
MAGNETIC RESONANCE IMAGING RESEARCH CORE

Standard Operating Policies and Procedures

Magnetic Resonance Imaging Research Core

MRI Research Core Policies and Procedures

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1. PURPOSE

The purpose of the MRI Research Core Policies and Procedures is to maintain safe laboratory practice during research scans at the MRI Research Core facility within the Geisinger-Bucknell Autism & Developmental Medicine Institute. It has been reported that MR related injuries, fatalities, and equipment damage were the apparent result of failure to follow established safety guidelines. For the purpose of maintaining safe MRI practices, recommendations from the *ACR Guidance Document for Safe MR Practices: 2013* are used. This document may be found on the [ACR MR Safety website](#). In addition to safety policies, this document describes standard operating procedures of the MRI Research Core. Because MRI technology continues to progress, this is a living document that will be updated as needed.

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2. PERSONNEL DEFINITIONS

2.1 MRI Research Core Committee

The MRI Research Core Committee (“Committee”) consists of the Director of the Geisinger Institute for Advanced Application, the Director of the Autism & Developmental Medicine Institute, the MRI Research Core Manager, and several “power users” of the Core facilities. The primary function of the committee is to review and recommend strategic acquisitions, assist with research proposal reviews, and review policy violations and report correction action recommendations. Annually, a program review will be performed by the Committee to set strategic goals and review policies for adoption.

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2.2 MRI Research Core Manager

The MRI Research Core Manager (“Manager” or “Management”), Sam Fielden, is the primary contact for all MRI Research Core activities, including equipment related questions and concerns and MRI safety training.

2.3 MRI Technician

The MRI Technician (“Technician” or “Tech”) is a person whose primary employment duties consist of operating MRI scanner equipment. See [Section 2.5](#) for further information, as a Technician is also classified as an MRI Scanner Operator by definition.

2.4 MRI Research User

The MRI Research User (“Researcher”) is a Principal Investigator (PI), staff member, trainee, or laboratory assistant who utilizes the MRI scanner for research purposes. A Researcher may or may not be an MRI Scanner Operator, defined below. Under the ACR guidelines, Researchers are designated “Level 1 MR personnel.” Briefly, Researchers are permitted inside the scanner control room (“Zone III”) and the scanner room itself (“Zone IV”) in order to assist in set-up of research experiments, but are excluded from operating the scanner itself. Researchers are also permitted to be responsible for accompanying Research Participants throughout Zone III, but NOT Zone IV. Refer to [Appendix B](#) for definitions of MR Safety Zones and to the [ACR Guidance document](#), Sections 2 and 3 for further details regarding MR personnel.

2.5 MRI Scanner Operator

The MRI Scanner Operator (“Operator”) is a Researcher or Technician who has been more extensively trained and educated in the broader aspects of MR safety issues and is specially trained in the operation of the scanner. Operators have authority to stop any procedure they deem exceed safe practices. Under the ACR guidelines, Operators are designated “Level 2 MR personnel.” At least one Operator must complete the safety screening of any non-MR personnel and must accompany any Research Participant into the scanner room itself (“Zone IV”). Refer to the [ACR Guidance document](#), Sections 2 and 3 for further details.

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2.6 Non-MR Personnel

All those not having successfully complied with the MR safety guidelines are designated non-MR personnel. Non-MR Personnel may include Research Participants, family members of Participants, healthcare practitioners, maintenance workers, cleaning crew, emergency responders, etc.

2.7 Research Participant

A Research Participant (“Participant”) is a non-MR person who is placed into the bore of the MRI scanner for research purposes.

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3. SAFETY-RELATED POLICIES AND PROCEDURES

Participant safety during MRI studies is essential. As there are inherent risks associated with MRI, the Geisinger-ADMI MRI Research Core follows [ACR safety operational recommendations](#) to protect the health and safety of all personnel and participants who enter the MRI Suite.

3.1 Training & Certification for Researchers

Prior to participating in MRI Research Core activities, all Researchers are required to complete:

- (1) The MRI Safety Screening AND
- (2) MRI Safety training via the GOALS system

The [Screening Form](#) will be completed by the Manager. Documentation of the completion of the MRI Safety GOALS course must also be provided to the Manager via screenshot-and-email and must be completed annually. The MRI Safety Screening form must be repeated in the event of any trauma, procedure, or surgery experienced or undergone where a ferromagnetic object or device may have become introduced to the body. Completion of these requirements will be documented via the [New Users Check-off Form](#), which will remain with the Core.

