

## TUFTS UNIVERSITY SCHOOL OF MEDICINE

### *2020 Revised Policy on Industry Conflicts of Interest*

#### **EXECUTIVE SUMMARY**

Tufts University School of Medicine (TUSM), in an effort to recognize the potential effects of faculty-industry relationships, and to educate its students, hereby adopts the following policy:

- This policy applies to all TUSM faculty and administrators (“TUSM faculty”) and all TUSM students.
- TUSM faculty and students shall not accept or use personal gifts and hospitality from representatives of industry regardless of the nature or value of the gift, except as noted herein.
- TUSM faculty and students shall not accept industry-funded meals except those in conjunction with CME activities that comply with the Accreditation Council on Continuing Medical Education (“ACCME”) standards for commercial support.
- TUSM faculty engaged by industry to provide consulting services must do so for scientific purposes and pursuant to a consulting contract that identifies specific tasks and deliverables and contains payment provisions commensurate to the tasks.
- Industry sales representatives are not permitted to interact with TUSM students except under the direct supervision of TUSM faculty in a structured learning environment.
- All CME events hosted at, or sponsored by, TUSM must comply with the ACCME Standards for Commercial Support of Educational Programs; for all off-campus, non-TUSM continuing education events, TUSM faculty must be aware of industry influence and participate only on the basis of the criteria set forth in this Policy.
- TUSM faculty participation in ghostwriting is prohibited; industry-sponsored speaking engagements is only permitted when the content and materials are developed and/or controlled solely by the faculty member.
- TUSM faculty involved in research must comply with the Conflict of Interest policies set forth by the Tufts University Office of Research Administration or the institution sponsoring the research.
- TUSM faculty and guest lecturers involved in teaching TUSM students must disclose relationships with industry that relate to the content of their course or lecture or clinical teaching.

All TUSM-employed faculty, all course and clerkship directors, all administrative leaders, all faculty serving on TUSM Standing Committees and all key

educational faculty as identified by the administrative leadership of the school are also required to report their relationships with Industry on an annual basis. TUSM faculty with appointments at TUSM affiliates are expected to report their relationships with Industry to their TUSM affiliate.

- All TUSM faculty and staff shall be notified of this policy.
- All TUSM students will receive a minimum of three (3) hours of instruction on Conflicts of Interest.
- The Effective Date of this Revised Policy is November 1, 2020.
- The TUSM Conflicts of Interest Advisory Committee oversees the implementation of this Policy.

## TUFTS UNIVERSITY SCHOOL OF MEDICINE

### *2020 Revised Policy on Industry Conflicts of Interest*

#### **A. Introduction**

This policy addresses the dynamic interaction between medical school faculty and the pharmaceutical and medical device industries. This Policy is intended to identify, clarify and avoid conflicts of interest between industry and Tufts University School of Medicine ("TUSM") faculty, administrators and students. Membership in the TUSM community is a privilege, subject to the policies and responsibilities set forth by Tufts University. TUSM faculty are also subject to any university-wide Conflict of Interest policies.

To this end, TUSM adopts the following Policy:

#### **B. Scope of Policy: Definition**

(a) This 2020 Revised Policy on Industry Conflicts of Interest ("COI") applies to all TUSM faculty and administrators (hereafter referred to collectively as "TUSM faculty") in their activities at TUSM, at TUSM-affiliated institutions and in any capacity where they are identified as TUSM faculty. It also applies to all TUSM administrators, staff and students. Affiliated institutions have made every effort to align their COI policies with this TUSM policy. In case of conflict, the policy of the faculty member's primary employment relationship prevails.

(b) While this policy addresses many aspects of Industry relationships, it supplements and does not supersede any existing Conflict of Interest policies of Tufts University, TUSM or other institutions where TUSM faculty hold appointments. For purposes of this policy, "industry" is defined as all pharmaceutical manufacturers, biotechnology companies, medical device<sup>1</sup> and hospital equipment suppliers and their sales and marketing representatives.

#### **C. Statement of Policy**

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<sup>1</sup> The definition of "medical devices" as used here follows the definition and guidance provided by the Federal Safe Medical Device Act of 1990, as amended (21 CFR 821.1, [www.fda.gov/cdrhlcomplguidance1169.html](http://www.fda.gov/cdrhlcomplguidance1169.html)).

It is the policy of TUSM that education, clinical and research activities must be free from influence created by improper financial relationships with, or gifts provided by, representatives of industry. TUSM faculty and students are prohibited from participating in any commercial inducements (gifts, subsidies or hospitality) of any size or nature. The following specific limitations are set forth for purposes of guidance only. For other circumstances, TUSM faculty should consult in advance with their deans, department chairs or TUSM's Dean and Vice Deans to obtain further guidance and clarification. Charitable gifts provided by industry in connection with fundraising done by or on behalf of TUSM are addressed in other Tufts University policies.

