

Creighton University School of Medicine Policies

POLICY: Conflict of Interest with Industry

GOVERNING BODY: Executive Committee

APPROVAL DATE: July 9, 2010

REVISED DATE: September 13, 2019

LCME ACCREDITATION STANDARD REFERENCE: Element 1.2 Conflict of Interest Policies

PURPOSE

To provide guidance to School of Medicine faculty, staff, house staff and students engaged with health care industry representatives selling products and services and/or participating in other opportunities for outside professional compensated activities. CUSOM must continue to make it possible for faculty and staff to advance teaching, service and research through collaborations with industry in a manner that avoids real or perceived conflicts of interest or commitment. This policy is designed to move CUSOM towards a model policy on conflicts of interest and commitment.

In addition, all individuals to whom this policy applies, must comply with all other related policies that may be applicable at other institutions (for example, clinical affiliates) with which they are affiliated.

SCOPE

This policy applies to all Creighton University School of Medicine personnel, including faculty, staff and trainees. It does not include research and related activities, which are included in the Office of Research and Compliance Services Policies: The Conflict of Interest Policy and the Financial Conflict of Interest Policy:

www.creighton.edu/researchcompliance/conflictinterest/about/index.php

DEFINITIONS

"Products and services" include medical devices, equipment, supplies, products and pharmaceuticals and health care services

"Industry" is defined as any person or company that produces health care goods and/or services, including any pharmaceutical, medical device, medical publishing, or medical equipment company. It also includes any person or company seeking to do or doing business with CUSOM faculty, staff or trainees.

"Conflict of Interest" (COI) involves a situation in which faculty, staff, house staff or student have financial or other personal considerations that may compromise, or have the appearance of compromising, their professional judgment or integrity in teaching, clinical care, conducting or reporting research, or performing other CUSOM obligations.

"Conflict of Commitment" (COC) occurs when a trainee, faculty or staff member engages in an outside activity that interferes, or appears to interfere, with fulfillment of that individual's obligations to CUSOM, even if the outside activity is valuable to CUSOM or contributes to the trainee, faculty or staff member's professional development and competence.

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POLICY

This policy complements existing Creighton University policies related to COI and COC. It provides additional specifications for CUSOM faculty, staff and trainees on issues related to unique complexities within our medical care, education and research endeavors.

To ensure the integrity of CUSOM's core missions, its interactions with industry must prevent conflicts of interest as well as avoid the appearance of such conflicts. High quality clinical care will be maintained in an environment where faculty, staff and trainees are free from the influence of Vendors when choosing Medical Products. This policy is established to achieve such an environment.

COC is another important component of this policy and is often closely linked to COI. The primary responsibility of faculty, staff, and trainees at CUSOM is to participate in core missions of CUSOM; extramural activities that create COCs must be disclosed to and approved by the Department Chair with the concurrence of the Dean.

The following individuals must complete the External Relationships Disclosure Form (available on the Office of Academic and Faculty Affairs website), and submit it to the Office of Academic and Faculty Affairs at least annually at the time of annual evaluation:

- Faculty members in the categories described under Purpose and Scope above
- Professional and Scientific Staff

If there are no changes from the prior year, an attestation statement to that effect may be submitted instead. However, the form must be updated on an annual basis, to reflect any new relationships or changes to existing external relationships. Response to all written requests for information regarding COI or COC shall be provided within five business days of receipt of the request.

PROCEDURE:

1. Vendor Access should follow affiliate policy but in general should comply with the following guidelines:

- a) Vendors should not be permitted in any patient areas except to provide in-service training on devices or equipment and only by appointment.
- b) Vendors are permitted in non-patient areas by appointment only.
- c) Appointments may be made at the discretion of the faculty member or Department Chair.

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- d) Proof of appointment must be documented (e.g., calendars, books, or electronic appt record).
- e) Meetings with Vendors where trainees are present should include a balanced presentation regarding generally available scientific data regarding each product. The Faculty Sponsor responsible for the meeting shall be present with the trainees for any presentation and ensure a balanced presentation occurs. Meetings shall be in locations conducive to informational exchange.
- f) Vendors are required to pick up their own advertising materials after their appointments. If advertising materials or information brochures are to be left with a department or clinic, the Faculty Sponsor must approve the use and placement of such brochures for educational purposes only.

