



<b>Tufts Medical Center Hospital-Wide Policy</b>	<b>Subject:</b> Conflict of Interest	
<b>Issuing Departments:</b> Corporate Compliance Research Administration		<b>Latest Revision Date:</b> 11/30/2020  <b>Latest Review Date:</b>

**Part A. General Conflict of Interest**

**I. Introduction**

Medicine and science today often require the dynamic interaction between clinicians/scientists and pharmaceutical, bio-technology and medical device industries. This policy is intended to provide a road map for the ethical and legal means of accomplishing those interactions. This policy identifies real and potential conflicts of interest between the clinicians and scientists at Tufts Medical Center (Tufts MC) and pharmaceutical manufacturers, biotechnology companies, medical device and hospital equipment suppliers (such companies referred to herein both collectively and individually as “Industry”) and includes potential and/or perceived conflicts of interest related to engagement with outside entities that are or could be perceived to be related to your institutional responsibilities (“Other Interactions”) jointly referred to as “Interactions”.

This policy is divided into two parts. Part A applies to all physician members of the Tufts MC active medical staff and all investigators and researchers (“Covered Persons”) to the extent the particular issue applies to their situation regardless of whether or not it is related to Research. Part B applies to all investigators and researchers (including physician members of the Tufts MC active medical staff) in the performance of research activities. Part A guides all Covered Persons through non-research related Interactions. Part B guides all Covered Persons through research-related Interactions.

Prior to the Effective Date of this Policy, Tufts MC maintained a separate Conflict of Interest in Research Policy (last revision date, January 2014) and a separate Physician-Industry Conflict of Interest Policy (last revision date, March 2016). This Policy combines both prior policies into a single document.

Most medical advances over the past several decades have resulted from collaborations between Industry, foreign entities and academia. Any policy on conflicts of interest must serve to foster continuation of such favorable relationships, while managing potential conflicts and avoiding unmanageable conflicts. It is essential that medical practice, research and education not be subverted by unmanageable financial conflicts and/or influence, including those driven by commercial, foreign influence and/or other motives. It is equally important that academic medical centers, including Tufts MC, communicate to employees and House

Staff the reasons for and ways of avoiding inappropriate commercial and/or foreign influence and to model appropriate ethical and professional behavior. At the same time, Tufts MC recognizes how essential it is to encourage and facilitate constructive relationships between Industry, foreign entities and health care practitioners, investigators, and educators, for the benefit of its patients and the community at large, provided these relationships comport with legal and ethical standards.

Difference exists between perceived and actual conflicts of interest. The former exists when a relationship between an external entity and a Covered Person is established but the relationship does not undermine the Covered Person's unbiased conduct.

Actual conflict exists when the Covered Person stands to gain from decisions or behavior influencing their primary duties or where they have fiduciary responsibilities to an organization doing business with Tufts MC. Both actual and perceived conflicts of interest must be identified and, if needed, managed or avoided.

To this end, Tufts MC adopts the following policy:

## **II. Scope of Policy**

- a) This policy applies to all physician members of the Tufts MC active medical staff ("Tufts MC Practitioners") and research investigators and research staff including Tufts MC Practitioners who also engage in Research ("Tufts MC Researchers"). Collectively, Tufts MC Practitioners and Tufts MC Researchers will be referred to as "Covered Persons" and individually as "Covered Person" for the purpose of this policy.
- b) For purpose of this policy, "Industry" is defined as all pharmaceutical manufacturers, biotechnology companies, medical device<sup>1</sup> and hospital equipment suppliers and their representatives. "Other Interactions" are defined as any other engagement with an outside entity as may be described in this policy and/or the eRES COI information collection portal that are or could be perceived to be related to your institutional responsibilities. Jointly, for the purposes of this policy, "Industry" and "Other Interactions" will be referred to as "Interactions".
- c) This policy applies to Covered Persons' interactions with employees and agents of Industry and other entities, specifically those individuals whose purpose is to provide information to clinicians about company products, whether or not such personnel are classified in their company in a "sales" or "marketing" capacity.

## **III. Statement of Policy**

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<sup>1</sup> The definition of "medical devices" as used here follows the definition contained in 105 CMR 970.000 implementing M.G.L. c 111N, Pharmaceutical and Medical Device Manufacturer Conduct, as enacted under Chapter 305 of the Acts of 2008, An Act to Promote Cost Containments, Transparency and Efficiency in the Delivery of Quality Health Care

Tufts MC recognizes that appropriate business and commercial relationships can exist between Industry and other entities and Covered Persons, provided that they comport with legal and ethical standards. Such relationships are desirable and result in the advancement of health care knowledge and practice. It is the policy of Tufts MC that medical education, teaching and research activities must be free from influence created by improper financial relationships, with, or gifts provided by, representatives of Industry and other entities. Covered Persons are prohibited from participating in any commercial inducements (gifts, subsidies or hospitality) of any size or nature. This policy provides guidance related to specific situations, set forth in Section V below. For other circumstances, Covered Persons should consult in advance with their Division Chief, Department Chair(s), Tufts MC's Office of the General Counsel or Research Administration to obtain further guidance and clarification. Charitable gifts provided by Industry and/or other entities in connection with fundraising done by or on behalf of Tufts MC are not covered by this policy.

