

Additional Template Language for Studies
Involving Magnetic Resonance Imaging (MRI) Procedures

Protocol

Please include the following language in the Protocol if a contrast agent is being used.

Subjects will be screened for renal impairment prior to administration of gadolinium-based contrast agents (GBCA) as it is routinely done in the Radiology Department at UT Southwestern. A creatinine determination 30 days prior to the research MRI examination must be available to calculate an eGFR. An eGFR calculation may be repeated closer to the MRI appointment if the patient's medical condition has changed. An eGFR ≥ 30 mL/min/1.73m² is considered acceptable for administration of a standard weight-based dose of GBCA for research purposes.

Consent Form

Some or all of the following information may be appropriate for your study

Under the section titled "What is involved in the study?" subsection "Procedures and Evaluations during the Research:" please insert the following:

You will have magnetic resonance imaging (MRI) of your [insert part of the body]. For this procedure, you will lie quietly inside a large, doughnut-shaped magnet for about [insert time interval] minutes.

For patients undergoing MRI of the head, please also include:

Your head will rest in a special helmet-like holder to help you keep your head still.

Under the section titled "What are the risks of the study?", please state the following:

There are no known risks from exposure to magnetic fields. You may experience nervousness and/or anxiety due to the loud banging made by the machine while it is taking pictures and from confinement in a tight space (claustrophobia). If you become anxious, you can stop the procedure at any time

You may also experience some discomfort and fatigue from lying still during imaging.

If you have any metal clips or plates in your body, you should tell the investigator. MRI may not be appropriate if you are pregnant or are trying to become pregnant. MRI may not be appropriate if you have permanent eyeliner or eyebrows or any pieces of metal in your body, such as the following:

- heart pacemaker, heart valve replacement, or aortic clips
- metal fragments in your eyes, skin, or elsewhere in your body
- brain clips or pieces of metal used in aneurysm surgery or intercranial bypass

- venous umbrella
- pieces of metal in the body resulting from work as a sheet-metal worker or welder
- clips placed in an internal organ
- prosthetic devices, such as middle ear, eye, joint, or penile implants
- joint replacement.
- hearing aid that cannot be removed
- neurostimulator
- insulin pump
- intrauterine device (IUD)
- shunts or stents
- metal mesh or coil implants
- metal plate, pin, screws, or wires, or any other metal implants

If contrast will be used, the following paragraph is also required.

The contrast agent you will receive is FDA-approved and used routinely for MRI exams. It contains a material called Gadolinium (dye solution used to highlight organs or tissues during imaging). The injection of Gadolinium may cause discomfort like headache, nausea, strange taste, or coldness at site of injection. These symptoms occur in less than 1 out of 20 patients receiving Gadolinium and go away quickly. There is a small risk of a severe allergic reaction that can cause breathing difficulties and/or low blood pressure, and these symptoms are extremely rare (approximately 1 in 10,000 to 1 in 100,000 administrations). In the unlikely event you experience these symptoms, a physician and nursing staff will be available to evaluate and, if necessary, provide treatment.

People with severe kidney failure who receive Gadolinium (dye solution used to highlight organs or tissues during imaging) are at risk of developing a disorder called Nephrogenic Systemic Fibrosis (NSF). This disease can cause wide spread tissue scarring or hardening (fibrosis). In rare cases NSF can lead to lung and heart problems and cause death. If you have severe kidney failure and receive gadolinium, the risk of developing NSF is 1-5%. We may perform a blood test 30 days before your MRI to check how well your kidneys are working before you receive the Gadolinium. This test may be repeated closer to your MRI appointment if your medical condition has changed. If your kidneys are working at levels known to be at risk for NSF, you will not receive Gadolinium. You will not receive Gadolinium for research purposes if you have sickle cell disease (a disease of the blood cells) since it may put you at risk of developing hemolysis (breakdown of blood cells).