



Tufts University Policy on Conflict of Interest: Research

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1. Introduction and Purpose

Tufts University (the “University”) places extremely high value on Research (as defined below) integrity and academic freedom. Objectivity in the conduct of Research is critical to these institutional values. Relationships with industry and other outside entities are important to the support and advancement of Research but can present special challenges with respect to protecting and complying with these institutional values.

In the context of conducting Research, the primary interest of a researcher should be the objective conduct of the Research. Coupled with this, the researcher, the University, and the public share an interest in the complete, objective and timely communication of Research results. While the University expects that all of its faculty and other Research staff should carry out their professional responsibilities with the highest standards of personal integrity, it is necessary to provide measures to reduce, eliminate or manage situations in which a secondary interest could be reasonably expected to influence the design, conduct or reporting of Research. For this reason, the University has adopted this Research Conflicts of Interest Policy (the “Policy”).

The existence of a conflict of interest does not necessarily mean that a conflicted individual has acted, or is expected to act, inappropriately. It is the existence of the competing interests that gives rise to the conflict of interest and the need to reduce, eliminate or manage it.

This Policy shall be made publicly available on the University’s webpage

2. Applicability

This Policy applies to all Investigators (as defined below) at the University who are participating in Research, regardless of the source of Research funding. This Policy applies to Investigators involved in Research for which the University is the funding applicant, recipient, or subrecipient. The Policy also applies to all other Research conducted at, or under the auspices of, the University. Thus, this Policy applies even if the Investigators are not employees or faculty members of the University (*e.g.*, physicians who provide services under an exclusive contracting arrangement).

The requirements of this Policy apply in addition to the requirements in other University policies, including the policy on conflicts of commitment.

3. Responsibility

The University designates the Associate Vice Provost for Research Compliance (“AVPRC”) and the Chair of University Research Conflict of Interest Review Committee (“Research COI Committee”), as the cognizant institutional officials for purposes of the PHS (as defined below) objectivity in research regulations. The Office of the Vice Provost for Research (“OVPR”) shall assist the institutional officials in soliciting and reviewing disclosures of SFIs (as defined below) from each Investigator who is planning to participate in, or is participating in, Research.

Please contact FCOI@tufts.edu if you have any questions or concerns about Financial Conflicts of Interest.

4. Definitions

- a) **FCOI Report** means the University’s report of an FCOI to a PHS Awarding Component.

- b) **Financial Conflict of Interest (“FCOI”)** means an SFI that could directly and significantly affect the design, conduct, or reporting of Research.
- c) **Financial Interest** means anything of value, whether or not the value is readily ascertainable, including but not limited to cash compensation and stock or options in a company, whether publicly traded or privately held.
- d) **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.
- e) **Immediate Family** includes: (i) a spouse or domestic/common law partner of an Investigator, (ii) an Investigator’s child, grandchild, parent, grandparent, sibling, uncle, aunt, nephew, or niece, or the spouse of any such person; (iii) a person having a step-relationship described in (ii) above; (iv) a parent-in-law or a brother- or sister-in-law of an Investigator; or (v) any other relative currently living with an Investigator or whose assets such Investigator controls.
- f) **Institution of Higher Education** means an educational institution in the United States that is a public or other nonprofit institution and meets the other requirements set forth at 20 U.S.C. § 1001(a). It does not include any college, university or institute outside the United States.
- g) **Institutional Responsibilities** means an Investigator’s professional responsibilities on behalf of the University, including all activities that derive or descend from the Investigator’s standing or expertise and are tied to those responsibilities and activities the Investigator was hired to perform and for which the Investigator is paid by the University. Some examples are, Research, Research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- h) **Investigator** means the project director (“PD”) or principal investigator (“PI”) and any other person, regardless of title or position, who is responsible for (as opposed to merely assisting with) the design, conduct, or reporting of Research funded by a sponsor, or proposed for such funding, which may include, for example, collaborators or consultants.
- i) **Management Plan** means a written agreement between the University and an Investigator to manage an FCOI.
- j) **NIH** means the U.S. National Institutes of Health.
- k) **NSF** means the U.S. National Science Foundation.
- l) **PHS** means the Public Health Service of the U.S. Department of Health and Human Services, which includes NIH as one of its constituent parts.
- m) **PHS Awarding Component** means the organizational unit of the PHS that funds Research that is subject to this Policy, including but not limited to NIH.
- n) **Public Health Service Act or PHS Act** means the statute codified at 42 USC § 201 et seq.

