

Tufts Medical Center Hospital-Wide Policy	Subject: Conflict of Interest in Research	File Under:
Issuing Department: Research Administration		Latest Revision Date: August 2012. In Effect as of August 24, 2012
Original Procedure Date: November 2010	Page 1 of 14	Approved By: See Approval Signature Page

I. Purpose

This policy will go into effect on August 24, 2012.

As an institution dedicated to excellence in patient care research and training, Tufts Medical Center, Inc. (“Tufts MC”) places a high value on research integrity and academic freedom. Objectivity in the conduct of research, the freedom to disseminate ideas through publication of research results, the protection of the rights and interests of research subjects, maintenance of public trust, and the ability to ensure that the conduct of research at Tufts MC is not compromised are critical to these institutional values. Relationships with industry and other outside entities, while important to the support and advancement of research, can present special challenges in protecting these institutional values.

In the context of conducting research, the primary interest of a researcher should be the objective conduct of the research. The researcher, Tufts MC, and the public also share an interest in the complete, objective and timely communication of research results. While Tufts MC expects that all of its investigators and other research staff should carry out their professional responsibilities with the highest standards of personal integrity, it is necessary to acknowledge and to avoid or manage situations where a secondary interest could reasonably be expected by others to influence decision-making.

To say that one has a conflict of interest does not necessarily mean that the individual involved acted or is expected to act inappropriately. It is the existence of the competing interests that creates the initial conflict of interest concern.

Conflict of interest can be defined as a situation in which an investigator’s external interests undermine, appear to undermine, or have the potential to undermine the investigator’s ability to perform his or her ethical, legal, or professional duties. The potential for personal gain or the existence of competing interests must not jeopardize or appear to jeopardize the integrity of the research, its design, or the interpretation or reporting of research results.

II. Eligibility

This Policy applies to all investigators employed by Tufts MC and the Tufts Medical Center Physician's Organization and other individuals — such as researchers, postdoctoral fellows and visiting researchers — who are responsible for the design, conduct or reporting of research at Tufts MC. "Investigator" in this Policy refers to such physicians and other individuals. Additionally, this policy applies to those individuals listed as key personnel participating in PHS research, as defined by PHS regulation at 42 CFR 50.603, Subpart F. The PHS regulations are designed to promote objectivity in PHS-funded research by establishing standards to ensure that the design, conduct, and reporting of research funded under PHS grant awards is not biased by any conflicting financial interests of an Investigator.

III. Policy

Tufts MC Policy on Conflict of Interest in Research requires the disclosure by all Key Personnel of all significant financial interests or associations with other organizations on an annual basis and to update this information within 30 days of any change. In addition, the investigator must certify that there is no change, or update the information, with each application for funding or each submission of a protocol for human subjects research.

For Investigators not subject to the PHS policy, disclosure must be made at the time of each grant or Institutional Review Board (IRB) submission and updated within 90 days if there is any change.

This Policy supplements Tufts MC Policy on Industry Conflicts of Interest. As a result, certain activities may be subject to both policies. For example, a Tufts MC physician employee (who is subject to Tufts MC Policy on Industry Conflicts of Interest) who wishes to enter into a consulting agreement would be subject to the review, disclosure and written agreement requirements of Tufts MC Policy on Industry Conflicts of Interest. If that Tufts MC investigator is also responsible for the design, conduct or reporting of research at Tufts MC, then he or she is subject to this Policy on Conflict of Interest in Research. That individual's financial interests would be subject to an additional level of review pursuant to this policy.

IV. Procedure

Conflict of Interest Terms

Accurate understanding of the requirements depends upon an accurate understanding of each term's meaning. In 42 CFR § 50.603, PHS's codification of its policies, the terms are defined as follows:

Institutional Responsibility: means an Investigator's professional responsibilities on behalf of the Institution, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and serving on panels such as the Institutional Review Board (IRB) or Data and Safety Monitoring Boards (DSMB).

Investigator: This term refers to the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by the agency or proposed for such funding. For PHS funded projects this includes all those identified as Key Personnel by

the institution in the grant application, progress report, or any other report submitted to the PHS by the institution.

PHS: means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

PHS Awarding Component: The organizational unit of the PHS that funds the research that is subject to this subpart.

Research: Research means a systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product development.

Significant Financial Interest (SFI):

(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 subject to the PHS policy (those listed as Key personnel on a PHS funded project) 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.

(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.

*With regard to investment vehicles, “does not directly control” means that the investigator has no decision-making power with respect to the investment vehicle, including what the investment vehicle includes or how it is managed.

Categories of Conflict of Interest in Research

Because the appropriate approach to each situation depends on its specific facts, this Policy does not contain an exhaustive list of fixed rules regarding conflicts of interest in research. For example, several external interests taken together, any one of which might be permitted, could amount to a conflict of interest in research. Further, individuals who seek funding from, or who work on, a research project funded by an external sponsor must comply not only with this Policy but also with that sponsor’s requirements, if any, related to disclosure, management, and avoidance of conflicts of interest.

