

Grand Valley State University
Institutional Review Board (IRB)

Title: <i>Conducting IRB meetings: voting</i>	
Section: 020.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 11/08/2011 Revised: 09/10/2013 Reviewed: 10/28/2014 Revised by HRRPPC: 04/25/2017 Revised by HRRPPC: 11/28/2017	Approved by RIO/HRPA: 11/21/2011 Revision Approved: 09/10/2013 Revision Approved by AIO/RIO: 04/25/2017 Revision Approved by AIO/RIO: 04/16/2018
Effective Date: 01/21/2019	
Related documents: 010: <i>IRB board composition</i> 030: <i>Office of Research Compliance and Integrity document retention and maintenance</i>	

Policy

1. All regular members of the IRB who are in attendance (either physically or via electronic means) at a convened board meeting and who are not recused are entitled to one vote on each and all motions presented to the committee for vote.
2. At least one scientist, one non-scientist, and one unaffiliated member must be in attendance (either physically or via electronic means) at any full board meeting when reviewing research protocols that require full board review.
3. An alternate member of the committee may vote on motions affecting protocol approvals only in place of any regular member who is absent. All alternate members in attendance (either physically or via electronic means) may vote along with regular members on all other motions presented to the committee for vote.
4. The IRB chair is a regular member of the committee with full voting privileges.
5. Prior to initiating any protocol 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 protocols under review at that meeting.
6. 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 of the full board at a convened meeting at which a quorum has been established.
7. All subject matter of board meetings that is related to protocols, including discussion involving researchers or participants, or is otherwise of a sensitive nature, shall be treated as confidential information.

Procedures

1. Alternatives

- a. 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 be notified by the IRB chair of their voting privileges when the alternate member arrives to the meeting. If more alternates are in attendance than regular members are absent, and there is no reasonable basis for supporting one alternate over another based on experience or professional expertise, the selection of the alternate member(s) granted voting privileges shall be made by the chair using a random lottery.

2. Quorum

- a. A quorum is established when both of the following conditions are met:
 - i. A simple majority of members, including the chair or a vice-chair acting as chair, are in attendance (either physically or via electronic means) and able to vote (e.g. not disqualified from voting due to conflict of interest)
 - ii. At least one scientist, one non-scientist, and one unaffiliated member (see IRB Policy 010. *IRB board composition*) must be in attendance.
- b. A majority of the quorum must vote in favor of a motion for the motion to be approved. 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 at any time a quorum is temporarily lost, no votes on motions requiring a quorum may be made until a quorum is restored.
- c. Quorum is required for the IRB to take any approval-related actions on protocol submissions that require full board review and for any IRB policy-related actions.
- d. If a protocol or policy affects prisoners involved in research, the IRB prisoner representative must be present at the meeting.

3. 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.

4. 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 during the discussion and voting. 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.

5. Virtual Attendance via Electronic Means

- a. 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 stays open throughout the meeting. Temporary disconnections that are quickly re-established shall not affect the member's attendance status.

- b. 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 and are secure. 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.
- c. 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.

6. Recording Board actions in the Minutes

- a. 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 the meeting attendance, whether the motion was seconded, summary of any controverted issues, any amendments made to the motion and their 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 IRB Policy 030. *Office of Research Compliance and Integrity document retention.*

Background

1. 45 CFR §46.108 IRB functions and operations

Except when an expedited review procedure is used (as described in §46.110), an IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

2. 45 CFR §46.109 IRB review of research

- a. An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy, including exempt research activities under §46.104 for which limited IRB review is a condition of exemption.
- b. An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure IRB

approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

3. 45 CFR §46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research
 - a. An IRB may use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized or research for which limited IRB review is a condition of exemption under §46.104(d)(2)(iii) or (d)(3)(i)(C). Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108 (1a).