

Standard Operating Procedure (SOP)

SOP Number: SOP CW AHC 241	SOP Name: AHRI Personnel Financial Interests
Location: *Company-Wide Policies	Responsible Department: Research Services
Executive Owner	Original Creation Date: 01/18/2022
Executive Director of Research Services	
Effective Date: 08/16/2023	Review Date: 08/16/2023

- **I. SCOPE:** This standard operating procedure (SOP) applies to all AdventHealth Research Institute (AHRI) Personnel, excluding those responsible for the design, conduct, or reporting of research, who are required to follow CW AHC 104 Financial Conflict of Interest in Research Individual.
- **PURPOSE:** All AdventHealth employees are required to disclose conflicts of interest as set forth in CW CR 101.7 Conflict of Interest. This SOP sets forth additional requirements for AHRI Personnel, to promote objectivity in research and provide a reasonable expectation that the management and oversight of research at AdventHealth will be free from bias.
- III. **QUALIFIED PERSONNEL**: AHRI Personnel
- **IV. TRAINING:** Research Conflict of Interest Training
- V. <u>SUPPLIES & EQUIPMENT</u>: Not Applicable

VI. PROCESS/PROCEDURE:

- A. Conflict of interest (COI) training is required of all AHRI Personnel initially upon employment at AdventHealth and at least every 4 years. Re-training may be required when a person is found non-compliant with a management plan or this SOP.
- B. All AHRI Personnel are required to submit a COI Disclosure and, when applicable, an SFI Disclosure. All COI Disclosures and SFI Disclosures must be to the best of the individual's knowledge and belief.
 - 1. AHRI Personnel are required to submit a COI Disclosure upon initial employment at AdventHealth.
 - 2. COI Disclosures must be submitted at least annually or within 30 days of discovering or acquiring a new Significant Financial Interest (SFI).
 - 3. A newly discovered and acquired SFI must be documented with a new SFI Disclosure within 30 days of acquisition. An updated COI Disclosure may also be necessary.
 - 4. COI Disclosures expire annually from the date previously signed.
 - 5. The COI Disclosure and SFI Disclosure are located on the AHRI SharePoint site, the Forms Library at IRBnet.org, or https://www.adventhealthresearchinstitute.com/.
 - 6. The completed form(s) must be submitted via email to AdventHealth Office of Research Integrity and Compliance (ORIC): ORL.ORI@adventhealth.com.
 - 7. If there is an SFI/potential conflict, the completed form(s) must also be submitted via email to:

- a) Their immediate manager; and
- b) The manager one level above their immediate manager
- C. The completed forms will be reviewed by AdventHealth ORIC, and their immediate manager and the manager one level above their immediate manager when applicable, to determine if a conflict exists and if the conflict requires management.
 - 1. If the conflict does not require management, no further action will be taken.
 - 2. If the conflict requires management, ORIC will work with the applicable managers to develop a plan sufficient to limit AHRI Personnel's influence over the conduct or integrity of research conducted under the auspices of AdventHealth.

VII. <u>DEFINITION(S)</u>:

AdventHealth Research Institute (AHRI) Personnel: Employees involved in the oversight and management of research that work under the auspices of the AdventHealth Research Institute. This specifically excludes those responsible for the design, conduct, or reporting of research, who are required to follow CW AHC 104 Financial Conflict of Interest in Research - Individual. AHRI Personnel also includes any data safety monitoring board members, regardless of employment status.

COI Disclosure(s): A reporting form that is collected annually and at various transaction points from AHRI Personnel who are subject to this policy. It requires AHRI Personnel to report SFIs and sponsored or reimbursed travel, that reasonably appear to be related to their professional expertise and institutional responsibilities.

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 AHRI Personnel or an immediate family member with an outside entity that reasonably appears to be related to the AHRI Personnel'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 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 AHRI Personnel 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.
 - 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.
- **VIII. EXCEPTION(S):** AHRI Personnel responsible for the design, conduct, or reporting of research, who are required to follow CW AHC 104 Financial Conflict of Interest in Research Individual.
 - **IX. REFERENCE(S)**: Not Applicable
 - X. RELATED DOCUMENT(S) / ATTACHMENT(S):
 - CWCR 101.7 Conflict of Interest
 - Financial Conflict of Interest in Research Individual
 - Research Oversight