- o) **Research** means a systematic investigation, study or experiment 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 (*e.g.*, a published article, book or book chapter) and product development (*e.g.*, a diagnostic test or drug). This term includes, but is not limited to, 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, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award. This term also includes educational activities funded by the NSF.
- p) **Senior/Key Personnel** means the PD/PI and any other person identified as senior/key personnel by the University in the grant application, progress report, or any other report submitted to the federal sponsor by the University under this Policy.
- q) **Significant Financial Interest (“SFI”)** means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s Immediate Family) that reasonably appears to be related to the Investigator’s Institutional Responsibilities:
- With regard to any publicly traded entity, an SFI exists if the value of any remuneration received from the entity (or related entities) 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;
 - With regard to any non-publicly traded entity, an SFI exists if the value of any remuneration received from the entity (or related entities) in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, **or** when the Investigator (or the Investigator’s Immediate Family) holds any equity interest (*e.g.*, stock, stock option, or other ownership interest);
 - Intellectual property rights and interests (*e.g.*, patents, copyrights), upon receipt of income related to such rights and interests;
 - The occurrence of any reimbursed or sponsored travel from a single entity (or related entities) that exceeds \$5,000 in a year, if related to the Investigator’s Institutional Responsibilities. For this purpose, sponsored travel includes circumstances in which an entity (or related entities) pays travel expenses for the benefit of the Investigator (or his or her Immediate Family), in which case, the exact monetary value of the travel expenses may not be readily ascertainable by the Investigator, but the Investigator should use his or her judgment to report travel expenses that reasonably appear to exceed \$5000.

The term “significant financial interest” does NOT include the following types of financial interests:

- Salary, royalties, or other remuneration paid by the University to the Investigator if the Investigator is currently employed or otherwise appointed by the University, including payments of a share in royalties by the University related to the Investigator’s assignment of intellectual property rights assigned to the University and agreements to share in royalties related to such rights;
- 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;¹ or
- Income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of Higher Education, an academic teaching hospital, a medical center, or a Research institute that is affiliated with an Institution of Higher Education.

For purposes of annual and ongoing disclosure to Tufts set forth in Section 5.1, below, if the Investigator is currently employed or otherwise appointed by the University, the Investigator is not required to report salary, royalties, or other remuneration paid by the University to the Investigator, including payments of a share in royalties by the University related to the Investigator's assignment of intellectual property rights assigned to the University and agreements to share in royalties related to such rights. Reporting of such income is not needed because the University is already presumably aware of institutional funds paid to an Investigator. Based on such knowledge of institutionally-derived income, the University may consider payments of shares of royalties or other institutionally-derived remuneration to an Investigator in determining whether a conflict of interest exists and must be managed.

- r) **Small Business Innovation Research (“SBIR”) Program** means the extramural Research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. The term SBIR Program also includes the Small Business Technology Transfer (“STIR”) Program, which was established by Public Law 102-564.

