UC DAVIS
UNIVERSITY OF CALIFORNIA

SOP: IRB Meeting Preparation				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-040	06/15/2017	C. Gates	C. Kiel	1 of 2

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 5-10 business days before a meeting date.

1.3 The process ends when IRB members are notified of the agenda.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Administrative and current procedural updates.

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 When the IRB members review research that is being conducted outside of the United States, the members will have sufficient expertise to determine the acceptability of the research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. If the IRB membership does not include such expertise, the information will be provided through a knowledgeable consultant or other resource.

3.5 At least one unaffiliated member is generally present at convened meetings.

3.6 IRB members are provided sufficient information so that each member can provide an opinion on whether the regulatory criteria for approval are met.

3.7 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.

4 With the exception of Committee D, review materials are made available to all IRB members at least 5 business days before convened meetings.

4.1 If a submission is added on to a Committee A, B or C meeting, the members will receive the review materials in advance of the meeting and will be allowed sufficient time to complete a thorough review prior to the start of the meeting.

4.2 If documents are added to or removed from a submission prior to a meeting, the members will be notified prior to deliberation and vote.

4.3 Members who attend Committee D meetings will receive review materials in advance of the meeting, and will be allowed sufficient time to complete a thorough review prior to start of the meeting.

5 RESPONSIBILITIES

5.1 IRB staff members carry out these procedures.

6 PROCEDURE

6.1 Confirm which IRB members (regular, alternate, and chairs) will be present at the meeting.

6.2 Consult “DATABASE: IRB Roster (HRP-601)” (or equivalent) to be aware of the experience, expertise, and representational capacity of the IRB.

6.3 Review all submissions placed on the agenda for a convened IRB meeting to determine expertise required.

6.4 Prepare an agenda for the meeting.

6.4.1 Assign a primary reviewer to each agenda item.

6.4.2 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.

6.4.3 If the scientific/scholarly reviewer is not an IRB member, determine whether the scientific/scholarly reviewer has a Conflicting Interest as defined in “SOP: Definitions (HRP-001).” If so, assign another scientific/scholarly reviewer.

6.5 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.

6.5.1 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.

6.5.2 Follow the procedures in "SOP: Consultation (HRP-051)" to obtain consultants. Note any consultants on the agenda.

6.5.2.1 If the agenda includes research with vulnerable populations, ensure the members will have access to appropriate expertise and knowledge to determine the acceptability of involving the vulnerable populations.

6.5.2.2 If the agenda includes research being conducted outside of the United States, ensure the members will have access to appropriate expertise and knowledge of the country to ascertain the acceptability of the proposed research.

6.5.2.3 If the agenda includes research involving prisoners, ensure a member designated as a Prisoner Representative will attend the meeting.

6.6 For individuals who are provided hard copy materials prepare and deliver the review materials using "WORKSHEET: Review Materials (HRP-301)" according to the individual's role.

6.7 Notify IRB members of the agenda.

7 MATERIALS

7.1 DATABASE: IRB Roster (HRP-601)

7.2 SOP: Consultation (HRP-051)

7.3 SOP: Definitions (HRP-001)

7.4 WORKSHEET: Review Materials (HRP-301)

7.5 WORKSHEET: Quorum and Expertise (HRP-305)

8 REFERENCES

8.1 45 CFR §46.108(b)

8.2 21 CFR §56.108(b)