

Conflict of Interest Policy on Education, Clinical Care, and Administration for Faculty and Researchers at Columbia University Irving Medical Center

Introduction

As University Officers of Instruction (“Faculty”) and Officers of Research (“Researchers”), the Faculty and Researchers of the Columbia University Irving Medical Center (CUIMC) have responsibilities for research, education, clinical service, administration, and other professional duties. For students and trainees, CUIMC Faculty and Researchers not only provide training but also serve as models of professional conduct. In carrying out all of their responsibilities, CUIMC Faculty and Researchers are expected to uphold the highest standards of professional integrity.

One aspect of professional integrity that is addressed in a variety of University and CUIMC-wide policies is conflict of interest (COI). CUIMC Faculty and Researchers are bound by these policies, which focus both on conflicts of interest and conflicts of commitment with respect to research, intellectual property and administrative functions.

The purpose of the CUIMC COI Policy is to reinforce some general principles set forth in University policies and to address in detail two areas particularly relevant to CUIMC: clinical care and education. These critical activities must not be compromised by conflict of interest or even the appearance of conflict.

Academic-industry collaborations are encouraged by the Bayh-Dole Act of 1980 (1), and by long-standing policies of Columbia University. Nationally, relationships between health science school faculty and commercial entities are widespread (2, 3), especially in clinical research and educational activities (4). As a consequence of academic-industry relationships, potential questions may arise regarding the intellectual independence of faculty who are involved with commercial enterprises (5, 6). Even perceived conflicts of interest can undermine the credibility of academic and clinical functions. Interactions with industry should be conducted in such a manner as to avoid or minimize conflicts of interest. When real or potential conflicts arise, they must be promptly and appropriately addressed (6).

To avoid, identify and, if necessary, address potential conflicts of interest, this Policy requires all full-time and part-time, both salaried and non-salaried, (whether on-site at CUIMC, at affiliate institutions, or off-site) CUIMC Faculty and Researchers to adhere to the policy described herein. This policy also requires that CUIMC Faculty and Researchers submit an annual Conflict of Interest disclosure statement of commercial support (defined below) pertaining to education/training and clinical service, in addition to other University conflict 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 and Researchers must also abide by them. CUIMC Faculty and Researchers adherence to these policies for limiting potential or perceived conflicts helps to avoid conflicts of interest. Annual disclosure in itself does not constitute avoidance or management of conflicts of interest. Failure to comply with mandatory policies will prompt formal review by the COI Review Committee on Education, Clinical Care,

and Administration with recommendations to the Dean of each school, and may lead to sanctions up to and including non-renewal of appointment.

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.
2. Bekelman JE, Li Y, Cary P, Gross CP. Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A systematic review. JAMA 289:454-465, 2003.
3. Campbell EG, Gruen RL, et al. A National Survey of Physician-Industry Relationships. New Engl J Med 356:1742-50, 2007.
4. Campbell EG, Weissman JS, et al. Institutional Academic Industry Relationships. JAMA 298:1779-86, 2007.
5. Brennan TJ, Rothman DJ, et al. Health Industry Practices That Create Conflicts of Interest: A policy proposal for academic medical centers. JAMA 295:429-33, 2006.
6. Licurse A, Barber E, Joffe S, Gross C. The impact of disclosing financial ties in research and clinical care: a systematic review. Arch Intern Med. 170:675-82, 2010.

Conflict of Interest

Annual disclosure of all financial interests relating to clinical and educational activities is required. In the annual disclosure, faculty and researchers are required to disclose outside financial interests related to any of their professional clinical or educational activities, even if such professional activity is performed outside of Columbia or its affiliates. They should include any interest of a biomedical nature that is dependent on their clinical or educational expertise or responsibilities for the University. Disclosures must be submitted using the University's online Rascal system (www.rascal.columbia.edu). Faculty and Researchers are required to identify commercial entities from which they have derived financial interest in the preceding year or expect to do so in the upcoming year, and the amount of that interest. This disclosure requirement includes all payments and loans to Faculty and Researchers or their immediate family (per University definition). It excludes payments to Faculty and Researchers for service to government or academic entities (per University definition). Reporting excludes relevant travel expenses except as defined by University COI policies on research (see "Travel").

In addition, commercial support should be appropriately disclosed to trainees, students, patients, professional audiences, staff, and colleagues.

