1 PURPOSE

1.1 This SOP establishes the process to prepare for a convened IRB meeting.

1.2 The process begins when the meeting agenda is closed, approximately 10 working days before a meeting date.

1.3 The process ends when the IRB members attending the meeting have been notified of the meeting agenda and their assignments.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Revised from the 5.30/2017 version.

3 SOP Statement

3.1 The IRB does not place limits on the number of items on the agenda.

3.2 Agendas are used to communicate to the IRB research that has been approved by expedited procedures.

3.3 At least one IRB member or consultant is responsible for scientific/scholarly review of research.

3.4 Protocols are reviewed by IRB members and consultants with sufficient expertise.

3.5 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.

3.6 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 Review materials are provided before convened meetings through the electronic system unless requests are made for materials to be provided outside the electronic system. The electronic system is web-based and can be accessed from any location with internet access.

3.8 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.

3.9 An IRB Vice Chair may chair convened meetings when required.

3.10 Review materials are accessible to all IRB members as they are placed on the agenda at least 5-7 days before convened meetings.

3.11 A new information item that requires immediate action to protect the rights and welfare of subjects may be placed on the next IRB agenda at any time prior to the meeting.

3.11.1 IRB members attending the meeting will be notified of any additional new information items added to the agenda.

4 RESPONSIBILITIES

4.1 IRB/HRPP 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 IRB Roster Sheet and/or electronic system 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 a report of all approvals by non-committee (expedited) procedures since the last agenda was generated and attach to the current agenda to inform IRB members of the reviews.

5.5 Prepare an agenda for the meeting.

5.5.1 Use the electronic system to assign a primary reviewer to each agenda item.

5.5.2 Use the electronic system to assign a scientific/scholarly reviewer to each agenda item who has scientific/scholarly expertise in the area of research

5.5.3 The primary reviewer and scientific/scholarly reviewer may be the same individual.

5.5.4 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.

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 on the agenda.

5.7 For all reviewers (IRB members, scientific/scholarly reviewers, consultants):

5.7.1 Send the agenda through the electronic system to deliver a link to review materials.

5.7.2 Notify the reviewers of their assignments through the electronic system or through email.

5.7.3 Provide materials to Ad hoc Scientific/scholarly reviewers or consultants that are not IRB members through the electronic system or through email.

6 MATERIALS

6.1 IRB Roster Sheet (HRP-601)

6.2 SOP: Consultation (HRP-051)

6.3 SOP: Definitions (HRP-001)

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

7 REFERENCES

7.1 45 CFR §46.108(b)

7.2 21 CFR §56.108(b)

7.3 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