Human Research Protection Program Conflict of Interest Policy

Definitions:

Investigator Conflict of Interest - circumstances which may bias or conflict with the integrity of human subject research related to a specific research study. These circumstances may be personal or financial. Personal interests include not only the individual's own interests, but also those of which the individual has a familial or close personal relationship.

Institutional Review Board (IRB) Member Conflict of Interest - includes the interest of an IRB member (including alternates, consultants, and non-voting members) and his or her immediate family (spouses and dependent children) which may affect or have the appearance of affecting the review of human subjects research or the integrity of human subjects research.

To whom conflict of interest disclosure applies

Individuals covered by the conflict of interest policy include researchers, research staff, and their immediate family members (spouses and dependent children).

For NIH/PHS grants

Definitions, as Outlined in 42CFR50, part F

For all Public Health Service grant awards, including grants from the National Institute of Health, a Financial Conflict of Interest is defined as:

A Financial Conflict of Interest exists when the Institution, through its designated officials, reasonably determines that an Investigator's Significant Financial Interest is related to an NIH-funded research project and could directly and significantly affect the design, conduct, or reporting or the NIH-funded research.

The 2011 revised regulation defines a "Significant Financial Interest" as follows:

(1) A financial interest consisting of one or more of the following interests 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:

> (i) 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;

(ii) 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); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of 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 their 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 Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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.

Criteria for Determining conflict of interest for an IRB Member or Consultant

An IRB member or consultant is prohibited from participating in the review of a research protocol in which they have a conflict of interest, as defined above. The IRB member or consultant with a conflict of interest may provide information requested by the IRB.

To determine if an IRB member or consultant has a conflict of interest for review of human subjects research, the following circumstances, including financial and non-financial, should be considered:

- Interests of immediate family members
  - Immediate family members include spouse, children, and persons with whom he or she maintains living arrangements that approximate a family relationship.
- Being a member of the research team
- Has a financial interest in the research with value that cannot be readily determined
- Has a financial interest in the research with a value that exceeds $5,000
- Has received or will receive compensation that may be affected by the outcome of the study
- Has a proprietary interest in the research, such as a patent, trademark, copyright, or licensing agreement
- Has received previous payments in the past 12 months from the sponsor that exceeds $5,000
- Is the direct supervisor of a member of the research team
- Is an executive or director of the agency sponsoring the research
- Has any interest that the IRB member believes may conflict with his or her ability to objectively review the protocol

Process for Identifying and Reporting IRB Member / Consultant Conflicts of Interest

For IRB members and consultants, disclosure of any conflict of interest will be indicated on the protocol reviewer form. The IRB Chair will also ask for disclosure of any conflict of interest at the beginning of the IRB meeting prior to discussion and voting on studies listed on the meeting agenda. Any IRB member with a declared conflict of interest will not be assigned as a primary or secondary reviewer for a research study. Consultants may provide information to the IRB but any conflict of interest must be indicated on their reviewer form. Any declared conflicts of interest from members or consultants and actions taken during the meeting as a result of these conflicts will be documented in the meeting minutes.

For expedited review procedures, if the IRB Chair is unable to conduct the review due to conflict of interest, the IRB Vice-Chair may conduct the review.

During the IRB meeting, any IRB members with conflicts of interest may remain in the room during discussion of the study to provide information to the IRB, but must leave the room for final discussion and voting. The member(s)' name and recusal from voting for conflict of interest will be documented in the minutes. IRB members with a conflict of interest do not count towards the quorum required for voting on research studies.

For FDA marketing applications for a drug, biological product, or device

The Financial Disclosure by Clinical Investigators regulation (21 CFR part 54) requires applicants who submit a marketing application for a drug, biological product or device to submit certain information concerning the compensation to, and financial interests and arrangements of, any clinical investigator conducting clinical studies covered by the regulation. For guidance on financial disclosure to FDA:

https://www.fda.gov/media/85293/download

Financial conflicts of interest for investigators

Woman's Hospital Research Center will comply with the 2011 revised Financial Conflict of Interest Policy for PHS (Public Health Service), including NIH (National Institutes of Health), grant awards, as defined in 42CFR50, part F. This policy will be made accessible on the Woman's Hospital intranet, as well as by written request. All identified Financial Conflicts of Interest, as determined by the Research and Development Committee, will be reported to NIH (as necessary) and the IRB. Financial conflicts of interest should be disclosed by the investigator, regardless of the funding source.

