

ICF SECTION: STUDY PROCEDURES

What is an MRI?

Magnetic Resonance Imaging (MRI) is a type of scan that uses radio waves to take detailed pictures of the body. You will be asked to lie on an MRI table where the technologist will place a receiver on the part of your body to be studied. You will be provided a blanket for comfort and earplugs since the MRI makes noises while it is scanning. You will still be able to hear some sound to ensure you can communicate with the technologist and can follow any direction given throughout the MRI scan. The technologist will slowly slide you into the MRI magnet where radio waves will be transmitted into you.

Screening for MRI

You must complete a screening evaluation form in advance of the MRI exam for the presence of medical implants or other foreign bodies that could pose an injury when undergoing MRI. The screening is only as effective as the provided medical history. In cases where there is insufficient information to evaluate the risks associated with an implant or foreign body, the MRI study will not be allowed to proceed.

What is a contrast agent? (only needed for studies with MRI contrast)

A contrast agent can brighten the MRI images and provides more detail. During the MRI scan you will be given an intravenous injection of a contrast drug called gadolinium. Gadolinium is an FDA-approved drug given for many different types of MRI examinations during routine clinical care.

What are MRI Dielectric pads? (only needed for studies using dielectric pads)

To improve the quality of brain MRI scans obtained at 7 Tesla, you may have thin pads placed near your head that look similar to a gauze pad. These pads improve the images. The pads are not yet approved by the FDA, but they have passed extensive testing for safety and durability by their manufacturer according to accepted standards.

ICF SECTION: POTENTIAL RISKS

Flying Objects

The greatest risk of MRI is a magnetic object flying through the air toward the magnet and hitting you. To reduce this risk, we require that all people involved with the study remove all magnetic metal from their clothing and all magnetic metal objects from their pockets. No magnetic metal objects are allowed to be brought into the magnet room at any time except by approved personnel. In addition, once you are in the magnet, the door to the room will be closed so that no one inadvertently walks into the room.

Medical Implants and Foreign Bodies

There is a potential risk of MRI for participants with medical implants or other metallic objects in their body. All participants undergoing MRI scanning must complete a screening evaluation in advance of the study for the presence of medical implants or other foreign bodies that could pose an injury. Every effort will be made to ensure that disclosed implants or foreign bodies do not pose a risk to participants. In cases where there is insufficient information to evaluate the risks associated with an implant or foreign body, the MRI study will not be allowed to proceed.

Possible Side Effects

Possible side effects related to the MRI scan include:

Possible:

- Anxiety/stress
- Claustrophobia
- Discomfort
- Nausea/vomiting
- Tingling in arms

Rare, but serious:

- Injury related to the presence of metallic or surgical implants or metal pieces in the body and the MR magnet. This also includes: wearable sensors, medicinal patches, certain types of tattoos, and hair weaves containing metallic threads. It is important that you let the MRI team know about whether you have these before the MRI procedure.

Pregnancy (only needed for studies unrelated to pregnancy)

Although there are no known risks related to MRI on pregnant participants or a fetus, there is a possibility of yet undiscovered pregnancy-related risks. Since there is no possible benefit from participating in this protocol for a pregnant participant, we will exclude participants who are pregnant.

Pregnancy (only needed for studies at 3T or lower fields where participants are pregnant or will not be tested for pregnancy)

Although there are no known risks related to MRI on pregnant participants or a fetus, there is a possibility of yet undiscovered pregnancy-related risks. The MRI scan you will receive complies with the recommendations of the American College of Radiology guidelines for safe MRI research during pregnancy.

Incidental Findings

This MRI is not a clinical scan. It is possible that during the course of the research study, the Investigator may notice an unexpected finding(s). Should this occur, the finding(s) will be considered by the appropriate personnel and the PI will inform you if the finding requires any further

action on your part. These possible finding(s) may or may not be significant and may lead to anxiety about your condition and to further work-up by your physician.

Research Risk (only needed for studies including experimental sequences and/or coils)

Some of the pulse sequences and/or RF coils are not FDA approved but are considered to pose no more than minimal risk.

No Radiologist Reading/Interpretation

The MRI performed under this protocol is not for medical purposes, and the images are not planned to be interpreted by a Radiologist.

Gadolinium Retention (only needed for studies using MRI contrast)

Discuss any medication you are taking. All MRI contrast agents contain a metal called gadolinium. Small amounts of gadolinium can stay in the body for several months to years. This is much less with the contrast agents used at Penn Medicine, which are among the most stable agents. Importantly, no harmful health effects related to gadolinium retention have been shown at this time. Nephrogenic Systemic Fibrosis (NSF) is a very rare disease that can occur in people with severe kidney problems. However, no cases of NSF have been caused by the stable agents that we currently use at Penn Medicine.

IV Line Placement (only needed for studies using MRI contrast)

Multiple needle-sticks may be necessary if a vein cannot be properly accessed, and this will be carried out upon your permission.

IV Contrast Risks (only needed for studies using MRI contrast)

Part of your MRI study will require the injection of a gadolinium contrast agent into your blood stream. There is a rare possibility that you could have an adverse reaction to the contrast agent such as rash, hives, itching, mild headache and nausea. You may also experience some minor discomfort and low risk of bleeding, infection and bruising associated with Intravenous catheter placement.

Pregnancy (Note: Include this sentence with the pregnancy risk clause listed above for studies using MRI contrast)

Gadolinium-based IV contrast agents are not approved in pregnant participants and therefore pregnant participants will be excluded from this trial.

7T Magnetic Field Strength (only needed for studies using the 7T magnet)

The FDA has approved the use of 7 Tesla (7T) MRI scanners for diagnostic use and considers magnetic field strengths up to 8.0T to pose no more than minimal risk. No persistent adverse effects have been reported by facilities with magnetic field strengths at 7T. However, some people have reported transient dizziness, nausea, or a metallic taste upon being moved into and out of the

scanner. These effects typically last less than 10 minutes and can be minimized by reducing the speed at which the person is moved inside the magnet.

7T Dielectric Pads (only needed for studies using the 7T magnet and dielectric pads)

These pads contain a conductive material that could cause irritation if directly contacting your skin, but that material is completely sealed in a strong, thick plastic.