5. Disclosure of SFIs

5.1 Disclosure Generally

The Investigator must disclose (and/or update, as applicable) his or her SFIs, and those of his or her Immediate Family, to the OVPR on the following five (5) occasions:

- Upon joining the University;
- During the annual disclosure process when Investigators receive an email instructing them to engage in this process, which typically occurs between February and April of each year;
- Prior to the time the Investigator submits an application or proposal for Research (and with each submission of a protocol for human subject research to the Institutional Review Board (“IRB”). In order to fulfill the disclosure obligation in this circumstance, Investigators shall note whether they have completed the most recent annual disclosure form. If there are any changes to the disclosure in the annual form or the Investigator did not complete the annual form, they also must submit the Financial Interest Disclosure Form with the proposal;

¹ For the avoidance of doubt, any financial interests received from a foreign government office, unit or agency (local, provincial/state or national), a foreign institution of higher education, a foreign academic teaching hospital, a foreign medical center, or a foreign research institute must be disclosed. This also applies to income from service on a foreign advisory committee as described in the next bullet regarding service on an advisory committee or review panel.

- Prior to the Investigator's expenditure or use of any Research funding;
- Within 30 days of the Investigator's discovering or acquiring a new SFI (e.g., through purchase, marriage, inheritance, etc.).

It is the responsibility of the 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 has submitted an annual disclosure form as required by this Policy.

Reimbursed or sponsored travel from a single entity (or related entities) that does not exceed \$5,000 in a year (including any reimbursed or sponsored travel for an Investigator's Immediate Family members) is not required to be disclosed.

The details of this disclosure of reimbursed or sponsored travel must include, at a minimum:

- Dollar amount or value (which may be estimated for sponsored travel whose value reasonably appears to exceed \$5000)
- Purpose of the trip
- Identity of the sponsor/organizer
- Destination
- Duration of the trip
- The name(s) of the Investigator's Immediate Family Member(s), if such individuals reimbursed or sponsored travel.

5.2 Activities that Must Be Reported Regardless of Whether SFI Exists

The following activities must be disclosed, regardless of whether an SFI exists or any remuneration is received. These activities typically will be subject to oversight as an FCOI.

- An Investigator participates in clinical Research on a technology that was developed by the Investigator or his or her Immediate Family members, but which is owned by or licensed to a business in which the Investigator or an Immediate Family member, has a consulting relationship, a management position, or an SFI.
- An Investigator or his or her Immediate Family member serves on the board of directors or scientific advisory board of a business from which the Investigator receives sponsored Research support or with which the University has a contractual relationship known to the Investigator.

6. Review of Significant Financial Interests

6.1 Generally

The OVPR will review all disclosures, request additional information if necessary, and provide information on disclosed SFIs to the AVPR and the Research COI Committee.

The Research COI Committee or the AVPR, or their designees, shall determine whether each disclosed SFI relates to any Research proposed to be conducted by the Investigator and/or his or her Institutional Responsibilities related to Research. If related, the Research COI Committee will determine whether the related SFI constitutes an FCOI, that is, whether the SFI could directly and significantly affect the design, conduct, or reporting of any Research.

The Research COI Committee or the AVPR, as applicable, will document the basis for, and conclusion of, its decision as to whether an SFI relates to the Research and/or Institutional Responsibilities related to the Research and, if related, whether the SFI constitutes an FCOI. The University shall retain such documentation as required in Section 15 of this Policy.

The review of SFIs shall occur prior to the University's expenditure of any funds (or prior to a funding application submission, if required) and reasonably promptly upon any disclosure by an Investigator as required by this policy.

6.2 Certain Interests Presumed to Constitute FCOIs

The following activities are presumed to constitute FCOIs. Such activities must be disclosed, are not permitted without express authorization of the University, and will typically be prohibited, or permitted only with continuing oversight:

- An Investigator receives sponsored Research support (whether in dollars or in kind) for Research from a business in which he or she or his or her Immediate Family holds an SFI.
- An Investigator participates in clinical Research on a technology owned by or licensed to a business in which the Investigator, or his/her Immediate Family, has an SFI.
- An Investigator makes patient referrals to a diagnostic company in which he or she or his or her Immediate Family has an SFI.
- An Investigator directs the purchase of supplies for the University to a business in which he or she or his or her Immediate Family has an SFI.
- An Investigator conducts Research externally that could be conducted within the University.
- An Investigator assigns a student, fellow or other trainee to a project in which the Investigator or his or her Immediate Family has an SFI.
- An Investigator assumes an executive position in an outside entity engaged in commercial or Research activities related to the Investigator's field.
- An Investigator receives funding or salary from or holds an appointment at a foreign governmental, academic or industry entity.
- An Investigator performs Research relating to University-owned intellectual property on the basis of which the Investigator receives royalty or related income.