The Research and Development Committee will review all Financial Conflict of Interest disclosures for submitted research proposals, determine if a Financial Conflict of Interest exists, and take appropriate management action as necessary. The IRB will be notified of any conflicts of interests, including any management plan, as determined by the Research and Development Committee, at such time as the study is under full board IRB review. The Research and Development Committee will make a reasonable determination if any Significant Financial Interest could affect the research. The IRB has the final authority to decide if the conflict of interest and its management allow the research to be approved.

The Financial Conflict of Interest disclosure applies to any Investigator receiving funding from PHS, including NIH, as well as any study receiving funding from other sources. The Investigators include the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by PHS or NIH. These Investigators may include collaborators or consultants.

Any Financial Conflict of Interest disclosure should also include the Investigator's spouse and dependent children. If the research project is a clinical trial, all Investigators must disclose any Financial Conflict of Interest in each public presentation of the results of the research.

Submission of Financial Conflict of Interest Disclosures

A Financial Conflict of Interest disclosure should be submitted by each Investigator:

- Upon submission of NIH-funded research, or research receiving funding from other sources, for review by the Research and Development Committee and/or Woman's Hospital Institutional Review Board
- Within 30 days of a discovery or acquisition of a new Significant Financial Conflict of Interest
- At least annually, during the period of award
- For any PHS/NIH travel-related reimbursements or sponsored travel, the investigator(s) should disclose the purpose of the trip, the identity of the sponsor, the destination, and the duration.

Records of Financial Conflict of Interest disclosures and any resulting action and management plan will be kept for three years.

Management Plans

If a Financial Conflict of Interest is determined to exist, the management plan may include:

- Public disclosure of all Financial Conflict of Interests when presenting the results of the research
- Disclosure of any Financial Conflict of Interests directly to participants
- An appointment of an independent monitor to protect the design, conduct, and reporting of research against bias as a result of the Financial Conflict of Interest
- Modification of the research plan
- Reduction or elimination of the Financial Conflict of Interest
- Severance of relationships that create the Financial Conflict of Interest

Reporting Requirements to HHS/NIH funded studies

All Financial Conflict of Interests will be reported to NIH, as applicable. This report will include:

- The role of the conflicted investigator in the research project
- The conditions and requirements of the management plan
- How the management plan is designed to safeguard the objectivity of the research project

- The Investigator's agreement and confirmation of the management plan
- How the management plan is to be monitored

Education

Organizational officials, investigators, study coordinators, and R&D/IRB members are required to complete education pertaining to financial conflicts of interest through online CITI training, initially and through refresher courses every three years. Education will also be provided to these entities when Woman's HRPP financial conflict of interest policies are revised in a manner that changes researcher requirements. Additional education may be required if a researcher is non-compliant with financial conflict of interest policies and procedures.

Disclosure and Management Procedures

The purpose of this policy and procedure is to provide a guideline for the disclosure and management of financial conflicts of interest that could bias the design, conduct, or reporting of research proposed to or supported by the U.S. Public Health Service (PHS), National Science Foundation (NSF), or any other outside funding entities. The policy is based on the PHS regulations at 42 Code of Federal Regulations Part 50, Subpart F, 45 Code of Federal Regulations Part 94, and the NSF Grant Policy Manual Section 510. This policy and procedure will apply to any person paid by, under the control of, or affiliated with Woman's Hospital, such as medical staff, scientists, trainees, technicians and other staff members, students, fellows, guest researchers, or collaborators at Woman's Hospital, engaged in any research, research training, research-related grant, or cooperative agreement supported by or for which support is requested from PHS, NSF, or any other outside funding entities.

