Standard Operating Procedure (SOP)

SOP Number: SOP CW AHC 220	**SOP Name:** IRB End Approval Dates
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 all Institutional Review Board (IRB) staff members responsible for post IRB review procedures.

II. PURPOSE: This SOP describes the calculation of the End Approval Date.

III. QUALIFIED PERSONNEL: The Organization Official carries out these procedures or ensures that others carry them out.

IV. TRAINING: Not applicable

V. SUPPLIES & EQUIPMENT: Not applicable

VI. PROCESS/PROCEDURE:

A. The following research has no End Approval Date. However, the date will be captured in the IRB electronic submission system as a means to remind Investigators to close studies once completed:
   1. Exempt research
   2. Research that does not require continuing review per HRP-400 WORKSHEET – Criteria for Approval.

B. For all other research:
   1. The action date is:
      a) The date the convened IRB or Designated Reviewer made determination to approve the research; or
      b) The date the IRB confirmed that the responsive materials met the requirements of a convened IRB or Designated Reviewer determination to conditionally approve the research.
   2. The approval interval is the period of approval granted by the convened IRB or Designated Reviewer. (e.g., 1 year, 6 months, 3 months)

C. For initial review, the End Approval Date is the action date plus the approval interval minus one day. (For example, if the research was approved for one year with an action date of April 15, 2020, the End Approval Date is April 14, 2021.)

D. For continuing review, the new End Approval Date is the action date plus the approval interval minus one day.

E. For modifications, the End Approval Date is unchanged.

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):

Electronic Code of Federal Regulation (*e-CFR™*). (June 18, 2015). 21 CFR, §56.109(f): IRB Review of Research. Retrieved from: Click here.

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 are located on the AdventHealth Research Institute website
  - HRP-400 WORKSHEET – Criteria for Approval