When a person employed by the University accepts a position as an officer or a board member of another company or organization, he or she may be taking on a fiduciary duty to act in the best interests of that organization. In situations where that company or organization is doing business with, sponsoring Research at, or licensing intellectual property from the University, a conflict of interest exists. Such a conflict of interest must be disclosed and either managed or eliminated.

7. Implementation of Management Plans

If an FCOI exists, the Research COI Committee, in collaboration with the OVPR, shall prepare a Management Plan to reduce, eliminate, or manage the FCOIs, including any financial conflicts of a subrecipient Investigator. The Management Plan will be reviewed by the Dean of the Investigator's school. The Dean or the Dean's designee for this purpose may approve the plan, require the conflict be eliminated, or decline to allow the Research to take place. No modification of the Management Plan may be made by the Dean without the approval of the Research COI Committee.

A Management Plan may include conditions or restrictions such as:

- Public disclosure of the FCOI (*e.g.*, when presenting or publishing the Research results);
- For Research involving human subjects, disclosure of the FCOI directly to participants in the informed consent document;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the Research against bias resulting from the FCOI;
- Modification of the Research plan;
- Change of personnel or personnel responsibilities or disqualification of personnel from participation in all or a portion of the Research;
- Reduction or elimination of the FI (*e.g.*, sale of an equity interest); or
- Severance of relationships that create the FCOI.

A Management Plan typically will require that an Investigator must:

- Disclose periodically to others working in the laboratory or collaborating on a research project any outside financial interest in a health care, biomedical, scientific, technology or other company that could affect or be affected by the research being conducted and document such disclosure.
- Inform others working in the laboratory, or who are collaborating on a research project, about the nature of any sponsored awards or other research support received from such companies, including its specific scope of work and the time and effort allocations applicable to those persons.
- Disclose his or her financial interests to the thesis committees of any graduate students working in the lab.

When the Dean (or his or her designee), Research COI Committee or the AVPR determines that the FCOI cannot be managed, the conflict must be eliminated or the Research prohibited. Factors to consider when making that determination include such considerations as:

- the involvement of human or animal 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 the University, and
- the level of difficulty involved in managing the conflict relative to the benefit of doing the Research.

An approved plan for management or elimination of the FCOI must be in place before Research begins. Grant applications may be submitted while the University is considering an SFI, provided that the University will not draw down or utilize the funds unless the FCOI can be managed or eliminated.

Nothing in this Policy shall be construed to preclude the University from imposing, in its sole discretion, a Management Plan with respect to an SFI determined not to rise to the level of an FCOI or a financial interest that does not rise to the level of an SFI but is determined to conflict with an Investigator's Institutional Responsibilities.

When the University implements a Management Plan, it will monitor Investigator compliance with the Management Plan on an ongoing basis until the completion of the federally-funded Research project or the elimination of the conflict whichever comes first.

8. Reporting Financial Conflicts of Interest

8.1 PHS-Specific Reporting Requirements

This section applies only to awards funded by PHS Awarding Components, including NIH. It does not require reporting of FCOIs for projects not funded by PHS Awarding Components. However, the University may in its discretion require external reporting of identified FCOIs in other circumstances (*e.g.*, as required by a private foundation funding award).