3.2 Training & Certification for MRI Scanner Operators

Approved Operators of the MRI equipment at Geisinger/ADMI understand that safe operation within the MRI environment and the administration of this safety policy and procedure is their responsibility while at Geisinger/ADMI.

In addition to the requirements (1) and (2) for Researchers in Section 3.1, Operators must:

- (3) Walkthrough the facility and discuss with the Manager safety-relevant policies and procedures. During the walkthrough, all of the points listed on the New Users Check-off Form will be discussed, with special attention given to emergency procedures involving the emergency shut-down and emergency quench buttons.
- (4) Obtain and maintain basic CPR certification. CPR training consists of an online course followed by an in-person skills assessment, held once a week by the Nursing Education department. Contact the MRI Research Core Manager to schedule both components.
- (5) Demonstrate basic competence at scanner controls, judged by direct observation of the user by the Manager during 3 scans. The purpose of the observation is to ensure basic competence at scanner controls (table control, initiating a new scan, data transfer, etc.). Full training of personnel to use specialized protocols or sequences for new users is the responsibility of each PI.

The completion of these requirements will also be documented via the [New Users Check-off Form](#), which will remain filed with the Core.

3.3 Screening of Research Participants

All Participants are required to complete the [MRI Safety Screening](#) prior to participating in MRI Research Core activities. No person shall enter Zone III without the authorization of a Level 2 MR person (either a Research Operator or an MRI Technician).

To save time and paperwork, it is strongly recommended that all Participants complete the MRI safety pre-screening questionnaire prior to scheduling a scan. Pre-screening can be done over the phone, or by mailing/emailing a copy of the [MRI Safety Screening Form](#) for the person to complete and return. Any YES responses on the form must be further

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investigated by asking questions and, if necessary, obtaining written documentation of any past surgeries, injuries or implants.

The safety screening must be reviewed again on-site the day of the scan by a minimum of 2 separate individuals. At least one of these individuals must be an Operator. Two MRI safety trained individuals must be on site when any MRI study is being performed on a Participant. One Operator's presence is sufficient for phantom or other non-human scanning.

3.3.1 Exclusionary Criteria

Participants with any of the following implants or conditions are excluded from participating in MRI studies:

- Metal in the eyes or an injury to the eyes involving a metal object or fragment (such as metallic slivers, shavings or a foreign body)
- A pacemaker or implanted cardioverter defibrillator
- Eye implants (prosthesis, retinal tack, eyelid wire or spring)
- Electronic implant or device
- Magnetically-activated implant or device
- Internal electrodes or wires
- Tissue expander (e.g., to expand tissue prior to a breast implant. Breast implants themselves are not exclusionary)
- Shunts (spinal or interventricular)
- Vascular access port and or catheter
- Neurostimulator system, spinal cord stimulator, bone growth/bone fusion stimulator
- Aneurysm clips
- Any type of non-removable pump (pain, drug infusion, insulin, etc.)
- Tattoos above the neck to include permanent cosmetics (e.g., eye or lip liner, etc.)
- Ear surgeries, implants (cochlear and otologic), stapes, prosthetic ear bone
- For males, penile implant
- Any implant labeled MR unsafe
- Any implant labeled MR conditional that is not deemed safe at the operating field strength
- Any implant for which clear and unambiguous documentation cannot be provided to verify the implant is MR safe at the operating field strength
- Pregnant females (see Subsection 3.3.5.1 and Appendix C)

3.3.1.1. Pregnancy and Research Scans

For all MRI studies where the MRI is being done solely for research, when the research is not specifically to study pregnant women or fetuses, pregnant women should be excluded. All IRB protocols should have provisions to address the possibility that a woman is pregnant. See [Appendix C](#) for the Geisinger summary statement on this topic.

3.3.2 Criteria that May Exclude Research

Participants with any of the following conditions may be cleared for research MRI after appropriate investigation of the situation, as described in [Section 3.3](#).

