AdventHealth

POLICY

Policy #	Policy Name
CW AHC 104	Financial Conflict of Interest in Research - Individual
Policy Location	**Responsible Department**
*Company-Wide Policies	Research Services
Executive Owner	**Original Creation Date**
Executive Director of Research Services	01/18/2022
Policy Effective Date	**Policy Review Date**
01/06/2025	01/06/2025

I. **SCOPE:** This policy applies to all Research Personnel at AdventHealth, including those planning to participate or who are participating in research funded by the U.S. Public Health Service (PHS) or any other grantor, including foundations, to which 42 Code of Federal Regulations (CFR) 50 Subpart F or Uniform Guidance - 2 CFR 200.112 apply.

II. **PURPOSE:** The purpose of this policy is to:

- Promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from Financial Conflict of Interest (FCOI).
- Ensure the integrity of research and protect human subjects participating in research at AdventHealth.

III. **POLICY:** Research conducted under the auspices of AdventHealth shall be carried out in accordance with ethical and professional standards and integrity. AdventHealth strives to ensure that research performed at this institution shall remain free from the introduction of bias related to any identified conflicting financial interests.

IV. PROCEDURE/GUIDELINES:

A. Conflict of interest (COI) training is required of all Research Personnel initially upon employment at AdventHealth, or upon being identified as part of a research study team at AdventHealth, and at least every 4 years.
   1. Re-training may be required when policy revisions affect investigator requirements, or when an Individual is found non-compliant with this policy or an FCOI Management Plan.
   2. The Office of Research Integrity and Compliance (ORIC) has training available on this FCOI policy, including the responsibilities of Research Personnel regarding disclosure of financial interests, and all applicable federal regulations.

B. All Research Personnel are required to submit a COI Disclosure form(s) to the best of the Individual's knowledge and belief.
   1. Research Personnel are required to submit a COI Disclosure form(s), initially upon employment at AdventHealth, upon being identified as part of a research study team

on a research study at AdventHealth, or prior to proposal submission when an entity requires compliance with PHS Regulations.

2. COI Disclosures must be submitted at least annually, within 30 days of discovering or acquiring a new Significant Financial Interest (SFI), and no later than the time of application for all federally funded research.
3. All Sponsored or Reimbursed Travel within the previous 12 months shall be disclosed. The COI Disclosure collects travel information, which must include the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration.

C. COI and SFI Disclosures will be reviewed and acted upon within 60 days of submission to AHRI/ORIC.

1. Upon submission to ORIC, the COI Disclosure and, if applicable, any SFIs are reviewed by ORIC for completeness and determination of any potential conflicts. If any SFI declarations have been disclosed, the COI Disclosure(s) are submitted to the COI Official/designee for additional review and determinations.
2. The COI Official/designee will review all SFI disclosures submitted and determine if any potential conflicts exist based on the nature and value of reported SFI.
3. Determination of relatedness of the SFI to a current research study takes into consideration, at a minimum, the following facts and circumstances:
   a) Entity is the sponsor of a research study.
   b) Entity provides funding for a research study.
   c) Role of SFI holder on research study.
   d) Entity or competitor manufactures, makes, or provides an article, device, drug, or service being evaluated or used in a research study.
   e) Any Foreign Entity providing funding to the Individual.
   f) An SFI that could be affected by the research or is in an entity whose financial interest could be affected by the research.
4. The COI Official/designee must review SFIs against research studies, funded or proposed for funding by any sponsor that requires compliance with PHS Regulations, prior to expenditure of any funds or as required by the terms and conditions of the award.
   a) ORIC will verify that Research Personnel identified by AdventHealth Office of Sponsored Programs (OSP) have a current COI Disclosure, SFI Disclosure, and completed COI training on file.
   b) Prior to Institutional Clearance being given to a research project by OSP and throughout the duration of a research project, any reported SFIs that are determined to create an FCOI with the potential of introducing bias, will be managed, minimized, or eliminated.
5. The COI Official/designee will determine whether the SFIs create an FCOI that could directly and significantly affect the design, conduct, or reporting of the research study

and require reports to be submitted to the funding agency as stated in the terms and conditions of the award.