The following examples are intended to illustrate principles that underlie the Policy. Some of the activities in these examples may also represent conflicts of commitment. Individuals who have questions about how this Policy applies to a particular research activity should seek advice from the Vice President of Research Administration.

Activities Not Ordinarily Reportable

Except as otherwise indicated in this Policy, activities of the following types generally need not be disclosed:

- An individual receives royalties for published scholarly works and other writings.
- An individual receives payments under Tufts MC’s intellectual property policy (although such payments should be disclosed to human subjects, if applicable).
- In situations, such as investment funds, where the holder’s equity is managed by someone else without the holder knowing or being able to influence the identity of companies in the portfolio at any given time (e.g., mutual funds), no disclosure is required.

Reportable Activities

Activities of the types described in the following examples must be disclosed, and in most circumstances will be subject to oversight as a potential conflict of interest:

- An individual participates in clinical research on a technology that was developed by the individual or his or her spouse or dependent child, but which is owned by or licensed to a business in which neither the individual, nor the spouse or dependent child, has a consulting relationship, a management position or a Significant Financial Interest.
- An individual or his or her spouse or dependent child serves on the board of directors or scientific advisory board of a business from which the individual receives sponsored research support or is conducting human subject research.

- An individual publishes the results of research which could have an impact on a Significant Financial Interest of his or hers, provided that the individual discloses his or her Significant Financial Interest in the publication.

The following examples represent types of activities presumed to constitute major conflicts of interest. Such activities must be disclosed, are not permitted without express authorization of Tufts MC, and usually will be prohibited, or permitted only with continuing oversight:

- An individual receives sponsored research support (whether in dollars or in kind) for clinical or basic research from a business in which he or she or his or her spouse or dependent child holds a Significant Financial Interest (equity interest exceeding \$10,000 in value and/or representing more than 5% ownership).
- An individual participates in clinical research on a technology owned by or licensed to a business in which the individual, or his/her spouse or dependent child, has a Significant Financial Interest.
- An individual conducts research externally that could be conducted within Tufts MC.
- An investigator assigns a resident, fellow or other trainee to a research project in which the individual has a Significant Financial Interest.
- An individual assumes an executive position in an outside entity engaged in research activities related to the individual’s field.

Typical Relationships

The following table has been developed to provide guidance to Tufts MC community in structuring relationships with industry. Even if a proposed relationship is addressed in the following table, faculty, employees, trainees, etc. are required to abide by the disclosure and review process for potential conflicts laid out in this Policy.

Table 1: Financial Interests and Conduct of Research Activities

All financial interests at any level are subject to Tufts MC Policy on Industry Conflict of Interest and must be disclosed to Tufts MC for review. Conflicts should be disclosed to the research team and publicly when submitting publications and making presentations.

Activity	Potential Conflict?	Allowability	Management Plan Required	Exceptions? (See below)
1. Consulting	Y	Allowed to conduct the study, subject to the requirements of Tufts MC Policy on Industry Conflict of Interest (including requirements for disclosure and implementation of a written agreement), and personal compensation must not total more than \$10,000 per year per sponsor, combined with other forms of financial compensation in the aggregate. Disclosure required of \$5,000 a year or greater required.	Required if greater than \$10,000 in aggregate per year from and single funding source	Y-1
2. Speaking fees	Y	Allowed to conduct the study, subject to the requirements of Tufts MC Policy on Industry Conflict of Interest (including requirements for disclosure and implementation of a written agreement), and personal compensation must	Required if greater than \$10,000 in aggregate per year from and	Y-1

		not total more than \$10,000 per year per sponsor, combined with other forms of financial compensation. Disclosure required of \$5,000 a year or greater required.	single funding source	
3. Director Fees	Y	Allowed to conduct the study, subject to the requirements of Tufts MC Policy on Industry Conflict of Interest (including requirements for disclosure and implementation of a written agreement) and personal compensation must not total more than \$10,000 per year per sponsor. Disclosure required of \$5,000 a year or greater required..	Required if greater than \$10,000 in aggregate per year from and single funding source	Y-1
4. Free trips enticements or other benefits unrelated to any academic (research or training) activity	Y	Not allowed.		N
5A. Equity* in privately held company for studies involving human subjects	Y	Disclosure and committee review required. May not be allowed.	Required	Y-2
5B. Equity in privately held company for studies NOT involving human subjects	Y	May be allowed after disclosure, review and approval by Tufts MC Conflict of Interest Committee. Disclosure required.		Y-2
6. Equity in publicly traded company	Y	Must disclose equity interests greater than \$5,000 or greater than 5% ownership. All disclosures greater than \$10,000 or greater than 5% ownership will be reviewed for allowability on a case by case basis. Disclosure required.	Required if greater than \$10,000 in aggregate per year from and single funding source	Y-2
7. Royalty interest	Y	Must disclose royalty interests greater than \$5,000. All disclosures greater than \$10,000 will be reviewed for allowability on a case by case basis.	Required if greater than \$10,000 in aggregate per year from and single funding source	Y-2
8. Bonus for enrollment / recruitment of research subject	Y	Receipt of such bonuses is not allowed.	n/a	N
9. Finder fees and referral fees	Y	Receipt of such fees is not allowed.	n/a	N
10. Reimbursement of travel expenses	N	Reimbursement of reasonable and necessary expenses in conjunction with research, consulting, speaking or directorship activities		Y-3

