Standard Operating Procedure (SOP)

SOP Number: SOP CW AHC 218	**SOP Name:** Undue Influence of the HRPP
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 Organization Official at AdventHealth.

II. PURPOSE: This procedure establishes the process to manage allegations of undue influence of the Human Research Protection Program (HRPP). This procedure begins when the Organization Official learns of an allegation of undue influence of the HRPP. This procedure ends when any undue influence of the HRPP has been mitigated.

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. Individuals responsible for business development may not serve as IRB members and may not be involved in daily operations of the review process and may not discuss business development with IRB members.

B. Staff may explain written procedures to individuals involved in the review process.

C. Individuals at AdventHealth may not:

1. Provide information beyond an explanation of written procedures that might influence or appear to influence the review process determinations made as part of the criteria for approval.
2. Communicate AdventHealth's financial issues regarding specific protocols to individuals responsible for the review process.
3. Answer questions about AdventHealth's business issues posed by individuals responsible for the review process where the answers might influence or appear to influence review decisions.

D. When the IRB does not follow written procedures, AdventHealth can require the IRB to re-review the submission and disapprove research approved by the IRB.

E. All individuals at AdventHealth are required to ensure that allegations of undue influence of the HRPP or review process are reported to the Organization Official within 5 days of becoming aware of the allegation.

F. Gather information to determine the veracity of the report using discretion regarding the most efficient and effective methods. Methods to gather information can include, but are not limited to:

1. Interviews of individuals inside and outside AdventHealth
2. Review of records inside and outside AdventHealth
3. Consultation with internal or external entities

G. If the report has no basis in fact, take no further action under this SOP.

H. Take appropriate steps to eliminate the undue influence using discretion regarding the most efficient and effective methods. Steps may include, but are not limited to:

1. No action
2. Verbal counseling
3. Education
4. Reassignment of duties
5. Termination of employment
6. Document the findings and actions, if any, related to undue influence of the HRPP.

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):

21 CFR §56.109(a), §56.109(f), §56.112, §56.113

45 CFR §46.109(a), §46.109(e), §46.112, §46.113

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