Standard Operating Procedure (SOP)

SOP Number: SOP CW AHC 212	**SOP Name:** New Information
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 Institutional Review Board (IRB) staff members at AdventHealth.

II. PURPOSE: This procedure establishes the process to manage new information including information related to IRB operations. This procedure begins when an IRB or others receive information that is not a request for a determination (regardless of whether the information is reportable) or receives reportable new information as part of a submission. This procedure ends when HRPP Personnel or IRB Executive Chair has determined whether the information requires reporting to the convened IRB.

III. QUALIFIED PERSONNEL: IRB staff members or IRB Executive Chair carry out these procedures. All individuals who can make decisions about new information carry out these procedures or ensure they are carried out by other personnel. Individuals unsure of a decision in this SOP are to bring new information to higher level official for a determination. IRB Executive Chair or IRB vice-chair follows this SOP before placing an item of new information on the IRB agenda.

IV. TRAINING: Not applicable

V. SUPPLIES & EQUIPMENT: Not applicable

VI. PROCESS/PROCEDURE:

A. All decisions that information represents Serious Noncompliance, Continuing Noncompliance, an Unanticipated Problem Involving Risks to Subjects or Others, a Suspension of IRB Approval, or a Termination of IRB Approval are to be confirmed by the Director, Office of Research Integrity and Compliance (Director, ORIC) and reported to the Research Oversight Committee.

B. Ask the following six questions.

1. Does the information represent an Allegation of Noncompliance? If yes:

   a) Discuss allegations of IRB Noncompliance with the Director, ORIC.
   b) Evaluate the Allegation of Noncompliance to determine whether there is a basis in fact.
   c) If the final determination is that the Allegation of Noncompliance has basis in fact, then this represents Noncompliance.

2. Does the information represent Noncompliance? If yes:

   a) Discuss allegations of IRB Noncompliance with the Director, ORIC

b) Evaluate the Noncompliance to determine whether it is Serious Noncompliance or Continuing Noncompliance.

3. Does the information represent Serious Noncompliance?
4. Does the information represent Continuing Noncompliance?
5. Does the information represent an Unanticipated Problem Involving Risks to Subjects or Others?
6. Does the information represent a Suspension of IRB Approval or a Termination of IRB Approval?

C. If the answers to all six questions above are "no":

1. Respond as needed to any complaint, query, or input.
2. Follow any other applicable SOPs.
3. If an acknowledgement is expected, follow SOP CW AHC 211 Post Review to notify the submitter.
4. No further action is required under this SOP.

D. Consider whether any immediate actions might be necessary to protect the rights and welfare of current or future subjects while additional information is gathered. If so, take those actions, notify the institution, sponsor, contract research organization (CRO), or site management organization (SMO), as applicable, and notify the Director, ORIC.

E. Consider whether immediate notification of the institution, sponsor, CRO, or SMO might be appropriate. If so, notify the institution, sponsor, CRO, or SMO, as applicable, and notify the Director, ORIC.

F. If more information is needed, contact the submitter to gather new information.

G. If the information represents Noncompliance that is neither Serious Noncompliance, nor Continuing Noncompliance, evaluate any submitted corrective action.

1. If the corrective action plan is insufficient, contact the research team to develop a sufficient correction action plan. If the research team is unable to develop a sufficient corrective action, consider the Noncompliance to be Continuing Noncompliance.
2. If the research team develops a sufficient corrective action, follow SOP CW AHC 211 Post Review to notify the submitter.

H. If the information represents Serious Noncompliance, Continuing Noncompliance, an Unanticipated Problem Involving Risks to Subjects or Others, a Suspension of IRB Approval, or a Termination of IRB Approval:

1. Notify the Director, ORIC.
2. Bring the information to the attention of the IRB Executive Chair or IRB vice-chair for consideration of whether any immediate actions are necessary to protect the rights and welfare of subjects in advance of the meeting.
3. Send for Committee Review.

VII. 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.

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

IX. REFERENCE(S):

45 CFR 46.103(b)(5) Pre-2018

45 CFR 46.108(a)(4) 2018 Requirements

21 CFR 56.108

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
- SOP CW AHC 211 Post Review