	SOP: IRB Meeting Conduct – Committee Review		
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1 PURPOSE


- 1.1 This SOP establishes the process to conduct convened meetings.
- 1.2 The process begins when the meeting is called to order.
- 1.3 The process ends when the meeting is adjourned.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 Revised from the 5/30/2017 version
- 2.2 Revised from the 6/30/2019 version

3 SOP Statement

- 3.1 The IRB meets monthly or bi-monthly, if needed, to provide timely review of research, except when the regularly scheduled meeting falls on or near a holiday.
- 3.2 The IRB may meet more often when needed.
- 3.3 Meetings are conducted in person or via teleconference.
- 3.4 No limit is placed on the volume of agenda items reviewed.
- 3.5 The Meeting Chair is responsible to:
 - 3.5.1 Lead the IRB meeting
 - 3.5.2 Facilitate IRB review
 - 3.5.3 Ensure this SOP is followed
 - 3.5.4 Monitor the IRB's decisions for consistency
 - 3.5.5 Ensure that IRB members are free to participate in discussions
 - 3.5.6 Ensure that IRB members attending by teleconference can actively and equally participate in all discussions.
- 3.6 A Vice Chair or other member designated by the chair may carry out the responsibilities of the Chair when required.
- 3.7 IRB members are to know the definition of Conflicting Interest and to disclose any Conflicting Interest.
- 3.8 IRB members must maintain confidentiality of IRB deliberations.
- 3.9 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.
- 3.10 All IRB members who are part of quorum may vote. If both a primary and alternate member attend the IRB meeting, only one counts toward quorum so only one may vote.
- 3.11 The IRB chair (and vice chair, where applicable), votes as a regular member.
- 3.12 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. Use HRP-305 - WORKSHEET - Quorum and Expertise as a guide.
- 3.13 If quorum is lost during a meeting and cannot be restored, remaining agenda items will be moved to the next available agenda of an IRB with the appropriate scope.
- 3.14 Absent IRB members may submit written comments but may not vote.
- 3.15 Consultants may join the convened meeting when their assigned item is up for review.
 - 3.15.1 Consultants may present their reviews and answer questions but may not vote.
 - 3.15.2 Consultants will leave the convened meeting when the IRB has no more questions about the item.
 - 3.15.3 Consultants with a conflicting interest may not review items for the IRB, except to provide information requested by the IRB.
- 3.16 Observers that have received approval by the IRB Chair or HRPP Director may attend meetings.
- 3.17 System member representatives may observe IRB meetings as needed.

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- 3.17.1 Observers may not participate in IRB deliberations unless requested to serve as a consultant.
- 3.17.2 Observers may not vote.
- 3.17.3 Observers must agree to maintain confidentiality of IRB proceedings.
- 3.17.4 Observers may be asked to exit the meeting when an agenda item involves non-compliance.
- 3.18 The IRB reviews research in accordance with the applicable regulatory criteria for approval.
- 3.19 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.
- 3.20 Administrative, minor or prescriptive changes or requirements (modifications required to secure approval) may be reviewed for approval by the IRB chair, designated individual or IRB/HRPP staff.
- 3.21 The applicable 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 use as guides as needed for conducting meetings and to 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 response.
- 5.3 Ask IRB members if there are any questions about the report of completed non-committee (expedited) reviews that was made available to the IRB prior to the meeting.
- 5.4 For each item on the agenda involving review:
 - 5.4.1 Table the item when notified by IRB/HRPP staff when Quorum and Expertise requirements for review of a specific item are not met. Use HRP-305 - WORKSHEET - Quorum and Expertise as a guide.¹
 - 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.
 - 5.4.3 If there is a consultant present, ask the consultant to present his or her review to the IRB.
 - 5.4.4 If a consultant provided written information to the IRB, ask the primary reviewer to present that information to the IRB.
 - 5.4.5 Ask the scientific or scholarly reviewer or primary reviewer to present the scientific or scholarly review to the IRB.
 - 5.4.6 Ask the primary reviewer to lead the IRB through a discussion of the criteria for approval (for reference see: HRP-314 - WORKSHEET - Criteria for Approval) and applicable 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 or other procedural issues. Items tabled are put on the next available IRB agenda.

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- 5.4.7 For 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) have the primary reviewer to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects including notification of the new information; for reference use the HRP-321 - WORKSHEET - Review of Information Items.
- 5.4.8 Summarize the IRB's consensus regarding any protocol specific findings justifying a determination when required by a checklist and not previously determined and documented.
- 5.4.9 Make a motion for one of the following actions:
- 5.4.9.1 Approve: Made when all criteria for approval are met.
- 5.4.9.1.1 Include in the motions for initial and continuing review a specific period of approval (continuing review interval) when applicable and the level of risk (minimal risk or greater than minimal risk). The period of approval cannot exceed one year for:
- 5.4.9.1.1.1 FDA regulated Research
- 5.4.9.1.1.2 Research Subject to the Pre-2018 Common Rule.
- 5.4.9.1.1.3 Research where Continuing review is not required in accordance with the 2018 Common Rule but the reviewer has determined otherwise
- 5.4.9.1.2 State any new protocol specific findings that require documentation.
- 5.4.9.1.2.1 When reviewing modifications determine if the changes might affect an ongoing participant's willingness to participate and require notification or re-consent.
- 5.4.9.2 Modifications Required to Secure Approval: Made when the initial, continuing, or modification submission will meet the criteria for approval with administrative, minor or prescriptive changes or requirements that can be verified by the IRB Chair, IRB/HRPP staff or a designated reviewer without judging whether the changes made by the investigator meet the regulatory criteria for approval.
- 5.4.9.2.1 When making this motion summarize the IRB's required modifications and the reasons for those changes.
- 5.4.9.2.2 The submission does not return to the convened board for verification.
- 5.4.9.2.3 For initial and continuing review, include in the motion a specific period of approval (continuing review interval) when applicable and the level of risk (minimal or greater than minimal risk). The period of approval cannot exceed one year for:
- 5.4.9.2.3.1 FDA regulated Research
- 5.4.9.2.3.2 Research Subject to the Pre-2018 Common Rule.
- 5.4.9.2.3.3 Research where Continuing review is not required in accordance with the 2018 Common Rule but the reviewer has determined otherwise

