

Research MRI Safety Committee Standard

STUDY PERSONNEL RESPONSIBILITY

Category: Magnetic Resonance Imaging (MRI) Safety

Procedure #: MR.SOP.13

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

PURPOSE:

The mission of the Research MRI Safety Committee at the Medical College of Wisconsin (MCW) is to foster an environment for the safe use of MRI in research at MCW on behalf of the Office of Research. Inherent to that mission is ensuring that plans are in place to manage research participants and be prepared for possible emergency or urgent situations. The purpose of this document is to provide guidelines to study personnel for preparing to manage research participants during emergencies.

DEFINITIONS:

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

Principal Investigator:

A Principal Investigator (PI) is 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.

Study Personnel:

Study personnel are individuals including a student, staff member or laboratory assistant 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 research subject is a human or animal participant who is placed into the bore of the MRI scanner for research purposes.

<u>Magnetic Environment</u>: 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.

<u>MRI</u>: 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).

Research MRI scanner operator: This is 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.

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.

POLICY:

The PI must have an approved IRB or IACUC protocol for the study before study personnel will be allowed to schedule Medical College MRI scanner time (See MR.SOP.16 *Review of Research MRI Applications* and MR.SOP.12 *General Scanner Usage*). Once approval is obtained, Study Personnel are responsible for the following:

- Obtaining informed consent from the research participants
- Providing for the care and any necessary treatment of the research participants
- Screening the research participants or other individuals, including accompanying parents or spouses, for safety risks, prior to entering the magnet room
- Instructing, along with the MRI research Scanner Operator, the research participant in proper use of the emergency squeeze ball
- Having a plan in place from the PI for managing an illness or injury of the research subject
- Physiological monitoring if utilized, during the procedure
- Designing and implementing any task or activity used during the procedure
- Reporting to the MRI research Scanner Operator any problems with specific equipment, including what the problem was or what went wrong during the study so that corrections and / or repairs can be made and so that the problem is documented in the daily log
- Ensuring, along with the MRI research Scanner Operator, that coils, shim files, configuration files, and all computers are returned to standard usage or as directed for each specific system
- Ensuring, along with the MRI research Scanner Operator, that all accessories and/or devices are to be turned off properly, cords and cables wound, and returned to their designated storage area
- Reporting to the MRI research Scanner Operator if a supply item is becoming low in quantity especially if the last, or near last of an item is used
- Removing a research subject or individual who becomes ill or injured immediately from the magnetic environment
- Cleaning the equipment according to MR.SOP.06 Infection and Allergy Control.
- Ensuring, along with the MRI research Scanner Operator, that all equipment is restored to normal operation upon completion of the MRI study.

Emergency procedures and contact information are posted at each scanner. If an individual or research subject becomes ill or injured, the institutional policies for the specific scanner location must be followed as posted, and the Principal Investigator must report any emergency incident to the MRI Safety Committee.

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