



## **Informed Consent Form Radiation Risk Language**

University of Arizona Radiation Safety Committee Human Use Subcommittee model risk language.

**Bone Scan:** Bone scans are used to determine the presence and/or extent of certain abnormalities in your bones and require the injection of a small amount of radioactive substance into your vein. The radioactivity injected in your body will expose you to radiation. The amount of radiation is small, so your radiation exposure is low, and the risk is considered small. There is a chance that you may experience discomfort, pain or swelling at the injection site and, as is the case with any injection, there is an increased risk of infection at the site.

**Diagnostic x-ray (Radiography):** Diagnostic x-rays may be repeated if required by the study, or if clinically indicated by your doctor. Such procedures as described above in this consent form are to evaluate your disease. The total radiation dose you will receive from the x-rays in this study are small and the risks are negligible.

**CT scan:** There is a potential risk from the radiation exposure received from a CT scan, but this risk from a single CT scan is considered small. Sometimes, an intravenous (in the vein) contrast dye is given with a CT scan. This contrast dye is iodine based. A person who has allergies is more likely to have an allergic reaction to the dye. This reaction may be mild, such as skin rash or hives, to severe, such as breathing difficulties or shock. You will be closely monitored and treated should an allergic reaction occur. A severe allergic reaction would require immediate medical treatment and could result in permanent disability or death. You should discuss any history of allergies or concerns with your doctor. You may also experience discomfort related to lying still in an enclosed space for a prolonged period.

**PET Scan (Positron Emission Tomography):** A PET scan is a nuclear imaging test that scans your body and produces images for detecting abnormalities such as cancer. Before the scan, a radiopharmaceutical is injected into your vein which helps visualize your body function in the PET scan. The amount of radiation to your body from this scan is considered low and the risk is considered small. There is a chance that you may experience discomfort, pain or swelling at the injection site and, as is the case with any injection, there is an increased risk of infection at the site.

**Fluoroscopy:** Fluoroscopy carries some risks, as do other X-ray procedures. Fluoroscopy is an x-ray imaging procedure and it used to image physiological motion in the body or for imaging a catheter insertion and manipulation (to direct the movement of a catheter through blood vessels, bile ducts or the urinary system). The radiation dose the patient receives varies depending on the individual procedure. Fluoroscopy can result in relatively high radiation doses, especially for complex interventional procedures which require fluoroscopy be administered for a long period of time. Radiation-related risks associated with fluoroscopy include:

- skin injuries, which are rare and usually happen only during prolonged or complicated procedures or when there are problems during the procedure, and
- radiation-induced cancers; this risk is considered small.

**Mammogram:** The risks to you associated with mammograms are small. Some discomfort can be associated with mammograms because of breast compression. Mammograms also require exposure to a small amount of radiation and the risk is considered small.



**MUGA scan:** The MUGA heart scan takes images of the beating heart to see how well your heart is pumping blood. It will be done using a radioactive tracer. The radioactive tracer will be injected through a needle placed in the vein of your arm. The amount of radiation is very low and the risk is considered very small. The radiology staff will check you closely for an allergic reaction, which is rare but could be life-threatening. There is a chance that you may experience discomfort, pain or swelling at the injection site and, as is the case with any injection, there is an increased risk of infection at the site.

**MRI scan:** Having an MRI (Magnetic Resonance Imaging) scan involves lying still on a table that slides into a tunnel slightly wider than your body. People who feel uncomfortable in confined spaces may feel uncomfortable in the narrow cylinder. If you feel uncomfortable in confined spaces, please tell your study doctor. Your study doctor may give you a medication to make you feel more comfortable.

An intravenous (in the vein) contrast dye is given with an MRI. Some people can have allergic reactions to the dye put in their veins for these tests. The allergic reactions can cause itching or rash. More serious allergic reactions can cause difficulty breathing, dangerously low blood pressure, or kidney damage. Some patients with kidney disease may have a severe reaction of skin thickening, joint pain and/or swelling, and in rare cases, lung and heart problems and even death.

MRI uses powerful magnets to make images. Therefore, people with certain metal implants, such as pacemakers, should not have an MRI. If you have an implant or any metal in your body, please check with your study care doctor to know whether you can have an MRI or not. For people without metal implants, there are no known health risks associated with exposure to the magnet. As images are taken, a loud banging noise is produced. Earplugs or headphones will be available if needed. The MRI can be stopped at any time at your request, but the scan may not be complete.