		are allowed, subject to the requirements of Tufts MC Policy on Industry Conflict of Interest (including requirements for disclosure). For Investigators subject to the PHS policy all travel reimbursement or directly provided travel must be disclosed regardless of value.		
11. Negotiation of Clinical Trial Agreements with an anticipated residual balance beyond actual anticipated costs.	N	Planning a “contingency” for unforeseen events and potential complications is appropriate		N/A
12. Mutual funds in healthcare sector	N	Not a conflict. All mutual fund ownership is allowed.		N/A

^{Y-1} Personal compensation from activities such as consulting fees, director fees, speaker fees, etc. can exceed \$10,000 per annum in aggregate provided all of the following conditions are met:

- Full disclosure is made to Tufts MC’s Conflict of Interest Committee (“COIC”) and the committee approves the exception based on its understanding of the accuracy of the following conditions:
- The Investigator possesses unique expertise or capability or the hospital possesses unique resources within the Eastern Massachusetts region
- Such compensation is disclosed to the research subject
- The proposed consulting arrangement meets all other requirements of Tufts MC Policy on Industry Conflicts of Interest, including the requirement for review and approval of a written consulting agreement.
- The Investigator agrees to abide by an additional public disclosures or mitigation plan if he/she chooses to maintain the Conflict of Interest.

^{Y-2} The Conflict of Interest Committee discourages exceptions, but the presumption (of not allowing such conflicts) is rebuttable for causes such as; that there is no reasonable alternative, that COI is managed via a plan; and there is important health benefit to be accrued.

^{Y-3} Disclosure of travel must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Conflict of Interest Committee (or its designee) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a Conflict of Interest. This disclosure requirement applies only to those investigators subject to the PHS policy.

* See definitions

Special Considerations

Publication

Tufts MC requires in all its contracts for support of research or education that the researchers be free to objectively analyze and publish all results of their work. Tufts MC may accept reasonable delays on publication (normally not to exceed 120 days) that allow for the protection

of intellectual property, the deletion of confidential information provided by a research sponsor or for the completion of a multi-site clinical trial.

Residents/Fellows

An important part of the training of house staff (e.g., residents and fellows) is mentored research. Tufts MC and the Investigators who oversee research conducted by or involving house staff must ensure that the educational interests of these trainees are not compromised by institutional or individual conflicts of interest. Care must be taken to ensure that the source of research funding does not cause a change in the training experience. House staff should not be placed in a situation where publication will be unduly restricted or excessively delayed (any delay greater than 120 days will be considered excessive) or where the financial interests of the company or the mentor will influence the direction of the research project. House staff must be able to publicly present dissertations and theses and to publish their research.

Human Subjects

In situations where research could involve risk to human subjects, the protection of those subjects must be of paramount concern. With each protocol involving human subject research, each Investigator must submit to the IRB a conflict of interest disclosure. Forms that indicate a possible conflict of interest will be forwarded by the IRB to the Office of Research Administration and will be subject to the review and management procedure described under “Review and Management of Conflicts of Interest” below. IRB approval will not be granted until the conflict of interest oversight or management plan has been set up and approved by the Conflicts of Interest Committee (“COIC”). Tufts MC may prohibit research that involves a conflict of interest even if the IRB approves the research.

In accordance with federal regulations governing human subject research, a study participant is to be fully informed of research related risks before he or she consents to participate in the research. Informed consent forms and procedures should include the disclosure of any conflict of interest that could reasonably appear to influence an investigator’s judgment in conducting the research.

Additionally, no IRB may have a member participate in the IRB’s initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB (45 CFR 46.107(e)).

Special Considerations for Start-up Companies

In situations where an Investigator obtains or owns equity in a company that relates to his or her research, it is especially important to be mindful of conflicts of interest and conflicts of commitment. Care should be taken to keep sight of what is the property of Tufts MC versus what belongs to the company. The Investigator should assure that time invested in the company does not exceed the amount of time allowed for outside activities under his or her employment agreement and does not compromise his or her ability to perform his or her regular duties and obligations to Tufts MC or to funding agencies. Tufts MC facilities and resources may not be used for the benefit of the company without a written agreement authorizing the use approved by the Office of General Counsel (“OGC”) and the Office of Research Administration.

