Human subjects research at The Center for Magnetic Resonance Research (CMRR)

Required approvals prior to beginning human subjects research at CMRR:

- PI and research staff need to be <u>registered with CMRR</u> (On-boarding process that includes registration at CMRR, verification that safety training has been completed, and access card/keys assigned. See SOP <u>here</u>)
- <u>Pre-IRB review</u> (necessary to obtain IRB approval for work at CMRR, reviewed by the CMRR Safety Committee. See policy <u>here</u>)
- 3) IRB approval (Must have University of Minnesota IRB approval to conduct human research at CMRR, subjects cannot be scanned using another institutions IRB approval)
- <u>PARS approval</u> (CMRR specific project application request system, reviewed by CMRR committees as appropriate. See policy <u>here</u>)

Data acquisition requirements:

- 1) Use of standard CMRR forms (link to policy)
 - a. <u>Screening Form</u>
 - b. <u>Subject Information Form</u>
 - c. Exit Questionnaire
 - d. Magnet Safety F.A.Q

Field Strength	Screening Form	Subject Information	Exit Questionnaire
		Form	
3T	Required	Not Required	Optional
4T & 7T	Required	Required	Optional
9.4T & 10.5T	Required	Required	Required

2) Consent form template

- a. Includes some required language
- 3) <u>Scheduling magnet time on calendars</u>
- 4) <u>Magnet operator training</u> (if planning on operating the scanner)
 - a. Scheduling an MR Technologist
- 5) Volunteer Handling
 - a. <u>General guidelines/expectations</u>
 - b. <u>Recruitment process</u> for Dept. of Radiology researchers
- 6) <u>MR-Professional sign off process</u> (process to clear scans involving participants with implants, reviewed by the CMRR Safety Committee, audited for compliance)
- 7) Data policy at scanners

- 8) Use of Protected Health Information (PHI) at scanners
- 9) General scanning policies
 - a. 2-person rule
 - b. Contrast injections
 - c. Use of Non-Standard Equipment in Scanner Room
 - d. <u>Hearing protection</u>
 - e. <u>Metalworker Policy</u>
 - f. <u>Emergency Procedures</u>
 - g. Gowning/scrub requirement
 - h. Policies specific to Dept. of Radiology researchers
 - i. Policy for the use of <u>family members as research subjects</u>
 - ii. Policy to minimize coercion
- 10) <u>Mailing list enrollment</u> (important communications/announcements are sent via the mailing lists. See policy <u>here</u>)
- 11) <u>Parking</u>

Post data acquisition requirements:

- 1) <u>Abnormal scan/incidental findings review process</u> (radiologist review of abnormal scans offered as a service. See policy <u>here</u>)
- 2) <u>Tracking process for scans at systems above 3T</u> (used to notify participants in the event that new information about repeat scans becomes available, contact information is held indefinitely)
 - a. Document scanning protocol
- 3) <u>Billing</u>
- 4) Grant acknowledgment
- 5) <u>Reporting equipment problems</u>
- 6) <u>Reporting of safety incidents or near incidents</u>