Standard Operating Procedure (SOP)

SOP Number: SOP CW AHC 206	**SOP Name:** Committee Review Conduct
Location: *Company-Wide Policies	**Responsible Department:** Research Services
Executive Owner Executive Director of Research Services	**Original Creation Date:** 01/18/2022
Effective Date: 04/04/2022	**Review Date:** 04/04/2022

I. SCOPE: This standard operating procedure (SOP) applies to the Institutional Review Board (IRB) Meeting Chair at AdventHealth.

II. PURPOSE: This procedure establishes the process to conduct an IRB meeting. This procedure begins when the meeting is called to order and ends when the meeting is adjourned.

III. QUALIFIED PERSONNEL: Meeting Chair

IV. TRAINING: Not applicable

V. SUPPLIES & EQUIPMENT: Not applicable

VI. PROCESS/PROCEDURE:

A. The Meeting Chair is responsible to:
   1. Lead the IRB meeting.
   2. Facilitate IRB review.
   3. Ensure this SOP is followed.
   4. Monitor the IRB's decisions for consistency.
   5. Ensure that IRB members are free to participate in discussions.
   6. Ensure that IRB members attending by teleconference can actively and equally. participate in all discussions
   7. Vote as an IRB member.

B. The Meeting Chair is expected to:
   1. Help IRB members meet their expectations in CW AHC 109 IRB Member Review Expectations.
   2. Encourage IRB members to:
      a) Ask questions.
      b) Speak their minds at every protocol review.
      c) Share information that has not been discussed.
      d) Listen and learn from the group.
      e) Respect dissenting opinions.
      f) Think and vote independently.
   3. Mentor and guide IRB members to use the criteria for approval by:

a) Facilitating IRB members' understanding of the research to the degree sufficient to apply the criteria for approval.
b) Having IRB members base concerns, problems, and recommended changes on the criteria for approval.
c) Removing issues from consideration when the Meeting Chair and IRB members determine they do not affect the criteria for approval.
d) Obtaining assistance when the Meeting Chair and IRB members are uncertain whether an issue affects the criteria for approval.
e) Framing difficult or controverted issues in terms of the criterion that is the basis of the controversy.
f) Taking votes on the criterion for approval that is the basis for a controversy, if after sufficient discussion a controverted issue remains unresolved,
g) Reminding IRB members who believe that one or more criteria for approval voted are not met that they should not vote for approval.
h) Supporting and rewarding dissent based on the criteria for approval.

4. Encourage IRB member engagement by:
    a) Reinforcing IRB member expectations.
    b) Encouraging IRB members to use their unique perspective to contribute to IRB deliberations.
    c) Providing recognition and praise to IRB members.
    d) Caring about each IRB member as a person.
    e) Encouraging IRB members to develop in their review skills.
    f) Ensuring opinions of IRB members count.
    g) Communicating the mission of the AdventHealth IRB to protect human subjects.

C. IRB members are to know the definition of Conflicting Interest and self-identify their Conflicting Interests.
D. The Meeting Chair may determine that certain IRB members have voting status and others have non-voting status.
    1. The number of IRB members with voting status is not greater than the number of regular IRB members on the IRB roster.
    2. During the meeting the Meeting Chair may change who has voting status and who has non-voting status.
    3. The Meeting Chair is responsible to notify the IRB staff at the meeting of any change in IRB members' voting status.
E. All IRB members who are part of quorum may vote, including any IRB chairs, IRB vice-chairs, and Meeting Chairs.
F. Ad hoc substitutes may not serve as IRB members.

G. Absent IRB members may submit written comments but may not vote.

H. Consultants may not vote.

I. Observers may attend meetings, but:
   1. May not participate in IRB deliberations unless requested by the IRB to serve as a consultant.
   2. May not vote.
   3. Must agree to maintain the confidentiality of the IRB proceedings.

J. When a protocol is ambiguous, the IRB may resolve the ambiguity by obtaining written information from the sponsor or investigator in advance of the meeting as an alternative to contingent approval, IRB members must be made aware of this information, either orally or in writing.

K. The Meeting Chair is responsible to:
   1. Call the meeting to order.
   2. Ask whether anyone has a Conflicting Interest related to any agenda item.
   3. For each study review:
      a) If there are individuals (either IRB members or consultants) with a Conflicting Interest related to an agenda item:
         i. IRB members may ask questions of those individuals.
         ii. If physically present, ask those individuals to leave the room.
         iii. If present by teleconference, set the conference equipment to block communications.
      b) If the study is eligible for Non-Committee Review, the IRB can take no action and have the item reviewed by Non-Committee Review.
      c) Take no action on the item when notified by an IRB staff member that quorum requirements are not met[i] or when there is insufficient time. Move the item to another meeting.
      d) If one or more consultants are involved:
         i. Inform the IRB members of any Conflicting Interest.
         ii. Have those present at the meetings discuss their findings.
      e) Have the primary presenter:
         i. Have the individual(s) with scientific/scholarly expertise discuss the scientific/scholarly review.
         ii. Review relevant findings of Regulatory Review and Regulatory Review contingencies.
         iii. For a review related to an Unanticipated Problem Involving Risks to Subjects or Others, Serious Noncompliance, Continuing Noncompliance, Suspension of IRB

