenthesis 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 exposure to radiation, 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.”

**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:

“Tests included in this study, (enter non-SOC studies here) are employed routinely in the care of patients with medical conditions. They involve exposure to radiation, 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.”

“Tests included in this study, (enter non-SOC studies here) are employed routinely in the care of patients with medical conditions. They involve exposure to radiation, 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.”

“Tests included in this study, (enter non-SOC studies here) are employed routinely in the care of patients with medical conditions. They involve exposure to radiation, 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.”

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.

You or your family will be advised if we actually used 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.”