Marshfield Clinic

Marshfield Clinic Research Foundation IRB (MCRF IRB) as IRB of Record

1. SCOPE

1.1. System Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. IRB Authorization Agreement (IAA)
- Arrangement that allows an institution holding a Federal-Wide Assurance (FWA) to defer IRB review to a second FWA-holding institution.

2.2. IRB of Record
- The Institutional Review Board (IRB) responsible for the initial and continuing review and approval of a given research project.

3. PROCEDURE BODY

Marshfield Clinic Research Foundation (MCRF) maintains an Institutional Review Board (IRB) that is established to review research involving human subjects conducted by investigators from Marshfield Clinic and St. Joseph's Hospital (SJH). MCRF IRB is given authority to review and approve, require modification in, disapprove, suspend or terminate any human subjects research. This authority covers its investigators, and extends to institutions for which MCRF is serving as IRB of Record, per specific IRB Agreements.

In some cases, MCRF IRB may agree to serve as IRB of Record for an external organization that is engaged in human subjects research as part of a study approved or under review by MCRF IRB. There are specific guidelines used to evaluate this regulatory responsibility.

3.1. MCRF IRB will consider serving as the IRB of Record for external personnel when:

a. The role of the external personnel is limited to activities such as data analysis or consultation; or

b. The study is minimal risk (as defined by 45 CFR 46.110(b)(1,2) and 63 FR 60364 60367 (1-7)), and the role of the external personnel is either limited or very clearly defined (e.g., administration of a survey tool, assisting with subject recruitment); or

c. The study is eligible for review using an existing IRB Reliance Partner, such as Wisconsin IRB Consortium (WIC), National Cancer Institute Central IRB (NCI CIRB) Health Care Systems Research Network (HCSRN) formerly HMORN, Great Plains Collaborative (GPC), StrokeNet or other established IRB collaborations.

- For WIC, HCSRN and GPC studies, MCRF IRB will consider IRB of Record Responsibilities for clinical trials and exemptions.

3.2. MCRF IRB will typically not consider serving as IRB of Record when:

a. Marshfield Clinic or SJH physicians, staff or students are not engaged in the research;

b. MCRF IRB does not have, and is not able to garner, sufficient knowledge of local research context, as required by its Federal-Wide Assurance (FWA), to assume oversight for the external institution;

c. The study is expected to qualify for exemption from IRB review; or

d. MCRF Office of Research Integrity & Protections (ORIP) determines that MCRF IRB is unlikely to be able to adequately oversee the external site or personnel in a manner that will ensure the protection of human research subjects.

3.3. Determining When MCRF will serve as IRB of Record for External Personnel

a. MCRF IRB Chair, IRB Administrator or designee will determine whether MCRF IRB will accept IRB review for another institution for minimal risk studies. For studies greater than minimal risk the determination will be made by the IRB Chair or IRB Administrator, as well as the MCRF Associate Director and/or Legal Counsel, if appropriate.

- For research involving Aurora Health Care, Medical College of Wisconsin and UW-Madison's Health Sciences IRB, MCRF investigators should follow the procedure at www.wicshare.com
- For Health Care Systems Research Network (HCSRN) studies, the MCRF PI must submit a completed HCSRN Multi-Site Research Cover Sheet with his or her IRB Application.
- For Great Plains Collaborative (GPC) studies, the MCRF PI should contact the Reliance Coordinator for the network and the local IRB Administrator
- all other requests to accept IRB oversight for another institution, the MCRF PI or research staff must contact MCRF Office of Research Integrity & Protections (ORIP) to discuss on a study-by-study basis. Based upon 3.1 and 3.2 above, the IRB Chair or Administrator will determine whether serving as IRB of Record is feasible.
- Any external personnel will be required to provide ORIP with proof of required CITI human subject protection training and completion of COI.
- The MCRF PI is responsible for communicating all IRB requirements to the external collaborator and for facilitating IRB required reporting.

b. Any IRB retains the right to conduct review of research in which its institution is engaged, at any point in the research.

3.4. Completion of an IRB Deferral Agreement

a. When MCRF IRB agrees to serve as IRB of record, a formal agreement is required, per federal regulations.

- IRB Authorization Agreement (IAA)
  - An IAA is always needed when MCRF IRB agrees to serve as IRB of Record for external collaborators affiliated with an institution that has its own IRB.
  - MCRF ORIP will facilitate the development and processing of IAAs when agreeing to serve in this capacity. The MCRF PI is responsible for providing ORIP with detailed contact information for the collaborating investigator's IRB Administrator.

- GPC and Western IRB have a global reliance agreement in place therefore an IAA is not needed.

☐ Independent Investigator Agreement (IIA)

- An IIA is required when MCRF IRB agrees to serve as IRB of Record for external collaborators who are not affiliated with an institution that has its own IRB.
- MCRF ORIP will facilitate the development and processing of IIAs when agreeing to serve in this capacity.

4. ADDITIONAL RESOURCES

4.1. References:
- Deferral of MCRF IRB Review to an External IRB
- MCRF Investigators and Multi-Site Research

4.2. Supporting documents available:
- IRB Application

5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control transferred from Policy & Handbook Library - #957.4. Removed supporting documents as they are no longer applicable. Added information about GPC and WIRB collaborations. Changed name from HMORN to HCSRN, Health Care Systems Research Network. Added personnel who are able to cede/accept review.
2.0	
3.0	

6. DOCUMENT PROPERTIES

Primary Author: Scheller, Lori A
Co-Author(s):
Approver(s): This document has been electronically signed and approved by: Ziemba, Steven J PHD on: 12/1/2015 4:06:16 PM