

Zuckerman Institute MRI Platform Safety Manual

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Table of contents

MR Platform Team	2
Overview	3
Safety Zones	4
Zone Access and Safety Training	5
Device Labeling	6
Device Testing	6
MRI Risks and Precautions	7
Safety Screening Procedures	9
Tattoo Policy	10
Scanner Operating Modes	12
Emergency Procedures	14
Appendix: Metal Screening Forms	16

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Overview

The purpose of this document is to provide a centralized overview of safety policies and procedures of the Magnetic Resonance Imaging (MRI) Platform at the Zuckerman Mind Brain Behavior Institute (ZI), located in the Jerome L. Greene Science Center on the Manhattanville Campus of Columbia University. The ZI MRI Platform houses two 3T Siemens Prisma MRI systems for human and non-human primate imaging, and a 9.4 T Bruker Biospin MRI for small animal imaging.

The MRI Platform is committed to ensuring the safety of all staff, researchers, and study participants who participate in neuroimaging at ZI. All MRI users, including Principal Investigators using the Platform for their studies, should review this document to familiarize themselves with the safety regulations, requirements, and procedures. Topics covered in this manual will be organized by topic and cover areas such as safety training, procedures, labels, and risks, as well as instructions for emergency situations and reporting incidents.

Our MRI scanners are used for research purposes only. All human or animal research studies conducted at the ZI MRI Platform must be approved by an Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC), which will have jurisdiction over the activities taking place on the Platform. In addition to following our general guidelines and procedures, it is the responsibility of individual researchers to ensure that all study procedures comply with IRB or IACUC rules, regulations, and approved protocols.

Safety Zones

Zone 1:

Safety zone 1 encompasses unrestricted areas of the Zuckerman Institute where there are no risks related to the magnetic fields created by our MRI scanners. Zone 1 includes the lobby area before the security gate, and is publicly accessible without restrictions

Zone 2:

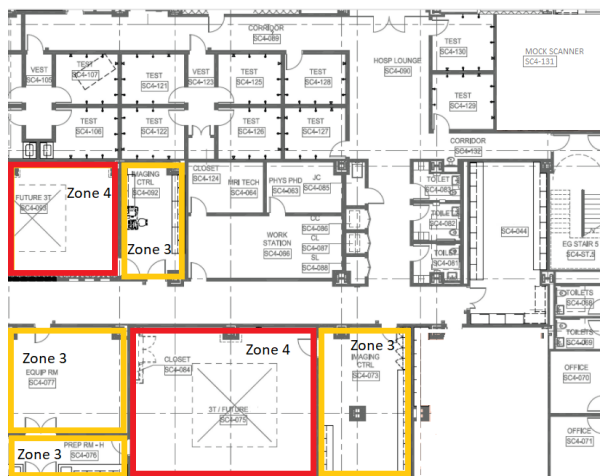
Safety Zone 2 includes all areas of ZI between the security checkpoint and Zone 3. These are areas with no MRI-related risks, but to which access is limited. Zone 2 comprises the majority of the building. It includes every area except the lobby and MRI rooms (control rooms, magnet rooms, equipment rooms, and the animal preparation room).

Zone 3:

Safety Zone 3 includes any areas where there is not a direct MRI-related risk, but which contain unsecured access to the MR systems. Zone 3 areas are only accessible to MR staff and authorized personnel. It includes the control rooms for the MRI systems as well as the animal preparation room for the June scanner. Access to Zone 3 is highly restricted. With few exceptions, only certified scanner operators are given swipe card access to Zone 3.

Zone 4:

Safety Zone 4 encompasses the rooms which contain the scanners themselves. There are risks in Zone 4 due to the presence of static (always on) and varying electromagnetic fields (activated during scanning). Zone 4 can only be accessed through Zone 3 by or in the presence of authorized personnel with the required safety training. Zone 4 access is restricted to individuals who have filled out a MR Safety screening form.



Zone Access and Safety Training

There are three levels of Safety Zone Access and Safety Training at the MRI Platform:

Level I: Level 1 personnel includes all Zuckerman Institute staff (Operations, Facilities, Public Safety) who have completed Level I MR safety training. These individuals have access to Zone 2. They are authorized to work in Zone 3 and Zone 4 as needed, but only if accompanied by Platform staff who will screen them in advance and test all necessary tools to ensure safety.

Level II: Level II personnel are individuals who have gone through the Level II safety training for ZI MRI users. To receive level II training, users must attend two sessions, one virtual and one at JLG, and answer all questions correctly on a written exam. After completing training, the researcher may request swipe card access to SC-4. Level II training must be renewed through a Rascal refresher every year. Users will receive email reminders to complete the rascal training. After three reminders, the swipe card access to the MR systems will be revoked.

