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| Policy # CW AHC 104 | Policy Name Financial Conflict of Interest in Research - Individual |
| Policy Location *Company-Wide Policies | Responsible Department Research Services |
| Executive Owner Executive Director of Research Services | Original Creation Date 01/18/2022 |
| Policy Effective Date 04/04/2022 | Policy Review Date 04/04/2022 |

- 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).
 - Support efforts to manage or eliminate the potential of bias in research, 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. 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.
1. 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.
 2. ORIC offers training in a variety of formats, such as:
 - a) ORIC sponsored in-service with live question and answer
 - b) ORIC approved online COI training module; AdventHealth Learning Network (ALN) is utilized for AdventHealth employees and affiliates. Non-AH Research Personnel will utilize the AdventHealth Research Institute (AHRI) external website:

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<https://www.adventhealthresearchinstitute.com/research/office-research-integrity/resources>

- B. All Research Personnel are required to submit a COI Disclosure and, when applicable, an SFI Disclosure(s). All COI Disclosures and SFI Disclosures must be to the best of the Individual's knowledge and belief.
1. Research Personnel are required to submit a COI Disclosure, 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. A newly discovered and acquired SFI must be documented through completion of a new SFI Disclosure, within 30 days of acquisition. An updated COI Disclosure may also be necessary.
 4. COI Disclosures expire one year from the date previously signed.
 5. The COI Disclosure and SFI Disclosure may be found on the Research Services SharePoint site, in the Forms Library at IRBnet.org, or the website <https://www.adventhealthresearchinstitute.com/>.
 6. The completed form(s) must be submitted to AdventHealth ORIC via email: ORL.ORIC@adventhealth.com.
 7. If COI Disclosures are not submitted as required and within 30 days of the expiration date of the previous COI Disclosure, this will constitute non-compliance.
 8. 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, the SFI Disclosure are reviewed by ORIC for completeness and determination of any potential conflicts.
 - a) If no declarations have been disclosed:
 - i. COI Disclosure is signed and dated by the COI Official/designee.
 - ii. COI Disclosure is filed and maintained by ORIC.
 - b) If any declarations have been disclosed, COI Disclosure and related SFI 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.

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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) If funded by PHS, when AdventHealth through its COI Official/designee reasonably determines that the SFI 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 by any entity that requires compliance with PHS Regulations, prior to expenditure of any funds or as required by the terms and conditions of the award. 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.
 5. The COI Official/designee will determine if any disclosed SFIs are related to any research studies funded by any entity that requires compliance with PHS Regulations, and if the SFIs create an FCOI with the research study, requiring 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 <40k, COI Official/designee develops FCOI Management Plan.
 - b) If the SFI is >40k, 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.

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- 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) COI Official/designee notifies AdventHealth Institutional Review Board (IRB), the regulatory specialist, operations manager, and supervisor, via uploading finalized FCOI Management Plan to the Florence eRegulatory system.
 - d) The COI Official/designee will obtain Individual's acceptance of the finalized FCOI Management Plan with their wet ink or electronic signature, in accordance with PHS Regulations. 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.
 - e) FCOI Management Plan with signatures is stored within ORIC or Florence eRegulatory system.
 - f) The COI Official may consult with AdventHealth Legal, AdventHealth Corporate Responsibility, ROC, Research Services Executive Director, or external legal counsel, as necessary when developing an 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 the Individual to disclose their 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

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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. The compliance monitoring plan will be developed and tailored to the Individual's FCOI Management Plan when appropriate. Compliance monitoring plan may take into account the number of subjects anticipated to be enrolled, amount of SFI, and the Individual's responsibility on the project or research.
- 2. 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. Approximately 10-25% of FCOI Management Plans attributed to industry sponsor funded studies will be monitored for compliance. Each compliance monitoring plan and results will be documented upon completion within an acceptable time frame and will be stored within the ORIC department. COI Official/designee reserves the right to monitor any FCOI Management Plan when deemed appropriate.
- 3. Elements monitored may include, but are not limited to, review of the following:
 - a) Informed consent involving SFI Disclosure notification to the patient.
 - b) Signature on informed consent to confirm Individual is not consenting

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- c) Clinical assessments of study eligibility criteria, intervention outcomes, or safety assessments.
 - d) Research Personnel, to ensure compliance of the analysis, interpretation, or reporting of study results.
 - e) OpenPayment website for confirmation of previously reported SFI amount.
 - f) Presentations and publications for disclosure of SFI, as appropriate.
 - g) Review of committee agenda, minutes, and voting records, if applicable.
 - h) Review of purchasing agreements.
- G. Non-compliance and Corrective and Preventative Action (CAPA) plans
1. Non-compliance includes, but is not limited to the following:
 - a) COI Disclosure and training not submitted within 30 days upon hire.
 - b) COI Disclosure not submitted prior to participation in a research study.
 - c) COI Disclosure and training not submitted timely by Individual within 30 days of expiration date.
 - d) Updated COI Disclosure and SFI Disclosure not submitted within 30 days of acquiring a new SFI.
 - e) SFI not disclosed and ORIC informed by another source. (Example: OpenPayment website)
 - f) SFI not identified and reviewed by COI Official/designee within the applicable time frame.
 - g) COI Disclosure or SFI Disclosure not reviewed and managed, within the timeframe defined per policy or regulations, by COI Official/designee.
 - h) Failure of the Individual to comply with FCOI Management Plan.
 2. If it is determined that non-compliance occurred, a CAPA plan will be developed. The CAPA will include a retrospective review if required by law, regulations (e.g. PHS Regulations), or the terms and conditions of an agreement that provides support for research.
 3. 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 the Individual has an FCOI with.
 - d) Reason for the retrospective review.
 - e) Detailed methodology used for the review.
 - f) Time period or dates of non-compliance.
 - g) Time period or dates to be audited for the retrospective review.
 - h) Documents to be audited/reviewed for the retrospective review.