Prior to drawing down or utilizing any funds under a PHS award, the University must report to the PHS awarding component the existence of an FCOI (including an FCOI of any subrecipient) in an FCOI Report. In these cases, the University will ensure the interest has been managed, reduced, or eliminated in accordance with the regulation.

For Investigators who are new to a project, or for newly identified FCOIs for existing Investigators, an FCOI Report shall be submitted within 60 days of identification of the FCOI.

For any FCOIs previously reported by the University with regard to an ongoing PHS-funded Research project, the University will provide to the PHS Awarding Component an annual FCOI Report that addresses the status of the FCOIs and any changes to the Management Plan for the duration of the PHS-funded Research project. The annual FCOI Report will specify whether the financial conflict is still being managed or explain why the FCOIs no longer exists. The University will provide annual FCOI Reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

8.2 NSF Reporting Requirements

If the Research is sponsored by the NSF, the University's registered NSF contact will keep the NSF's Office of the General Counsel appropriately informed if the University finds that it is unable to manage satisfactorily an FCOI.

8.3 The FCOI Report

Any FCOI Report required by the regulation shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the University's Management Plan. Elements of the FCOI Report shall include, but are not necessarily limited to the following:

- Project/Contract number;
- PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOIs;
- Name of the entity with which the Investigator has an FCOI;
- Nature of the financial interest (*e.g.*, equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest (dollar ranges are: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;

- A description of how the financial interest relates to the PHS-funded Research and the basis for the University’s determination that the financial interest conflicts with such Research; and
- A description of the key elements of the University’s Management Plan, including:
 - Role and principal duties of the conflicted Investigator in the Research project;
 - Conditions of the Management Plan;
 - How the Management Plan is designed to safeguard objectivity in the Research project;
 - Confirmation of the Investigator’s agreement to the Management Plan;
 - How the Management Plan will be monitored to ensure Investigator compliance; and
 - Other information as needed.

9. Untimely Disclosures and Failures to Review SFIs

9.1 Review

When the University identifies an SFI that was not disclosed timely by an Investigator or was not previously reviewed by the University during an ongoing sponsored Research project (*e.g.*, was not timely reviewed or reported by a subrecipient), the Research COI Committee or the AVPR shall:

- review the SFI,
- determine whether it is related to federally-funded Research,
- determine whether an FCOI exists, and, if so:
- Implement, on at least an interim basis, a Management Plan that shall specify the actions that have been, and will be, taken to manage such FCOIs going forward.

The Research COI Committee or the AVPR shall review the new SFI promptly, so that the University can meet its obligation to disclose any subsequently identified FCOIs to a PHS Awarding Component within 60 days.

All PHS-funded Research is subject to the requirements under Section 10, when there has been an unidentified and/or unmanaged FCOI in PHS-funded research.

9.2 Management

Depending on the nature of the FCOI, the Research COI Committee or the AVPR may determine that additional interim measures are necessary with regard to the Investigator’s participation in the Research project between the date that the FCOI or the Investigator’s noncompliance is determined and the completion of the retrospective review. In those cases, in consultation with the cognizant Dean, the AVPR may impose interim management measures.

When the Research COI Committee 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 an FCOI that was not timely managed or reported by the University as required by applicable federal regulations, the University shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations or papers.

10. Retrospective Review of Unidentified or Unmanaged FCOIs in PHS-Funded Research

10.1 Retrospective Review

Whenever (i) an FCOI is not identified or managed in a timely manner; (ii) the University fails to review or manage FCOIs; or (iii) the Investigator fails to comply with an FCOI Management Plan, the University will, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's activities and the sponsored Research project to determine whether any Research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such Research.

The University is required to document the retrospective review and such documentation shall include, but not necessarily be limited to, all of the following key elements:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has an FCOI;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (*e.g.*, methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusions of the review.

10.2 Updates to FCOI Report and Mitigation Report

Based on the results of the retrospective review, the University will update the previously submitted FCOI Report, specifying the actions that will be taken to manage the FCOI going forward.

