



**STANDARD OPERATING PROCEDURE**  
**Office of Research Compliance & Integrity**

<b>Title:</b>	Financial Conflict of Interest in Research Policy
<b>Version:</b>	3.1
<b>Effective Date:</b>	November 15, 2012
<b>Approved By:</b>	Institutional Official Financial Conflict of Interest in Research Committee

**1.0 PURPOSE**

The purpose of this policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of funded research, grants or cooperative agreements will be free from bias resulting from Investigator’s financial conflicts of interest (and/or of the Investigator’s spouse and/or dependent children). This policy complies with the following federal regulations:

- Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought
- Title 45 Code of Federal Regulations (CFR), Part 94, Responsible Prospective Contractors
- Title 21 Code of Federal Regulations (CFR), Part 54, Financial Disclosure by Clinical Investigators

**2.0 SCOPE**

This policy applies to each Investigator participating in, or planning to participate in the design, conduct, or reporting of research at Summa Health System **regardless of funding source**. This policy does not apply to applications and awards supported under the Small Business Innovation Research Phase I Program or the Small Business Technology Transfer Phase I program.

If a research project involves subcontractors, subgrantees, or subawardees (collectively subrecipients), the subrecipient institution must provide written assurance that a financial conflict of interest policy is in effect at that institution and compliant with all applicable federal regulations. Should Public Health Service (PHS) or National Science Foundation (NSF) funds be subcontracted by Summa Health System to a subrecipient institution without a conflict of interest policy, a written agreement must state that this policy shall apply to the subrecipient.

### 3.0 DEFINITIONS

- 3.1 **Conflict of Interest Administrator (COIA)** – the Summa Health System official responsible for the implementation of this policy, including the solicitation and initial review of disclosures of significant financial interest from research Investigators.
- 3.2 **Conflict of Interest Management Plan** – written plan developed by the Financial Conflict of Interest in Research Committee (FCOIRC), or designees, in collaboration with the Investigator to manage conflicts by mitigating, reducing or eliminating Financial Conflicts of Interest so that the design, conduct or reporting of research is free from bias or the appearance of bias.
- 3.3 **Entity** – any domestic or foreign, public or private, entity or organization (excluding a Federal agency) from which an Investigator (and/or the Investigator’s spouse and/or dependent children) receives remuneration, or in which any person has an ownership or equity interest.
- 3.4 **Financial Interest** – anything of monetary value or potential monetary value held by the Investigator, the Investigator’s spouse and/or dependent children whether or not the value is readily ascertainable.
- 3.5 **Financial Conflict of Interest**– a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of research.
- 3.6 **Institution** - any domestic or foreign, public or private, entity or organization (excluding a Federal Agency) that is applying for, or receives, PHS or NSF research funding.
- 3.7 **Institutional Official** – the individual who is legally authorized to act for the institution, and on behalf of the institution.
- 3.8 **Institutional Responsibilities** – an Investigator’s professional responsibilities on behalf of Summa Health System including, but not limited to, activities such as research, research consultation, teaching, professional/clinical practice, institutional committee memberships, and service on panels such as Institutional Review Boards, Institutional Animal Care and Use Committees or Data and Safety Monitoring Boards, etc.
- 3.9 **Investigator** – the project director/principal investigator and any other person, regardless of title or position, who has the ability to independently influence the design, conduct, or reporting of research, or a proposal for funding, including persons who are subcontractors, collaborators, or consultants.

- 3.10 **Management** – actions taken by the Financial Conflict of Interest in Research Committee to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, and to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- 3.11 **PD/PI** - project director or principal investigator of a PHS-funded research project.
- 3.12 **Public Health Service (PHS) Awarding Component** – the organizational unit of the PHS that funds the research (e.g., National Institutes of Health).
- 3.13 **Research** – a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research through which an investigator collects data through intervention or interaction with animal or human subjects, or from identifiable private information. The term encompasses basic and applied research and product development. The term also includes any such activity for which research funding is available from a PHS or NSF Awarding Component through a grant or cooperative agreement, whether authorized under the PHS, NSF, or other statutory authority.
- 3.14 **Senior/Key Personnel** – the Project Director/Principal Investigator and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS or NSF by the Institution under this subpart.
- 3.15 **Significant Financial Interest (SFI)** –
1. A financial interest consisting of one or more of the following interests of the Investigator (and/or of the Investigator’s spouse and/or dependent children) that reasonably appears to be related to the Investigator’s institutional responsibilities:
    - 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 the 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, travel reimbursement). Equity interests includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
    - 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 (and/or the Investigator's spouse and/or dependent children) holds **any** equity interest (e.g., stock, stock option, or other ownership interest); or

- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. Any reimbursed or sponsored travel (i.e., that which is paid on behalf of a PHS funded investigator so that exact monetary value may not be readily available) related to an Investigator's institutional responsibilities. This applies only to PHS-funded Investigators.
  3. The term *significant financial interest* **does not** include the following types of financial interests:
    - Salary, royalties, or other remuneration paid by Summa Health System to the Investigator if the Investigator is currently employed or otherwise appointed by Summa Health System, including intellectual property rights assigned to Summa Health System and agreements to share in royalties related to such rights; 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.
    - Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local 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.
    - 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.
    - Travel by a PHS-funded Investigator that is reimbursed or 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.

3.16 **Small Business Innovation Research (SBIR) Program** – the extramural research program for small businesses established by the awarding

components of certain Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. The term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Public law 102-564.

## **4.0 POLICY**

### **4.1 Disclosure of SFIs**

Each Summa Health System Investigator (see definition) must complete a Financial Conflict of Interest in Research Disclosure Form annually and must update the disclosure under the following circumstances:

- Within 30 days of discovery or acquiring a new financial interest that relates to their institutional responsibilities
- No later than at the time of application by the Office of Sponsored Programs (OSP) for PHS or NSF funded research to any PHS or NSF Awarding Component

PI/PDs are additionally responsible for:

- Providing a list of all Investigators, who will be associated with a PHS or NSF funded grant and/or contract application, to OSP prior to submission of the application by OSP.
- Ensuring all Investigators involved in the study comply with the above disclosure procedures.

All Investigators are required to complete the annual disclosure form even if they have no financial interests to report.

Investigators will be required to verify that they have a current FCOI in Research Disclosure on file at the time of application to the Institutional Review Board (IRB) or the Institutional Animal Care and Use Committee (IACUC) for approval of any new research proposals.

Investigators conducting clinical studies for the U.S. Food and Drug Administration (FDA) applications for a human drug, biological product or device must also comply with the FDA requirement that require financial disclosure to be updated both during the course of the study and for one year following the completion of the study.

### **4.2 Review of FCOIs**

The Conflict of Interest Administrator (COIA), in collaboration with the Financial Conflict of Interest in Research Committee (FCOIRC), will review disclosure forms to determine whether an Investigator's disclosed significant financial interest could directly and significantly affect the design, conduct or reporting of the research, and therefore constitutes a Financial Conflict of Interest (FCOI).

The Investigator may be included in making this determination.

#### **4.3 Management of FCOIs**

If a FCOI is identified for an Investigator conducting a PHS or NSF funded research project, a Management Plan will be developed in consultation with the FCOIRC and implemented prior the release of any PHS or NSF funds. If an Investigator discloses within the 30 day window of acquiring a new SFI, it will be reviewed by the COIA, in collaboration with the FCOIRC, to determine if it is truly a FCOI. If the SFI is determined to be a FCOI, a management plan, at a minimum an interim plan, will be developed and implemented within 60 days from the date of disclosure by the Investigator.

FCOI for Investigators conducting non-PHS/NSF funded research will be evaluated on a case-by-case basis and Management Plans will be developed and implemented as needed.

A Management Plan will include conditions and/or restrictions that have been, or will be taken, to ensure that the design, conduct or reporting of research is free from bias or the appearance of bias. A draft of the Management Plan will be provided to the Investigator for review and comment before it is finalized.

If the Institution identifies a SFI that was not disclosed or reviewed in a timely manner it will be reviewed within 60 days from the date the SFI was identified, to determine if the SFI is actually a FCOI. An interim management plan will be implemented when necessary.

#### **4.4 Monitoring**

Investigator compliance with Management Plans will be monitored by the Office of Research Compliance & Integrity. The frequency of monitoring will be dictated by sponsor/agency requirements and Management Plan provisions.