D. FCOI Management Plans and Research Oversight Committee (ROC)
   1. COI Official/designee will determine if an FCOI Management Plan is necessary.
   2. FCOI Management Plans implemented will be tailored to the following:
      a) The amount of the SFI(s).
      b) The nature of the SFI(s).
      c) The level of involvement or the role of the Individual (research team member) with a specific SFI in the related research project.
   3. If an FCOI is identified, the COI Official/designee will develop an FCOI Management Plan as follows:
      a) If the SFI is <$40,000, COI Official/designee develops FCOI Management Plan.
      b) If the SFI is >$40,000, COI Official/designee drafts FCOI Management Plan. FCOI Management Plan will be submitted to the ROC Chair or Vice-Chair for their review and assessment. The ROC Chair or Vice-Chair will determine via email whether the plan needs a full ROC review and vote.
         i. If ROC Chair or Vice-Chair determine it does not need full ROC review, the FCOI Management Plan is finalized, including any requested changes in their approval.
         ii. If ROC Chair or Vice-Chair determine it does need full ROC review, the FCOI Management Plan will be submitted via email or at convened ROC meeting for a vote. After voting, the FCOI Management Plan, incorporating any requested changes, is finalized.
      c) The COI Official/designee will obtain Individual's acceptance of the finalized FCOI Management Plan with their wet ink or electronic signature. Once signed by all applicable parties, the FCOI Management Plan must be implemented prior to study start. If an Individual discloses a new SFI during an ongoing study and it is determined that an FCOI exists, then the new or updated FCOI Management Plan must be implemented as soon as possible.
      d) The COI Official may consult with AdventHealth Legal, AdventHealth Corporate Responsibility, ROC, or external legal counsel, as necessary when developing an FCOI Management Plan.
      e) COI Official/designee notifies AdventHealth Institutional Review Board (IRB), Protocol Review Monitoring System (PRMS) coordinator, the regulatory specialist, operations manager and supervisor, of the signed and finalized FCOI Management Plan.
   4. Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:

a) Abstaining from participation in obtaining informed consent except to answer questions the potential research subject may have.
b) Disclosing the FCOI(s) directly to the participants, when the research involves human subjects (for example, in the informed consent form or letter of invitation).
c) Providing a statement of public disclosure of FCOI (such as when presenting or publishing the research).
d) Abstaining from conducting the clinical assessments of study eligibility criteria, intervention outcomes, or safety assessments.
e) Disallowing the Individual to be the sole person involved in the analysis, interpretation, or reporting of study results.
f) Requiring disclosure of the Individual's FCOI and FCOI Management Plan to the study team members on a specified research project for which the Individual has an SFI.
g) Adding an independent person to the research project team to monitor the project, who is capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI.
h) Modifying the research plan, for example: 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).
i) Reducing or eliminating the SFI (e.g., sale of an equity interest).
j) Severing relationship(s) that create the FCOI (for example, stepping down as a paid board member).
k) Limit/restrict decision making responsibilities, such as, abstaining from voting on any boards or committees with research oversight responsibilities.

E. All FCOI Management Plans are submitted to the AdventHealth IRB for review.
1. The IRB has the authority to decide whether an FCOI and FCOI Management Plan, as reported to the IRB by the COI Official, allows the research to meet criteria for approval.
2. Notification to IRB of FCOI Management Plans.
a) AdventHealth IRB - AdventHealth IRB cannot remove any elements of the FCOI Management Plan however, it can add additional mitigating or management plan elements as needed. Should AdventHealth IRB add an element to the FCOI Management Plan, AdventHealth IRB is required to notify the regulatory specialist team of the additions.
b) External IRB – The regulatory specialist team will notify the external IRB of record of the FCOI Management Plan and when it is implemented or revised. The external IRB cannot remove any elements of the FCOI Management Plan however,

it can add additional mitigating or management plan elements as needed. Should the external IRB add an element to the FCOI Management Plan, the external IRB is required to notify the regulatory specialist team of the additions.

