MCW IRB Committee Procedures

MEETING MINUTES AND CONDUCT OF THE IRB MEETING

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

Applies to: Institutional Review Board Committees

PURPOSE:
To provide an overview of the process of a convened meeting of the Medical College of Wisconsin (MCW) and Institutional Review Board (IRB) Committees.

DEFINITIONS:
Quorum: When a majority of the voting IRB membership is present. In addition, there must be at least one scientific member and one non-scientific member present.

PROCEDURE:

Preparation for Meeting

1. IRB Committee members are expected to confirm or decline attendance at IRB Committee Meetings within eBridge. The IRB Coordinator II (C2) will confirm attendance to ensure that quorum will be met.
    a. The IRB C2 will confirm that appropriate representation will be present at the meeting.
2. The IRB C2 will prepare the agenda for each convened IRB Committee meeting using eBridge.
3. At least ten (10) calendar days prior to a scheduled IRB meeting, the IRB C2 will send the meeting agenda and material for review to all members of the IRB Committee via eBridge.

During the Meeting:

1. IRB C2 will notify the IRB Chair once quorum has been established in the meeting as defined in this procedure.
    a. The IRB C2 will monitor the attendance at the meeting to ensure quorum is maintained throughout the entire meeting.
2. At a convened meeting for research to be approved, the IRB C2 will confirm the following:
    a. The motion for approval has received an affirmative vote from a majority of the members present at the meeting and;
    b. Quorum as defined in this procedure was not lost during the discussion or the vote.
3. The IRB C2 will alert the IRB Chair if quorum is lost during the meeting, to stop any discussion or motions until quorum as defined in this procedure is restored.

Recording Minutes During the Meeting
The IRB C2 is responsible for drafting meeting minutes in enough detail to document the IRB Committee discussions, controverted issues, and determinations. The minutes of all IRB Committee meetings must be in sufficient detail to demonstrate:

1. Announcements at the meeting include:
    a. Information discussed during the IRB meeting is confidential

b. A request that any member declare a conflict of interest with any submission at the beginning of the meeting. If members have a conflict of interest, they must leave the room during discussion and voting on that submission
c. A reminder to members to review the "Exempt/Expedited/Mods" tab in eBridge for information regarding submissions approved by the Committee through the expedited or exempt process.
d. Whether an alternate is voting and for whom they are voting, or a consultant is present to discuss a specific submission;
e. A reminder that when a member leaves the room or misses a portion of the discussion, they may not vote or count towards quorum.
f. Whether there are visitors attending the meeting and they have the IRB Chair's approval to do so.

2. When waivers of HIPAA authorization and informed consent requirements are requested for screening purposes, or when there is a request for waiver of documentation of consent, the Committee has found that criteria for approval at 45 CFR 164, 45 CFR 46.116, and 45 CFR 46.117 have been met, as appropriate.
3. When a submission is approved, the criteria for approval found in regulations 45 CFR 46.111, 21 CFR 56.111, 21 CFR 312.34 or 21 CFR 812.36 have been discussed and determined to be met.
4. The level of risk (e.g., minimal or greater than minimal) and the approval period (review interval) appropriate to the level of risk are determined.
5. For research involving a device, the Committee reviews relevant information about the device to make a Significant/Nonsignificant Risk or IDE exempt device determination in accordance with 21 CFR 812 or 812.2(b).
6. Additional criteria for the review of research which may involve minors, prisoners, pregnant women and fetuses or individuals who may be decisionally impaired are applied and set forth in the following procedures:
   a. *IRB Member SOP: Research Involving Prisoners*
   b. *IRB Member SOP: Research Involving Pregnant Women and Fetuses*
   c. *IRB Member SOP: Research Involving Children*
   d. *IRB Member SOP: Research with Subjects Likely to Manifest or Develop Decreased Decisional Ability*
7. When project revisions are requested or a project is disapproved, the basis for the revisions or disapproval has been discussed and relevant regulatory criteria that not met have been identified.

Remote Participation

Committee members may participate via remote platforms (Zoom, WebEx or telephone). The IRB meeting minutes will document that IRB Committee member:

- Have received all pertinent material prior to the meeting; and
- Can actively and equally participate in the discussion of all submissions.

Distribution of Minutes.

1. The IRB C2 will utilize eBridge for completing a draft of the IRB Committee meeting minutes and will forward the draft minutes to the IRB Chair for review and communication of any necessary revisions.
2. Once the IRB Chair has approved the meeting minutes, the minutes will be sent to all members of the Committee via eBridge.
   a. The minutes will be distributed prior to the next meeting and will be listed on the agenda.
3. The Committee members will review and be prepared to vote on the minutes at the next convened meeting.
   a. IRB members should communicate any changes before or during the review of the minutes at the meeting.

REFERENCES:

45 CFR 164
45 CFR 46.116
45 CFR 46.117
45 CFR 46.111
21 CFR 56.111
21 CFR 312.34
21 CFR 812.36
21 CFR 812
21 CFR 812(b)

SUPPORTING DOCUMENTS:

IRB Member SOP: Research Involving Prisoners
IRB Member SOP: Research Involving Pregnant Women and Fetuses
IRB Member SOP: Research Involving Children
IRB Member SOP: Research with Subjects Likely to Manifest or Develop Decreased Decisional Ability

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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

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