

<b>SOP Number:</b> SOP CW AHC 217	<b>SOP Name:</b> Organizational Financial Interests
<b>Location:</b> *Company-Wide Policies	<b>Responsible Department:</b> Research Services
<b>Executive Owner:</b> Executive Director of Research Services	<b>Original Creation Date:</b> 01/18/2022
<b>Effective Date:</b> 08/16/2023	<b>Review Date:</b> 08/16/2023

- I. **SCOPE:** This standard operating procedure (SOP) applies to the Conflicts of Interest (COI) Official at AdventHealth.
- II. **PURPOSE:** This procedure establishes the process to evaluate and manage financial interests of the Organization. This procedure begins when the COI Official identifies an organizational financial interest that can affect the conduct of research. This procedure ends when the Human Research Protection Program (HRPP) Personnel have been provided an updated list of the AdventHealth’s financial interests.
- III. **QUALIFIED PERSONNEL:** The COI Official carries out these procedures.
- IV. **TRAINING:** Not applicable
- V. **SUPPLIES & EQUIPMENT:** Not applicable
- VI. **PROCESS/PROCEDURE:**
  - A. An organizational financial conflict of interest exists when any of the following could affect the design, conduct, or reporting of research:
    1. Licensing, technology transfer, patents
    2. Investments of AdventHealth
    3. Gifts to AdventHealth when the donor has an interest in the research
    4. Financial interests of senior administrators, including individuals identified in CW AHC 103 Designations in Research, and the individuals to whom they report
    5. Other financial interests
  - B. Senior administrators are required to disclose their financial interests to the research COI Official:
    1. Upon joining AdventHealth
    2. Every year
    3. When there are changes to their financial interests
  - C. AdventHealth considers investments under the control of independent investment managers (e.g., endowment) to be equivalent to diversified mutual funds and therefore not subject to disclosure under this policy.
  - D. AdventHealth officials may notify the COI Official of any change in the AdventHealth’s financial holdings not controlled by AdventHealth’s investment managers.
  - E. The evaluation and management of an organizational conflict of interest may not vary by funding or regulatory oversight.

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- F. Organizational financial conflict of interest management plans (Management Plans) and Research Oversight Committee (ROC)
1. COI Official will make an initial assessment of whether a reported significant institutional financial interest related to the research exists and then take the following actions:
    - a. If it is determined that a significant institutional financial interest does not exist, the disclosing individual shall be notified that no action is necessary.
    - b. If it is determined that a significant institutional financial interest exists, but it cannot directly and significantly affect the proposed research the investigator will be instructed to disclose the institutions relationship in a presentations, publications, proposals and consent documents.
    - c. If it is determined that a significant institutional financial interest could potentially directly and significantly affect the research, a Management Plan will be developed and implemented to either reduce or eliminate the potential conflict.
  2. Management Plans implemented will be tailored to the following:
    - a. The amount of the significant institutional financial interest.
    - b. The nature of the significant institutional financial interest.
    - c. In cases where an organizational financial conflict of interest involves an institutional administrator, the follow shall also be considered:
      - i. The degree of direct and immediate authority that institutional administrator has over the research and the people involved in the performance and reporting of the research.
      - ii. Whether a plan for separation of oversight of the staff conducting the human subject research by the institutional administrator with the conflict can be implemented that is both practical and effective while the administrator remains in the assigned leadership position.
    - d. Whether the studies involve AdventHealth intellectual property.
    - e. Areas of opportunity for potential bias to be entered into research.
  3. If an organizational financial conflict of interest exists and may be managed, the COI Official will develop a Management Plan as follows:
    - a. All Management Plans must require disclosure to the public and to the human subjects enrolled in the research.
    - b. COI Official notifies AdventHealth Institutional Review Board (IRB), ROC, the principal investigator, the regulatory specialist, operations manager, and supervisor, via uploading finalized FCOI Management Plan to the Florence eRegulatory system.
    - c. Management Plan with signatures is stored within Office of Research Integrity and Compliance or Florence eRegulatory system.
    - d. The COI Official may consult with AdventHealth Legal, AdventHealth Corporate Responsibility, ROC, Research Services Executive Director, or

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external legal counsel, as necessary when developing an Management Plan.

4. Additional management tools that may be used to minimize the risk to the institution may include, but are not limited to:
  - a. In cases where the organizational financial conflict of interest involves a AdventHealth administration, the following may be applicable:
    - i. Abstaining from participation in obtaining informed consent except to answer questions the potential research subject may have.
    - ii. Abstaining from conducting the clinical assessments of study eligibility criteria, intervention outcomes, or safety assessments, if related to a senior administrator.
    - iii. Disallowing an AdventHealth employee from being the sole person involved in the analysis, interpretation, or reporting of study results.
    - iv. limit/restrict decision making responsibilities, such as, abstaining from voting on any boards or committees with research oversight responsibilities.
  - b. Requiring the Organization to disclose the organizational financial conflict of interest and Management Plan to the study team members on a specified research project for which the Organization has a significant institutional financial interest.
  - c. An independent monitoring mechanism to be established which could include any of the following:
    - i. Data safety monitoring board
    - ii. Independent monitor
    - iii. Independent reviewer
  - d. Modifying the research plan, for example:
    - i. change of personnel or personnel responsibilities on the research project, including disqualification of personnel from participation in all or a portion of the research (e.g., not participating in the informed consent process with the exception of answering any questions a potential participant may have).
  - e. Reducing or eliminating the significant institutional financial interest (e.g., sale of an equity interest).
  - f. Severing relationship(s) that create the organizational financial conflict of interest (for example, stepping down as a board member).
  - g. Utilization of external IRB for review and monitoring.
  - i. Permitting only certain procedures/analysis to take place in AdventHealth.
5. All Management Plans are submitted to the AdventHealth IRB for review.

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- a. The IRB has the authority to decide whether an organizational financial conflict of interest and Management Plan, as reported to the IRB by the COI Official, allows the research to meet criteria for approval.
6. Notification to IRB of Management Plans.
- a. AdventHealth IRB - AdventHealth IRB cannot remove any elements of the Management Plan however, it can add additional mitigating or management plan elements as needed. Should AdventHealth IRB add an element to the Management Plan, AdventHealth IRB is required to notify the regulatory specialist team of the additions.

**VII. DEFINITION(S):** For capitalized terms not defined in this policy, refer to CW AHC 104 Financial Conflict of Interest in Research – Individual .

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):** Not applicable

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

- [Research Oversight](#)
- [Designations in Research](#)
- [Financial Conflict of Interest in Research - Individual](#)
- [Human Research Protection Program](#)