



**Origination:** 07/2012  
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**Owner:** Tina Noonan: Executive Director of Research  
**Department:** Research Support Services  
**References:**  
**Applicability:** St. Vincent Indiana excluding St. Vincent Evansville/Warrick

## Financial Conflict of Interest for PHS Funded Research

### PURPOSE

The goal of this Policy is to assure the objectivity in Public Health Service (PHS) funded research by establishing standards to ensure that the design, conduct and reporting of such research will not be biased and/or influenced by financial conflicts of interest of an Investigator. This Policy implements federal disclosure requirements pertaining to objectivity in research promulgated by the U.S. Public Health Service (PHS) in 42 CFR Part 50 and 45 CFR Part 94.

This Policy is intended to supplement, but not replace, the Ascension Health and St. Vincent Health system corporate responsibility and conflict of interest policies and procedures referenced below.

### SCOPE

This Policy applies to all personnel who conduct Research, or assist in the performance of such Research activities, where that Research is performed at or under the auspices of any St. Vincent Health system hospital or subsidiary organization (individually or collectively "SVH") covered by the St. Vincent Indianapolis Health Federalwide Assurance for the Protection of Human Subjects (FWA) #00001631 (see ATTACHMENT A).

This Policy applies only to Research projects for which the SVH submits a proposal to, or receives research funding from, directly or indirectly, the Public Health Service (PHS). This Policy sets forth requirements that each Investigator who is planning to participate in, or is participating in, such Research, must follow; however, this Policy does not apply to SBIR (Small Business Innovation Research) Program Phase I applications.

### DEFINITIONS

*Financial Conflict of Interest (fCOI):* A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded Research.

*Reviewing Official:* an official designated by SVH to solicit and review completed Disclosure Forms from each Investigator, and to determine whether any reported Significant Financial Interest is a Financial Conflict of Interest.

*Institutional Responsibilities:* an Investigator's professional responsibilities on behalf of SVH, including

activities such as research, teaching, clinical or other professional practice, Hospital committee memberships, and service on panels such as the Institutional Review Board (IRB).

*Investigator:* For the purposes of this policy, an Investigator is any individual responsible for the design, conduct, or reporting of Research funded by the PHS. This includes the Principal Investigator, Co-Investigators, and any other individual, regardless of title or position, who is responsible for the design, conduct, or reporting of this Research.

*Research:* a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge

*Significant Financial Interest (SFI):* For the purposes of this Policy, a Significant Financial Interest is either of the following:

- Any interest of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities, including, but not limited to, one or more of the following:
  - 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 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); equity interest 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 (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest);
  - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- Any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to the Investigator's Institutional Responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by 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.

The term Significant Financial Interest **does not** include the following types of financial interests:

- salary, royalties, or other remuneration paid by SVH to the Investigator if the Investigator is currently employed or otherwise appointed by SVH, including intellectual property rights assigned to SVH 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 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; or income from service on advisory committees or review panels for 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.

*PHS Awarding Component:* The organizational unit of the Public Health Service (PHS) that funds the Research. This includes, but is not limited to, the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Food and Drug Administration (FDA), and the Agency for Healthcare Research and Quality (AHRQ).

## **POLICY**

This Policy establishes a process of disclosure and independent review when an Investigator has Significant Financial Interest(s). When SVH determines that such an interest might reasonably appear to affect the Research directly and significantly, SVH will take steps to manage or to eliminate the conflict.

## **Investigator Responsibilities**

### **Training**

Prior to engaging in PHS-funded Research, each Investigator must complete the SVH-designated training program with regard to the PHS COI regulations. This training will include information regarding this Policy, the Investigator's responsibilities regarding disclosure of Significant Financial Interests, and the Federal Financial Conflict of Interest (fCOI) regulations. Training must be repeated at least every four (4) years thereafter, and within thirty (30) days of when any of the following occurs:

- When this Policy, the Disclosure Form, or Hospital procedures related to this Policy are revised in any manner that affects the Investigator's responsibilities thereto;
- an Investigator is newly hired, is appointed by, or receives approval of medical staff privileges from, SVH; or,
- an Investigator is found to not be in compliance with this Policy or a management plan.

