SOP: IRB Meeting Conduct and HRPP After Action

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1 PURPOSE

1.1 This procedure establishes the process to conduct convened IRB meetings.
1.2 The process begins when the IRB members gather for a convened meeting.
1.3 The process ends when all decision letters are distributed to the principal investigators with protocols considered during the meeting.

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 vote as a regular members.
3.3 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, attendance of IRB members who participate through teleconference, and IRB members who are recused due to a conflicting interest.
3.4 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.
3.5 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 full (convened) IRB.
3.6 Minor or prescriptive changes or requirements (modifications required to secure approval) may be reviewed for approval by the IRB chair or a designated individual.
3.7 If requested by the HRPP Director or IRB Chair, HRPP Protocol Coordinators with agenda items must attend the meeting to serve the following functions:
  3.7.1 To serve as a resource to IRB members regarding the protocol, related regulations, and the pre-review;
  3.7.2 To document the IRB's decision regarding the protocol, any revision requests, and other pertinent information to include in the PI decision letter template
3.8 For the purposes of accurate note taking and documentation of IRB decisions, IRB meetings are recorded.
  3.8.1 Any meeting participant can request a pause of the recording at any time.
  3.8.2 Once meeting minutes are complete, recordings are deleted.
3.9 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

4.1 The IRB chair carries out procedures listed in section 5 below. In the absence of the chair the vice chair may preside over convened meetings. If neither the chair nor the vice chair is present, an experienced member of the IRB may be temporarily appointed as "acting chair" by the IRB chair.
4.2 Primary reviewers lead IRB members through consideration of the regulatory criteria for approval.
4.3 IRB members may consult external experts, HRPP staff, PIs, and other study staff for additional information as needed, however, only IRB members participate in the deliberation and voting.

4.4 The HRPP Administrative Assistant takes the meeting minutes (SOP: IRB Meeting Minutes, HRP-043).

5 PROCEDURE

5.1 The HRPP Administrative Specialist starts the meeting recording when the IRB Chair (or designee) is ready to begin.

5.1.1 The recording is stopped after the IRB training tidbit and a new recording is started to capture the IRB meeting. The training tidbits are retained separately and used for training.

5.2 IRB Chair (or designee) calls the meeting to order and notes whether quorum is achieved.

5.3 IRB Chair (or designee) asks IRB members if there are any questions about the report of completed non-committee reviews that was made available to the IRB before the meeting.

5.4 For each agenda item involving the initial review, amendment, or continuing review of a protocol:

5.4.1 If there is a consultant present, ask the consultant to present his or her review to the IRB.

5.4.2 If a consultant provided written information to the IRB, ask the primary reviewer to present that information to the IRB.

5.4.3 If applicable, ask the scientific or scholarly reviewer or primary reviewer to present the scientific or scholarly review to the IRB.

5.4.4 The primary reviewer asks whether any IRB member has a Conflicting Interest

5.4.5 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 full (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.

5.4.6 If applicable, invite the principal investigator(s) to join the meeting. The IRB members should ask the investigator(s) to provide any additional information or clarifications that would assist them in making a decision about approving the research. The investigators(s) should be given the opportunity to ask any questions about the process and procedures that will help them understand the review process and what will happen after the meeting.

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

5.4.8 Make a motion for one of the following actions:

5.4.8.1 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.

5.4.8.2 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 HRPP 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

5.4.8.3 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.

5.4.8.4 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.

5.4.8.5 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 full (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.

5.4.9 Review any modifications required to secure approval to ensure that the HRPP staff has recorded them.

5.4.9.1 Ensure that the required modifications include all final contingencies on "CHECKLIST: Pre-Review (HRP-401)."

5.4.9.2 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 HRPP staff, but if there is a management plan, it must return to the full (convened) IRB for review.

5.5 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):

5.5.1 Have the primary reviewer use the "WORKSHEET: Review of Information Items (HRP-321)" to lead the full (convened) IRB through a discussion of what actions are needed, if any, to protect subjects.

5.5.2 Restate the IRB's consensus regarding any actions that need to be taken to protect subjects.

5.5.3 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).

5.5.4 Open the floor for additional discussion.

5.5.5 Call for a vote.

5.5.5.1 Only IRB members may vote.

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

5.5.5.3 Neither consultants nor non-member HRPP staff may vote.

5.5.5.4 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.)

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

5.5.7 Provide any written information provided by a member or consultant to the HRPP staff.

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

5.7 Following the board meeting the HRPP staff will debrief and discuss next steps for each action.

5.7.1 Protocol coordinators with agenda items must attend the meeting – attendance is optional for other coordinators.

5.7.2 The IRB Chair provides a general overview of the meeting and provide the outcome for each action on the agenda along with detailed information for any action that will require each protocol.

5.7.3 The respective protocol coordinator is responsible for drafting the decision letters and revisions requests. The protocol coordinators can access any notes taken during the meeting and the recording of the meeting as needed.

5.7.4 The draft decision letters and revision request should be completed within 24 hours of the debriefing discussion and sent to the IRB Chair for review.

5.7.5 Once the IRB Chair approves the drafts, the HRPP Administrative Specialist will send the decision letters to the research team.

5.7.6 Once meeting minutes are approved during the following IRB meeting, the HRPP Administrative Specialist deletes the meeting recording.

6 MATERIALS

6.1 CHECKLIST: Pre-Review (HRP-401)
6.2 CHECKLIST: Waiver or Alteration of 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: Prisoners (HRP-415)
6.6 CHECKLIST: Minors (HRP-416)
6.7 CHECKLIST: Cognitively Impaired Adults (HRP-417)
6.8 CHECKLIST: Non-significant Risk Device (HRP-317)
6.9 CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)
6.10 SOP: IRB Meeting Preparation (HRP-040)
6.11 WORKSHEET: Review Materials (HRP-301)
6.12 WORKSHEET: Quorum and Expertise (HRP-305)
6.13 WORKSHEET: Pre-Review (HRP-308)
6.14 WORKSHEET: Criteria for Approval (HRP-314)
6.15 WORKSHEET: Advertisements (HRP-315)
6.16 WORKSHEET: Payments (HRP-316)
6.17 WORKSHEET: Short Form of Consent Documentation (HRP-317)
6.18 WORKSHEET: Additional Federal Agency Criteria (HRP-318)
6.19 WORKSHEET: Criteria for Approval for HUD (HRP-323)
6.20 WORKSHEET: Review of Information Items (HRP-321)

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.