

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, approximately 10 days before a meeting date.
- 1.3 The process ends when IRB meeting agenda materials have been sent or made available to IRB members.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None.

3 POLICY

- 3.1 At least one IRB member or consultant is responsible for scientific/scholarly review of research.
- 3.2 Protocols are reviewed by IRB members and consultants with sufficient expertise.
- 3.3 When IRB members review research that involves vulnerable subjects, at least one individual who is knowledgeable about or experienced in working with such subjects will be present at the meeting.
- 3.4 IRB members are provided sufficient information so that each member can provide an opinion on whether the regulatory criteria for approval are met.
- 3.5 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.
- 3.6 Review materials are provided to all IRB members at least 7 days before convened meetings.

4 RESPONSIBILITIES

- 4.1 IRB 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 HRP-601 - DATABASE - IRB Roster 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.
- 5.4 Prepare an agenda for the meeting.
 - 5.4.1 Assign a primary reviewer to each agenda item.
 - 5.4.2 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 Execute the "Assign Reviewers" activity in the meeting workspace to assign a primary reviewer to each agenda item
 - 5.4.4 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
 - 5.4.5 If the scientific/scholarly reviewer is not an IRB member, determine whether the scientific/scholarly reviewer has a Conflicting Interest as defined in HRP-001 - SOP - Definitions. If so, assign another scientific/scholarly reviewer.
- 5.5 Use HRP-305 - WORKSHEET - Quorum and Expertise to ensure that the meeting will be appropriately convened and to ensure the IRB will have the appropriate expertise for each protocol.

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- 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 HRP-051 - SOP - Consultation to obtain consultants. Note any consultants on the agenda.
- 5.6 For individuals who are provided materials (IRB members, scientific/scholarly reviewers, consultants):
 - 5.6.1 Prepare review materials using HRP-301 - WORKSHEET - Review Materials according to the individual's role.
 - 5.6.2 Ensure review materials are available in the submission using HRP-301 - WORKSHEET - Review Materials.
 - 5.6.3 Provide all Conflict of Interest Management Plans.
 - 5.6.4 Deliver or mail review materials.
 - 5.6.5 Execute the "Send Agenda" activity in the meeting workspace to deliver review materials to reviewers.

6 MATERIALS

- 6.1 HRP-001 - SOP – Definitions
- 6.2 HRP-051 - SOP – Consultation
- 6.3 HRP-301 - WORKSHEET - Review Materials
- 6.4 HRP-305 - WORKSHEET - Quorum and Expertise
- 6.5 HRP-601 - DATABASE - IRB Roster

7 REFERENCES

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