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- i) Findings of the retrospective review including, but not limited to:
 - i. No negative findings;
 - ii. No bias found;
 - iii. Biased design, conduct, or reporting of results.
 - j) Conclusions of the review.
 - k) 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 the 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.
4. 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 the 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

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H. 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. Requirement to develop and complete a CAPA plan acceptable to the COI Official, with ORIC input, approval, and oversight of the CAPA. Additional training and education may be required as part of the CAPA.

I. Enforcement

1. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Research Personnel/AdventHealth compliance, as appropriate.
2. Several enforcement mechanisms will ensure compliance with AHRI policy so that any reported SFIs that are determined to be an FCOI will be managed, minimized, or eliminated. Institutional Clearance or an administrative hold may be required, including but not limited to:
 - a) If an Individual has not submitted required COI Disclosures and completed COI training, the project will not receive Institutional Clearance until disclosures and training documentation have been submitted, reviewed by ORIC and any required FCOI Management Plans have been created and implemented.
 - b) If there is a lapse in annual COI Disclosures by any Individual on a research project, the project may be put on administrative hold until the COI Disclosure has been submitted and reviewed by the COI Official/designee, or the Individual may be removed from any active research studies.
 - c) If non-compliance is found, a CAPA plan may be developed.
 - d) Corrective actions may be required as part of a retrospective review or as part of a mitigation report.
 - e) Education modules will be available to be included as part of CAPA plans.

J. 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:

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- 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. FCOI quarterly and on-going reports:
- a) COI Disclosure and FCOI non-compliance metrics are to be reported on a quarterly basis to leadership.
 - b) COI and SFI Disclosure reports and metrics are to be reported at ROC meetings on a quarterly basis.
 - c) FCOI Management Plans >40k are to be reported on an on-going basis to the ROC Chair and Vice-Chair.
- K. 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.
- L. 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.
- M. 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).
- N. Public Access

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1. This policy will be publicly available as required by PHS Regulations.
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.

O. 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 that is collected annually and at various transaction points from Individuals who are subject to this policy. It requires Individuals to report SFIs and Sponsored or Reimbursed Travel, 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 in ORIC. The Executive Director of Research Services will serve as the COI Official when a conflict involves the Director of Research Integrity.

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Corrective and Preventative Action: A set of proposed activities that are required to correct deficiencies and bring them back into compliance with applicable policies and procedures.

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).

Human Research Protection Program (HRPP): A comprehensive system to ensure the protection of human subjects taking part in research.

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).

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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): It's a committee that provides specific oversight, support and resources to the research conducted at AHRI.

SFI Disclosure(s): A reporting form that Individuals use to report the required details of their SFI(s).

Significant Financial Interest (SFI): A financial interest of the Individual or an Immediate Family Member with an Outside Entity that reasonably appears to be related to the Individual's Institutional Responsibilities.

- An SFI exists if the value of any remuneration received from the entity in the twelve (12) months preceding the date of the AdventHealth COI Disclosure and the value of any equity interest in the entity as of the date of the AdventHealth COI Disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes, but is not limited to, the following:
 - Salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, speaking fees, paid authorship, etc.).
 - Equity interest, in a publicly traded company, includes any stock, stock option, or other ownership interest as determined through reference to public prices or other reasonable measure of fair market value.
- An SFI exists when there are proprietary interests or intellectual property rights (e.g., patents, trademarks, copyrights, licensing agreements, royalties, etc.).
- An SFI exists when the Individual or an Immediate Family Member holds any equity interest in a non-publicly traded entity (e.g., equity, stock, stock options, or other ownership interest).
- An SFI exist in any form of direct or indirect remuneration, including travel reimbursement, from a Foreign Entity.
- SFI does not include the following:
 - Salary paid by AdventHealth.

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- Other remuneration paid by AdventHealth directly to AdventHealth employees.
- Income from investment sources such as mutual funds or retirement accounts, as long as the Individual does not control investment decisions made in these investment sources.
- Income from seminars, lectures, or teaching engagements sponsored by a United States (U.S.) government agency, or a U.S. institution of higher education.
- Income from service on advisory committees or review panels for a U.S. government agency, or a U.S. 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. 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.

United States Government Agency: A United States federal, state, or local government agency.

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

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