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- 5.4.9.2.4 State any new protocol specific findings that require documentation.
 - 5.4.9.2.4.1 When reviewing modifications determine if the changes might affect a participant's willingness to participate and require notification or re-consent.
- 5.4.9.3 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.
 - 5.4.9.3.1 When making this motion, summarize the IRB's reasons for the decision and describe recommendations that may make the research approvable.
 - 5.4.9.3.2 The submission along with any changes must return to a subsequent convened meeting for approval.
- 5.4.9.4 Disapprove: Made when the research does not qualify for Approval or Modifications Required to Secure Approval and there are extensive deficiencies, or the IRB has no recommendations that might make the protocol approvable.
 - 5.4.9.4.1 When making this motion, summarize the IRB's reasons for the decision and recommendations, if any.
- 5.4.9.5 Suspension: Based on new information the previously approved research no longer meets the criteria for approval, but some research activities may meet the criteria for approval or the IRB has recommendations that may make the research meet the criteria for approval.
 - 5.4.9.5.1 Include in the motion: Which research activities must stop or be modified.
 - 5.4.9.5.2 If the research in its entirety no longer meets the regulatory criteria for approval, include in the motion: Stop all research procedures (except as noted below) and stop enrollment.
 - 5.4.9.5.3 If stopping enrollment will adversely affect the best interests of currently enrolled subjects, include in the motion: Which subjects can continue and what procedures can be performed.
 - 5.4.9.5.4 Lead the IRB members through a discussion of to consider what additional actions are needed, if any; for reference use HRP-321 - WORKSHEET - Review of Information Items
 - 5.4.9.5.5 Summarize the IRB's reasons and recommendations.
- 5.4.9.6 Termination: Based upon new information the previously approved research no longer meets the criteria for approval and the IRB has no recommendation to make the research approvable.
 - 5.4.9.6.1 Lead the IRB members through a discussion of additional actions to consider. Use HRP-321 - WORKSHEET - Review of Information Items as a guide, as needed.
 - 5.4.9.6.2 Summarize the IRB's reasons for the decision.
- 5.4.10 Open the floor for additional discussion.
- 5.4.11 Ensure that the IRB staff taking minutes has recorded the IRB's actions, required modifications, reasons, recommendations, determinations, and findings.
- 5.4.12 Ensure that the required modifications include all final contingencies in the Pre-Review activity, if any.
 - 5.4.12.1 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

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verified by the IRB/HRPP staff, but if there is a new management plan, it must return to the convened IRB for review.

- 5.4.13 Call for a vote.
 - 5.4.13.1 Only IRB members may vote.
 - 5.4.13.2 If a member and an alternate are both present, only one may vote.
 - 5.4.13.3 Consultants may not vote.
 - 5.4.13.4 For a motion to be approved, it needs the approval of more than half of the members present at the meeting. Example: (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.)
 - 5.4.13.5 Record the vote by electronic polling when available or by voice or show of hands.
- 5.4.14 Re-invite IRB members with a Conflicting Interest back into the meeting.
- 5.4.15 Provide any written information provided by a member or consultant to the IRB staff.
- 5.5 Adjourn the meeting when there is no further business or when notified by IRB staff that quorum has been lost and cannot be restored.

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-308 - WORKSHEET - Pre-Review
- 6.5 HRP-314 - WORKSHEET - Criteria for Approval
- 6.6 HRP-315 - WORKSHEET - Advertisements
- 6.7 HRP-316 - WORKSHEET - Payments
- 6.8 HRP-318 - WORKSHEET - Additional Federal Agency Criteria
- 6.9 HRP-321 - WORKSHEET - Review of Information Items
- 6.10 HRP-401 - CHECKLIST - Pre-Review
- 6.11 HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process
- 6.12 HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent
- 6.13 HRP-412 - CHECKLIST - Pregnant Women
- 6.14 HRP-415 - CHECKLIST - Prisoners
- 6.15 HRP-416 - CHECKLIST - Children
- 6.16 HRP-417 - CHECKLIST - Cognitively Impaired Adults
- 6.17 HRP-418 - CHECKLIST - Non-Significant Risk Device

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.
- 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.2.D, II.2.E, II.2.G, II.2.E-II.2.E.2, II.2.F-II.2.F.3