AdventHealth

POLICY

Policy # CW AHC 109	**Policy Name** IRB Member Review Expectations
Policy Location *Company-Wide Policies	**Responsible Department** Research Services
Executive Owner: Executive Director of Research Services	**Original Creation Date** 01/18/2022
Policy Effective Date 04/04/2022	**Policy Review Date** 04/04/2022

I. **SCOPE:** This policy applies to all AdventHealth Institutional Review Board (IRB) members.

II. **PURPOSE:** This policy establishes the expectations of IRB members for IRB reviews. For convened IRB meetings, this policy applies to all members who will be present with voting status. For review using the expedited procedure, this policy applies to the Designated Reviewer who fulfills the roles described for the primary presenter, and the scientific/scholarly reviewer, or obtains consultation for these roles.

III. **POLICY:**

A. Treat all oral and written information obtained as part of the review process as confidential, and do not disclose or use confidential information without prior authorization.

B. For each review consider whether you have a Conflicting Interest.
   1. Know the definition of Conflicting Interest.
   2. If you have a Conflicting Interest, do not participate in that review (including discussion or voting) except to provide information requested by the IRB.

C. Attend meetings you are committed to attend. If you cannot attend a meeting that you previously committed to attend, immediately notify IRB staff.

D. In advance of the meeting:
   1. Review the submitted materials as directed in (IRB Review Chart Attachment).
   2. Consider the criteria in all applicable worksheets and checklists.
   3. If during your review, you:
      a) Need answers to questions about the submitted materials, ask Meeting Chair or IRB staff.
      b) Need minutes or other information in the IRB record that you cannot access directly, ask the IRB staff.

c) Think one or more criteria are not met, consider what specific and directive changes would make the protocol approvable.

4. If you are the primary presenter:
   a) Fill out applicable checklists with preliminary judgments as to whether each criterion is met and provide preliminary study-specific findings justifying determinations marked with "▪ ."
   b) Review all submitted materials for consistency, including the following when they exist:
      i. The complete protocol including any previously approved protocol modifications
      ii. Investigator brochure
      iii. For research that has to follow Pre-2018 Requirements, the HHS approved protocol
      iv. HHS-approved template consent document
   c) Prepare to lead the discussion at the meeting.
5. If you are the prisoner representative and the protocol involves prisoners as research subjects, determine whether the criteria in HRP-308 CHECKLIST – Prisoners are met, be present when the protocol is reviewed, and provide a review either orally or in writing.
6. If you are an IRB member with scientific or scholarly expertise, additionally review the submitted materials in enough depth to evaluate whether the materials accurately describe the subject risks, subject benefits, and knowledge to result, whether alternative procedures consistent with sound research design could reduce risk, and whether the research design is sound enough to yield the expected knowledge.

E. At meetings
1. Share your unique input to get all the issues on the table.
   a) If you have a question, ask.
   b) If you have information that has not been discussed, share it.
2. Think critically and use the criteria for approval to decide whether to approve research.
   a) If you have a concern, problem, or recommended change, be able to base it on the criteria for approval. If you are unsure of the basis, ask.
   b) If you think a criterion for approval is not met, say so.
   c) If you think the criteria for approval are not met, do not vote for approval.
3. Make decisions by majority rule, not consensus.
   a) Listen and learn from the group, but think and vote independently
   b) Know that dissent is healthy and expected.

c) Respect the opinions

F. Improve your knowledge over time.
   1. Participate in required and optional continuing education.
   2. Accept constructive feedback.

IV. PROCEDURE/GUIDELINES: Not Applicable

V. DEFINITION(S): For capitalized terms not defined in this policy, refer to CW AHC 107 Definitions in Human Research.

For capitalized designations not defined in this policy, refer to CW AHC 103 Designations in Research.

VI. EXCEPTION(S): See CW AHC 101 Research Oversight

VII. REFERENCE(S):
Humanitarian Device Exemption (HDE) Program: Guidance for Industry and Food and Drug Administration Staff

VIII. RELATED DOCUMENT(S) / ATTACHMENT(S):
- CW AHC 101 Research Oversight
- CW AHC 107 Definitions in Human Research
- CW AHC 103 Designations in Research
- CW AHC 108 Human Research Protection Program
- CW AHC 109 - Exhibit A - IRB Review Chart
- CHECKLISTS are located on the AdventHealth Research Institute website
  - HRP-308 CHECKLIST – Prisoners