- History of surgical procedures that may or may not contain implants
- Injury involving an object or foreign body, such as a BB, bullet, shrapnel, or shard of metal
- Joint replacement (hip, knee, etc.)
- Bone/joint pin, screw, nail, wire, plate, etc
- Surgical staples, clips, or metallic sutures
- Artificial limb
- Wire mesh implant

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- Heart valve prosthesis
- Insulin pump
- For females, IUD
- Metallic stents, filters, or coils
- Other implants not listed above
- A history of claustrophobia
- Medication patches (nicotine, nitroglycerine, contraceptive, pain)

3.4 Scanning Research Participants

The following subsections briefly outline methods to safely perform MRI examinations to avoid the major sources of harm that may endanger Participants during a study.

3.4.1 Peripheral Equipment

Normally, no peripheral equipment, other than that provided by the scanner manufacturer, is allowed into the scan room. However, for research purposes, the Core recognizes the need for MR-safe non-standard or novel equipment to be present for specific studies. The Manager will work with the PI employing such equipment to determine proper use, storage, and education for Researchers. While the Manager is available upon request to assist in initial setup, proper training in the use of peripheral equipment is the responsibility of each PI, and only properly trained individuals should operate these devices and monitoring equipment in the magnetic environment.

3.4.2 Radio Frequency (RF) Electromagnetic Fields

During normal operation of the scanner, RF energy deposited into the body results in tissue heating. Some imaging techniques deposit more energy than others; however, at no point should the amount of heating become uncomfortable, particularly when the system cooling fans are in operation. If a Participant complains of excessive heating, scanning should be stopped immediately and inspection for metallic objects on or around the Participant should commence. All non-essential electrically conductive materials must be removed from the MR system bore, including unused RF coils, cables, and wires prior to imaging. Failure to do so may result in skin burns to the Participant.

3.4.3 Time Varying Magnetic Fields (Gradients)

3.4.3.1. *Peripheral Nerve Stimulation*

Participants should be instructed not to clasp their hands or in any other way form a closed loop with their extremities to reduce or avoid peripheral nerve stimulation (PNS). Researchers must continuously monitor Participants being scanned and stop scanning immediately if any PNS is reported or suspected.

3.4.3.2. *Acoustic Noise*

Participants must be supplied with hearing protection to meet OSHA guidelines; either foam earplugs and/or a headset system. Any person who remains in the scanner room during data acquisition must wear hearing protection.

3.4.4 Infection Control

The scanning table and any other surfaces that have come in contact with the Participant must be cleaned and the linens changed BEFORE placing another Participant on the scanning table. Gloves must be removed and disposed of properly BEFORE touching common areas such as scanner keyboard, log books, light switches, counter surfaces and other objects.

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Surfaces touched with gloves must be cleaned properly before leaving the area. All biohazard material must be disposed of according to regulations. No food or drinks of any kind are allowed in the console area.

3.4.5 Incident Reporting

Any injury, incident, or near incident must be reported to the PI and the Committee using the [Incident Report Form](#), and to Risk Management/Patient Safety via MIDAS within 24 hours. The incident may also need to be reported to the Institutional Review Board, which should be determined by the PI of the study.

Equipment damage and/or failures should be reported to Core Management immediately. Malfunctions of equipment due to breakage or failure may present a safety risk.

A facility safety breach must be reported to Management immediately. Examples of facility safety breaches include: failed door locks allowing access to the restricted MR suite, flooding, electrical hazards, and obvious structural faults. The Core will report the safety breach to the appropriate facility officer and to the Committee as necessary.

3.4.6 Gadolinium Use for Participants

Gadolinium use is permitted in research studies, but it is not considered as part of a routine MRI. All studies proposing the use of gadolinium must therefore be approved by the Institutional Review Board and will likely have more stringent safety requirements applied.

3.5 Research Participant Monitoring

Research Participants must be escorted throughout the MRI Suite at all times by a qualified Operator and may never be left unattended. Research participants are escorted into the scanner room by the Operator conducting the scan.

Continued Participant monitoring will commence during the MRI research scan using appropriate techniques. The Operator should provide the emergency squeeze ball to Participants and make sure the Participant is comfortable with its use. Operators must remain in verbal contact with the participant throughout the scan.

3.6 Termination of Scanning and Participant Evacuation

Researchers and Operators must be prepared at all times to handle an emergency involving a Participant, and must be able to identify signs that the Participant is experiencing discomfort or distress.

