**MEETING MINUTES AND CONDUCT OF THE IRB MEETING**

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

Applies to: Institutional Review Board Committees

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**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

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