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

Required approvals prior to beginning human subjects research at CMRR:

1) PI and research staff need to be registered with CMRR (On-boarding process that includes registration at CMRR, verification that safety training has been completed, and access card/keys assigned. See SOP here)
2) Pre-IRB review (necessary to obtain IRB approval for work at CMRR, reviewed by the CMRR Safety Committee. See policy here)
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)
4) PARS approval (CMRR specific project application request system, reviewed by CMRR committees as appropriate. See policy here)

Data acquisition requirements:

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

<table>
<thead>
<tr>
<th>Field Strength</th>
<th>Screening Form</th>
<th>Subject Information Form</th>
<th>Exit Questionnaire</th>
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</thead>
<tbody>
<tr>
<td>3T</td>
<td>Required</td>
<td>Not Required</td>
<td>Optional</td>
</tr>
<tr>
<td>4T &amp; 7T</td>
<td>Required</td>
<td>Required</td>
<td>Optional</td>
</tr>
<tr>
<td>9.4T &amp; 10.5T</td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
</tr>
</tbody>
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2) Consent form template
   a. Includes some required language
3) Scheduling magnet time on calendars
4) Magnet operator training (if planning on operating the scanner)
   a. Scheduling an MR Technologist
5) Volunteer Handling
   a. General guidelines/expectations
   b. Recruitment process for Dept. of Radiology researchers
6) MR-Professional sign off process (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. Hearing protection
   e. Metalworker Policy
   f. Emergency Procedures
   g. Gowning/scrub requirement
   h. Policies specific to Dept. of Radiology researchers
      i. Policy for the use of family members as research subjects
      ii. Policy to minimize coercion
10) Mailing list enrollment (important communications/announcements are sent via the mailing lists. See policy here)
11) Parking

Post data acquisition requirements:

1) Abnormal scan/incidental findings review process (radiologist review of abnormal scans offered as a service. See policy here)
2) Tracking process for scans at systems above 3T (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) Billing
4) Grant acknowledgment
5) Reporting equipment problems
6) Reporting of safety incidents or near incidents