



Research MRI Safety Committee Standard

REPORTING REQUIREMENTS

Category: Magnetic Resonance Imaging (MRI) Safety

Procedure #: MR.SOP.10

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. Accidents or injuries that occur near the magnetic environment and malfunctions of equipment due to breakage or failure may present a safety risk to research subjects and other individuals and therefore must be addressed. The purpose of this document is to identify the appropriate channels of communication for emergency, adverse, or unexpected events.

DEFINITIONS:

Accidents, Injuries, and Incidents: Unexpected events or occurrences that may involve harm to a research subject, study personnel or employees.

Equipment Damage or Failure: Events or occurrences that may involve harm to equipment, inside or outside of the MR scanner room, which result in the malfunction of equipment from normal operation.

Near Miss: Any event or situation that, due to a deviation from standard operating procedures, has the potential to lead to an accident, injury, or incident or equipment damage or failure, but did not, purely by chance or timely intervention.

POLICY:

All accidents, injuries, incidents and equipment damage or failure must be reported to the Research MRI Safety Committee, and if they occur during a study, also to the PI of record for the study. The Research MRI Safety Committee will then determine if the situation needs to be further reported to Medical College of Wisconsin Office of Public Safety; Children's Wisconsin or Froedtert Hospital Institutional Review Board; and/or Medical College of Wisconsin Institutional Animal Care and Use Committee.

PROCEDURE:

- A. Accidents, injuries, incidents, and near misses
 1. Must be reported within 24 hours of occurrence to:
 - a. Principal Investigator if the incident occurs during a study
 - b. Research MRI Safety Committee
 2. Must be reported by:
 - a. Personnel conducting the study if the incident occurs during a study
 - b. Scanner Operator or individual on site if the incident is unrelated to a study
- B. Equipment damage or failure
 1. Must be reported to the MRI Scanner Operator who will then inform the

Research MRI Safety Committee and administration

2. Timeframe of the report:
 - a. Within 1 hour of occurrence, if the damage/failure affects the primary function of the MRI System
 - b. Within 8 hours of occurrence, if the damage/failure affects the ancillary function of the MRI System
 - c. Within 24 hours of occurrence, if the damage/failure affects components of the MRI System that do not affect the system's ability to image
3. Must be reported by: Study Personnel if discovered during a study

Approval Date:	02/15/2024
Effective Date:	02/15/2024
Review Date:	02/15/2024
Revision History:	01/2009, 12/17/2012, 11/13/2014; 8/20/2020; 4/20/2023
Approved By:	Research MRI Safety Committee