

Conflict of Interest (COI) Policy Regarding Education and Clinical Care For Faculty at the Columbia University College of Dental Medicine

Introduction

As University Officers of Instruction, Research and/or Administration, the faculty of the Columbia University College of Dental Medicine (CDM faculty) have responsibilities for research, education, clinical care services, and administrative and other professional duties. For students and trainees, CDM faculty not only provide training but also serve as models of professional conduct. In carrying out their responsibilities, CDM faculty are expected to uphold high standards of professional integrity.

One aspect of professional integrity that is addressed in a variety of University and Columbia University Medical Center (CUMC)-wide policies is conflicts of interest. CDM faculty must focus their attention on conflicts of interest with respect to our educational, clinical care, and research activities, intellectual property and administrative functions such as purchasing.

The purpose of this new CDM Conflict of Interest (COI) Policy is to reinforce some general principles set forth in University policies and to address in detail two areas particularly relevant to CDM: clinical care and education. These essential CDM activities must not be compromised by conflict of interest or even the appearance of a conflict. Academic-industry collaborations are encouraged by the Bayh-Dole Act of 1980(1). Nationally, relationships between dental school faculty and commercial entities are widespread, especially in relationship to clinical care activities. As a consequence of academic-industry relationships, potential questions may arise regarding the intellectual independence of faculty who are involved with commercial entities. Even perceived conflicts of interest may undermine the credibility of academic and clinical functions. Interactions with industry should be conducted to avoid or minimize conflicts of interest. When real or potential conflicts arise, they must be promptly and appropriately addressed.

To avoid, identify and, if necessary, address potential conflicts of interest, this Policy requires all full- and part-time CDM faculty at the CUMC campus and elsewhere, to adhere to the new policy described herein. This policy also requires that CDM faculty submit an annual Conflict of Interest disclosure statement of significant commercial support (defined below) pertaining to education/training and clinical service, in addition to other University conflicts of interest disclosure requirements, such as those pertaining to research and administration.

This Policy adds to the existing University policies. To the extent there are other University policies or federal or state laws that govern COI issues, faculty must abide by them. CDM faculty adherence to these guidelines for limiting potential or perceived conflicts will help avoid conflicts of interest. Annual disclosure in itself does not constitute avoidance or management of conflicts of interest.

Implementation

The Senior Associate Dean for Academic Affairs and the Associate Dean for Clinical Affairs at CDM will oversee implementation of this policy, in coordination with other University offices involved in conflicts of interest disclosure and management, including the offices of the Executive Vice President for Research and the General Counsel. Consistent with University policy, CDM Section Chairs, Division Directors, and other supervisors are charged with maintaining institutional standards within their areas of responsibility and are required to notify the two individuals listed above of any significant violations of these guidelines on conflicts of interest. Any issues that are not resolved administratively will be referred to a standing CDM COI Committee, chaired by the Senior Associate Dean for Academic Affairs at CDM. This committee will meet semi-annually, but additional meetings may be called if suspected violations of the COI policy are identified. This committee will work jointly with the standing CUMC COI Committee on Research when COI committee inquiries involve research activities. All financial and other personal information related to faculty disclosures will be kept confidential and shared only on a need-to-know basis.

CDM faculty must know and abide by the applicable conflicts of interest policies and, if needed, adhere to plans to manage or monitor conflicts as determined by the appropriate University dean, other officer, director or committee. The Associate Dean for Student and Alumni Affairs provides oversight for conflicts of interest issues involving CDM students. The Associate Dean for Student and Alumni Affairs will be responsible for assuming that students, particularly those in leadership positions in student organizations, understand and adhere to these policies.

CDM COI Policies

I. Support for Educational Activities, Including Meals: Support from commercial entities, including but not restricted to refreshments served at educational programs, must be paid for by an unrestricted educational grant from the vendor. To separate commercial funding from education, this support must be overseen by Section Chairs, Division Directors, or by Section Administrators, rather than by individual CDM faculty or Program Directors. At the end of each fiscal year, CDM Sections must report, by Division, commercial donations received and how these funds were spent. The reports shall be submitted to the CDM business office for review and approval, before being forwarded to the Senior Associate Dean for Academic Affairs.

Commercial entities should not provide direct support for refreshments at educational activities (i.e., lunch and learn sessions) at CDM. To avoid contact with patients receiving clinical services, industry representatives or their agents may not attend educational activities when held in clinical areas where direct patient care is provided at the same time.

For non-CDM educational activities occurring off-campus, such as conferences and professional meetings, CDM faculty are strongly encouraged to follow similar guidelines. Commercial support beyond a modest standard for expenses related to continuing dental education (CDE) activities will require appropriate disclosure. Support beyond legitimate expenses may raise questions regarding a faculty member's objectivity (see VI below).

II. Gifts: Columbia CDM faculty, trainees, staff, and dental students may not personally accept gifts, including cash, of any value from commercial entities. Donations of supplies and equipment can be given to the College. No display of materials bearing a commercial logo is permitted in patient areas. This includes items such as clocks and pens. Commercial support for faculty activities lacking direct professional relevance is considered a gift and, therefore, is not permitted. Faculty may accept gifts from patients if not actually or appearing to affect clinical care, though gifts may not be accepted in lieu of remuneration for billable services. Contributions to Columbia University or to CDM are not covered by this policy, and are subject to University and CDM policies.

