

Magnetic Resonance Imaging Standard Language for Consent Documents

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The consent form language options outlined in this document should be used for all research projects that include MR imaging for research. Please consult with the MRI division if you are unsure of what procedures will be required for your imaging protocol.

PROCEDURES SECTION

Magnetic Resonance Imaging (MRI) scans create images of the body using a strong magnet and radio waves. There is no radiation involved in an MRI exam. Most MRIs take about 60 minutes. *Revise if the timing of your MRI is different.*

You may not take part in this study if you have any metal or device in your body which is not compatible with MRI. Examples include certain pacemakers, defibrillators, aneurysm clips, or other implanted electronic or metallic devices, shrapnel, or other metal.

Choose either (a) or (b) depending on whether skull X-rays will be performed or not:

(a) If you have a history of metal in your head or eyes, you will need an x-ray exam of your skull in order to find out if the MRI exam is safe for you.

(b) If you have a history of metal in your head or eyes, you cannot take part in this study.

The MRI machine periodically makes loud banging noises. We will provide earplugs or headphones for you to wear during the MRI exam.

If contrast will be used for the MRI exam, add the following language

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.

Insert if using 7T MRI:

In this study you will undergo a type of MRI called 7T MRI, which uses a stronger magnet than standard MRI. While some 7T scanners are FDA approved, some are not yet approved by the FDA and are considered investigational devices. The 7T scanner used at this site is not FDA approved.

Since this study involves 7T MRI, it is especially important that you tell your study doctor if you have any medical implants or metal in your body in order to determine if it is safe for you to undergo 7T MRI.

RISKS SECTION

While no significant risks have been found from the use of MRI scans, you may be bothered by the noise made by the MRI scanner and by feelings of being closed in (claustrophobia).

Insert if using 7T MRI:

You may feel more claustrophobic in the 7T MRI scanner. You may also experience mild nausea and dizziness in the 7T MRI scanner.

If gadolinium contrast will be used for the MRI exam, add the following language:

The contrast agent you will receive is FDA-approved and used routinely for MRI exams. It contains a material called gadolinium.

- About 1 in 100 people may notice discomfort, tingling or warmth in the lips, metallic taste in the mouth, tingling in the arm, nausea, or headache. These symptoms go away quickly.
- There is a small risk of an allergic reaction to gadolinium. However, a severe allergic reaction occurs in less than one in 300,000 people.
- The placement of the needle (small plastic tube) to give you the gadolinium may cause minor pain, bruising and/or infection at the injection site.
- There is a small risk (about 1 in a 1000) that some of the contrast agent may leak into your arm around the injection site ('extravasation'), which may cause pain, swelling or discoloration.

People with severe kidney failure who receive gadolinium are at risk of developing Nephrogenic Systemic Fibrosis/Nephrogenic Fibrosing Dermopathy (NSF/NFD). This disease causes fibrosis (the formation of too much connective tissue in the skin and internal organs). This is a serious disease, which can result in death.

You should notify the study team or MRI staff if:

- You are allergic to gadolinium
- You have kidney problems

Studies have shown that gadolinium contrast agents may accumulate in various parts of your body, including bone, brain, and other organs. The amount accumulated increases with the number of times gadolinium is administered. There is no evidence currently that this is associated with any adverse health effects.

If you have any concerns, you should discuss with your doctor the benefits and risks of receiving gadolinium contrast agent.

If a screening skull x-ray is done, add the following radiation risk language:

If you require an x-ray examination of your head and eyes, the total amount of radiation you will receive from that x-ray examination is 0.01 rems. Radiation that occurs naturally (cosmic radiation, radon, etc.) causes whole body radiation exposures of about 0.3 rems per year. People who are exposed to radiation at their jobs are permitted to receive whole body exposure of 5 rems per year.

Use of investigational agent or an agent other than gadolinium:

If your research study involves the use of an investigational agent or an agent other than gadolinium, the risks section must be specific to the agent being studied. This information can be found within the Sponsor's Investigator's Brochure or the package insert. Please consult with the MRI division if you are unsure of the contrast needs for your research.

PREGNANCY RISKS SECTION

If the MRI exam will NOT include a contrast agent, use the following language:

There are no known risks from MRI imaging without contrast during pregnancy. There may be risks that are currently unknown.

If the MRI exam WILL include a contrast agent, use the following language:

MRI imaging is not known to cause risk to the developing fetus. However, there may be risks that are not known at this time. MRI contrast is known to cross the placenta and subsequent risks to the developing fetus are not known. You may have an MRI scan without contrast if the study allows this. If possible, you should wait until after your pregnancy is completed before having contrast-enhanced MRI imaging.