

The guidelines in the following document will be implemented using a phased approach over the next 3 years, with opportunities for review and revision after one year. Further communication on how the guidelines will be implemented and educational sessions on how to interpret the policies within Schulich will be communicated in future. In addition, coordination with the London Hospitals Standards for Business Conduct policy will occur. In the interim, units should continue to proceed with activities until further communication is provided.

If there are specific questions, please contact Dwayne Martins, Chief Operating Officer at dwayne.martins@schulich.uwo.ca

Policy and Guidelines for Interactions between Schulich School of Medicine and Dentistry and Pharmaceutical, Biotech, Medical Device and Research Equipment Supplies Industry (“Industry”)

Purpose

The purpose of this policy is to establish guidelines for the interactions between the Schulich School of Medicine and Dentistry (SSMD), its faculty, staff and students and partners in Industry. These interactions include those with representatives of the pharmaceutical, biotech, medical device and research equipment industry. Such interactions can be positive and of benefit to the Mission of the School of Medicine and Dentistry in service, education and research. It is imperative however, that such relationships be above reproach such that potential and real conflicts of interest are recognized and managed appropriately and cannot endanger patient safety, the integrity of our educational programs or the reputation of faculty or institution.

Statement of policy

It is the policy of SSMD to adhere to the highest ethical standards and legal requirements, to avoid conflicts of interest, improper relationships and other interactions with Industry that may suggest the appearance of a conflict of interest or an improper relationship. A conflict of interest is defined as a situation that occurs when there is a divergence between an individual’s private interests and his or her general professional obligations such that an independent observer might reasonably question whether the individual’s professional actions or decision are determined by considerations of personal gain, financial or otherwise. Individuals must consciously and actively divorce clinical care decisions from any perceived or actual benefits expected from any company. It is unacceptable for patient care decisions to be influenced by the possibility of personal financial gain. When conflicts of interest do arise, they must be addressed appropriately.

Scope

This policy applies to faculty, staff and learners of the SSMD. When in affiliated institutions, faculty and learners will abide by the relevant guidelines of that institution or, where no such guidelines apply, by the standards set in this document. Where two guidelines exist, it is expected that faculty and learners will abide by the higher standard of the two. All medical faculty are required to abide by the CMA Guidelines for Interactions with Industry. All dental faculty are expected to abide by the CDA Code of Ethics. All faculty, whether full time or adjunct are expected to follow these guidelines whenever and wherever they are engaged in teaching responsibilities for SSMD or using their SSMD titles. They are in addition to existing University of Western Ontario Conflict of Interest Guidelines. Faculty who fall under the UWOFA collective agreement are not authorized on their own to enter into contracts with Industry unless the contract is for private consulting i.e. faculty members cannot commit the corporate university in a contract, a confidential disclosure or a material transfer agreement with an outside interest or use their SSMD title in such contracts. If a faculty member is unsure about a situation, it is recommended they contact the Industry Liaison office of the University.

This policy addresses the following types of interactions with Industry:

Gifts

Pharmaceutical samples

Site access by pharmaceutical representatives

Site access by Device Manufacturer Representatives

Continuing Professional Education

Participation in Industry-Sponsored Programs

Industry-Sponsored Scholarships and other Educational Funds for Trainees

Food

Professional Travel

Ghostwriting

Purchasing

Consulting Relationships

Professionalism and medicine

Interactions between faculty, students and staff and industry that are prohibited within the academic health science centre are also prohibited off-site.

The SSMD commits to developing educational programs at all levels, undergraduate, post-graduate and continuing education to raise awareness of possible challenges to professionalism presented by relationships with Industry. These programs will be developed regularly monitored and evaluated under the direction of the appropriate education Associate Dean who will be accountable for them. This is in keeping with the SSMD commitment to a culture of professionalism.

At no time will a faculty or staff member make available a list of students or CPD/CME/CDA participants with contact information, at any level.

Specific policies and practices

Gifts to individuals – faculty, staff, students and trainees will not accept any gifts of any value from Industry representatives either on-campus or off-campus. This includes gifts from equipment and service providers, as well as pharmaceutical and device providers.

