



**TITLE:** Conduct of IRB Meeting

**PURPOSE:** Conduct convened IRB meetings in accordance with the applicable regulatory criteria for approval

**RESPONSIBILITIES:** IRB Chairs  
HSPP Staff

**PROCEDURES:**

No official business may be conducted when the convened IRB is notified by HSPP staff that the meeting quorum has been lost.

- **QUORUM REQUIREMENTS:** For a motion to be approved, it needs the approval of more than half of the members present at the meeting (e.g. 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).

The following procedures are carried out by the Chair of the convened IRB:

1. Call the meeting to order.
2. Ask IRB members whether anyone has a Conflicting Interest in any item on the agenda and note the responses.
3. Discuss any Conflicts of Interest reviewed by the Institutional Review Committee (IRC).
4. Conduct ongoing IRB member education.
5. Review and discuss other general business items.
6. For each business item:
  - a. Table the item when notified by HSPP staff that requirements for review of a specific item as provided in “W305 - Evaluation of Quorum and Expertise” are not met.
  - b. If there are IRB members with a Conflicting Interest, invite the IRB to ask questions of these members, if needed, and then ask those members to leave for discussion and voting.
  - c. The primary reviewer leads the IRB through the review. The IRB determines:
    - i. Which regulatory criteria are met,
    - ii. Which are not met, and
    - iii. Which would be met if the investigator modified the protocol as requested by the IRB.
  - d. The consultant, if attending, presents their review. If the consultant provided written information, present this information to the IRB.
  - e. If there is a scientific review, scientific member presents their review to the IRB.
  - f. The secondary reviewer presents the review of the consenting documents.
  - g. Open the floor for discussion.
  - h. Review any modifications required by the IRB to secure approval to ensure that they are duly recorded by HSPP staff.
  - i. Review any final contingencies from the HSPP staff’s pre-review and determine if any must be met as a condition of IRB approval.
  - j. Make final determinations as to whether the regulatory criteria for approval are met.



- k. Entertain a motion and second by IRB members for one of the following actions:
    - i. **Approve**, made when all criteria for approval are met:
      1. Risk level;
      2. Continuing review interval for initial or continuing review; and
      3. Any additional regulatory criteria required for approval.
    - ii. **Approval with Conditions**, made when IRB members require specific conditions such that a designated reviewer can determine whether an investigator has made the required changes without determining whether the change meets the regulatory criteria for approval. When making this motion, the assigned primary reviewer restates the changes required by the IRB members and the IRB member's reasons for those changes.
      1. Risk level;
      2. Continuing review interval for initial or continuing review; and
      3. Any additional regulatory criteria required for approval.
    - iii. **Defer**, made when the research does not qualify for Approval or Changes 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.
    - iv. **Disapprove**, made when the research does not qualify for Approval or Changes 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
  - l. Call for vote. Only IRB members may vote. If a member and an alternate are both present, only one may vote.
    - i. Record the number of members voting For, Against, Abstain, Absent, and Recused.
    - ii. Consultants may not vote.
  - m. The IRB Chair votes as a regular member. Provide any written information provided by a member or consultant to the HSPP staff.
  - n. Re-invite IRB members with a Conflicting Interest back into the meeting.
7. For each Unanticipated Problem Involving Risks to Subjects or Others, Serious or Continuing Non-Compliance, or Suspension or Termination of IRB Approval have the primary reviewer:
    - a. Use the "W306 - Review of Information Items" to have the convened IRB make any necessary determinations.
    - b. Make a motion reflecting any actions required by the IRB members.
  8. If the IRB approves a motion involving a Suspension of IRB Approval or Termination of IRB Approval follow SOP-015: Suspension or Termination of IRB Approval.
  9. Adjourn the meeting when there is no further business.

**MATERIALS:**

- SOP-015: Suspension or Termination of IRB Approval



- Operations Manual
- W312 - Advertisements
- W313 - Payments
- W311 - Criteria for Approval and Additional Considerations
- W314 - Criteria for Approval and Additional Considerations for Humanitarian Use Device (HUD)
- W305 - Evaluation of Quorum and Expertise
- W306 - Review of Information Items
- W318 - Short Form of Consent Documentation

**REFERENCES:**

- 45 CFR §46.109, §46.116, §46.117.
- 21 CFR §50.20, §50.25, §50.27, §56.109, §56.111.
- OHRP's "Guidance on IRB Approval of Research with Conditions"

**REVIEW/REVISIONS:** From 10/01/2010 version: Added that continuing IRB member education occurs at each meeting; Changed "Modifications Required to Secure Approval" to "Approval with Conditions" and indicated that the convened IRB designates a person to review the conditions (This does not have to be the Designated Reviewer); Reference OHRP's "Guidance on IRB Approval of Research with Conditions"; Removed reference to checklists which have been incorporated into the Investigator Manual; Removed the requirement that the names of those who abstain must be listed.

From 08/01/2011 version: Added reference to Operations Manual.

From 01/2014 version: Renumbered from P&P-041; References to P&P-026 revised to SOP-015 to reflect new numbering system.