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

2 REVISIONS FROM PREVIOUS VERSION
2.1 Correction of spelling and grammatical errors throughout SOP.
2.2 Replaced all references to “IRB” with “HRRC.”

3 POLICY
3.1 The HRRC reviews research in accordance with the applicable regulatory criteria for approval.
3.2 The HRRC chair votes as a regular member.
3.3 If quorum is lost during a meeting, the HRRC cannot take further action or vote until the quorum is restored, even if more than half of the members are still present. Reference “WORKSHEET: Quorum and Expertise (HRP-305)” for quorum requirements.
3.4 Investigator conformance or compliance with minor or prescriptive changes or requirements (modifications required to secure approval) may be verified by the HRRC chair or a designated individual.
3.5 When substantive changes or requirements, requests for more information for HRRC consideration, and other issues related to the criteria for approval are required by the HRRC, these submissions do not qualify for “approval” or “modifications required to secure approval.” In such cases, the submission is deferred and requires review and approval by the convened HRRC.
3.5.1 “Substantive Changes” are defined as those ineligible for “Modifications Required to Secure Approval” as defined in the procedures section of this SOP.
3.6 The worksheets and checklists listed below in “Section 6: MATERIALS” are available to HRRC members in advance of meetings per “SOP: HRRC Meeting Preparation (HRP-040)” to conduct meetings and evaluate regulatory requirements.
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4 RESPONSIBILITIES
4.1 The HRRC chair, vice chair or designated member when the chair is not present, carries out these procedures.
4.2 The HRRC Chair leads HRRC members through consideration of the regulatory criteria for approval.

5 PROCEDURE
5.1 Call the meeting to order.
5.2 Ask HRRC members whether anyone has a Conflict of Interest in any item on the agenda. The HRPO staff member notes the responses. Reference “SOP: Conflicting Interests of HRRC Members (HRP-050).”
5.3 For each business item involving review of a protocol:
  5.3.1 Table the item when notified by HRPO staff that 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 HRRC members with a Conflict of Interest, invite the HRRC 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 Conflict of Interest present by teleconference are to disconnect for discussion and voting.
  5.3.3 HRRC members and consultants with a conflict of interest are not counted toward quorum for the conflicted study.
  5.3.4 HRRC members with a conflict are documented in the minutes as being absent for discussion and voting for the conflicted study with an indication that a conflict of interest was the reason for the absence.
  5.3.5 If there is a consultant present, ask the consultant to present his or her review to the HRRC.
  5.3.6 If a consultant provided written information to the HRRC, present that information to the HRRC.
  5.3.7 Ask the scientific or scholarly reviewer or primary reviewer to present the scientific or scholarly review to the HRRC.
  5.3.8 Ask the primary reviewer(s) to lead the HRRC through a discussion of his/her review of the submission. The HRRC chair will then lead the discussion through the approval criteria in the HRRC Chair Guide” and all referenced checklists (listed below) to have the convened HRRC 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 HRRC.
  5.3.9 For new information (Unanticipated Problem Involving Risks to Subjects or Others, Serious Non-Compliance, Continuing Non-Compliance, Suspension of HRRC Approval, or Terminations of HRRC Approval) have the primary reviewer use the "WORKSHEET: Review of Information Items (HRP-321)" to lead the convened HRRC through a discussion of what actions are needed, if any, to protect subjects.

¹ “Tabled” is not an action of the HRRC, but is a status based on the inability of the HRRC to take an action because of reasons of quorum.
5.3.10 Restate the HRRC's consensus regarding any protocol specific findings justifying a determination when required by a checklist and not previously determined and documented.

5.3.11 Make a motion for one of the following actions:

5.3.11.1 Approve (with a specific continuing review interval for initial or continuing review): Made when all criteria for approval are met and there are no conditions or contingencies that have to be satisfied before the approval can become effective. Include in motions for initial and continuing review the period of approval and the level of risk.

5.3.11.2 Modifications Required to Secure Approval (with a specific continuing review interval for initial or continuing review): Made when HRRC members require specific minor or prescriptive modifications such that an HRPO staff member or HRRC chair can verify 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 or HRRC chair restates the modifications required by the HRRC members and the HRRC member's reasons for those changes.

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

5.3.11.4 Disapprove: Made when the research does not qualify for Approval or Modifications Required to Secure Approval and the HRRC has no recommendations that might make the protocol approvable. When making this motion, the assigned primary reviewer or the HRRC chair describes the HRRC member's reasons for the decision.

5.3.11.5 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 HRRC through a discussion of what actions are needed, if any, to protect subjects. The assigned primary reviewer or the HRRC chair describes the HRRC member's reasons for the decision.

5.3.12 Open the floor for additional discussion.

5.3.13 Review any modifications required to secure approval to ensure that the HRPO staff has accurately recorded them.

5.3.13.1 Review recommended contingencies and special determinations provided by staff in the Pre-Review. Ensure that the required modifications include all final contingencies in the Pre-Review activity and that the special determinations remain accurate. Have the HRPO staff edit the Pre-Review, if necessary.
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5.3.13.2 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 HRRC staff, but if there is a management plan, it must return to the convened HRRC for review.

5.3.14 Call for a vote.
5.3.14.1 Only HRRC members may vote.
5.3.14.2 If a member and an alternate are both present, only one may vote.
5.3.14.3 Consultants may not vote.
5.3.14.4 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.)

5.3.15 Re-invite HRRC members with a Conflict of Interest back into the meeting.
5.3.16 Provide any written information provided by a member or consultant to the HRPO staff to be uploaded with the meeting minutes.

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

6 MATERIALS
6.1 CHECKLIST: Pre-Review (HRP-401)
6.2 CHECKLIST: Committee Review Recommendations (HRP-403.XX)
6.3 CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)
6.4 CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)
6.5 CHECKLIST: Pregnant Women (HRP-412)
6.6 CHECKLIST: Non-Viable Neonates (HRP-413)
6.7 CHECKLIST: Neonates of Uncertain Viability (HRP-414)
6.8 CHECKLIST: Prisoners (HRP-415)
6.9 CHECKLIST: Children (HRP-416)
6.10 CHECKLIST: Cognitively Impaired Adults (HRP-417)
6.11 CHECKLIST: Non-significant Risk Device (HRP-317)
6.12 CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)
6.13 SOP: IRB/HRRC Meeting Preparation (HRP-040)
6.14 WORKSHEET: Review Materials (HRP-301)
6.15 WORKSHEET: Quorum and Expertise (HRP-305)
6.16 WORKSHEET: Criteria for Approval (HRP-314)
6.17 WORKSHEET: Advertisements (HRP-315)
6.18 WORKSHEET: Payments (HRP-316)
6.19 WORKSHEET: Short Form of Consent Documentation (HRP-317)
6.20 WORKSHEET: Additional Federal Agency Criteria (HRP-318)
6.21 WORKSHEET: Criteria for Approval for HUD (HRP-323)
6.22 WORKSHEET: Review of Information Items (HRP-321)

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