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

SOP Number / Version: SOP004 / Version 2
Approval Date: 17 June 2014
Implementation Date: 01 July 2014
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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 tracking of human subjects and/or patients that are scanned on MR scanners above 3T housed at CMRR.

2 Scope

This procedure will apply to all personnel who are involved in conducting human subjects research at CMRR on scanners above 3T.

3 Definitions

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

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 Tracking

At the conclusion of every scan involving human subjects taking place on scanners above 3T at CMRR the researcher is required to scan the CMRR Subject Information Form using the dedicated scanner located near the front desk (mail alcove room 1-108) that will send electronic copies of the documents to a secure server. Please see https://www.cmrr.umn.edu/internal/sops/CMRR_Document_Scanning_Protocol_SOP.pdf for details on how to use the scanner. Scanner use instructions are also posted near the scanner. The Department of Radiology Research Study Coordinator will review the scanned documents daily for completeness and will enter all pertinent information into the secure encrypted subject tracking database. After a volunteer completes their first study, the subject is given a CMRR-generated study participant number. Upon completion of each subsequent study, the CMRR Research Study Coordinator logs the study in the database. This allows the CMRR to monitor, track, and limit (when necessary) the number of studies that each participant has performed on each system and allows us to notify participants of significant new information that develops over the course of MRI research. The researcher must use the most current versions of this form which can be found by visiting the link found below.

5.2 Possible Exemption

The possibility exists that certain studies may be exempt from this requirement, but the CMRR will require written confirmation from the IRB that a particular study is exempt.

5.3 Compliance

CMRR will conduct random audits, cross checking digital files with magnet calendars, to ensure compliance with this SOP. Individuals found to be violating this procedure will have CMRR access revoked.

6 References

N/A

7 Forms and Templates

7.1 Subject Information Form:
https://www.cmrr.umn.edu/policies.new/nc-cms/content/upload/CMRR_Subject_Information_Form.pdf

8 Appendices / Tables

N/A

9 Revision History

Version Number	Approval Date	Change from Previous Version
1	18 June 2012	Original Version
2	17 June 2014	Reduced # of Forms Being Tracked and Eliminated the requirement for 3T scans