F. Compliance Monitoring

1. FCOI Management Plans attributed to PHS funded studies will be monitored for Individual compliance as required by PHS Regulations and per the terms and conditions of an award. Each compliance monitoring plan and results will be documented upon completion within an acceptable time frame and will be stored within the ORIC department.
2. COI Official/designee reserves the right to monitor any FCOI Management Plan regardless of funding agency, when deemed appropriate.
3. Elements monitored may include, but are not limited to, review of the following:
   a) Stipulations as described in the FCOI Management Plan.
   b) OpenPayment website for confirmation of previously reported SFI amount.
   c) Review of purchasing agreements.
   d) Review of whether COI disclosures were provided in a timely manner.
4. If it is determined that non-compliance occurred, where an FCOI is not identified or managed in a timely manner, a retrospective review may be conducted if required by law, regulations (e.g. PHS Regulations), or the terms and conditions of an agreement that provides support for research. Non-compliance that could result in the need of a retrospective review include:
   a) Failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institution to constitute a Financial Conflict of Interest;
   b) Failure by the Institution to review or manage such a Financial Conflict of Interest; or
   c) Failure by the Investigator to comply with a Financial Conflict of Interest management plan;
5. A retrospective review will be completed within 120 days of ORIC's date of determination of non-compliance. The retrospective review will identify:
   a) Project number, title, and principal investigator.
   b) The Individual with the FCOI.
   c) Name of the entity with whom the Individual has an FCOI with.
   d) Reason for the retrospective review.
   e) Detailed methodology used for the review.
   f) Findings of the retrospective review including,
   g) Conclusions of the review.
   h) Corrective actions required include, but are not limited to:
      i. Update previously submitted FCOI report on eRA Commons, if applicable.

ii. Complete a mitigation report if bias was found.

iii. In the event the Department of Health and Human Services (DHHS) determines a PHS-funded clinical research project with the purpose of evaluating the safety or effectiveness of a drug, device, or treatment has been designed, conducted, or reported by an Individual with an FCOI that was not managed or reported by AdventHealth per the federal regulations, AdventHealth shall require the Individual involved to:

- Disclose the FCOI in each public presentation of the results of the research.
- Request an addendum to previously published presentations.

6. If a mitigation report is required, it will contain the following:

a) The elements contained in the retrospective review.

b) An analysis of the impact of bias, including but not limited to:

i. Description of bias.

ii. Impact of bias on project, quantified if possible.

iii. Extent of harm (past, current, future).

iv. Analysis of whether project is salvageable.

c) Corrective actions that are required may include, but are not limited to:

i. Plan of action to eliminate or mitigate the effect of the bias. Update previously submitted FCOI report on eRA Commons, if applicable.

ii. File the mitigation report as required by the terms and conditions of an award if Research Personnel are affiliated with an externally funded research study or grant which requires compliance with PHS Regulations.

iii. Monitor compliance with the FCOI Management Plan.

iv. In the event DHHS determines a PHS-funded clinical research project with the purpose of evaluating the safety or effectiveness of a drug, device, or treatment has been designed, conducted, or reported by an Individual with an FCOI that was not managed or reported by AdventHealth per the federal regulations, AdventHealth shall require the Individual involved to:

- Disclose the FCOI in each public presentation of the results of the research.
- Request an addendum to previously published presentations

G. Violations of the requirements of this policy may result in one or more of the following (without limitation):

1. Human subjects research that does not comply with this policy, may not receive Institutional Clearance and may not begin the study or utilize hospital services.
2. AdventHealth or IRB suspension or hold of the associated study(ies) involved.
3. Employee discipline or other administrative actions as appropriate.
4. Additional training and education may be required.

5. If there is a management plan in place and non-compliance with the plan is found, a re-review may be conducted, and additional FCOI Management Plan stipulations may be required.

