

Standard Operating Procedures		
SOP #103.7 Revision 7	TITLE: IRB Meeting Conduct	Effective Date: 1/21/2019
Approved By: OIRB Director	Signature 	Date 1/21/2019
Approved By: IRB Chair	Signature 	Date 1/21/2019

PURPOSE

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

REVISIONS FROM PREVIOUS VERSION

Removed requirement for grant congruency review and submission of IRB roster to DHHS based on revisions to the common rule

POLICY

All regular members who are in attendance at a convened board meeting and who are not recused are entitled to one vote on each and all motions presented to the board for vote. An alternate member of the board may vote on motions affecting protocol approvals only in place of any regular member who is absent. All alternate members in attendance may vote along with regular members on all other motions presented to the board for vote. The IRB Chair is a regular member of the board with full voting privileges.

Prior to initiating any review at a meeting of the full board, the Chair shall establish and the meeting minutes shall reflect that a quorum is present 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 agenda items are limited to ensure adequate time is allotted for quality review. IRB members are provided copies of their completed reviewer checklists and access to project documents via IRBNet. Meetings are held once monthly; ad hoc meetings may be conducted if needed, if adequate quorum can be obtained.

As noted in the federal regulations 45 CFR 46 subparts 108, 109 and 110, disapproval of a proposed protocol requires a majority of the voting members at a convened meeting at which a quorum has been established.

All subject matter of board meetings that is related to submissions, including discussion involving researchers or participants, or is otherwise of a sensitive nature, shall be treated as confidential information.

RESPONSIBILITIES

Execution of SOP: OIRB Director, OIRB Staff, IRB, IRB Chairs.

PROCEDURE

Meeting Preparation

The agenda is closed and published in IRBNet approximately one week prior to the scheduled meeting. Members are notified of the published agenda and their review assignments through the IRBNet system. Reviewers are requested to upload their completed reviews into IRBNet no later than two 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 are scheduled for, presented at, and voted on at a convened IRB meeting. Submissions requiring full board review are assigned to at least one primary reviewer (usually two reviewers are assigned to new projects) based on the IRB member's background and expertise as applicable.

Board members are provided all documents 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 or be available to speak by phone, but will not be present for the board's discussion or vote. Faculty advisors (as 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 and presenting recommendations to the board.

All IRB members 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.

Primary reviewer(s) will present the submission to the IRB members at the convened meeting, after which the board will discuss the project and vote.

Consultant Review

Primary 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 or other identified concern. OIRB staff may initiate review by an outside consultant, the reviewer may contact OIRB staff to arrange for the consultant review prior to the project being presented at a convened meeting, or the primary reviewer may initiate the contact for verbal information from an outside consultant. In either 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 (in accordance with SOP 201) 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 deferred 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 primary reviewer will present the consultant review to the board. The IRB may ask the consultant to attend the meeting or be available for audio conferencing at the discretion of the reviewer.

Alternates

Alternate members are appointed to the board in general and do not serve as alternates to specific individual board members. In the event a regular member is absent and an alternate member is eligible to vote, the eligible member shall attend the meeting and have full voting privileges.

Quorum

A quorum is established when a simple majority of members, including the chair or vice-chair acting as chair, are in attendance and able to vote (e.g. not disqualified from voting due to conflict of interest). A quorum shall be calculated as follows:

- At least one non-scientist is in attendance (see SOP 101 Composition and Membership of the IRB).
- At least one non-affiliated/community member is in attendance for at least 9 of the 12 meetings per year.
- Quorum requires a simple majority of the total number of voting members as documented in the IRB roster.
- If the research involves populations vulnerable to coercion or undue influence, OIRB staff ensure that adequate representation is present for discussions.

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.

If a protocol affects prisoners involved in research, 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 refusal to vote either for or against a motion and does not affect the total members required to establish a 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. Recused members must leave the room in which the discussion and voting take place. Such recusals will be noted in the minutes. A recusal constitutes an absence and absent members may not be counted toward establishing or maintaining a 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.

Virtual Attendance via Electronic Means

If a board member is unable to be physically present at a convened meeting, attendance may be established by electronic means. Members participating by electronic connection count toward a quorum and may participate as voting members. 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 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 these 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 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 determines the risk level and provides protocol specific examples as appropriate. Also, the IRB considers 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 makes a motion and then the convened IRB votes for or against or abstains 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 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. OIRB staff send the PI an approval letter.
2. **MODIFICATIONS REQUIRED/APPROVED WITH CONDITIONS:** A vote of approval with conditions indicates that the IRB has approved the protocol pending submission of minor, directive modifications and that the IRB has given the Chair (and/or other IRB member or OIRB staff) the authority to approve the minor modifications. A vote of approval with conditions 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 or informed consent documents are required as a condition of approval, approval must

be deferred pending subsequent review of responsive material by the convened IRB (see below).

OIRB staff send the researcher a letter describing the modifications requested by the IRB. The PI responds to the IRB's suggested revisions in writing and sends the response and any supporting documents to OIRB staff, who verify whether the requested modifications are complete via administrative review. OIRB staff may forward the responses to the Chair or primary reviewer for additional review, if appropriate.

3. **DEFERRED (TABLED):** A vote of deferred indicates that the IRB withholds approval pending submission of major, substantive revisions/additional information. OIRB staff 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 deferral with the researcher. If the vote is for a deferral, OIRB staff schedule the PI's response to the requested revisions for review by the full board; the IRB may or may not require the PI to attend.

4. **DISAPPROVED:** If the vote is for disapproval, OIRB staff 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 does not meet the federal criteria for IRB approval. A disapproval may be appealed to the IRB.

During the convened meeting, the IRB determines 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 OIRB assigns the start of the approval period as the date of the convened IRB meeting. If a protocol has received a conditional approval and the PI completes the revisions, the date conditions are met is the approval date and the approval period start 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.

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 with their resolutions, any motion and its outcome, and the total number of votes on the motion including votes for, against, and abstaining. Documentation of the minutes shall be retained as stated in SOP 104.

REFERENCES

45 CFR 46.108(b)
21 CFR 56.108