SUBJECT: RESEARCH INVESTIGATOR CONFLICT OF INTEREST

PURPOSE STATEMENT: Consistent with our Core Values, especially the Core Values of Integrity and Excellence, Saint Vincent will ensure objectivity of human-subjects research and clinical investigations and avoid actual or perceived conflicts of interest in review of human research at Saint Vincent Health System.

POLICY STATEMENT: To assure compliance with federal regulations [PHS 42 C.F.R 50 (f) and 45 C.F.R 94], the Saint Vincent Health System IRB requires research investigators to disclose significant conflicts of interest (COI) related to human research studies.

In addition to the types of financial conflicts of interest as defined in these policies and procedures, SVHS may require reporting of other financial conflicts of interest in its policies as deemed appropriate.

As a participant in public health service (PHS) research, Saint Vincent Health System will comply with all Department of Health and Human Services Requirements.

DEFINITIONS:

1) Significant Financial Interest (SFI)- (a) any remuneration or equity interest that exceeds $5,000 when aggregated over 12 months prior to the date of disclosure (b) SFIs can be that of the investigator, her/his spouse, or family member.

2) Financial Conflict of Interest- a significant financial interest that could directly and significantly affect the design, conduct or reporting of research.

3) Investigator- the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, or proposed for such funding, which may include, for example, collaborators or consultants.

4) Remuneration/Equity Interests- include salary, consulting fees, honoraria, paid authorship; stock, stock options, intellectual property rights and interests (copyrights/patents) or other
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ownership interest. Also included is travel that is reimbursed or sponsored by an entity other than 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.

DISCLOSURE REQUIREMENTS: Investigators (as defined in this policy) must disclose all financial interest, remunerations or equity interest received/held from a company related to research being conducted via a COI disclosure form at the time of initial IRB application and yearly there after.

REMUNERATION NOT REQUIRING DISCLOSURE:

1) Salary, royalties, or other remuneration paid by the Institution to the Investigator.

2) Intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights.

3) Any ownership interest in the Institution held by the Investigator.

4) Income from seminars, lectures, advisory committees, review panels, 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.

Reference:
Federal Register / Vol. 76, No. 165 / Thursday, August 25, 2011 / Rules and Regulations
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PROCEDURES/GUIDELINES

A) Overview

The Department of Health and Human Services requires all institutions participating in PHS funded research to abide by the following:

1) Maintain an up to date written policy regarding financial COI and make it available on a publicly accessible Web site.

2) Inform each investigator of the COI policy, her/his responsibilities regarding disclosure of significant financial interests (SFI), and require each investigator to complete COI training at least every 4 years.

3) Take reasonable steps to ensure sub-recipients comply with financial COI regulations and designate the Corporate Compliance Officer to solicit and review disclosures of SFI.

4) Require disclosures at least annually or within 30 days of discovering or acquiring a new SFI and provide guidelines on how the institutional official determines that a financial COI is an SFI related to PHS funded research.

5) Take actions to manage financial COIs, provide initial and ongoing financial COI reports to PHS and maintain records of disclosures, their review, determinations, and any subsequent actions for at least 3 years.

6) Establish an enforcement mechanism to sanction Investigators who are noncompliant, require investigator disclosures no later than the time of application for PHS funds, and certify compliance with these regulations in each PHS application.

B) SVHS IRB Disclosure Process

The Medical Staff Office will mail out the Conflict of Interest Packet for Investigators of all Research Studies annually or within 30 days of discovering an investigator has acquired a
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new SFI. The Medical Staff Office will then track the outflow of Conflict of Interest Packets and the inflow of signed Acknowledgement Sheets and Disclosure Statements. (Refer to SVHS Interdepartmental Policy A-3 on Conflicts of Interest for the evaluation process of a disclosure statement form.) The Disclosure Form and Acknowledgement Sheet must be returned to the Saint Vincent Health Systems Medical Staff Office by the deadline noted in the Conflict of Interest Packet for Investigators of all Research Studies.

C) Review of Conflict of Interest Disclosures

The SVHS Corporate Compliance Officer will, within 10 days of disclosure, review the disclosures and determine whether a financial conflict of interest exists and whether it is related to the PHS-funded research.

The Corporate Compliance Officer will then notify the IRB chairman, SVHS CEO and SVHS Board Chairman of identified Financial Conflicts of Interest.