H. Reports
   1. All required FCOI reports will be submitted to the funding agency as required by the terms and conditions of the award(s) and, when applicable, per PHS Regulations.
      a) Initial FCOI reports will be submitted prior to the expenditure of external funds (for new awards or awards that are new to AdventHealth).
      b) Annual FCOI reports will be provided in the time and manner specified by the funding agency (at the same time as the grantee's annual progress report, multi-year progress report, or at the time of extension, if applicable).
      c) Additional subsequent FCOI reports will be submitted in the following circumstances:
         i. Within sixty (60) days of new, or newly identified, FCOIs for existing Research Personnel.
         ii. Within sixty (60) days of identification of a new Individual added to an externally funded research project which requires compliance with PHS Regulations.
         iii. Following a retrospective review to update a previously submitted report, when applicable.
      d) A mitigation report will be submitted after conducting a retrospective review, if it is determined that a research project or a portion thereof, was biased in the design, conduct, or reporting prior to the identification and management of the FCOI.
      e) In the event that an Individual fails to comply with this policy or FCOI Management Plan, and subsequently that failure appears to have biased the design, conduct, or reporting of the research, it will be promptly reported by AdventHealth including the corrective action plan to address the non-compliance.
   2. If an Investigator fails to comply with this policy, and it is determined to have a SFI that is related to funded research and appears to have biased the design, conduct, or reporting of the research, COI Official/designee will promptly notify the funding agency, as required.
   3. If AdventHealth is required by law, regulation or other obligation to report additional information not identified as a SFI concerning a financial interest, the covered individual shall provide the required information upon request. Examples include, but are not limited to, disclosure requirements related to venture or other capital financing and the disclosure of foreign contracts. In the event a foreign contract is requested, an authenticated English version of the contract shall be provided.

I. Subrecipient Requirements: If AdventHealth carries out any portion of an award through a subrecipient (e.g., subcontractors or consortium members), AdventHealth will take

reasonable steps to ensure that subrecipient investigators and its Research Personnel comply with PHS Regulations.

1. AdventHealth will incorporate terms and conditions in subaward agreements that require the subrecipient to either comply with the subrecipient's PHS compliant conflict of interest policy or with this policy.
2. AdventHealth will provide timeframes for the subrecipient to provide AdventHealth with information necessary for AdventHealth to complete its FCOI reporting requirement to the funding agency.

J. Compliance with this policy and any associated procedures, or work instructions will be subject to auditing and monitoring activities by ORIC and the applicable Corporate Responsibility office(s).

K. Public Access

1. This policy will be publicly available as required by PHS Regulations for Senior/Key Personnel.
2. Upon receipt of a valid, written request to ORIC concerning any FCOI related to an externally funded research project which requires compliance with PHS Regulations, information as required by the terms and conditions of the award and per federal regulations will be made available to the requester within five (5) business days of receipt of such a request. If the request meets the criteria, the specific information released will be limited to:
   a) The Individual's name, title and role with respect to the research project;
   b) The name of the entity in which the SFI is held;
   c) The nature of the SFI;
   d) The approximate dollar value of the SFI, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.
      i. Updates to a request will only be provided upon receipt of a subsequent valid written request when they meet the criteria for release.
      ii. Information concerning the SFI of an Individual shall remain available for response to the public's written request for at least 3 years from the date that the information was most recently updated.

L. Records Maintenance and Availability

1. All FCOI associated records, forms, reports and reviews will be stored electronically within ORIC.
   a) Associated records will be kept for a minimum of 3 years after the close of a research project or 3 years from the date the final expenditures report was submitted to the funding agency as required by the terms and conditions of the award.

b) All records will be available to the funding agency upon inquiry either for submission to the funding agency upon request, or for an onsite review of all pertinent records.

2. FCOI records may be stored electronically.

V. DEFINITION(S):

COI Disclosure(s): A reporting form(s) that is collected annually and at various transaction points from Individuals who are subject to this policy. It requires Individuals to report any SFIs and Sponsored or Reimbursed Travel, and those of the Individual's Immediate Family Member, that reasonably appear to be related to their professional expertise and Institutional Responsibilities.

