

**University of Minnesota**  
**Center for Magnetic Resonance Research**  
**Standard Operating Procedure**  
**Reporting, Tracking and Reviewing Safety-Related Incidents**

SOP Number / Version: SOP002 / Version 1

Approval Date: 15 March 2013

Implementation Date: April 1, 2013

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<b>Approval Signatures</b>	<b>Date</b>
Author/Owner:	
Regulatory Compliance Coordinator:	
Center Director:	

**1 Purpose**

The purpose of this procedure is to define the process for systematically investigating, documenting, analyzing and reporting non-conformities which have a potentially harmful effect on research subjects and safety within the CMRR facility.

**2 Scope**

This procedure will apply to any study performed on human or animals in which subject safety was unexpectedly impacted as a result of machine malfunction or human error on any system or within any lab in CMRR or CCIR research space. This procedure will also apply to safety-related accidents, not involving human or animal subjects, which occur in CMRR research space. This procedure does not apply to accidents in common spaces, such as bathrooms and waiting area, which are not directly related to research studies.

**3 Definitions**

Standard Operating Procedure

A document providing detailed written procedural instructions to achieve consistency and uniformity of the performance of a specific function.

Unanticipated Problem	Any problem or event which, in the opinion of the facility or researcher, was unanticipated, reflects new or increased risk to the subjects and was possibly related to research procedures.
Potential Unanticipated Problem	Serious error or mishap that had the potential to cause an unanticipated problem but failed to do so because of chance or because it was intercepted.
Safety Accident	Any unplanned or unanticipated event which caused or could have caused personal injury, environmental damage or property loss.

#### **4 Responsibility**

It is the responsibility of all users of the CMRR facility to adhere to this SOP.

It is the responsibility of the owner/author listed above and the CMRR Safety Committee to review the content of this SOP for accuracy and continued applicability on at least an annual basis.

#### **5 Procedure**

##### **5.1 Problem Identification**

Researchers conducting a scan in which an unanticipated problem, a potential unanticipated problem or a safety accident occurs are to immediately notify the CMRR Safety Officer Jeramy Kulesa, [Kulesa@cmrr.umn.edu](mailto:Kulesa@cmrr.umn.edu)). The researcher should provide a detailed description of the incident.

##### **5.2 Root Cause Analysis**

Upon receiving a report of an unanticipated problem, potential unanticipated problem or safety accident, the CMRR Safety Officer, Jeramy Kulesa, will initiate a Corrective and Preventive Action investigation.

**5.2.1** All individuals with relevant knowledge of the event and surrounding circumstances are to be identified through conversations with individual reporting the incident.

**5.2.2** Individuals with direct knowledge of the event will be requested to submit a written description of the event.

**5.2.3** In the case of an equipment failure, the equipment manufacturer or CMRR equipment engineers will be contacted to obtain written corrective actions taken.

**5.2.4** All information obtained will be summarized into a document for the CMRR Safety Committee to analyze and assess the adequacy of corrective and/or preventative measures.

**5.3 Corrective and preventative action documentation and tracking**

To document corrective and preventive action, the CMRR Safety Office will issue a corrective and preventative action notice (CAPAN) and log the CAPAN on the CAPAN log. Any written correspondence, reports or notes will be attached to the CAPAN.

**5.4 Corrective and preventative action implementation**

The CMRR Safety Committee will review the CAPAN and determine an appropriate course of action and identify the person(s) responsible for ensuring the actions are accomplished in a timely manner. This review will typically take place at the regularly scheduled Safety Committee meeting. However, in the event of a significant unanticipated problem or safety accident, the CMRR Safety Committee will convene in a special session.

The CAPAN will be reviewed monthly until it is closed. This determination will identify who is responsible for implementing the appropriate course of corrective action.

**5.5 Mandatory Reporting / Communication**

**5.5.1** In the situation of an unanticipated event to a human subject or animal subject, the CMRR Safety Officer will request the PI to submit an unanticipated event report to the IRB or IACUC per the reporting requirements of those organizations.

**5.5.2** If an employee is injured, the employee must report the job-related injury as soon as practical to the employee's supervisor per University of Minnesota Administrative Policy – Reporting Workers Compensation Related Injuries.

**5.5.3** The CMRR Safety Officer will summarize the event in an email to the members of the CMRR Safety Committee, CMRR Operations and CMRR Leadership Team within 24 hours of the being notified of the event.

**5.5.4** The CMRR Safety Officer will submit a CAPAN to the reporting researcher and any other parties requesting information about the incident.

## **5.6 Monitoring Plan**

The CMRR Safety Committee will perform 2 reviews prior to closing out a CAPAN.

Closeout of CAPAN will be tracked by the Building Safety Officer (Jeremy Kulesa, [Kulesa@cmrr.umn.edu](mailto:Kulesa@cmrr.umn.edu)),. Records of CAPAN will be maintained for at least 2 years. The CMRR Safety Committee will review completed CAPAN at least annually after completion of the corrective or preventive action.

## **6 References**

**6.1** University of Minnesota Administrative Procedure – Reporting Workers Compensation Related Injuries - [University Policy](#)

**6.2** Internal Review Board Form for Unanticipated Problems that may Involve Risks to Subjects or Others (UPIRTSO) – [IRB Form](#)

## **7 Forms and Templates**

**7.1** Corrective and Preventative Action Plan

**7.2** Corrective and Preventive Action Form Log

## **8 Appendices / Tables**

N/A

## **9 Revision History**

Version Number	Approval Date	Change from Previous Version

Center for Magnetic Resonance Research	Center for Clinical Imaging Research
<b>Internal Corrective / Preventative Action Notice (CAPAN)</b>	

Request Number	Click here to enter text.		
Date Reported	Click here to enter text.		
Basis of Request	<input type="checkbox"/> Unanticipated Problem <input type="checkbox"/> Potentially Unanticipated Problem <input type="checkbox"/> Safety Accident		
Initiator: Click here to enter text.	Email: Click here to enter text.	Phone: Click here to enter text.	Department: Click here to enter text.

### Problem Reported

Click here to enter text.

### Evaluation of Problem

Problem Found	Click here to enter text.
Root Cause of Problem	Click here to enter text.

### Permanent Corrective Action

Suggested Solutions/Preventions	Click here to enter text.
Action Taken	Click here to enter text.
Implementation Date	Click here to enter text.
Approved by	Click here to enter text.
Date	Click here to enter text.

### Monitoring

Review #1	Click here to enter text.
Review #2	Click here to enter text.
Closed Out Date	Click here to enter text.

Center for Magnetic Resonance Research	Center for Clinical Imaging Research
<b>Corrective and Preventative Action Tracking Log</b>	

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