#### **4.5 Special Considerations for Human Subject Research**

While this policy applies to all types of research, special precautions must be taken to protect human subjects who participate in research at Summa Health System. If a FCOI is identified for an Investigator, the Investigator will need to provide a compelling justification for his/her participation in the research. Compelling justification includes factors such as unique Investigator expertise, unique institutional resources, unique access to particular patient populations, nature of the science, level of risk to human subjects, and the degree to which the financial interest and research are linked. The FCOI and the compelling justification will be reviewed by the COIA, in collaboration with the FCOIRC, to determine if a Management Plan is appropriate, or if the investigator will be prevented from participating in the research. Research will not be allowed to

begin until the appropriate Management Plan or actions have been taken by the FCOIRC to mitigate or eliminate the FCOI, and any other necessary actions, such as Institutional Review Board approval or the contract has been fully executed.

#### **4.6 Appeals**

Investigators may appeal FCOIRC decisions in writing within 15 days of receipt of a management plan or other decision of the committee. The written appeal should include details regarding the Investigator's concern and/or compelling circumstances which support the request for a proposed revision to a FCOIRC decision. If, following FCOIRC review of the appeal, the original decision stands, the case will be presented to the Institutional Official whose decision will be final.

### **5.0 RECORD RETENTION**

Summa Health System will maintain all records related to the implementation of this policy for at least three years after:

- the date of creation;
- the date of termination or completion of a research award or contract;
- the submission of the final expenditures report; or
- the date of final resolution of any investigation, audit, or similar action involving the records.

### **6.0 CONFIDENTIALITY**

Financial information disclosed in compliance with this policy will be kept confidential. Information will be disclosed only on a need-to-know basis as required to perform the review and evaluation required by the policy.

### **7.0 ENFORCEMENT**

Failure on the part of an Investigator to comply with this policy may result in disciplinary action and/or sanctions; including formal reprimand, non-renewal/termination of appointment or affiliation, and/or any other enforcement action mandated by the applicable funding agency or Summa Health System.

7.1 Federal regulations require reports to project sponsors regarding violations of this policy. Project sponsors may impose additional sanctions including the suspension or termination of an award or debarment from receiving future awards.

7.2 Upon request, information regarding the disclosure and management of financial conflicts of interest will be made available to the Department of Health and Human Services.

- 7.3 If the Department of Health and Human Services determines that a PHS-funded project to evaluate a drug, medical device or treatment was conducted by an Investigator with a conflict that was not disclosed or managed, the Investigator must disclose the conflict in each public presentation of the results of the research.
- 7.4 Summa Health System may take any necessary actions such as closing existing research or denying future research by the Investigator.

## 8.0 AMENDMENTS

The FCOIRC may modify this policy to conform to organizational changes and circumstances including revisions to federal or state law or regulations. The FCOIRC will develop, and modify as necessary, procedures to implement this policy.

## 9.0 PHS FUNDED RESEARCH

The following **additional** requirements apply to all research funded by the PHS of the U.S. Department of Health and Human Services and any PHS Awarding Component including the NIH.

### 9.1 Reporting

Summa Health System will provide to the PHS Awarding Component a FCOI report as outlined in the regulations:

Initial Report: Prior to expenditure of any funds under the NIH-funded research project the Institution will provide a FCOI report regarding any SFI found to be a FCOI. Summa Health System will also provide a FCOI report within 60 calendar days from the date of a new SFI disclosure determined to be a FCOI, a new Investigator with an identified FCOI becomes engaged in the project or when the Institution identifies a FCOI not previously disclosed. This report will include the following information:

- Grant/Contract Number
- PD/PI
- Name of Investigator with FCOI
- Nature of the FCOI (e.g., equity, consulting fees, travel reimbursement or honoraria)
- Value of the financial interest 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
- Description of how FCOI relates to PHS-funded research and the basis for the determination that the financial interest conflicts with such research
- Key elements of the Management Plan

Annual updates to this report will be submitted to the PHS Awarding Component for the duration of the research project. The annual report will include:

- Status of the FCOI
- Changes to the Management Plan
- Justification if FCOI no longer exists

## 9.2 Subrecipients

For PHS or NSF-funded research that involves subcontractors, subgrantees or subawardees (collectively subrecipients) at other Institutions, Summa Health System will require a written agreement that includes terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient Institution will apply to subrecipient Investigators. This agreement will specifically address time periods to meet disclosure and/or financial conflict of interest reporting requirements.

Subrecipient Institutions who rely on their Financial Conflict of Interest policy must report identified financial conflicts of interests to the awardee Institution in sufficient time to allow the awardee Institution to report the FCOI to the PHS or NSF Awarding component.