Gifts or compensation may not be accepted for simply attending a talk by an Industry representative, for prescribing or changing a patient's prescription, or for simply attending a CME event or other activity or conference (unless the individual is speaking or presenting at the event).

Pharmaceutical samples- pharmaceutical samples may be of benefit to patients who might not otherwise be able to afford a needed medication. They may also be useful for therapeutic trials. For these reasons, such samples are acceptable, but only if they are not given directly to a physician. This may be achieved by an arms length arrangement with an individual in a physician's office or a centrally managed system. Voucher systems, where available, are preferred.

Site access by pharmaceutical representatives- access by pharmaceutical representatives to individual physicians is by appointment or invitation and only in an area where or when patients are not present. Any involvement of learners in such activities must be under the supervision of a faculty member and approached as an educational opportunity.

Site access by device manufacturers representatives- site access by sales and marketing representatives are not permitted in patient care areas where such exist at SSMD, except to provide in-service training on devices and other equipment and then only by appointment. These individuals will only be present during patient care if there has been prior disclosure and signed consent by the patient or substitute decision maker. Any learner interaction with such industry representatives will be for educational purposes only and then only under faculty supervision. Affiliated institutions have their own guidelines with respect to access by device manufacturers that must be followed.

Continuing Professional Development/Continuing Medical Education/Continuing Dental Education (CPD/CME/CDE)-all CPD/CME/CDE programs offered/endorsed by SSMD are subject to audit to ensure compliance with the standards for accreditation by the Committee of the Accreditation of CME (CACME.), Royal College of Dental Surgeons of Ontario (RCDSO), and American Dental Association/Continuing Education Recognition Program (ADA/CERP). Industry support for CPD/CME/CDE may be provided to the Faculty of Medicine and Dentistry, to an individual Department/Division or the CPD Office, but must not be given to an individual faculty member, staff, student or trainee. The CPD office must be informed in advance of a request to Industry for grants to support educational events. Agreements governing grants supporting educational events must receive prior approval by the CPD Office. All educational programs will meet CACME/RCDSO/ADA/CERP standards. The content of all educational activities must be determined by the program planners or the committee members. Industry sponsors of educational programs may not determine the content or selection of speakers for educational programs and must not be members of the content planning committee. In the case of CPD/CME/CDE activities the organization of events must comply with policies of the CPD Office (e.g. Disclosure, use of logo etc.) and meet the accreditation standards of the Royal College of Physicians and Surgeons and/or the College of Family Physicians of Canada or Royal College of Dental Surgeons of Ontario.

Industry funding for educational Undergraduate, Graduate and Postgraduate programs- All funding accepted from Industry or third parties for educational programming must be free of actual or perceived conflict of interest and must be provided in the form of an educational grant. The Undergraduate, Graduate and Postgraduate medical education programs of the SSMD will not solicit or accept direct funding from Industry for their educational activities. Funds for educational activities may be provided to the School of Medicine and Dentistry or to an individual department, but must not be given to an individual faculty member, staff, student or trainee. Agreements governing grants supporting educational activities must receive prior approval by the Undergraduate, Graduate or Postgraduate Office as appropriate.

Participation in industry-sponsored programs- Faculty, students and trainees are prohibited from attending non-CPD/CME accredited events or which fail to follow Rx and D guidelines, that are marketed as CPD/CME. Industry sponsorship of journal clubs must follow the general guidelines of accredited CPD/CME events in that the content is to be determined by the learners under supervision of faculty. There must be no overt or covert advertising or marketing taking place during this activity. Further, they are prohibited from accepting payment for simply attending a CPD/CME event or accepting gifts at such events. With the exception of presenting research results from industry sponsored projects faculty are discouraged from participating in 'speaker's bureaus' which are often more about marketing than education. A speaker's bureau is defined as where a speaker is under contract to a company, and thus an agent of the company AND the speaker does not have editorial control of the content.

