

**TEMPLATE TEXT FOR POTENTIAL HARMS SECTION OF MRI RESEARCH
CONSENT FORMS**

1. THE MRI MAGNET

Metal Objects

Before being enrolled in this study, you must fill out a MRI screening form and have an interview with (*name here*) in order to find out if the MRI scan is safe for you. Please ensure that all of your questions/ concerns are answered prior to signing the consent form.

The MRI scanner is a powerful magnet. Because metal objects are strongly attracted to the magnet, any metal objects you are carrying or wearing must be removed prior to the MRI scan to avoid potentially severe injury. Metal objects (e.g., hair barrettes, oxygen bottles) can be strongly attracted to the MRI magnet becoming projectiles and can cause serious injury to anyone in the MRI scanner room. The screening process and safety training of MRI personnel will reduce potential injury due to projectiles.

Implants

The magnet may cause metal or implants inside your body (e.g. embedded metal filings, aneurysm clips) to heat up or move leading to potentially serious injury or death. The magnet may also affect some electronic or magnetic devices (e.g., cardiac pacemakers). In some cases, having a particular device or implant means you should not have a MRI scan. After the screening process, a *nurse/technologist* will inform you if you are in a high risk group.

Magnetic Fields

To date, there are no known long-term health risks from the magnetic field or radio waves from the magnetic resonance imaging (MRI) scanner.

The “static” magnetic fields are not known to cause serious health risks.

The “switched” magnetic fields may cause sensations of warmth, seeing spots or tingling. These sensations occur only rarely, and are always temporary. The magnetic fields are kept at low levels to help prevent these side-effects. Fans are used to provide cooling within the MRI bore.

2. NOISE

MRI scanning produces a loud noise that could cause temporary or, very rarely, permanent hearing damage if appropriate sound protection is not used or does not remain in place. You will be given ear plugs or headphones in order to protect your ears.

3. CONFINED SPACE

The MRI scan will take approximately (*X*) minutes. The MRI magnet is shaped like a long tube and may cause some people to feel cramped. If you feel anxious in confined

spaces you may not want to participate in the study. If you decide to participate and begin to feel anxious within the MRI magnet, you can tell the MRI operator to stop the scan.

4. POSSIBLE DISCOVERY OF UNEXPECTED FINDINGS

The possibility of unexpected findings carries with it some risks. Your insurability or employability may be affected. Scans reviewed by a radiologist will become part of your medical record. You may also be worried or anxious as you await the results of follow-up tests. Further tests may be recommended in order to determine the nature and significance of any unexpected finding on your MRI scan and these tests themselves may have risks.

-----USE WHERE APPLICABLE-----

5. ONGOING DISCLOSURE OF POTENTIAL HARMS

If new findings about the potential harms of the MRI technique become available during the time of the study, the researcher will let you know.

6. MRI WITH SEDATION

For this study, you may be given a sedative before your MRI scan. This sedative should cause you to either relax or fall asleep during the scan. The sedative will be given to you by *mouth/through a needle in one of your veins/in your nose/etc.*

To see if it is safe to sedate you, a *nurse/doctor/technologist/etc* will ask you about any health conditions, medications, and allergies you may have that could increase the risk of sedation. The side-effects of sedation commonly include drowsiness, confusion, dizziness, and impaired judgment. In extremely rare cases, a reaction to sedation could cause problems with your heart, lungs, and brain that could lead to brain damage and/or death. For this reason, you will be monitored during your MRI scan to look for any sign of problems and in order that you can be treated quickly if there is a problem. So, for your safety while you are sedated or asleep, a trained *nurse/doctor/technologist/etc* will watch you and your *breathing/heart rate/blood oxygen level/etc* will be monitored.

Also, for your safety, you will be watched carefully after being sedated for the MRI scan. You will be discharged home only when the *nurse/doctor/technologist/etc* has decided that you have recovered enough from the sedation. You will still be a bit sleepy when you are discharged. If you are able to walk, you will be discharged only when you are able to walk normally. If you are leaving the hospital, you will still be too sleepy to drive, or take the bus or a taxi, so you must be brought home by a family member or friend.

Other Monitoring Equipment

While inside the MRI magnet, stickers with wires connected to a heart monitor will be attached to your skin. Your skin may become warm where these stickers are attached. This is normal and not harmful. These stickers have been carefully tested and are safe for

MRI scans. In some situations, other types of monitors will be used to help keep you safe during the scan.

7. MRI WITH CONTRAST ENHANCEMENT

The contrast agent (a mixture given through a needle) you will receive is often used for MRI scans. Insertion of the IV needle may cause minor pain, bruising and/or infection at the injection site. Occasionally, more than one injection site may be needed (e.g., due to vein size). The injection of contrast agent through an IV needle in your arm may cause you to feel discomfort, generalized coldness, a tingling sensation in the throat, nausea or headache. These symptoms go away quickly. Allergic reactions are rare, but they may be life threatening.

For your safety, trained staff will attend to the administration of the contrast agent and will be ready for any potential emergency that could arise due to an allergic reaction to the contrast agent.

8. PREGNANCY

There is no evidence of injury or harm from MRI scans to the fetus. However, there may be risks to the fetus associated with MRI scanning during pregnancy that are unknown at this time.

You will be screened by a *nurse/doctor/technologist/researcher* who will ask you if you are pregnant or not. You must inform the *nurse/doctor/technologist/researcher* if you are or may be pregnant.