University of Minnesota
Center for Magnetic Resonance Research
Standard Operating Procedure
Affirmative Screening Form Answers

SOP Number / Version: SOP005 / Version 3
Approval Date: 02 August 2017
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Approval Signatures	**Date**
Author/Owner:	
Regulatory Compliance Coordinator:	
Center Director:	

1 Purpose

The purpose of this procedure is to define the process for obtaining clearance to scan individuals with affirmative answers on the CMRR Volunteer Screening Form or admit individuals into the scanner console room with affirmative answers on the CMRR Console Room Screening Form. This SOP is a critical component in maximizing the safety of all individuals observing or being scanned at CMRR.

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.
Volunteer Screening Form	Utilized for research subjects and persons accompanying subjects into the room housing the scanner.
Console Room Screening Form	Utilized for individuals accompanying research subjects into the magnet console room, but who will not enter the room housing the scanner.

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 CMRR Volunteer Screening Form

The CMRR Volunteer Safety Screening Form is broken into 3 sections. The sections are designed to ensure an appropriately qualified individual is making the determination of whether to allow an individual to be scanned.

- Section 1
  - Requires only signature of the researcher. No additional signatures required prior to scanning. Items listed as needing to be removed must be removed prior to scan.

- Section 2
  - If subject answers "yes" to any question in this section, the signature of anyone listed on the IRB protocol as able to consent, MR Professional (See Below), or CMRR MR Technologist is required prior to scanning subject
    - If the research personnel does not feel qualified or comfortable to make a determination of safety they should consult a MR Professional or CMRR MR Technologist.
    - If none of these individuals are physically present to sign the Screening Form in person, the following method is an acceptable alternative:
      - Email-Obtain written approval via email from the approving individual's University assigned x.500 email address. This requires a copy of email be attached to screening form.

- Section 3
  - If subject answers "yes" to any question in this section, the signature of MR Professional (See Below) is required prior to scanning.
    - If none of these individuals are physically present to sign the Screening Form in person, the following method is an acceptable alternative:
      - Email-Obtain written approval via email from the approving individual's University assigned x.500 email address. This requires a copy of email be attached to screening form.
  - A short description detailing rationale for approving scan to proceed is encouraged.

- Example: *The stent that the patient/volunteer has is model #XXXX this stent has been deemed MR conditional at 3T. All conditions will be met with this scan therefore I deem it low risk.*

For section 2 and 3, approval documentation can be acquired prior to the scan day (preapproval). Preapproval documentation must be attached to screening form including hard signature or email approval from University assigned x.500 email address

MR Professionals can be contacted directly via phone or email, they can be paged to the front desk during normal operating hours, or an email can be sent to cmrr-mr-professionals@umn.edu. Under no circumstances should this email include identifying information for the individual in question. You should include as much information about the object in question as possible (make, model #, material, size, date implanted, etc.) along with details about the proposed scan including anatomy being scanned, field strength, coils, and sequences when known. You should also include the urgency of the decision (i.e the volunteer is ready to go into the scanner or the scan is scheduled for next Friday). The MR professionals will make every effort to respond in a timely manner, but the possibility exists that the decision will require additional information that may not be readily accessible or that the MR Professionals are unable to respond in the timeframe required.

If a researcher is unable to obtain written approval to affirmative answers in section 2 and/or 3, the CMRR requires the scan to be cancelled.

In addition to completing the screening form, individuals completing screening forms may be asked to provide additional information regarding the item(s) in question including, but not limited to, copies of their medical records.

5.2 CMRR Console Room Screening Form

Any affirmative answer excludes the individual from access to the console room.

5.3 Section 2 and Section 3 Named individuals – as of 08/02/2017

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5.4 Compliance

Select screening forms from each PI will be reviewed quarterly by the CMRR Safety Officer to ensure compliance with this policy. Individuals found to be repeatedly violating this procedure will have CMRR access revoked.

6 References

N/A

7 Forms and Templates

7.1 Volunteer Screening Form
https://www.cmrr.umn.edu/policies.new/nc-cms/content/upload/CMRR_Subject_Safety_Screening Form 03.15.2017.pdf

7.2 Console Room Screening Form
https://www.cmrr.umn.edu/policies.new/nc-cms/content/upload/CMRR_Console_Room_Screening_Form.pdf

8 Appendices / Tables

N/A

9 Revision History

Version Number	Approval Date	Change from Previous Version
1	03 December 2012	Original Version
2	01 June 2014	Removed requirement to scan screening forms and updated members of MR-Professionals group
3	02 August 2017	Updated Medical Director, MR Technologists, and members of MR Professionals. Updated links to most recent versions of forms. Removed phone approval as an option.