Standard Operating Procedure (SOP)

SOP #: 403.001	Financial Conflict of Interest in Research - Individual	
Executive Owner: Vice President Research Operations		Effective Date: 8/29/2016 Review Date: 3/26/2019

Scope	This Standard Operating Procedure (SOP) applies to all individuals involved in the design, conduct, or reporting of research at AdventHealth Orlando.
Purpose	The purpose of this process is to provide specific and detailed instruction on how Policy 400.005 Financial Conflicts of Interest (FCOI) in Research: Individual is carried out and enforced.
Qualified Personnel	Staff of the Office of Research Integrity (ORI)
Training	The Office of Research Integrity (ORI) has training available on the FCOI policy, including the responsibilities of Research Personnel regarding disclosure of financial interests, and all applicable federal regulations. Training is required of all AdventHealth Orlando Research Personnel initially and at least every four (4) years, with the exception of Residents in the Graduate Medical Education (GME) program. The GME Residents are not required to complete FCOI training unless they are participating in a Public Health Service (PHS) funded project. The ORI offers training in a variety of formats, such as: • ORI sponsored in-service with live question and answer. • ORI developed paper and pencil module. • ORI developed computer-based learning module.
Supplies & Equipment	Not applicable
Procedure	**A. Disclosure of Financial Interests** Completion and Submission of COI Disclosure Forms: 1. AdventHealth Orlando Research Personnel who are new to the institution or new to a project should complete the required COI Disclosures no later than at the time of application for external funding, expenditure of external funds, the submission of a research study to the IRB, or being added to a research study team. 2. The COI Disclosure and SFI Disclosure Forms may be found in the Forms Library at IRBnet.org. 3. The completed form(s) is submitted to the ORI via email to the AdventHealth Orlando Office of Research Integrity email inbox: FH.ORI@adventhealth.com. **B. Review of Disclosures Submitted to the AdventHealth Orlando ORI** 1. Upon receipt by the ORI, the COI Disclosure and SFI Disclosure forms are reviewed for the following: a. Completeness of form(s)

b. Legibility of writing

c. Signature

d. Date of FCOI Training (verified by ORI staff)

2. If no declarations have been disclosed,

   a. COI Disclosure form is signed by the COI Official or designee.

   b. COI Disclosure form is filed for the AdventHealth Orlando Research Personnel team member.

3. If any declarations have been disclosed, COI Disclosure form and related SFI Disclosure Form(s) are submitted to the COI Official for additional review and determinations.

C. Determination

The COI Official will review all disclosures of SFIs and make the following determinations:

1. By nature and combined value of the SFI's reported, determine if a FCOI:

   a. Exists,

   b. Potentially exists,

   c. May be perceived to exist, or

   d. Does not appear to exist.

2. Determine if a management plan is necessary.

   This is determined when the SFI is related to a current or future project in the following ways, including, but not limited to:

   a. The SFI-related entity is the sponsor of a research study.

   b. The SFI-related entity provides funding for a research study.

   c. The SFI-related entity manufactures, makes, or provides an article, device, drug, or service being evaluated or used in a research study.

3. Determine if any disclosed SFIs are related to any research projects funded by any entity that requires compliance with 42 CFR 50 Subpart F and, as a result, if any reports are required to be submitted to the Funding Agency as stated in the terms and conditions of the award.

D. Management Plan

1. If a potential FCOI is identified, the COI Official will:

a. Develop and implement a management plan. The COI Official may consult with AdventHealth Orlando Research Legal or Corporate Compliance as necessary in developing a management plan.

b. Notify the Individual.

c. Obtain the Individual's acceptance of the plan with his/her signature.

d. Plan with signatures is stored within the ORI Department.

2. Notify the IRB by any of the following methods:
   a. At a regularly scheduled IRB meeting
   b. Via email
3. Management plans implemented will be tailored to:
   a. The amount of the SFI(s).
   b. The nature of the SFI(s).
   c. The level of involvement and/or the role of the Individual with a specific SFI in the related research project.
4. Examples of conditions or restrictions that might be imposed to manage a FCOI include, but are not limited to:
   a. Abstaining from participation in the recruitment of subjects and 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. Abstaining from conducting the clinical assessments of study eligibility criteria, intervention outcomes, or safety assessments.
   d. Disallowing the Individual to be the sole person involved in the analysis, interpretation, or reporting of results.
   e. Requiring the Individual to disclose his/her FCOI and Management plan to the other research personnel on a specified research project for which the Individual has an SFI.
   f. 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.
   g. 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).

h. Reducing or eliminating the financial interest (e.g., sale of an equity interest).

i. Severing relationship(s) that create financial conflicts (for example, stepping down as a paid board member).

j. Providing a statement of public disclosure of FCOI (such as when presenting or publishing the research).

