HRP-040 | 10/9/2024 | Author: T. Bechert | Approver: J. Opalesky

**SOP: IRB Meeting Preparation**

1. **PURPOSE**
   1. This procedure establishes the process to prepare for a convened IRB meeting.
   2. The process begins when the agenda is closed, approximately 7 days before a meeting date.
   3. The process ends when IRB meeting agenda materials have been sent or made available to IRB members.
2. **REVISIONS FROM PREVIOUS VERSION**
   1. Added confidentiality agreement and conflict of interest policy review for IRB meeting guests; incorporated additional meeting preparation workflow steps; 10/2/23.
   2. Removed reference to retired FB Tracking Document, added step to finalize reviewer notes, added step to invite PAM&E monitor to Chair’s meeting, clarified timing for confidentiality agreement and conflict of interest policy review for IRB consultants; 8/19/24.

* 1. Clarified that the agenda is closed at 8:00 a.m. Eastern Time 7 business days prior to a meeting; 10/9/24.

1. **POLICY**
   1. At least one IRB member or consultant is responsible for scientific/scholarly review of research.
   2. Protocols are reviewed by IRB members and consultants with sufficient expertise.
   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.
   4. IRB members are provided sufficient information so that each member can provide an opinion on whether the regulatory criteria for approval are met.
   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.
   6. Review materials are provided to all IRB members at least 7 days before convened meetings; completed reviews are requested in advance of the meeting to allow follow-up by the IRB Chair and/or Principal Investigator.
   7. IRB meeting guests will sign a confidentiality agreement and conflict of interest policy review statement in advance of attendance.
   8. IRB consultants will sign a confidentiality agreement and conflict of interest policy review statement in advance of receiving materials or reviewing and consulting on studies.
2. **RESPONSIBILITIES**
   1. IRB staff members carry out these procedures unless otherwise noted.
3. **PROCEDURE**
   1. Confirm which IRB members (regular, alternate, and chairs) will be present at the meeting.
   2. Consult HRP-601 - DATABASE - IRB Roster to be aware of the experience, expertise, and representational capacity of the IRB.
   3. Review all submissions ready for assignment to a convened IRB meeting. The agenda is closed at 8 a.m. Eastern Time 7 business days prior to a meeting.
   4. Begin to prepare an agenda for the meeting.
      1. Assign each submission to the meeting date and select Reviewer 1 and 2 using the “Schedule for IRB Meeting” activity. The reviewers may not be a member of the study team.
      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.
      3. Add comments for each agenda item regarding special determinations or other study status information identified.
      4. 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. 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.
      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.
      2. Follow the procedures in HRP-051 - SOP - Consultation to obtain consultants. Note any consultants on the agenda.
   6. Obtain a signed confidentiality statement and conflict of interest policy review statement for all IRB meeting guests and consultants.
   7. Securely send any protocol materials needed by non-IRB members for scientific or consultant review.
   8. In the RAMS-IRB Meetings tab, select the upcoming meeting to produce an agenda and execute the “Generate Agenda” activity. Select “Yes” to replace the existing agenda document. Enter the date of the most recent IRB panel meeting agenda generated date through the upcoming meeting date to pull the completed expedited reviews onto the agenda. Download the created agenda .
      1. Execute the “Send Agenda” activity to provide the agenda to the IRB members who are attending the meeting.
      2. Provide meeting logistics, including circulation of a virtual meeting invitation, to members confirmed to attend, as indicated.
   9. The assigned Reviewer 1 and Reviewer 2 will complete their review of the submission.
      1. The reviewer will execute the “Finalize Reviewer 1 (or 2)” activity and document their written review of the submission; upload any new or revised special determination checklist drafts under the Admin Docs tab.
   10. Perform additional review of agenda items and reviewer comments during weekly Chair’s Meeting:
       1. Facilitate clarification with the Principal Investigator for any items unresolved by reviewers or the IRB Chair.
       2. Schedule the Principal Investigator to attend the IRB meeting for discussion, where applicable.
       3. Invite the PAM&E monitor to attend the Chair’s Meeting where monitoring reports are included in submissions on the agenda.
       4. The IRB Chair or HRPP Director can add or remove items.
       5. The IRB Chair finalizes the agenda.
   11. Execute the “Meeting In Progress” activity in RAMS the day of the meeting.
4. **MATERIALS**
   1. HRP-001 - SOP – Definitions
   2. HRP-051 - SOP – Consultation
   3. HRP-305 - WORKSHEET - Quorum and Expertise
   4. HRP-601 - DATABASE - IRB Roster
5. **REFERENCES**
   1. 45 CFR §46.108(b)
   2. 21 CFR §56.108(b)
   3. AAHRPP elements I.1.F, I.5.D, I.6.B, I.7.A, I-9, II.1.B, II.1.D, II.1.E, II.2.D, II.2.G, II.2.E-II.2.E.2