Investigators and staff who own equity in a company should not personally negotiate or attempt to influence the licensing terms that Tufts MC offers to that company. An attorney or executive of the company with no connection to Tufts MC should be used for that purpose. The needs and interests of residents and fellows must be carefully considered. The Office of Research

Administration will work closely with investigators who are starting companies and the individual's department chair. A special conflict of interest oversight committee may be convened and meet at least annually as long as the Investigator remains involved with the company. This committee will be a subcommittee of the COIC and should consist of one member of the COIC and two individuals who are familiar with the area of research. The subcommittee will report annually to the COIC. Alternatively, in lieu of the subcommittee, the COIC Chair can work with the Investigator and submit the plan to the COIC committee for review. Once the plan is approved and in place, the department Chair may ensure annual reports are conducted and submitted to the COIC.

Disclosing Conflicts of Interest in Research

Investigators subject to the PHS Conflict of Interest policy must disclose all Significant Financial Interests (as defined above) held by themselves, their spouse or their dependent children on an annual basis. This information must be updated within 30 days of any change. With each application for funding or each submission of a protocol for human subjects research, each Investigator is required to update any changes in their SFI or certify that no such changes have occurred.

Investigators not subject to the PHS policy must disclose SFI with each application for funding or each submission of a protocol for human subjects research, and within 90 days of any change. If the research proposal involves human subjects, disclosure must be made to the Institutional Review Board (IRB). If the research project does not involve human subjects the disclosure must be made to the Director of Grants and Contracts. It is the responsibility of each Investigator to update this information any time that it changes. It is the responsibility of the Principal Investigator ("PI") to ensure that each Investigator working under his or her direction on a research project or receiving support from his or her grant or contract receives a copy of this Policy and discloses Significant Financial Interests as required by this policy.

In addition to the need to disclose conflicts of interest in research to Tufts MC and, as necessary, to funding agencies, it is also important that such conflicts be disclosed to others who might be affected by the research. This includes, for example, human subjects, other researchers who might rely on the research results, and the public. For studies involving human subjects, the informed consent form must disclose the nature of the conflict to potential research subjects, if required by the Institutional Official. It is expected that all researchers will disclose conflicts of interest related to specific research projects at any time that the results of that research are presented or published.

Regulations apply to subgrantees, collaborators of grantees (e.g. consortia) or subcontractors

If research related to a PHS funded project is undertaken by a sub-recipient or subcontract, reasonable steps will be taken to assure that the sub-recipient is in compliance with the PHS policy. This can either be through certification by the sub-recipient as part of the written agreement that they have in place a Conflict of Interest Policy that is in compliance with the PHS regulations or through requiring the sub-recipient key-personnel to comply with, "The Conflict of Interest Model Policy" included as an attachment to this Policy. The written agreement with the sub-recipient must specify the time period for which the sub-recipient key-personnel must report SFI.

Review and Management of Conflicts of Interest

Review

Review of disclosed Significant Financial Interests (SFI) will be the responsibility of the Conflict of Interest Committee (COIC) made up of The Vice President of Research Administration and the Chief Scientific Officer or their designees with other members as assigned by the Office of General Council (OGC)

Investigators must disclose SFI as described in the section “Disclosing Conflicts of Interest in Research”, above. Disclosures that indicate a potential conflict of interest are reviewed in the following manner.

In instances where the disclosed financial interest is minimal (less than \$10,000 per year and less than 5% equity ownership) and/or only requires a straight-forward and modest plan to reduce, eliminate or manage the potential conflict in accordance with the foregoing tables, the Vice President of Research Administration may elect to conduct an expedited review and approval. These actions are reported by the Vice President, Research Administration to the Conflict of Interest Committee (COIC) on a quarterly basis so that all disclosures are shared with the membership of the committee.

Where there are questions or the SFI is not determined to be minimal Conflict of Interest, the Vice President of Research Administration will contact the PI and Department Chair in order to review the COI who may jointly agree on a plan. If still unresolved at the PI and Department Chair level, The Vice President of Research Administration and Department Chair will prepare an information packet for the COIC’s review.

The information packet will be reviewed by the COIC. Based on the information provided to the COIC, the COIC may recommend the conflict be eliminated, may decline to allow the research to take place, or may recommend a management plan. The Vice President of Research Administration, Department Chair, and COIC is authorized to consult with the OGC related to any disclosure form.

If the COIC recommends that the research proceed, a plan for management or elimination of any conflicts shall be prepared. The plan and the review packet are then sent to the COIC for review and recommendation. The COIC's comments and disposition are sent to the COIC chair, who will make the final decision on behalf of Tufts MC as to whether or not a conflict of interest can be appropriately managed or eliminated.

