



MRI

(Magnetic Resonance Imaging)

Safety Policies and Procedures

MRI Safety Committee
Medical College of Wisconsin
Milwaukee, Wisconsin 53226

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MRI Safety Policies and Procedures

Purpose

The purpose of the MRI Safety Policies and Procedures is to maintain safe laboratory practice, during research procedures, in the magnetic resonance (MR) imaging areas affiliated with MCW. It has been reported by others, 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: 2007** and the **2008 Joint Commission Sentinel Event Alert** risk reduction strategies are used. Because MRI technology continues to progress, this is a living document that will be updated as needed.

Definitions

MRI Safety Committee

The MRI Safety Committee is a recognized sub-committee of the MCW Joint Committee on Safety. Members are appointed for terms of three years, by the Senior Associate Dean for Research. Current MRI Safety Committee members and contact information are listed below. The full MRI Safety Committee meets monthly.

<u>Voting Committee Members</u>	e-mail	Phone (414)
Chair: Alan S. Bloom, Ph.D. Professor, Pharmacology & Toxicology	abloom@mcw.edu	456-5266
Mark Hohenwarter, M.D. Associate Professor, Radiology	mhohen@mcw.edu	805-2173
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Ericka Schrang, R.N. Radiology, CHW	eschrang@chw.org	266-3180

Tom Prieto, Ph.D. is the primary contact for equipment related questions and concerns. Julie Peay, BSM, RTR (MR), FSMRT, is the primary contact for MRI safety training.

MRI Research User

The MRI Research User, hereafter researcher, is a Principal Investigator (PI) who has an IRB or IACUC approved protocol and utilizes one or more of the MRI scanners at MCW for research purposes and / or a student, staff member or laboratory assistant for whom the PI is responsible.

Individuals

For this document, individuals are employees, staff, PIs or other personnel who are working and /or conducting studies in the MRI area.

Research Participant

A research participant is a human subject who is placed into the bore of the MRI scanner for research purposes.

MRI Scanner Operator

The MRI scanner operator is an individual who is an MCW employee, has completed the MRI safety training and is specially trained in the operation of one or more of the MRI scanners. There are two levels of scanner operators:

- Individuals who are allowed to operate the scanner for phantom and / or animal studies
- Individuals who are allowed to operate the scanner for human research participant studies

Individuals who are allowed to operate the scanner for research participant studies must have current documentation as to valid Red Cross or equivalent cardiopulmonary resuscitation (CPR) training.

It should be noted that the trained MCW MRI scanner operators have authority by the MRI Safety Committee to stop any procedure that they deem exceeds safe practices.

Policies

Safety Training

- Individuals working within the magnetic environment must complete the required MRI Safety Training prior to conducting or participating in studies.
- All Researchers must renew the MRI Safety Training on an annual basis.

Standard of Practice at MCW

MRI Safety Approval

- Researchers must have approval via the electronic MRI Safety form, from the MRI Safety Committee, before an IRB or IACUC protocol is approved.
- Only researchers with approved protocols are allowed to schedule MRI scanner time for research studies.

Individuals

- Individuals working within the magnetic environment must be screened for safety risks prior to entering the magnetic field. This includes individuals who may be accompanying a research participant. THERE ARE NO EXCEPTIONS TO THIS POLICY.
- Two MRI safety trained individuals should be on site when any MRI study is being performed.
- Two MRI safety trained individuals must be on site when a human research participant is being scanned. NOTE: the research participant may not count as one of the MRI safety trained individuals.
- MRI scanner operators scanning human research participants must have current CPR training.

- At least one MRI safety trained MCW employee, student or faculty member must be present during the scanning.
- Researchers using the MRI system for human studies must have an approved IRB protocol prior to scanning human research participants.
- Researchers using the MRI system for animal studies must have an approved IACUC protocol prior to scanning any animal models.
- Researchers using the MRI system for non-human or non-animal studies should notify the MRI safety committee of their work.
- Individuals who are or may be pregnant are not allowed to remain in the MR scanner room while the RF and gradients are operating.