#### **IV. Conflict of Commitment**

Tufts MC recognizes that the contributions and activities of an individual to the Medical Center may extend beyond the work done directly for the Medical Center. Tufts MC also understands and supports the desire of an individual, within the constraints set forth below, to earn and accept outside income and/or accept an unpaid role for activities that do not create a conflict of interest or a conflict of commitment. Tufts MC recognizes that such activities may enhance the individual's overall professional stature, may expand his/her level of medical sophistication, and may serve to advance medical research and education.

A conflict of commitment occurs when the commitment to an individual's external activities adversely affects his or her capacity to meet his/her Tufts MC Commitments. This form of conflict involves a perceptible reduction of the individual's time and energy devoted to Tufts MC Activities. Tufts MC requires that its and its affiliate's employees meet their teaching, administrative and clinical obligations, and remain productively involved in their research and other scholarly pursuits. External activities that compromise or diminish an individual's capacity to meet these obligations represent a conflict of commitment, regardless of the nature of these activities. Conflicts of Commitment are prohibited. In all individual cases, the appropriate Tufts MC Department Chair, Division Chief, and/or Institute Director may determine whether such external activities constitute a prohibited conflict of commitment, and refuse to allow the Covered Person to participate in that activity on that basis. All Conflicts of Commitment determinations may also be subject to further review by the Hospital's Conflict of Interest Committee. For research related conflicts, the determinations may be subject to further review by the Hospital's Conflict of Interest in Research Committee.

No Covered Person may accept salaried employment at another institution, while employed full-time by Tufts MC. Covered Persons may engage in consulting relationships or moonlighting arrangements subject to the approval of their Department Chair or supervisor, and subject to the additional provisions of Section V.4, below. Covered Persons who are employed by Tufts MC on a part-time basis may not engage in consulting or other external activities during the time they have committed to Tufts MC.

#### **V. Specific Activities**

## 1. **Gifts**

Covered Persons may not accept use personal gifts from representatives of Industry and/or other entities regardless of the nature or value of the gift.

The following items are considered gifts and are not permitted.

- a) Free items of any nature or description, including, *e.g.*, pens, notepads, totes, pharmaceuticals sample for personal use, including those provided by Industry at professional conferences and other non-Tufts MC Events (as defined below) and complimentary tickets to sporting or other events.
- b) Payment to attend meetings, lectures and conferences where the Covered Person is not a presenter or participating according to a formal agreement
- c) Payment for participation in on-line CME activities
- d) Hospitality, whether on or off-campus, except as set forth below

Industry choosing to make charitable contributions to Tufts MC may contact the Tufts MC Development Office. All such charitable contributions are subject to applicable policies maintained by Tufts MC.

Industry choosing to make charitable contributions to Tufts MC clinical or research department educational funds or unrestricted educational funds may contact the relevant Tufts MC Department Chair, who will coordinate with the Tufts MC Development Office or Tufts MC Research Administration, as appropriate. All such charitable contributions are subject to applicable policies maintained by Tufts MC.

## 2. **Meals**

Industry funded meals or refreshments provided by sales or marketing representative are prohibited on Tufts MC's campus except those in conjunction with Continuing Medical Education that comply with the standards of the Accreditation Council of Continuing Medical Education ("ACCME") or similar accreditation program with regard to content validation and means. Tufts MC will not hold any Industry-sponsored talks or lunches that do not meet such accreditation criteria. Off campus meals may be provided in accordance with Section V.6(b) below.

## 3. **Industry Supported Scientific and Educational Activities**

- a) Speaking Engagements

Tufts MC allows Industry support of scientific and educational activities that are independent of the influence and bias of the supporting company.

