South Shore Health System

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v1.2

Conflict of Interest Disclosure Policy for Human Subjects Research

PURPOSE OF POLICY

Financial or other incentives may negatively impact the collection, analysis and interpretation of data, scientific objectivity and integrity and ultimately the public interest. The purpose of this policy is to identify, monitor and control conflicts of interest among investigators and the organization.

For research that involves human subjects, the investigators and all those involved in the design, conduct or reporting of the research must disclose whether they or their immediate family members (i.e., spouse or dependent children) have any of the financial interest related to the research where related to the research means an interest in the sponsor or the product or the service being evaluated.

POLICY SUMMARY

All investigators are required to adhere to the institution's policies on conflicts of interest.

DEFINITIONS

Conflict of Interest: A set of conditions in which judgment concerning a primary interest (e.g., subject welfare, integrity of research, institution's reputation or prestige) could be biased by a secondary interest (e.g., personal or financial gain).

Significant conflict of interest - defined as anything of monetary value, including but not limited to:

-salary or other payments for services (e.g., consulting fees or honoraria);
-equity interests (e.g., stocks, stock options or other ownership interests);
-intellectual property rights (e.g., patents, copyrights and royalties from such rights).

A significant financial interest is related to the research when the significant financial interest could be affected by the research; or is in an entity whose financial interest could be affected by the research.

Financial conflict of interest - defined as a significant financial interest that could directly and significantly affect the design, conduct, or reporting of human subject research

Immediate Family or Family Member: Includes spouse, ancestors, brothers, sisters (whole or half blood), children (natural or adopted), grandchildren, spouse and steps thereof, and any person residing with individuals covered under this policy.

Organizational Conflict of Interest- Financial contributions, licensing, technology transfer or patents, or other financial interest in the research in excess of $500,000 that have the potential to place undue influence on the human research protection program or undermine the protection of participants in research.

Covered clinical study means any study of a drug or device in humans submitted in a marketing application or reclassification petition subject to this part that the applicant or FDA relies on to establish that the product is effective (including studies that show equivalence to an effective product) or any study in which a single investigator makes a significant contribution to the demonstration of safety. This would, in general, not include phase l tolerance studies or pharmacokinetic studies, most clinical pharmacology studies (unless they are critical to an efficacy determination), large open safety studies conducted at multiple sites, treatment protocols, and parallel track protocols. An applicant may consult with FDA as to which clinical studies constitute "covered clinical studies" for purposes of complying with financial disclosure requirements.

POLICY INFORMATION

I. Purpose
The purpose of this policy is to identify, monitor and control conflicts of interest among investigators and the organization.

II. Scope
a. This policy applies to all research or research activities regardless of the funding source, as well as to research activities without external funding.
b. For research that involves human subjects, all those involved in the design, conduct or reporting of the research must disclose whether they or their immediate family members (i.e., spouse or dependent children) have any financial interest related to the research

III. Definitions
Investigator - any person, regardless of title or position, who is responsible for the design, conduct or reporting of research or research activities.

Significant conflict of interest - defined as anything of monetary value, **including** but not limited to:

- salary or other payments for services (e.g., consulting fees or honoraria);
- equity interests (e.g., stocks, stock options or other ownership interests);
- intellectual property rights (e.g., patents, copyrights and royalties from such rights).

a. A significant financial interest is related to the research when the significant financial interest could be affected by the research; or is in an entity whose financial interest could be affected by the research.

- b. Significant Financial Interest does <u>NOT</u> include:
    - salary, travel reimbursements or other non-royalty remuneration from the Hospital if the Investigator is currently employed or otherwise appointed by the Hospital;

- 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;
- 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;
- 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.

Financial conflict of interest - defined as a significant financial interest that could directly and significantly affect the design, conduct, or reporting of human subject research

Organizational Conflict of Interest- Financial contributions, licensing, technology transfer or patents, or other financial interest in the research in excess of $500,000 that have the potential to place undue influence on the human research protection program or undermine the protection of participants in research.