### **Disclosure**

When an Investigator has a Significant Financial Interest, as defined above, a written Significant Financial Interest Disclosure Form (Disclosure Form; located in Appendix A) detailing that interest is required to be submitted to SVH's designated Reviewing Official. This Disclosure Form must be filed no later than at the time of application for PHS-funded Research. The lead principal investigator on a proposed application for PHS funding is responsible for ensuring submission of a Disclosure Form for all participating Investigators.

Each investigator must update his or her SFI disclosures by completing a new Disclosure Form. Throughout the period of the award, this update must occur at least annually, as well as within thirty (30) days of a new SFI being discovered or acquired. One annual disclosure will be sufficient to cover all on-going PHS-funded Research.

The Investigator must cooperate with all requests from the applicable PHS Awarding Component and/or SVH for additional information as needed. All such internal disclosures will be treated as confidential personal information.

# SVH Responsibilities

## Review of Disclosures and Management of fCOI

### Initial review and management:

Prior to SVH's expenditure of any funds under a PHS-funded Research project, the Reviewing Official will review all Investigators' Disclosure Forms; determine whether any Significant Financial Interests relate to PHS-funded Research; determine whether a fCOI exists; and, if so, develop and implement a management plan that specifies the actions that have been, and will be, taken to manage such fCOI.

### Review and management in the course of a PHS-funded Research project:

Whenever, in the course of an ongoing PHS-funded Research project, an Investigator who is new to participating in the Research project discloses a Significant Financial Interest; an existing Investigator discloses a new Significant Financial Interest; or SVH identifies a Significant Financial Interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by SVH during an ongoing PHS funded Research project, the Reviewing Official will, within sixty (60) days: review the disclosure of the Significant Financial Interest; determine whether it is related to PHS-funded Research; determine whether a fCOI exists; and, if so, implement, on at least an interim basis, a management plan that specifies the actions that have been, and will be, taken to manage such fCOI. Depending on the nature of the Significant Financial Interest, SVH may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded Research project between the date of disclosure and the completion of SVH's review.

Examples of conditions or restrictions that may be imposed to manage an fCOI include, but are not limited to:

- Public disclosure of the fCOI;
- For Research projects involving human subjects, disclosure of the fCOI directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct and reporting of the Research against bias resulting from the fCOI;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research;
- Reduction or elimination of the financial interest; or
- Severance of relationships that create financial conflicts.

### Requirements for retrospective review:

In addition to the above requirements, whenever an fCOI is not identified or managed in a timely manner including failure by the Investigator to disclose a Significant Financial Interest that is determined by SVH to constitute an fCOI; failure by SVH to review or manage such an fCOI; or failure by the Investigator to comply with an fCOI management plan, SVH will, within 120 days of SVH's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded Research project to determine whether any PHS-funded Research, or portion thereof, conducted during the time period of the

noncompliance, was biased in the design, conduct, or reporting of such Research. SVH is required to document the retrospective review, including all of the following key elements:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the fCOI;
- Name of the entity with which the Investigator has an fCOI;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusions of the review.

Based on the results of the retrospective review, if appropriate, SVH will update the previously submitted fCOI report, specifying the actions that will be taken to manage the fCOI going forward. If bias is found, SVH will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the Research project and SVH's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the Research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the Research project is salvageable). Thereafter, SVH will submit fCOI reports annually. Depending on the nature of the fCOI, SVH may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded Research project between the date that the fCOI or the Investigator's noncompliance is determined and the completion of SVH's retrospective review.

## **Monitoring:**

Whenever SVH implements a management plan, SVH will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded Research project.

## **Reporting of Financial Conflicts of Interest**

### **Initial fCOI Report:**

Prior to SVH's expenditure of any funds under a PHS-funded Research project, SVH will provide to the PHS Awarding Component an fCOI report regarding any Investigator's Significant Financial interest found by SVH to be an fCOI and ensure that SVH has implemented a management plan in accordance with this Policy. In cases in which SVH identifies an fCOI and eliminates it prior to the expenditure of PHS-awarded funds, SVH does not need to submit an fCOI report to the PHS Awarding Component.