In cases where Tufts MC determines that it cannot manage the conflict, it may require that the conflict be eliminated or that the research not proceed. Factors in this decision might include such considerations as the involvement of human subjects in the research, the level of risk involved, the nature and significance of the conflict, the potential for having a serious adverse impact on the scientific field or on the reputation of Tufts MC, whether or not the individual involved is uniquely qualified to conduct the research and the level of difficulty involved in managing the conflict relative to the benefit of doing the research.

Decisions of the COIC Chair may be appealed to the President and CEO of Tufts MC, whose decision on these matters will be final.

An approved plan for management or elimination of the conflict of interest must be in place before the research begins and funds are drawn down. Federal grant applications may be submitted while Tufts MC is considering a possible conflict of interest with the understanding that Tufts MC will not accept the funds unless the conflict can be managed or eliminated. Sponsored research agreements with non-federal research sponsors will not be signed until completion of the COIC's review unless the agreement can be made contingent on Tufts MC's ability to resolve the conflict of interest concerns.

Managing Conflicts

The regulations require the designated official at Tufts MC, the Vice President of Research Administration, to review all financial disclosures made and to follow the process described above by making a determination with respect to managing, reducing, or eliminating any conflict identified. The PHS regulations specifically state "a conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the funded research."¹ The following are examples of conditions or restrictions that can be put into place to either manage or eliminate conflict:

- Public disclosures of Significant Financial Interest;
- Monitoring of research by independent reviewers;
- Disqualification from participation in all or a portion of the research funded by the agency;
- Divestiture of Significant Financial Interests; or
- Severance of relationships that create actual or potential conflicts.

An example of a plan could entail the following:

- Disclose the support the Investigator received from the company or other sponsor.
- Disclose the Investigator's financial relationship with company.
- Describe the steps taken to inform current or new house staff (e.g., residents and fellows) and other trainees of the conflict of interest.
- Determine whether house staff projects are different in any way from those of other members of the group with respect to the way they interface with company's goals, and whether the project has been altered in direction because of a change in those goals.
- Demonstrate how publications and meeting presentations (within Tufts MC and external) are handled to allow the co-existence of the company's and academic goals.
- State whether house staff or other trainees were included in patents obtained by the group.
- State whether house staff were compensated beyond their standard salary for work performed under the sponsoring company.

¹ 42 C.F.R. § 50.605(a).

- Ensure that all conflicts of interest are disclosed.

Once a management plan is in place it is reviewed annually by the COIC, and the Investigator is required to inform the COIC of any changes in the COI.

Tufts MC's Requirement to Report to PHS

Prior to the expenditure of any funds on a PHS funded project, the institution will review all reported significant financial interests of all applicable personnel, determine if there is any Financial Conflict of Interest (FCOI), determine a management plan for the Conflict of Interest and report all FCOI to the PHS according to requirement set forth by PHS regulations.

Public Disclosure

For those investigators who are subject to the PHS requirements, Tufts Medical Center will post on a publicly accessible website information related to all FCOI in accordance with PHS policies.

Failure to Disclose a Conflict of Interest

Failure to disclose the existence of a COI can result in disciplinary action or sanctions at the institutional level and involve restitution, criminal prosecution, or corrective action by the funding agency or Tufts MC. Allowing a conflict of interest to influence one's judgment in the context of research may also constitute or lead to scientific misconduct.

If a SFI is found that has not been reported in a timely manner the Institution will, within 60 days, determine if the SFI is a COI and institute a management plan. Within 120 days the Institution will perform a retrospective review of the Investigator's research activities to determine if there is any additional non-compliance. This review will be documented to be in compliance with PHS policies.

TRAINING

All investigators at Tufts Medical Center will be required to undergo Conflict of Interest training either in-person or on-line at least once every four (4) years and provide certification to the Office of Research Administration that they have completed such training. In addition, training must be undertaken if any of the following occurs:

1. The Institution revises this Policy
2. An Investigator is found to be not in compliance with this Policy.

Record Retention

The Office of Research Administration will retain records of all financial disclosures and all actions taken by Tufts MC with respect to conflicts of interest in research.

Tufts MC is required to keep all records as follows:

- **For grants or cooperative agreements** – for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. 74.53(b) for different situations
- **For research contracts** – for three years after final payment or, where applicable, for the other time periods specified in 48 CFR part 4, subpart 4.7.

Responsibility of:

Research Administration

Author:

Douglas Reichgott
Director, Financial and Regulatory Operations
Research Administration

Date:

August 2012

Tufts Medical Center

Policy Approval Signature Page

Policy Title:

Conflict of Interest in Research

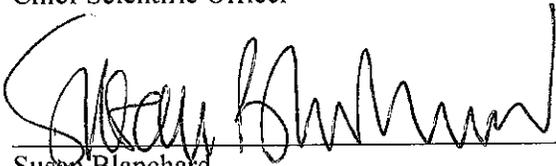
Approval Signature/Title:

Date:



8/19/12

Richard H. Karas, M.D., Ph.D.
Chief Scientific Officer



8/14/2012

Susan Blanchard
Vice President, Research Administration

CONFLICT OF INTEREST MODEL POLICY

(suggested for use by subrecipients who are not prime awardees of HHS/PHS funding)

INTRODUCTION

[The subrecipient may want to insert its own statements, principles or standards regarding financial conflicts of interest.]