3.6.1 Reasons for Terminating a Scan

The MRI Operator should terminate the scan when any of the following occur:

- The Participant experiences any symptoms of claustrophobia, such as increased perspiration, increased heart rate, difficulty breathing, or tightness of the chest. Most Participants experiencing these symptoms will ask to be removed from the scanner. However, they may not associate the symptoms with claustrophobia.
- The Participant experiences pain or discomfort, to include warming of the skin, muscle tingling, etc.
- The Participant feels ill or experiences dizziness or nausea.
- The Participant experiences a medical emergency or becomes unresponsive.
- Power Outage
- Fire alarm.
- Scanner console freezes (and problem is not resolved by rebooting the scanner).

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- Head coil malfunctions.
- Gradient errors occur.
- Cold head is not working.
- Chiller malfunctions.

***A Participant must never be asked to remain in the magnet when experiencing discomfort or distress and should never be kept in the scanner while technical concerns are evaluated.**

3.6.2 Emergency Evacuation Procedure for a Responsive Participant

***STOP the scan procedure.**

- Move the table out of the magnet using the toggle switch.
- Lower the table down to the floor as low as possible.
- Have the Participant sit up, but do not have them get up off the table right away.
- Assess the research Participant.
- If the Participant is experiencing a medical emergency, call 911 and follow emergency notification procedures as indicated in the [EMERGENCY PROCEDURES, Section 5](#), of this document.
- If the symptoms subside and the participant feels better, the participant may be escorted from the facility, and a recommendation made to the participant for follow-up with a medical professional if the symptoms recur.

3.6.3 Emergency Evacuation for a Nonresponsive Participant

***If the participant becomes unresponsive at any time during the procedure, scanning should be stopped immediately.**

***STOP the scan procedure.**

- Bring the table all the way out of the bore (do not lower the table).
- Remove all coils.
- Bring the MR SAFE stretcher next to the table.
 - MR SAFE stretcher may be in scan room OR in CT room
- Roll the Participant with the table pad to face the counter and cabinetry in the room and slide the white transfer board halfway under the subject and table pad.
- As one unit, slide the Participant and table pad across the white board onto the stretcher. (The board is to be used as a bridge.)
- Wheel the MRI stretcher, with the Participant on it, out of the scanner room into the Zone III corridor.
- Close the scanner door completely.
- Open the hallway door and wheel the Participant out into the main corridor.

Call 911 and follow emergency notification procedures as indicated in the [EMERGENCY PROCEDURES, Section 5](#), of this document. Note: Emergency responders should NOT be allowed access to the scanner room for nonresponsive patients, as they have not been cleared to enter the MRI suite.

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4. OPERATIONAL POLICIES AND PROCEDURES

4.1 New Study Initiation

Before a new study, the following information must be furnished to the MRI Research Core Manager:

- Project Title
- Principal Investigator
- Account Number to Charge
- Sponsor
- Department
- Contact Person
 - Telephone Number
 - E-mail
 - Internal Zip Code

Additionally, if the study is NOT being conducted under the MRI Research Core's Technical Development IRB, a copy of the IRB approval form for the study in question must be submitted prior to scheduling or scanning any patients/volunteers.

Please use the [New Study Initiation Form](#) to supply this information and submit to Core Management at sfielden@geisinger.edu. Confirmation must be received before any scan time is scheduled.

4.2 Scheduling and Cancellations

Scheduling is currently handled via a shared Outlook calendar in 30-minute blocks, with a 30-minute minimum. Contact the Core Manager for access. The Core is currently exploring options for an online scheduling system.

The priorities for scanner use are as follows: (1) critical patient care, (2) funded research scans, (3) elective clinical scanning, (4) system updates / maintenance, (5) protocol or technical development, (6) training. Any higher-priority scan may bump a lower-priority scan at any time.

Cancellations are allowed at no charge provided notice is given to the Core prior to the scheduled scan time. However, the booking fee ([Section 4.3](#)) will still be charged.

4.3 Hours, Rates, and Billing

Current daytime hours available for scanner use are Monday, Wednesday, Thursday, and Friday 2 – 6pm. After-hours use of the scanner is permitted, but it is understood that no assistance will be available during those times. The current rate for scanner usage is \$425/hr.