### **Subsequent fCOI Reports:**

For any Significant Financial Interest that SVH identifies as conflicting after SVH's initial fCOI report during an ongoing PHS-funded Research project, SVH will provide to the PHS Awarding Component, within sixty (60) days, an fCOI report regarding the fCOI and ensure that SVH has implemented a management plan in accordance with this Policy and, if required, a retrospective review and a mitigation report according to this Policy.

## Contents of an fCOI report:

Any fCOI report required under this Policy will include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of SVH's management plan. Elements of the fCOI report will include, but are not necessarily limited to the following:

- Project number;
- PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the fCOI;
- Name of the entity with which the Investigator has an fCOI;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest (dollar ranges are permissible: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot readily be determined through reference to public prices or other reasonable measures of fair market value;
- A description of how the financial interest relates to the PHS-funded Research and the basis for SVH's determination that the financial interest conflicts with such Research; and
- A description of the key elements of SVH's management plan, including:
  - Role and principal duties of the conflicted Investigator in the Research project;
  - Conditions of the management plan;
  - How the management plan is designed to safeguard objectivity in the Research project;
  - Confirmation of the Investigator's agreement to the management plan;
  - How the management plan will be monitored to ensure Investigator compliance; and
  - Other information as needed.

## Annual fCOI Report:

For any fCOI previously reported by SVH with regard to an ongoing PHS-funded Research project, SVH will provide to the PHS Awarding Component an annual fCOI report that addresses the status of the fCOI and any changes to the management plan for the duration of the PHS-funded Research project. The annual fCOI report will specify whether the fCOI is still being managed or explain why the fCOI no longer exists. SVH will provide annual fCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

## Enforcement

Failure to comply with this Policy, including failure to file a complete or timely Disclosure Form or update or to comply with any conditions or restrictions imposed on the conduct of the project under this Policy, including a management plan, will be grounds for discipline up to and including termination of employment, appointment, and/or medical staff privileges.

In addition, if the failure of an Investigator to comply with this Policy or an fCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded Research, SVH is required to promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to SVH for further action, which may include directions to SVH on how to maintain appropriate objectivity in the PHS-funded Research project. In addition, federal regulations may require reports to the federal sponsor of any information which may show a violation of SVH policy. Sponsors may impose special award conditions or may suspend or



terminate the award and/or debar an Investigator from receiving future awards in the event of failure to comply with applicable federal regulations on disclosure, review, and management of Significant Financial Interests related to federally sponsored projects.

## Records

Records regarding Disclosure Forms, the Reviewing Official's determinations, and SVH's actions regarding management of an fCOI will be retained by SVH for three years beyond the date of the final expenditure report submitted to PHS under an award.

## Public Accessibility

In compliance with Federal regulations, this Policy will be made publicly accessible through the St. Vincent Health Web site. Information (including, at least, the minimum elements as provided in the regulation) regarding fCOIs identified under this Policy held by senior/key personnel (as defined by regulation), will be made provided to a requestor within five (5) calendar days of a written request.

## REFERENCES

Federal Regulations at 42 CFR Part 50 and 45 CFR Part 94

Ascension Health System Policy: Corporate Responsibility and Conflicts of Interest

Ascension Health System Policy: Outside Business Activities

Ascension Health System Procedure: Conflicts of Interest

St. Vincent Health System Policy: Corporate Responsibility

St. Vincent Health System Procedure: Conflict of Interest Procedures

## Attachments:

[FWA Update March 1 2017.pdf](#)

## Approval Signatures

Step Description	Approver	Date
Leadership Community	Lisa Andrews: Risk Management Coordinator, Health	07/2017
CMO Advisory Committee	Lisa Andrews: Risk Management Coordinator, Health	07/2017
	Dr. Richard Freeman: Chief Medical Officer	04/2017
	Troy Shaffer: CRO/Corporate Responsibility Consultant	03/2017
	Tina Noonan: Executive Director of Research	03/2017