This policy governing financial conflict of interest applies to all Investigators of the Institution. The Institutional Official is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the Institutional official is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to Institutional policy.

DEFINITIONS

Clinical Trial means any research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices or medical or other clinical procedures, such as surgery. [option for those organizations conducting clinical trials as a subawardee]

Conflict of Interest Committee (COI Committee) means the Institution's committee or individual that advises the Institutional Official on conflict of interest matters. The committee consists of <to be completed by subrecipient>. [option: a committee is specifically not required]

Family means any member of the Investigator's immediate family, specifically, any dependent children and spouse.

Financial Interest means anything of monetary value received or held by an Investigator or an Investigator's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

- a) salary, royalties, or other remuneration from the Institution;
- b) income from the authorship of academic or scholarly works;
- c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For Investigators, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Significant Financial Interest means a Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000; or
- c) if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- d) is income related to intellectual property rights and interests not reimbursed through the Institution.

Financial Conflict of Interest means a Significant Financial Interest (or, where the Institutional official requires disclosure of other Financial Interests, a Financial Interest) that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of Institutional research.

Institutional official means the individual within the Institution that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's Family related to the Investigator's institutional responsibilities. For the purposes of this policy, the Institutional Official is designated as <to be completed by subrecipient>.

Institutional responsibilities means the Investigator's responsibilities associated with his or her Institutional appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.

Investigator means any individual who is responsible for the design, conduct, or reporting of PHS sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

Public Health Service or *PHS* means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

Research means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The

- term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

CONFLICT OF INTEREST:

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this policy informs faculty about situations that generate conflicts of interest related to research, provides mechanisms for Investigators and the Institution to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the Institutional official.

1) DISCLOSURE OF FINANCIAL INTERESTS

All Investigators are required to disclose their outside financial interests to the Institution on an annual and on an ad hoc basis, as described below. The Institutional official is responsible for the distribution, receipt, processing, review and retention of disclosure forms. [option; a committee is specifically not required--The COI Committee will assist with the review of those forms and processes.]

Regardless of the disclosure requirements, the Investigator, in his or her own best interest, is encouraged to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest.

a) Annual Disclosures

All Investigators must disclose their Significant Financial Interests to the Institution, through the Institutional Official, on an annual basis. All forms should be submitted to the Institutional official or designee by <March 1 for the previous calendar year or as determined by the subrecipient>.

b) Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their Significant Financial Interests to the Institution, through the Institutional Official, within 30 days of their initial appointment or employment.

Prior to entering into sponsored projects or applications for sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must submit to the Institutional Official an ad hoc updated disclosure of his or her Significant Financial Interests with the outside entity. The Institution will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Institutional official an ad hoc disclosure of any Significant Financial Interest they acquire during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

c) Travel

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.

2) REVIEW AND DECISION OF THE INSTITUTIONAL OFFICIAL

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Institutional Official or designee for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Institutional Official will take action to eliminate, reduce, or manage the conflict, as appropriate. [option; a committee is specifically not required--The Institutional Official may consult the COI Committee for guidance in specific cases, or in the application of the policy to particular situations.]

A Financial Conflict of Interest will exist when the Institutional Official or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-supported research. If the Institutional Official determines that there is a Financial Conflict of Interest that can be managed, he or she must require and approve a written management plan before any related research goes forward. The affected Investigator or the COI Committee is responsible for developing and submitting a proposed management plan, in consultation with the Institutional Official.

To address complex situations, oversight committees may be established by the Institutional Official to periodically review the ongoing activity, to monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

3) CLINICAL TRIALS [option for those organizations conducting clinical trials as a subawardee]**a) Review of Significant Financial Interests Related to Clinical Trials**

Clinical trials involve particularly sensitive issues if the Investigator has a Financial Interest related to the clinical trial.

- b) [The subrecipient may want to insert its own statements, principles or standards regarding financial conflicts of interest as they may relate to clinical trials or human subjects research, and under what circumstances this type of research may be conducted when a financial conflict of interest exists.]

4) REPORTING TO PHS

Should any reported conflict or non-compliance require reporting to PHS, the Institutional official will report in accordance with PHS regulations. If the funding for the Research is made available from a prime PHS-awardee, such reporting shall be made available to the prime awardee such that they may fulfill their reporting obligations to the PHS.