Subrecipients who do not have such a conflict of interest policy will be required to follow the Summa Health System FCOI in Research policy. A subrecipient's failure to promptly comply with the Summa Health System policy will be considered grounds for immediate termination by Summa Health System of any applicable subcontract or subaward. The written agreement terms required by Summa Health System will contain a provision that subrecipients will report to Summa Health System as the awardee Institution, any identified FCOI in sufficient time to allow Summa Health System to report and manage the FCOI to meet the reporting obligations described above.

## 9.3 Travel Disclosure

PHS-funded Investigators must disclose the occurrence of reimbursable or sponsored travel related to their institutional responsibilities, **regardless of the value**. At a minimum the travel disclosure must include:

- Purpose of the trip
- Identity of the sponsor/organizer
- Destination
- Length
- Monetary value, if known

The disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:

- a federal, state, or local government agency

- an Institution of higher education as defined at 20 U.S.C. 1001(a)
- an academic teaching hospital
- a medical center, or
- a research institute that is affiliated with an Institution of higher education

Travel disclosures will be reviewed by the FCOIRC to determine if the travel represents a FCOI with PHS-funded research. Additional information may be requested by the FCOIRC at the time of review. Disclosure of travel must occur no more than 30 days after the last day of the trip.

#### **9.4 Public Accessibility**

This policy will be posted, on the Summa Health System public website. In addition, information concerning identified FCOIs held by senior/key personnel will be made available to requestors via **an email** response within five business days from when the COIA receives the request. This information may be requested by calling **the Office of Research Administration** or emailing [research@summahealth.org](mailto:research@summahealth.org)

The written response will include:

- Investigator's name
- Investigator's role in the research project
- Name of the entity in which the FCOI is held
- Nature of the FCOI
- Approximate dollar value of the FCOI or a statement that the value cannot be readily determined

This information will remain available for three years from the date the information was most recently updated.

#### **9.5 Training Requirements**

PHS and NSF-funded Investigators must complete FCOI training prior to engaging in research related to any PHS or NSF-funded grant or contract and at least every four years thereafter. Training must also be completed *as soon as reasonably possible* under the following circumstances:

- This policy changes in a manner that affects Investigator requirements
- An Investigator is new to Summa Health System and will be working on PHS or NSF-funded research
- An Investigator is found to be noncompliant with this policy or their FCOIRC-approved Management Plan.

## 9.6 Investigator/Institutional Non-Compliance

If a SFI is not disclosed or reviewed in a timely manner, Summa Health System will review the Investigator's financial interest, and determine if it is related to PHS/NSF-funded research; determine whether a FCOI exists, and if so:

- Implement a Management Plan for ongoing research, at a minimum implement an interim Management Plan
- Complete a retrospective review of Investigator's activities and the PHS-funded research project within 120 days of a non-compliance finding to determine if bias was present in the design, conduct, or reporting of such research; and
- If bias/non-compliance is found, the Institution will promptly inform the PHS/NSF Awarding Component by submitting a mitigation report.

If the retrospective review finds that the Investigator knew, or should have known about the FCOI related to his/her institutional responsibilities, but failed to disclose in compliance with this policy, the costs associated with the retrospective review and mitigation report may be pulled from the Investigator's Indirect Cost Allocation portion, the Investigator's Department, or directly billed to the Investigator. If the Department of Health and Human Services determines that a PHS-funded clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a conflicting interest that was not managed or reported by Summa Health System, the Investigator must disclose the FCOI in each public presentation of the results of the research and must request an addendum to previously published presentations.

## 10.0 DOCUMENT HISTORY

<b>Version/ Effective Date</b>	<b>Author</b>	<b>Section Changed &amp; Reason for Revision</b>
1.0/ November 1, 2011	B. Strelec	Policy Revision
2.0/August 17, 2012	LaMantia/ Strelec/ Eaton/ Conrad	Policy Revision
3.0/September 17, 2012	Frederick/ Eaton	Policy Revision
3.1/November 15, 2012	T. Frederick	Section 4.1 revised for clarification



## **11.0 RELATED FORMS/DOCUMENTS**

Financial Conflict of Interest in Research Disclosure Questionnaire  
Financial Conflict of Interest in Research Supplemental Form  
Basic Management/Monitoring Plan Process  
Frequently Asked Questions Regarding COI  
Financial Conflict of Interest in Research Committee Charter