

Policy # 400.005	Policy Name Financial Conflict of Interest in Research - Individual
Policy Location AdventHealth Orlando	Responsible Department Research Services
Policy Owner or Executive Owner Executive Director of Research Services	Original Creation Date Not applicable
Policy Effective Date 4/20/2021	Policy Review Date 4/20/2021

- I. SCOPE:** This policy applies to all Research Personnel and HRPP Personnel involved in the design, conduct, or reporting of research at AdventHealth Orlando, including those planning to participate or who are participating in research funded by the U.S. Public Health Service (PHS) or any other grantor to which 42 Code of Federal Regulations (CFR) 50 Subpart F and Uniform Guidance - [2 CFR 200.112](#) applies.
- 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 and/or eliminate the potential of bias in research, ensure the integrity of research, and protect human subjects participating in research at AdventHealth Orlando.
- III. POLICY:**
1. Research conducted under the auspices of AdventHealth Orlando shall be carried out in accordance with ethical and professional standards and integrity.
 2. AdventHealth Orlando strives to ensure that research performed at this institution shall remain free from the introduction of bias related to any identified conflicting Financial Interests.
 3. Conflict of Interest (COI) Training is required of all HRPP Personnel and Research Personnel initially upon employment at AdventHealth Orlando, or upon being identified as part of a research study team on a research study at AdventHealth Orlando, and at least every 4 years in accordance with [SOP 403.001](#). Re-training may be required when COI policy or SOP revisions affect investigator requirements, or when an Individual is found non-compliant with COI policy or an FCOI Management Plan.
 4. All HRPP Personnel and Research Personnel are required to submit COI Disclosure initially upon employment at AdventHealth Orlando or upon being identified as part of a research study team on a research study at AdventHealth Orlando and to submit

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updated COI Disclosures at least annually, and 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 in accordance with [SOP 403.001](#). All COI disclosures must be to the best of the Individual's knowledge and belief.

5. All Sponsored or Reimbursed travel in the 12 months prior to disclosure shall be disclosed in accordance with [SOP 403.001](#).
6. COI/SFI Disclosures will be reviewed and acted upon within 60 days of submission to AdventHealth Orlando Office of Research Integrity (ORI) in accordance with [SOP 403.001](#).
7. Research Oversight Committee (ROC) Chair and/or Co-Chair to review identified ORI prepared FCOI Management Plan summaries and determine Management Plans to be reviewed and voted on by ROC in accordance with [SOP 403.001](#).
8. All FCOI Management Plan summaries are submitted to the AdventHealth Orlando Institutional Review Board (IRB) for review.
9. COI quarterly reports are submitted to the ROC.
10. Prior to Institutional Clearance being given to a research project by the Office of Sponsored Programs (OSP) and throughout the duration of a research project, any reported Financial Interests that are determined to be a Conflict of Interest with the potential of introducing bias will be managed, minimized, or eliminated in accordance with [SOP 403.001](#).
11. Compliance with this policy and any associated SOPs, and/or Work Instructions will be subject to auditing and monitoring activities by the Office of Research Integrity and Corporate Responsibility.
12. Violations of the requirements of this policy may result in one or more of the following (without limitation):
 - 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 in support of the study.
 - Institutional or IRB suspension or hold of associated study and/or studies involved.
 - Employee discipline and/or other administrative actions as appropriate
 - Requirement to develop and complete a Corrective and Preventative Action (CAPA) acceptable to the Office of Research Integrity with Research Compliance input, approval and oversight of the CAPA. Additional training and education may be required as part of the CAPA.

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13. This policy and related standard operation procedure(s) identified below will be publicly available.

[SOP 403.001: Financial Conflict of Interest in Research Process - Individual](#)

IV. PROCEDURE/GUIDELINES: Not applicable

V. DEFINITION(S):

Conflict of Interest (COI): Any situation in which financial, professional or personal obligations may compromise, or present the appearance of compromising, professional judgment in designing, conducting, analyzing, reporting, or supporting research; or licensing, selling, sharing or commercializing the results of research. Conflicts of interest can be real or perceived.

COI Official: The COI Official shall be the Director of Research Integrity in the Office of Research Integrity (ORI). The Executive Director of Research Services will serve as the COI Official for the Director of Research Integrity.

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.

Financial Interest (FI): Anything of monetary value from a publicly traded entity or a non-publicly traded entity, whether or not the value is readily ascertainable.

Foreign Entity: includes any foreign individual, 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).

HRPP Personnel: Individuals involved in the oversight of research.

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 HRPP Personnel or Research Personnel subject to this Policy 400.005.

Institutional Responsibilities: Institutional Responsibilities means a Research Personnel's professional responsibilities on behalf of AdventHealth Orlando, which, for

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example, may include but are not limited to activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

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 a 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.

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 Orlando or any other corporation controlled by, controlling, or under common control with (of) Adventist Health System Sunbelt HealthCare Corporation d/b/a AdventHealth.

Research Personnel: Individuals involved in designing, conducting, or reporting research.

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 Orlando COI disclosure and the value of any equity interest in the entity as of the date of the AdventHealth Orlando 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 includes any stock, stock option, or other ownership interest as determined through reference to public prices or other reasonable measure of fair market value.
 - Proprietary interests or intellectual property rights (e.g., patents, trademarks, copyrights, licensing agreements, royalties, etc.).
- A SFI exists when the Individual or an Immediate Family Members) holds any equity interest in a non-publicly traded entity (e.g., stock, stock options, or other ownership interest).
- SFI does not include the following:

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- Salary paid by AdventHealth Orlando or AdventHealth.
- Other remuneration paid by AdventHealth or AdventHealth Orlando directly to AdventHealth Orlando 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, but, is related to an Individual's Institutional Responsibilities. This excludes any travel paid for either by AdventHealth Orlando; any other corporation controlled by, controlling, or under common control with (of) Adventist Health System Sunbelt HealthCare Corporation d/b/a AdventHealth; or a U.S. government agency. Sponsored or Reimbursed Travel shall be reported as part of SFI.

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

VI. EXCEPTION(S): Not applicable

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](#)

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

Policy [400.001 HRP-001 Definitions in Research](#)

SOP [403.001 Financial Conflict of Interest in Research Process - Individual](#)

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