III. Consultation: CDM faculty are obligated to comply with Columbia University's policy on conflict of commitment: a maximum of 20% of time may be allowed for outside consulting activity for full-time faculty, provided that the outside activity does not compromise obligations to the University (Faculty Handbook, Appendix J). Consulting activities should have no objectionable influence on teaching, research or patient care activities (Faculty Handbook, Appendix L). Consulting activities include, but are not limited to individual compensation received in connection with an outside activity, including making commercially supported professional presentations, as well as providing expert testimony on behalf of industry.

Annual disclosure of all non-clinical and non-academic consultation is required for all significant financial support, defined as: the total annual net remuneration in the preceding or current calendar year that exceeds \$10,000 from any single commercial entity (per University definition). This threshold of significance includes all payments and loans to a faculty member or his/her immediate family (per University definition). It excludes payments to faculty for service on advisory committees or review panels for public or nonprofit entities. Reporting excludes relevant travel expenses (see below).

IV. Continuing Dental Education: CDE presentations and all associated materials should be educational rather than geared towards marketing or promotional purposes. Therefore, content must be independent of commercial influence for presentation by or for CDM faculty, trainees, staff or dental students. Prior to presentation or publication, CDM faculty must disclose relationships with relevant commercial entities to the CDM CDE Office and to their audiences. Where there is an acknowledged potential conflict of interest, the content to be presented or published must be reviewed by another CDM faculty member or members who is/are free of such a conflict and who will certify that it is free of commercial influence. This person or these persons will be assigned by the Senior Associate Dean for Academic Affairs.

For non-Columbia CDE, CDM Faculty must disclose relevant conflicts of interest to and abide by the management practices of the sponsoring organization. If none are in place, then the policies defined in this document should be followed. Regardless of location or sponsor, CDM faculty are at all times responsible for the content of presentations and materials.

V. Non-CDE Presentations: All presentations must be of one's own materials, not those created or supplied by drug or device companies or their agents. Presentations should be for the purpose of education and not for marketing or promotion. Educational materials created or supplied by companies or their agents must be identified as such.

VI. Travel: Commercial support of CDM faculty travel is limited to payment for legitimate professional speaking and consulting engagements. Commercial support of travel should be reasonable and of a modest standard. Travel must be in accordance with Columbia's Travel and Entertainment Policy. Commercial support of trainees for travel, awards, and fellowships must be administered through their respective Sections.

VII. Speakers' Bureaus: Membership in a Speaker's Bureau is defined as an arrangement that involves approval by a sponsoring commercial entity or its agent to give a presentation concerning the entity's products or services. Due to concerns that marketing imperatives may at times conflict with intellectual independence, CDM faculty are strongly discouraged from membership in a Speaker's Bureau for commercial entities or their agents. Should faculty engage in these activities, the content and format of their presentations, as with all other professional presentations, should be educational and independent of commercial influence and not for marketing purposes. Appropriate disclosure is required, as part of Consultation activities (see above).

VIII. Ghost Writing: CDM faculty, trainees, staff and dental students are prohibited from authoring or co-authoring articles written by employees of commercial entities, where their name or Columbia title is used without substantive contribution. If commercial employees are co-authors, they should be acknowledged as such. Any articles or other materials written in conjunction with commercial entities must include full disclosure of the role of each author, as well as other contributions or participation by such commercial entities. CDM faculty authors who collaborate with commercial entities must retain and maintain editorial independence at all times.

IX. Inventions: Patents, royalty agreements, and licensing must be disclosed as applicable on Columbia's annual COI form and in accordance with University and federal intellectual property policies. For decisions where specific expertise of faculty could be critical, such ties may require oversight rather than removal from the decision-making process. Financial ties to inventions must be appropriately disclosed to trainees and patients.

X. Drug, Equipment, Device, and Supply Vendor Representatives: This policy is in development. There is an *ad hoc* Task Force on Vendor Relations charged with developing more comprehensive CDM policies and procedures about vendor representatives visiting CDM. Vendor relations are important but must be maintained so that there is no conflict of interest in any presentation to CDM faculty, students, and staff. All vendors providing materials, devices, and supplies to be utilized in patient care who wish to present, discuss, and demonstrate such items must complete a vendor request and questionnaire form. This form must be approved and signed by the Associate Dean for Clinical Affairs.

XI. Drug and Device Samples: Samples are solely for patient use, not for personal use by CDM faculty or staff. Sample storage, access, and distribution by faculty practitioners, not trainees,

must be compliant with applicable regulations and Columbia University Health Care (CUHC) policies for safe storage and administration of medications. CDM faculty should avoid actual or apparent conflicts of interest with regard to use and distribution of samples. Drug or device information for patients should be appropriate to their own condition, objective, and deliberately distributed by CDM faculty, e.g., not casually available in waiting rooms or other patient areas.

XII. Voluntary faculty: Voluntary CDM faculty (“Zero Salary Faculty”) must act in the best interests of their professional duties at CDM, including patient care, research, and education. In this capacity, they should avoid any potential or perceived conflicts of interest.

Citations

1. Technology Transfer: Administration of the Bayh Dole Act by Research Universities, U.S. General Accounting Office report to congressional committees. GAO/RCED-98-126, 1998. www.gao.gov/archive/1998/rc98126.pdf

(C:IBL 08-09, misc.)
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