Standard Operating Procedure (SOP)

SOP Number: SOP CW AHC 204	**SOP Name:** Non-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:** 02/12/2024

I. SCOPE: This standard operating procedure (SOP) applies to the Research Personnel and Institutional Review Board (IRB) staff members, chair, and committee members at AdventHealth.

II. PURPOSE: This procedure establishes the process to conduct Non-Committee Review. This procedure begins when a Designated Reviewer has been notified to conduct a Non-Committee Review and ends when a Designated Reviewer has notified the IRB staff member handling the submission of the completion of the review.

III. QUALIFIED PERSONNEL: Designated Reviewers; IRB staff members

IV. TRAINING: Not applicable

V. SUPPLIES & EQUIPMENT: Not applicable

VI. PROCESS/PROCEDURE: Designated Reviewers are to review the materials described in CW AHC 109 IRB Member Review Expectations. Designated Reviewers may not disapprove research.

A. Consider whether you have a Conflicting Interest. If so, assign the review task to another Designated Reviewer.

B. If the request is for study closure that does not meet HRP-413 WORKSHEET – Closure Criteria, communicate with the Investigator.

   1. If the Investigator withdraws the submission, stop processing.
   2. If the Investigator will not withdraw the submission, return to the IRB staff member handling the submission for Committee Review.

C. Consider whether you have sufficient expertise to review the submission. If you need additional expertise, follow SOP CW AHC 210 Consultation. Sufficient expertise includes as applicable for the research:

   1. Scientific or scholarly expertise
   2. Knowledge of or experience working with vulnerable populations
   3. Qualification as a prisoner representative
   4. Knowledge of the country in which the research is conducted
   5. Medical licensure for FDA-regulated test articles
   6. Knowledge of federal agency requirements for DOD, DOE, DOJ, ED, EPA, or EPA research
   7. Concern with the welfare of children with disabilities or individuals with mental

disabilities as subjects, if the research is funded by the National Institute on Disability and Rehabilitation Research and purposefully requires inclusion of these subjects

8. Knowledge of community based participatory research

D. If there is missing information, follow the procedures in SOP CW AHC 201 Regulatory Review.

E. Take one of the following actions:

1. "Not Human Research": The submission does not meet the definition of Human Research based on HRP-421 WORKSHEET – Human Research.
2. "Human Research Not Engaged": The submission meets the definition of Human Research but does not engage the institution based on HRP-422 WORKSHEET – Engagement.
3. "Approve": The initial, continuing, or modification submission meets either:
   a) The criteria in HRP-423 WORKSHEET – Exemption, or
   b) The criteria in HRP-424 WORKSHEET – Expedited, HRP-400 WORKSHEET – Criteria for Approval, and other applicable worksheets and checklists as determined by the Regulatory Review, or
   c) For continuing review or review of modifications to previously approved HUD uses, the criteria in HRP-424 WORKSHEET – Expedited and HRP-450 WORKSHEET – Criteria for Approval HUD.
   d) Document that the IRB determined that the proposed research met the criteria for approval. In the case of a financial interest that is Related to the Research document instead that the IRB determined that proposed research with the management plan for the financial interest met the criteria for approval.
4. "Conditionally Determine Not Human Research": The submission with changes can be determined "Not Human Research."
5. "Conditionally Determine Human Research Not Engaged": The submission with changes can be determined "Human Research Not Engaged."
6. "Conditionally Approve": The submission with changes can be granted the action of "Approve." Document that the IRB determined that the proposed research with the requested modifications met the criteria for approval. In the case of a financial interest that is Related to the Research document instead that the IRB determined that proposed research with the requested modifications and with the management plan for the financial interest met the criteria for approval.
7. "Close": The submission meets HRP-413 WORKSHEET – Closure Criteria.
8. Refer to the IRB staff member handling the submission for Committee Review.

F. Document the action using HRP-211 FORM - Non-Committee Review or equivalent:

1. If the action is "Approve" or "Conditionally Approve," document whether the approval level was "Exempt" or "Expedited."
   a) For "Exempt," document the category or categories allowing the exemption in

HRP-423 WORKSHEET – Exemption.

b) For "Expedited," document the category or categories allowing review using the expedited procedure in HRP-424 WORKSHEET – Expedited

c) For "Expedited," document either that continuing review is not required or document the period of approval (not to exceed one year) and the reason for continuing review. If continuing review is determined to be required but is not required by HRP-400 WORKSHEET – Criteria for Approval, document the rationale for the determination.

2. If the research falls into a category in HRP-424 WORKSHEET – Expedited Review allowing initial review by the expedited procedure that is greater than Minimal Risk, document that rationale for the greater than Minimal Risk determination.

G. Update Regulatory Review findings as needed.

H. Notify the IRB staff member handling the submission when done.

I. Return any materials that are part of the permanent record.

J. Destroy or return any temporary copies of materials.

VII. DEFINITION(S):

For capitalized terms not defined in this SOP, refer to CW AHC 107 Definitions in Human Research.

For abbreviations not defined in this SOP, refer to CW AHC 102 Abbreviations in Research.

VIII. EXCEPTION(S):

See CW AHC 101 Research Oversight

IX. REFERENCE(S):

Not applicable

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

- CW AHC 101 Research Oversight
- CW AHC 107 Definitions in Human Research
- CW AHC 102 Abbreviations in Research
- CW AHC 109 IRB Member Review Expectations
- CW AHC 108 Human Research Protections Program
- SOP CW AHC 210 Consultation
- SOP CW AHC 201 Regulatory Review
- WORKSHEETS are located on the AdventHealth Research Institute website
  - HRP-413 WORKSHEET – Closure Criteria
  - HRP-421 WORKSHEET – Human Research
  - HRP-422 WORKSHEET – Engagement
  - HRP-423 WORKSHEET – Exemption
  - HRP-424 WORKSHEET – Expedited
  - HRP-400 WORKSHEET – Criteria for Approval

  - HRP-450 WORKSHEET – Criteria for Approval HUD
- FORMS are located in IRBNet
  - HRP-211 FORM - Non-Committee Review (See SOP CW AHC 204 - Exhibit A for template)