

James Madison University Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
TITLE: The Conduct of IRB Meetings			
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OBJECTIVE

To describe policies and procedures for the preparation, scheduling, and conduct of convened meetings of the Institutional Review Board (IRB).

GENERAL DESCRIPTION

The James Madison University (JMU) IRB conducts convened meetings in accordance with applicable federal requirements and institutional policy for full board review [[45 CFR 46.108](#)].

RESPONSIBILITY

Execution of SOP: IRB Chair, IRB Members, Office of Research Integrity (ORI); Principal Investigator (PI)/Study Personnel

PROCEDURES

Preparation and Distribution of the Agenda

1. The ORI staff develop, maintain, and revise the IRB meeting schedule, as appropriate. The dates are available on the ORI website. ORI staff handle the meeting rooms after confirming the meeting dates.
2. The ORI staff create an agenda and provide a hard copy to the members prior to the meeting.
3. The ORI staff send the agenda packet to IRB members via email notification.
4. The ORI staff distribute appointment notice to the PI for initial full board review protocols via email.
5. The agenda serves as a guideline for the conduct of the meeting. The agenda for the meeting may include additional discussion items at the discretion of the IRB Chair, ORI staff, or IRB members.

Quorum Requirements

1. A majority (half of the committee members plus one) of the IRB members must be present.
2. At the convened meeting, at least one member whose primary concerns are in nonscientific areas must be present.

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3. Alternate members may attend in the place of absent regular members in order to meet the quorum requirements. (See Membership of IRB SOP)
4. The IRB does not consider ad hoc and cultural consultants to establish a quorum.
5. Members must excuse themselves from the meeting during a vote when they have a conflict of interest. In such cases, they do not count as a part of the members necessary to constitute a vote or majority. If the quorum is lost during a meeting (e.g., loss of a majority through excused members with conflicting interests or early departure or absence of a non-scientist member, etc.), the IRB does not take further protocol actions that require a vote unless quorum is restored.

Review of Protocols

1. The IRB Chair, Vice Chair, or any voting IRB member may chair the convened meeting. The Chair will serve as the official representative of the IRB, and will chair all IRB meetings. In the absence of the Chair, the Vice Chair will lead the IRB meeting. In the event that the Vice Chair is unavailable as well, the Chair or Vice Chair will designate another regular IRB member to chair the meeting.
2. For initial full review, the IRB invites the PI(s) and advisor, if applicable, to attend the convened meeting. The IRB, IRB Chair, or ORI staff may grant permission for the co-investigator or knowledgeable party to attend in place of the PI. The IRB, IRB Chair/Vice Chair, or ORI staff may also waive this attendance requirement.
3. For other types of review, IRB members, the IRB Chair, or ORI staff may also invite or require the PI to attend, when deemed appropriate.
4. To the extent possible, the proceedings of the meetings are confidential. Individuals such as students or representatives from non-JMU IRBs may request to attend as observers. Upon receipt of these requests, ORI staff or the IRB Chair may grant permission for attendance by these individuals. The ORI staff obtain a statement of confidentiality from observers who have permission to attend. Observers do not receive a copy of application materials.
5. IRB members do not participate in the review of any component of a project in which the member has a conflict of interest, except to provide information requested by the IRB.
6. See Initial Full Review, Continuation Review, Protocol Violations, Modification, Deviations and Exceptions-IRB Review of Changes, and Noncompliance SOPs for discussion of review outcomes and controverted issues.

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7. ORI staff are responsible for preparing meeting minutes. (See Minutes of IRB Meeting SOP # 13.)

Tele/Videoconference Participation

1. The IRB may conduct convened meetings by telephone or video conferencing as long as IRB member(s) have received a copy of all of the documents under review at the meeting, a quorum as defined above is present, and discussion occurs in real time.
2. Such members count as part of the quorum and may vote. "Telephone polling" (where ORI staff or others contact IRB members individually by telephone) does not qualify as a convened meeting. To allow for appropriate discussion, all members must be connected simultaneously for a teleconference to take place.

Voting

1. IRB members may not vote by proxy (i.e., members not present at the convened meeting may not vote on an issue discussed during a convened meeting). However, members can provide written comments for IRB consideration.
2. Voting at a convened meeting takes place under the following conditions:
 - A majority of the members for a specific IRB must be present (or connected via speakerphone/video) for all reviews/actions voted on at a convened meeting;
 - A passing vote must consist of a majority of members present (or connected via speakerphone/video) voting in favor of the motion;
 - An individual who is not listed on the Office for Human Research Protections membership roster may not vote with the IRB;
 - Ex-officio members of the IRB may not participate in the vote;
 - The non-scientist member must always be present for a vote;
3. Requirements with respect to voting members are:
 - The IRB Chair votes as a regular member.
 - Members who are alternates for each other may attend the same meeting, but only one member may vote on any one item being reviewed.
 - An alternate member may not vote in place of a member unless s/he is an alternate specifically for that member.
 - When voting members have a conflict of interest on an item, they may neither serve as the primary reviewer nor vote on the item.
 - Consultants who are not members of the IRB may not vote.

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4. If the outcome of the IRB vote approved pending submission of minor revisions, the IRB Chair or ORI staff, as appointed by the Chair, may review and approve the PI's response on behalf of the IRB under an expedited review procedure.

REVISION HISTORY

Version No.	Brief Description of Changes	Created on Date
00	Creation of SOP	7/22/2015

SIGNATURE HISTORY

Name and Title	Signature	Date

REFERENCES

- [45 CFR 46.103](#)
- [45 CFR 46.107\(e\)](#)
- [45 CFR 46.108](#)

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