PURPOSE:
The success of Creighton University School of Medicine (CUSOM) depends on a talented and creative faculty and staff who earn regional, national and international recognition for their contributions to teaching, research, clinical care, community service, and the advancement of their diverse clinical and scientific specialties. As a result of their expertise and experience, faculty and staff have opportunities to engage in professional activities with commercial entities, professional and scientific organizations and journals, as well as other universities and governmental agencies. Such activities can help faculty and staff develop their knowledge and skills; contribute to the growth and development of their area of expertise; and enhance the academic mission of the department, school and university. Participation in these activities may also create real and/or perceived conflicts of interest and conflicts of commitment. For the reasons outlined, 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.

SCOPE:
This Policy establishes guidelines for interactions with the health care industry and other opportunities for outside professional compensated activities. It applies to all Teaching-Research, Clinician-Educator, Affiliate, Research, Resident, Adjunct and Special faculty members, fellow and resident physicians, all staff employed by CUSOM, and all of its students/trainees. Contributed Service faculty members are encouraged to comply with this policy. Associated entities include all departments within CUSOM. In addition, all individuals to whom this policy applies, must comply with all other related policies that may be applicable at other institutions with which they are affiliated. If there is a discrepancy in any part of the policy with other institutions' policies, the individual must seek advice regarding resolution of the discrepancy from his/her supervisor.

The Policy is intended to supersede existing departmental policies on COI and COC and it 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. Individual departments within CUSOM may choose to adopt more stringent boundaries or monitoring based on unique specialty-based circumstances or local faculty preferences. For clarity, the Policy does not supersede or negate a faculty or staff member’s obligations under the University’s Policy on Financial Conflict of Interest (Guide to Policies, Policy No. 3.1.10) and any disclosures or other actions taken under the Policy are in addition to those required under the Policy on Financial Conflict of Interest.
Interactions with industry in an academic medical center may contribute to research, education, and patient care, and some of these interactions may lead to important clinical and educational innovations. However, these interactions must be held to high ethical standards including complete transparency to ensure that they do not create unintended conflicts of interest or compromise the integrity of the institution's mission. A growing body of literature suggests that because academic physicians have allowed themselves to be exposed to "profound influence from the pharmaceutical and medical device industries" (DeAngelis, JAMA 2008), academic medical centers need to take seriously the possibility of unintentional/unconscious bias in favor of industry that results from such interactions (Cain & Detsky, JAMA 2008).

CUSOM has a professional responsibility to provide exceptional patient care, outstanding educational programming, and rigorous independent scientific inquiry, and to accomplish these missions with high ethical standards. 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.

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.

DEFINITIONS:
"Conflict of Interest" (COI) involves a situation in which faculty, staff, or trainees 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.

"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.
**POLICY:**
The relationship we have with our patients is in part a fiduciary relationship. Patients trust us and rightly expect us to act in their best interest. Patients should be confident that decisions regarding their care are not influenced by the self-interest of their health care providers.

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.

**Core Values**

- Faculty and staff should be contributing to advances in teaching, research and clinical care in their clinical and research specialties. In some instances, these advances will best be accomplished by collaboration with industry. The value of these efforts should be recognized by CUSOM and the public.
- Decision-making about the core missions of CUSOM – educational programming and research activities – should be unfettered by relationships with industry and the conduct of CUSOM faculty, staff and trainees should avoid even the appearance of a COI. Patients, trainees and the public should be aware of this principle.
- Gifting relationships – regardless of the size of the gift – are well documented to influence decision-making of the recipient. Since all gifting has the potential to induce feelings of a need for reciprocity, faculty, trainees and staff should avoid accepting gifts from industry sources. Gifts of unbranded items primarily for the benefit of patients or that serve a genuine educational function (e.g., textbooks, anatomical models for use in examination rooms) may be accepted per CUSOM’s Vendor Policy. Unrestricted educational grants from industry may be given directly to the Department or Division for non-CME activities. The funds must be deposited in a University-designated educational account.
• Faculty and staff who choose to engage in outside compensated professional activities must be able to document clearly what services were provided and any compensation received. Any potential COI and COC must be disclosed and managed.
• Complete avoidance of financial conflicts with industry can be accomplished only by eschewing financial ties with industry. However, the risk of conflicts may be significantly reduced by full disclosure and adherence to the parameters of this policy. Full disclosure of potential conflicted relationships is critical, but disclosure alone does not eliminate COI or constitute its full management.
• In the course of their work at CUSOM, faculty and staff may not refer anyone to outside businesses if the referral will generate a benefit to the employee.