Technical development or training time is available at no cost after-hours. Technical development or training time is also available during daytime hours at no cost; HOWEVER, these reservations are given the lowest priority on the schedule and can be bumped at any time in favor of research studies.

Actual time used on the scanner will be determined by the timestamps of the first and last DICOM images generated on the scanner, rounded to the nearest quarter-hour. To account for time used in the scanner facilities without actually using the scanner and to encourage efficient use of the scanner, an amount equal to 15 minutes will be billed on top of the DICOM-determined time to account for experimental set-up and clean-up, regardless of actual time used.

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Example billing scenarios			
Actual time used on the scanner, determined from DICOM timestamps	Time Used	Setup Time	Total charged
00 min (cancelled scan)	00 min	15 min	15 min
20 min	15 min	15 min	30 min
40 min	45 min	15 min	60 min
60 min	60 min	15 min	75 min

4.4 Applying for Pilot Scan Time

Proposals for MRI scan time for pilot studies are accepted on a rolling basis, will be reviewed by the Committee at the end of each month, and decisions will be announced in the first week of the following month. Please submit completed [applications](#) via e-mail attachment to Core Management at sfielden@geisinger.edu.

4.4.1 Eligibility

Geisinger Investigators and Physicians are permitted to apply for pilot scan time. Post-Doctoral Fellows, Residents and Fellows may serve as Co-Investigators, but must be sponsored by a Geisinger Investigator or Physician.

4.4.2. Review

Proposals will be reviewed by the MRI Research Core committee. Each proposal will be evaluated on the basis of scientific merit, demonstration of need, and potential for successful extramural research support.

4.4.3. Award

- Awarded scan time must be used within 1 year and scan time must be scheduled in advance
- An account under project name will be created at the MRI Research Core for the purpose of scheduling
- In general no more than 25 pilot scans will be collected under this mechanism.

4.4.4. Reporting

Following award of pilot scan time, investigators will be asked to provide the information included in the “reporting” section of the Pilot Scan application. Current and historical recipients of pilot scans will be contacted annually to update their reported data.

4.4.5. Questions

All questions regarding the pilot scan time application process, award process, review criteria, or reporting requirements may be directed to MRI Research Core management at sfielden@geisinger.edu.

4.5 Grant Review

Any grant proposal that includes use of the Core should be reviewed by Core Management to ensure scientific and financial accuracy. The relevant sections should be provided to the Core at least 2 weeks prior to the grant submission date.

Text describing equipment and facilities is available upon request.

4.6 Incidental Findings

All IRBs must include provisions for incidental findings, but because research images are non-diagnostic in nature, Participants should be made aware during the consent process that their data is unlikely to be yield actionable medical

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information. See [Appendix D](#) for the Geisinger summary statement on this topic that describes a minimum necessary policy for events in which gross abnormalities are found in the course of MRI research. The IRB will determine on an individual protocol basis whether more stringent procedures are necessary.

4.7 Post MRI Scanning Procedures

The Core MRI system is a valuable asset for both research and clinical use. It is important that all MRI users ensure the facility and equipment are maintained in good working order. Upon completion of the MRI study, the researcher must ensure that all equipment is restored to normal operation. Researchers will ensure that all coils are returned to their proper storage locations, cords and cables wound, and all presentation accessories, devices, and monitors are turned off and stored properly (if appropriate). If there is a problem with specific equipment, it must be reported to Core Management.

The final procedure to be completed after a research session is to run the scanner's automated Quality Assurance (QA) test on the coil used during the research. The purpose of running the daily QA test after each research session is to ensure proper hand-off of the scanner back for clinical use and to create documentation (log files) to this effect. Completion of this test takes less than 5 minutes and can be completed while other clean-up/data transfers are taking place. Please follow the instructions [here](#) for the procedure.

4.8 Data Retention

In general, DICOM images remain on the host computer for 2-6 weeks after each scan procedure, depending on scanner use. Raw image data remains only until the host computer is next rebooted. Therefore, at this time, it is the responsibility of the Researcher to retrieve the necessary data/images from the scanner at the time that the scan is conducted. The MRI Research Core is currently exploring options for a more comprehensive data retention solution.

It is recommended that each Researcher save copies of each of their protocols in the event that the host computer malfunctions or a scanner upgrade is performed. Instructions for saving and installing protocols can be found [here](#).