Industry sponsored scholarships and other educational funds for trainees-Sponsored scholarships and other educational funds such as Fellowships are a welcome way for Industry to support education. Such donations must be made centrally to the administration of SSMD or an affiliated hospital and it must be clear that there is no *quid pro quo* expectation or commitment. Support provided through affiliated hospitals is governed by hospital rules around such arrangements. Selection of recipients of such support will be done without Industry involvement.

Food-Unless attending an approved CPD/CME/CDE event faculty, staff, students and trainees may not accept food or meals within the AHSC or off-site.

Professional travel-Unless for legitimate reimbursement or for contractual services, funding for travel by faculty, staff, students and trainees is not acceptable.

Ghostwriting- All SSMD personnel should always be responsible for the content of any publication, presentation or slides presented in their name. Under no circumstances will faculty, students or trainees be listed as co-authors on professional presentations of any kind, oral or written that are ghostwritten by any party. Ghostwriting is understood to occur when a paid professional writer, whether or not medically trained, writes something credited to someone else.

Purchasing-Decisions relating to the purchasing of equipment and services must be free of bias. If SSMD personnel, or their direct family members, have financial interests in the pharmaceutical, devices, equipment industry or providers of services, they must declare this interest and excuse themselves from decisions related to any purchases related to these conflicting interests. In situations in which a person's expertise is needed to evaluate a product or service and in which that person has any ties, this must be declared to those responsible for making the final decision.

Consulting relationships-Faculty members have special knowledge and competencies and an obligation to share these with others, including Industry. Consulting contracts may only be entered into after discussion with the faculty member's Dean, Chair or administrator. Such contracts must provide details on specific tasks and deliverables, and the payment must be commensurate with tasks assigned. Arrangements that pay faculty without clearly defined associated duties are considered gifts and are prohibited. The SSMD reserves the right to require faculty and employees to request changes in their consulting agreements to bring them into line with these policies.

Educational materials-Faculty may wish to enter into agreements with Industry to develop educational materials. If the faculty member is covered by the UWO Collective Agreement and if the work can be classified as 'a major paid professional activity' then UWO must be involved in negotiations. Any income accruing from the content, organization and the medium for delivery of all educational material produced by faculty must be established by a tripartite agreement involving the faculty member(s), Industry partner and UWO. No contract will be negotiated that would interfere with the right of any SSMD student to defend his/her thesis. The content of any materials produced must not give the impression that SSMD approves of or endorses a specific product, service or treatment.

Philanthropic gifts-gifts of a philanthropic nature from Industry to a faculty member, Department or Division must be made through the SSMD Development office or affiliated hospital. There must be no possibility of a *quid pro quo* arrangement.

Research

The fundamental principle underlying all research must be freedom to do unbiased research and to disseminate, without restriction, the results obtained. Before signing any Industry contract, the ownership and/or the flow of revenues from the project must be clearly stipulated. If there is any uncertainty, it is strongly recommended that the researcher check with the University Industry Liaison office, Chair or institute director for guidance.

Research will be conducted in a manner consistent with the Tri-council Policy Statement titled: Ethical Conduct for Research Involving Humans.

Any research entered into by SSMD faculty, trainees and students must be ethically approved by the Research Ethics Board of the University. No research contract or arrangement should be entered into that limits the right to publish or to disclose the results of the study or report adverse events which occur during the course of the study.

Remuneration for participating in research must not constitute enticement, but may cover reasonable time and expenses. Receiving remuneration for simply finding research subjects, so called finder's fees, are not acceptable.

Before commencing an Industry-funded research study, it is the responsibility of the researcher to ensure that there is a signed tripartite agreement satisfactory to the researcher, the Industry partner, and the institution(s) in which the research will be conducted. This agreement must outline the responsibilities and accountability of each party, and reference the institutional policies by which the study will be conducted.

Reporting and Enforcing

These policies will be rolled out over the first three years of their initiation and will be accompanied by a faculty wide educational program.

All relationships with Industry will be disclosed to the Department Chair, or in the case of the Chair, to the Dean, on an annual basis. Any changes to such relationships will be reported when they occur.