E. Compliance Monitoring

1. At the time a management plan is implemented for a specific Research Personnel, a compliance monitoring plan will also be established by the ORI to ensure compliance with the Management Plan on an ongoing basis until the completion of the project. The compliance monitoring plan will be tailored to the Individual's management plan. The compliance monitoring plan will be stored within the ORI Department.
2. At the time of application to any Funding Agency that requires compliance with 42 CFR 50 Subpart F, the ORI will verify that Research Personnel identified by the AdventHealth Orlando Office of Sponsored Programs (OSP) team have current COI and SFI Disclosure Forms on file.
3. At the time of award from any Funding Agency that requires compliance with 42 CFR 50 Subpart F, and prior to the expenditure of any such funds, or as required by the terms and conditions of the award, the ORI will verify that Research Personnel identified by the AdventHealth Orlando Office of Sponsored Programs (OSP) team have current COI and SFI Disclosure Forms on file.

F. <u>Non-Compliance and Corrective Action</u>

1. In the event that possible non-compliance is identified, a Non-Compliance Review and Action Plan will be conducted. Possible non-compliance includes, but is not limited to:
   a. SFI not reported, but discovered by another source.
   b. SFI not disclosed timely by individual.
   c. SFI not identified by AdventHealth Orlando (failure to identify SFI when information was available to make such identification).
   d. SFI not reviewed in a timely manner by AdventHealth Orlando.
   e. SFI not managed in a timely manner by AdventHealth Orlando.
   f. Failure of the Individual to comply with his/her FCOI Management Plan.

2. The Non-Compliance Review will document the difference between the expected date of the event for compliance and either the actual date of the event or the date of discovery of non-compliance. If this difference is outside of the expected timeframe, then it will be determined that non-compliance occurred. The expected timeframes are as follows:
    a. SFI not reported, but discovered by another source = within 30 days of date of FCOI education or 1st COI disclosure form signed.
    b. SFI not disclosed timely by the Individual = within 30 days of signing COI and/or SFI form; within 30 days of acquisition of a new SFI; and/or within 30 days of ORI request of form(s).
    c. SFI not identified by AdventHealth Orlando (failure to identify SFI when information was available to make such identification) = after submission to the ORI but within 60 days of COI Official's signature.
    d. SFI not reviewed in a timely manner by AdventHealth Orlando = within 60 days of COI/SFI form signed by Research Personnel.
    e. SFI not managed in a timely manner by AdventHealth Orlando = within 60 days of COI/SFI form signed by personnel.
    f. Failure of the Individual to comply with his/her FCOI Management Plan = immediately upon request and provision of management plan to SFI holder (but <30 days).
3. If non-compliance was ruled out by the above steps, then no further action will be taken.
4. If it was determined that non-compliance occurred, an Action Plan will be developed, which will include a Retrospective Review if it is determined that the non-compliance pertains to a SFI that is related to a research study, funding application for and/or receipt of external funding from an entity that requires compliance with 42 CFR 50 Subpart F.
5. The Retrospective Review will be completed within 120 days of the ORI's date of determination of non-compliance.
6. The Retrospective Review will identify:
    a. Reason for the Retrospective Review.
    b. Time period or dates of non-compliance.
    c. Time period or dates to be audited for the Retrospective Review.
    d. Documents to be audited/reviewed for the Retrospective Review.
    e. Findings of the Retrospective Review including, but not limited to:
        1) No negative findings;
        2) No bias found;

3) Biased design, conduct, and/or reporting of results.

f. Corrective Actions Required including, but not limited to:

1) Update previously submitted FCOI report on eRA Commons, if applicable.

2) Complete a Mitigation Report if bias was found.

3) In the event the Department of Health and Human Services (DHHS) determines that 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 Investigator with an FCOI that was not managed or reported by the Institution per the federal regulations, the institution shall require the Investigator involved to:

a) Disclose the FCOI in each public presentation of the results of the research.

b) Request an addendum to previously published presentations.

7. 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:

1) Description of bias.

2) Impact of bias on project, quantified if possible.

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

4) Analysis of whether project is salvageable.

c. Corrective Actions Required, including, but not limited to:

1) Plan of action to eliminate or mitigate the effect of the bias.

2) Update previously submitted FCOI report on eRA Commons, if applicable.

3) 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 42 CFR 50 Subpart F.

4) Monitor compliance with the FCOI Management Plan.

5) In the event DHHS determines that 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 Investigator with an FCOI that was not managed or

reported by the Institution per the federal regulations, the institution shall require the Investigator involved to:

a) Disclose the FCOI in each public presentation of the results of the research.

b) Request an addendum to previously published presentations.

G. Sub-recipients

If AdventHealth Orlando carries out any portion of an award through a sub recipient (e.g., subcontractors or consortium members), AdventHealth Orlando will take reasonable steps to ensure that sub recipient investigators and its Research Personnel comply with 42 CFR Part 50 Subpart F.

1. AdventHealth Orlando will incorporate terms and conditions in sub award agreements that require the sub recipient to either comply with the sub recipient's FCOI policy or with AdventHealth Orlando FCOI policy.
2. AdventHealth Orlando will provide timeframes for the sub recipient to provide AdventHealth Orlando with information necessary for AdventHealth Orlando to complete its FCOI reporting requirement to the Funding Agency.