Contact Core Management for help installing custom sequences, RF pulses, and image reconstruction programs.

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5. EMERGENCY PROCEDURES

Emergency Notification

When an emergency situation arises, contact emergency services by dialing 911. Provide the following information:

- Name and telephone number of the caller.
- Nature of the emergency (e.g., medical emergency, technical problem, fire, etc.).
- Specify that this is the SVI Research MRI Core 3T Suite with magnetic hazards.
- Special considerations (e.g., hazardous gases present, people trapped, number of people injured and type of injuries, electrical hazards, property damage and access routes to the emergency).

Visible Flames in Building

1. Try to extinguish if small
2. Help anyone in the magnet room to get out
3. Press “Emergency Shut-Down” Switch
NOT the “Magnet STOP” aka Quench button
4. Leave Building
5. Call 911. See above.

Smoke in Building

1. Press “Emergency Shut-Down” Switch
NOT the “Magnet STOP” aka Quench button
2. Help anyone in the magnet room to get out
3. Leave Building
4. Call 911. See above.

LIFE THREATENING human injury in magnet due to crushing or impaling metal

1. Press “Magnet STOP” aka Quench button
WARNING: QUENCHING THE MAGNET COSTS TENS OF THOUSANDS OF DOLLARS TO REPAIR AND MAY PERMANENTLY DAMAGE THE MRI
2. Call 911. See above.
3. Try to help injured person without adding to injuries while waiting for EMT

Medical Emergency

1. Try to assist victim
2. Call 911. See above.

Quench

1. Help anyone in the magnet room to get out
2. Prop open scanner room door to aid ventilation
3. All persons are to be evacuated from the MR Suite
4. Call 911. See above.

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APPENDIX A: RISKS ASSOCIATED WITH MRI

Magnetic resonance Imaging (MRI) uses the magnetic characteristics of certain nuclei in the body, and especially the hydrogen nucleus (proton) to generate images. It is based on the premise that these nuclei exhibit a magnetic moment. The hydrogen atom is an elementary part of water and fat and is, therefore, the most prevalent element in the human body. When a person is placed in the scanner, the magnetic movement of the hydrogen nuclei aligns with the direction of the magnetic field. A radio frequency (RF) field is briefly turned on and off to cause the magnetic moment to realign briefly. The scanner detects the motion of the magnetic moments of the protons as they return to their equilibrium position along the strong magnetic field of the scanner.

Static Field Strength

When the MRI scanner is on, the static magnetic field (the main magnetic field of the scanner) is always present. Magnetic field is measured in units of Tesla (T). One Tesla equals 10,000 gauss, and is 20,000 times stronger than the magnetic pull of the earth. Field strength increases in a nonlinear manner as an object gets closer to the bore (or center) of the magnet. The magnetic attraction of the MR scanners for ferromagnetic objects can result in a missile or projectile effect as these objects are pulled toward the bore of the magnet with great force. In addition to the hazard of projectiles, the static magnetic field can cause ferromagnetic objects within the body (such as aneurism clips, metal slivers, etc.) to move or torque, resulting in potentially serious injury. The static field can also disrupt the function of electrically, magnetically, or mechanically activated implants such as pacemakers. The closer a pacemaker is to the magnet; the more likely it is to become completely dysfunctional. For this reason, all MRI manufacturers are required to identify a 5-gauss pacemaker exclusionary zone to avoid the possibility of pacemaker dysfunction. This exclusionary zone extends from the center of the magnet in all directions to the distance at which the field strength equals 5 gauss (0.5 mT)

Missile Effect

The missile effect or projectile effect refers to the capability of the fringe field of the static magnetic field to attract a ferromagnetic object, drawing it rapidly into the scanner with considerable force. When this occurs, the missile effect can pose a significant risk to anyone in the path of the projectile, and cause significant damage to the scanner. To guard against accidents from metallic projectiles, the 5 gauss line should be clearly demarcated and the area with that line kept free of ferromagnetic objects. Personnel and research Participants must remove all metallic personal belongings (hearing aids, analogue watches, jewelry, belts, etc.) before entering the magnet room, as well as any clothing with magnetic fasteners. All equipment to be taken into the scanner room, housekeeping supplies (bucket, broom, mop, etc.), research equipment (props), tools, and emergency equipment (litter, fire extinguisher, etc.) must be made of nonferrous material and be classified as MR safe.