1. Prior to the submission of an application for outside funding or the signing of a cooperative agreement with outside funding entities, each investigator must submit a written disclosure of all known Significant Financial Interests (including those of the investigator's spouse and dependent children) to the Medical Director of Woman's Hospital Research Center. The disclosure must include all Significant Financial Interests that would reasonably appear to be affected by the project for which funding is sought and in entities whose financial interests would reasonably appear to be affected by the project. Only financial interests relating to the particular project need be disclosed.

2. Investigator will be defined as the principal investigator, co-investigators, and any other person responsible for the design, conduct, or reporting of the project.

3. Significant Financial Interests will be defined as anything of monetary value, including but not limited to:

    - salary or other payments for services (e.g., consulting fees, honoraria, grants to fund ongoing research, or compensation in the form of equipment);
    - equity interests (e.g., stocks, stock options or other ownership interests); and
    - intellectual property rights (e.g., patents, copyrights and royalties from such rights).

4. The term Significant Financial Interests will not include:

    a) Salary, royalties, or other remuneration from Woman's Hospital;

    b) Any ownership interests in the institution, if the institution is an applicant under the Small Business Innovation Research program;

    c) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;

    d) Income from service on advisory committees or review panels for public or nonprofit entities;

    e). An equity interest that when aggregated for the investigator and the investigator's spouse and dependent children, meets both of the following criteria: Does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity;

    f). Salary, royalties or other payments that when aggregated for the investigator and the investigator's spouse and dependent children over the next twelve months, are not expected to exceed $10,000.

    Provided, however, that the exclusions in items a), d), and e) will not apply if the compensation or transfer of an equity interest is conditioned upon a particular outcome.

5. Financial disclosures must be updated annually in writing during the period of the award and as new reportable significant financial interests are discovered or acquired (within 30 days of discovery).

6. The financial disclosures will be submitted to the Medical Director of Woman's Hospital Research Center (R&D Chair) for review of potential conflict of interest. A potential conflict of interest will be defined as a divergence between an individual's private interests

and his or her professional obligations to Woman's Hospital such that an independent observer might reasonably question whether the individual's professional actions or decisions are influenced or determined by considerations of personal financial gain.

7. If the Medical Director of Woman's Hospital Research Center identifies a significant potential conflict of interest, the financial disclosures will be forwarded to the Research and Development Committee.

8. The Research and Development Committee will be responsible for determining whether or not a conflict of interest exists and what conditions or restrictions if any, should be imposed by Woman's Hospital to manage such conflicts.

9. A conflict of interest will be determined to exist that relates to the research when the Research and Development determines that a Significant Financial Interest exists that could directly and significantly affect the design, conduct, or reporting of the project or may adversely affect the protection of participants. Actual conflict of interest will depend on the situation and not on the character or actions of the individual investigator.

10. The Research and Development Committee may request any information that it deems necessary to assist in the conflict of interest determination including, but not limited to, copies of research agreements, consulting agreements, correspondence, curriculum vitae, publication reprints, checks, and cashier records.

11. The Research and Development Committee will provide a written report to the IRB with the study submission for review regarding the determination of whether or not a conflict of interest exists. The IRB will consider this written report in the review process. If a conflict of interest has been identified, a Resolution Plan recommending what actions should be taken by Woman's Hospital to manage, reduce, or eliminate the conflict will also be submitted. The IRB will review the management plan and consider if frequent monitoring of the study may be necessary. The IRB has the final authority to determine if the management plan allows the research to be approved.

12. The Resolution Plan may impose conditions or restrictions to manage, reduce, or eliminate conflicts of interest that may include, but not be limited to:
    - public disclosure of significant financial interests;
    - monitoring of research by independent reviewers;
    - modification of the research plan;
    - disqualification from participation in all or a portion of the research;
    - divestiture of Significant Financial Interests and / or severance of relationships that create actual or potential conflicts, or such other sanctions as may be determined to be appropriate by the Research and Development Committee.

