

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.
- 1.4 The process contains the appeal process.

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, where applicable, vice chair) votes as a regular member.
- 3.3 Meetings are conducted in person or via teleconference or videoconference.
- 3.4 IRB attendance is captured by documenting it 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.
- 3.5 If quorum is lost during a meeting, the IRB cannot take votes until the quorum is restored.
- 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 subcommittee or individual designated by the IRB.
- 3.8 The worksheets and checklists described in **3.203 (HRP-301) - WORKSHEET - Review Materials** and listed below in "Section 6: MATERIALS" are provided to IRB members in advance of meetings per **5.001 (HRP-040) - SOP - IRB Meeting Preparation** to conduct meetings and meet regulatory requirements.

4 RESPONSIBILITIES

- 4.1 The IRB Chair, or Vice Chair, or designee carries out these procedures, unless otherwise noted.
- 4.2 The IRB Chair, Vice Chair, or designee leads 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 **5.201 (HRP-305) - WORKSHEET - Quorum and Expertise** are not met.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 Acknowledge notification from the Conflicts of Interest Committee that an institutional conflict of interest has been identified and review their recommendations or plans to manage, mitigate, or eliminate institutional conflicts of interests, when applicable.

- 5.4.4
- 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 a primary reviewer to present that information to the IRB.
- 5.5.3 Ask the scientific or scholarly reviewer(s) or primary reviewer(s) to present the scientific or scholarly review to the IRB.
- 5.5.4 Ask the Chair or designee to lead the IRB through a discussion of the criteria in **4.202 (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. Include in motions for initial and continuing review the period of approval and the level of risk.
- 5.5.6.2 Approval with Stipulations: (with a specific continuing review interval for initial or continuing review when applicable): Made when all the determinations required for approval of proposed research or changes as submitted with stipulations. Research activities may be initiated or continued if the investigator either (a) adheres to the stipulation(s) as required by the IRB or (b) submits clarifications or additional documents, such that, the IRB is able to make a determination that the stipulation(s) are met.
- 5.5.6.3 Approval with Condition(s) (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(s) restates the modifications required by the IRB members and the IRB member's reasons for those changes. The Committee may also determine whether sub-committee re-review is appropriate and whether the changes must be brought back to the Full Board or may be approved by the subcommittee following 3.6 and 3.7.
- 5.5.6.4 Defer/Table: Made when: (a) the research does not qualify for Approval or Approval with Conditions and the IRB has recommendations that might make the protocol suitable for approvable, (b) expert consultation is identified as needed; (c) when Executive Committee IRB review is appropriate or (d) quorum is lost. When making this motion, the assigned primary reviewer(s) describes the IRB member's reasons for the motion and describes recommendation(s) to make the research approvable.
- 5.5.6.5 Disapprove: Made when the research does not qualify for Approval or Approval with Conditions and the PI has not made suitable changes that might make the protocol approvable. When making this motion, the

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assigned primary reviewer(s) describes the IRB member(s) reasons for the motion.

5.5.6.6 Suspension or Termination of IRB Approval: When making this motion, have the Chairperson or designee use **10.201 (HRP-321) - WORKSHEET - Review of Reportable Events** Items to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects. The Chairperson or designee describes the IRB member's reasons for the motion.

5.5.7 Review any modifications required to secure approval to ensure that the IRB staff has recorded them.

5.5.7.1 Ensure that the required modifications include all final contingencies on **3.102 (HRP-401) - CHECKLIST - Pre-Review**.

5.5.7.2 Ensure that the required modifications include all final contingencies in the Pre-Review activity.

5.5.7.3 For a pending investigator financial interest review indicate that a determination that the financial interest is not a conflict of interest or has been managed by the COI Committee and communicated to IRB staff through eIRB+. If there is a management plan, it is reviewed by the HRPP Director to determine whether the convened eIRB+ must review.

5.6 For each agenda item that is reportable 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 Chairperson or designee use **10.201 (HRP-321) - WORKSHEET - Review of Reportable Events** 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).

5.6.3.1 When a study is suspended, the convened IRB may remove study suspension and reinstate IRB approval (see **10.004 (HRP-026) – SOP – Suspension or Termination Issued Outside of Convened** for consistency in process). The IRB must have sufficient documented information that the raised concerns and issues have been rectified.

5.6.3.2 All determinations made by the convened IRB will be clearly documented in the IRB meeting minutes.

A formal notification from the HRPP office will be made to the PI and a copy will be included in the study file.

