

SLEIC 3T MRI

Safety Risk Statement for Investigators and Visitors

Revision history

Revised	By	Comments
2011-08-22	SLEIC Staff	Approved
2013-10-13	Rick Gilmore	Converted to Markdown

Risks in the 3T SLEIC Scanner Room

This form describes the risks assumed by investigators or visitors who either:

1. Enter the scanner room, or
2. Volunteer for development scans.

As an investigator/visitor who will enter the scanner room or an investigator who will participate in a development scan as a volunteer you are agreeing to:

- Answer the SLEIC 3T MRI safety screening questions accurately
- Tell the scanner operator about all metallic devices or implants in/on your body
- Not bring any metal devices (e.g., pens, coins, keys, credit cards) into the scanning room.
- Remove any articles of clothing with metal inserts or clasps before entering the scanner room if asked to do so by the scanner operator.
- Ask if you are unsure about any items BEFORE entering the scanner room

All investigators who enter the scanner room must be over 18 years old.

1. Entering the scanner room (i.e., going past the 5 Gauss line):

Investigators or visitors who enter the scanner room need to be aware that they may be exposed to the danger of projectile motion in case something ferromagnetic is accelerated toward the bore. If you have any implants or explants (medical devices or clips, etc. either inside or outside the body) you should not enter the scanner room unless the implant/explant has been approved for use in a 3T field and has been reviewed by the scanner operator. You will be asked to fill out the investigator/visitor

safety screening form that will be kept in a secure locked file in the SLEIC facility.

If you have any concerns you should **not** enter the scanner room.

2. Volunteering for development scans:

Only investigators who have passed SLEIC 3T MRI Safety Training are allowed to volunteer for development time scans (without an IRB). NONE of the scans performed during project development are designed to detect or evaluate any medical conditions. They are intended solely for project development purposes.

To date, 150 million MRI studies have been performed around the world. We will be following standard MRI procedures and safety guidelines. MRI has been shown to be extremely safe as long as proper safety precautions are taken. MRI uses strong magnetic fields and radiowaves to make pictures of the body. There is no exposure to x-rays or radioactivity during an MRI scan. Levels of energy used are within FDA safety limits.

3. Discomforts and risks of the MRI:

The most common reasons people are uncomfortable during an MRI scan include:

- The volunteer must stay still.
- The scanner is loud and ear protection is required. Ear protection is not optional.
- The scanner bore and coils can cause a claustrophobic feeling in some people.

Risk of injury is very low during an MRI scan. However, MRI is not safe for everyone. It may not be safe for you to have an MRI scan if you have any metal containing iron in or on your body. This is because metal containing iron can pose a safety risk when in the presence of strong magnetic fields. Radiowaves may also heat the body and metallic objects within or on the body, possibly resulting in burns. Before you are allowed in the scanner room, you will be asked a set of questions to determine if it is safe for you to have an MRI scan at this time. For example, it may not be safe to have an MRI scan if you have a cardiac pacemaker, aneurysm clips, an intrauterine device (IUD), etc. For your safety, it is very important that you answer all questions truthfully.

It is possible that you may feel uncomfortable or confined once inside the scanner. This feeling usually passes within a few minutes as the experimenters talk with you and the study begins. You might experience dizziness, mild nausea, or tiny flashing lights in your field of vision. These sensations are mostly due to movement while inside the magnet and can be minimized by holding still. All of these sensations should stop shortly after you leave the magnet.

4. Incidental findings

The investigators for this project are not trained to perform medical diagnosis, and the scans to be performed in the study are not optimized to find abnormalities. On occasion, a member of the research team may notice a finding on a scan that seems abnormal. When a finding is noticed, the investigator or designate may consult a physician

specialist, such as a radiologist or neurologist, as to whether the finding merits further investigation. If the specialist recommends further follow-up, the investigator or another designate will contact you within 48 hours of the recommendation and suggest that you contact your private medical provider for follow-up. To facilitate follow-up care, you may be given a copy of your images upon written request. Being told about a finding may cause anxiety as well as suggest the need for additional tests and financial costs. Medical insurance may be affected whether or not the finding is ultimately proved to be of clinical significance. Costs for clinical follow-up are not covered in the cost of research. The decision as to whether to proceed with further examination or treatment lies with you.

Please provide contact information so that you can be reached in the event of an incidental finding.

Address _____

Phone _____

Volunteers should be completely comfortable. There are many explanations for not wanting to volunteer on a given day. Perfectly reasonable explanations for not wanting to volunteer on a given day include discomfort with answering the screening questions, allergy symptoms, headache, any sign of illness, having had too much caffeine to hold still, not having gotten enough sleep to listen to directions once in the scanner, etc. If you decide not to enter the scanner room or participate in the development time scan, you may simply decline and you do not need to tell the scanner operator why.

You may also stop the scan at any time without penalty.

I have read and understood the entire contents of this form and have had the opportunity to ask questions regarding the information on this form.

I understand that this form will be kept on file by SLEIC in a locked file cabinet in a locked room. Only SLEIC personnel will have access to this information.

I have been informed of the risks of entering the SLEIC 3T scanner room and of the risks involved if I participate in a scan as a volunteer for project development.

Investigator or Visitor

Signature: _____

Printed Name: _____

Date: _____

Scanner Operator

Signature: _____

Printed Name:_____

Date:_____