Research Participant

- Research participants in MRI studies must be screened for safety risks prior to entering the magnetic field. THERE ARE NO EXCEPTIONS TO THIS POLICY.
- Research participants in MRI studies must be treated within institutional, local and federal guidelines and regulations.
- Implants, devices and other objects within or on research participants or other individuals intending on entering the magnetic environment must be investigated by the manufacturer label and this investigation must be documented prior to the individual or research participants entering the scanner magnet room.
- Manufacturer documentation which includes the FDA approval must be obtained to ensure safety of implants, devices or other objects at 3.0T.
- Manufacturer documentation must be obtained that ensures the safety of devices and accessories when using the 9.4T (animal) MRI scanner.
- Individuals who have Vagal Nerve Stimulation (VNS) implants are NOT safe to participate in a functional MRI (fMRI) study due to the rapid gradient switching required for Echo Planar Imaging (EPI) utilized in fMRI.
- Individuals and research participants with suspected metallic ocular injury must be investigated and if necessary, cleared by a medical doctor before entering the magnetic environment or participating in an MRI study. Individuals and research participants with suspected metallic injury must be excluded from the MRI environment or study unless cleared by a radiographic exam.
- Research participants must be evaluated for medical status that would indicate a safety risk and or prevent a successful MRI study.
- The research participant must be given an emergency squeeze ball with instructions for use by the researcher or the scanner operator.
- Researchers must interview research participants identified during pre-screening as having tattoos and proceed accordingly.
- Researchers must interview research participants identified during pre-screening as having medication patches and contact their physician or exclude the individual from the study. Researchers may not remove medication patches prescribed by physicians.

MRI Scanner Operator

- MRI Scanner operators must be trained as evidenced by signed documentation.
- MRI scanner operators who scan research participants must have current CPR documentation.
- The MRI scanner operator must verbally monitor the research participant throughout the procedure.
- MRI scanner operators have the authority to stop MRI procedures that are deemed by them to be unsafe.

Emergency or Illness

- An individual or research participant who becomes ill or injured must be removed, from the magnetic environment, immediately by the researcher or scanner operator.

- If an individual or research participant becomes ill or injured the institutional policies for the scanner location must be followed.
- If there is a Magnet Emergency, institutional policies for that specific scanner location must be followed.
- The researcher must report any emergency incident to the MRI Safety Committee.

Equipment

- Any equipment to be used within the magnet room must be approved by the MRI Safety Committee designee.
- All material and equipment must be tested for ferromagnetic properties with a hand held magnet outside of the fringe field before being brought within the magnetic field inside the scanner room.

Gadolinium Use for Research Subjects

Policy of the MCW MRI Safety Committee

Re: Safety of Gadolinium-based contrast agents for Research Subjects

Background: Due to an apparently small but serious risk of Nephrogenic Systemic Fibrosis (NSF) in individuals with severely compromised kidney function, the FDA issued an updated safety advisory regarding gadolinium contrast agents (May 2007). The MCW MRI Safety Committee recognize that research subjects may be less likely to receive clinical benefit from MRI than patients for whom it is clinically indicated. Therefore, stricter standards of safety are appropriate for research subjects than clinical patients. Investigators may employ more cautious standards than these. Applications indicating Gadolinium will be used in the study will be reviewed by the full committee for approval.

Policy for research studies using gadolinium-based contrast agents in Magnetic Resonance Imaging (MRI):

1. Pregnant women should not receive gadolinium contrast agents in research studies.
2. For adult research participants with known GFR (Glomerular Filtration Rate) values:
 - a. If the GFR value obtained within 6 weeks of the date of the research scan is ≥ 90 mL/min/1.73m² (normal kidney function), then MRI scanning with any FDA approved gadolinium contrast agent at FDA recommended adult dose range is permitted. Doses greater than the FDA recommendation would require specific approval by the MRI Safety Committee.
 - b. If the GFR value obtained within 6 weeks of the date of the research scan is between 60 and 89 (mild kidney dysfunction), then MRI scanning with an FDA approved gadolinium contrast agent other than Omniscan is permitted at FDA recommended adult dose range. Doses greater than the FDA recommendation would require specific approval by the MRI Safety Committee.
 - c. If the GFR value obtained within 6 weeks of the date of the research scan is < 60 (moderate to severe kidney dysfunction), a repeat GFR should be done within 4 weeks of the scan. If the GFR remains < 60 , then gadolinium contrast agents should not be administered without specific justification of proposed dose range and added risk of NSF by the Principal Investigator, and approval by the MRI Safety Committee.
 - d. If GFR value obtained within 4 weeks of the date of research is < 30 (severe to very severe kidney dysfunction or end stage renal failure (ESRF) with or without dialysis) then gadolinium contrast agents should not be administered without specific justification of proposed dose range and recognized increased risk of NSF by the Principal Investigator, and approval by the MRI Safety Committee.
3. For adult research participants with unknown GFR values: Based on population studies of renal disease, GFR values are required before gadolinium infusion for any participants with a history of:
 - Renal disease (including solitary kidney, renal transplant, renal tumor)
 - over age over 55.