5.6.4 The fully convened IRB may terminate IRB approval of research if:

5.6.4.1 Termination is the most favorable response to help prevent or reduce the likelihood of serious harm to subjects.

5.6.4.2 The study is confirmed to be in serious and/or continuing noncompliance with applicable rules, procedures, and/or policies.

5.6.4.3 There must be sufficient evidence or just cause before a decision to terminate a study is made including an opportunity for the PI to respond to the IRB's concerns.

5.6.4.4 The determination to terminate the study approval will be clearly documented in the IRB meeting minutes.

5.6.4.5 A formal notification will be sent to the PI and a copy will be included in the study file.

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- 5.6.6 Formal notification for suspension/termination of IRB approval shall include:
 - 5.6.6.1 An explanation of the extent of the suspension/termination in terms of enrollment, recruitment, interventions, interactions, and data analysis.
 - 5.6.6.2 The reason(s) for the suspension/termination.
 - 5.6.6.3 As appropriate, a request for the PI to initiate any appropriate corrective actions intended to protect the rights and welfare of current subjects or others.
 - 5.6.6.4 Notice that the PI may make an appeal. An appeal will be considered by the convened IRB.
- 5.6.7 The HRPP Office will work with the IO to report any suspension or termination of IRB approval in accordance with the **10.001 (HRP-024) - SOP- Reportable New Information**.
- 5.7 Open the floor for additional discussion.
- 5.8 Call for a vote.
 - 5.8.1 Only IRB members may vote.
 - 5.8.2 If a member and an alternate are both present, only one may vote.
 - 5.8.3 Consultants may not vote.
 - 5.8.4 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.)
 - 5.8.5 Re-invite IRB members with a Conflicting Interest back into the meeting.
 - 5.8.6 Provide any written information provided by a member or consultant to the IRB staff.
- 5.9 Adjourn the meeting when notified by IRB staff that quorum has been lost or when there is no further business.
- 5.10 Appeal process:
- 5.11 The IRB may act to disapprove research, but such action may only be taken at a convened meeting. When an IRB takes action to disapprove research, the Principal Investigator will be provided with a written notification of the action. The notification shall explain the reasons for the decision. The PI may appeal the decision by submitting a response in writing. In the event that an appeal is not submitted, or the IRB reviews the appeal and does not change its decision to disapprove the research, the decision of the IRB is final. Institutional officials may not approve research that has been disapproved by the IRB.

6 MATERIALS

- 6.1 3.102 (HRP-401) - CHECKLIST - Pre-Review
- 6.2 3.201(HRP-308a) MA Pre-Review
- 6.3 3.202(HRP-308b) PA Preliminary Administrative Review (PAR)
- 6.4 3.203 (HRP-301) - WORKSHEET - Review Materials
- 6.5 4.202 (HRP-314) - WORKSHEET - Criteria for Approval
- 6.6 4.203 (HRP-318) - WORKSHEET - Additional Federal Agency Criteria
- 6.7 5.001 (HRP-040) - SOP - IRB Meeting Preparation
- 6.8 5.201 (HRP-305) - WORKSHEET - Quorum and Expertise
- 6.9 6.101 (HRP-419) - CHECKLIST - Waiver of Consent Process for Emergency Research
- 6.10 6.202 (HRP-317) - WORKSHEET - Short Form of Consent Documentation
- 6.11 6.208 (HRP-410) - WORKSHEET - Waiver or Alteration of Consent Process
- 6.12 6.207 (HRP-411) - WORKSHEET - Waiver of Written Documentation of Consent
- 6.13 7.201 (HRP-412) - WORKSHEET - Pregnant Women
- 6.14 7.202 (HRP-413) - WORKSHEET - Non-Viable Neonates
- 6.15 7.203 (HRP-414) - WORKSHEET - Neonates of Uncertain Viability
- 6.16 7.204 (HRP-415) - WORKSHEET - Prisoners
- 6.17 7.205 (HRP-416) - WORKSHEET - Children

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- 6.18 7.101 (HRP-417) - CHECKLIST – Adults with Impaired Decision-Making Capacity
- 6.19 8.201 (HRP-418) - WORKSHEET - Non-Significant Risk Device
- 6.20 8.204 (HRP-323) - WORKSHEET - Criteria for Approval HUD
- 6.21 9.202 (HRP-315) - WORKSHEET - Advertisements
- 6.22 9.203 (HRP-316) - WORKSHEET – Payments
- 6.23 10.201 (HRP-321) - WORKSHEET - Review of Reportable New Information

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