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 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 the current 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.
   5.5 Use the “WORKSHEET: Evaluation of 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.
      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 “SOP: Consultation to the IRB” to obtain consultants. Note any consultants on the agenda.
   5.6 Prepare review materials for IRB members and consultants using “WORKSHEET: Review Materials.”
   5.7 Deliver or mail review materials to all IRB members and consultants.
   5.8 Place a copy of all review materials in the protocol file.

6 MATERIALS
   6.1 SOP: Consultation to the IRB.
   6.2 WORKSHEET: Review Materials.
   6.3 WORKSHEET: Evaluation of Quorum and Expertise.

7 REFERENCES
### SOP: IRB Meeting Preparation

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7.1 45 CFR §46.108(b)

7.2 21 CFR §56.108(b)