



IRB Meeting Conduct

I. Purpose

To define policies and procedures for conducting full board meetings of the Institutional Review Board (IRB) in accordance with federal regulations.

II. Revisions from Previous Version

None.

III. Definitions

None.

IV. Policy

All members are expected to prepare for meetings by reviewing submissions and to engage in the discussion of submissions at the IRB meeting. Prime members who attend a convened board meeting and who are not recused are entitled to one vote on each and all motions presented to the board. An alternate member of the board may vote on motions affecting protocol approvals only in place of any corresponding scientific or nonscientific absent prime member of whom they share this designation. The IRB Chairs are prime members of the board with full voting privileges.

Prior to initiating any review at a meeting of the full board, the IRB Chair, in consultation with IRB staff, will confirm quorum is met, and the voting members, alternates, and consultants collectively constitute sufficient and appropriate expertise to review the full range of submissions under review at that meeting. Care will be taken to ensure that the number of agenda items allow adequate time for quality review. The IRB members are provided all study and reviewer documents in WRG-HS. There are eight convened meetings a month, four for Cancer and four for General. Ad hoc meetings may be conducted if needed.

Note that disapproval of research can only occur at a convened IRB meeting.

The IRB meetings (including discussions about submissions, discussions involving researchers or participants, and other topics of a sensitive nature) are to be treated as confidential information.

V. Procedure

Meeting Preparation

The draft agenda is finalized two weeks prior to the scheduled meeting and the final agenda is sent one week before the IRB meeting. Members will be notified of their review assignments through WRG-HS at the same time. Reviewers will upload their completed reviews into WRG-HS no later than five days prior to the scheduled meeting. In exceptional circumstances, a submission may be added to the agenda after it closes, in which case all members will be immediately notified.

Primary Review System

Submissions that require full board review will be scheduled for, presented at, and voted on at a convened IRB meeting. Submissions requiring full board review will be assigned to at least one primary reviewer based on the IRB member's background and expertise as applicable.

Board members will be provided all study documents that have been submitted by the researcher. Additional information may be requested from researchers to resolve questions prior to the meeting. Researchers may be asked to attend the meeting to answer questions, but will not be present for the board's discussion nor vote. Faculty advisors (as Principal Investigator (PI) of record) will be required to attend to answer questions along with the student researcher if the research is a student project.

The primary reviewer is responsible for:

- Informing the IRB of any inconsistencies between the detailed protocol and the summary application materials;
- Conducting an in-depth review;
- Determining whether the project meets the federal criteria for approval, ensuring that the research meets ethical principles and standards for protecting research participants, making appropriate determinations with protocol specific justifications, and presenting recommendations to the board.

All IRB members will review all items on the agenda in advance of the meeting (including those protocols for which the IRB member is not the primary reviewer) in enough depth to be familiar with the protocol and other research related documents, to be prepared to discuss the submission at the meeting, and to be prepared to determine whether the project meets the regulatory criteria for approval, ethical principles and standards for protecting research participants, and applicable determinations.

Secondary Reviewers

When a secondary reviewer is assigned, they are also expected to conduct a review addressing the same responsibilities outlined above for the primary reviewer. A secondary reviewer often focuses on the consent document(s) more in depth than the primary reviewer; however, their review is not limited to this.

Primary and secondary reviewers will present the submission to the IRB members at the convened meeting, after which the board will discuss and vote on the protocol.

Consultant Review

Assigned reviewers may request the use of an outside consultant if they feel additional expertise is needed to evaluate a project's scientific merit, risk/benefit ratio, and/or any other identified concern. The IRB staff may initiate review by an outside consultant, the reviewer may contact the IRB staff to arrange for the consultant review prior to the project being presented at a convened meeting, or the assigned reviewers may initiate the contact for verbal information from an outside consultant. In any case, the person who initiates the contact with the outside consultant will ask the person if they or a family member have a potential COI with the project before proceeding with any exchange of information.

At its discretion, the IRB may ask an outside consultant to review a study for additional assessment of an identified concern. If so, the decision regarding approval will be tabled until information is reviewed at a convened meeting. If an outside consultant review has been obtained, all IRB members will receive the consultant's review and any supporting documents. A Chair or assigned reviewer will present the consultant's review to the board. The IRB may ask the consultant to attend the meeting at the discretion of the reviewer.

Alternates

Alternate members do not serve as alternates to specific individual board members. In the event a prime member is absent and an alternate member is eligible to vote, the eligible member shall attend the meeting and vote in place of any corresponding scientific or nonscientific absent prime member of whom they share this designation.

Quorum

Quorum is required for the IRB to make determinations on submissions that require full board review. A majority of the quorum must vote in favor of a motion for the motion to carry. Discussion on motions may proceed with fewer members present than a quorum, but no votes may be cast or counted until a quorum is present.

A quorum is established when a simple majority of prime members, including at least one nonscientist, are in attendance and able to vote (i.e. not disqualified from voting due to conflict of interest). At least one non-

affiliated/community member is in attendance for the majority of meetings per year. If the research involves vulnerable populations, IRB staff ensure that adequate representation is present for discussions.

If a protocol includes prisoners as participants, an IRB prisoner representative who is a voting member must be present at the meeting and assigned as a primary reviewer.

Abstentions

An abstention is a decision not to vote either for or against a motion. Abstentions count toward quorum. Only members who are eligible to vote on the motion may abstain from voting. Members are not required to state a reason for their abstention.