Conflict of Commitment

Full-time Faculty and Researchers "may not participate in any outside activities, for or without compensation, that will absorb an undue amount of their time and thereby interfere with the performance of their duties as Officers of the University." Moreover, "Faculty may not engage in outside activities that directly compete with the mission and interests of the University or are in conflict with their University responsibilities, regardless of the time they require." (Faculty Handbook: Obligations and Responsibilities of Officers of Instruction and Research). "...An officer should not accept a regular and continuing position with significant responsibilities for the management of an outside commercial enterprise or without appropriate approvals [from their department chair or the VP&S Office of Academic Affairs] accept any other outside position that would impair the officer's ability to fulfill his or her obligations to the University." (Faculty Handbook Appendix E: Conflict of Commitment.)

A conflict of commitment may exist even when a faculty member observes the time limit for outside activities set by the University (ordinarily not more than one day a week), and even if the activities are limited to the summer months, if the outside activities are in conflict with their University responsibilities. Outside activities may not adversely affect the faculty's independence or compromise the integrity of the University. [Faculty Handbook, Obligations and Responsibilities of Office of Instruction and Research – Outside Interests and Employment.]

Executive Positions, or Other Special Relationships

Full-time Faculty and Researchers may not hold executive positions with outside companies or organizations.

"Executive Position" means any position, whether compensated (through salary, fees, equity, etc.) or uncompensated, that includes responsibility for a material segment of the operation or management of a Business. This term includes any management role, such as a regular salaried,

un-salaried, or otherwise compensated position (e.g., chief executive or another officer position with responsibilities for management, strategy, operations, finances, informatics, or personnel) that involves day-to-day management of a material segment of the Business. This term also pertains to Board of Director or Board of Trustees positions that involve operational responsibilities.

See also the *Conflict of Commitment* policy above.

National and International Research Studies

Service in a leadership position (e.g. as national or international principal investigator), or as other key personnel (or equivalent) in a national or international research study, is considered a University activity and, in general, must be subject to an appropriate research agreement between the sponsor or other relevant party and the University. This requirement must be met regardless of whether Columbia otherwise participates in the research study, e.g., as a clinical site for enrollment. The University's Sponsored Projects Administration (SPA) or the Clinical Trials Office (CTO) may be consulted to set up a research agreement with the University.

For the purpose of this policy, a national study is defined as any multi-site study, whether or not Columbia University is involved as a study site. An international study is any study performed with one or more study sites outside of the USA.

Support for Educational Activities, Including Meals at CUIMC

Support from commercial entities must be for unrestricted educational use. Commercial entities should not provide direct support for refreshments at educational activities at CUIMC. 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 being given concurrently. (Refer to School-Specific Implementation Requirements section on commercial support for education.)

Support for Off-Campus Educational Activities, Including Meals

For educational activities occurring off-campus, such as conferences and professional meetings, Faculty and Researchers are strongly encouraged to follow similar standards of unrestricted educational support. Disclosure of commercial support is required. Support beyond legitimate expenses may raise questions regarding a Faculty or Researcher's objectivity (see Travel below).

Outside Activities with Commercial Support

All external activities with commercial support, including but not limited to consulting, speaking, expert testimony, must be consistent with Columbia University policies on conflict of interest, conflict of commitment, and use of the University name. Columbia University's policy on conflict of commitment states that a maximum of one day a week may be allowed for outside consulting activity for full-time Faculty and Researchers, provided that the outside activity does not compromise obligations to the University (Faculty Handbook, Appendix E). External activities cannot be allowed to influence teaching, research or patient care activities (Faculty Handbook, Appendix E). (See also below under *Use of Confidential Information*.)

Gifts

CUIMC Faculty and Researchers, trainees, and students may not accept gifts of any value, including cash or commodities, from commercial entities whose businesses are in any way relevant to their professional duties. No display of materials bearing commercial logos is permitted in patient areas: clocks, pens, books, articles of clothing, etc. Faculty and Researchers may accept gifts from patients if not actually affecting or appearing to affect clinical care, though gifts may not be accepted in lieu of remuneration for billable services. Contributions to Columbia University or New York-Presbyterian [Hospital] are not covered by this policy, and are subject to University and Hospital policies (including the University Vendor Gift and Invitation Policy).

Use of the University Logo or Name

Faculty and Researchers are prohibited from use of the name or logo of the University (or a clinical affiliate) in sponsoring or recommending any commercial service or product, regardless of whether that officer has any interest in the promotion. Faculty and Researchers may identify their status and title as a University employee, if such identification is not used to imply University sponsorship or endorsement (Faculty Handbook, Appendix E). Commercial support for educational activities may be credited by text but not by use of commercial logos.