H. Enforcement

1. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Research Personnel/Institution compliance, as appropriate.
2. A number of enforcement mechanisms will ensure compliance with AdventHealth Orlando policy so that any reported financial interests that are determined to be a potential FCOI will be managed, minimized, or eliminated. These include, but are not limited to:
    a. ORI Institutional Clearance for a research project will be contingent on FCOI Training and COI Disclosures being completed and up-to-date for all research personnel on a research project.
        1) If an Individual has not submitted required FCOI Training and Disclosures, the project will not receive Institutional Clearance until s/he submits required FCOI Training and COI Disclosures, they have been reviewed, and any required Management Plans have been created and implemented.
        2) If there is a lapse in annual COI Disclosures by any Individual on a research project, the Institutional Clearance is put on hold until the COI Disclosures have been made or the Individual is removed from the research team.

b. If non-Compliance is found, an Action Plan is developed (See Non-Compliance and Corrective Action section of this SOP).

c. Corrective Actions may be required as part of a Retrospective Review (See Non-Compliance and Corrective Action section of this SOP).

d. Corrective Actions may be required as part of a Mitigation Report (See Non-Compliance and Corrective Action section of this SOP).

e. Education modules (above and beyond the regular FCOI Training) will be available to be included as part of Action Plans or Corrective Actions.

I. FCOI Reports

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 the federal regulations.

1. Initial FCOI reports will be submitted prior to the expenditure of external funds (for new awards or awards that are new to AdventHealth Orlando).
2. Annual FCOI reports for the duration of the project period including any extensions. 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, if applicable, at the time of extension).
3. Additional subsequent FCOI Reports will be submitted in the following circumstances:
   a. Within sixty (60) days of new, or newly identified, FCOIs for existing Research Personnel.
   b. Within sixty (60) days of identification of a new Individual added to an externally funded research project which requires compliance with 42 CFR 50 Subpart F.
   c. Following a retrospective review to update a previously submitted report, when applicable.
4. 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.
5. In the event that an Individual fails to comply with this policy and/or a 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 the Institution including the corrective action plan to address the non-compliance.

J. Public Access

1. Upon written receipt of a valid, written request to the AdventHealth Orlando ORI concerning any significant FCOI related to an externally funded research project which requires compliance with 42 CFR 50 Subpart F, 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.
2. Updates to a request will only be provided upon receipt of a subsequent valid written request for those requests that meet the criteria for release.
3. 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.

K. Records Maintenance and Availability

1. All associated COI forms, including but not limited to COI Disclosure Forms, SFI Disclosure Forms, FCOI Training documentation, FCOI reports, as well as compliance reviews and retrospective reviews if applicable, 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. 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.

Definition(s)

Outside Entity: Any corporation, partnership, limited liability company, sole proprietorship, firm, franchise, unincorporated association organization, holding company, joint stock company, business or real estate trust, or any other legal entity organized for profit or charitable purposes, but excluding AdventHealth Orlando or any other corporation controlled by, controlling, or under common control with (of) AdventHealth Orlando.

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 Compliance and Education Manager for Responsible Study Conduct in the Office of Research Integrity (ORI). The supervising Vice President will serve as the COI Official for the Compliance and Education Manager

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.

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

Individual: The individual signing the AdventHealth Orlando COI form includes the interests of the Individual's spouse and dependent children.

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

Research Personnel: Includes all individuals involved in the design, conduct, or reporting of research at AdventHealth Orlando (AdventHealth Orlando employees or employees of AdventHealth Orlando affiliates, AdventHealth Orlando Medical Staff, AdventHealth Orlando Volunteers, AdventHealth Orlando Consultants, credentialed students) who are listed as a Research Team Member on a specific research project being conducted at AdventHealth Orlando. Also includes all AdventHealth Orlando Research Senior Leadership, Research Services staff (includes ORI staff, AdventHealth Orlando Legal, AdventHealth Orlando OSP, and AdventHealth Orlando Research Finance personnel), IRB staff/members, and all AdventHealth Orlando research department employees.

Significant Financial Interest (SFI): A financial interest of the Individual (and those of the Individual's spouse and dependent children) 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 the Individual's spouse or dependent children) 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:
  - Salary paid by AdventHealth Orlando.
  - Royalties or other remuneration paid by 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 government agency, or an institution of higher education.
  - Income from service on advisory committees or review panels for a government agency, or an institution of higher education.

Sponsored or Reimbursed Travel: Sponsored or reimbursed travel is that which is paid 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 or a government agency. Sponsored or reimbursed travel shall be reported as part of SFI.

Reference(s)

Electronic Code of Federal Regulations (e-CFR™). (November 16, 2015). Title 42, Part 50, Subpart 50: Promoting objectivity in research. Retrieved from Website.

Related Documents	**Policy** 400.005: Financial Conflict of Interest in Research
Keywords	COI, FCOI, Conflict of Interest