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 None.

3 POLICY
3.1 The IRB reviews research in accordance with the applicable regulatory criteria for approval.
3.2 The IRB chair votes as a regular member.
3.3 If quorum is lost during a meeting, the IRB cannot take votes until the quorum is restored, even if more than half of the members are still present.
3.4 Substantive changes or requirements, requests for more information for IRB consideration, and other issues related to the criteria for approval require review and approval by the convened IRB.
3.5 Minor or prescriptive changes or requirements (modifications required to secure approval) may be reviewed for approval by the IRB chair or a designated individual.
3.6 The worksheets and checklists described in “WORKSHEET: Review Materials (HRP-301)” and listed below in “Section 6: MATERIALS” are provided to IRB members in advance of meetings per “SOP: IRB Meeting Preparation (HRP-040)” to conduct meetings and meet regulatory requirements.
3.7 For Veterans Administration (VA) Research “Substantive Changes” are defined as those ineligible for “Modifications Required to Secure Approval” as defined in this SOP.

4 RESPONSIBILITIES
4.1 The IRB chair 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 involving review of a protocol:
   5.3.1 Table the item when notified by IRB staff when requirements for review of a specific item as defined in “WORKSHEET: Quorum and Expertise (HRP-305)” 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.
      5.3.2.1 For Veterans Administration (VA) research, members with a Conflicting Interest present by teleconference are to 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 Ask the scientific or scholarly reviewer or primary reviewer to present the scientific or scholarly review to the IRB.

\(^1\) “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.
5.3.6 Ask the primary reviewer to lead the IRB through a discussion of the criteria in the “WORKSHEET: Criteria for Approval (HRP-314)” 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.

5.3.7 For new information (Unanticipated Problem Involving Risks to Subjects or Others, Serious Non-Compliance, Continuing Non-Compliance, Suspension of IRB Approval, or Terminations of IRB Approval) have the primary reviewer use the “WORKSHEET: Review of Information Items (HRP-321)” to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects.

5.3.8 Restate the IRB's consensus regarding any protocol specific findings justifying a determination when required by a checklist and not previously determined and documented.

5.3.9 Make a motion for one of the following actions:

5.3.9.1 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.

5.3.9.2 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 an IRB staff member 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 member’s reasons for those changes.

5.3.9.3 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 member’s reasons for the decision and describes recommendation to make the research approvable.

5.3.9.4 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 member’s reasons for the decision.

5.3.9.5 Suspension or Termination: 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 (HRP-321)” 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.

5.3.10 Open the floor for additional discussion.

5.3.11 Review any modifications required to secure approval to ensure that the IRB staff has recorded them.

5.3.11.1 Ensure that the required modifications include any necessary review considerations in the Pre-Review activity.

5.3.11.2 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 the IRB staff, but if there is a management plan that includes
5.3.12 Call for a vote.
   5.3.12.1 Only IRB members may vote.
   5.3.12.2 If a member and an alternate are both present, only one may vote.
   5.3.12.3 Consultants may not vote.
   5.3.12.4 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.)

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

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

5.4 Adjourn the meeting when notified by IRB staff that quorum has been lost or when there is no
further business.

6 MATERIALS

6.1 CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)
6.2 CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)
6.3 CHECKLIST: Pregnant Women (HRP-412)
6.4 CHECKLIST: Non-Viable Neonates (HRP-413)
6.5 CHECKLIST: Neonates of Uncertain Viability (HRP-414)
6.6 CHECKLIST: Prisoners (HRP-415)
6.7 CHECKLIST: Children (HRP-416)
6.8 CHECKLIST: Cognitively Impaired Adults (HRP-417)
6.9 CHECKLIST: Non-significant Risk Device (HRP-317)
6.10 CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)
6.11 SOP: IRB Meeting Preparation (HRP-040)
6.12 WORKSHEET: Review Materials (HRP-301)
6.13 WORKSHEET: Quorum and Expertise (HRP-305)
6.14 WORKSHEET: Pre-Review (HRP-308)
6.15 WORKSHEET: Criteria for Approval (HRP-314)
6.16 WORKSHEET: Advertisements (HRP-315)
6.17 WORKSHEET: Payments (HRP-316)
6.18 WORKSHEET: Short Form of Consent Documentation (HRP-317)
6.19 WORKSHEET: Additional Federal Agency Criteria (HRP-318)
6.20 WORKSHEET: Criteria for Approval for HUD (HRP-323)
6.21 WORKSHEET: Review of Information Items (HRP-321)

7 REFERENCES

7.2 45 CFR §46.109, §46.116, §46.117.