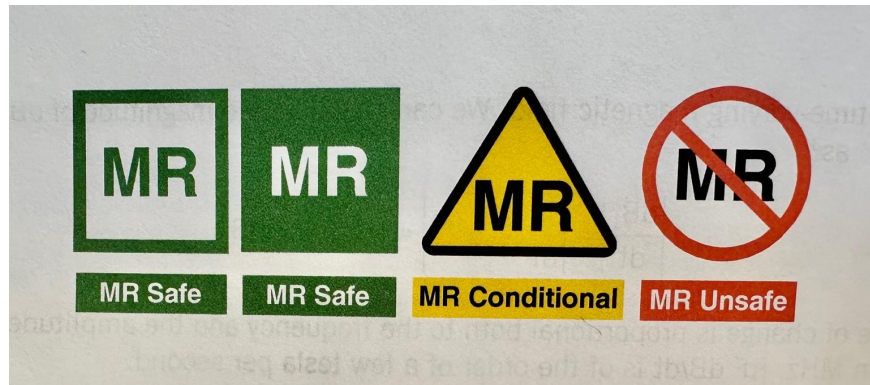
Level II personnel are authorized to work in Zones 3 and 4 (unless there is a medical reason they cannot enter Zone 4), however they do not have swipe card access to these areas.

Level III: Level III personnel are individuals who are able to access Zones 3 and 4 and operate the MR system without supervision from MR Platform Staff. Level III training involves independently operating a scanner and console under the supervision of an MR Staff member. Certification is granted upon successful completion of a practical exam.

Note that all non-MR and Level I personnel must be accompanied by trained staff before entering Zone 3, and must be fully screened on any day they enter Zone 4. "Non-MR personnel" includes research participants, first responders (paramedics, firefighters), and visitors.

At least two individuals who have completed Level II safety training must be present at all human scans, and at least one of them must also have Level III training.

Device Labeling



All equipment in Zones 3 and 4 must be labeled with an MR device label, indicating one of the following categories. Researchers must work with an MR Platform staff member to test and label any equipment which they will be storing or using in Zones 3 or 4.

MR Safe: No metals

MR Conditional: Non-Magnetic metals

MR Unsafe: Ferromagnetic metals & electronics

Device Testing

A trained researcher can test an unlabeled item to determine its category:

- To check if the item has any metal, use a hand-held metal detector
- If metal is detected, check if that metal is ferromagnetic using a small magnet

MRI Risks and Precautions

Several risk factors are associated with MRI, and the MR Platform has policies and procedures in place to minimize these risks.

The main magnetic field (B0). The main magnetic field is very strong and always on. It strongly attracts ferromagnetic metals, meaning any object containing such metals can become a dangerous projectile if brought into Zone 4. This can lead to severe injury or death if anyone is in the path of the object. To prevent this, the ZI MR Platform has strict rules regarding zoning, testing, labeling, and safety training, which are described throughout this manual.

The main magnetic field can also affect ferromagnetic metal in the body, like certain implants, shrapnel, or other fragments. These items can twist or move, which can cause internal injury. The main magnetic field can also disrupt the functioning of electronic devices. Electronic implants such as pacemakers and neurostimulators can malfunction or be damaged, posing severe health risks. The ZI MR Platform requires that everyone (researchers, participants, staff, first responders) who may need to enter Zone 4 fill out a screening form in advance. If a person has potentially risky metal or electronics in their body, they are not allowed to enter Zone 4.

Time-varying magnetic field gradients. Gradient coils are used to spatially encode the MR signal by varying the strength of the magnetic field along different spatial axes. During image acquisition, gradients are changed rapidly, which can induce currents in conductive materials, including biological tissue. This can sometimes cause participants to experience sensations of tingling or twitching, known as peripheral nerve stimulation (PNS). PNS can often be alleviated by slight repositioning of the participant.

Additionally, the rapid switching of gradients results in noise loud enough to potentially cause hearing damage. Research participants must wear hearing protection (earplugs) when they are being scanned.

The radiofrequency electromagnetic field (B1). Radiofrequency (RF) pulses used to excite hydrogen protons in the tissue of interest may cause tissue heating. To minimize risk, researchers must use padding and positioning to maintain separation between participants and the RF coil as well as the scanner bore. In addition, close attention must be paid to Specific Absorption Rate (SAR) levels throughout the scan.

RF fields may also induce currents in conductive loops, increasing burn risk. Staff are trained to avoid conductive loops by positioning wires straight and away from skin contact, and by positioning participants to avoid clasped hands or crossed legs.