Further, if bias was found, the University promptly will notify the PHS or other federal awarding component, if any, and submit a mitigation report, including at a minimum the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the University's plan of action or actions taken to eliminate or mitigate the effect of the bias (*e.g.*, impact on the Research; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the Research project is salvageable). If the PHS refers the matter back to the University for further action with directions on how to maintain appropriate objectivity in the PHS-funded Research project, the University will cooperate with such directions.

11. Public Accessibility Requirements

Prior to the University's expenditure of any funds under a PHS-funded Research project, the University will ensure public accessibility, via a written response to any requester within five business days of a request, of information concerning any SFI disclosed to the University that meets the following three criteria:

- The SFI was disclosed and is still held by Senior/Key Personnel;
- The University determines that the SFI is related to the PHS-funded Research; and

- The University determines that the SFI is an FCOI.

The information that the University makes available via a written response to any requester within five business days of a request, will include, at a minimum, the following:

- Investigator's name;
- Investigator's title and role with respect to the Research project;
- Name of the entity in which the SFI is held;
- Nature of the SFI; and the approximate dollar value of the SFI
 - Dollar ranges are: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

The University will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the University's identification of a new FCOIs, which must be requested subsequently by the requestor.

Information concerning the SFIs of an individual subject to this Policy shall remain available for responses to written requests for at least three years from the date that the information was most recently updated.

Written request should be mailed to:

Associate Vice Provost for Research Compliance and Environmental Health & Safety
Tufts University | Office of the Vice Provost for Research
136 Harrison Ave. (75K-950)
Boston, MA 02111

12. PHS Award Subrecipients (subgrantees, subcontractors, collaborators and consortium members)

If the University carries out PHS-funded Research through a sub-recipient (*e.g.*, subcontractors or consortium members), the University as the awardee institution will incorporate as part of a written agreement with the sub-recipient terms that establish whether this policy or the sub-recipient's own FCOI policy will apply to the sub-recipient's Investigators.

If the sub-recipient's Investigators must comply with the sub-recipient's FCOI policy, the sub-recipient shall certify as part of the agreement referenced above that its policy complies with 42 CFR Part 50 Subpart F or 45 CFR Part 94, as applicable. If the sub-recipient's Investigators must comply with the sub-recipient's FCOI policy, the agreement referenced above shall specify time period(s) for the sub-recipient to report all identified FCOIs to the Research COI Committee, with the same level of detail as required in Section 8.3. Such time period(s) shall be sufficient to enable the Research COI Committee to provide timely FCOI Reports, as necessary, to the PHS as required by 42 CFR Part 50 Subpart F or 45 CFR Part 94, as applicable. After it receives a report of any FCOI identified by a sub-recipient, the Research COI Committee may, in its sole discretion, impose any additional conflict management measures that it deems necessary, and such measures will be communicated to the sub-recipient through the Tufts Principal Investigator and the Tufts [Office for Sponsored Programs].

If the sub-recipient cannot, or does not, provide such certification, the agreement shall state that sub-recipient Investigators are subject to the University's policy for disclosing SFIs that are directly related to the sub-recipient's work for the University. The agreement shall specify the manner and time in which the sub-recipient's investigators are to disclose SFIs to the Research COI Committee. Such time period(s) shall be sufficient to enable the Research COI Committee to comply timely with its review, management, and reporting obligations under 42 CFR Part 50 Subpart F or 45 CFR Part 94, as applicable. When the sub-recipient is required by the agreement to comply with the University's policy, the reporting requirement will be carried out by and through the Research COI Committee.

13. Human Subjects Research

13.1 Presumption Against Interested Human Subjects Research:

When Research could involve risk to human subjects, the protection of those subjects must be of paramount concern. The University adheres to a rebuttable presumption that a financially interested Investigator will not be permitted to conduct any related Research that involves interventions with human subjects. Management of an identified FCOI must include development and implementation of a Management Plan that specifies the actions that have been or will be taken to manage such FCOI. For a similar presumption that applies to human subjects research in which the University as an Institution has an interest, see the [*Institutional Conflict of Interest Policy*].

