

SOP: IRB Meeting Conduct				
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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 Administrative and current procedural updates.
- 2.2 Information about continuing review of research.
- 2.3 Removed stipulation that the IRB makes decisions about whether or not a COI exists.
- 2.4 Clarified “block voting” process when reviewing continuing review. Formatting updates for clarity

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 may be reviewed for approval by the IRB chair or a Designated Reviewer or a designated IRB staff member.
- 3.6 The list of protocols approved using the expedited procedure (initial reviews, continuing reviews, and reviews of modifications to previously approved research), including 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).” The materials are used to conduct meetings and meet regulatory requirements. No other technology is used to conduct meetings or meet regulatory requirements.

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: Evaluation of 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.
 - 5.3.3 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. (See “WORKSHEET: Scientific or Scholarly Review (HRP-320)
 - 5.3.6 Ask the primary reviewer to lead the IRB through a discussion of the criteria in the “WORKSHEET: Criteria for Approval and Additional Considerations (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.

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.

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5.3.7 For new information (Unanticipated Problem Involving Risks to Subjects or Others, Serious or Continuing Non-Compliance, or Suspension or Termination 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 For continuing review of research, the IRB determines:

- 5.3.8.1 Whether the protocol needs verification from sources other than the researchers that no material changes had occurred since previous IRB review.
- 5.3.8.2 Whether the current consent document is still accurate and complete.
- 5.3.8.3 Whether any significant new findings that arise from the review process and that might relate to participants' willingness to continue participation will be provided to participants.

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

5.3.10 Make a motion for one of the following actions:

- 5.3.10.1 Approve: Made when all criteria for approval are met. Include in motions for initial and continuing review the period of approval or a statement that no continuing review is required and the level of risk. When making this motion, have the primary reviewer use the “WORKSHEET: Approval Periods (HRP-319)” to lead the convened IRB through a discussion of the appropriate approval period.
- 5.3.10.2 Modifications Required to Secure Approval: Made when IRB members require specific modifications such that an IRB staff member, IRB Chair, or 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, the reasons for those changes, the level of risk, and the approval period or a statement that no continuing review is required. When making this motion, have the primary reviewer use the “WORKSHEET: Approval Periods (HRP-319)” to lead the convened IRB through a discussion of the appropriate approval period. If the research expires before the conditions are reviewed and approved, all research activities must stop until approval is obtained.
- 5.3.10.3 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.
- 5.3.10.4 Disapprove: Made when the research does not qualify for Approval, Modifications Required to Secure Approval, or Deferral 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.
- 5.3.10.5 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 (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.
- 5.3.10.6 Unanticipated problem involving risks to subjects or others: Made when an event occurs in the study that is unexpected, related, or probably related, and indicates there are risks to subjects that were previously unknown.
- 5.3.10.7 Open the floor for additional discussion.

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

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recorded them. Ensure that the required modifications include all final contingencies on 'CHECKLIST: Pre-Review (HRP 401), or equivalent.

5.3.12 When a financial conflict of interest is reported, the Committee will review the reported related financial interest as outlined in HRP-055.

5.3.13 Call for a vote.

5.3.13.1 Only IRB members may vote.

5.3.13.2 If a member and an alternate are both present, only one may vote.

5.3.13.3 Consultants may not vote.

5.3.13.4 Only core IRB members' votes will be counted and documented in the meeting minutes. If the minutes specify the substitution of an alternate member for a core member, the alternate member's vote is counted for items reviewed while they acted as a substitute.

5.3.13.5 For a motion to be approved, it needs the approval of more than half of the voting 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.)

5.3.13.6 The IRB may vote on a group of studies (block voting) during the continuing review of research after all members have had the opportunity to thoroughly consider and discuss the studies individually and convey any concerns prior to the voting. Additionally, members have the option to vote in favor of certain studies, to vote against others, or to abstain from others.

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

5.3.15 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: Pre-Review (HRP-401)

6.2 CHECKLIST: Waiver or Alteration of the Consent Process (HRP-410)

6.3 CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)

6.4 CHECKLIST: Pregnant Women (HRP-412)

6.5 CHECKLIST: Non-Viable Neonates (HRP-413)

6.6 CHECKLIST: Neonates of Uncertain Viability (HRP-414)

6.7 CHECKLIST: Prisoners (HRP-415)

6.8 CHECKLIST: Children (HRP-416)

6.9 CHECKLIST: Cognitively Impaired Adults (HRP-417)

6.10 CHECKLIST: Non-significant Risk Device (HRP-418)

6.11 CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)

6.12 CHECKLIST: HIPAA Waiver of Authorization (HRP-441)

6.13 SOP: IRB Meeting Preparation (HRP-040)

6.14 WORKSHEET: Review Materials (HRP-301)

6.15 WORKSHEET: Evaluation of Quorum and Expertise (HRP-305)

6.16 WORKSHEET: Criteria for Approval and Additional Considerations (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 and Additional Considerations for HUD (HRP-323)

6.22 WORKSHEET: Review of Information Items (HRP-321)

6.23 WORKSHEET: Approval Periods (HRP-319)

7 REFERENCES

7.1 21 CFR §50.20, §50.25, §50.27, §56.109, §56.111.

7.2 45 CFR §46.109, §46.116, §46.117.