SOP: IRB Meeting Preparation				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
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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 14 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 with such subjects will be present at the meeting.

3.4 HRPP Protocol Coordinators conduct a thorough pre-review of protocol submission and provide IRB members with 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 10 days before convened meetings.

4 RESPONSIBILITIES

4.1 The HRPP Director/IRB Administrator and the IRB Chair carryout these procedures.

4.2 HRPP staff members provide support and assistance as specified and requested.

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 Between the date of protocol is submitted and the agenda deadline, the assigned HRPP Protocol Coordinator works with principal investigator as needed to ensure the submission is complete, that all issues are addressed, and the submission is ready for IRB review.

- 5.3.1 When the protocol coordinator determines that the protocol is ready to be added to the agenda, they will develop context notes summarizing for the IRB-member reviewer any details or remaining concerns related to approval. These notes are to be provided to the IRB members with the agenda and other meeting materials.
- 5.3.2 The protocol coordinator assigned to each protocol or action will participate in the agenda planning for their assigned protocols.

5.4 Review all submissions placed on the agenda for a convened IRB meeting.

5.5 The HRPP Director/IRB Administrator and the IRB Chair meet 2 weeks before the scheduled meeting to develop the agenda.

- 5.5.1 Enumerate the protocols and actions to be considered during the meeting.
- 5.5.2 Prioritize agenda items to address the most time-sensitive first and placing less time-sensitive items toward the end in case time runs out and the leftover items must be tabled.
- 5.5.3 Allocate rough time estimates for each action, depending on complexity, risk level, and other considerations.
- 5.5.4 Assign primary and secondary reviewers for each protocol and action and determine if a consultant is needed.

5.5.5 Determine whether the scientific/scholarly reviewer has a Conflicting Interest as defined in "SOP: Definitions (HRP-001)." If so, assign another scientific/scholarly reviewer. If so, assign another scientific/scholarly reviewer.

5.5.6 Discuss investigators that should be invited to the meeting for any new protocols or actions that would benefit from the investigator's presence. The HRPP Administrative Assistant will extend invitations to investigators invited to attend the meeting and confirm their attendance.

5.5.7 Decide on the IRB training tidbit for the meeting and coordinate with the presenter of the tidbit (IRB Chair, HRPP staff, other).

5.6 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.

5.6.1 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.

5.6.2 Follow the procedures in "SOP: Consultation (HRP-051)" to obtain consultants. Note any consultants and any other invited guests on the agenda.

5.7 For individuals who are provided materials (IRB members, scientific/scholarly reviewers, consultants):

5.7.1 Prepare review materials using "WORKSHEET: Review Materials (HRP-301)" according to the individual's role.

5.7.2 Ensure review materials are available in the submission using "WORKSHEET: Review Materials (HRP-301)."

5.7.3 Deliver or mail review materials.

6 MATERIALS

6.1 DATABASE: IRB Roster (HRP-601)

6.2 SOP: Consultation (HRP-051)

6.3 SOP: Definitions (HRP-001)

6.4 WORKSHEET: Review Materials (HRP-301).

6.5 WORKSHEET: Quorum and Expertise (HRP-305).

7 REFERENCES

7.1 45 CFR §46.108(b)

7.2 21 CFR §56.108(b)