Rotational and Translational Forces

Rotational force-is a force that causes a ferrous object to turn and align along the magnetic field.

Translational force- is a force that causes a ferrous object to be pulled toward the center of the magnet.

Implants and devices that are not proven MR safe pose a serious health risk due to torque and heating. Implants tested to be safe at 1.5 T are not necessarily safe at 3 T. All implants and devices must be documented as MR safe before being permitted in the MRI Suite. Information and guidelines can be found at www.MRISafety.com.

To prevent damage or injury due to torsion or translational forces, all individuals who enter the magnet room must be prescreened to determine if they have any ferrous material in their body. Comprehensive safety screening reviews potential injuries involving ferrous material and the presence of ferromagnetic devices or implants (clips, screws, shunts, etc.) as well as cosmetic concerns such as permanent eyeliner, tattoos, hair weaves or braids, and permanent retainers.

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Magneto hydrodynamic Effect

Magneto hydrodynamic effects are phenomena that arise from the motion of electrically conducting fluids (like blood) in the presence of electric and magnetic fields. These effects become more evident with an increase in static magnetic field strength. Within the MRI environment, magneto hydrodynamic effects may cause vertigo, nausea, or visual sensation from electrical stimulation of the eye.

Radiofrequency Fields

The MRI signal is created by RF pulses through a transmit core. Conducting materials within the RF field may result in a concentration of electrical currents sufficient to cause excessive heating and tissue damage. Absorption of RF power by tissue is described in terms of Specific Absorption Rate (SAR) which is expressed in watts/kilograms (W/kg) and is defined as the average energy dissipated in the body per unit mass and time. According to the FDA, the SAR must be no greater than 4 W/kg averaged over the whole body for any 15-minute period, 3 W/kg averaged over the head for any 10-minute period, 8 W/kg in tissue in the head or torso, or 12 W/kg in tissue in the extremities for any period of 5 minutes.

Acoustic Noise

Movement of the gradient coils due to switching of the gradient magnetic field is the main source of considerable acoustic noise within the scanner room, registering up to 140 decibels (dB). Participants in MRI studies are required to wear disposable foam ear plugs and/or headphones (both, when possible). Ear plugs can reduce noise by 30dB. Other individuals who must remain in the room while scanning (e.g., parent) will also be given earplugs.

Cryogenic Liquids and Quench

The coils of the superconducting magnet are immersed in liquid helium to prevent excessive heat buildup. Under normal operation the helium slowly boils off, but in extraordinary circumstances, an uncontrolled boil off of helium can occur in what is called a spontaneous quench. This event is accompanied by a loud noise, which would startle persons in the facility and surrounding area. Although the helium is vented to the building exterior to prevent the creation of a hypoxic environment, there is a potential for displacement of oxygen within the 3T MRI Suite and the creation of a hypoxic environment.

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APPENDIX B: DEFINITIONS OF MR SAFETY ZONES

Access to the 3T MRI scanner is controlled by a coded lock system. Authorization for access to the 3T MRI suite is limited and will be granted upon certification as a Research User.

The area where the 3T MR scanner is housed is divided into four safety zones in accordance with the ACR Guidance for Safe MR Practices: 2013.

Zone I includes all areas accessible to the general public (i.e. waiting room).

Zone II indicates the interface between publicly-accessible Zone I and the restricted Zones III and IV (e.g. patient changing rooms).

Zone III is the region in which free access by unshielded non-MR personnel or ferromagnetic objects or equipment can result in serious injury or death. Zone III is restricted and the participants are greeted and screened before entering Zone III. The MRI Console Room and MRI Equipment Room are part of Zone III.

Zone IV is synonymous with the MR scanner laboratory, that is, the physical confines of the room within which the MR scanner is located. Zone IV, by definition, will always be located within Zone III as it is the MR magnet and its associated magnetic field that generates the existence of Zone III. The 5 gauss line (0.5Mt) extends into the console room along the wall shared with ZoneIV. Therefore, anyone with a pacemaker is not permitted entry to the console room. The presence of this field poses no risks to others who are certified to enter the MRI suite.

