

	Institutional Review Board	
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Responsibility: OIRB		Page 1 of 4

Conduct of IRB Meetings
Policy and Procedure

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I. Policy

- A. The HSC IRB conducts convened meetings in accordance with applicable federal requirements for full review (See [Policy on Policies Policy and Procedure](#)).

II. Procedures

- A. The agenda and packet are available to IRB members prior to the convened meeting as indicated in the [Receiving, Routing, and Administrative Review of Submissions Policy and Procedure](#). This 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, the OIRB staff, or VPR.
- B. Quorum Requirements and Ensuring Appropriate Representation at Convened Meetings
 - 1. Quorum Members are those members that count towards a quorum. Quorum Members are all the IRB voting members. The Chair counts towards a quorum.
 - 2. A quorum is defined as a majority of the quorum members present ([attendance](#) by teleconference is acceptable in order to be counted towards a quorum). Examples of how to calculate the majority of the Quorum members is as follows: e.g., If the number of Members that count towards a Quorum (Quorum Members) = 16, a Majority = 9; if Quorum Members = 15, a Majority = 8; if Quorum Members = 14, a Majority = 8)
 - 3. At the convened meeting, at least one member whose primary concerns are in nonscientific areas, and represent the general prospective of the participants must be in attendance.
 - 4. When FDA-regulated research is reviewed, there must be at least one member in attendance who is a licensed physician.
 - 5. When [VA Research](#) is reviewed:
 - a) The research compliance officer may serve as a nonvoting consultant, as needed. The research compliance officer may attend meetings of the IRB when requested by the committee.

6. When prisoner research is reviewed, there must be at least one prisoner representative in attendance. For DHHS-funded research, the organization certifies to OHRP that the duties of the IRB have been fulfilled as outlined in the [Reporting Policy and Procedure](#). Additionally, a majority of the Board (exclusive of member(s) representing prisoners) will have no association with any prison(s) involved in the research being reviewed, apart from their membership on the Board.
7. When Research involving individuals vulnerable to coercion or undue influence or sensitive types of research/procedures is reviewed there must be at least one knowledgeable IRB member or consultant attending the IRB Meeting.
8. Alternate members may attend in the place of absent regular members in order to meet the quorum requirements. (See [Membership of IRB Policy and Procedure](#))
9. The IRB does not consider ad hoc and cultural consultants to establish a quorum.
10. At least one un-affiliated member must attend 6 out of 9 convened meetings per year. This member need not serve one role on the IRB (i.e., the unaffiliated member may also represent the general perspective of participants). The IRB does not consider this member to establish a quorum.
11. Members must excuse themselves from the meeting prior to discussion and during a vote when they have a conflict of interest (See [HOP 10.1.6](#)). In such cases, they do not count as a part of the members necessary to constitute a vote or majority.
12. 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, members who leave for any reason at any time do not count towards the quorum), the IRB does not take further protocol actions that require a vote unless the quorum is restored.

C. Review of Protocols

1. The IRB Chair, Alternate Chair, IRB Director or Associate Director or any voting IRB member may chair the convened meeting.
2. For review of research at a convened meeting, the IRB may request that PIs (or another knowledgeable party) attend the convened meeting when deemed appropriate.
3. To the extent possible, the proceedings of the meetings are confidential. Individuals such as prospective board members or representatives from non-HSC IRBs attend as observers if approved by the OIRB staff or Chair. The OIRB staff obtains a statement of confidentiality from observers who have permission to attend and they excuse themselves from meetings prior to discussion and during a vote when they have a conflict of interest concerning any protocol (See [HOP 10.1.6](#)). Observers do not receive a copy of application materials.
4. IRB members, consultants, observers 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 [HOP 10.1.6](#))

5. See [Initial Review of Research Policy and Procedure](#), [Continuation Review Policy and Procedure](#), [Modification and Amendments Policy and Procedure](#), and [Noncompliance Policy and Procedure](#) policies for discussion of review outcomes and controverted issues.
6. The OIRB staff is responsible for preparing meeting minutes. (See [IRB Minutes Policy and Procedure](#))

D. Tele/Videoconference Participation

1. The IRB may conduct convened meetings by telephone or video conferencing as long as IRB members have received a copy of all of the documents under review at the meeting (see section titled "Route a package" in the [Receiving, Routing, and Administrative Review of Submissions Policy and Procedure](#)), 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 the OIRB 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.
3. If the member has a conflict of interest, that member may not be present during the vote or discussion (see [IRB Member and Consultant Conflict of Interest Policy and Procedure](#)) and prior to the review must have terminated the connection, not just be placed on "hold."

E. Voting

1. IRB members may not vote by proxy (i.e., members not present at the convened meeting or not 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.
2. The voting may include a show of hands or written ballots at the discretion of the chair.
3. At the time of voting, the chair asks members to vote separately for each item with the following choices: for, against or abstain.
4. Voters against or abstaining may be offered the opportunity to comment either verbally or in writing and have their comments added to the minutes.
5. Voting at a convened meeting takes place under the following conditions:
 - a) A quorum of the members for a specific IRB must attend for each review/action voted on at a convened meeting;
 - b) A passing vote must consist of a majority of members in attendance voting in favor of the motion;
 - c) An individual who is not listed on the official IRB roster provided to the Office for Human Research Protections prior to the meeting may not vote with the IRB;

- d) Ad hoc and cultural consultants may not participate in the vote;
- e) A non-scientific member must always be in attendance for a vote;
- f) A physician must be in attendance to vote on FDA-regulated research;
- g) If the outcome of the IRB vote is to approve pending submission of minor revisions, the IRB Chair, Director or designated Expedited Reviewer may review and approve the PI's response on behalf of the IRB under an expedited review procedure.

III. References

- A. Definitions (see [Glossary](#))
- B. Regulatory (see [Policy on Policies Policy and Procedure](#))