The FDA Guidance for Industry – Supported Scientific and Educational Activities (1997) identifies and defines the several factors, which in their totality, are used to evaluate the activities and determine their independence.<sup>2</sup>

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<sup>2</sup> The factors are:

- 1) Industry control of content and selections of presenters and moderators
- 2) Disclosure of Industry support to audience

It is the policy of Tufts MC that these factors are satisfied with regard to speaking engagements when (1) Covered Persons exercise independent medical judgments as to the content of the presentation<sup>3</sup>, (2) Covered Persons are not prohibited by the Industry sponsor from making editorial comments on the presentation to conform speakers independent medical judgment. Covered Persons may not be compensated for participation in any educational or informational event sponsored by Industry at which Industry exerts influence or control over the tone, or views presented. A Covered Person may only present Industry-prepared presentation materials where the Covered Person retains discretion to select and edit materials from a library proposed by Industry (Industry-Prepared Talk<sup>3</sup>). The Tufts MC COIC may determine a speaking engagement to be inconsistent with this Policy, for reasons including but not limited to any engagement with compensation in excess of fair market value. As of March 1, 2021, Covered Persons' participation in any Industry-Prepared Talk shall be consistent with the Industry-Prepared Talk Procedure as in effect from time to time, attached hereto as Exhibit A.

b) Authorship

Tufts MC prohibits acceptance of service of a ghostwriter provided by Industry. Ghostwriting occurs when (1) a representative or agent of Industry makes a contribution to an article or other published material in a manner consistent with the International Committee of Medical Journal Editors ("ICMJE") criteria for authorship or contributorship; and (2) the contribution, including the author or contributor's relationship to Industry, is not disclosed.

ICMJE criteria require that all authors and contributors must be disclosed. Determination of "authorship" under ICMJE criteria is based on:

- i) Substantial contributions to the conception and design, acquisition of data, or analysis and interpretation of data;
- ii) Drafting the article or revising it critically for important intellectual content; and
- iii) Providing final approval of the version to be published

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- 3) Focus of the program
  - 4) Relationship between the provider and the supporting company
  - 5) Provider involvement in sales and marketing
  - 6) Provider's demonstrated failure to meet standards of independence, balance and scientific rigor in prior presentations
  - 7) Industry support of repeated presentations
  - 8) Industry influence over audience selection
  - 9) Whether there are opportunities for meaningful discussion and the ability to ask questions
  - 10) Dissemination of materials after the program
  - 11) Whether there are any ancillary promotional activities conducted by Industry sales and marketing staff
  - 12) Whether any complaints have been raised by presenters or attendees about Industry influence over the program

<sup>3</sup> Massachusetts Pharmaceutical and Medical Device Manufacturer Code of Conduct, 105 C.M.R. S 970.0001

“Contributors” are those who have provided assistance, such as technical help or writing assistance.

#### **4. Consulting Relationships**

Tufts MC recognizes the value of consulting relationships and the benefit of making the knowledge, training and intellectual achievements of Covered Persons available to government, business, and other organizations for the good of the community at large. Tufts MC also recognizes the potential value of these activities to Tufts MC and Covered Persons. However, consulting arrangements that offer Covered Persons compensation without specific, associated duties (i.e., duties such as participating on scientific advisory boards that meet regularly) are considered “gifts” and are prohibited.

In order to avoid the appearance of impropriety or remuneration or gifts disguised as consulting arrangements, Covered Persons engaged by Industry or other entities to provide consulting services must do so pursuant to a written consulting agreement that identifies specific tasks and deliverable and contain payment provisions that are fair market value and commensurate with the assigned tasks and deliverables. Industry – funded travel pursuant to a consulting agreement is permitted so long as the travel is disclosed and the travel arrangements are not lavish.

Review and advance approval of written consulting agreements by the Tufts MC Office of the General Counsel is required for any consulting agreement where total value paid to the Covered Person exceeds \$2,500 per calendar year.

When the Covered Person receives compensation from a single entity (a “Supplier”) which exceeds \$10,000 per calendar year, or has an ownership interest in a Supplier, the Covered Person is encouraged to verbally disclose such compensation or ownership interest before recommending, prescribing or using any of the Supplier’s medical devices, pharmaceuticals, medical care related products or services with their patients. Research disclosures will be managed according to Part B of this policy.

#### **5. Site Access, Use of Tufts MC Name and Resources, and Complimentary Drug Samples/Devices**

- a) Industry sales representatives are not permitted in any Tufts MC area where patient care might occur except to provide training and guidance on the proper uses of pharmaceuticals, medical devices and equipment, and then, only by prior appointment.

Industry sales representatives are not permitted to interact with Tufts MC house Staff except under the direct supervision of Tufts MC physicians in a structured learning environment. Tufts MC administrative offices may not provide Industry representatives with email addresses or mail distribution lists. Any involvement of students and trainees in meeting with Industry representatives may only occur for educational purposes and only under the supervision of a Tufts MC Physician.

- b) On-campus vendor fairs intended to showcase drugs or medical devices are permitted only with the prior approval of the Office of the General Counsel.

