



Research MRI Safety Committee Standard

SAFE MRI SCANNING

Category: Magnetic Resonance Imaging (MRI) Safety

Procedure #: MR.SOP.011

Applies to: Investigators, study personnel, Medical College of Wisconsin (MCW) staff

PURPOSE:

MR-related injuries and the few fatalities that have occurred at other institutions were the apparent result of failure to follow safety policies or the use of inappropriate or outdated information. The Medical College of Wisconsin has maintained safe MRI scanning procedures in research studies using MRI for more than 30 years. The purpose of this document is to outline the procedures which should be followed when using MRI for research.

DEFINITIONS:

Accompanying parents, spouses, or others: individuals who, after thorough safety screening would be allowed to enter the magnetic environment to provide company and or comfort for the research subject.

Equipment: machines that may be used for MRI studies to monitor physiological processes or provide the stimulus or physical task for the study.

Magnetic Environment: the area where the magnetic field is greater than 5 gauss resulting in the potential for objects to become missiles or projectiles as they are attracted into the magnetic field of the scanner. Individuals who may have cardiac pacemakers or other implants and devices may be at risk to enter the magnetic environment. The magnetic field is always present and is three dimensional around the scanner.

Materials: pads, cushions or other objects that are not mechanical in nature but are used with or near the research subject during the MRI procedure.

MRI Safety Training: the instruction consistent with [American College of Radiology Training Level 2](#) that must be completed prior to working within the magnetic environment. This training addresses the safety risks of working in the magnetic environment as well as the proper screening of research subjects.

MRI: Magnetic Resonance Imaging which uses a strong static or main magnetic field, radio frequency pulses and time varying magnetic fields or gradients to produce anatomic images, spectroscopy, angiography, and functional data (fMRI).

Principal Investigator: the individual who is ultimately responsible for the procedures, study team personnel and research subjects involved in the study. The PI has an IRB or

IACUC approved protocol and utilizes one or more of the MRI scanners at MCW for research purposes.

Registered Technologist (RT): a medical professional who is certified by the American Registry of Radiologic Technologists or equivalent certifying agency in one or more of the following disciplines: radiography, nuclear medicine, radiation therapy, mammography, computed tomography, magnetic resonance imaging, cardiovascular interventional technology, or quality management.

Research MRI Scanner Operator: an MCW employee who has completed the MRI safety training and is specially trained in the operation of one or more of the MCW MRI scanners. A research MRI scanner operator may be a Registered Technologist.

Research Study Personnel: individuals including students, staff members or laboratory assistants for whom the PI of the study is responsible, and who are at the MR scanner site during the study or may be recruiting subjects for the study.

Research Subject: a human or animal participant who is placed into the bore of the MRI scanner for research purposes.

Safety Screening: the process of inquiring about the safety of individuals, including research subjects prior to entering the magnetic environment. Safety screening also applies to checking equipment for safety prior to being used in the magnet room.

PROCEDURES:

A. Prior to MRI Scanning

1. All personnel working within the magnetic environment or responsible for screening research participants are required to complete MRI Safety Training. (See *MRI Safety Training*, MR.SOP.08)
 - a. Prior to beginning the MR scanning session, the Research MRI Scanner Operator will confirm that all members of the study team present are current with MRI Safety Training.
 - b. Individuals present at the scanner site but not current with MRI Safety Training are not allowed into the scanner magnet room. They may remain in the control room.
2. The Principal Investigator of the study is required to complete MRI Safety Training if he/she will be entering the magnetic environment or screening participants. (See *MRI Safety Training*, MR.SOP.08)
3. At least one Medical College of Wisconsin employee, student or faculty member must be present for all MRI scanning. This applies to all scanning hours including the evenings and weekends.
4. Study personnel and/or the scanner operator on duty will have the subject participating in the study change from street clothes, including undergarments which contain metallic microfibers, into the MR safe gown/scrubs provided.
5. Study personnel should screen the research subject or other individuals, including accompanying parents or spouses, for safety risks, prior to entering the magnet room. (See also *Implants and Devices*, MR.SOP. 05)
6. The Research MRI Scanner Operator should confirm that study team personnel are safe to enter the magnetic environment.
7. Individuals who have Vagal Nerve Stimulation (VNS) or Deep Brain Stimulation (DBS) implants are NOT safe to enter the 3T or higher magnetic field of the scanner.
8. Individuals with metal in or near the eyes are not safe to enter the scanner magnet room whether or not they are participating in the study.

