**Consent form module: MRI +/- gadolinium procedures and risks**

**Version: 2/1/2024**

***Insert this information in the appropriate sections. The statements in blue are optional, to be used as appropriate for the study.***

**Include in “WHAT WILL HAPPEN IF I PARTICIPATE”**:

MRI (Magnetic Resonance Imaging) is a way for us to see inside your body. MRI uses a powerful magnet, radio waves and a computer to produce detailed pictures of organs, bones and other internal body structures. For the MRI, you will lie on a table inside a scanner tube for about [state how long], while the scanner moves the reading unit over the areas of your body to be scanned. [The MRI used for research is not for diagnosis or treatment and will not look for abnormalities.]

*If a Gadolinium contrast agent will be used*: A liquid containing a gadolinium contrast “dye” will be injected into your vein. This increases the ability of the MRI scan to show certain tissues in the brain or elsewhere in the body.

*[Optional] X-ray exam Procedure*: If you might have metal in your body as a result of past injuries, hobbies, employment, or other life experiences, then an x-ray exam of your affected body part(s) may be done.

**Include in “CAN I STOP BEING IN THE PROJECT?”**:

You may stop at any time, including during the MRI scan.

**Include in “RISKS” or “OTHER RISKS OF THE RESEARCH PROJECT” as applicable**:

There is no exposure to x-rays or radioactivity during an MRI (Magnetic Resonance Imaging) scan, and the risk of injury is very low. However, MRI is not safe for everyone. Serious injury or death can result if you go into the scanner with certain metal objects in or attached to your body. For example, it is not safe to have an MRI scan if you have a cardiac pacemaker, defibrillator, certain metal or implants in your body or have metal in or near your eye.

The MRI scanner makes loud banging sounds that can cause hearing damage, but with earplugs properly worn, there is no known risk of permanent hearing damage. Rarely, your hearing may be less sensitive for several days after an MRI scan, but if this happens your hearing should return to normal within a few days. Some individuals may feel hot or dizzy during the MRI scan. This varies from person to person. You may feel some discomfort because you are lying still for a long time, or because of the padding used to keep your head from moving. Some people feel anxious being in closed or narrow spaces. The scanner operator will be in constant contact with you, and if you choose, you can be taken out of the scanner quickly. Please alert staff to any concerns during the procedure.

*If a Gadolinium contrast agent will be used*: Side effects, such as mild headache, nausea, or burning at the injection site can occur from the gadolinium contrast “dye”. Some people are allergic to gadolinium, experiencing hives and itchy eyes, or very rarely, a bee-sting type of severe allergic reaction (anaphylactic shock). Use of gadolinium may be linked to a rare but sometimes fatal condition (nephrogenic systemic fibrosis or NSF) in people with severe chronic kidney disease or acute kidney problems. Therefore, before you are given this dye for MRI, your risk factors for kidney disease will be reviewed and a blood test will be done to check for kidney disease.

In addition, there may be some unknown or unanticipated risks or discomforts in addition to those specified above because some of the procedures are relatively new and are attempts to advance medical knowledge. Every known precaution will be taken to ensure your personal safety and to minimize discomfort.

**Include in “REPRODUCTIVE RISKS” within “Risks to subjects who could become pregnant”**:

The safety of an MRI during pregnancy is unknown. [Pregnant women will not be allowed to participate in this study. Therefore, one of the following must be indicated

|  |
| --- |
| Initial next to one of the following |
| **INITIAL** | I am not pregnant. |
| **INITIAL** | I am pregnant; therefore, I cannot take part in this study. |
| **INITIAL** | I don’t know if I am pregnant, therefore I cannot take part in this study. |