#### **D. Specific Activities**

##### 1. Gifts

TUSM faculty and students shall not accept or use personal gifts from representatives of industry 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 but not limited to pens, notepads, totes, pharmaceutical samples for personal use.
- (b) Payment to attend meetings, lectures and conferences
- (c) Payment for participation in online CME activities.
- (d) Hospitality (e.g., complimentary tickets to sporting or other events) funded by industry, whether on or off-campus, except as set forth below.

Industry choosing to make charitable contributions to TUSM may contact the Development Office or any other charitable foundation legally organized to support TUSM. All such charitable contributions are subject to applicable policies maintained by TUSM.

##### 2. Meals

Industry-funded meals or refreshments provided by sales or marketing representatives are prohibited at TUSM except those in conjunction with Continuing Medical Education that comply with the standards of the Accreditation Council of Continuing Medical Education ("ACCME") with regard to content validation and means. See subsection 6 below. TUSM will not hold any industry-sponsored talks or meals that do not meet ACCME criteria.

##### 3. Industry-Sponsored Speaking/Ghostwriting.

- (a) Industry-Sponsored Speaking and Lectures

Consistent with the *FDA Guidance for Industry-Supported Scientific and Educational Activities, (1997)*, speaking engagements that convey information about a Company's products or conferences that are sponsored by a Company

are usually promotional activities. TUSM prohibits speaking at promotional activities.

A promotional activity, whether or not compensated, is characterized by the following:

- 1) The speaker appears to act as a Company's agent or spokesperson for the purpose of disseminating Company or product information; or
- 2) The Company develops and/or controls the content of the presentation, which may include creating or having final approval over the slides or presentation materials or setting limits on the scope of discussion;
- 3) Requests for exemptions should be directed to the TUSM Office of Conflicts of Interest Administration for review by the COI Advisory Committee.

(b) Ghostwriting

TUSM prohibits faculty serving as a ghostwriter. Ghostwriting occurs when (1) a representative of a Company or its agent 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; (2) the contribution exerts influence or control over the content of the article; (3) the contribution, including its relationship to a Company, is not disclosed; or (4) a faculty member claims credit for any material authored in a manner inconsistent with ICMJE standards.

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

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

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

4. Consulting Relationships

TUSM recognizes the value of consulting relationships and its duty to make available the knowledge, training and intellectual achievements of TUSM faculty to government, business and other organizations. TUSM also recognizes the potential value of these activities to TUSM and TUSM faculty. Nevertheless, consulting arrangements that support marketing efforts or offer TUSM faculty a guaranteed compensation without specific, associated duties (such as

participating on scientific advisory boards that do not meet regularly or do not have specific, assigned tasks) are considered “gifts” and are thus prohibited. In order to avoid an appearance of impropriety or gifts disguised as consulting arrangements, TUSM faculty engaged by industry to provide consulting services must do so pursuant to a consulting contract that identifies specific tasks and deliverables and contains payment provisions that are consistent with the assigned tasks. Industry-funded travel pursuant to a Consulting Contract is permitted.

5. Site Access and Complimentary Drug Samples/Devices

- (a) Industry (including pharmaceutical and medical device) sales representatives are not permitted in any TUSM area except to provide training and guidance on the essential uses of devices and equipment, and only by appointment.

Industry (including pharmaceutical and medical device) sales representatives are not permitted to interact with TUSM students except under the direct supervision of TUSM faculty in a structured learning environment. Educational and administrative offices may not provide industry representatives with email addresses or mail distribution lists. Any involvement of students and trainees in meetings with industry representatives may only occur for educational purposes and only under the supervision of a TUSM faculty member.

- (b) On-campus vendor fairs intended to showcase drugs or medical devices are permitted only with the prior approval of the TUSM Office of the Dean. Such events must comply with the "gifts" provision of Sections 1 of this policy. Vendors may not be permitted to distribute free samples, meals, raffle tickets or other gifts to attendees.
- (c) Complimentary drug samples and medical devices are prohibited at TUSM.
- (d) On-campus demonstrations of research equipment prior to purchase are permitted.
- (e) In the event that purchasing of drugs or devices for patient care on or behalf of TUSM is sought, TUSM must first create a Pharmaceutical and Device Procurement Committee that consists of members with no financial relationship with manufacturers including consulting contracts, grants or any other arrangement resulting in gifts or compensation to members.

6. Continuing Medical Education

- (a) *TUSM-Sponsored Events*

All continuing education events held at TUSM or sponsored by TUSM 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.