B. Alarms and Warnings

1. Building alarms that warn of fire or other dangers should be noted and action taken accordingly.
2. Weather situations that require action should be noted and followed.
3. Scanner system malfunctions that require intervention should be reported immediately.
4. Oxygen sensors, present at the MFRC and Daniel M. Soref Imaging Research Facility scanners emit a very loud, piercing sound.
 - a. If the alarm sounds, individuals should not enter the scanner room.
 - b. The Emergency Exhaust Fan (wall switch) should be turned on.
 - c. MCW Public Safety (414-955-8299) should be called; Public Safety will notify Environmental Health and Safety (EHS).
 - d. The scanner room must not be entered until cleared by EHS.
 - e. EHS (x8007) should be notified if O₂ percentage is observed to be trending downward; recalibration is needed; normal O₂ level is 20.9%.
 - f. No entry is allowed into the scanner room if O₂ is 19.5% or less.

C. Safe MRI Scanning Practices

1. To maintain safe laboratory practice when scanning human subjects, typically at least two individuals besides the research subject 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. However, the Research MRI Safety Committee reserves the right to evaluate whether a Registered Technologist may safely scan the proposed research population alone.
2. Any study personnel or individual who remain in the scanner room during data acquisition must wear hearing protection.
3. Study personnel and MRI research Scanner Operators must continuously monitor research subjects being scanned in a study and stop scanning immediately if any peripheral nerve stimulation is reported or suspected, and correct the situation before proceeding.
4. Only properly trained individuals should operate devices and monitoring equipment in the magnetic environment. Manufacturer recommendations for safe use of all devices must be followed.
5. All non-essential electrically conductive materials must be removed from the MRI system bore, including unused RF coils, cables and wires prior to scanning.
6. Only electrically conductive devices, equipment, accessories and materials that have been thoroughly tested by Medical College of Wisconsin Research MRI Safety Committee personnel and determined to be safe for MRI procedures are allowed.

D. Safe MRI Scanning with Human Subjects

1. The Research MRI Safety Committee authorizes the Medical College of Wisconsin Research MRI Scanner Operators to prohibit or stop a procedure that they deem exceeds safe practices.
2. There are three levels of Research MRI Scanner Operators:
 - a. Individuals who are allowed to operate the scanner for phantom and/or animal studies.
 - b. Individuals who are allowed to operate the scanner for human subject research studies. These individuals must have current documentation as to valid Red Cross or equivalent basic life support cardiopulmonary resuscitation (CPR) training.
 - c. Research Technologists, who are allowed to operate the scanner for all research studies.

3. Subjects should be positioned so that there is no skin to skin contact or bare skin to scanner surfaces to reduce the risk of burns. Heat resistant cushions / pads should be used as insulators.
4. Research subjects must be supplied with hearing protection to meet the OSHA / NIOSH regulations (e.g. either the foam ear plugs or a head set system).
5. The intercom and auditory stimulus equipment must be adjusted to not exceed safe dB levels for the research subject.
6. Study personnel or the Research MRI Scanner Operator should instruct the subject in proper use of the emergency squeeze ball.
7. Research subjects 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).
8. Phase and Frequency encoding directions must be selected carefully by the Research MRI Scanner Operators to avoid peripheral nerve stimulation.
9. RF pulse timing sequences that exceed FDA SAR limits must not be used.

E. Following MRI Scanning

1. If there is a problem with specific equipment, the study team must report the problem to the Research MRI Scanner Operator so that the problem is documented in the daily log, as to what the problem was or what went wrong during the study so that corrections and/or repairs can be made.
2. Study personnel will ensure that coils, shim files, configuration files, and all computers are returned to standard usage or as directed for each specific system. (See *Study Personnel Responsibility*, MR.SOP.013) All accessories and/or devices are to be turned off properly, cords and cables wound, and returned to their designated storage area. (See *Study Personnel Responsibility*, MR.SOP.013)
3. All study personnel are expected to execute proper and orderly procedures every time studies and or developmental work is performed.
4. Post scanning cleaning should follow the *Infection and Allergy Control*, MR.SOP.06.
5. Upon completion of the scanning session, study personnel must ensure that all equipment is restored to normal operation.

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