MCW IRB Committee Procedures

CONDUCT AND EXPECTATIONS OF IRB MEMBERS

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

Applies to: Institutional Review Board Committees

PURPOSE:
This document outlines the general expectations and conduct of Medical College of Wisconsin (MCW) IRB Committee Members. IRB Committee Members are evaluated on an annual basis regarding their regulatory knowledge, participation and general conduct and provided with feedback.

DEFINITIONS:
N/A

PROCEDURE:
MCW IRB members will follow the outlined general expectations and conduct themselves accordingly.

General Expectations

1. Complete IRB Member Conflict of Interest form annually, identify potential conflicts of interest that might interfere with the member's ability to be an objective participant, declare any potential conflicts of interest at the beginning of each meeting, and recuse oneself from all deliberations on any protocols identified with a potential conflict of interest in accordance with *IRB Member SOP: Conflicts of Interest – IRB Committee Members*.
2. To complete and maintain HSRP training certification.
3. To attend at least 75% of convened meetings per year and to notify the IRB Coordinator II (C2) of any changes in availability via eBridge and/or email as soon as known.
4. To arrive at each meeting on time, and to stay for the entire duration of the meeting, insofar as possible.
5. To review meeting minutes before each meeting for accuracy and be prepared to offer corrections, if needed and vote on the minutes.
6. To complete assigned primary or secondary review assignments approximately 24 hours in advance of each meeting at least 75% of the time.
    1. Completion of the assigned reviews is defined as recommendation of a motion and uploading the reviews into eBridge and using the appropriate checklists. All procedures for review and checklists are available via the HRPP website.
    2. This responsibility also includes contacting the Investigator or project staff directly (or asking the IRB C2 or the IRB Chair) with reviewer questions prior to the IRB meeting to optimize the review process.

7. To limit or avoid interruptions during the meeting (i.e., checking email, responding to pages and calls, or performing other professional activities, if possible).

IRB Member Responsibilities

1. All members are expected to review the materials for each agenda item before each meeting, to participate fully in the review of each proposed project.
2. All expedited reviews are expected to be completed within five (5) business days from being assigned a submission, or ten (10) business days if a secondary review is needed
    a. For minimal risk projects assigned to a designated reviewer, and the submission qualifies for expedited review, the reviews should be completed within ten (10) business days.
3. IRB members will treat the research projects including the eBridge Smartform, protocols, and supporting data documents confidentially.
    a. If applicable, all paper copies of the research documents and supporting data are returned to the IRB staff at the conclusion of the review for professional document destruction.

Primary Reviewer

1. The MCW IRB utilizes a Primary Reviewer system for review of all IRB submissions under review. The Primary Reviewers responsibilities include:
    - 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
    - Understand and explain the project's procedures, risks, benefits, etc. to the IRB Committee utilizing the appropriate reviewer checklist
    - Contact the Investigator and/or project team prior to the IRB Committee meeting or completion of review to answer questions or clarify areas of concern.
        - If for any reason the Primary Reviewer does not want to contact the Investigator and/or project team, they may request that the IRB Coordinator II (C2) or the IRB Chair make contact on their behalf.
    - Complete the appropriate reviewer checklist and any additional checklists as appropriate, then upload to eBridge.
    - Review the submission against applicable regulations for approval
    - Document questions or concerns for discussion
    - Document any proposed modifications
    - Be prepared to make a motion

Secondary Reviewer

1. The MCW IRB utilizes a Secondary Review for all initial submissions, when submissions require subject matter expertise (prisoner or pediatric representation), as part of training of new IRB Committee members, and may also be utilized at the IRB Chair's discretion. The Secondary Reviewers responsibilities include:
    - 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

- Focus the review around the consent process, the recruitment methods. This includes reviewing the proposed consent form(s) and recruitment materials.
- Contact the Primary Reviewer, Investigator, and/or project team prior to the IRB Committee meeting or completion of review to answer questions or clarify areas of concern.
    - If for any reason the Secondary Reviewer does not want to contact the Investigator and/or project team, they should request that the Primary Reviewer, IRB C2 or the IRB Chair to make contact on their behalf.
- Complete the appropriate reviewer checklist and upload to eBridge
- Review the submission against the applicable regulations for approval
- Document questions or concerns for discussion
- Document any proposed modifications
- Be prepared to make a motion

Review of Meeting Agenda Items:

1. Over the course of a meeting, all IRB members should:
    - Evaluate each project application, amendment, reportable event, continuing progress review or 6-Year Renewal in light of the federal regulations criteria for approval (45 CFR 46.111 and/or 21 CFR 56.111) and to not approve any submission unless all these criteria (at minimum) are satisfied.
    - Determine the potential risks, benefits, and risk-benefit ratio for each project, amendment, reportable event, or continuing progress review in accordance with federal regulations and institutional policies and procedures.
    - Determine whether the Investigator has proposed a “safety monitoring plan” that is adequate and commensurate with the level of risk posed by each project, as it begins, is changed, and is periodically reviewed.
    - Recommend an approval period commensurate with the risk/benefit ratio of the project being reviewed, never to exceed 1 year.
    - Ask the IRB Chair, the IRB staff, or the HRPP office for guidance on governing regulations and institutional policies whenever relevant.
    - Ask the IRB Chair to seek legal guidance from the MCW General Counsel or Risk Management, as relevant.
    - Ask the IRB Chair for expert medical or scientific consultation as needed in accordance with *IRB Member SOP: Assigning Reviewers and the Use of Consultants*.
    - Ask the IRB Chair to request that the Investigator or the Investigator’s staff attend the IRB meeting to answer questions or discuss issues, as relevant.

REFERENCES:

45 CFR 46.111
21 CFR 56.111

SUPPORTING DOCUMENTS:
IRB Member SOP: Conflicts of Interest – IRB Committee Members
IRB Member SOP: Assigning Reviewers and the Use of Consultants

Effective Date:	07/01/2023
Version number:	5.0
Previous Version/date:	4.0, 06/15/2018
Responsible Office:	HRPP Office
Approval Date:	05/30/2023

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