*(b) Non-TUSM-Sponsored (Off-Campus) Events*

Industry support of CME, 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 CME programs are not a guise for marketing, all CME events in which TUSM faculty or Students attend or participate should conform to the following guidelines:

- 1) Financial support by industry must be fully disclosed by the Sponsor to the participants before beginning the activity;
- 2) The program content, including slides and written material, must be determined by the faculty planners and presenters and not the industry sponsor;
- 3) The program must deliver a balanced assessment of diagnostic and therapeutic options and promotes objective scientific discourse;
- 4) All planners and presenters must fully disclose to the audience all related financial interests; and
- 5) All CME programs must be available on equal terms to all interested practitioners, and may not be limited to attendees selected by Industry sponsor(s). Industry funding for such programs must be used to improve the quality of the education provided and not to support hospitality except for meals and only at a modest level. Industry funding may not be accepted for social events that do not have an educational component. Industry funding may not be accepted to support the costs of internal (non-CME) department meetings or retreats (either on- or off-campus).
- 6) Payment for attendance at industry-sponsored events is prohibited.

*(c) Courses and Lectures at TUSM*

TUSM faculty and their guest speakers involved in teaching students must disclose relationships with industry that relate to the content of their course or lecture. Course directors must do so as often as necessary to avoid the appearance of influence. This includes a declaration during any slide presentation and in any course syllabus.

The curriculum required for all first-year TUSM medical students contains a minimum of three hours of instruction devoted exclusively to the subject of Conflicts of Interest in Medicine.

*(d) Scholarship and Trainee Grants*

In the event that TUSM receives industry funding for scholarships or trainee funds for the medical education of medical students, it must first establish an Oversight Committee using a rotating physician chair to review and oversee all sponsorship by industry that exceeds \$10,000 in order to assess the possibility of conflicts of interest and to propose management or elimination of the conflicts. Funds may not be earmarked to support particular individuals and industry may not have a role in selecting recipients.

**E. Disclosure and Instruction**

(1) . All TUSM-employed faculty, all course and clerkship directors, all administrative leaders, all faculty serving on TUSM Standing Committees and all key educational faculty as identified by the TUSM administrative leadership are required to report their relationships with Industry to TUSM on an annual basis. TUSM faculty with staff privileges at TUSM affiliates are expected to comply with policies of their TUSM affiliate and report their industry relationships.

(2) As to conflicts of interest related to research, all members of the research staff, including trainees, are required to disclose relationships with industry and other conflicts of interest. All TUSM faculty and students must comply with the Conflict of Interest policies set forth by the Tufts University Office of the Vice Provost for Research and the Tufts University Institutional Review Board.

(3) As to Continuing Education, all TUSM speakers and planners must disclose all industry relationships and support and comply with the disclosure and resolution requirements set forth by ACCME prior to implementing any TUSM-sponsored CME programs.

(4) All TUSM students will receive a minimum of three (3) hours of instruction on Conflicts of Interest.

(5) TUSM faculty primarily based at TUSM affiliates must comply with the COI policies of their affiliated institutions. Faculty engaged in any activities permitted by those institutions that do not comply with the 2020 TUSM Revised Policy on Industry Conflicts of Interest may not identify themselves using their TUSM faculty appointments.

**F. Enforcement**



(e) Alleged violations of this policy shall be investigated by the TUSM Office of the Dean. When indicated, such alleged violations of this policy shall be referred to the individual's dean and department chair or to the individual's immediate supervisor who shall, in conjunction with the TUSM Office of the Dean, 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.

(f) Industry representatives who are found to violate this Policy or trespass on TUSM property will be escorted away from the premises. Other appropriate sanctions will be taken, as necessary, and their industry principals will be notified.

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

This 2020 Revised Policy on Industry Conflicts of Interest shall become effective as of November 1, 2020. All TUSM faculty and students shall be notified of this policy and it will be posted on the TUSM website. All TUSM students will receive classroom education concerning COI and the 2020 TUSM Revised Policy on Industry Conflicts of Interest.

#### **H. *Advisory Committee; COI Management***

Industry relationships disclosed to TUSM are reviewed and managed through the Office of the Dean.

Industry relationships of TUSM faculty at TUSM's institutional affiliates are managed at the affiliates. Although COI data collection, analysis and management resides with the affiliated institutions, those faculty holding educational or administrative leadership roles may be required to disclose to both parties (TUSM and affiliated institution).

The TUSM Advisory Committee on Industry Conflicts of Interest meets at minimum annually to review the TUSM COI policy and procedures, institute necessary updates, and define standards for COI disclosure and management based on evolving LCME, ACCME, state, and federal requirements. The TUSM Advisory Committee on Industry Conflicts of Interest is also available on an *ad hoc* basis to assist the Office of the Dean in analyzing and managing conflicts of interest at TUSM, and to assist the TUSM affiliates in analyzing and managing Conflicts of Interest concerning TUSM faculty at their institutions.