- Diabetes – by self-report, on inquiry.
- Hypertension – by self report and / or current measurement.
- Note: If the participant reports a history of proteinuria or chronic Non-Steroidal Anti-Inflammatory Drug (NSAID) use, GFR values may be obtained at the discretion of the PI and/or medical director.
- Note: A history of severe hepatic disease, liver transplant or pending liver transplant. GFR assessment as near as possible to administration of Gadolinium.

4. No research participant should receive a cumulative dose of gadolinium contrast agent over a 48 hour period that exceeds the FDA recommended dose range.

This policy is advisory, and the MCW MRI Safety Committee will continue to consider each study on its own merits. *Approved: September 12, 2007; MRI Safety Committee*

Static Magnetic Field

- Only properly pre-screened individuals are allowed in the magnetic environment of the MR scanner room THERE ARE NO EXCEPTIONS TO THIS POLICY.
- Only equipment and accessories approved by the MRI Safety Committee are allowed to enter the magnetic environment of the MR scanner room.
- Any incident or near incident of a projectile accident must be reported to the MRI Safety Committee.

Radio Frequency (RF) Electromagnetic Fields

- Only properly trained individuals should operate devices and monitoring equipment in the magnetic environment.
- RF pulse timing sequences that exceed FDA SAR limits must not be used.
- Only electrically conductive devices, equipment, accessories and materials that have been thoroughly tested by MCW personnel and determined to be safe for MR procedures are allowed.
- Manufacturer recommendations for safe use of all devices must be followed.
- All non-essential electrically conductive materials must be removed from the MR system bore, including unused RF coils, cables and wires prior to scanning.

Time Varying Magnetic Fields: Gradients

Potential Nerve Stimulation

- Research participants must be instructed to not clasp their hands or in any other way form a closed loop with their extremities to reduce or avoid peripheral nerve stimulation (PNS).
- Phase and Frequency encoding directions must be selected carefully by the scanner operator to avoid peripheral nerve stimulation.
- Researchers must continuously monitor research participants being scanned in a study and stop scanning immediately if any peripheral nerve stimulation is reported or suspected, and correct the situation before proceeding.
- Individuals who have Vagal Nerve Stimulation (VNS) implants are NOT safe to participate in a functional MRI (fMRI) study due to the rapid gradient switching required for Echo Planar Imaging (EPI) utilized in fMRI.

Acoustic Noise

- Research participants must be supplied with hearing protection to meet the OSHA guidelines; either the foam ear plugs or a head set system.
- Any researcher or individual who remains in the scanner room during data acquisition must wear hearing protection.
- The intercom and auditory stimulus equipment must be adjusted to not exceed safe dB levels for the research participant.

Infection Control

- The scanning table and any other surfaces that have come in contact with the research participant must be cleaned and the linens changed BEFORE placing another research participant on the scanning table.
- The scanning table, coil and all other surfaces that may have come in contact with an animal need to be cleaned following the completion of the study.
- 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.
- Surfaces touched with gloves must be cleaned properly before leaving the area.
- All biohazard material must be disposed of according to regulations.

Reporting

- Injuries to personnel or a research participant must be reported to the Principal Investigator (PI) and the MRI Safety Committee.
- Any incident or near incident of a projectile accident must be reported to the MRI Safety Committee by the scanner operator or researcher involved.
- Equipment damage and or failures must be reported to the scanner operator.
- Facility safety breaches must be reported by the scanner operator to the MRI Safety Committee.

Standard Operating Procedures

The use of Magnetic Resonance Imaging (MRI) presents known safety hazards. Policies and Standard Operating Procedures have been developed so that employees, researchers, students, colleagues, study participants, and associated equipment remain safe in the magnetic environment. All personnel working within the magnetic environment are required to complete MRI safety training. The MCW MRI Safety Committee has developed a MRI Safety Manual containing additional pertinent safety information, which can be found at: <http://www.mcw.edu/display/mrisafety.htm>

MCW employees and support staff assigned to work in the MRI area(s) are required to adhere to the MRI Safety Policies and Standard Operating Procedures.

Components of the MRI scanner system that present potential risks are:

The static or main Magnetic field of the system inside the scanner room

- This strong magnetic field is always present.
- The risk of the strong magnetic field increases the closer an object is to the bore or opening of the magnet.
- Objects that are ferromagnetic may become projectiles with the potential to cause serious injury.
- Objects that are ferromagnetic may pin someone against the magnet in a life threatening manner.
- Everyone must be screened for potential contraindication to safety prior to entering the magnetic field.
- All equipment must be evaluated for potential risk prior to being safely placed in the magnetic field.

