HRP-041 | 03/01/2024 | Author: T. Bechert | Approver: S. Brooks

**SOP: IRB Meeting Conduct**

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. Added consideration of meeting recordings and summary of voting (section 5.12.1.3); 10/6/23.
3. **POLICY**
	1. The IRB reviews research in accordance with the applicable regulatory criteria for approval.
	2. The IRB chair (and vice chair, where applicable), votes as a regular member.
	3. Meetings are conducted in person or via teleconference.
	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.
	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.
	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.
	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.
	8. The worksheets and checklists described in HRP-301 - WORKSHEET - Review Materials and listed below in “Section 6: MATERIALS” are provided to IRB members in advance of meetings per HRP-040 - SOP - IRB Meeting Preparation to conduct meetings and meet regulatory requirements.
	9. For Veterans Administration (VA) Research “Substantive Changes” are defined as those ineligible for “Modifications Required to Secure Approval” as defined in this SOP.
	10. Meeting recordings are not required but are not prohibited. When recordings are obtained, they are subject to IRB record retention and disposal procedures.
4. **RESPONSIBILITIES**
	1. The IRB chair carries out these procedures, unless otherwise noted.
	2. Primary reviewers lead IRB members through consideration of the regulatory criteria for approval.
5. **PROCEDURE**
	1. The IRB Coordinator may choose to record virtual meetings.
	2. Call the meeting to order.
	3. Ask IRB members whether anyone has a Conflicting Interest in any item on the agenda and note the responses.
	4. 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. Ask IRB members if there are any questions about the prior meeting minutes.
		1. The IRB acknowledges receipt of the finalized minutes.
	6. For each agenda item:
		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.[[1]](#footnote-1)
		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.
			1. For Veterans Administration (VA) research, members with a Conflicting Interest present by teleconference are to disconnect for discussion and voting.
	7. 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. Ask the scientific or scholarly 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 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. Restate the IRB’s consensus regarding any protocol specific findings justifying a determination when required by a checklist and not previously determined and documented.
		6. 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 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.
		7. Obtain a second to the motion.
		8. Review any modifications required to secure approval to ensure that the IRB staff has recorded them.
			1. Ensure that the required modifications include all final contingencies in the Pre-Review activity.
			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 IRB staff, but if there is a management plan, it must return to the convened IRB for review.
	8. 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 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.
		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. For submissions in response to a previous Suspension of IRB approval:
			1. Have the primary reviewer summarize any corrective actions taken by the Principal Investigator.
			2. Based on this new information, determine whether the corrective actions are sufficient to address the issues that prompted the suspension.
			3. Make a motion for the IRB’s determination to either lift the suspension of IRB approval or that additional action items are required to protect subjects.
		5. Obtain a second to the motion.
	9. Open the floor for additional discussion.
	10. Amend the original motion as indicated after board deliberation.
		1. Obtain a second to the amended motion.
	11. Call for a vote.
	12. Only IRB members may vote.
		1. If a member and an alternate are both present, only one may vote.
			1. Consultants may not vote.
			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.)
			3. The meeting coordinator will summarize the vote, including HRPP processes to facilitate the actions of the vote where reportable findings occur.
	13. Re-invite IRB members with a Conflicting Interest back into the meeting.
	14. Provide any written information provided by a member or consultant to the IRB staff.
	15. Adjourn the meeting when notified by IRB staff that quorum has been lost or when there is no further business.
	16. Upload meeting recording files to the shared drive.
6. **MATERIALS**
	1. HRP-040 - SOP - IRB Meeting Preparation
	2. HRP-301 - WORKSHEET - Review Materials
	3. HRP-305 - WORKSHEET - Quorum and Expertise
	4. HRP-308 - WORKSHEET - Pre-Review
	5. HRP-314 - WORKSHEET - Criteria for Approval
	6. HRP-315 - WORKSHEET - Advertisements
	7. HRP-316 - WORKSHEET - Payments
	8. HRP-317 - WORKSHEET - Short Form of Consent Documentation
	9. HRP-318 - WORKSHEET - Additional Federal Agency Criteria
	10. HRP-321 - WORKSHEET - Review of Information Items
	11. HRP-323 - WORKSHEET - Criteria for Approval HUD
	12. HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process
	13. HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent
	14. HRP-412 - CHECKLIST - Pregnant Women
	15. HRP-413 - CHECKLIST - Non-Viable Neonates
	16. HRP-414 - CHECKLIST - Neonates of Uncertain Viability
	17. HRP-415 - CHECKLIST - Prisoners
	18. HRP-416 - CHECKLIST - Children
	19. HRP-417 - CHECKLIST - Cognitively Impaired Adults
	20. HRP-418 - CHECKLIST - Non-Significant Risk Device
	21. HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research
	22. HRP-441 - CHECKLIST - HIPAA Waiver of Authorization
7. **REFERENCES**
	1. 21 CFR §50.20, §50.25, §50.27, §56.109, §56.111.
	2. 45 CFR §46.109, §46.116, §46.117.
	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
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. [↑](#footnote-ref-1)