COI Official: The COI Official shall be the Director of Research Integrity and Compliance in ORIC. The Senior Vice President of Corporate Responsibility of AdventHealth will serve as the COI Official when a conflict involves the Director of Research Integrity.

FCOI Management Plan: The plan that is developed when a SFI exists that is related to a research project. The plan outlines the means of action to address an FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias. All FCOI Management Plans use the "Significant Financial Interest (SFI) Summary and FCOI Management Plan" template.

Financial Conflict of Interest (FCOI): A Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of a research or grant project.

Foreign Entity: Any foreign individual, official, corporation, business association, partnership, trust, society or any other entity or group that is not incorporated or organized to do business in the United States, as well as international organizations, foreign governments and any agency or subdivision of foreign governments (e.g. diplomatic missions).

Immediate Family Member: The immediate family of the Individual includes spouse and dependent children.

Individual: A specific Research Personnel subject to this policy. The Individual signing the AdventHealth COI Disclosure form includes the interests of the Individual's spouse and dependent children.

Institutional Clearance: Action required and provided by the Office of Sponsored Programs (OSP) in order to initiate a research project.

Institutional Responsibilities: A Research Personnel's professional responsibilities on behalf of AdventHealth, which, for example, may include but are not limited to activities such as the design, conduct, or reporting of research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Open Payments: A national transparency program that collects and publishes information about financial relationships between the health care industry (i.e. drug and device companies) and providers (i.e. physicians and teaching hospitals).

Outside Entity: Any individual, corporation, partnership, limited liability company, sole proprietorship, firm, franchise, unincorporated association organization, holding company, joint stock company, business or real estate trust, any other legal entity organized for profit or charitable purposes, or Foreign Entity. Outside Entities specifically excludes AdventHealth or any other corporation controlled by, controlling, or under common control with (of) Adventist Health System Sunbelt HealthCare Corporation d/b/a AdventHealth.

PHS Regulations: Public Health Service (PHS) regulations on "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought," 42 C.F.R. Part 50, Subpart F. (These regulations have also been adopted and implemented by non-PHS entities.)

Research Personnel: Individuals involved in the design, conduct, or reporting of research.

Research Oversight Committee (ROC): A committee which provides specific oversight, support and resources to the research conducted at AHRI.

Significant Financial Interest (SFI):

1. A financial interest consisting of one or more of the following interests of the Individual (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Individual's Institutional Responsibilities:
   a) With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
   b) With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve

months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

c) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests that when aggregated, exceeds $5,000.

2. The term *significant financial interest* does not include the following types of financial interests:
   a) Salary, royalties, or other remuneration paid by AdventHealth to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
   b) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
   c) Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
   d) Income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Sponsored or Reimbursed Travel: Sponsored or Reimbursed Travel is that which is paid by an Outside Entity on behalf of the Individual and may or may not be reimbursed to the Individual and is related to an Individual's Institutional Responsibilities. This excludes any travel paid for either by Adventist Health System Sunbelt HealthCare Corporation d/b/a AdventHealth and any subsidiary or affiliate or a U.S. federal, state, or local government agency. Sponsored or Reimbursed Travel shall be reported as part of SFI. As noted above, any form of direct or indirect remuneration from a Foreign Entity, including travel reimbursement, must be disclosed as an SFI.

VI. EXCEPTION(S):

An exception exists for AdventHealth University (AHU) students, who are not AdventHealth employees, and not participating in a U.S. federally funded project.

See CW AHC 101 Research Oversight

VII. REFERENCE(S):

Code of Federal Regulations – Electronic (e-CFR). (November 5, 2015). Title 42, Chapter 1, Part 50, Subpart F: Promoting Objectivity in Research. Retrieve from: e-CFR.

Uniform Guidance - 2 CFR 200.112

Open Payments Website

VIII. RELATED DOCUMENT(S) / ATTACHMENT(S):

- CW AHC 101 Research Oversight
- SOP CW AHC 241 AHRI Personnel Financial Interests
- SOP CW AHC 217 Organizational Financial Interests