1 PURPOSE
1.1 This procedure establishes the process to conduct convened meetings.
1.2 The process begins when the IRB members gather for a convened meeting.
1.3 The process ends when the meeting is adjourned.

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

3 POLICY
3.1 The IRB reviews research in accordance with the applicable regulatory criteria for approval.

4 RESPONSIBILITIES
4.1 The IRB Chair carries out these procedures with assistance from the IRB staff.
4.2 The lead reviewers lead IRB members through consideration of the regulatory criteria for approval.

5 PROCEDURE
5.1 Call the meeting to order.
5.2 Ask for any corrections to the minutes.
5.3 Ask IRB members whether anyone has a conflicting interest in any item on the agenda. Note this on the agenda.
5.4 For each business item:
   5.4.1 Table the item when notified by IRB staff when requirements for review of a specific item as defined in “CHECKLIST: Evaluation of Quorum and Expertise” are not met.
   5.4.2 If there are IRB members with a conflicting interest, invite the IRB to ask questions of those members and then ask those members to leave for discussion and voting.
   5.4.3 If there is a consultant present, ask the consultant to present their review to the IRB.
   5.4.4 If a consultant provided written information to the IRB, present that information to the IRB.
   5.4.5 If there is a scientific review, ask the scientific member to present their review to the IRB.
   5.4.6 Note any contingencies required by IRB staff.
   5.4.7 Have the lead reviewer lead the IRB through the review as described below.
   5.4.8 Open the floor for additional discussion.
   5.4.9 Review any modifications required by the IRB to secure approval to ensure that the IRB staff has recorded them.
   5.4.10 Entertain a motion.
   5.4.11 Call for a vote.
      5.4.11.1 Only IRB members may vote.
      5.4.11.2 If a member and an alternate are both present, only one may vote.
      5.4.11.3 Consultants may not vote.
      5.4.11.4 For a motion to be approved, it needs the approval of more than half of the members present at the meeting. (If there are 10 or 11 members present at the meeting, 6 votes are required for approval, which is greater than 5 and 5.5, respectively.)
   5.4.12 Re-invite IRB members with a conflicting interest back into the meeting.
   5.4.13 Provide any written information provided by a member or consultant to the IRB staff.
5.5 For each protocol requesting approval have the lead reviewer:
   5.5.1 Use the “WORKSHEET: Criteria for Approval” and all referenced checklists (listed below) to have the convened IRB determine which regulatory criteria are met, which are not met, and which would be met if the investigator modified the protocol as requested by the IRB.
5.5.2 Restate the IRB’s consensus regarding protocol specific findings justifying a determination when required by a checklist.

5.5.3 Make a motion for one of the following actions:

5.5.3.1 Approval (with a specific continuing review interval for initial or continuing review): Made when all criteria for approval are met.

5.5.3.2 Modifications Required to Secure Approval (with a specific continuing review interval for initial or continuing review): Made when IRB members require specific modifications such that the IRB chair can determine whether an investigator has made the required changes without judging whether a change meets the regulatory criteria for approval. When making this motion, the assigned lead reviewer restates the modifications required by the IRB members and the IRB member’s reasons for those changes.

5.5.3.3 Tabled: Made when the IRB determines that it is unable to approve a protocol and the IRB can describe modifications the might make the research approvable. When making this motion, the assigned lead reviewer describes the IRB member’s reasons for this decision, describes modifications that might make the research approvable, and gives the investigator an opportunity to respond to the IRB in person or in writing.

5.5.3.4 Defer: Made when the research does not qualify for Approval or Modifications Required to Secure Approval and the IRB has recommendations that might make the protocol approvable. When making this motion, the assigned primary reviewer describes the IRB member’s reasons for the decision and describes recommendation to make the research approvable.¹

5.5.3.5 Disapproval: Made when the IRB determines that it is unable to approve a protocol and the IRB cannot describe modifications the might make the research approvable. When making this motion, the assigned lead reviewer describes the IRB member’s reasons for the decision and gives the investigator an opportunity to respond to the IRB in person or in writing.

5.6 For each problem have the lead reviewer:

5.6.1 Use the “CHECKLIST: Review of Information Items” to have the convened IRB make any necessary determinations.

5.6.2 Make a motion reflecting any actions required by the IRB members.

5.7 Temporarily adjourn the meeting when notified by IRB staff that quorum has been lost.

5.8 Adjourn the meeting when there is no further business.

6 MATERIALS

6.1 WORKSHEET: Advertisements.

6.2 WORKSHEET: Payments.

6.3 WORKSHEET: Review of Information Items.

6.4 CHECKLIST: Non-Significant Risk Device.

6.5 WORKSHEET: Criteria for Approval for Humanitarian Use Devices (HDE).

6.6 WORKSHEET: Criteria for Approval.

6.7 CHECKLIST: Evaluation of Quorum and Expertise.

6.8 CHECKLIST: Cognitively Impaired Adults.

6.9 CHECKLIST: Children.

6.10 CHECKLIST: Research Involving Neonates.

¹ If desired, “Defer” and “Disapprove” can be combined into one “Disapprove” determination.
6.11 CHECKLIST: Pregnant Women.
6.12 CHECKLIST: Prisoners.
6.13 CHECKLIST: Waiver or Alteration of the Consent Process.
6.14 CHECKLIST: Waiver of Written Documentation of Consent.

7 REFERENCES
7.2 45 CFR §46.109, §46.116, §46.117.