



Research MRI Safety Committee Standard

OBTAINING APPROVAL FOR USE OF NON-STANDARD EQUIPMENT & MATERIALS

Category: Magnetic Resonance Imaging (MRI)

Standard #: MR.017

Applies to: Investigators, study personnel, MRI staff

PURPOSE:

The advancement of research may entail the use of innovative equipment or materials within the MRI environment. MRI-related injuries can result from failure to follow safety policies or the use of inappropriate or outdated information with respect to such devices, equipment, and materials. The purpose of this document is to ensure objects are safe to operate within and or be brought into the magnetic environment.

DEFINITIONS:

Equipment: Machines that may be used for MRI studies, including but not limited those used to monitor physiological processes or provide the stimulus or physical task for the study.

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

MRI Environment: Also referred to as Zone IV or the MRI scanner room, the MRI environment is the 3-D volume surrounding the MR system that contains both the Faraday shielded volume and the 0.9 -mT field contour (9 gauss (G) line). This volume is the region in which a medical device might pose a hazard from exposure to the electromagnetic fields produced by the MR equipment and accessories and for which access control is part of the risk mitigation.

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).

POLICY

The use of non-standard equipment and materials in the MRI environment must be evaluated for safety and approved by the Research MRI Safety Committee prior to use.

PROCEDURES:

- A. The Principal Investigator (PI) wishing to use non-standard equipment or materials in the MRI environment should contact the Research MRI Safety Committee (RMSC) Office at MRiresearch@mcw.edu with a brief description of the non-standard equipment or materials and their desired use.
- B. The RMSC Office will coordinate with the RMSC Chair who will establish a sub-group of the RMSC.
- C. The subcommittee will meet with the PI to discuss a review plan.
- D. Following the meeting, the PI should submit a formal plan including benchmarks for safety validation for the RMSC to review. The plan should be submitted to MRiresearch@mcw.edu.
- E. Once the RMSC approves the plan, the PI should submit data validating that the benchmarks of the plan have been met.
- F. The RMSC will review the data, and once the Committee is satisfied the non-standard equipment or materials will be safe to use in the MRI environment, the RMSC can vote to approve the use.
- G. The RMSC will issue an approval letter to the PI to document that the non-standard equipment or materials have been evaluated for safety and approved for use in the MRI environment.

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