SOP 1.6.1 **Full Board Meeting**

General Description:

This document describes the policies and procedures for the preparation, scheduling, and conduct of convened meetings of the Institutional Review Board (IRB) at George Mason University (GMU). GMU conducts convened meetings in accordance with applicable federal requirements for full board review under the Department of Human Health & Services (DHHS) regulations: 45 CFR 46.108, 21 CFR 56.108, and 38 CFR 16.108.

Procedures:

Roster

1. The roster is comprised of at least five members with varying backgrounds and expertise to promote complete and adequate review of research activities commonly conducted at GMU. The roster must also have one non-scientific member, one scientific member, and one unaffiliated member who is also not immediately related to someone affiliated with GMU.
2. Every nondiscriminatory effort will be made to ensure that the IRB does not consist entirely of women or entirely of men; including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. The members must also be from more than one profession.
3. The roster must include members with appropriate representative capacity for research including vulnerable subjects such as prisoners, children, and pregnant women.
4. If missing the appropriate representative capacity, or area of expertise, outside consultants can be used. Consultants need not be listed on the roster.
5. The current roster listing the board members and alternates, along with member expertise or representative capacity, is kept up to date on the institution's Federal Wide Assurance (FWA) which is filed with the Office of Human Research Protections (OHRP) of DHHS.
6. The roster is also saved within IRBNet, the Research Development, Integrity, and Assurance (RDIA) website, and on the RDIA shared drive.
7. Any changes made to the roster are updated within the roster on file within the FWA, the roster in IRBNet, the RDIA website, and roster in the RDIA shared drive.
8. Committee members have their membership renewed as-needed, per their appointment letter. The FWA is renewed every 5 years or when there is a change in the roster, per OHRP requirements.

Quorum

1. A majority of the IRB members must be present at the convened meeting.
2. At the convened meeting, at least one member whose primary concerns are in nonscientific areas must be present.
3. If a study includes vulnerable populations, a member (or consultant) with appropriate expertise and/or representative capacity must be present for the review.
4. Alternate members may attend in the place of absent regular members in order to meet the quorum requirements.
5. The IRB does not consider ad hoc and cultural consultants to establish a quorum.
6. 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 the quorum is restored.

Meeting Frequency

1. Meetings are held on a monthly basis.
2. If there are no protocols or other items that require full board review during a month, then the scheduled meeting can be cancelled.

Use of Alternates/Consultants

1. IRB meeting minutes document when an alternate IRB member replaces a voting IRB member and for whom the alternate is substituting.
2. When an alternate substitutes for a primary member, the alternate member receives and reviews the same material that the primary reviewer received or would have received.
3. If a consultant is present, they receive and review the relevant material for the meeting items they are contributing to the review of.
4. Consultants do not count towards quorum nor do they vote on the final determinations, however, they do contribute to the discussion on items and help to inform the board on particular issues related to their area of expertise prior to the vote. They can contribute in writing or in-person.

Voting

1. IRB members may not vote by proxy (i.e., members not present at the convened meeting or participating in the teleconference/videoconference call may not vote on an issue discussed during a convened meeting). However, members can provide written comments for IRB consideration. The IRB staff will convey these written comments to the rest of the board during the meeting discussion(s).
2. Researchers who have been invited to attend the meeting in order to answer questions about their research, which is under IRB review, must leave the meeting before the final discussion and vote on their protocol.
3. Voting at a convened meeting takes place under the following conditions:
    - A majority of the members 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.
    - Ad hoc and consultants may not participate in the vote.
    - A non-scientist member must always be present for a vote.
4. If the outcome of the IRB vote is that minor modifications are required, the IRB Chair or the Chair's designee who was present at the meeting may review and approve the PI's response on behalf of the IRB.

Related Forms, Guidance, and SOPs:

- SOP 1.6.2 IRB Minute Taking and Storage of Minutes
- SOP 2.5.1 Full Board Review
- DHHS 45 CFR 46
- FDA 21 CFR part 56

Responsibility:

Institutional Review Board (IRB)
IRB Staff in the Research Development, Integrity and Assurance office (RDIA)

IRB Chair
IRB Members
Researchers
Consultants
Alternates

Approval and Version History:

Please contact irb@gmu.edu if you have any questions about this policy or the version and approval history.

Date First Effective:	December 14, 2016
Revision Date:	[DATE]
Current Version #:	1

Approved By	Title and Division	Date Approved
Aurali Dade	Associate Vice President, Research Development, Integrity and Assurance	December 14, 2016
Laurie Meamber	IRB Chairperson	December 14, 2016