Marshfield Clinic

MCRF Investigators and Multi-Site Research

1. SCOPE

1.1. System Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. **Great Plains Collaborative (GPC)** – Network of medical centers (**The Children's Mercy Hospital, University of Iowa, University of Kansas Medical Center, Medical College of Wisconsin, University of Minnesota, University of Nebraska Medical Center, University of Texas Health Sciences Center at San Antonio, University of Texas Southwestern Medical Center and University of Wisconsin-Madison, University of Missouri, Indiana University and Marshfield Clinic)** focused on improving healthcare delivery through ongoing learning, adoption of evidence-based practices and active research dissemination. The GPC has an IRB reliance agreement which allows for eligible studies involving one or more GPC institutions to be reviewed by a single IRB of record.

2.2. **Wisconsin IRB Consortium (WIC)** – Wisconsin Institutional Review Boards (**Aurora Health Care, Marshfield Clinic, Medical College of Wisconsin, Univ. of Wisc. Madison**) collaborating among member institutions' IRBs in order to provide more effective and efficient oversight of multi-site human subject research protocols in Wisconsin and reduce costs and duplication of effort among the member institutions and affiliated investigators. The Consortium has established one agreement that allows any of the IRBs to serve as IRB of record.

2.3. **Health Care Services Research Network (HCSRN) formerly HMORN** – Network of health care systems including MCRF collaborating in population-based research that measurably improves health and health care. The IRB reliance agreement allows for ceding to a single IRB of Record of data-only, epidemiological and health services research. It can not be used for prospective biomedical research studies of human participants involving drugs, device or biologics.

2.4. **Commercial Centralized IRBs** – Independent provider of regulatory and ethical review services for human research. MC has a Master Service Agreement (MSA) with **Western/Copernicus Group (WCG/WIRB) IRB** allowing for eligible industry sponsored drug and device clinical trials to be deferred to them as deemed appropriate by the MCRF IRB. WIRB and Copernicus IRBs are AAHRPP accredited.

3. PROCEDURE BODY

This document provides information on the requirements that exist when Marshfield Clinic plans to engage in multi-site research with collaborating institutions.

3.1. If a non-Marshfield Clinic site has its own FWA and IRB of record, then both Marshfield Clinic's IRB and the other site's IRB will review and approve the research, unless MCRF IRB determines that to avoid duplication of effort only one IRB needs to review and approve. In this case, an IRB Authorization Agreement (IAA) is required

between the Marshfield Clinic and the other institution unless an IRB reliance agreement or Master Service Agreement (MSA) is already in place.

3.2. An institution that holds an FWA and that is either a) the primary awardee under a federal grant, contract, or cooperative agreement supporting research to which the FWA applies, or b) the coordinating center for federally-conducted or federally–supported research to which the FWA applies, is responsible for ensuring that all collaborating institutions engaged in such research operate under an appropriate OHRP-approved or other federally-approved assurance for the protection of human subjects. When Marshfield Clinic subcontracts under a federal award, or serves as the coordinating site for federally funded research, documentation of a site's assurance is accomplished through language in a subagreement coordinated by The Office of Sponsored Programs.

- Each non-Marshfield Clinic site that routinely engages in federally funded or supported research activities must have its own federal-wide assurance (FWA) and an IRB of record.
- Non-Marshfield Clinic sites that do not routinely engage in federally funded or supported research, are not generally required to have an FWA and IRB of record. In case of this scenario in a multi-site collaboration, each person engaged in research activities at that site may be listed on the Marshfield Clinic IRB application and will be required to enter into an individual or institutional investigator agreement (IIA).

3.3. In the case of IRB Exempt multi-site research, Marshfield Clinic will not enter into an IRB Authorization Agreement or Individual Investigator Agreement, except if special arrangements are made. (e.g. the Wisconsin IRB Consortium (WIC) agreement)

- If a non-Marshfield Clinic site has its own IRB, then both MCRF IRB and the other site's IRB must review and exempt the research.

3.4. All investigators and key personnel listed on a Marshfield Clinic IRB application for multisite research studies involving human subjects must complete human subjects training as specified in the procedure, "Human Subject Protection Training." They must also have completed the Conflict of Interest (COI) training and disclosure requirements as outlined in the Investigator Conflict of Interest in Research policy.

3.5. MCRF IRB may act as IRB of record for a non- Marshfield Clinic site, and the procedure document, "Marshfield Clinic as IRB of Record," will be followed.

3.6. Additional IRB Review Requirements of Multi-Site Research Studies when MC is the Coordinating Center:

- A description regarding how the coordinating center will ensure for each site that any required IRB approval is in place before the initiation of research involving human subjects;
- A description of the reporting obligations of the sites to the coordinating center:
- What events need to be reported e.g., unanticipated problems, adverse events; and non-compliance or new research findings; and
- To whom reports should be made.

3.7. MCRF IRB may or may not defer its review of a protocol to another institution's IRB.

- See "Deferring/Ceding Review to External IRB" procedure

4. ADDITIONAL RESOURCES

4.1. References:

- Deferring/Ceding Review to an External IRB
- Determining Engagement in Research
- Marshfield Clinic Research Foundation IRB (MCRF IRB) as IRB of Record

4.2. Supporting documents available:

- None

5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control transferred from Policy & Handbook Library - #880.3. Updated title of Non-Compliance procedure. Added definitions. Added process for GPC and WIRB deferred studies. Change Name of HMORN to HCSRN. Revise types of studies allowable for deferral. Edited terminology for deferral process to be consistent with other applicable policies/procedures.
2.0	3.1 add Master Service Agreement (MSA) 3.7 – 3.9 deleted section pertaining to process for defer/cede to another institution and added reference to see "Deferring/Ceding Review to an External IRB" procedure
3.0	

6. DOCUMENT PROPERTIES

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