

**University of Minnesota
Center for Magnetic Resonance Research
Standard Operating Procedure
Subject Screening**

SOP Number / Version: SOP011 / Version 2

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Author/Owner: Jeramy Kulesa

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

1 Purpose

The purpose of this procedure is to define the process for administration of the CMRR safety screening form.

2 Scope

This procedure will apply to all personnel who are involved in conducting human subjects research at CMRR.

3 Definitions

Standard Operating Procedure	A document providing detailed written procedural instructions to achieve consistency and uniformity of the performance of a specific function.
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4 Responsibility

It is the responsibility of all personnel who perform the functions listed in Section 2 to adhere to this SOP.

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

5 Procedure

5.1 Subject Screening

- The most current version of the CMRR screening form must always be used
 - Screening forms from other institutions are not acceptable
- Any person entering the MR scanner room (the room that houses the scanner) must complete a screening form that is reviewed by the investigator prior to entering the room
- A new screening form must be completed by subjects for each day they are scanned
- All appropriate signatures must be obtained prior to the scan
- Screening form must be filled out the day of the scan
- Screening form must be used anytime anyone is being scanned including for development purposes
 - Screening forms for development scans can be shredded at the conclusion of the scan

The researcher must go over the volunteer screening form line-by-line with the research participant to ensure that the research subject fully understands what is being asked and so that they have an opportunity to ask any questions they may have. This process can be done in the lobby, but if more privacy is required, or requested, this can be done in one of the subject preparation/consenting rooms. Please note that some of these rooms require reservations. Since these rooms are located beyond the secure area research subjects must be escorted at all times and should be verbally screened prior to leaving the lobby to ensure that they do not have any implanted device (pacemaker, aneurysm clip, etc.) that could be hazardous to their health when exposed to magnetic fields greater than 5 gauss.

Affirmative answers on the screening form must be cleared according to the CMRR policy regarding affirmative screening answers. Screening forms will be reviewed quarterly by the CMRR Regulatory Compliance Coordinator to ensure compliance.

Once the screening form has been completed and all necessary approvals have been obtained the research subject should be escorted to a changing room and asked to change into a CMRR provided gown or scrubs according to the CMRR policy on subject gowning. If the study has obtained an exemption to the gowning policy the research subject should be instructed to remove all metallic, or potentially metallic, items from themselves and place them in one of the lockers located in the lobby or in one of the preparation rooms. Once they have changed or removed all metallic items the researcher should verbally verify that the research subject does not have any metallic or potentially metallic items on them. Briefly describe that any objects that may have been overlooked could cause problems with the images at a minimum, but could also cause bodily harm to the research subject either via burns or projectile effects. Research subjects are not allowed to bring any metallic objects into the console room, including backpacks, phones, jackets, etc.

N/A

7 Forms and Templates

7.1 CMRR Subject Safety Screening Form:

<https://www.cmrr.umn.edu/policies/irb.php>

8 Appendices / Tables

N/A

9 Revision History

Version Number	Approval Date	Change from Previous Version
2	7/17/2018	Added bulleted list to more clearly define SOP, replaced link to subject information form with screening form link