D) Enforcement Mechanisms for Non-Compliance

Saint Vincent Health System IRB may require one or more of the following actions be taken to address financial conflicts of interest, as well as failures to disclose financial conflicts of interest in a timely manner:

1. Public disclosure of financial conflicts of interest when presenting or publishing research

2. For research projects involving human subjects, disclosure of financial conflicts of interest directly to participants

3. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research

4. Reduction or elimination of the financial interest
E) Financial Conflicts of Interest Occurring After Initial Disclosure

The Corporate Compliance Officer will notify the IRB chairman, SVHS CEO and SVHS Board Chairman of the newly identified Financial Conflict of Interest.

F) PHS Reporting Requirements

Prior to the expenditure of any funds under a PHS-funded research project, SVHS will provide the PHS Awarding Component a report regarding any Investigator’s significant financial interest. In cases in which SVHS IRB identifies a financial conflict of interest and it is eliminated prior to the expenditure of PHS-awarded funds, SVHS will not submit an FCOI report to the PHS Awarding Component.

The FCOI report to the PHS Awarding Component shall include the following information:

1) Project number
2) Name of Project Director/Principal Investigator or name of main contact if a multiple Project Director/Principal Investigator model is used
3) Name of the Investigator with the FCOI
4) Name of the entity with which the Investigator has a financial conflict of interest
5) Nature of the financial interest (e.g., equity consulting fee, travel reimbursement, etc.)
6) Value of the financial interest (can be a dollar range) 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
7) A description of how the financial interest relates to the PHS-funded research and the basis for SVHS’s determination that the financial interest conflicts with such research
8) A description of the key elements of SVHS’s management plan including:
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a. Role and principal duties of the conflicted Investigator in the research project
b. Conditions of the management plan
c. How the management plan is designed to safeguard objectivity in the research project
d. Confirmation of the Investigator’s agreement to the management plan
e. How the management plan will be monitored to ensure Investigator compliance
f. Other information as needed

During an ongoing PHS-funded research project, if a FCOI is identified after the initial FCOI report, SVHS will provide an updated FCOI report to the PHS Awarding Component within sixty days, and ensure that the investigator has implemented a management plan.

For any conflict of interest previously reported, SVHS will provide the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report will specify whether the financial conflict is still being managed or explain why it no longer exists. SVHS will provide annual FCOI reports to the PHS Awarding Component for the duration of the project period in the time and manner specified. This duration will include extensions with or without funds.

G) For Financial Conflicts of Interest that are NOT Identified/Managed in a Timely Manner

If the IRB identifies that a potential conflict of interest was not disclosed in a timely manner by the Investigator, the Chief Compliance Officer will, within 10 days, review the conflict of interest and determine whether it is a significant financial conflict of interest and whether it is related to PHS-funded research.

If a financial conflict of interest is confirmed to have not been disclosed or required management actions not taken in a timely manner, the IRB will, within 120 days of the hospital’s determination of noncompliance, complete a retrospective
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review. This retrospective review will investigate the Investigator’s activities to determine whether, during the time period of noncompliance, research was biased in the design, conduct or reporting.

The retrospective review will include:

1) Project number
2) Project title
3) PD/PI or contact PD/PI if multiple PD/PI model is used
4) Name of the Investigator with the FCOI
5) Name of the entity with which the Investigator has a financial conflict of interest
6) Reason(s) for the retrospective review
7) Detailed methodology used for the retrospective review, including the review process, composition of the review panel, and documents reviewed
8) Findings of the review
9) Conclusions of the review

The IRB will notify the SVHS CEO, Corporate Compliance Officer and Board Chairman of the findings of the Retrospective Review and the steps that will be taken to manage the financial conflict of interest going forward.

Based on the results, the IRB may also notify the PHS Awarding Component and submit a mitigation report. The mitigation report will include:

1) The key elements documented in the retrospective review
2) A description of the impact of the bias in the research project
3) The IRB’s plan to eliminate or mitigate the effect of the bias, impact on the research, and extent of harm (will include any qualitative and quantitative data to support any actual or future harm, and analyze whether the research project is salvageable)

The IRB will monitor Investigator’s compliance with the management plan on an ongoing basis until the completion of the research project.

H) Disclosure of Financial Conflicts of Interest on a Publicly Accessible Website
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SVHS will ensure public accessibility of this policy, via a publicly accessible website. If requested, Saint Vincent IRB will disclose information regarding identified significant financial conflicts of interest within 5 business days of a request.

1) Maintenance of Records and Certification

The IRB will maintain records of disclosures, their review, determinations, and any subsequent actions on all FCOI-related records for at least 3 years from the date of the completion of the research study and/or for PHS funded research; the final expenditures report is submitted to PHS (NIH). The IRB will also provide a certification regarding compliance with the regulation, including the training requirement with each PHS application.