

## Model MRI Risk Information for IRB Consent Forms

May 17, 2023

The Joint MR Research Safety Committee recommends the following language or its equivalent be included in the "Risks" section of IRB Informed Consent Forms when Magnetic Resonance Imaging (MRI) is performed for research purposes.

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MRI is a noninvasive and generally safe procedure. There are no known significant risks or side effects associated with MRI scans. However, the very strong magnet in the MRI equipment can attract metals and affect electronic devices in a way that can cause significant harm. In order to determine if it is safe for you to have a MR exam, the person facilitating your exam will ask you a series of questions. It is very important that you answer these questions accurately and thoroughly.

The MRI scanner may produce loud banging or tapping sounds during the scan which could be uncomfortable or painful. Feelings of claustrophobia (fear of being trapped in enclosed spaces) may occur during the scan as well. These risks are reduced by the use of ear protection and procedures that allow you to always be in contact with the person operating the scanner.

Under some circumstances, individuals may experience minor muscle twitching or a tingling sensation during the scan. It may cause mild discomfort, but it is not harmful to you.

In rare cases, contact with the MRI equipment, conductive materials such as wires or other metallic objects, metallic content of tattoos, or some skin-to-skin contact may result in excessive heating and burns during the scan. The operators of the MRI scanner will take steps to minimize these risks.

Although there is no known harm to a fetus from MRI scanning, there may be risks that are unknown. If you are or think you might be pregnant, you should not participate in this study.

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*(if contrast is to be administered)*

You will have a contrast agent (dye) injected through a needle in a vein in your arm or hand. The contrast agent is used to improve the images of certain parts of your body. The contrast agent you will receive is FDA-approved and used routinely for MRI exams. It contains a material called gadolinium.

- You may notice discomfort, tingling or warmth in your lips, a metallic taste in your mouth, tingling in your arms, nausea, or a headache. These symptoms go away quickly.
- There is a small risk of an allergic reaction to gadolinium. You should notify the study team or MRI staff if you have had a prior allergic reaction to gadolinium or a severe allergic reaction to insect stings or nuts or other foods.
- The placement of the needle to give you the gadolinium may cause minor pain, bruising and/or infection at the injection site.
- There is a small risk that some of the contrast agent may leak into your arm around the injection site, which may cause pain, swelling or discoloration.
- If your kidney function is below normal, there is a risk of a rare but serious disease called nephrogenic systemic fibrosis. For safety, your kidney function will be tested before you have any dye injected.
- Small amounts of gadolinium contrast agent can be retained in the brain and other organs for months to years after injection. However, there are no known harmful effects of gadolinium retention.

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*(if the study includes the use of non-FDA approved equipment)*

Some of the imaging software and hardware used in your scan are not approved by the FDA, but are similar to components that have been approved by the FDA. Risks as identified in testing to date are similar to those for FDA approved software and hardware.