Such events must comply with the “gifts” provision of Section V.1 of this policy. Vendors may not be permitted to distribute free samples, meals, raffle tickets or any other gifts to attendees.

- c) Tufts MC’s name, facilities, and equipment are to be used solely for furtherance of Tufts MC’s mission and not for the benefit of, or to imply Tufts MC’s support of non-Tufts MC activities. The name Tufts Medical Center may not be used without the express approval of the Office of the General Counsel. Except for incidental uses of telecommunications and office equipment (e.g., telephones, computers), employees, including all Covered Person, may not use Tufts MC resources, including facilities, equipment or information, for non-Tufts MC purposes. Specifically, Covered Persons are not permitted to use clinical or research laboratory areas for personal gain. Tufts MC may grant permission to a Covered Person or other employee to use Tufts MC facilities in pursuit of outside activities or interest, but will usually do so only where there is evidence that the work will be significant benefit to Tufts MC. Confidential information acquired through conduct of Tufts MC business or research activities may not be used for personal gain, and unauthorized access to such information may not be granted. Unless specifically authorized by the Covered Person’s Department Chair or supervisor and the Office of the General Counsel, an individual may not use the name of Tufts Medical Center or its letterhead in sponsoring or recommending any commercial service or product.
- d) Any complimentary drug samples or medical devices received by Tufts MC must be received through the Tufts MC Pharmacy or the relevant department in accordance with the Pharmacy or relevant department’s policies and procedures. See “Sample Medications” policy #4007.
- e) On-campus demonstrations of research equipment or medical devices are permitted.

## **6. Continuing Medical Education**

- a) Tufts MC-Sponsored Events
  - i. All continuing education events held at Tufts MC or sponsored by Tufts MC will fully comply with the standards set forth by the Accreditation Council on Continuing Medical Education (“ACCME”), whether or not Continuing Medical Education (“CME”) credit is awarded.
  - ii. Industry support for CME must be made to the appropriate clinical department. The Department Chair will determine the suitability of the Industry support, receive and account for the monetary support and distribute funds for CME – certified activities and programs through a central repository. Full documentation, including a signed commercial support agreement, is required.
- b) Non-Tufts MC-Sponsored (Off-Campus) Events

Industry support of off-campus CME, third-party scientific or educational conferences or professional meetings (together “Non-Tufts MC Events”), in whole or in part, can benefit the health of the public by ensuring that current, evidence-based medical information is provided to healthcare practitioners. In order to ensure that potential for bias is minimized and that Non-Tufts MC Events are not a guise for sales and or marketing activities, all Non-Tufts MC Events in which Covered Persons attend or participate must conform to the following guidelines, as determined by the Covered Person’s Department Chair:

- i. Financial support by Industry must be fully disclosed by the event sponsor to the participants before beginning the activity;
- ii. The program content, including slides and written material, must be the work product of the physician planners and presenters and not the Industry sponsor;
- iii. The program must deliver a balanced assessment of diagnostic and therapeutic options and promote objective scientific discourse;
- iv. All program planners and presenters must fully disclose to the audience all related financial interests;
- v. If Industry provides funding to support a Covered Persons’ attendance at a Non-Tufts MC Event, the attendee(s) must be determined by the relevant Tufts MC Department Chair or Division Chief, and may not be limited to attendees selected by Industry sponsor(s);
- vi. Industry funding for such programs should be used to improve the quality of the education provided and not to support hospitality except for meals and then only at modest levels. Industry funding may not be accepted for social events that do not have an educational component; and
- vii. Industry is not permitted to pay for or reimburse Covered Persons for the direct costs (including attendance fees, travel and lodging expenses) of attending a professional conference or other Industry-sponsored events unless the Covered Person is a presenter, and only when the Covered Person’s presentation materials are not subject to Industry influence or control over the content, tone, or views presented; provided that it is acceptable for Industry to provide review and additional content necessary to ensure compliance with FDA regulations, so long as the Covered Person retains editorial discretion over the remainder of the information presented.

## **7. Affiliations**

When a person employed by Tufts MC 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 Tufts MC, a conflict of interest exists. Such a conflict of interest must be disclosed using the procedures set out herein and either managed or eliminated.

If an individual receives compensation for serving as an officer or a board member of another company or organization, this compensation must be fair market value and memorialized in a written agreement that has been reviewed and approved in advance by the Tufts MC Office of the General Counsel.

