



SOP: IRB Meeting Preparation

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1 PURPOSE

- 1.1 This procedure establishes the process to prepare for a convened IRB meeting.
- 1.2 The process begins when the agenda is closed.
- 1.3 The process ends when IRB meeting agenda materials have been made available to IRB members.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 Revised from previous version 11/22/2018

3 POLICY

- 3.1 At least one IRB member or consultant is responsible for scientific/scholarly and ethical review of research.
- 3.2 Protocols are reviewed by IRB members and consultants with sufficient expertise.
- 3.3 IRB members are provided sufficient information so that each member can provide an opinion on whether the regulatory criteria for approval are met.
- 3.4 Alternate IRB members serve the same function as other IRB members, except that if the alternate IRB member and the regular IRB member for whom the alternate member is substituting are both present, only one member may vote.
- 3.5 Review materials are provided to all IRB members before convened meetings.

4 RESPONSIBILITIES

- 4.1 IRB Office staff members carry out these procedures.

5 PROCEDURE

- 5.1 Confirm which IRB members (regular, alternate, and chairs) will be present at the meeting.
- 5.2 Consult "DATABASE: IRB Roster (HRP-601)" to be aware of the experience, expertise, and representational capacity of the IRB.
- 5.3 Review all submissions placed on the agenda for a convened IRB meeting.
 - 5.3.1 The number of items on the agenda is dependent on who confirms to attend (5.1), expertise (5.2) and fixed length of the meeting.
- 5.4 Prepare an agenda for the meeting.
 - 5.4.1 Execute the "Assign Reviewers" activity in the meeting workspace to assign a primary reviewer to each agenda item.
 - 5.4.2 Execute the "Assign Reviewers" activity in the meeting workspace to assign a scientific/scholarly reviewer to each agenda item who has scientific/scholarly expertise in the area of research. The primary reviewer and scientific/scholarly reviewer may be the same individual.
 - 5.4.3 If the scientific/scholarly reviewer/consultant is not an IRB member, determine whether the scientific/scholarly reviewer/consultant has a conflict of interest as defined in the University Policy on Conflict of Interest and Conflict of Commitment. If so, assign another scientific/scholarly reviewer/consultant.
- 5.5 Use "WORKSHEET: Quorum and Expertise (HRP-305)" to ensure that the meeting will be appropriately convened and to ensure the IRB will have the appropriate expertise for each protocol.
 - 5.5.1 If the meeting will not meet the quorum and expertise requirements, take steps to obtain the required attendance of members and consultants or cancel the meeting.
 - 5.5.2 Follow the procedures in "SOP: Consultation (HRP-051)" to obtain consultants. Note any consultants on the agenda.



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- 5.6 Individuals are provided materials electronically (IRB members, scientific/scholarly reviewers, consultants).
- 5.7 Follow-up on reviewers' assignments prior to the meeting day.
 - 5.7.1 Provide reviewers the resources and information they require to complete their review (as applicable).

6 MATERIALS

- 6.1 DATABASE: IRB Roster (HRP-601)
- 6.2 SOP: Conflicting Interests of IRB Members and Consultants (HRP-050)
- 6.3 SOP: Consultation (HRP-051)
- 6.4 WORKSHEET: Review Materials (HRP-301).
- 6.5 WORKSHEET: Quorum and Expertise (HRP-305).
- 6.6 POLICY: Policy on Conflict of Interest and Conflict of Commitment (HRP-053)

7 REFERENCES

- 7.1 45 CFR §46.108(b)
- 7.2 21 CFR §56.108(b)