2. Site Access and Industry Displays

- a) Industry displays must meet the following requirements:
- b) Compliance with the CUSOM Vendor Policy (e.g., not displayed in patient areas)
- c) Permission from the Department Chair
- d) Compliance with the Accreditation Council for Continuing Medical Education (ACCME) standards if the event is a CME program

4. Continuing Medical Education

- a) All CME activities sponsored by the Continuing Education Center for Professional and Corporate Excellence (Creighton University) must be following ACCME regulations, requirements, standards, and guidelines.
- b) Educational grants for CME events must be accompanied by a Written Agreement of Commercial Support signed prior to the event by a representative of Creighton University and a representative of the Company providing the Grant.
- c) CUSOM faculty, staff, and trainees are expected to comply with the CME regulations (e.g. honoraria limits) at other institutions where they may be invited to make presentations.
- d) Any Vendor support of University-sponsored CME activities must be consistent with the standards of the Continuing Medical Education Division and the Accreditation Council for Continuing Medical Education (ACCME). The ACCME Standards may be found at www.accme.org.

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5. Vendor Donations

Unrestricted educational donations from Vendors may be given directly to the Department or Division for non-CME activities. The funds must be deposited in a University-designated educational account.

- a) Vendor funding for educational training programs, such as fellowships, must be pursuant to a written agreement with and approved by the University. (Proposals and agreements for educational grants must be routed through Grants Administration.) The choice of recipient shall be determined solely by the University and shall not in any way be related to actual or potential future business generated between the University or recipient and the Vendor.

6. Honoraria

- a) Honoraria may not be accepted for any on-campus educational activities.
- b) In accordance with the Federal Anti-kickback Statute, personnel may not accept funds directly from Vendors in a passive capacity. The Anti-kickback Statute prohibits acceptance of unearned income and other remuneration from Vendors when the intent may be to influence purchases of or prescribing the Vendor's products. In addition, any compensation arrangement between personnel and a Vendor must be structured to meet the personal services and management contracts safe harbor under the Anti-kickback Statute as closely as possible, which requires:
 - i. Any compensation arrangement with a Vendor must be pursuant to a written agreement that covers all the services to be provided and has a term of not less than one year. If services are to be provided on a periodic, sporadic or part-time basis, the agreement shall specify the schedule of such intervals, their length and the charge for the intervals;
 - ii. The aggregate compensation paid over the term of the agreement must be set in advance, consistent with fair market value in arms-length transactions and not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs;
 - iii. The services performed under the agreement must not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law; and
 - iv. The aggregate contracted services must not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

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7. Industry Compensation

- a) Consultative relationships between faculty, staff, and trainees and industry may provide valuable avenues to speed development and dissemination of innovations.
- b) Faculty may accept compensation from Vendors for reasonable and legitimate services rendered (e.g., consultant arrangements, speaker programs) if consistent with the faculty member's Faculty Employment Agreement with the University. [Staff may not receive compensation from Vendors for services outside the scope of the staff member's employment with the University without approval from the staff member's Department and Human Resources.]
- c) All consulting arrangements with industry (including scientific advisory boards, data safety monitoring boards, other advisory/scientific boards) must be accompanied by a time-limited contract or letter of invitation/agreement that outlines specific deliverables, tasks, responsibilities, and compensation that is consistent with the expertise provided.
- d) All consulting agreements must be submitted to the Department Chair and undergo legal review prior to being forwarded to the Dean of CUSOM for review and approval prior to execution.
- e) Consulting agreements that involve the assignment of intellectual property rights must comply with the Creighton University Intellectual Resource Management (IRM) Technology Transfer policies available at:
<http://www.creighton.edu/irm/technologytransfer/researchersinventors/index.php#c78305>.
- f) Disclosure of consulting relationships must be fully transparent and documented, including the amount of financial compensation received.

8. Speaking and Training for Industry

- a) CUSOM faculty, staff, and trainees may participate on industry speakers' bureaus, but such activity is discouraged. Any materials provided to them for this purpose should in general not be used for teaching/training medical/graduate students, residents or fellows at CUSOM. However, if certain materials are used, e.g. for specific procedures related to a device, the industry affiliation associated with it must be disclosed to students/trainees by the presenter.
- b) Participation on informal or loosely defined 'advisory boards' must comply with the requirements for consulting agreements.
- c) Faculty, staff, and trainees who provide training and/or educational presentations for industry, Medical Education Communication Companies

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(MECCs), or similar commercial enterprises must comply with the requirements for consulting agreements.

9. Attendance at Industry-Sponsored Events

- a) CUSOM faculty, staff, and trainees cannot accept any form of compensation (e.g., travel expenses, lodging, or gifts) directly from industry, MECCs, or similar commercial enterprises for attending a professional meeting or conference, except as related to industry speakers' bureaus or advisory boards.
- b) Educational or promotional programs developed by industry representatives, MECCs, or similar commercial entities are not allowed at a CUSOM event, whether the event is held within or outside of CUSOM facilities.
- c) All outside speakers must disclose to the audience any relevant relationships they have with industry prior to their presentation.

10. Compensation for Serving as an Expert Witness

- a) Serving as an expert witness in legal matters involving outside professional compensation must be disclosed to and monitored by the Department Chair with oversight by the Dean.

