Standard Operating Procedure (SOP)

SOP Number: SOP CW AHC 215	**SOP Name:** Continuing Review Not Required
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 Research Personnel and Institutional Review Board (IRB) staff members, chair, and committee members at AdventHealth.

II. PURPOSE: The AdventHealth IRB will maintain oversight for studies that the IRB determined do not require continuing review. The purpose of this SOP is to define the requirements for studies that do not require continuing review.

III. QUALIFIED PERSONNEL: IRB Executive Chair, IRB members, IRB staff members, Investigators, and Research Personnel.

IV. TRAINING: Not applicable

V. SUPPLIES & EQUIPMENT: Not applicable

VI. PROCESS/PROCEDURE:

A. AdventHealth IRB may determine a study does not require continuing review. Examples include:

1. Research subject to 2018 Requirements and
   a) Eligible for expedited review, or
   b) Eligible for exempt review, or
   c) All interventions are complete and now only includes analyzing data, even if the information or biospecimens are identifiable, or
   d) All interventions are complete and now only includes accessing follow up clinical data from clinical care procedures.
2. Research subject to Hybrid Requirements and Pre-2018 Requirements or Original Rule at the discretion of the AdventHealth IRB.
3. AdventHealth IRB reserves the right to require continuing review for any study regardless of whether it meets a category outlined above.

B. If the AdventHealth IRB determines a study does not require continuing review, the following is required:

1. Follow the CW AHC 112 Investigator Obligations in Research
2. Maintain valid training to conduct research at AdventHealth in accordance with AdventHealth Research Institute policies.
3. On an ongoing basis, submit the following to the AdventHealth IRB:

a) Amendments to any study procedures, documents, protocol, or informed consent.
b) Changes in local study personnel via a revised Research Personnel log
c) Reviews preparatory to research forms when adding personnel with this responsibility and when adding this responsibility to existing personnel.
d) Promptly Reportable Information in accordance with CW AHC 111 Prompt Reporting Requirements in Research.

4. On an annual basis, submit the Research Personnel log to the AdventHealth IRB.
5. Research not requiring continuing review remains subject to AdventHealth policies and procedures related to the conduct of research including, but not limited to, AdventHealth Research Services policies and SOPs.
6. When research is complete, submit a study closure to AdventHealth IRB.

VII. DEFINITION(S): For capitalized terms not defined in this policy, 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 111 Prompt Reporting Requirements in Research
- CW AHC 112 Investigator Obligations in Research