Research MRI Safety Committee Standard

IMPLANTS AND DEVICES

Category: Magnetic Resonance Imaging (MRI)

Safety Procedure #: MR.SOP.05

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

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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. Because there is no perceived benefit to the research subject for participating in a study, we must ensure the risk to the research subject is minimal. The purpose of this document is to provide guidelines for ensuring the safety of human subjects, study personnel and others who may have an increased safety risk due to an implant or other device.

DEFINITIONS:

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.

Conditions: Specifications determined by the manufacturer for the implant or device that allow safe MR scanning which include:

a. Static Magnetic Field
b. Spatial Gradient Field
c. Maximum MR system reported, whole body averaged specific absorption rate (SAR)

Spatial Gradient Field: The variations (gradients) over distance (space) in the main static magnetic field from isocenter, the center of the magnetic field, within concentric rings.

PROCEDURES:

A. Study personnel must screen the research subject or other individuals, including accompanying parents or spouses, for safety risks, prior to entering the magnet room. (See also *Safe MRI Scanning*, MR.SOP.11)

B. Documentation of conditions for safe implant or device management are required to ensure the wellbeing of the research subject or other individual in the magnetic environment. The manufacturer of the implant or device must be identified, and the safety of the implant/device verified with written documentation. The manufacturer can be contacted to obtain the written conditions or a peer reviewed publication regarding the device or implant can be provided.
   1. The assurance of safety and conditions needs to be verified in writing before the research subject or other individual is brought to the MR environment.

2. The written documentation should include the FDA date stamp that verifies the device is MRI safe within the specific conditions which will be used for the study, or the peer reviewed publication should include its full bibliographic information.
3. Conditions specified by the manufacturer of the implant or device, or the peer reviewed publication must be followed to maintain the safety of the research subject or other individual.
4. Note that the spatial gradient of the magnetic field refers to variations over distance in the main static magnetic field and that the spatial gradient of the magnetic field is a different configuration for each of the Medical College magnets.

C. Exemptions may be made on a case-by-case basis when insufficient documentation is provided by the device manufacturer or when there is question as to whether a proposed protocol will exceed device limitations.
   1. The Principal Investigator must refer the case to the Research MRI Safety Committee with a description of the device, the documentation obtained from the device manufacturer, and the proposed scanning protocol including the subject's weight, projected distance of device to magnet isocenter when imaging, proposed scanner, and that scanner's reported maximal SAR and dB/dt for each scan via e-mail: MRIresearch@mcw.edu
   2. In some instances, only a subset of this information will be needed for review. Documentation of approval for the inclusion of a subject with such an exemption in a research study must be provided to the scanner operator prior to subject entry into the magnetic environment.

D. Research subjects or other individuals with items indicated in the written documentation as *not* safe should be excluded from participating in a research study. (The same individual may be allowed to have a clinical MRI scan because the risk to benefit ratio in a diagnostic scenario is considered.)

E. Any questions or concerns about implants and devices should be referred to the Research MRI Safety Committee: MRIresearch@mcw.edu.

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