Standard Operating Procedure (SOP)

SOP Number: SOP CW AHC 211	**SOP Name:** Post Review
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 Institutional Review Board (IRB) staff members at AdventHealth.

II. PURPOSE: This procedure establishes the process to communicate the IRB findings and actions. This procedure beings when the IRB has completed a review and ends when the IRB has communicated its findings and actions.

III. QUALIFIED PERSONNEL: IRB staff members carrying out these procedures.

IV. TRAINING: Not applicable

V. SUPPLIES & EQUIPMENT: Not applicable

VI. PROCESS/PROCEDURE:

A. AdventHealth does not need to directly report to a regulatory agency, if the agency has been notified by alternate mechanisms.

B. OHRP does not require organizations to report Unanticipated Problems Involving Risks to Subjects or Others, Serious Noncompliance, and Continuing Noncompliance when unrelated to the local context.

C. Calculate the End Approval Date following SOP CW AHC 220 IRB End Approval Dates.

D. Complete the applicable template notification or when necessary, draft a unique notification.

E. Update any newly approved consent document with the approval and expiration dates.

F. Within 10 days of a decision send the notification to:

1. The Investigator
2. Study contacts
3. The DOD component[i], when the research involving human subjects is DOD-supported and the notification involves any of the following:
   a) Significant changes to the research protocol are approved by the IRB, the results of the IRB continuing review
   b) A change in the IRB used to review and approve the research to a different IRB
   c) Communication from any federal department or agency or national organization informing AdventHealth that any part of its Human Research Protections Program (HRPP) is under investigation for cause
4. Sponsor, when the notification is

a) a disapproval of a request for a waiver of the consent process for planned emergency research that is FDA-regulated (21 CFR 50.24(e)).
b) Information that has been publicly disclosed about the initiation of a study involving a waiver of the consent process for planned emergency research that is FDA-regulated (21 CFR 50.24(7), 56.109(g)).
c) Information that has been publicly disclosed following completion of the study involving a waiver of the consent process for planned emergency research that is FDA-regulated (21 CFR 50.24(7), 56.109(g)).

5. Other individuals or organizations, when determined to be appropriate by the HRPP Administrator, IRB Executive Chair, or Organization Official

G. Within 10 days of a decision, the following individuals or entities must receive notification from AdventHealth or the institution where the research is being conducted, when the notification involves an Unanticipated Problems Involving Risks to Subjects or Others, Serious Noncompliance, Continuing Noncompliance, Suspension of IRB Approval, or Termination of IRB Approval:

1. Organization Official
2. If research is sponsored: sponsor or contract research organization
3. If funded: office responsible for oversight of the grant or contract
4. Legal counsel
5. Risk Management department(s)
6. Site management organization or equivalent, when the research is reviewed on behalf of such an organization
7. Institutional contact, when the research is associated with an institution.
8. For unauthorized use, loss, or disclosure of individually identifiable information: privacy officer
9. For violations of information security requirements: information security officer
10. For research subject to regulation when reporting is required by the agency (E.g., DOD, EPA, FDA, HHS, VA)
11. For international or collaborative research involving collaboration with a local research ethics committee or equivalent: The local research ethics committee or equivalent
12. Additional contacts, when required by any relevant agreement
13. Other individuals or organizations, when determined to be appropriate by the HRPP Administrator, IRB Executive Chair, or Organization Official

H. Make any newly approved consent documents, scripts, or assent documents available to the submitter.

I. Update Regulatory Review findings as needed.

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.

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

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

IX. REFERENCE(S):

21 CFR 50.24
21 CFR 56.109

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

- CW AHC 107 Definitions in Human Research
- CW AHC 103 Designations in Research
- CW AHC 102 Abbreviations in Research
- CW AHC 101 Research Oversight
- CW AHC 108 Human Research Protection Program
- SOP CW AHC 220 IRB End Approval Dates

[i] Send to the Human Research Protections Officer (HRPO) of the DOD component, which is the individual who is delegated the responsibilities as defined in paragraph (a)(2) of section 252.235-7004 of Reference (n). There may be more than one HRPO in a DOD Component. Some DOD Components may use a different title for the person(s) with the defined responsibilities.