



Figure 1- 3T MRI Pavilion 10th Floor

Descriptions for the study procedures section of the ICF.

What is an MRI?

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?

Note: Only needed if the study is an MRI with 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 given for many different types of MRI examinations during routine clinical care.

What are MRI Dielectric pads?

Note: Only needed if the study uses dielectric pads

MRI Dielectric Pads for the 7T scanner:

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.

Descriptions of MRI Risks for the risk section of the ICF.

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 subjects with medical implants or other metallic objects in their body. All subjects undergoing MRI scanning must complete a screening evaluation risk 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 insure that disclosed implants or foreign bodies do not pose a risk to subjects. 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 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

Note: Only needed for studies unrelated to pregnancy

Although there are no known risks related to MRI on pregnant women 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 woman, we will exclude women who are pregnant.

Incidental Findings Clause

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 Clause

Note: The following language is required to be written into the ICF of all protocols that include experimental sequences and/or coils. If you are unsure, if your protocol includes experimental sequences and/or coils, please consult with the Radiologist on study and CAMRIS.

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.

NEW! Gadolinium Retention

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

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

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 language of MRIs noted above.

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

7T Clause (if using the 7T magnet)

The FDA has approved the use of 7 Tesla 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 (if applicable)

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.