The Radio Frequency (RF) that is produced when the MRI scanner is operating

- Research participants and animals must be protected from potential heating and burns.
- The FDA sets limits to the amount of heating or the Specific Absorption Rate (SAR) that is allowed.
- Equipment and accessories must be used properly and safely to prevent heating or burns to the research participant or animal.

The Gradients or Time Varying Magnetic Fields

- Rapidly changing gradient fields used in MRI have the potential to cause peripheral nerve stimulation.
- Gradients produce excessive acoustic noise levels for which hearing protection must be provided and worn.

Ancillary equipment used for experiments

- All equipment placed in the magnetic environment must be considered for heating or any other potential safety risk.

Safe Laboratory Practice

To maintain safe laboratory practice, at least two MRI Safety Trained individuals, besides the research participant being scanned, must be in the immediate area at all times. That is, the operator of the scanner and another individual who has completed MRI safety training. The MRI scanner operator performing studies with research participants must have current cardiopulmonary resuscitation (CPR) training as evidenced by a signed document. For animal and phantom studies two MRI safety trained individuals should be on site. At least one MCW employee, student or faculty member must be present for all MRI scanning. This applies to all scanning hours including the evenings and weekends.

Safety Training

Safety Training for all MRI Researchers is mandated by the MRI Safety Committee and has evolved to include a three step program. The request for MRI Safety Training is located on the Biophysics web-site: <http://www.mcw.edu/display/router.asp?docid=11090>. A renewal of MRI safety training is required annually.

Static Magnetic Field

The most common breaches of MRI safety occur due to an object being attracted to the Static Magnetic Field. An individual may be struck, injured or trapped against the magnet by the object. Equipment may be damaged by slamming into the magnet or being struck by another object that is accelerating rapidly due to the strong attraction of the magnetic field.

The researcher must be aware of which objects and devices are safe to move into the static magnetic field.

MRI Safety Screening

Each individual must be checked for safety or pre-screened prior to entering the magnetic environment of the scanner room. A standardized form is used for evaluating the safety of an individual BEFORE that individual is permitted within the magnetic environment. MRI Safety Screening Training is a segment of the requirement for MRI researchers.

Equipment Screening and Operation

All equipment used for research MRI studies, including projectors and stimulus producing apparatus, must be tested for MRI safety BEFORE entering the magnetic field. MRI safe equipment is developed for specific magnetic field strengths and MRI system configurations. Equipment that may operate safely within a magnet room is NOT necessarily safe to operate in another magnet room even if the magnets are the same static field strength. Routine inspection and maintenance of equipment must be performed. Broken or malfunctioning equipment must be identified and reported to the MR scanner operator.

Emergency Safety Procedures

In an emergency, orderly and proper procedures ensure the safety of individuals, researchers and the research participant. The first priority is to remove research participants or individuals from the magnetic environment. Emergency contact information is posted at each MRI scanner location.

Research Participant Scanning

It is essential that there is constant communication between the research participant within the MRI scanner and the scanner operator. Every research participant is given a signal squeeze ball that will alert the scanner operator of a difficulty even when the scanner is running and producing loud noises. During the quiet times of the study the scanner operator should maintain verbal contact with the research participant. A research participant who does not respond verbally requires immediate investigation to ensure the research participant's well being.

Medical Emergency

In case of a research participant or other individual with a medical emergency of illness or injury: the individual or research participant must be assisted out of the magnet room. Then a call for assistance per procedure at that specific site is implemented.

Emergency Stop

If there is an emergency such as an equipment failure that could cause injury; sparking of equipment or a fire, the scanner operator or designee should immediately perform an emergency stop.

Magnet Emergency

If an individual or research participant is restrained or pinned by a ferrous object to the magnet: Assess if the situation is life threatening, if YES an emergency rundown to quench magnet can be performed by an authorized person.

If an individual or research participant is restrained by a ferrous object to the magnet and is NOT in a life threatening situation, call for assistance to determine the optimal way of releasing the individual or research participant from the magnetic field. If a quench is necessary proceed as above.

Report the incident as an accident and call for assistance to ensure ferrous object is removed from the field properly.

Emergency Quench

A quench includes the rapid release of cryogenics and results in the loss or significant decrease of the magnetic field. A quench should ONLY be performed by authorized personnel in dire emergency that involves a serious personal injury or life threatening situation.

Note: in extraordinary circumstances such as an earthquake or explosion, resulting in an uncontrolled quench, the oxygen level in the magnet room may significantly decrease possibly making breathing difficult.