11. Professional Services and Professional Affiliations

Outside professional service activities are a normal expectation of faculty at an academic medical center. Participation in, and receipt of compensation for, these activities is allowed and generally does not require disclosure.

- a) The following activities generally do not require disclosure:
- b) Holding office in, or undertaking an editorial office or duties for a scholarly journal, academic press, or professional organization
- c) Serving as a referee for a scholarly journal or an academic press
- d) Serving on a professional review board or peer review bodies
- e) Attending or presenting at events sponsored by professional organizations or academic institutions, such as professional meetings, workshops, colloquia, symposia, seminars, or training programs
- f) Visiting other sites in connection with accreditation, audits, sponsored project reviews, or like activities

12. Gifts from Vendors may be accepted only as follows:

- a) Gifts for personal use may be accepted from industry representatives, including small gifts such as pens, post-its, coffee mugs, notepads, calendars, and refrigerator magnets.

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- b) Gifts for the benefit of patients (e.g. anatomical models for use in exam rooms) that are not more than \$50 in value may be accepted.
- c) A written Letter of Agreement must accompany gifts of equipment and materials from industry to clarify intent and to document that no quid pro quo is expected. The agreement must be approved by the Department Chair prior to being forwarded for approval to the Dean of the SOM. Obtaining equipment for patient care must also be vetted by institutional purchasing and/or procurement departments.
- d) Teaching aids (e.g., textbooks) may be accepted by faculty and staff on behalf of the School or one of its departments or divisions.
- e) CUSOM will accept only those unbranded industry-supplied patient education materials that relate to therapies approved by the appropriate reviewing body, e.g., clinical site Pharmacy and Therapeutics committees.

13. Meals

Any meals accepted from industry representatives by faculty, staff, trainees, and departments or divisions should be occasional, of modest cost, and only in conjunction with an informational presentation in an environment conducive to that presentation. This includes both meals brought on-site and meals provided at local restaurants or national meetings.

- a) Meals, snacks, or refreshments at CUSOM events are allowable only when purchased through a CUSOM account.

14. Travel, Educational Scholarships or Educational Events, Training, Visiting Professorships, and GME Stipends

- a) Industry support for these items and events may only be provided in the form of unrestricted educational grants with monies going directly into a department or division account. While requests for unrestricted grants and gifts may be directed in a specific area, they should be worded in general terms, e.g., “for trainee travel to meetings,” “for trainee educational retreats,” “for grand rounds speakers,” “for support of CME activities,” etc., clearly indicating that department, division, and/or individual recipients will be completely free of any industry influence in all of their decision-making relative to the disbursement of the educational grant.
- b) Decision-making about who receives a stipend or scholarship must occur without any input from industry representatives. No quid pro quo can be required or expected from awardees.

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- c) No stipend, scholarship, or professorship at CUSOM can be labeled as an industry-sponsored award without the approval of the Department Chair and the Dean of the SOM.

15. Drug Samples/Vouchers/Patient Assistance

- a) Industry-supplied drug samples and vouchers for distribution to patients by faculty and trainees are discouraged. They should only be used under extreme circumstances when medically necessary for patients who cannot afford them. Clinical site policies regarding their use must be followed.
- b) Faculty, staff, and trainees may assist patients in applying for pharmaceutical companies' assistance programs.

16. Training Assistance

- a) Off-site training on new equipment or devices cannot be provided at industry expense unless the training is specifically included in the contract under which the equipment or device is acquired.
- b) Industry representatives providing on-site training or assistance must comply with applicable policies regarding vendor representative presence in the hospital and operating rooms.
- c) Training activities must be clearly differentiated from sales activities.

17. Medical School Curriculum and Disclosure to Trainees

- a) The medical school curriculum must have no influence from any industry regarding content or methods of teaching
- b) All teachers in a classroom/small group/laboratory setting must disclose to the trainees any potential or actual COIs with industry
- c) The Office of Medical Education will ensure adherence with this part of the policy

18. Publishing

- a) Faculty, staff, and trainees cannot participate in ghost authorship. Ghost authorship is the failure to name, as an author, an individual who has made substantial contributions to a scientific manuscript.
- b) When submitting manuscripts, CUSOM faculty, staff, and trainees must disclose all relevant financial interests to journal editors. Further information on appropriate publishing practices is contained in the guideline published by the International Committee of Medical Journal Editors –

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Policy Violations

Any CUSOM faculty/staff member or trainee not complying with this policy shall be subject to appropriate disciplinary action. Violations may lead to disciplinary action including written warning, suspension or termination of status in accordance with Creighton University Personnel Policies

ADMINISTRATION AND INTERPRETATIONS

Questions regarding interpretation of this policy should be directed to the School of Medicine Associate Dean for Planning and Business Affairs.

AMENDMENT

The School of Medicine reserves the right to modify, amend, or terminate this policy at any time.