

SOP: IRB Meeting Conduct

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 (and vice chair, where applicable), votes as a regular member.
- 3.3 Meetings are conducted in person or via teleconference.
- 3.4 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, attendance of IRB members who participate through teleconference, and IRB members who are recused due to a conflicting interest. Members are absent when recused and do not count towards quorum while recused.
- 3.5 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.
- 3.6 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.
- 3.7 Minor or prescriptive changes or requirements (modifications required to secure approval) may be reviewed for approval by the IRB chair or a designated individual.
- 3.8 The documents, worksheets, and checklists described in HRP-301 - WORKSHEET - Review Materials are provided to IRB members in advance of meetings per HRP-040 - SOP - IRB Meeting Preparation to conduct meetings and meet regulatory requirements.

4 RESPONSIBILITIES

- 4.1 The IRB chair carries out these procedures, unless otherwise noted.
- 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 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.
- 5.4 For each agenda item:
 - 5.4.1 Table the item when notified by IRB staff that requirements for review of a specific item as defined in HRP-305 - WORKSHEET - Quorum and Expertise are not met.ⁱ

- 5.4.2 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.
- 5.5 For each agenda item involving the initial review, modification or continuing review of a protocol:
 - 5.5.1 If there is a consultant present, ask the consultant to present his or her review to the IRB.
 - 5.5.2 If a consultant provided written information to the IRB, ask the primary reviewer to present that information to the IRB.
 - 5.5.3 Ask the scientific or scholarly reviewer or primary reviewer to present the scientific or scholarly review to the IRB.
 - 5.5.4 Ask the primary reviewer to lead the IRB through a discussion of the criteria in HRP-314 - WORKSHEET - Criteria for Approval 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.
 - 5.5.5 Restate the IRB's consensus regarding any protocol specific findings justifying a determination when required by a checklist and not previously determined and documented.
 - 5.5.6 Make a motion for one of the following actions:
 - 5.5.6.1 Approve (with a specific continuing review interval for initial or continuing review when applicable): Made when all criteria for approval are met.
 - 5.5.6.2 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.
 - 5.5.6.3 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.
 - 5.5.6.4 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.
 - 5.5.6.5 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 HRP-321 - 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.
 - 5.5.7 For motions of "Approval" or "Modifications Required to Secure Approval", for initial and continuing reviews, include the risk level and approval period. Confirm whether the continuing review interval should be annual, or more frequently than annual based on considerations such as the nature and level of risks, the degree of uncertainty regarding the

risks, subject vulnerability, investigator experience, the IRB's experience with the investigator or sponsor, the projected rate of subject enrollment, or whether the study involves novel procedures.

- 5.5.8 For modifications in response to a previous Suspension of IRB approval:
 - 5.5.8.1 Have the primary reviewer summarize any corrective actions taken by the Principal Investigator.
 - 5.5.8.2 Based on this new information, determine whether the corrective actions are sufficient to address the issues that prompted the suspension.
 - 5.5.8.2.1 If not, make an appropriate motion and identify the additional action items are required to protect subjects.
- 5.5.9 Review any modifications required to secure approval to ensure that the IRB staff has recorded them.
 - 5.5.9.1 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, it must return to the convened IRB for review.
- 5.6 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):
 - 5.6.1 Have the primary reviewer use HRP-321 - WORKSHEET - Review of Information Items to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects.
 - 5.6.2 Restate the IRB's consensus regarding any actions that need to be taken to protect subjects.
 - 5.6.3 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).
- 5.7 Open the floor for additional discussion.
- 5.8 Call for a vote.
- 5.9 Only IRB members may vote.
 - 5.9.1 If a member and an alternate are both present, only one may vote.
 - 5.9.1.1 Consultants may not vote.
 - 5.9.1.2 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.)
- 5.10 Re-invite IRB members with a Conflicting Interest back into the meeting.
- 5.11 Provide any written information provided by a member or consultant to the IRB staff.
- 5.12 Adjourn the meeting when notified by IRB staff that quorum has been lost or when there is no further business.

6 MATERIALS

- 6.1 HRP-040 - SOP - IRB Meeting Preparation
- 6.2 HRP-301 - WORKSHEET - Review Materials
- 6.3 HRP-305 - WORKSHEET - Quorum and Expertise
- 6.4 HRP-314 - WORKSHEET - Criteria for Approval
- 6.5 HRP-321 - WORKSHEET - Review of Information Items

6.6

7 REFERENCES

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

7.2 45 CFR §46.109, §46.111, §46.116, §46.117.

7.3 AAHRPP elements I.1.F, I.5.A, I.5.D, I.6.B, I.7.A, I-9, II.1.B, II.1.D, II.1.E, II.2.D, II.2.G, II.2.E-II.2.E.2, II.2.F-II.2.F.3

ⁱ “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.