Approval, or Termination of IRB Approval lead the IRB members through a discussion of HRP-411 WORKSHEET – New Information.

iv. Lead the IRB through a discussion of the criteria in applicable worksheets.

v. When a checklist is applicable, discuss the checklist determinations and study-specific findings supporting those determinations.

vi. Summarize the IRB's consensus.

f) Make or have an IRB member make a motion for one of the following regardless of whether the information is the first application, a response to a conditional approval or deferral:

i. "Approve": The initial, continuing, or modification submission meets the criteria for approval.

- For initial and continuing review, include in the motion the level of risk (minimal risk or greater than minimal risk), and either that continuing review is not required, or the period of continuing review (not to exceed one year).
- If continuing review is not required by HRP-400 WORKSHEET – Criteria for Approval but the IRB requires continuing review, have the IRB provide the rationale for requiring continuing review.
- If the approval relates to suspended research, document the decision as "Approve But Continue Suspension."

ii. "Modifications Required" ("Conditionally Approve"): The initial, continuing, or modification submission will meet the criteria for approval with minor or prescriptive changes or requirements that can be verified without considering the criteria for approval.[ii]

- For initial and continuing review, include in the motion, the level of risk (minimal risk or greater than minimal risk), and either that continuing review is not required, or the period of continuing review (not to exceed one year).
- If continuing review is not required by HRP-400 WORKSHEET – Criteria for Approval but the IRB requires continuing review, have the IRB provide the rationale for requiring continuing review.
- Summarize the IRB's required modifications and reasons.
- If the approval relates to suspended research, document the decision as "Conditionally Approve But Continue Suspension."

iii. "Defer": The initial, continuing, or modification submission does not meet the criteria for approval and also does not meet the criteria for "Disapprove." Summarize the IRB's reasons and recommendations, if any.

iv. "Disapprove": The initial, continuing, or modification submission does not meet the criteria for approval and the IRB considers the research to have extensive deficiencies. Summarize the IRB's reasons and recommendations, if any.

v. "Suspend": Based on new information the previously approved research no longer meets the criteria for approval, but some research activities meet the criteria for approval or the IRB has recommendations that may make the research meet the criteria for approval.
   - Include in the motion: Which research activities must stop or be modified.
   - 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.
   - If stopping research will adversely affect the best interests of currently enrolled subjects, include in the motion: Which subjects can continue and what procedures can be performed.
   - Lead the IRB members through a discussion of HRP-411 WORKSHEET – New Information to consider additional actions.
   - Summarize the IRB's reasons and recommendations.

vi. "Terminate": Based on new information the previously research no longer meets the criteria for approval and the IRB has no recommendations to make the research approvable.
   - Lead the IRB members through a discussion of HRP-411 WORKSHEET – New Information Items to consider additional actions.
   - Summarize the IRB's reasons.

vii. "Lift Suspension": When the IRB determines that based on a modification submission or new information the previously suspended research meets the criteria for approval.

viii. "Approve in Principle": When a federal funding agency requires IRB approval before grant monies can be released, and the investigator does not have the funding to complete the research proposal until the grant monies are released, the Board may provide a preliminary opinion on the proposed research.

ix. "Acknowledge": The sponsor or the investigator require an affirmative reply in response to submitted materials but an action of "Approve" is not applicable.

g) Ensure that the IRB staff member taking minutes has recorded the IRB's actions, required modifications, reasons, recommendations, determinations, and findings.

h) Call for a vote of IRB members "For," "Against," or "Abstaining." If more than half the IRB members present votes "For," the motion is approved.

   i. A tie vote for to approve a motion for "Approve" or "Conditionally Approve" is considered to be an IRB decision of "Defer."

   ii. Have individuals with a Conflicting Interest rejoin the meeting.

4. Adjourn the meeting when there is no further business or when notified by an IRB staff member that quorum for all remaining agenda items cannot be met.
5. If there are remaining agenda items, move them to another meeting.

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

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

IX. REFERENCE(S): Not applicable

X. RELATED DOCUMENT(S) / ATTACHMENT(S):

- CW AHC 107 Definitions in Human Research
- CW AHC 101 Research Oversight
- CW AHC 108 Human Research Protection Program
- CW AHC 109 IRB Member Review Expectations
- WORKSHEETS are located on the AdventHealth Research Institute website
    - HRP-400 WORKSHEET – Criteria for Approval
    - HRP-411 WORKSHEET – New Information

[i] If quorum is lost during a meeting, the IRB cannot take votes until the quorum is restored. If required members (e.g. non-scientific) leave the room and quorum is lost votes cannot be taken until the quorum is restored, even if half of the members are still present.

[ii] 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.