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 12 days before a meeting date.
   1.3 The process ends when IRB meeting 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 to indicate review materials are available electronically; replaces version dated
       7/7/2011.

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 Copy review materials to shared drive for access to all IRB members and deliver or mail packets to
       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: Evaluation of Quorum and Expertise.
6.3 WORKSHEET: Review Materials.

7 REFERENCES

7.1 45 CFR §46.108(b)

7.2 21 CFR §56.108(b)