Recusals

Any board member with a conflict of interest must recuse themselves from the discussion and voting on any motion pertaining to the conflict. Such recusals will be noted in the minutes. A recusal constitutes an absence and absent members may not be counted toward establishing or maintaining quorum. The board may, at its discretion, invite a member with a conflict of interest to stay for the discussion only to answer questions about the research, but recused members will not be present for the deliberation and vote.

Virtual Attendance via Electronic Means

Attendance at meetings may be established by electronic means. Members participating by electronic connection count toward a quorum and may participate as voting members as outlined above. For purposes of establishing and recording voting privileges, any board member who attends the meeting by electronic connection shall be considered in attendance as long as the connection is maintained throughout the meeting. Temporary disconnections that are quickly re-established shall not affect the member's attendance status.

The electronic equipment utilized must adequately allow the member to hear the discussions and be heard by all others in attendance, and may utilize speaker-phone, teleconferencing, internet-based virtual meeting software, or any another means that meet the requirements stated in this section. Methods of virtual attendance relying on electronic connections should allow the member(s) to participate in real-time. Meeting minutes should indicate the specific electronic method of attendance used by the members, including connection and disconnection times. A member in virtual attendance who is recused from participating in discussion and voting on a matter presented to the board must electronically disconnect from that portion of the meeting. The connection, disconnection, and reconnection times should be noted in the meeting minutes.

For matters requiring a vote, a member in virtual attendance must have received documents made available to all other board members and had sufficient time to review such materials. Members may not simply phone in votes or otherwise participate only in the voting for approval of research protocol, but must also be present for the majority of the related discussion.

IRB Review

During discussion, the IRB members will raise only those issues that the board determines do not meet the federal criteria for approval as specified in 45 CFR 46.111 and 21 CFR 56.111 (and Subparts as applicable). In addition, the IRB will determine the risk level and provide protocol specific justifications as appropriate. Also, the IRB will consider whether the PI's preliminary assessment of federally mandated specific findings requirements (e.g., request for waiver of informed consent) are acceptable with respect to meeting federal requirements.

An IRB member will make a motion, followed by a second, and then the voting members vote for, against, or abstain from one of the following four actions:

1. APPROVED: IRB approval - A vote for approval indicates that the IRB has concluded that the research and consent/assent forms and related documentation meet the federal criteria for approval. IRB approval verifies that the IRB agrees with the assessment of the protocol and/or specific findings as described by the PI in the application. The IRB has no changes to the research. The IRB staff will send the PI an approval letter and stamped consent form(s).

2. **DIRECTIVE MODIFICATIONS:** A vote of directive modifications required indicates that the IRB has approved the protocol pending submission of directive modifications and that the IRB has given the Chair (and/or other IRB member or IRB staff) the authority to review and approve the directive modifications outside of the meeting. A vote of modifications required can only be made if any requested modifications are not relevant to the determinations required by the IRB under the Common Rule or its Subparts (if applicable). If substantive modifications regarding the protocol, informed consent documents, or related study documents are required as a condition of approval, the protocol must be tabled pending subsequent review of revised material by the convened IRB (see below).

The IRB staff will send the researcher a letter describing the modifications requested by the IRB and will inform the PI of a deadline to address the requested revisions. The PI will respond to the IRB's suggested revisions in writing and submit the response and any supporting documents in WRG-HS. The designated reviewer (e.g., Chair, member, or staff) will verify whether the requested modifications are complete via administrative review. When verifying modifications, IRB staff may forward the responses to the Chair or other reviewer for additional review, if appropriate. Once modifications are verified as completed, the IRB staff will send the researcher an approval letter and stamped consent form(s).

3. **SUBSTANTIVE MODIFICATIONS:** A vote of tabled indicates that the IRB withholds approval pending submission of substantive revisions/additional information. IRB staff will send the researcher a letter that includes a description of the revisions or additional information requested. In some cases, the IRB may appoint one or more members of the IRB to discuss the reasons for revisions with the researcher. If the submission has been tabled, the IRB staff will inform the PI of a deadline to address the requested revisions. Once returned, the submission will be reassigned to the convened board. The IRB may or may not request the PI to attend.

4. **DISAPPROVED:** If the vote is for disapproval, IRB staff will send the researcher a letter describing the reasons for disapproving the project or amendment. Disapproval of a project or amendment usually occurs when the IRB determines that the risk of the procedures outweighs any benefit to be gained or if the proposed research is illegal or does not meet the federal criteria for IRB approval. Researchers may not resubmit after a submission has been disapproved. A disapproval may be appealed to the IRB.

During the convened meeting, the IRB will determine the approval period, as appropriate to the degree of risk, but not less frequently than once per year. The IRB may set a shorter approval period for high-risk protocols or protocols with previous compliance issues.

When a protocol receives final approval, the expiration date is set based on the date of the convened IRB meeting. If a protocol has received a determination of modifications required and the PI completes the revisions, the date the modifications are verified is the approval date and the expiration date is set from the meeting date of the convened IRB on which the IRB initially reviewed the protocol. Should there be serious concerns or a lack of significant information requiring the convened IRB to complete its review and issue approval of the project at a subsequent meeting, the approval period starts with the date of the subsequent convened IRB meeting at which the protocol received approval.

Recording Board Actions in the Minutes

All motions made by any board member for consideration by the full board shall be summarized and recorded in the meeting minutes. The summary shall be in sufficient detail to reflect meeting attendance, conflict of interest disclosures and related recusals, summary of any controverted issues and their resolutions, any motion and its outcome, and the total number of votes on the motion including votes for, against, and abstentions.

VI. References

45 CFR 46.108(b)
21 CFR 56.108