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Researchers must maintain frequent communication with participants throughout the scan and immediately investigate any reports of warmth, heating, or burning sensations. Each participant should be provided with the squeeze ball, which triggers a tone and flashing light on the intercom unit at the console when activated. Participants should be instructed to use the squeeze ball if they need to communicate, especially if they experience warmth, burning, tingling, or any other form of discomfort.

IMPORTANT: Emphasize to participants that they should squeeze the ball immediately if they feel discomfort, rather than waiting for a sensation to intensify or subside. Researchers should promptly pause the scan (to stop the noise) and use the intercom to assess the participant's condition. Clear communication with participants is one of the most critical tools for preventing injuries, including burns, during MRI sessions.

Safety Screening Procedures

All researchers complete the ZI MR Platform safety screening form as part of their initial MR safety training. This is to ensure it will be safe for them to work in the MR environment.

Before scanning a participant at the Zuckerman Institute, the researcher must have that participant fill out the ZI MR Platform safety screening form. This form must be completed twice: once as soon as possible when enrolling a participant in a study, and again on the same day the scan takes place. The first screening is needed very early because some potential MRI contraindications will take time and effort to review and cannot be handled the day of the scan. Because of this, the MR Safety Officer is available to review any potential safety issues in advance. The procedure for safety screening is as follows:

- Screen your potential participant as early as possible.
- Inform the Safety Officer of any contraindications at least 7 days prior to the scan
- If the participant has an implant or medical device, please provide:
 - The full description of make, model, materials, dimensions, position, and year it was placed in the body.
 - If an implant contains metal or electronic components, provide an FDA MRI Label. If you can't find one online, contact the manufacturer. If you cannot provide an FDA label, please let the Safety Officer know as soon as possible and provide any other information you can.
- If the participant has tattoos:
 - Provide a detailed description with the following information as soon as possible:
 - width and height in cm, location, when and where it was done, colors, density, and the size of the empty space between multiple tattoos
 - Note if there are any long straight stripes; closed loops; especially which encircle a limb, finger, or toe, or sharp pointy shapes like barbed wire or thorns
 - Tattoos must be visually inspected, either via photo or (if that is not possible due to study constraints or participant discomfort) in person on the scan date by the MR Safety Officer or Technologist; If the tattoo is inspected the day of the scan, there is still a chance the participant will not be cleared for scanning.

The Safety Officer will respond and request any additional information that is needed. Please note that if an FDA label for an implant cannot be provided, clearance will depend on the judgment of the MR Safety officer.

Tattoo Policy

Individuals with tattoos are at an increased risk for RF- induced burns while undergoing an MRI. While this risk is still minimal for the majority of people with tattoos, extra care should be taken. The FDA safety categorization for all tattoos is 'conditional,' meaning that the safety depends on the specific tattoo and scanning conditions. In some cases, the risk may be greater than minimal, in which case the participant should not be cleared for participation in most research studies run at ZI. In general, RF- induced heating is a complex process and depends on many factors: the frequency of the RF pulse, the specific heat coefficient, density, and conductivity of the material, circulation, ventilation, and ambient temperature. In addition to tattoos or permanent make-up acting as an RF antenna, burns can also be induced by applying gradients to the B0 field. Given the difficulty and uncertainty in predicting how any specific tattoo will react to a given protocol, caution should be exercised.

Scanning is high risk for the following types of tattoos:

- Head or neck tattoos larger than 2 cm
- Non-professional
- Got recently (past month)
- Sleeve or other limb covered

There are many other dimensions to tattoos that can affect the risk of RF burn:

- Specific spatial patterns, including connected loops and points
- Opaque pigment, colors, density
- Size (> 2 cm) or number of tattoos in close proximity
- Location on body

For tattoos with these characteristics, clearance will involve the judgment of the MR safety officer or technologist. For some cases, if there are a small number of these features, the participant will be cleared for scanning, warned of the potential risk, and told to alert the person running the scan if they feel any sensation at all during the scan. In other cases with large numbers of the above features, such as large dark tattoos with many loops and edges, it will be recommended that the participant not be scanned.

In cases where there is concern about the risk of a full protocol, we can arrange to scan subsets of sequences with the following modifications:

- Only using Siemens product sequences
- Removing lower priority sequences to shorten total scan time

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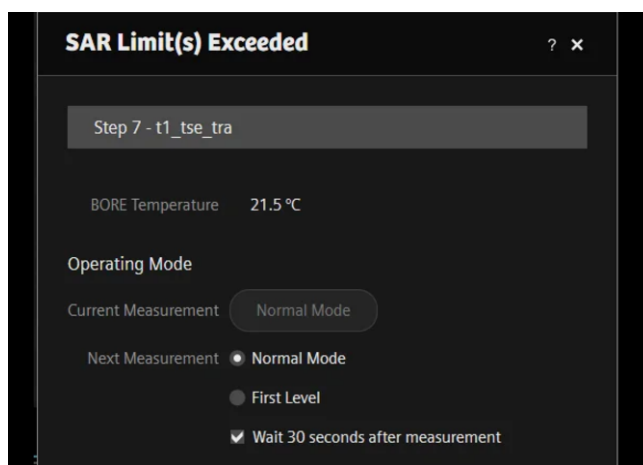
- Shortening individual sequences where possible
- Allowing 2-3 minute breaks in between all sequences to cool down
- Cold compress over tattoos

For any individual research study, the details of this “stepdown” protocol will be worked out in advance and approved by the PI, safety officer, and physicist.