## **VI. Conflict of Interest Committee**

This policy will be administered by the Tufts MC Conflict of Interest Committee (the “Tufts MC COIC”). The Chief Medical Officer will act as the Chairman of the Tufts MC COIC (the “COIC Chair”). The Tufts MC COIC shall include the Chairs of the Departments of Medicine, Surgery and Pediatrics (or their designees), the Chief Medical Officer, the Chief Scientific Officer and/or the vice President of Research Administration, a representative from the Office of the General Counsel, the Chief Compliance Officer and at least one at-large physician member. The at-large physician member is appointed by the COIC Chair, to serve for a predetermined term and may include a house officer or others at the request of the Chair. The Tufts MC COIC may meet independently or in conjunction with the conflict of Interest committee of Tufts University School of Medicine, when reviewing a potential conflict of interest that involves a Covered Person who is employed by Tufts MC or one of its affiliates and is also on the faculty of Tufts University School of Medicine. The COIC Chair will bring the attention of the Tufts MC COIC any items requiring the Tufts MC COIC’s review and make actionable recommendations to the Tufts MC COIC.

Meeting of the Tufts MC COIC may be in person or by teleconference. A quorum is comprised of 51% or more of the Tufts MC COIC membership.

## **VII. Disclosure, Management and Enforcement of Conflicts of Interest**

### **1. Disclosure**

#### **a) Annual Disclosure**

All Covered Persons are required to report their relationships with Industry on an annual basis. All submissions are made via the eRES system maintained by Corporate Compliance and Research Administration jointly on behalf of Tufts Medical Center.

#### **b) Updated Disclosures**

All Covered Persons are required to submit updated disclosure forms within 90 days of any change and within 30 days if the Covered Person is also considered Key Personnel on a DHHS-funded project.

#### **c) Research-Related Disclosure**

All Tufts MC Practitioners engaged in research and all members of the

research staff, including trainees, are required to disclose relationships with Industry and other potential or real conflicts of interest on a project-specific basis pursuant to Part B of this policy.

d) CME-Related Disclosure

As to Continuing Medical Education, all Covered Persons who are presenting or planning CME events must disclose all Industry relationships and support and comply with the disclosure and resolution requirements set forth by ACCME prior to the initiation of any Tufts MC sponsored CME programs.

## 2. Review of Disclosures

a) Philosophy of Review

Tufts MC recognizes and supports appropriate Interactions between Industry and other entities with Covered Persons that comport with legal and ethical requirements. Tufts MC also recognizes that potential conflicts of interest range in seriousness and complexity based on the scope of the business and commercial interest involved. Tufts MC will conduct reviews of all disclosures in a manner that takes into account the totality of the facts and circumstances to ensure that all Interactions are free of improper influence and are conducted in a manner that supports the mission of Tufts MC.

b) Initial Review by Department Chair/Division Chief or Office of the General Counsel

Department Chair/Division Chiefs provide initial review of all annual disclosures submitted by Covered Persons, except that the Chief Medical Officer reviews annual disclosures made by Department Chairs/Division Chiefs. In the instance where a Covered Person is also engaged in Research, the Research review will occur first and then be routed for further review as noted above.

In instances where the disclosure form discloses no conflicts and/or only requires a straight-forward and modest plan to reduce, eliminate or manage the potential conflict, the Department Chair /Division Chief or the Chief Medical Officer, as the case may be, may elect to conduct an expedited review in conjunction with the Office of General Counsel. These actions are reported to the entire Tufts MC COIC on a quarterly basis by the Department Chair/Division Chief and Office of the General Counsel so that all expedited reviews are shared with the membership of the Tufts MC COIC.

c) Additional Review by Tufts MC COIC Chair and Office of General Counsel

Where a Division Chief has questions about a disclosure he or she will first confer with the Department Chair. When the question remains open after this consultation, or when the Department Chair/Division Chief/Chief Medical Officer and/or Office of the General Counsel, as the case may be, determine that the disclosed activity poses a potential conflict of interest, the Department Chair/Division Chief/Chief Medical Officer and/or Office of the General

Counsel will prepare an information packet for review by the COIC Chair. The COIC Chair will contact the Covered Person who will have an opportunity to present additional information.

Based on the information provided, the COIC Chair may recommend that i) the conflict be eliminated, ii) the proposed activity be prohibited, or iii) a conflict of interest management plan be implemented.

### 3. Management or Elimination of Conflicts

If the COIC Chair recommends that management or elimination of a conflict is required, such a plan shall be prepared by the COIC Chair in collaboration with the Office of the General Counsel and Compliance. The plan recommended by the COIC Chair and the Office of the General Counsel must be reviewed and approved by the Tufts MC COIC. Subject to the appeal to the Tufts MC CEO as outlined in Section VII.4 below, the decisions of the Tufts MC COIC will be final. The COIC Chair will communicate the decision of the Tufts MC COIC to the Department Chair/Division Chief and to the Tufts MC Practitioner involved.

