

Tufts Medical Center Hospital-Wide Policy	Subject: Conflict of Interest in Research	File Under:
Issuing Department: Research Administration		Latest Revision Date: January 2014
Original Procedure Date: November 2010	Page 1 of 9	Approved By: See Approval Signature Page

I. Purpose

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. This includes those individuals defined as “investigator” below.

III. Policy

Investigators subject to the Public Health Service (“PHS”) Conflict of Interest policy must disclose all Significant Financial Interests (as defined below) 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 subject research, each Investigator is required to update any changes in their SFI (“Significant Financial Interest”) 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 subject 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”) as described below.

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.

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

In 42 CFR § 50.603, PHS's codification of its policies, the terms are defined as follows:

Institutional Responsibility: 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: 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. 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: 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: 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 received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000 (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.

Typical Relationships

Appendix 1 is intended to provide guidance to the 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.

Appendix 2 is 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.

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 for review. Once the plan is approved and in place, the department Chair may ensure annual reports are conducted and submitted to the COIC.

Small Business Innovation Research (SBIR)/ Small Business Technology Transfer (STTR)

SBIR/STTR funding mechanisms present additional concerns related to potential conflict of interest. In order to manage these concerns, the following will apply for all SBIR/STTR and similar grants.

- The Principal Investigator for the small business SBIR/ application and the Principal Investigator for the subcontract to Tufts MC must be different individuals.
- The small business entity's scope of work must represent a significant portion (over half) of the research and/or development activities for the entire award.
- The small business must have evidence of functioning space in which research and/or development activities can and will take place.
- Any exceptions to these policy statements must be reviewed and approved by the Conflict of Interest in Research Committee

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 Counsel (“OGC”).

In instances where the disclosed financial interest is minimal (less than \$10,000 per year and less than 5% equity ownership), the source of the financial interest is a not-for-profit organization and/or the significant financial interest is clearly not related to the research activity being performed) the Vice President of Research Administration may 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 a potential Financial Conflict of Interest (“FCOI”), the Vice President of Research Administration will contact the PI and Department Chair in order to review the FCOI 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.

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

Appendix 3 lists possible management plans for situations where a Significant Financial Interest is determined to be a potential Conflict of Interest.

Once a management plan is in place it is reviewed at least annually by the COIC.

Tufts MC's Requirement to Report to PHS

Prior to the expenditure of any funds on a PHS funded project with a reportable FCOI, the institution will report all FCOI to the PHS according to requirements set forth by PHS regulations.

Public Disclosure

Upon written request the following information will be provided for those investigators subject to the PHS policy:

- Name and role on the project of the person with the financial conflict of interest;
- The name of the entity in which the financial interest is held;
- The nature of the financial interest;
- The approximate value of the financial interest (in ranges).

Failure to Disclose a Significant Financial Interest

Failure to disclose the existence of a SFI 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.

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 FCOI 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.

Allowing a conflict of interest to influence one's judgment in the context of research may also constitute, or lead to, scientific misconduct.

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

Date:

January 2014

Tufts Medical Center

Policy Approval Signature Page

Policy Title:

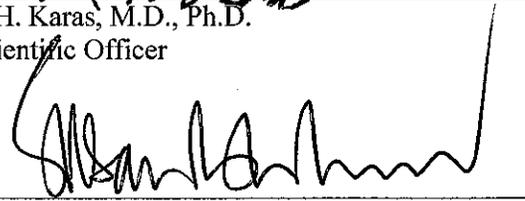
Conflict of Interest in Research

Approval Signature/Title:

Date: 1/15/14



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



Susan Blanchard
Vice President, Research Administration

1/15/14

APPENDIX 1: Financial Interests and Conduct of Research Activities

All financial interests at any level are subject to Tufts MC Policy on Conflict of Interest Research 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	Allowability	Management Plan Required?
1. Consulting	Must disclose compensation \$5,000 or greater in the previous 12 months. All disclosures \$10,000 or greater 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 if activity is deemed to be related to the research activity.
2. Speaking fees	Must disclose compensation \$5,000 or greater in the previous 12 months. All disclosures \$10,000 or greater 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 if activity is deemed to be related to the research activity.
3. Director Fees	Must disclose compensation \$5,000 or greater in the previous 12 months. All disclosures \$10,000 or greater 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 if activity is deemed to be related to the research activity.
4. Free trips enticements or other benefits unrelated to any academic (research or training) activity	Not allowed.	Not allowed.
5A. Equity* in privately held company for studies involving human subjects	Disclosure and committee review required. May not be allowed.	Required if activity is deemed to be related to the research activity.
5B. Equity in privately held company for studies NOT involving human subjects	May be allowed after disclosure, review and approval by Tufts MC Conflict of Interest Committee.	
6. Equity in publicly traded company	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.	Required if greater than \$10,000 in aggregate per year from and single funding source if activity is deemed to be related to the research activity.
7. Royalty interest	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 if activity is deemed to be related to the research activity.
8. Bonus for enrollment / recruitment of	Receipt of such bonuses is not allowed.	n/a

research subject		
9. Finder fees and referral fees	Receipt of such fees is not allowed.	n/a
10. Reimbursement of travel expenses	Reimbursement of reasonable and necessary expenses in conjunction with research, consulting, speaking or directorship activities 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 if in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000.	
11. Negotiation of Clinical Trial Agreements with an anticipated residual balance beyond actual anticipated costs.	Planning a “contingency” for unforeseen events and potential complications is appropriate	
12. Mutual funds in healthcare sector	Not a conflict. All mutual fund ownership is allowed.	

Appendix 2: Reportable Activities

The examples below are for illustration purposes only. This should not be considered to be a comprehensive list.

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.

Appendix 3: Management Plan Examples

The examples below are for illustration purposes only. This should not be considered to be a comprehensive list.

- 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.
- Ensure that all conflicts of interest are disclosed.