Radio Frequency (RF) Electromagnetic Fields

MRI research studies are to be conducted so that safety risks from RF, including potential tissue heating and burns to the research participant, are eliminated. RF may damage electronic or implanted medical devices. Equipment that is not RF shielded may be damaged or may cause spurious signals when operated in the magnetic field.

Note: Pulse sequences with 180° refocusing pulses (such as spin-echo EPI and inversion-recovery prepped flow sequences) have much higher RF power deposition (potential heating) than sequences without 180° pulses, such as gradient recalled echo planar imaging, GRE-EPI.

Time Varying Magnetic Fields: Gradients

Nerve Stimulation

The application of momentary magnetic field gradients (dB/dt) can induce current in conductive materials, including nerve or muscle tissue. Research participants should be instructed to report any sensations to the scanner operator so that corrective action can be implemented. The FDA considers the procedure to be of significant risk any time the rate of change of the gradient fields (dB/dt) is sufficient to produce severe discomfort or painful nerve stimulation.

Acoustic Noise

Acoustic noise produced during the MRI scanning procedure is known and documented. Research participants must be provided hearing protection. Individuals remaining in the scanner room while the gradients are operating must wear hearing protection. The FDA follows the OSHA guidelines which limits the permitted decibel level based on the time duration of the exposure.

Infection Control

All surfaces that have come into contact with a research participant, animal model or any other potential infectious substance must be properly cleaned before the next MRI study is conducted. The prevention of any infectious material of research participant or animal model origin from being transferred in any way to another research participant, animal or individual is the responsibility of all researchers.

Research Participants

For research participants infection control includes cleaning the scanning table, coil, positioning pads, the emergency squeeze ball and any other surfaces that have come in contact with the subject. These surfaces as well as linens must be cleaned or replaced BEFORE placing another research participant on the scanning table. All used linens are to be placed in the appropriate hamper. Any spills or bodily fluids must be cleaned thoroughly with a disinfectant solution or bleach.

Animal Models

Handling of all animal models for MRI research studies will be according to the policies and procedures of the Biomedical Resource Center (BRC). For animal models, the bite bar, coil parts, and other surfaces must be cleaned between experiments. It is the responsibility of the researcher to clean up ALL biological substances (blood, hair, urine, feces, secretions, tissue) from all contact surfaces. This includes: the scanner table, inside and outside of all RF coils, bite bars, counters and work surfaces. Appropriate cleaning solutions, gloves and towels are available for use.

Post MRI Scanning Procedures

The MRI scanners at MCW are utilized by a variety of researchers. 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. If there is a problem with specific equipment, it must be reported to the MR scanner operator. Report to the MR scanner operator if a supply item is becoming low in quantity especially if the last, or near last of an item is used.

Researchers will ensure that coils, shim files, configuration files, and all computers are returned to standard usage. All accessories and / or devices are to be turned off properly, cords and cables wound, and returned to their designated storage area.

Reporting Requirements

Accidents, Injuries and Incidents

Any accidents causing injury to an individual or research participant must be reported to the MRI Safety Committee by the researcher conducting the study. In case of an accident or injury when the principal investigator (PI) is not present, the researcher present must report to the PI. If an accident or injury occurs that is not related to an MRI study, then the scanner operator or individual on site who is responsible should report to the MRI Safety Committee.

Besides reporting to the MRI Safety Committee, the accident, injury or incident may need to be reported to the Medical College of Wisconsin, Public Safety; Froedtert Hospital, Institutional Review Board; and / or the Institutional Animal Care and Use Committee.

Equipment Damage or Failure

Malfunctions of equipment due to breakage or failure may present a safety risk to individuals and research participants. Damage or failure of equipment needs to be addressed immediately so that repairs or replacements can be made. Equipment problems are reported to the scanner operator. The scanner operator will address equipment issues, obtaining assistance if necessary. Failures that prevent normal operation or a safety risk are to be reported to the MRI Safety Committee.

Facility Safety Breach

A facility safety breach presents a risk to individuals, researchers and research participants. Examples of a facility safety breach are failed access points allowing non-trained or non-escorted individuals into the magnetic environment. Open access to the magnetic environment must be addressed immediately to prevent serious injury to individuals or equipment. Other potential safety breaches include: flooding, electrical hazards and obvious structural faults. Individuals and researchers should report any breaches to the scanner operator on duty. The scanner operator should report the safety breach to the appropriate facility officer and to the MRI safety committee as soon as reasonably possible.

References

Please see the MRI Safety Manual for references and additional information.