#### a) Management of Conflicts of Interest

The following are examples of conditions or restrictions that may be recommended by the Tufts MC COIC to manage or eliminate conflict:

- Public disclosure of the conflict of interest;
- Monitoring of proposed activity by independent reviewers;
- Disqualification from participation in all or a portion of the activity related to the conflict;
- Divestiture of financial interests that give rise to the conflict; or
- Severance of relationships that create actual or potential conflicts.

An example of a conflicts of interest management plan could entail the following:

- Disclose the Covered Person's financial relationship with Industry or entity.
- Describe the steps taken to inform current or new House Staff and other trainees of the conflict of interest.
- Demonstrate how publications and meeting presentations are handled to allow the coexistence of Industry and academic goals.

The foregoing list is for demonstration purposes only and is not intended to be complete or limit the measures utilized to manage or eliminate conflicts of interests.

Conflicts of interest management plans are reviewed annually by the COIC Chair.

#### b) Elimination of Conflicts of Interest

Where the Tufts MC COIC determines that a management plan cannot appropriately manage the conflict of interest, it may require that the conflict be eliminated or that the proposed activity not proceed. Factors in this decision may include the nature and significance of the conflict, the potential for having an adverse impact on the scientific field or on the reputation of Tufts MC, and/or the level of difficulty involved in managing the conflict relative to the benefit of the proposed activity.

#### 4. Appeal of Determination Made by Tufts MC COIC

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

#### 5. Enforcement of this Policy

- a) Alleged violations of this policy shall be investigated by the Tufts MC Office of the General Counsel. When indicated, such alleged violations of this policy shall be referred to the individual's Department Chair and to the individual's immediate supervisor who shall, in conjunction with the Office of the General Counsel determine what actions, if any, shall be taken. Such action may depend upon the seriousness of the violation, whether it is a first or repeat offense, and whether the violator knowingly violated the policy.
- b) Industry and other entity representatives who are involved in the violation of this policy or who trespass on Tufts MC property will be escorted from the premises and may be prohibited from further interaction with Covered Persons. Other appropriate sanctions will be taken, as necessary, and their Industry principals may be notified.

## **Part B. Research Conflict of Interest**

### **I. Introduction**

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 (COI) 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 COI concern.**

COI 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. Scope of Policy**

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. Statement of Policy**

Investigators with active Public Health Service (PHS) funding are subject to the PHS COI policy and must disclose all Significant Financial Interests (SFI) (as defined below) held by themselves, their spouse/domestic partner or their dependent child(ren) on an annual basis. This information must be updated within 30 days of any change. Investigators not subject to PHS funding regulations must update their disclosure(s) within 90 days of any change.

All investigators must disclose SFI on an annual basis and for each application and/or new award either certify that there is not a change to their disclosure or update their disclosure in eRES. A protocol-specific disclosure is required for all study team members with each submission to the eIRB.

It is the responsibility of the Principal Investigator (PI) to ensure that each Investigator working under their direction on a research project or receiving support from their grant or contract is aware of this policy and discloses SFI as required by this policy.

In addition to the need to disclose COI 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 Conflict of Interest in Research Committee (COIRC). It is also expected that all researchers will disclose COI related to specific research projects at any time that the results of that research are presented or published.

### **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 IRB or Data and Safety Monitoring Boards (DSMB).

**Investigator:** The PI, 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 funding entity 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/domestic partner and dependent child(ren)) that reasonably appears to be related to the Investigator's Institutional Responsibilities:
  - a) With regard to any publicly traded entity, a SFI 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;
  - b) 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/domestic partners and/or dependent child(ren)) holds any equity interest (e.g., stock, stock option, or other ownership interest) even if values at zero dollars; or
  - c) 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 (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), that exceeds \$10,000 from a single entity and is related to their Institutional Responsibilities. 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 (Tufts MC or Tufts MC PO) 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; 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 United States Federal, state, or local government agency, a United States Institution of higher education as defined at 20 U.S.C. 1001(a), a United States academic teaching hospital, medical center, or research institute that is affiliated with a United States Institution of higher education; or income from service on advisory committees or review panels for a United States Federal, state, or local government agency, a United States Institution of higher education as defined at 20 U.S.C. 1001(a), a United States academic teaching hospital, medical center, or research institute that is affiliated with a United States 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.

#### **IV. Specific Activities**

##### **1. Categories of COI 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 COIs in research. For example, several external interests taken together, any one of which might be permitted, could amount to a COI 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 COIs.

