University of Minnesota
Center for Magnetic Resonance Research
Policy
Pre-IRB Review Process

Policy Number / Version: POL017 / Version 1
Approval Date:
Implementation Date:
Author/Owner: Jeramy Kulesa

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

1. Purpose

The purpose of this policy is to define the Pre-IRB review process for research projects taking place at CMRR that include human volunteers.

2. Scope

This policy will apply to all personnel who are involved in scanning human subjects at CMRR.

3. Responsibility

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

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

4. Policy

IRB protocols for human research studies using Magnetic Resonance (MR) scanners housed at the Center for Magnetic Resonance Research (CMRR) require review by the CMRR Safety Committee **PRIOR to submission to the IRB**. CMRR's assessment will streamline the IRB application process and minimize delay in obtaining IRB approval for CMRR users.

The CMRR Safety Committee review replaces the requirement to submit IRB Appendix F (use of devices) for studies using CMRR MR devices. However, Appendix F will still be required for studies involving use of additional devices during MR (outside of the magnet, RF coils, and gradient coils) and for studies operating outside of IEC guidelines.

One assessment is required for each magnet included in an IRB protocol submission. Upon approval by the CMRR Safety Committee. Researchers will be provided with pdf approval letter(s) for each system. This approval letter must be included with the protocol submission to the IRB. Failure to include the required approval letter(s) will result in delays in getting protocols approved.

The CMRR Safety Committee review includes the use of the MR device itself along with any ancillary equipment that is intended to be used in the MR environment. This review will ultimately lead to our recommendation to the IRB of whether the use of the device should be considered exempt, non-significant risk, or significant risk. This process is also used to review whether we think the proposed study can be safely conducted at CMRR including whether the proposed ancillary equipment can be safely used in or near the MR scanner.

To initiate a review please visit: https://www.cmrr.umn.edu/preirb/

For more information about the Pre-IRB Review process please contact Jeramy Kulesa at 612-625-8847 or ande2445@umn.edu.

5. References

N/A

6. Appendices / Tables

N/A

7. Revision History

Version Number	Approval Date	Change from Previous Version