

13.0 PREPARATION, SCHEDULING, and CONDUCT of CONVENED MEETINGS of THE INSTITUTIONAL REVIEW BOARD (IRB)

13.1 OBJECTIVE

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

13.2 GENERAL DESCRIPTION

The Howard University IRB conducts convened meetings in accordance with applicable federal requirements for full review (i.e., 21 CFR 56.108, 45 CFR 46.108, and 38 CFR 16.108).

13.3 RESPONSIBILITY

Execution of SOPP: IRB Chair, IRB Members, Office of Regulatory Research Compliance (ORRC) Staff; Principal Investigator (PI)/Study Personnel.

13.4 PROCEDURES

13.4.1 Preparation and Distribution of the Agenda

- ORRC staff develops, maintains, and revises the IRB meeting schedule, as appropriate. The dates are available on the ORRC website, or by request. ORRC staff handles the meeting rooms and catering arrangements after confirming the meeting dates.
- ORRC staff creates an agenda approximately 7 calendar days before a meeting and upload all meeting documents for review by members of the appropriate IRB, unless special circumstances require adding a protocol to the agenda. If special circumstances exist, ORRC staff prepares an addendum to the agenda and distribute it to IRB members prior to the meeting.
- For each meeting, ORRC staff automatically generates the agenda in the computerized system. ORRC staff review the agenda for accuracy and completeness before distributing it to the IRB.
- ORRC staff notifies PI of meeting date for initial full review protocols.
- 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, ORRC staff, or IRB members.

13.4.2 Quorum Requirements

- A majority (e.g., IRB members = 12; majority = 7) of the IRB members must be present.
- At the convened meeting, at least one member whose primary concerns are in nonscientific areas must be present.
- When the IRB reviews FDA regulated research, there must be one member present who is a licensed physician.
- Alternate members may attend in the place of absent regular members in order to meet the quorum requirements (See Membership of IRB SOPP).
- The IRB does not consider ad hoc and cultural consultants to establish a quorum.
- 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.

13.4.3 Review of Protocols

- The IRB Chair, Vice Chair, or any voting IRB member may chair the convened meeting.
- For other types of review, IRB members, the IRB Chair, or ORRC staff may also invite or require the PI to attend, when deemed appropriate.
- To the extent possible, the proceedings of the meetings are confidential. Individuals such as students or representatives from non-HU IRBs may request to attend as observers. Upon receipt of these requests, ORRC staff or the IRB Chair may grant permission for attendance by these individuals. ORRC staff obtains a statement of confidentiality from observers who have permission to attend. Observers do not receive a copy of application materials.
- 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 (See IRB Member and Consultant Conflict of Interest SOPP).

- See Initial Full Review, Continuation Review, Protocol Violations, Modification, Deviations and Exceptions-IRB Review of Changes, and Noncompliance SOPPs for discussion of review outcomes and controverted issues.
- ORRC staff is responsible for preparing meeting minutes (See Minutes of IRB Meeting SOPP).

13.4.4 Tele/Videoconference Participation

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.

- Quorum as defined above is present, and discussion occurs in real time.
- Such members count as part of the quorum and may vote. "Telephone polling" (where ORRC 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.

14.4.5 Voting

- IRB members may not vote by proxy (i.e., members not present at the convened meeting or participating in the tele/videoconference call may not vote on an issue discussed during a convened meeting). However, members can provide written comments for IRB consideration.
- 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;
 - Ad hoc and cultural consultants may not participate in the vote;
 - The non-scientist member must always be present for a vote;
 - A physician must be present to vote on FDA regulated research;
- If the outcome of the IRB vote is a "2" (approved pending submission of minor revisions), the IRB Chair or the individual chairing the meeting may review and approve the PI's response on behalf of the IRB under an expedited review procedure.

13.5 REFERENCES

21 CFR 56.108c
21 CFR 56.109
45 CFR 46.108(a & b)
45 CFR 46.103
45 CFR 46.108
45 CFR 46.107(e)

14.0 REVIEW of DATA and SAFETY MONITORING PLAN(S)

14.1 OBJECTIVE

To describe Institutional Review Board (IRB) review of data and safety monitoring plan(s) (DSMP) to ensure adequate protection is in place for subjects.