Standard Operating Procedure (SOP)

SOP Number: SOP CW AHC 209	**SOP Name:** Not Otherwise Approvable Research
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 Organization Official at AdventHealth.

II. PURPOSE: This procedure establishes the process to review research that is not subject to federal regulation and is also not otherwise approvable under 21 CFR §50.54, 45 CFR §46.207, or 45 CFR §46.407, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children, pregnant women, fetuses, or neonates. This procedure begins when the convened IRB determines that research falls into a not otherwise approvable category. This procedure ends when the IRB is informed of the Organization Official's decision.

III. QUALIFIED PERSONNEL: Organization Official

IV. TRAINING: Not applicable

V. SUPPLIES & EQUIPMENT: Not applicable

VI. PROCESS/PROCEDURE:

A. Determine whether to review the research. If a determination is made not to review the research, inform the IRB and take no further action under this SOP.

B. Identify a panel of five or more experts in pertinent disciplines (e.g., science, medicine, education, ethics, and law) and relevant subject advocates willing to serve on a public panel.

   1. Determine whether any panel member has a Conflicting Interests.
   2. Do not use panel members with a Conflicting Interest.

C. Provide panel members with all information reviewed by the convened IRB.

D. Ask panel members to provide individual written recommendations.

E. Set a date for a meeting.

F. Conduct the meeting.

G. After the meeting have each panel member write an independent recommendation for one of the following:

   1. The research should proceed because it falls into an approvable research on HRP-307 CHECKLIST - Nonviable Neonates, HRP-306 CHECKLIST - Neonates of Uncertain Viability, or HRP-310 CHECKLIST – Children.

2. The research does not meet the above criterion but should proceed because the following criteria are met:
   a) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children or pregnant women, fetuses, or neonates.
   b) The research will be conducted in accordance with sound ethical principles.
   c) Adequate provisions are made for soliciting the assent of children, the permission of their parents or guardians, and the consent of subjects, as required by HRP-400 WORKSHEET - Criteria for Approval, HRP-307 CHECKLIST - Nonviable Neonates, HRP-306 CHECKLIST - Neonates of Uncertain Viability, or HRP-310 CHECKLIST - Children.
3. The research with modifications should proceed under one of the above criteria.
4. The research should not proceed.

H. Review the panel report and make one of these recommendations:
   1. Approve the research as submitted,
   2. Approve the research with modifications, or
   3. Disapprove the research.

I. Inform the IRB and the Investigator.

J. Place the study on the agenda of a convened IRB.

VII. DEFINITION(S):

For capitalized terms not defined in this SOP, 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

VIII. EXCEPTION(S):

See CW AHC 101 Research Oversight

IX. REFERENCE(S):

21 CFR §50.54
45 CFR §46.207
45 CFR §46.407

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

- CW AHC 107 Definitions in Human Research
- CW AHC 103 Designations in Research
- CW AHC 101 Research Oversight
- CW AHC 108 Human Research Protection Program
- WORKSHEETS and CHECKLISTS are located on the AdventHealth Research Institute website
  - HRP-400 WORKSHEET – Criteria for Approval
  - HRP-306 CHECKLIST – Neonates of Uncertain Viability

- HRP-307 CHECKLIST – Nonviable Neonates
- HRP-310 CHECKLIST – Children