# SOP 303: IRB Meetings

## Terms and Abbreviations

IRB: Institutional Review Board
IRB office staff: the IRB Manager, IRB Administrator, and any other IRB office staff, either collectively or individually

## Overview

IRB members convene regularly to review protocols involving human subjects. The IRB reviews all research protocols at convened meetings where a quorum has been established, except where an application is eligible for exempt or expedited review.

The IRB office staff prepares minutes of each meeting to document the IRB's review of research protocols, policy discussions, and continuing education.

**Investigators and Guests**
The IRB may invite investigators and/or research team members to attend the IRB meeting. This allows IRB members to ask questions and clarify information.

The IRB complies with the State of Wisconsin open meeting regulations. If a member requests that the IRB go into closed session, investigators and other guests will be asked to leave the room unless invited by the Chair to remain. The Chair will call for a motion to go into closed session.

**Confidentiality**
IRB members, staff, and guests are reminded at each meeting to maintain confidentiality of the IRB's discussions and decisions.

## Details and Procedures

**Meeting scheduling**
The IRB generally meets monthly, but may meet more or less often as needed. IRB office staff set the dates for meetings and contact members to ensure there will be quorum at the meeting.

IRB office staff conduct a pre-review of all submissions and determine the level of review required, consulting with IRB members or the Chair when necessary. All protocols deemed either to involve more than minimal risk or that require full board review for regulatory compliance (e.g. device studies where a "non-significant risk" determination is required), are placed on the next available meeting agenda.

**Materials**
Members receive the meeting agenda and all submitted materials for each full board review. The agenda includes:

- Research protocols for full board review
- Research that has been approved through exempt or expedited review procedures (including new submissions, amendments, continuing reviews, and reportable events)
- Research deferred to other institutions
- Post-approval reviews conducted

Submitted materials for full board reviews include:

- Study protocol
- Informed consent and assent documents
- Recruitment materials
- Data collection tools
- Any other documents deemed necessary or helpful for the review.

IRB office staff distribute the meeting materials at least 4 days before the meeting. This allows members sufficient time to review the materials and to contact investigators with questions if they choose.

**Quorum, Meeting Procedures, and Voting**
A quorum is defined as greater than 50% of the voting membership, including at least one member whose primary concerns are in nonscientific areas.

Voting members may attend meetings by teleconference or videoconference if:

1. They have received all items for review in advance of the meeting; AND
2. The equipment permits meaningful participation in discussion and voting.

A scientist and non-scientist must be present at each meeting. In order to in initiate a vote, a motion must be made by a voting member of the IRB and seconded. When a motion is not seconded, it does not go forward to a vote. Any motion that is seconded must go forward for a vote unless the person who made the motion withdraws it. If a motion does not pass, then the Chair will ask for another motion, and so on, until a motion passes or is withdrawn.

The approval of IRB actions requires the vote of a simple majority (greater than 50%) of the voting members present at the meeting. Only IRB members who attend the meeting may vote. Members who are unable to attend may submit written comments or questions prior to the meeting, but do not vote.

**Minutes**
The minutes are recorded in sufficient detail to document the following:

- IRB Member attendance and the presence of any invited investigators or guests.
- Motions to go into closed session, the reasons for doing so, the applicable statutory exemptions for closed sessions, and the board's vote on such motions.
- IRB committee acknowledgement of expedited and exempt reviews.
- Summary of the discussion and controverted issues for each research protocol reviewed.
- Decisions reached and any required modifications.

- Votes on the decisions, including a tally of votes for, against, and abstaining for each vote, and recusal of members due to conflicting interests.
- Reasons for requiring modifications to secure approval of a research protocol, for disapproving a research protocol, or suspending or terminating a research protocol.
- Documentation that a waiver or alteration of informed consent or a waiver of documentation of informed consent, if granted, is appropriate.
- The level of risk involved in the research.
- The review frequency for the next continuing review, if less than one year.
- For studies determined to be minimal risk, whether or not continuing review will be required.
- Policy discussions
- Any continuing education provided during a meeting

Members receive a copy of the minutes for review prior to the next meeting. Suggested modifications to the minutes are discussed at a full board meeting and agreed to by consensus, and the IRB staff modifies the minutes according to the IRB's recommendations.

## References

Wis. Stats. §§ 19.81-19.98

45 CFR §§ 46.108, 46.115

21 CFR §§ 56.108, 56.115

SOP 102: IRB Chair and Vice Chair

## Revision History

| Version | Date | Summary of Changes |
|---|---|---|
| 1 | 19 Feb 2020 | Initial version |
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