Standard Operating Procedure (SOP)

SOP Number: SOP CW AHC 214	**SOP Name:** Suspension and Termination by the Organization
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 institute a Suspension of IRB Approval or Termination of IRB Approval outside of a convened IRB meeting. This procedure begins when an authorized individual institutes a Suspension of IRB Approval or Termination of IRB Approval. This procedure ends when the authorized individual has notified HRPP Personnel.

III. QUALIFIED PERSONNEL: HRPP Personnel or IRB Executive Chair carry out these procedures or ensure they are carried out by other personnel.

IV. TRAINING: Not applicable

V. SUPPLIES & EQUIPMENT: Not applicable

VI. PROCESS/PROCEDURE:

A. Notify the Investigator of the Suspension of IRB Approval or Termination of IRB Approval and the reasons for the action.

B. Ask the Investigator for a list of currently enrolled subjects and their level of involvement in the research (e.g., active intervention or long-term follow-up).

C. Consider whether the rights and welfare of currently enrolled subjects may be adversely affected. If so, consider the following actions:

1. Transfer subjects to another Investigator
2. Make arrangements for clinical care outside the research
3. Allow continuation of some research activities under the supervision of an independent monitor
4. Require follow-up of subjects
5. Require adverse events or outcomes to be reported to the IRB
6. Notify current subjects
7. Other actions

D. Notify the IRB staff member, handling the protocol, of the action to place on the agenda of a convened IRB meeting.

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):

DOD Instruction 3216.02 November 8, 2011

OHRP Guidance: Prisoner Research - FAQs

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