I) Gifts

• Faculty, staff, and trainees should refrain from accepting gifts from industry except as noted above.
• Faculty, staff, and trainees cannot accept any compensation for attending marketing programs and cannot attend hospitality events that have no educational value e.g. golf outings, vacations, etc. funded by industry.

A) Small Gifts
• Gifts cannot be accepted from industry representatives, including small gifts such as pens, post- its, coffee mugs, notepads, calendars, and refrigerator magnets.

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

C) Travel, Educational Scholarships or Educational Events, Training, Visiting Professorships, and GME Stipends
• 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.

- 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.
- 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.

D) Medical or Educational Equipment, Supplies, Resources, or Programming

- 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.

E) Patient Education Materials

- CUSOM will accept for distribution to patients 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.
- Marketing materials cannot be accepted for distribution to patients.

F) Drug Samples/Vouchers/Patient Assistance

- 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 absolutely medically necessary for patients who cannot afford them. Clinical site policies regarding their use must be followed.
- CUSOM faculty, staff, and trainees cannot seek or accept industry-supplied drug samples for personal or family use.
- Faculty, staff, and trainees may assist patients in applying for pharmaceutical companies’ assistance programs.

G) Training Assistance

- 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.
Industry representatives providing on-site training or assistance must comply with applicable policies regarding vendor representative presence in the hospital and operating rooms.

Training activities must be clearly differentiated from sales activities.

H) Medical School Curriculum and Disclosure to Trainees

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

II) 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.

- The following activities generally do not require disclosure:

  1. Holding office in, or undertaking an editorial office or duties for a scholarly journal, academic press, or professional organization
  2. Serving as a referee for a scholarly journal or an academic press
  3. Serving on a professional review board or peer review bodies
  4. Attending or presenting at events sponsored by professional organizations or academic institutions, such as professional meetings, workshops, colloquia, symposia, seminars, or training programs
  5. Visiting other sites in connection with accreditation, audits, sponsored project reviews, or like activities

III) Outside Non-Professional Activities
• Participation in outside non-professional activities generally does not require disclosure unless the time devoted to them interferes with the employee’s CUSOM obligations.

IV) Compensation for Serving as an Expert Witness

• 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.

V) Industry Compensation

• Consultative relationships between faculty, staff, and trainees and industry may provide valuable avenues to speed development and dissemination of innovations.

A) Consulting Expertise

• 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.
• 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.
• 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.
• Disclosure of consulting relationships must be fully transparent and documented, including the amount of financial compensation received.

B) Speaking and Training for Industry

• 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 particular device, the industry affiliation associated with it must be disclosed to students/trainees by the presenter.
• Participation on informal or loosely defined 'advisory boards' must comply with the requirements for consulting agreements.
Policies and Procedures

- Faculty, staff, and trainees who provide training and/or educational presentations for industry, Medical Education Communication Companies (MECCs), or similar commercial enterprises must comply with the requirements for consulting agreements.
  
C) Attendance at Industry-Sponsored Events

- 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.
- 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.
- All outside speakers must disclose to the audience any relevant relationships they have with industry prior to their presentation.

VI) Formulary Review and Purchasing Committees

- Faculty, staff, and trainees are not eligible to discuss/vote on decisions at Pharmacy and Therapeutics or Product Evaluation Committee meetings if they or members of their immediate family have, or have had within the prior 12 months, a personal financial relationship or funded research pertaining to a related pharmaceutical or medical device company that is being considered or discussed.

VII) Site Access and Industry Displays

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

VIII) Continuing Medical Education

- All CME activities sponsored by Health Sciences Continuing Education must be in compliance with ACCME regulations, requirements, standards, and guidelines.
• 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.
• 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.

IX) Research


• Research-related travel expenses to investigator meetings prior or subsequent to the establishment of a research contract may be paid for by industry.

X) Non-Clinical Product Evaluation

• All gifting rules and regulations apply to non-clinical research except where noted below.
• No gifts/donations of any value that are personal in nature (e.g., coffee mugs, calendars, tee shirts, etc.) may be received.
• A vendor may donate laboratory consumables for evaluation purposes only by completing the brief, web-based Vendor Product Donation form and returning the form to the Department Chair.
• Donations exceeding $5,000 (vendor list price or equivalent) must receive prior approval from the Department Chair by completing the Vendor Product Donation Form and returning the form to the Department Chair.
• A vendor can offer promotional discounts, but gifts of a personal nature (e.g., gift cards, tee shirts, etc.) cannot be included with the promotion.

XI) Publishing

• 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.
• 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 -
Uniform Requirements for Manuscripts Submitted to Biomedical Journals:

XII) 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.

IV. REFERENCES:

School of Medicine Policy