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 Revisions for AAHRPP accreditation; replaces version dated 8/28/13.

3 POLICY
   3.1 The IRB reviews research in accordance with the applicable regulatory criteria for approval.
   3.2 The worksheets and checklists described in "WORKSHEET: Review Materials" and listed below in "Section 6: MATERIALS" are provided to IRB members in advance of meetings per “SOP: IRB Meeting Preparation” to conduct meetings and meet regulatory requirements. During meetings, materials under discussion are projected on a screen.

4 RESPONSIBILITIES
   4.1 The IRB chair (or IRB Vice Chair in IRB Chair’s absence) carries out these procedures.
   4.2 Primary reviewers lead IRB members through consideration of the regulatory criteria for approval.

5 PROCEDURE
   5.1 Call the meeting to order.
   5.2 Ask IRB members whether anyone has a Conflicting Interest in any item on the agenda and note the responses.
   5.3 For each business item:
      5.3.1 Table the item when notified by IRB staff when requirements for review of a specific item as defined in "WORKSHEET: Evaluation of Quorum and Expertise" are not met.¹
      5.3.2 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 or if present by teleconference, be placed on hold or disconnect for discussion and voting.
      5.3.3 If there is a consultant present, ask the consultant to present his or her review to the IRB.
      5.3.4 If a consultant provided written information to the IRB, present that information to the IRB.
      5.3.5 If there is a scientific review, ask the scientific member to present the review to the IRB.
      5.3.6 Have the lead reviewer lead the IRB through the review as described below.
      5.3.7 Open the floor for additional discussion.
      5.3.8 Review any modifications required by the IRB to secure approval to ensure that the IRB staff has recorded them.
         5.3.8.1 Ensure that the required modifications include all final contingencies on "CHECKLIST: Pre-Review."
         5.3.8.2 For a pending financial interest review indicate that a determination that the financial interest is not a conflict of interest or has been eliminated can be verified by a Designated Reviewer, and that if there is a management plan, it must return to the convened IRB for review.
      5.3.9 Entertain a motion by an IRB member.
      5.3.10 Call for a vote.
         5.3.10.1 Only IRB members may vote.
         5.3.10.2 If a member and an alternate are both present, only one may vote.
         5.3.10.3 Consultants may not vote.

¹ "Tabled" is not an action of the IRB, but is a status based on the inability of the IRB to take an action because of reasons of quorum.
### SOP: IRB Meeting Conduct

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<td>HRP-041</td>
<td>12/24/2013</td>
<td>L. Smith</td>
<td>Mary Klein, Ph.D.</td>
<td>2 of 3</td>
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5.3.10.4 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.)

5.3.11 Re-invite IRB members with a Conflicting Interest back into the meeting.

5.3.12 Provide any written information provided by a member or consultant to the IRB staff.

5.4 For each protocol requesting approval:

5.4.1 Ask the primary reviewer to lead the IRB through a discussion of the criteria in the "WORKSHEET: Criteria for Approval and Additional Considerations" and all referenced checklists (listed below) to have the convened IRB determine which regulatory criteria are met (or continue to be met), which are not met (or no longer met), and which would be met if the investigator modified the protocol as requested by the IRB.

5.4.2 Restate the IRB’s consensus regarding protocol specific findings justifying a determination when required by a checklist.

5.4.3 Make a motion for one of the following actions:

5.4.3.1 Approve (with a specific continuing review interval for initial or continuing review): Made when all criteria for approval are met. Include in motions for initial and continuing review the period of approval and the level of risk.

5.4.3.2 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 a Designated Reviewer 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 primary reviewer restates the modifications required by the IRB members and the IRB members’ reasons for those changes.

5.4.3.3 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 members’ reasons for the decision and describes recommendation to make the research approvable.

5.4.3.4 Disapprove: Made when the research does not qualify for Approval or Modifications Required to Secure Approval and the IRB has no recommendations that might make the protocol approvable. When making this motion, the assigned primary reviewer describes the IRB members’ reasons for the decision and gives the investigator an opportunity to respond to the IRB in person or in writing.

5.4.3.5 Suspension or Termination of IRB Approval: Made when current approved research does not qualify for Approval or Modifications Required to Secure Approval. When making this motion, have the primary reviewer use the "WORKSHEET: Review of Information Items" to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects. The assigned primary reviewer describes the IRB member’s reasons for the decision.

5.4.4 For new information (Unanticipated Problem Involving Risks to Subjects or Others, Serious or Continuing Non-Compliance, or Suspension or Termination of IRB Approval):

5.4.4.1 Have the primary reviewer use the "WORKSHEET: Review of Information Items" to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects.

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

5.5 Temporarily adjourn the meeting when notified by IRB staff that quorum has been lost.
5.6 Adjourn the meeting when there is no further business.

6 MATERIALS

6.1 CHECKLIST: Non-Significant Risk Device (FDA)
6.2 CHECKLIST: Pre-Review
6.3 CHECKLIST: Research Involving Cognitively Impaired Adults
6.4 CHECKLIST: Research Involving Children
6.5 CHECKLIST: Research Involving Pregnant Women
6.6 CHECKLIST: Research Involving Prisoners
6.7 CHECKLIST: Waiver or Alteration of the Consent Process
6.8 CHECKLIST: Waiver of Written Documentation of the Consent Process
6.9 CHECKLIST: Waiver of the Consent Process for Planned Emergency Research
6.10 SOP: IRB Meeting Preparation
6.11 WORKSHEET: Advertisements
6.12 WORKSHEET: Payments
6.13 WORKSHEET: Criteria for Approval and Additional Considerations
6.14 WORKSHEET: Criteria for Approval and Additional Considerations for HUD
6.15 WORKSHEET: Evaluation of Quorum and Expertise
6.16 WORKSHEET: Review Materials
6.17 WORKSHEET: Review of Information Items
6.18 WORKSHEET: Short Form of Consent Documentation

7 REFERENCES

7.2 45 CFR §46.109, §46.116, §46.117.