##### **2. Typical Relationships**

Appendix 1 is intended to provide guidance to the Tufts MC research community in structuring relationships with industry, although it is not an exhaustive list of all relationships with industry. Even if a proposed relationship is addressed in Appendix 1 investigators are required to abide by the disclosure and review process for potential conflicts laid out in this policy. If you are unsure about the need to disclose a financial interest, you are advised to disclose it so that it can be reviewed.

### 3. **Activities Not Ordinarily Reportable**

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

- a) An individual receives royalties for published scholarly works and other writings.
- b) An individual receives payments under Tufts MC's [intellectual property policy](#) (although such payments should be disclosed to human subjects, if applicable).
- c) 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.

### 4. **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.

### 5. **Residents/Fellows**

An important part of the training of house staff (e.g., residents and fellows) is mentored research. Tufts MC and 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 COIs. 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 could influence the direction of the research project. House staff must be able to publicly present dissertations and theses and to publish their research.

### 6. **Human Subjects**

With each protocol involving Institutional Review Board (IRB) review, each Investigator must submit to the IRB a protocol-specific COI disclosure via the eIRB system. Forms that indicate a possible COI 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 Research COIs" below. IRB approval will not be granted until the disclosure is reviewed and a response is provided to the IRB. Tufts MC may prohibit research that involves a COI even if the IRB approves the research protocol.

In accordance with federal regulations governing human subject research, a study participant is to be fully informed of research related risks before they consent to

participate in research. Informed consent forms and procedures should include the disclosure of any COI 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\(e\)](#)).

#### 7. **Start-up Companies**

In situations where an Investigator obtains or owns equity in a privately held company that relates to their research, it is especially important to be mindful of COIs 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 their employment agreement and does not compromise their ability to perform their 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 privately held company may not personally negotiate or attempt to influence the licensing terms that Tufts MC offers to that company. All investigators with equity in privately held companies will receive guidance from the Office of Research Administration similar to the letter in Appendix 2.

#### 8. **Small Business Innovation Research (SBIR)/ Small Business Technology Transfer (STTR)**

SBIR/STTR funding mechanisms may present additional concerns related to potential COI. Importantly, the PI for the small business SBIR/STTR and the PI for the subcontract at Tufts MC must be different unrelated individuals.

**All Tufts MC research projects involving an SBIR/STTR collaboration or involving a startup company, in which Tufts MC investigators working on the project hold equity interest in the company must be reviewed by the COIRC before the research project begins.**

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

If PHS funded research 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 COI policy that is in compliance with the PHS regulations or through requiring the sub-recipient key-personnel to comply with the Federal Demonstration Partnership COI Model policy. The written agreement with the sub-recipient must specify the time period for which the sub-recipient key personnel must report SFI.

## V. **Disclosure, Management and Enforcement of Conflicts of Interest in Research**

### 1. **Review and Management of Conflicts of Interest in Research**

Review of disclosed SFI will be the responsibility of the Research Administration.

In instances where the disclosed financial interest is minimal (less than \$10,000 per year and less than 5% equity ownership in a publically traded company), the source of the financial interest is a not-for-profit organization and/or the SFI is clearly not related to the research activity being performed the VP of Research Administration may conduct an expedited review/approval.

Where there are questions or the SFI is a potential Financial Conflict of Interest (FCOI), the VP of Research Administration will review and propose a management plan with any relevant information regarding SFI and active research to the COIRC for review and approval by majority vote. The COIRC may accept the proposed management plan, amend the management plan or decline to allow the proposed research to occur at Tufts MC if the FCOI remains as disclosed. Decisions of the COIRC may be appealed to the President and CEO of Tufts MC, whose decision on these matters will be final. If required by the COIRC an approved plan for management or elimination of the COI must be in place before the research begins and funds are drawn down. Sponsored research agreements with non-federal research sponsors will not be signed until completion of the review by the COIRC unless the agreement can be made contingent on Tufts MC's ability to resolve the COI concerns.

### 2. **Managing Conflicts**

When a SFI is determined to be a potential COI, a management plan must be put in place and reviewed at least annually by the COIRC.

### 3. **Appeal of Determination Made by Tufts MC COIRC**

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

### 4. **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 and management plans to the PHS according to requirements set forth by PHS regulations.

### 5. **Public Disclosure**

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

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

- e) Tufts MC approved management plan.

## 6. **Failure to Disclose a SFI**

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, if needed. For research subject to the PHS policy, within 120 days the Institution will perform a retrospective review of the Investigator's research activities to determine if any additional non-compliance needs to be documented.

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

## 7. **Training**

All investigators at Tufts MC will be required to undergo COI training through eRES at least once every four (4) years. In addition, training must be undertaken if any of the following occurs:

- a) the Institution revises this policy
- b) when an investigator is new to the institution
- c) an Investigator is found to be not in compliance with this policy

## 8. **Record Retention**

The Office of Research Administration will retain records of all research financial disclosures electronically through the eRES system or eIRB systems and all actions taken by Tufts MC with respect to COI in research. Tufts MC is required to keep all records as follows:

- a) **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
- b) **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](#).