5) INVESTIGATOR NON-COMPLIANCE

a) Disciplinary Action

In the event of an Investigator's failure to comply with this Policy, the Institutional official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional official is implemented.

A Institutional Official's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional official, will be described in a written explanation of the decision to the investigator, COI Committee [option], and, where applicable, the IRB, and will notify the individual of the right to appeal the decision.

b) Retrospective Review

In addition, if the Institutional Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, a [option] committee appointed by the Institutional Official will complete a retrospective review of the Investigator's activities and the research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Institutional official will update any previously submitted report to the PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. If bias is found, the report will include a mitigation report in accordance with the PHS regulations, including a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

6) TRAINING

Each Investigator must complete training on this Policy prior to engaging in research funded by PHS, and at least every four years thereafter. They must also complete training within a reasonable period of time as determined by the Institutional Official in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, or if it is

determined that the Investigator has not complied with this policy or with a management plan related to their activities.

7) RECORD RETENTION

The Institutional Official will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee.

8) CONFIDENTIALITY

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may make such information available to an agency funding research of the faculty member, to a requestor of information concerning financial conflict of interest related to PHS funding or to the primary entity who made the funding available to the Institution, if requested or required. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

9) PUBLIC ACCESSIBILITY

Prior to the expenditure of funds, the Institution will publish on a publicly-accessible website or respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

- a) The Significant Financial Interest was disclosed and is still held by the Investigator;
- b) A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
- c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the PHS policy.

10) REGULATORY AUTHORITY

This policy implements the requirements of 42 CFR 50 and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

Financial Interests Report

(submitted pursuant to the requirements of the institution name here Conflict of Interest policy)

Name: _____

I am reporting on activities: for the year _____
 as an addendum to my most recent report

<input type="checkbox"/> yes	<input type="checkbox"/> no	1. Compensation (including travel expenses). have you or a member of your Family received compensation from a for-profit entity for activities such as consulting, expert witness, advisory board membership, and the like? If yes, furnish information on an additional page.
<input type="checkbox"/> yes	<input type="checkbox"/> no	2. Equity. Do you or a member of your family own stock or hold stock options with a publicly-traded or privately-owned entity? If yes, furnish information on an additional page.
<input type="checkbox"/> yes	<input type="checkbox"/> no	3. Role. Do you or a member of your family serve as a director, trustee, officer or other key employee in a for-profit corporation, partnership, business, or other entity outside of the <u>institution name here</u> . If yes, furnish information on an additional page.
<input type="checkbox"/> yes	<input type="checkbox"/> no	4. Intellectual Property. Do you or a member of your family have rights to and/or receive royalties from intellectual property (including, patents copyrights and trademarks but excluding academic or scholarly works) licensed to and/or owned by a for-profit entity? Do NOT include intellectual property owned or managed by the <u>institution name here</u> . If yes, furnish information on an additional page.

Certification:

I have read and understand the institution name here's policy on Conflict of Interest in PHS Funded Projects and have completed this report to the best of knowledge and belief. If required, I will comply with any conditions or restrictions imposed by the institution name here to manage any real or perceived conflicts. Should my outside financial or managerial interests, or those of my Family, change in a way that results in different answers to any of the questions asked in this report, I agree to submit a revision.

 (date)

 (signature)

additional page(s) attached

Addition to Financial Interests Report of: _____

Reporting for self family member:
name: _____
relationship: _____

Name of External Entity: _____
Address of External Entity: _____

Type of external relationship: (check all that apply)

<input type="checkbox"/>	Consultant
<input type="checkbox"/>	Speaker
<input type="checkbox"/>	Advisory Board or Committee
<input type="checkbox"/>	Equity Holdings
<input type="checkbox"/>	Governing Board or Officer
<input type="checkbox"/>	Intellectual Property Rights
<input type="checkbox"/>	Royalty Income
<input type="checkbox"/>	Other (describe below)

Amount of compensation or financial interest in reporting period: \$ _____

If travel paid by entity:
Destination _____
Amount \$ _____

Comments or explanatory information:

[Code of Federal Regulations]
[Title 42, Volume 1, Parts 1 to 399]
[Revised as of October 1, 2000]
From the U.S. Government Printing Office via GPO Access
[CITE: 42CFR50]

[Page 180-183]

TITLE 42--PUBLIC HEALTH

CHAPTER I--PUBLIC HEALTH SERVICE,
DEPARTMENT OF HEALTH AND
HUMAN SERVICES

PART 50--POLICIES OF GENERAL APPLICABILITY--Table of Contents

Subpart F--Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought

Authority: 42 U.S.C. 216, 289b-1, 299c-3.

Source: 60 FR 35815, July 11, 1995; 60 FR 39076, July 31, 1995,
unless otherwise noted.

Sec. 50.601 Purpose.

This subpart promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an Investigator.

Sec. 50.602 Applicability.

