1. PURPOSE
   1. This procedure establishes the process to conduct convened meetings.
   2. The process begins when the IRB members gather for a convened meeting.
   3. The process ends when the meeting is adjourned.
2. REVISIONS FROM PREVIOUS VERSION
   1. None.
3. POLICY
   1. The IRB reviews research in accordance with the applicable regulatory criteria for approval.
   2. The IRB chair votes as a regular member.
   3. IRB attendance is captured by documenting in the IRB meeting minutes the IRB members and alternates in attendance, replacement of a voting member by an alternate, and IRB members who are recused due to a conflicting interest.
   4. 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.
   5. 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.
   6. Minor or prescriptive changes or requirements (modifications required to secure approval) may be reviewed for approval by the IRB chair or a designated individual.
   7. 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.
4. RESPONSIBILITIES
   1. The IRB chair carries out these procedures, unless otherwise noted.
5. PROCEDURE
   1. Call the meeting to order.
   2. Remind IRB members not to vote on any voting item on the agenda if they have a Conflicting Interest in that item.
   3. Ask IRB members if there are any questions about the report of completed non-committee reviews that was made available to the IRB prior to the meeting.
   4. For each agenda item:
      1. Table the item when notified by IRB staff that requirements for review of a specific item are not met, or consider whether the item can be reviewed on an expedited basis.
      2. If there are IRB members with a Conflicting Interest for consideration of new submissions, 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. For items on the agenda for continuing review or modification, IRB members that have a Conflicting Interest may remain in the meeting room, but will not vote regarding that research.
   5. For each agenda item involving the initial review, modification, or continuing review of a protocol:
      1. If there is a consultant present, ask the consultant to present his or her review to the IRB.
      2. If a consultant provided written information to the IRB, ask the primary reviewer to present that information to the IRB.
      3. If applicable, ask the PRC administrative reviewer or primary reviewer to present the scientific or scholarly review to the IRB.
      4. Ask the primary reviewer to lead the IRB through a discussion of the criteria in the Reviewer Checklist 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. The IRB will review COI status for each PI or Co-Investigator for all New Projects and Continuing Reviews to confirm that either: (1) There is no conflict for each PI or Co-Investigator, or (2) If there is a conflict identified for a PI and/or Co-I, the Board will prescribe a management plan.
      6. Restate the IRB’s consensus regarding any protocol specific findings justifying a determination when required by a checklist and not previously determined and documented.
      7. Invite a IRB member to make a motion for one of the following actions:
         1. Approve (with a specific continuing review interval for initial or continuing review when applicable): 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.
         2. Modifications Required to Secure Approval (with a specific continuing review interval for initial or continuing review when applicable): 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
         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.
         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. Suspension or Termination: Made when current approved research does not qualify for Approval or Modifications Required to Secure Approval. The assigned primary reviewer describes the IRB member’s reasons for the decision.
      8. Review any modifications required to secure approval to ensure that the IRB staff has recorded them.
         1. For a financial interest review, ensure that the IRB staff can verify that the IRB has determined that: (1) the financial interest is not a conflict of interest, (2) the financial interest has been eliminated, or (3) the financial interest can be eliminated through a management plan.
   6. For each agenda item that is 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):
      1. Have the primary reviewer lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects.
      2. Restate the IRB’s consensus regarding any actions that need to be taken to protect subjects.
      3. Make a motion for the IRB’s determination(s) regarding the action items (e.g. the motion is for the Principal Investigator to provide the IRB additional information regarding the status of currently enrolled subjects).
      4. Open the floor for additional discussion.
      5. Call for a vote.
         1. Only IRB members may vote.
         2. If a member and an alternate are both present, only one may vote.
         3. Consultants may not vote.
         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.)
      6. Re-invite IRB members with a Conflicting Interest back into the meeting, as applicable.
   7. Adjourn the meeting when notified by IRB staff that quorum has been lost or when there is no further business.
6. MATERIALS
   1. SOP: IRB Meeting Preparation (HRP-040)
7. REFERENCES
   1. 21 CFR §50.20, §50.25, §50.27, §56.109, §56.111.
   2. 45 CFR §46.109, §46.116, §46.117.