13. The Research and Development Committee will approve, disapprove, or recommend changes to the determination of conflict of interest and the Resolution Plan, if any, by a majority vote. The Research and Development Committee may also table the conflict of interest issue in order to seek additional information or legal advice.

14. In situations where the investigator(s) dispute the decision of the Research and Development Committee, the Chairperson will refer the matter to the Chief Executive Officer of Woman's Hospital, whose decision regarding the management of conflicts of interest will be final.

15. Prior to Woman's Hospital's expenditure of any funding awards, the Chief Executive Officer of Woman's Hospital will certify, in each application for the funding to which this subpart applies, that:

- Written and enforced administrative process exists to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought; and

- If any conflicting interest has been identified, assure that the interest has been managed, reduced or eliminated (but the nature of the interest or other details will not be identified).

- This process will also apply for any interest that Woman's Hospital identifies as conflicting subsequent to Woman's Hospital's initial report under the award. The report will be made and the conflicting interest managed, reduced or eliminated, at least on an interim basis, within sixty days of the identification.

16. If an unreported Significant Financial Interest of an investigator that biases the design, conduct, or reporting of the research is discovered, the Chief Executive Officer of Woman's Hospital will promptly notify the funding entity of the corrective action taken or to be taken, in accordance with applicable law or policy. The funding entity may provide further directions to maintain objectivity in the conduct of the project.

17. Woman's Hospital Research Center will maintain a record of all financial disclosures, minutes of Conflict of Interest deliberations, and all actions taken by Woman's Hospital with respect to each conflicting interest for at least three years from the date of submission of Woman's Hospital's final expenditures report or, where applicable, from the date specified by the funding agency.

18. A funding entity may review Woman's Hospital Research Center and investigator records relating to the project to determine compliance with this policy. If the funding entity decides that a particular conflict of interest will bias the objectivity of the project to the

extent that further corrective action is needed or that the conflict has not been appropriately managed, reduced, or eliminated, it may suspend funding until the matter is resolved.

19. If clinical research has been conducted to evaluate the safety or effectiveness of a drug, medical device, or treatment, and if that research is designed, conducted, or reported by an investigator with a conflicting interest that was not managed in compliance with this conflict of interest policy and procedures, federal law may require the investigator to disclose the conflicting interest in each public presentation of the results of the research.

20. Failure to comply with the conflict of interest policy and procedures or with restrictions /conditions imposed under the policy will be grounds for discipline. Disciplinary actions will be determined by Woman's Research and Development Committee. Such actions may range from a letter of reprimand to a recommendation of termination of the investigator's association with Woman's Hospital, and/or Woman's Hospital Foundation.

21. Recommendations for termination of the investigator's association with Woman's Hospital, and/or Woman's Hospital Foundation will be forwarded to the Director of Human Resources and the Vice President responsible for the area conducting the research and will be handled in accordance with the institution's established policies and procedures.

22. Subcontractors from other institutions must either comply with this policy by providing a completed financial disclosure form for each employee associated with the project or a certification, signed by an authorized official, that their institution is in compliance with Federal policies regarding investigator Significant Financial Interests disclosure and that their portion of the project is in compliance with their institutional policies. This requirement will be a mandatory part of the subcontracting process.

Sources: PHS 42 CFR Part 50.601-607

PHS 45 CFR Part 94.1-6

NSF Grant Policy Manual Section 510

Failure to Comply with Financial Conflict of Interest Policy

If an Investigator fails to comply with the Financial Conflict of Interest policy, Woman's Hospital Research Center will complete a review of the Investigator's activities to determine any bias in design or conduct of the research and will document the results of said review. If any bias is found to exist, the NIH will be notified and the impact of the bias will be reported. A plan of action will be implemented to eliminate or mitigate the effect of the bias.

Any further inquiries into the assessment or management of Financial Conflict of Interest will be conducted in accordance to the regulations outlined in 42CFR50, part F.