MCW IRB Committee Procedures

ASSIGNING REVIEWERS AND THE USE OF CONSULTANTS

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

Applies to: Institutional Review Board Committees

PURPOSE:
To describe the responsibilities of IRB members related to the review of project and project submissions. To describe the roles of primary reviewers, secondary reviewers, alternate members and consultants.

DEFINITIONS:
Institutional Review Board (IRB): The committee formally designated by an Institution to approve, monitor, and review 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.

Alternate IRB member: The role of the alternate member is to serve as a voting member of the IRB when the regular member is unavailable to attend a convened meeting. Alternate IRB members are appointed to the IRB Committee in the same manner as primary IRB members.

PROCEDURE:
Duties of IRB Members
The agenda, materials for review, protocols, proposed informed consent forms and other appropriate documents are distributed to members prior to the convened meetings at which the research is scheduled to be discussed.

1. All IRB members are expected to review the materials for each agenda item during the week preceding each meeting, in order to participate fully in the review of each proposed project.
2. All expedited reviews are expected to be completed within ten (10) business days from being assigned the submission.
3. IRB members will treat the research submissions, protocols, and supporting data confidentially.
    a. When applicable, any paper copies of the research documents and supporting data are returned to the IRB staff at the conclusion of the review for profession document destruction.

Primary Reviewer
The MCW IRB utilizes a Primary Reviewer system for review of all IRB submissions. A Primary Reviewer's responsibilities include:

1. Read and become familiar with the entire project submission including the eBridge Smart Form, consent form(s), protocol, data collections sheets, Investigator Brochure, and all documents that are submitted for IRB review.

2. Understand and explain the project's procedures, risks, benefits, etc. to the IRB Committee utilizing the appropriate reviewer checklist.
3. Contact the Investigator and/or research team prior to the IRB Committee meeting to answer questions or clarify areas of concern.
    - If for any reason the Primary Reviewer does not want to contact the Investigator and/or research team, they may request that the IRB Coordinator II (C2) or the IRB Chair make contact on their behalf.
4. Complete the appropriate reviewer checklist
5. Review the submission against applicable regulations for approval
6. Document questions or concerns for discussion
7. Document any proposed modifications
8. Be prepared to make a motion.

The Primary Reviewer is assigned by the IRB C2 to a submission based upon several different criteria. Choosing and assigning a Primary Reviewer should be made through assessment of the following criteria (in order):

1. Area of expertise, speciality, professional training or knowledge
2. Availability
3. Personal training or knowledge
4. No known or perceived conflict of interest in accordance with *IRB Member SOP: Conflict of Interest – IRB Committee Members*

Secondary Reviewer

The MCW IRB utilizes a Secondary Review for all initial submissions, submissions that require subject matter expertise (prisoner, pediatric or nursing representation), training of new IRB Committee members, upon request of the Primary Reviewer or at the IRB Chair's discretion. A Secondary Reviewers responsibilities include:

1. Read and become familiar with the entire project submission including the eBridge Smart Form, consent form(s), protocol, data collections sheets, Investigator Brochure, and all documents that are submitted for IRB review
2. Focus the review on the consent process, the recruitment process and related materials including consent forms and advertisements.
3. Contact the Primary Reviewer, Investigator, and/or research team prior to the IRB Committee meeting to answer questions or clarify areas of concern.
    - If for any reason the Secondary Reviewer does not want to contact the Investigator and/or research team, they should request that the Primary Reviewer, IRB C2 or the IRB Chair to make contact on their behalf.
        - Note: The Secondary Review should contact the Primary reviewer before contacting any other party to avoid repetitive contact.
4. Complete the appropriate reviewer checklist
5. Review the submission against the applicable regulations for approval
6. Document questions or concerns for discussion
7. Document any proposed modifications
8. Be prepared to make a motion

The Secondary Reviewer is assigned to a submission utilizing the same criteria by which the Primary Reviewer is selected.

Vulnerable Populations:

When the IRB reviews research that involve subjects likely to be vulnerable to coercion or undue influence, the IRB C2 evaluates each protocol and ensures that at least one IRB member knowledgeable about or experienced in working with such subjects will be present at the meeting.

For research funded by the National Institute on Disability and Rehabilitation Research

When the IRB reviews research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research subjects, the IRB must include at least one person primarily concerned with the welfare of these research subjects.

Alternate Members

The appointment and function of alternate members is the same for primary IRB members. The alternates' expertise and perspective are comparable to those of the primary member. The role of the alternate member is to serve as a voting member of the IRB when the regular member is unavailable to attend a convened meeting. When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member would have received.

The IRB roster identifies the primary member(s) for whom each alternate member may substitute. The alternate member will not be counted as a voting member unless the primary member is absent. The IRB meeting minutes will document when an alternate member replaces a primary member.

Use of Consultants

1. When necessary, the IRB Chair or the HRPP Director may solicit individuals from MCW, FH, Versiti, CW or the community with competence in special areas to assist in the review of issues or protocols, which require scientific or scholarly expertise beyond that available on the IRB.
2. The need for a consultant is determined in advance of the meeting by the HRPP Director or the IRB Chair by reviewing the projects and submissions scheduled to be reviewed at the meeting. The HRPP Office will ensure that all relevant materials are provided to the consultant prior to the meeting.
3. If the need for a consultant is determined during the review in the meeting, a motion will be made to defer the submission to a future convened meeting until a consultant can be identified and their review provided to the IRB.
4. Written statements of consultants will be kept in IRB records. Key information provided by consultants at meetings will be documented in the minutes. Written reviews provided by the outside reviewer will be filed with the eBridge submission.
5. IRB consultants will be asked to sign the *IRB Consultant Confidentiality Agreement and Conflict of Interest Certification Form* prior to receiving documents related to the protocol to be reviewed. Individuals who have a conflicting interest or whose spouse or family members have a conflicting interest with the sponsor of the research will not be invited to provide consultation.
6. The consultant's findings will be presented at the IRB meeting for consideration either in person or in writing. If in attendance, these individuals will provide consultation but may not participate in or observe the vote.
7. Ad hoc or informal consultations requested by individual members (rather than the convened committee) will be requested in a manner that protects the Investigator's confidentiality and is in compliance with the IRB conflict of interest policy (unless the question raised is generic enough to protect the identity of the particular PI and research project).

REFERENCES:

N/A

SUPPORTING DOCUMENTS:

MCW Corporate SOP: Research Involving Human Subjects and/or their Private Identifiable Information (RS.HS.010)
IRB Member SOP: Conflicts of Interest – IRB Committee Members
IRB Consultant Confidentiality Agreement and Conflict of Interest Certification Form

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