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APPENDIX C: PREGNANT WOMEN UNDERGOING MRI FOR RESEARCH

For all MRI studies where the MRI is being done solely for research, when the research is not specifically to study pregnant women or fetuses, we believe pregnant women should be *excluded*. The most important evidence / statement in support of this is based on the recent American College of Radiology (ACR) guidance document on MR safe practices written in 2013.¹ The ACR states that an attending radiologist should determine whether the benefit of an MRI during pregnancy outweighs the potential risk to the fetus. The ACR specifically states that an MRI scan should be done after pregnancy in all elective cases where the delay will not adversely affect the health of the baby or mother. Additional recent pertinent articles on the subject include a retrospective case-control study on 751 neonates exposed to MRI compared to 10042 non-exposed neonates. This study showed no growth or hearing impairment in the exposed group, but was limited by the lack of long-term followup (which animal studies have suggested may be important in studying cochlear development in the setting of MRI exposure), short duration of MRI exposure, and lack of testing at field strengths above 1.5T.² Another recent review article stated the concern that the long-term safety of MRI exposure to the fetus has not yet been definitively demonstrated, with few studies evaluating field strengths greater than 1T.³ If a pregnant woman undergoes MRI in the United Kingdom, their Medical Device Agency requires a SAR max of 10W/kg in the fetus, which we believe would be difficult to comply with in most research scans that often have relatively high SAR. The position of the US Food and Drug Administration is that most MRI studies are nonsignificant risk and hence the decision on whether to exclude pregnant women falls under the jurisdiction of a local IRB.

The process for excluding pregnant women should be as follows:

1. Children <18 years:
 - a. All females who are post-menarche will undergo a urine pregnancy test and be excluded if positive. Note that the consent should then include terminology about positive pregnancy tests under the “risks” section as follows:

Urine HCG pregnancy test:

All female participants under 18 years old who have had their first menarche (period) will be required to undergo a confidential urine HCG pregnancy test. Positive results may be surprising and unsettling to the participant, and, although minors have the right to confidential pregnancy testing in Pennsylvania, it will not be possible to do this confidentially for the current study. Positive results will therefore be disclosed to the parent/guardian.
 - b. Pre-menarchal children will *not* be required to undergo a urine pregnancy test
 - c. Participants and their parents / guardians should be notified of this policy before scheduling the research visit for MRI. All study flyers should also have the following statement:

“Female participants under 18 years old may be required to undergo a urine pregnancy test. If positive, both the participant and her parent will be notified of the result and excluded from the study.”
2. Adult females will be asked: “Is it possible that you are pregnant? If so we need to exclude you from the study due to a very slight change of unknown risks of exposing your baby to MRI.” If the participant answers yes, she will be required to undergo a urine pregnancy test, and excluded if positive.

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APPENDIX D: INCIDENTAL FINDINGS

After a review of several manuscripts on incidental findings related to MRI research¹⁻⁴, it is clear that there is no evidence base or consensus guidance on this topic. The primary controversies surround whether or not any findings should be reported to the research subject and/or his/her doctor, and whether each dataset should be reviewed and reported on by a radiologist or other specialist with clinical credentials. Research data are not acquired for the purpose of clinically assessing or screening a patient. Screening is an area of healthcare that is highly prone to identification of, and subsequent patient suffering from, false positives when it is performed with a lack of evidence-based studies showing improved outcomes in patients who undergo screening. For this reason, we believe that having official clinical reads of all research images should *not* be done or supported. This should be clearly outlined and disclosed to the research subjects during the consent process as follows:

“The data collected during this study is for research only. It is not being obtained for diagnostic purposes and will not be officially reviewed by a medical doctor. The data collected for this research study cannot be relied upon to determine the existence of unknown health problems. It is possible that the investigators involved in this research will notice something grossly abnormal. If this occurs, a specialist, Dr. XXX, will be asked to look at your data. If this physician believes the finding to be clinically significant, he/she will communicate the incidental findings to you, will generate an official report of the findings for your medical record, and will communicate these findings to your primary care doctor if you desire. If an incidental finding is identified, it may cause you emotional distress and result in unexpected healthcare costs.”

The above methodology for dealing with incidental findings is consistent with the most common practice in a recent survey of 146 MRI research centers in the United Kingdom.¹

References

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