13.2 IRB/IACUC Review:

The University's IRB has responsibility for approving human subjects Research and the University's Institutional Animal Care and Use Committee has responsibility for approving animal subjects Research. Nothing in this Policy shall be construed to affect their authority to determine if Research under their jurisdictions is allowed to proceed under the terms of the Management Plan developed by the Research COI Committee or AVPR.

With respect to human subjects and animal Research, the Research COI Committee or the AVPR will provide to the IRB or IACUC, as applicable, a notice of any SFIs and whether they were determined to constitute FCOIs for Investigators and a copy of any Management Plan imposed.

Because Investigators must submit to the IRB a conflict of interest disclosure for each protocol involving human subject Research, the IRB will facilitate review by the Research COI Committee and the AVPR by forwarding any possible conflict of interest to the OVPR for review and management under this Policy.

The University may prohibit Research that involves an FCOI even if the IRB approves the Research.

Members of the IRB and IACUC must maintain all Investigator financial disclosure information in strict confidence, subject only to disclosure to University counsel and administrators who have reason to know and inquire of such matters, and as otherwise required by law.

14. Training Requirement

Each Investigator is required to complete training regarding FCOIs prior to engaging in Research related to any federally funded grant and at least every two years, and immediately when any of the following circumstances applies:

- The University revises its FCOIs policies or procedures in any manner that affects the requirements of Investigators.
- An Investigator is new to the University.
- The University finds that an Investigator is not in compliance with this FCOIs policy or Management Plan.

A Conflict of Interest course is available to Investigators through the Collaborative Institutional Training Initiative (CITI). [Click here](#) for instructions on how to register and take the course.

15. Record Retention

The OVPR will maintain records relating to all Investigator disclosures of financial interests and Tufts' review of, and response to, such disclosures (whether or not a disclosure resulted in Tufts' determination of an FCOI) and all actions under this policy or retrospective review, including any Management Plans, for the longest of at least six years from:

- The date the final expenditures report is submitted to the PHS or other federal agency;
- When applicable, the starting dates specified in 45 CFR § 75.361 or § 94.4;
- The date of final payment;
- When applicable, for the time periods specified in 48 CFR Part 4, Subpart 4.7; or
- Until resolution of any federal agency action involving those records.

16. Additional Requirements

This section summarizes additional requirements.

16.1 Research COI Committee Membership

The Research COI Committee shall be composed of members as set forth and selected in accordance with the Conflict of Interest Protocol. Committee members are required to recuse themselves from discussion of conflicts when appropriate, particularly in the case of Research in which they are a collaborator.

16.2 Publication

In all its contracts for Research or education support, the University will require all sponsors of Research to permit researchers be free to analyze objectively and publish all results of their work. The University may accept reasonable delays on publication (normally not to exceed 90 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.

16.3 Students/Trainees

The University and the faculty who oversee student research must ensure that the educational interests of graduate students and postdoctoral fellow trainees are not compromised by institutional or individual conflicts of interest. The source of Research funding should not change students' or fellows' education or training experience. The financial interests of a research sponsor or the faculty or mentor should not influence the direction of the Research project. Students must be able to publicly present dissertations and theses and to publish their Research.

The Chair of the applicable department (or the Dean's designee for this purpose) must provide prior approval for a student's involvement in a corporate-sponsored Research project in which his or her advisor has any financial interest. The financial interest must be disclosed to both the Chair and the student prior to the start of the Research project.