Use of Confidential Information

Faculty or Researchers “should not accept employment or engage in any business or outside activity which he or she might expect would require or induce him or her to disclose confidential information acquired by reason of his or her University position.” In addition, Faculty or Researchers, whether in formal or informal settings, “must not disclose confidential information acquired by reason of his or her University position, or use such information for his or her or another’s gain or benefit” (Faculty Handbook, Appendix E). Faculty and Researchers must bear in mind that this prohibition includes disclosure of research results that have not been made public by publication or presentation.

When Faculty or Researchers engage in external activities (e.g. consultation, speaking, any paid or unpaid positions external to the University or its clinical affiliates), they are responsible for avoiding the communication, whether deliberate or inadvertent, of any confidential data (i.e. not published or otherwise publicly available). Particular care must be taken when interacting with external entities such as “hedge funds” or other businesses, for profit or not-for-profit, which could benefit from unpublished data.

Continuing Medical Education (CME), Continuing Nursing Education (CNE), and Continuing Dental Education (CDE)

CME/CNE/CDE presentations, and all associated materials in print or any other media, should be educational rather than geared towards marketing or promotional purposes. Therefore, content must be independent of commercial influence for presentation by or for Faculty and Researchers, trainees or students, except as prescribed by law (e.g. FDA requirements). Materials created or supplied by drug or device companies or their agents must be identified as such.

For Columbia-sponsored CME/CNE/CDE, prior to presentation or publication, Faculty and Researchers must disclose relationships with relevant commercial entities to the CME/CNE/CDE Office and to their audiences. In accordance with current policy, where there is an acknowledged potential conflict of interest, the content to be presented or published must be reviewed according to the policies set forth by the individual schools.

For non-Columbia CME/CNE/CDE, Faculty and Researchers must disclose relevant conflicts of interest to and abide by the management practices of those accrediting entities, and disclose relationships with relevant commercial entities to their audiences. Regardless of location or sponsor, Faculty and Researchers are responsible for the content of presentations and materials at all times.

Presentations, Publications, Materials and Communications

Faculty and Researchers are responsible for maintaining control of the content of the information they present in all publications, materials, and communications (enduring or electronic, including websites). All materials and presentations, both formal and informal (e.g. roundtable discussions), must be educational and not for marketing or promotion, whether or not Columbia University is directly involved (e.g. as site or sponsor). Faculty and Researchers must maintain full and final control over and responsibility for the content and format of the information they present. Presentations, publications, materials and communications should be independent of commercial influence. Disclosure of relevant commercial relationships with the sponsor to the intended audience is required.

Faculty and researchers may not include off-label information in presentations of FDA-regulated drugs and devices when sponsored by the relevant commercial entity (or its agent).

Participation in engagements where a Columbia University Faculty or Researcher gives a presentation that is designed or provided by a sponsoring commercial entity or its agent concerning the company's products or services (at times referred to as membership in a "Speakers' Bureau") is prohibited (with the exception of specific training agreements individually approved by the University, as described below). In particular, Faculty and Researchers are prohibited from speaking for industry if the arrangement has one or more of the following characteristics:

- a) A commercial entity (or its agent) dictates or controls content, or has binding approval of a presentation;
- b) Faculty and Researchers are expected to act as an agent or spokesperson for a commercial entity (or its agent) for the purpose of marketing;
- c) The sponsor (or its agent) creates the presentation and expects the use of their language for the presentation.

Faculty and Researchers are expected to convey that their presentations reflect their own work and views, and do not represent views held by Columbia University or its affiliates. Use of the Columbia name, logo, or images in presentations or associated materials is prohibited and cannot be used for co-branding (Faculty Handbook, 2008). Faculty and Researchers may identify themselves by their University title.

Endorsements

Faculty and Researchers may not participate in commercial communications that appear to be marketing or promotional activities for specific products related to their professional activities or duties. This prohibition pertains to endorsements made in person, or through electronic or print media. Faculty and Researchers must maintain final control over and responsibility for all communications and materials, and must adhere to policies on use of University or commercial logos (described above).

Self-Dealing

Full-time or part-time Faculty may not make clinical referrals to health care businesses in which the individual or a family member has a financial interest.

Training Agreements

Training by CUIMC Faculty and Researchers directed to those outside of CUIMC for the specific application of new procedures, devices or technologies that is compensated by commercial entities or their agents, requires prior formal written agreement with the University. Standards of training agreements should be educational and not promotional in nature. Faculty should be responsible for ensuring that the training they conduct upholds these standards.

Travel

Commercial support of travel (e.g. transportation, meals and lodging) of Faculty or Researchers must be limited to payment for legitimate professional speaking and consulting engagements. Commercial support of travel should be reasonable and of a modest standard (i.e. not lavish). 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 departments.