This subpart is applicable to each Institution that applies for PHS grants or cooperative agreements for research and, through the implementation of

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this subpart by each Institution, to each Investigator participating in such research (see Sec. 50.604(a)); provided, that this subpart does not apply to SBIR Program Phase I applications. In those few cases where an individual, rather than an institution, is an applicant for PHS grants or cooperative agreements for research, PHS Awarding Components will make case-by-case determinations on the steps to be taken to ensure that the design, conduct, and reporting of the research will not be biased by any conflicting financial interest of the individual.

Sec. 50.603 Definitions.

As used in this subpart:

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency).

Investigator means the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding. For purposes of the requirements of this subpart relating to financial interests, ``Investigator'' includes the Investigator's spouse and dependent children.

PHS means the Public Health Service, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated.

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 et seq.

Research means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development. As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority.

Significant Financial Interest means 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); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include:

(1) Salary, royalties, or other remuneration from the applicant institution;

(2) Any ownership interests in the institution, if the institution is an applicant under the SBIR Program;

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

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

(5) An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: 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; or

(6) 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.

Small Business Innovation Research (SBIR) Program means the extramural research program for small business that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Pub. L. 97-219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Pub. L. 102-564.

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Sec. 50.604 Institutional responsibility regarding conflicting interests of investigators.

Each Institution must:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with this subpart and inform each Investigator of that policy, the Investigator's reporting responsibilities, and of these regulations. If the Institution carries out the PHS-funded research through subgrantees, contractors, or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with this subpart, either by requiring those Investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with this subpart.

(b) Designate an institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in PHS-funded research.

(c)(1) Require that by the time an application is submitted to PHS each Investigator who is planning to participate in the PHS-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children):

(i) That would reasonably appear to be affected by the research for which PHS funding is sought; and

(ii) In entities whose financial interests would reasonably appear to be affected by the research.

(2) All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with this subpart for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records of all financial disclosures and all actions taken by the Institution with respect to each conflicting interest for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 74.53(b) for different situations.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application for the funding to which this subpart applies, that:

(1) There is an effect at that Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the PHS,

(2) Prior to the Institution's expenditure of any funds under the award, the Institution will report to the PHS Awarding Component the existence of a conflicting interest (but not the nature of the interest

or other details) found by the institution and assure that the interest has been managed, reduced or eliminated in accordance with this subpart; and, for any interest that the Institution identifies as conflicting subsequent to the Institution'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 that identification;

(3) The Institution agrees to make information available, upon request, to the HHS regarding all conflicting interests identified by the Institution and how those interests have been managed, reduced, or eliminated to protect the research from bias; and

(4) The Institution will otherwise comply with this subpart.

Sec. 50.605 Management of conflicting interests.

(a) The designated official(s) must: Review all financial disclosures; and determine whether a conflict of interest exists and, if so, determine what actions should be taken by the institution to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-

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funded research. Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:

(1) Public disclosure of significant financial interests;

(2) Monitoring of research by independent reviewers;

(3) Modification of the research plan;

(4) Disqualification from participation in all or a portion of the research funded by the PHS;

(5) Divestiture of significant financial interests; or

(6) Severance of relationships that create actual or potential conflicts.

(b) In addition to the types of conflicting financial interests described in this paragraph that must be managed, reduced, or eliminated, an Institution may require the management of other conflicting financial interests, as the Institution deems appropriate.

Sec. 50.606 Remedies.

(a) If the failure of an Investigator to comply with the conflict of interest policy of the Institution has biased the design, conduct, or reporting of the PHS-funded research, the Institution must 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 the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the funded project.

(b) The HHS may at any time inquire into the Institutional procedures and actions regarding conflicting financial interests in PHS-funded research, including a requirement for submission of, or review on site, all records pertinent to compliance with this subpart. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records and/or other information that may be available, the PHS Awarding Component may decide that a particular conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that the Institution has not managed, reduced, or eliminated the conflict of interest in accordance with this subpart. The PHS Awarding Component may determine that suspension of funding under 45 CFR 74.62 is necessary until the matter is resolved.

(c) In any case in which the HHS determines that a PHS-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 disclosed or managed as required by this subpart, the Institution must require the Investigator(s) involved to disclose the conflicting interest in each public presentation of the results of the research.

Sec. 50.607 Other HHS regulations that apply.

Several other regulations and policies apply to this subpart. They include, but are not necessarily limited to:

42 CFR part 50, subpart D--Public Health Service grant appeals procedure

45 CFR part 16--Procedures of the Departmental Grant Appeals Board
45 CFR part 74--Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Non-Profit Organizations, and Commercial Organizations; and Certain Grants and Agreements with States, Local Governments and Indian Tribal Governments
45 CFR part 76--Government-wide debarment and suspension (non-procurement)
45 CFR part 79--Program Fraud Civil Remedies
45 CFR part 92--Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments