MCW IRB Committee Procedures

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 the MCW and FH. All human subjects research conducted under the auspices of the MCW or FH must be reviewed by the MCW IRB prior to the initiation of the research.

DEFINITIONS:
Institutional Review Board (IRB): The committee formally designated by the institution to review, approve, and monitor biomedical and behavioral research involving humans with the aim to protect the rights and welfare of research subjects.

Scientist Member:
If one or more of the following apply, the 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:
Most persons who do not meet any of the criteria for “Scientist” may be considered for the “Non-Scientist” category. People 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 concerns would be in non-scientific areas, unless they also meet one of the criteria for “scientist”. Members who have training in both scientific and non-scientific disciplines, such as both a J.D. and R.N. will not be appointed to satisfy the Non-Scientist requirement.

Unaffiliated Member: Member who or whose immediate family member does not have current employment, or a current business relationship with either MCW, Froedtert Hospital, Froedtert Health, or Children's Hospital of Wisconsin; 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: Member who has 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

In accordance with DHHS and FDA regulations and guidance, the IRB is authorized:

1. 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;
2. 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;
3. To require progress reports at regular intervals, and whenever deemed necessary;
4. To observe, or have a third party observe, the consent process; and
5. To observe, or have a third party observe, the conduct of the research.

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 or FH officials may strengthen requirements and/or conditions, or add other requirements for MCW IRB approval or approval by another MCW or FH committee. 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

There are currently five (5) IRBs. The Institutional Officials (IO), the HRPP Director, and the Chairs of the IRBs will review the activity of the IRBs on at least an annual basis and make a determination as to the appropriate number of IRBs that are needed for the institution. 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*.

Scope of Research

Majority of the MCW IRB Committees review all types of human subject research. One of the IRB Committees has been developed with a special focus and review only a limited type of research as described below.

> Committee #5: The Committee and its members review all research which qualifies for not human subject, exempt or expedited review as defined by the federal regulations.

Appointment of IRB Chairs

The MCW Institutional Official, in consultation and approval with the IRB members, and the Director of the HRPP, appoints a Chair and Vice Chair for each IRB to serve for

renewable three-year terms. Any change in appointment, including reappointment or removal, requires written notification.

Appointment of IRB Members
The HRPP Director, IRB Chairs, and IRB staff assess each IRB Committee at least annually to ensure proper composition and expertise of the Committees. See IRB Member SOP: *Review and Evaluation of IRB Member Service.* New members are recruited and interviewed by the HRPP Director or designee. New members, including alternate members, are appointed by the MCW Institutional Official for a renewable three-year term.

Roles and Responsibilities:
IRB Chairs
The IRB Chair should be a highly respected individual, from within MCW or FH, fully capable of managing the IRB, and the matters brought before it with fairness and impartiality. The task of making the IRB a respected part of the institutional community will fall primarily on the shoulders of the Chair. The IRB must be perceived to be fair, impartial, and immune to pressure by the institution's administration, the investigators whose protocols are brought before it, and other professional and nonprofessional sources.

The IRB Chair is responsible for conducting Committee meetings and is a signatory for correspondence generated by the IRB.

The IRB Chair may designate other IRB members to perform duties, as appropriate, for review, signature authority, and other IRB functions, e.g., the Vice Chair and the HRPP Director.

The IRB Chair advises the IO and the HRPP Director about IRB member performance and competence.

The performance of the IRB Chair will be reviewed on an annual basis by the HRPP Director in consultation with the IO. If the Chair is not acting in accordance with the IRB's mission, following MCW policies and procedures, has an undue number of absences, or is not fulfilling the responsibilities of the Chair, they will be removed.

Vice Chair of the IRB
The Vice Chair serves as the Chair of the IRB in the absence of the Chair and has the same qualifications, authority, and duties as Chair.

Subcommittees of the IRB
The Chair, in consultation with the HRPP Director, may designate one or more other IRB members, i.e. a subcommittee, to perform duties, as appropriate, for review, signature authority, and other IRB functions.

Duties of a subcommittee may include the following:

1. Serve as designees of the IRB Chair for the expedited review of new or continuing protocols, and/or modifications of continuing protocols. The subcommittee must be experienced in terms of seniority on the IRB, and must be matched as closely as possible with their field of expertise to the project.
2. Review and approve revisions requiring only simple concurrence submitted by Investigators for a protocol given provisional approval, i.e. "Modifications Required", by the convened IRB.

3. Conduct an inquiry. A subcommittee may be appointed consisting of IRB members, and non-members if appropriate, to conduct an inquiry into allegations of non-compliance. The subcommittee is given a charge by the IRB, which can include any or all of the following:
    a. Review of protocol(s) in question;
    b. Review of FDA audit report of the investigator, if appropriate;
    c. Review of any relevant documentation, including consent documents, case report forms, subject's investigational and/or medical files etc., as they relate to the investigator's execution of her/his project involving human subjects;
    d. Interview of appropriate personnel if necessary;
    e. Preparation of either a written or oral report of the findings, which is presented to the convened IRB at its next meeting;
    f. Recommend actions if appropriate.

4. Conduct an on-site review. Determination of the review interval and the need for additional supervision and/or participation is made by the IRB on a protocol-by-protocol basis. For example, for an investigator who is performing particularly risky research, or for an investigator who has recently had a protocol suspended by the IRB due to regulatory concerns, an on-site review by an IRB subcommittee might occur or approval might be subject to an audit of project performance after a few months of enrollment, or after enrollment of the first several subjects.

IRB Membership

IRB members are selected based on appropriate diversity of the IRB Committee, including consideration of race, gender, cultural backgrounds, and specific community concerns. Additionally, members will represent diverse professions, knowledge, and experience. Each IRB will include scientific, non-scientific, and non-affiliated members. The structure and composition of the IRB must be appropriate to the amount and nature of the research that is reviewed. Every effort is made to have member representation and expertise that encompasses the research conducted at MCW or FH. The MCW IRB has procedures that specifically outline the requirements of protocol review by individuals with appropriate scientific or scholarly expertise.

In addition, the IRB will include members or obtain consultants who are knowledgeable about and experienced with vulnerable populations that typically participate in human subject research conducted at or overseen by the MCW IRB.

Upon appointment by the MCW Institutional Official, IRB members are authorized as voting members of the IRB. Each IRB member receives an appointment letter designing their responsibilities and the duration of their term of service.

The MCW IRB may also use Alternate IRB Members who will vote only when another member with similar knowledge or expertise is unable to attend an IRB meeting.

The IRB must promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects; and possess the professional competence necessary to review specific research activities. A member of the IRB may fill multiple membership position requirements for the IRB.

Composition of the IRB

Each MCW IRB will have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.

The IRB will be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

In addition to possessing the professional competence necessary to review specific research activities, the IRB will be able to ascertain the acceptability of proposed research in terms of institutional policies and regulations, applicable law, and standards of professional conduct and practice. The IRB will therefore include persons knowledgeable in these areas.

If the IRB regularly reviews research that involves a vulnerable category of subjects (e.g., children, prisoners, pregnant women, or handicapped or mentally disabled persons), consideration will be given to the inclusion of one or more individuals on the IRB, who are knowledgeable about and experienced in working with these subjects. When protocols involve vulnerable populations, the review process will include one or more individuals who are knowledgeable about or experienced in working with these subjects, either as members of the IRB or as consultants according to the *IRB Member SOP: Assigning Reviewers and Use of Consultants*.

Every nondiscriminatory effort will be made to ensure that the IRB does not consist entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. The IRB shall not consist entirely of members of one profession.

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.

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.

Each includes at least one member who represents the perspective of research participants.

Each IRB includes at least one member who is a Froedtert Hospital nurse.

One member may satisfy more than one membership category.

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

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