- If the Chair approves the involvement of the trainee in that Research and the trainee is a graduate student, the Chair will inform the student's thesis committee.
- If the individual is a fellow or a student who does not have a thesis committee, the Chair will work with the Research COI Committee in developing a Management Plan that will ensure the PI informs, in writing, students and postdoctoral trainees funded from this source about the conflict of interest, and in doing so inform the trainees that should they have concerns, they should contact their Department Chair or the Director of the graduate program in which they are enrolled.

16.4 Special Considerations for Start-up Companies

When a faculty member or a staff or such faculty member or staff's Immediate Family Member has an equity interest in a company that relates to such faculty member or staff's Research, it is especially important to be mindful of conflicts of interest and conflicts of commitment. For example, rigorous care should be taken to keep sight of what is the property of the University versus what belongs to the company and such company is not allowed to use the University resources, the University address or laboratory space. Such faculty member and/or staff must adhere to the requirements under the conflict of commitment policy and all applicable University conflict of interest policies. Such faculty member and/or staff should also be mindful of and disclose conflicts that will inherently arise if such faculty member or staff hires or engages University employees or students to work for a company owned or managed by such faculty member, staff or such faculty member or staff's Immediate Family Member. Faculty members and staff who own equity in a company should not personally negotiate or attempt to influence the licensing terms between the University and that company. To the extent the faculty member's interest must be disclosed under this policy, the OVPR will follow standard procedures under this policy so that the Research COI committee may conduct its review.

16.5 Special Considerations for SBIR/STTR Awards

If a company in which a faculty member has an equity interest is a recipient of a SBIR or STTR award and the University is a sub-recipient of the same award, the interested faculty member shall not serve as the Principal Investigator for the award for both the company and the University, because to do so would make the Investigator the primary person overseeing his or her own work as a sub-recipient. Therefore, the faculty member may only serve as PI either for the University or for the company in which he or she has an interest. Such interests must be disclosed under this policy and a determination made as to a Management Plan, if appropriate.

17. Enforcement

The Research COI Committee and the AVPR, to the extent feasible, will monitor Investigators' compliance with this Policy and applicable Management Plans and will refer any suspected violations to the Dean of the applicable school.

If a Dean finds that an Investigator has violated this Policy or the terms of an applicable Management Plan, the Dean will impose appropriate disciplinary action. Disciplinary action may include actions such as the removal of an individual as PI of a Research study or termination of employment.

Allowing an FCOI to influence one's judgment in the context of Research may also constitute scientific misconduct, which may result in disciplinary action under the University Policy on Misconduct in Research, and can also violate University policies relating to human subjects and animal research, for which the Investigator can be held accountable under the applicable policy.

18. Retaliation

Any act of retaliation or reprisal against an individual for reporting in good faith a potential conflict of interest of another individual or a violation of this Policy by another individual shall be a violation of this Policy. Any use of this Policy to report in bad faith an alleged potential conflict of interest by another individual shall be a violation of this Policy. Such violations will be dealt with through regular administrative processes for violations of University policies.

19. Revision

The University reserves the right to change this Policy from time to time. Proposed changes will normally be developed by those responsible for this Policy with appropriate stakeholders. The approval entities have sole authority to approve changes to this Policy. COI Protocol may be modified, from time to time, by the COI Steering Committee.

Questions

Please contact foi@tufts.edu.

Approval Entity(ies)

Office of the Provost
Office of Executive Vice President
Office of University Counsel
Academic Council
Office of the President

Approval Date

October 6, 2020

Effective Date

October 6, 2020

Executive Sponsor(s)

Nadine Aubry, Provost
Caroline Genco, Vice Provost for Research
Mary R. Jeka, General Counsel

Review Cycle

Every year or as determined by the Conflict of Interest Steering Committee

Related Policies

Policy on Conflict of Interest: Institutional Conflict
Policy on Conflict of Interest: Financial and Personal Conflict

Policy on Conflict of Interest: Review Protocol
Policy on Conflict of Commitment: Faculty
Policy on Conflict of Commitment: Non-Faculty Employees