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IV. Investigator Conflict of Interest Disclosure Process

1. At the initial and continuing review of a research protocol, the Investigator with a financial conflict of interest must submit a signed financial disclosure form disclosing any conflicts of interest.
    a. Investigators are required to report new significant financial interests using the conflict of interest declaration form within 30 days of acquisition or discovery.
2. Investigators must disclose to the Institutional Review Board existing conflict(s) of interest, specifically:
    a. Ownership interest (equity or stock options) of $5,000 or greater value when referenced to publicly traded prices or other measure of fair market value when aggregated for the immediate family.
    b. Ownership interest (equity or stock options) of any amount whose value cannot be referenced to publicly traded prices or other measure of fair market value.
    c. Ownership interest (equity or stock options) of any amount when the value of the interest would be affected by the outcome of the research.
    d. Ownership interest (equity or stock options) whose value represented 5% or more interest in any one single entity.
    e. Compensation of $5,000 or more in the past year when aggregated for the immediate family.
    f. Compensation of any amount when the value of the interest would be affected by the outcome of the research. This includes direct and indirect payments.
    g. Proprietary interest related to the research of any value including, but not limited to, a patent, trademark, copyright or licensing agreement.
    h. An application pending related to the research for a patent, trademark, copyright or licensing agreement
    i. Board or executive relationship related to the research, regardless of compensation.
3. All Investigators are required to complete CITI training before any study procedures can be conducted. This training includes a conflict of interest course. A refresher course must be completed every three years.
    a. An additional COI module within the CITI program is required for all investigators with PHS funding or as required by the IRB.
4. Investigators will receive additional training and notification from the IRB office:
    a. when the financial conflict of interest policies are revised in a manner that changes Investigator requirements
    b. when an Investigator is non compliant with financial conflict of interest policies

5. Investigators are required to ensure they are aware of any changes to the SSH financial conflict of interest policy
6. Failure to follow the conflict of interest policy may result in study suspension or other action as determined by the IRB or South Shore Hospital

V. Financial Conflict of Interest Management Plan Procedure

a. The financial conflict of interest management committee will be responsible for developing a conflict of interest management plan. The committee will be comprised of Compliance department representatives, the Director of the Office of Research, the Chair of the IRB, finance department representatives, and additional departmental representatives as needed.

i. The plan for management may include, but is not limited to:
- -Disclosure of financial conflicts of interests to participants
- -Modification of the research plan
- -Public disclosure of financial conflicts of interest (e.g. when presenting or publishing the research; to staff members; to Institutional Review Board(s)
- -Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research
- -Reduction or elimination of the financial interest

ii. In cases where the IRB determines that the financial interest will affect rights and welfare of subjects, disclosure of the interest to subjects will be deemed insufficient by itself as a means to manage the conflict(s). A different plan will be developed for review at a convened meeting of the IRB.

iii. In any case in which the HHS determines that an NIH-funded project of clinical research 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 the Institution as required by the regulation, the investigator(s) will be required to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

b. The financial conflict of interest management plan must be agreed to and signed by the investigator and the IRB administrator who will accept the plan on behalf of the management committee

c. For studies that require full board review, the financial conflict of interest management plan will be reviewed by the convened IRB and the convened IRB will have the final authority to approve or revise the financial conflict of interest management plan.

d. If the management plan is not reviewed at a convened meeting because the research does not require full board review, the management plan will be approved by the management committee and reported to the IRB at a convened meeting.

e. Records related to disclosures and management of financial conflicts of interests will be maintained for at least six years following study closure.

VI. Institutional Reporting of Financial Conflicts of Interest

1. Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by the Institution to be conflicting and ensure that the Institution has an FCOI report regarding any implemented a management plan in accordance with this part. In cases in which the Institution identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, the Institution shall not submit an FCOI report to the PHS Awarding Component.

2. For any significant financial interest that the Institution identifies as conflicting subsequent to the Institution's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), the Institution shall provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the Institution has implemented a management plan in accordance with this part.

In cases where an FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by the Institution (e.g., was not timely reviewed or reported by a subrecipient), the Institution will complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. If bias is found, the Institution will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

VII. FDA requirements for Financial Disclosure by Clinical Investigators (21 CFR 54)

1. Investigators are required to follow 21 CFR 54, when covered clinical studies are submitted to FDA in support of product marketing.

Covered clinical studies includes any study of a drug or device in humans submitted in a marketing application or reclassification petition that the applicant or FDA relies on to establish that the product is effective (including studies that show equivalence to an effective product) or any study in which a single investigator makes a significant contribution to the demonstration of safety. This would, in general, not include phase l tolerance studies or pharmacokinetic studies, most clinical pharmacology studies (unless they are critical to an efficacy determination), large open safety studies conducted at multiple sites, treatment protocols, and parallel track protocols. An applicant may consult with FDA as to which clinical studies constitute "covered clinical studies" for purposes of complying with financial disclosure requirements.

VIII. South Shore Hospital Conflict of Interest Policy

Each member of the management team (Administrative Team, Directors), employed physicians, key employees and other as identified are required to sign the disclosure statement on an annual basis and as required when the policy is changed.

REFERENCES

NIH, FDA 21 CFR 54

RELATED DOCUMENTS

GENERAL INFORMATION

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