Ghost Authorship and Ghost Writing

Contributions to medical literature made by or through commercial entities should be transparent with respect to authorship and the contribution of authors. Faculty and Researchers, trainees, and students are prohibited from authoring or co-authoring articles written by employees of commercial entities, or their agents, where their name or Columbia title is used without their 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. CUIMC Faculty and Researchers authors who collaborate with commercial entities must maintain editorial independence at all times.

Faculty and Researchers who are or become aware that a published paper on which they are authors contains contributions from an un-credited source who is employed by or through a commercial entity, should notify, in writing, the relevant journal editors to correct misstatements or omissions regarding those responsible for writing, co-authoring, or otherwise responsible for the paper. Comparable corrections and notifications, as appropriate, should be made in the Faculty or Researcher's CV, dossier for promotion and other academic documentation.

Inventions

Patents, royalty agreements and licensing must be disclosed as applicable on Columbia's annual COI forms and in accordance with University and federal intellectual property policies. For decisions where specific expertise of Faculty or Researchers could be critical (e.g. purchasing), such ties may require oversight rather than removal from the decision-making process. Financial ties to inventions need to be appropriately disclosed to trainees and patients.

Vendors of Goods and Services Related to Clinical Care

Drug and device representatives and other vendors of medical products coming to CUIMC shall have access to health care providers and staff only by appointment. Representatives must register with their Faculty or Researcher host in advance and wear badges identifying themselves as commercial agents (not just "visitors"). To avoid direct contact with patients, their family members, or other accompanying individuals, drug representatives are not allowed in areas where direct patient care is being given. Commercial representatives (or their agents) who are needed for device training, implementation or certification should be clearly identified to staff and to any patients involved in that training, and must comply with HIPAA regulations and NewYork-Presbyterian [Hospital] policies. Activities involving patients require prior informed consent for involvement of commercial personnel (or their agents). Health care providers and staff should ensure that drug and device representatives should have only minimum necessary access to patient health information.

Drug and Device Samples and Information

Samples are solely for patient use, not for personal use by Faculty and Researchers or staff. Sample storage, access, and distribution by Faculty and Researcher practitioners must be compliant with applicable regulations and departmental policies for safe storage and administration of medications. Faculty and Researchers 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 patients' condition, objective, and deliberately distributed by Faculty and Researchers (e.g. not casually accessible in waiting rooms or other patient areas). Use of sample medications in patient care should be documented in the medical record.

Family Relationships

Faculty and researchers are prohibited from being in a supervisory, subordinate or evaluation role with a family member at CUIMC or its affiliates. This policy applies to family relationships between faculty and researchers with any other faculty, researcher, staff, student, resident or other trainee at Columbia or its affiliates. If a family member is under consideration for selection (e.g. school admission or a post-doctoral training position) or is hired for a position where a family relationship may exist, that fact should be disclosed to the appropriate supervisor so that a management plan can be defined and implemented.

For the purpose of this policy:

- Family is defined as an individual who is related to a faculty member, including in-laws and descendants. This includes but is not limited to: spouse or domestic partner, siblings, children and grandchildren or those of your spouse or domestic partner, parent and grandparent, niece/nephew, aunt/uncle, cousin, in-law relationships or any other Family member.
- Columbia affiliates include the following current entities and any future entity defined by similar institutional relationships: (in alphabetical order) Bassett Hospital, Bronx VA Medical Center, Harlem Hospital Center, Helen Hayes Hospital, Hudson Valley Hospital, Lawrence Hospital (Bronxville), Mount Sinai Medical Center (Miami, FL), New York Presbyterian (NYP), New York State Psychiatric Institute (NYSPI), Research Foundation for Mental Health (RFMH), and Stamford Hospital.

School-Specific Implementation Requirements

Vagelos College of Physicians and Surgeons

All University Officers of Instruction (“Faculty”) and Officers of Research (“Researchers”), full time and part time both paid and unpaid, are required to file an annual disclosure. The annual disclosure must be submitted by December 15th each year.

The Vice Dean for Academic Affairs at CUIMC oversees the implementation of this policy, in coordination with other University offices involved in conflict of interest disclosure and management, including the offices of the Executive Vice President for Research and the General Counsel. Consistent with University policy, Department Chairs and other supervisors are charged with maintaining institutional standards within their areas of responsibility and are required to notify the Vice Dean of any significant violations of these guidelines on conflicts of interest. Any issues that are not resolved administratively are referred to the VP&S COI Committee on Education and Clinical Care, to be administered by the Vice Dean for Academic Affairs at CUIMC. This committee works jointly with the standing CUIMC COI Committee on Research when COI committee inquiries involve research activities. These committees comprise senior members of the CUIMC Faculty and Researchers, with *ex officio* representation from the offices of the Dean of the Faculty of Medicine and the University’s Office of the General Counsel. Information regarding industry relationships may be made publicly available.

