



Policy on Conflict of Interest Review Protocol

I. Administrative Process

a. Disclosure Survey:

- i.** The annual Conflict of Interest (COI) Questionnaire will be distributed to all relevant parties (as determined by the Conflict of Interest Steering Committee).
- ii.** For the 2020-21 Pilot Year, the Questionnaire will be distributed in accordance with a staggered schedule.
- iii.** Thereafter, the Questionnaire will be distributed out on such date(s) during the fiscal year as determined by the COI Steering Committee.

b. Committees:

- i.** The COI Steering Committee will consist of the following persons: Executive Vice President, Vice Provost for Research and General Counsel.
- ii.** The COI Review Committees will consist of the following (as described in more detail below) and the chair and the members will be appointed by the COI Steering Committee:
 - (a) the Financial COI Review Committee; and
 - (b) the Research COI Review Committee
- iii.** The COI Administrators who will assist the Review Committees will be appointed by the Conflict of Interest Steering Committee.

c. Responsibilities of the COI Administrators:

- i.** The COI Administrators shall be responsible for the COI Questionnaire and process, including, without limitation, any survey production, survey distribution and document retention. Response to constituent inquiries will be managed through the COI Administrators.
- ii.** The COI Administrators will execute the triage of the completed Questionnaire responses as follows:
 - 1.** All conflict disclosures will be shared with the COI Review Committees, unless the COI Review Committees determine otherwise.



2. Disclosures containing potentially high risk conflicts will be flagged by the COI Administrators for the COI Review Committees.
3. “High Risk Conflicts” involve the following:
 - (a) Possible impact or influence on integrity and independence of research, clinical trial, educational programs or patient care;
 - (b) Possible impact or influence on federally or state funded programs or research;
 - (c) Possible impact or influence on projects/purchases in excess of \$250,000 annually or \$1 million in the past 10 years;
 - (d) Possible impact or influence on high profile programs or projects at the University; or
 - (e) Personal interests possibly rising to the level of an institutional conflict of interest.
- iii. Summaries of conflict disclosures will be prepared by the COI Administrators to be presented to the applicable COI Review Committee;
- iv. The COI Administrators are responsible for interfacing with the individual/department/office/school in question if additional context is required or other questions need to be asked to gain a fuller picture of the conflict.

d. Management Letters and Plans:

- i. The COI Administrators are responsible for drafting the COI management plans, which will be reviewed by the applicable COI Review Committee for approval.
- ii. The COI management plans must be signed by the conflicted person/school/department/division and the most applicable supervisory authority.
- iii. Such supervisory authority will be required to report back to the COI Review Committee on an annual basis or as often as requested by the COI Review Committee on the status of compliance with the COI management plan.
- iv. The COI management plans must also be approved and signed by the following persons:
 - (a) by the Provost (if the conflicted party is a dean or if the Provost-level approval is recommended by the COI Review Committee) or



(b) by the Executive Vice President (if the conflicted division/office is in the central office; if the conflicted person is a Vice President or a Chief Investment Officer; if the conflict is an institutional conflict; or if the EVP-level approval is recommended by the COI Review Committee) or

(c) by the President (if the conflicted person is the Provost, the Executive Vice President, a Senior Vice President, the Chief of Staff or the General Counsel); or

(d) by the Audit Risk and Compliance Committee of the Board of Trustees (if the conflicted person is the President).

- v. The COI management plans incorporating the input of the committee shall include the following details:
 1. The nature of the conflict
 2. The prescribed course of action to manage the conflict
 3. Any additional stipulations related to management of the conflict
 4. Relevant signatures
 5. Identifying the person who is responsible for managing the conflict and compliance
- vi. The COI Administrators are responsible for maintaining all documentation related to COIs, including the following: original disclosures, letters to file, conflict management plans, supporting documents obtained via correspondence regarding the conflict.
- e. **Administrative Coordination.** The COI Administrators will be responsible for administrative coordination of committee meetings (scheduling, room reservations, materials, minutes) as well as provision of regulatory guidance to the committee and in-person support.
- f. **Required Disclosures.** The COI Administrator who is representing the Office for Vice Provost for Research is responsible for making sure that the appropriate COI disclosure is made to NIH, NSF and other government entities or grant agencies and is responsible for coordinating the conflict of interest review with the Institutional Review Board and IACUC.
- g. **Updating the COI Questionnaire.** The COI Administrators, with the assistance of the OVPR and the Office of University Counsel, shall be responsible for updating the COI Questionnaire as needed.

