



Research MRI Safety Committee Standard

REVIEW OF RESEARCH MRI APPLICATIONS

Category: Magnetic Resonance Imaging (MRI) Safety

Standard #: MR.016

Applies to: All applications reviewed by the Research MRI Safety Committee

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. This mission is accomplished by conducting timely reviews of human participant and animal studies using MRI, providing the necessary safety training for researchers and staff, ensuring only trained and safety screened individuals have access to the magnetic environment, evaluating the safe use of accessory equipment in or around the magnetic environment, and serving as an available resource for investigators and others. The purpose of this document is to describe the process of review and approval for Research MRI Safety Applications.

DEFINITIONS:

Administrative Processing: the mechanism by which amendments to approved MRI Applications are processed by the Research MRI Safety Office. With this mechanism, the Committee members do not review the application(s).

Exempt Studies: studies which do not require review by the Research MRI Safety Committee.

Expedited Review: the review process in which Research MRI Applications are reviewed and approved by 1-2 members of the Committee outside of a convened meeting of the Committee.

Full Committee Review: the review process in which Research MRI Applications are presented to the entire Research MRI Safety Committee for discussion and decision during a convened meeting of the Committee.

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.

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).

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.

POLICY:

The Research MRI Safety Committee will review the use of MRI systems for human participant, animal, and *ex vivo* studies which occur within the Froedtert and MCW Milwaukee network. The use will be evaluated for safety of all participants according to the most recent *American College of Radiology Guidance Document on MR Safe Practices* and other current peer-reviewed recommendations; approval will not be granted until all required MRI Safety Training has been completed.

PROCEDURE:

- A. Applications will typically be reviewed by Expedited Review unless the conditions for Full Committee or administrative processing are met. Expedited Reviews are reported to the Research MRI Safety Committee as a matter of information at the next regularly scheduled meeting.
- B. Full Committee Review (FCR) will typically be used in the following circumstances:
 - 1. Applications involving the use of new equipment
 - 2. Applications involving a patient population with deficits that require study team management
 - 3. Applications involving the use of a gadolinium-based contrast agent for a study participant with a non-cancerous condition
 - 4. When any Committee member requests FCR
- C. Amendments to approved applications which do not affect the use of scanners or safety of individuals can be processed administratively by the Research MRI Safety Office and reported to the Committee as a matter of information at the next regularly scheduled meeting. Examples include but are not limited to the following:
 - 1. Removal or addition of study staff with appropriate training
 - 2. Correction of grammar or typographical errors.
- D. Once approved, Research MRI Safety Applications which are incorporated into the MCW PRO SmartForms may need to be renewed at the time the corresponding 6 Year Renewal, and Research MRI Safety Applications which are incorporated into the MCW AUA SmartForms must be renewed at the time of the corresponding 3 Year *de novo* Renewal.
- E. A study is typically considered exempt from review by the Research MRI Safety Committee if the proposed study uses routine Standard of Care MRI scanning that is:
 - 1. Routinely performed for similar patients not enrolled in a study, AND
 - 2. Performed for this study at FH Radiology, CDI or other clinical department

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