



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 11/13/2013
- 2.2 08/08/2014
- 2.3 06/13/2014

3 GUIDING PRINCIPLES

- 3.1 All IRB Members will have access to the same review materials whether they attend in person or remotely via an electronic mechanism.
- 3.2 The IRB reviews research in accordance with the applicable regulatory criteria for approval.
- 3.3 The IRB chair votes as a regular member.
- 3.4 IRB members who have a conflict of interest with the research under review may participate in the review but must leave the room or be placed on hold during the deliberation and vote.
- 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 may be reviewed for approval by the IRB chair or designee.
- 3.8 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)."
- 3.9 Worksheets containing the criteria for approval and other materials being reviewed are projected by HSRO staff upon request of an IRB Member.

4 RESPONSIBILITIES

- 4.1 The IRB chair, Vice-Chair or other designee carries out these procedures.
- 4.2 Primary reviewers lead IRB members through consideration of the regulatory criteria for approval.
- 4.3 HSRO Staff provide review materials to the IRB members, monitor quorum, and ensure agenda is completed.

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 that requirements for review of a specific item as defined in "WORKSHEET: Quorum and Expertise (HRP-305)" are not met.
 - 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 primary reviewer to present the scientific or scholarly review to the IRB.
 - 5.3.6 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 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.



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- 5.3.7 For new information (Unanticipated Problem Involving Risks to Subjects or Others, Suspension of IRB Approval, or Terminations 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 If a conflict of interest exists, review the conflict.
 - 5.3.8.1 If a management plan has been approved by the Conflict of Interest Committee (COIC), consider whether the plan adequately eliminates/reduces the risk of bias.
 - 5.3.8.2 If the management plan has not yet been approved by the COIC, the IRB has two options:
 - 5.3.8.2.1 Assign a management plan and require the investigator to adhere to the plan.
 - 5.3.8.2.2 Table the review pending receipt of the management plan.
 - 5.3.8.3 If the first option is chosen:
 - 5.3.8.3.1 HSRO staff will obtain the management plan developed by the COIC and compare that plan to the plan developed by the IRB for consistency.
 - 5.3.8.3.2 If the COIC-approved plan is identical to or more stringent than the IRB approved plan, HSRO staff may give final approval to the submission if all other requirements to secure approval are met
 - 5.3.8.3.2.1 The IRB approval letter will require the investigator to comply with the plan developed by the COIC.
 - 5.3.8.3.3 If the COIC-approved plan is less stringent than the IRB approved plan:
 - 5.3.8.3.4 HSRO staff will notify the COIC of the discrepancy and determine whether there is additional information relating to the conflict for IRB review;
 - 5.3.8.3.5 If additional information exists, HSRO staff will schedule the submission for IRB Committee review for reconsideration.
 - 5.3.8.3.6 If additional information does not exist, the IRB's determination will stand and the IRB approval letter will include the COI management plan determined by the IRB.
 - 5.3.8.3.6.1 HSRO will send a copy of the approval letter to the COIC.
- 5.3.9 The Chair or presenter will restate the IRB's consensus regarding any protocol specific findings justifying a determination when required by a checklist and not previously determined and documented.
- 5.3.10 Make a motion for one of the following actions:
 - 5.3.10.1 Approve (with a specific continuing review interval for initial or continuing review): 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.
 - 5.3.10.1.1 Approve also includes 'Approved with modification': Made when IRB members make specific modifications to the research consent form(s) in order to grant approval.
 - 5.3.10.2 Modifications Required to Secure Approval (with a specific continuing review interval for initial or continuing review):
 - 5.3.10.2.1 Made when the IRB or expedited reviewer requires 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.



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- 5.3.10.2.2 When making this motion, the designated reviewer restates the modifications required by the IRB or expedited reviewer and the reasons for those changes
- 5.3.10.3 Table: Made when the IRB cannot approve the research at a meeting for reasons unrelated to the research, such as loss of quorum.
 - 5.3.10.3.1 When taking this action, the IRB automatically schedules the research for review at the next meeting.
- 5.3.10.4 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.
 - 5.3.10.4.1 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.
- 5.3.10.5 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.
 - 5.3.10.5.1 When making this motion, the assigned primary reviewer describes the IRB member's reasons for the decision.
- 5.3.10.6 Suspension or Termination: Made when current approved research does not qualify for Approval or Modifications Required to Secure Approval.
 - 5.3.10.6.1 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.
 - 5.3.10.6.2 The assigned primary reviewer describes the IRB member's reasons for the decision.
- 5.3.11 Open the floor for additional discussion.
- 5.3.12 Review any modifications required to secure approval to ensure that the HSRO staff has recorded them.
- 5.3.13 Call for a vote.
 - 5.3.13.1 Only IRB members may vote
 - 5.3.13.2 The IRB Chair and Vice-Chair are voting members of the IRB
 - 5.3.13.3 If a member and an alternate are both present, only one may vote.
 - 5.3.13.4 Consultants may not vote.
 - 5.3.13.5 For a motion to be approved, it needs the approval of more than half of the members at the meeting (If 9 members are present, 5 votes are required for approval)
 - 5.3.13.6 Re-invite IRB members with a Conflicting Interest back into the meeting.
 - 5.3.13.7 Provide any written information provided by a member or consultant to the HSRO staff
- 5.4 Adjourn the meeting when notified by HSRO 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 Consent Process (HRP-410)
- 6.2 CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)
- 6.3 CHECKLIST: HIPAA Waiver of Authorization (HRP-441)
- 6.4 CHECKLIST: Pregnant Women (HRP-412)
- 6.6 CHECKLIST: Non-Viable Neonates (HRP-413)
- 6.5 CHECKLIST: Neonates of Uncertain Viability (HRP-414)



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- 6.6 CHECKLIST: Prisoners (HRP-415)
- 6.7 CHECKLIST: Cognitively Impaired Adults (HRP-417)
- 6.8 CHECKLIST: Devices (HRP-317)
- 6.9 SOP: IRB Meeting Preparation (HRP-040)
- 6.10 WORKSHEET: Review Materials (HRP-301)
- 6.11 WORKSHEET: Quorum and Expertise (HRP-305)
- 6.12 WORKSHEET: Criteria for Approval (HRP-314)
- 6.13 WORKSHEET: Informed Consent (HRP-314B)
- 6.14 WORKSHEET: Advertisements (HRP-315)
- 6.15 WORKSHEET: Payments (HRP-316)
- 6.16 WORKSHEET: Short Form of Consent Documentation (HRP-317)
- 6.17 WORKSHEET: Additional Federal Agency Criteria (HRP-318)
- 6.18 WORKSHEET: Criteria for Approval for HUD (HRP-323)
- 6.19 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.