II. COI Review Committees

a. Process



- i. The COI Review Committees will be engaged in regularly scheduled meetings in order to evaluate newly disclosed conflicts of interest. Longer or more frequent sessions may be necessary immediately following the annual distribution of the COI Questionnaire.
- ii. The COI Review Committees will evaluate disclosures in order to determine if a significant conflict exists and prescribe appropriate conditions for management of the conflict.

b. Committee Structure

- i. The Financial COI Review Committee will comprise of administration and faculty. The Financial COI Review Committee may, from time to time, have faculty or staff members who are asked to serve on an ad hoc basis due to their involvement with a particular school or division or for their particular expertise. For an Institutional Conflict of Interest, the Financial COI Review Committee will be advised by an outside independent counsel or expert who is selected by the Committee;
- ii. The Research COI Review Committee will comprise of faculty members who engage in research and administration members. The Research COI Review Committee may, from time to time, have faculty members who are asked to serve on an ad hoc basis due to their expertise in a particular field of research.
- iii. The make-up of each committee (other than ad hoc members) will be 5-7 individuals with the goal of having at least a third of the members to consist of faculty members.
- iv. Committee members will be required to disclose and recuse themselves from discussion of conflicts where such members or their family members may have a conflict of interest.
- v. Each COI Review Committee shall determine, by a vote of a majority of such COI Review Committee members, the terms of mitigating a particular COI.
- vi. If a particular COI may be mitigated by a COI management plan, such plan shall be approved by a majority of the COI Review Committee members.

III. Appeals Process

- a. Upon receiving a determination of the the mitigation terms and the COI management plan, involved parties will have the right to appeal the COI Review Committee's decision, which request must be made within sixty days after the issuance of the COI management plan. Appeals will be routed through the applicable Dean of the School, the applicable Vice



Provost or the applicable Vice President to the applicable COI Review Committee at the next possible meeting of such applicable COI Review Committee.

- b. Appeals require a 3/4 majority of the applicable COI Review Committee to be approved or rejected; if a 3/4 consensus cannot be reached in the applicable COI Review Committee, the appeal will be elevated to the COI Steering Committee (as determined by the COI Steering Committee), for the final decision. If a 3/4 majority is reached in the applicable COI Review Committee, the COI Review Committee's decision is final.
- c. The appeals process will be outlined on the Conflict of Interest website and shall be submitted using a standardized form with sections summarizing the conflict, the conflicted individual's proposed changes to the management plan, and the recommendation of the applicable Dean of the School, the applicable Vice Provost or of the applicable Senior Vice President or Vice President.

IV. Post-Review Monitoring

- a. Regular post-review monitoring of executed COI management plans will be conducted by the person or the office identified in the COI management plans.
- b. A standard clause stating that the letter or the plan is eligible for post-review monitoring and briefly outlining the process will be included in the body of all eligible COI management plans.
- c. Three mechanisms exist for post-review monitoring:
 - i. A random sample of COI management plans will be audited periodically for compliance with such plans.
 - ii. COI management plans will be audited for-cause violation in the case of any relevant investigations or concerns reported through the Tufts Anonymous Reporting System (Ethicspoint), to the Office of University Counsel, to the COI Administrators, to the Executive Vice President's Office or to the Provost's Office.
 - iii. All individuals/departments/offices/schools with existing management plans will be asked to certify that they have adhered to the conditions of the letters and the plans as a part of their annual disclosure.

Policy on Conflict of Interest: Financial and Personal Conflict



This Protocol is subject to the provisions set forth in the University's Policy on Conflict of Interest: Financial and Personal Conflict and other related policies.

Revision

The University reserves the right to change this Protocol from time to time. Proposed changes will be adopted by the Conflict of Interest Steering Committee.

Questions

Please contact fcoi@tufts.edu.

Approval Entity(ies)

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

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October 6, 2020

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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: Financial and Personal Conflict
Policy on Conflict of Interest: Institutional Conflict
Policy on Conflict of Interest: Research Conflict
Policy on Conflict of Commitment: Faculty
Policy on Conflict of Commitment: Non-Faculty Employees