In all cases, patients with tattoos must be given a warning about heating and told to squeeze the alert ball if they experience any sensation in the area of the tattoo. Then the researchers can address the issue or stop the scan entirely.

Scanner Operating Modes

FDA and International Electrotechnical Commission (IEC) standards are used to define three modes of scanner operation. **Normal Mode** indicates routine functioning of the MRI which is considered safe. **First Level Operating Mode** indicates that some imaging parameters have reached a level which may cause stress to the participant. **Second Level Operating Mode** indicates that some imaging parameters have exceeded FDA or IEC limits for safe operation. The scanner will provide warnings if you are going to enter either First or Second Level Operating Mode for Specific Absorption Ratio (SAR) or Gradient Switching.



For SAR, Normal Mode does not exceed 2 W/kg averaged over the whole body mass and 3.2 W/kg averaged over the head mass in any 6 minute period. First level operating mode is below 4 W/kg averaged over the whole body mass and below 3.2 W/kg averaged over the head mass in any 6 minute period. Second level operating mode limits would need to be determined by the IRB for a specific study.

The First Level gradient switching warning is very common for research sequences and will indicate that the participant may experience peripheral nerve stimulation.

As a general policy, researchers are able to operate in Normal Mode or First Level Operating Mode while scanning at ZI with the following exceptions:

- They must comply with their IRB rules surrounding operating modes
- If a participant has an MR conditional implant, only Normal Mode is allowed for SAR. First Level Peripheral Nerve Stimulation (PNS) warnings are allowed for participants with implants unless otherwise stated on the implant's FDA label.

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For cases where a participant has an MR conditional implant, or where the IRB has not approved First Level operating mode, any sequences that produce a First Level Mode SAR warning must be skipped or modified. We do not allow Second Level operation for any imaging parameters without prior consultation with the MRI Platform team and explicit permission from an IRB. For unassisted scans, it is the responsibility of the Level III trained operator to ensure the appropriate operating mode is maintained.

Emergency Procedures

Emergency Buttons



From left to right:

- The quench button
- The O2 meter
- The fire alarm
- The power off button

Medical emergency

If a participant has a medical emergency, stop the scan immediately. One researcher should enter Zone 4, remove the participant from the scanner, and bring them to the labeled muster point at SC4-130 then remain with the participant throughout. At the same time, the other researcher should call Public Safety (3-3333) and inform them that there is a medical emergency in JLGSC SC4-130, and then contact Managing Director Raphael Gerraty at 212-853-4985. Public Safety will call 911.

Fire emergency

In the case of a fire emergency, immediately hit the emergency power shutoff button. One researcher should enter Zone 4, pull the black handle on the bed underside to unlock the table, and remove the participant from the scanner. The researcher should then bring the participant to the labeled muster point at SC4-130, then take a MR-conditional fire extinguisher from the corridor alcove, and return to the magnet room to assist with extinguishing the fire. At the same time, the other researcher should pull the fire alarm, get the MR conditional fire extinguisher located in Zone 3, use it to put out the fire, and call Managing Director Raphael Gerraty at

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212-853-4985. If the fire can not be extinguished with the two fire extinguishers, the researcher must quench the magnet.

Spontaneous quench

In case of a spontaneous quench, the O2 meter may sound its alarm, which indicates decreased oxygen in Zone 4. One researcher should enter Zone 4 and remove the participant from the scanner. Have them change and get their belongings, and escort them to the lobby. The other researcher should call Public Safety 3-3333 and tell them there is an equipment failure happening. Call Managing Director Raphael Gerraty at 212-853-4985, and call other MR Platform staff until someone arrives to take over. It is important that you wait in the waiting area (not Zone III) until MR Platform staff arrive.

When to intentionally quench the magnet

Only quench the magnet yourself in the following life threatening situations:

- Somebody is pinned to the magnet by a ferrous object
- There is an uncontrollable fire in or around Zone 4

These are the only circumstances in which you should quench the magnet. Do not quench the magnet in any other situation (e.g., a medical emergency, a small fire that does not require firefighters, or objects stuck to the bore).