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 7-10 days before a meeting date.
1.3 The process ends when agenda materials have been made available electronically to IRB members and IRB members have been notified of their availability.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Minor revisions for AAHRPP accreditation; replaces version dated 09/23/2009.

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 participants, at least one individual who is knowledgeable about or experienced in working with such participants 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 Agenda materials are provided to all IRB members at least one week 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 queue for a convened IRB meeting.
5.4 Prepare an agenda for the meeting.
   5.4.1 Assign a lead 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 lead reviewer and scientific/scholarly reviewer may be the same individual.
5.5 Use the “CHECKLIST: 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 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 agenda packets for IRB members and consultants using “WORKSHEET: Review Materials.”
5.7 Deliver or mail agenda packets to all IRB members and consultants.
5.8 Place a copy of all materials in the protocol file.

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

7.1 45 CFR §46.108(b)
7.2 21 CFR §56.108(b)