The presence of relationships to Industry that pose an actual or potential conflict of interest as defined in this policy will be disclosed verbally or by slide to learners in lectures, seminars or workshops. This will include current relationships and those within the past 5 years. This disclosure must include the name of the commercial interest, the nature of that relationship. Information that an individual has no relevant financial relationship must also be disclosed. Faculty, students and trainees will abide by the disclosure rules of sponsoring organizations at national/international meetings and in publications.

Any known or suspected breaches of these policies should be reported to the Department Chair, Dean or immediate supervisor who shall determine what if any actions will be taken. When conflicts arise that cannot be resolved at the Department level, the Dean's office is to be notified. It is recommended that the Dean be provided with the option to set a committee for review of conflict.

Depending on the seriousness of the breach, whether it is a first or repeat occurrence and whether the individual knowingly breached the policy or tried to conceal it, any of the following actions, singly or in combination may be taken. Enforcement will begin with the least restrictive sanctions and progress to greater sanctions only if necessary:

- a) Counseling of the individual
- b) Written reprimand, entered into their record
- c) Banning the individual from any further outside engagements for a period of time
- d) Requiring that the individual return any monies received from the improper relationship with a third party in contravention of this policy
- e) Requiring the individual to complete additional training on conflict of interest
- f) Removing the individual from the supervision of trainees or students
- g) Termination for cause.

Violations of these policies by Industry representatives will be managed through progressive warnings and restrictions on access.

Mechanism for Appeal

In situations where a faculty member wishes to appeal a decision made by a Chair with respect to conflict of interest or arrangements with Industry, or where the Chair wishes to seek further advice, the Dean shall appoint an appeal committee that will consist of representation from the Education offices, Research, Ethics and two Departmental Chairs.

Review of Policy

This policy will be reviewed one year after the implementation and every 3 years thereafter.

Documents reviewed

Relationships between the Schulich School of Medicine and Dentistry and non-University Partners.

Guidelines for Physicians in Interactions with Industry. Canadian Medical Association, 2007

Conflict of Interest: Recruiting of Subjects for Research Studies. College of Physicians and Surgeons of Ontario. Policy Statement #6-06. September, 2006

The University of Western Ontario, Policies and Procedures. 3.4 Conflicts of Interest

Tri-council Policy Statement: Ethical Conduct for Research Involving Humans. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada. 2005

Industry Funding of Medical Education: Report of an AAMC Task Force. Association of American Medical Colleges. June, 2008

LHSC/SJHC: Business Ethics in the Workplace, A Guide for Leaders, Physicians and Staff.
May, 2009

Interactions between the University of Manitoba's Faculty and the Pharmaceutical, Biotech, Medical Device, and Hospital and Research Equipment and Supplies Industries ("Industry").
Faculty Executive Council, Faculty of Medicine, The University of Manitoba.

University of Ottawa, Faculty of Medicine Policy of Interacting with Industry and Outside Agencies in a teaching environment. September, 2008

Stanford School of Medicine, Policy and Guidelines for Interactions between the Stanford School of Medicine, the Stanford Hospital and Clinics and Lucile Packard Children's Hospital with the Pharmaceutical, Biotech, Medical Device, and Hospital and Research Equipment and Supplies Industry ("Industry"). May, 2009

University of Rochester Medical Center Policy on Industry Interactions. June, 2008

University of Pittsburgh Industry Relationships Policy. November, 2007

Pennsylvania State University Individual Conflict of Interest Policy. September, 2007

Rx&D Code of Ethical Practices, January 2009

Rx&D Guidelines for Transparency in Stakeholder Funding, January 2009

CDA Code of Ethics http://www.cda-adc.ca/en/cda/about_cda/code_of_ethics/index.asp

University of Alberta, Conflict of Interest and Conflict of Commitment Disclosure Report for Academic Staff

The Harvard University Faculty of Medicine, Conflicts of Interest Report Form, Cycle 9 Disclosure Form, undated

SCCPD Position Paper on University CME/CPD Offices and Industry Relations (Draft proposal, May, 2010)

Approved at the Joint Schulich Council / ECSC meeting on June 4, 2010 –Review to occur in June 2011