## **Part C. Additional Information**

### **I. Related Documents**

- a) Appendix 1 Financial Interest and Conduct of Research Activities
- b) Appendix 2 Guidance for Investigators with Startup Companies
- c) [Tufts Medical Center Intellectual Property Policy](#)
- d) Exhibit A Speaking Engagement Procedures

### **II. References**

- a) 42 CFR 50.603 Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors
- b) 46 CFR 46 Basic HHS Policy for Protection of Human Research Subjects
- c) 45 C.F.R. 74.53 Retention and access requirements for records
- d) 48 CFR part 4, subpart 4.7 Contractor Records Retention

### **III. Effective Date; Distribution and Notification**

This policy shall become effective as of November 30, 2020. All Covered Persons shall be notified of this policy and it will be posted on the Tufts MC website.

## **APPENDIX 1: Financial Interests and Conduct of Research Activities**

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

Activity	Allowability	Management Plan Required?
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.
Speaking Bureaus	Subject to approval per Speaking Engagement Procedure as described in Exhibit A.	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.
Director/Officer	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.
Free trips enticements or other benefits unrelated to any academic (research or training) activity	Not allowed.	N/A
Equity and/or Stock Options* in privately held company	COIRC review required.	May be required if activity is deemed to be related to the research activity.
Equity and/or Stock Options 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	Required if greater than \$10,000 in aggregate per year from and single funding source if activity is

	allowability on a case by case basis.	deemed to be related to the research activity.
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.
Bonus for enrollment / recruitment of research subject	Not allowed.	N/A
Finder fees and referral fees	Not allowed.	N/A
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's Conflict of Interest Policy. 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 \$10,000 All disclosures \$10,000 or greater will	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.
Employment at publicly traded company (excluding Tufts MC)	Must disclose all employment that reasonably relates to your Institutional Responsibilities.	May be required, after reviewed by the COIRC.
Employment at a privately held company (excluding Tufts MC.)	Must disclose all employment that reasonably relates to your Institutional Responsibilities.	May be required, after reviewed by the COIRC.

## **APPENDIX 2- Sample Guidance for Investigators Startup Companies**

RE: Guidance for Investigators with Start-up companies

Dear Investigator,

Thank you for updating your significant financial interest disclosure for (“Company”).

Given your equity in the Company, I am providing the following information to assist with addressing potential future conflict(s) as you conduct activities at both Tufts Medical Center (Tufts MC) and the Company.

### **Data Management:**

- Data and/or know-how generated at Tufts MC is owned by Tufts MC.
- You may only share Tufts MC data and/or know-how with the Company as part of an appropriate agreement between Tufts MC and the Company. Requests to establish such an agreement must be initiated via the Office of Grants & Contracts.
- Terms of any agreement must be negotiated between Tufts MC and a designated negotiator on the Company’s behalf. A designated negotiator is a person other than yourself who can represent the company to Tufts MC.

### **Outside Work Activities:**

- No services that you perform as part of your work for the Company may overlap and/or serve as work you perform at Tufts MC. Any services provided to the company from Tufts MC must be consistent with the terms of the appropriate agreement(s) between Tufts MC and the Company.

### **Use of Facilities and Resources:**

- You and all persons working with you in any Tufts MC facility must take reasonable measures to ensure that no Tufts MC facilities and/or resources are used for the benefit of the Company, except as may be specified under terms of appropriate agreement(s) between Tufts MC and the Company.

### **Intellectual Property:**

- In the event the Company may be interested in either optioning or licensing Tufts MC-owned intellectual property, please note that the Company may not claim or assert rights to Tufts MC assets without a formal agreement between the Company and Tufts MC.

**Ongoing Compliance:**

- You are required to continue to comply with Tufts MC's conflict of interest policies and disclose any changes to your status per the policies. Any change in status may require additional review.

**Exhibit A**  
**Industry-Prepared Talk Procedure**

Effective March 1, 2021, all Industry-Prepared Talks need to be reviewed and approved in advance of the date of the Industry-Prepared Talk.

- Complete the Industry-Prepared Talk Request form found on EVA and submit to your Department Chair / Division Chief / Institute Director / supervisor as appropriate.
- After review, if approved, Department Chair / Division Chief / Institute Director / supervisor will forward to Compliance for additional review.
- Submissions will be reviewed and a response provided to the requestor within ten (10) business days.
- Failure to comply with this procedure may result in disciplinary action, up to and including termination.