INSTITUTIONAL REVIEW BOARD COMMITTEES

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Institutional Review Board Committees

PURPOSE:
Medical College of Wisconsin (MCW) has established Institutional Review Boards (IRB) to ensure the protection of subjects in human subjects research conducted under the auspices of MCW, Froedtert Health (FH), Versiti and Children's Wisconsin (CW). All human subjects research conducted under the auspices of the MCW, FH, or CW must be reviewed by the MCW IRB prior to the initiation of the research.

DEFINITIONS
Institutional Review Board (IRB): The committee formally designated by an Institution to review, approve, and monitor research involving humans with the aim to protect the rights and welfare of research subjects. Per **MCW Corporate SOP: Research Involving Human Subjects and/or their Private Identifiable Information (RS.HS.010)** MCW has designated the MCW IRBs as the IRB to review human subject research under the jurisdiction of MCW.

Scientist Member:
If one or more of the following apply, an IRB Member will be designated as a Scientist:

- Physician or other healthcare professional with clinical responsibility for patients
- Faculty appointment at an academic medical center (but not ethicists)
- Person employed in any research enterprise sector of a university or health care center (this category includes project coordinators, administrative assistants, and secretaries working for research projects)
- Person with MD, DO, or PA degree
- PhD level physical or biological scientist (but not PhD level ethicists)
- PhD or Masters level behavioral scientist or practitioner (including MSW)
- Person with a terminal research or health care provider degree (MPH, DNsc, NP, PharmD)

Nurses, pharmacists (RPh), and other biomedical health professionals (e.g. physical therapists) will be classified as Scientists (having "primary concerns in the scientific area.")

Non-Scientist Member:
Persons who do not meet any of the criteria for "Scientist" may be considered for the "Non-Scientist" category. Individuals whose background, training, occupation, and experience would incline them to review research activities from a standpoint outside of any biomedical or behavioral discipline are Non-Scientists, for purposes of this policy.

Lawyers, clergy, ethicists, and social workers are examples of persons whose primary

"scientist". Members who have training in both scientific and non-scientific disciplines, such as both a J.D. and R.N. will not be designated as a Non-Scientist.

Unaffiliated Member Member who or whose immediate family member does not have current employment, or a current business relationship with either MCW, FH, Versiti or CW; and who has no academic relationship with those institutions. An unaffiliated member may however be a present or past patient of any of these institutions.

Experienced IRB Member Members who have served for 1 year as an IRB member or has CIP certification or has 1 year of work experience within an IRB/HRPP office as a coordinator, analyst or a director. Experienced IRB members may be nominated by the IRB Chair and seconded by the HRPP Director or designee to serve as an expedited review.

PROCEDURE:

IRB Authority

1. In accordance with HHS and FDA regulations and guidance, the MCW IRB is authorized:
    a. To approve, require modifications to secure approval, or disapprove all research activities overseen and conducted under the auspices of the MCW including other institutions that defer review to MCW IRB.
    b. To suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subject.
    c. To require progress reports at regular intervals, and whenever deemed necessary.
    d. To observe, or have a third party observe, the consent process; and
    e. To observe, or have a third party observe, the conduct of the research.
2. Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of the institution. However, those officials may NOT approve research if it has been disapproved by the IRB. MCW, FH, Versiti or CW officials may strengthen requirements and/or conditions or add other requirements for MCW IRB approval or approval by another MCW, FH, Versiti or CW committee.
3. Changes to previously approved research proposals and/or consent forms must be approved by the IRB before initiating them. The IRB Chair makes the final determination whether the changes require convened Committee review or expedited review.

Number of IRBs

1. There are currently eight (8) IRB Committees.
2. The Institutional Officials (IO), the HRPP Director, and the IRB Chairs will review the activity of the IRBs on at least an annual basis and decide as to the appropriate number of IRB Committees that are needed for the institution.
    a. This determination will be based on the evaluation of the performance of IRB as described in **IRB Member SOP: Review and Evaluation of IRB Member Service**
    b. The MCW HRPP will also report annually to CW regarding the CW specific pediatric committees.

1. Majority of the MCW IRB Committees review all types of human subject research. Four (4) of the IRB Committees have been developed with a special focus and review only a limited type of research as described below.
    a. **Committee #5** : This Committee and its members review all research which qualifies for exempt or expedited review as defined by the federal regulations.
        i. Committee #5 primarily reviews Froedtert Health Nursing Research.
    b. **Committee #6** : This Committee provides review of urgent reportable event and amendment submissions for approved research projects, in order to initiate action on information which could impact subject safety and welfare. The scope of Committee #6 has evolved and expanded to review urgent new single patient treatment and compassionate use submissions.
        i. During times of national emergency and public health concerns,

6. Each IRB includes at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
7. Each IRB includes at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
8. Each includes at least one member who represents the perspective of research participants.
9. Each IRB includes at least one member whose expertise is in nursing.
    a. Committee 5 includes Froedtert Health nurses who represent Froedtert Hospital and Community Hospital Divisions.
10. Committees 7 and 8 are staffed according to the MCW/CW Joint Venture Agreement.
11. One member may satisfy more than one membership category.
12. The Director and staff of the MCW HRPP Office may be voting members of the IRB.

***Individuals who hold positions that are responsible for the business development of the organization, the review and approval of grants, contracts and/or sponsored programs at MCW or Froedtert Hospital are not eligible to serve as IRB Members or as ex-officio members on the Committee**

REFERENCES

45 CFR 46.107
21 CFR 56.107

SUPPORTING DOCUMENTS

IRB Member SOP: Assigning Reviewers and the Use of Consultants
IRB Member SOP: Review and Evaluation of IRB Member Service

Effective Date:	04/01/2024
Version number:	10.0
Previous Version/date:	9.0, 07/01/2023
Responsible Office:	HRPP Office
Approval Date:	03/15/2024

Approved By
HRPP Authorized Official: Ryan Spellecy, PhD, Director, HRPP
Human Research Protections Program (HRPP)
Office of Research
Medical College of Wisconsin