VP&S Faculty and Researchers are required to know and abide by the applicable conflict 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 Senior Associate Dean for Student Affairs provides oversight for conflicts of interest issues involving VP&S students.

Regarding commercial support for education: For VP&S, to separate commercial funding from education, this support must be overseen by Department chairs or heads of Centers or Institutes - rather than by divisions or individual VP&S Faculty or Researchers.

School of Nursing

The COI review committee will oversee implementation of this policy, in coordination with

CUSON deans for research and clinical practice and 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, faculty are charged with maintaining institutional standards within their areas of responsibility and are required to notify the COI Review Committee of any significant violations of these guidelines on conflicts of interest. Any issues that are not resolved administratively will be referred to a CUSON COI Committee on Education and Clinical Care, to be administered by the Dean of the School of Nursing and comprised of senior members of the CUSON faculty, with *ex officio* representation from the offices of the Dean and the University's Office of the General Counsel. Information regarding industry relationships may be made publicly available.

CUSON Faculty are required to 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 Dean of CUSON. The Associate Dean for Academic Affairs provides oversight for conflicts of interest issues involving CUSON students.

CUSON Faculty or Researchers jointly holding appointments at NYP or other clinical sites are also responsible for following COI policies required at those sites, including filing regular disclosures of those institutions.

Part-time, non-salaried Faculty (also known in CUSON as "Voluntary") must act in the best interests of their professional duties at CUSON including patient care, research and education. In this capacity, they should avoid any potential or perceived conflicts of interest.

Regarding commercial support for education: For CUSON, to separate commercial funding from education, the acceptance of such funds is reported to the COI Review Committee for inclusion in the annual report.

College of Dental Medicine

All University Officers of Instruction ("Faculty") and Officers of Research ("Researchers"), full-time and part-time (salaried and non-salaried), on site at CDM and off-site, paid and unpaid, are required to file an annual disclosure. The annual disclosure must be submitted by December 15th each year.

The Vice Dean for Finance and Administration at the CDM oversees the 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, Section Chairs and other supervisors are charged with maintaining institutional standards within their areas of responsibility and are required to notify the Vice Dean of any significant violations of these guidelines on conflicts of interest. Any issues that are not resolved administratively are referred to the CDM COI Committee on Education and Clinical Care, to be administered by the Dean and the Vice Dean for Finance and Administration. This committee works jointly with the CUIMC COI Committee on Research when the COI committee inquiries involve research activities. These committees are comprised of senior members of the CUIMC faculty, with *ex officio* representation from the

offices of the Dean of the Faculty of Medicine and the University's Office of the General Counsel. Information regarding industry relationships may be made publicly available.

CDM Faculty and Researchers are required to 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, or director of committee. The Vice Dean for Finance and Administration and the Senior Associate Dean of Clinical Services will determine the permissibility of vendor relationships for vendors providing goods and services to CDM, and are the officers who must authorize any mitigation plan that is required to manage a potential or perceived conflict of interest. The Associate Dean for Students and Admissions provides oversight for conflicts of interest issues involving CDM students.

Regarding commercial support for education: For CDM, to separate commercial funding from education, this support must be overseen by Section Chairs or heads of Centers, rather than by divisions or individual CDM Faculty or Researchers.

Mailman School of Public Health

The Vice Dean for Faculty Affairs at MSPH 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, Department Chairs, Center Directors and other supervisors are charged with maintaining institutional standards within their areas of responsibility and are required to notify the Vice Dean for Faculty Affairs of any significant violations of these guidelines on conflicts of interest. Any issues that are not resolved administratively will be referred to the MSPH Vice Dean for Faculty Affairs, who will work jointly with the standing CUIMC COI Committee on Research when COI inquiries involve research activities. The Vice Dean for Faculty Affairs may also consult with the University's Office of the General Counsel as needed. Information regarding industry relationships may be made publicly available.

MSPH Faculty are required to 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 Office of Education provides oversight for conflicts of interest issues involving MSPH students.

Part-time, non-salaried Faculty (also known in MSPH as "Voluntary") must act in the best interests of their professional duties at MSPH, including service, research and education. In this capacity, they should avoid any potential or perceived conflicts of interest.

Regarding commercial support for education: For MSPH, to separate commercial funding from education, this support must be overseen by Department Chairs or Center Directors rather than by individual MSPH Faculty or Researchers.