

Policy on Interactions between Schulich School of Medicine & Dentistry and Pharmaceutical, Biotech, Medical Device, Medical/Dental Supply, and Research Equipment Supplies Industry (“Industry”)

Purpose

The purpose of this policy is to establish guidelines for interactions between the Schulich School of Medicine & Dentistry (Schulich), its faculty, staff and learners, and representatives of the pharmaceutical, biotech, medical device and research equipment industries (“Industry”). While interactions with Industry can be positive and benefit Schulich’s mission, relationships with Industry must be above reproach. Potential and real conflicts of interest must be recognized and managed appropriately and must not endanger patient safety, the integrity of our research or educational programs, or the reputation of the institution or its faculty.

Overview

Ethical standards require that Schulich faculty, staff, and learners 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 their general professional obligations such that an independent observer might reasonably question whether the individual’s professional actions or decisions are determined by considerations of personal gain, financial or otherwise. The Canadian Medical Association notes that conflicts of interest may be real, potential, or perceived, and may exist even if no unethical or inappropriate act results from the conflict. Individuals must consciously and actively divorce decisions related to clinical care, education, or research from any perceived or actual benefits expected from any company. When real or perceived conflicts of interest arise, they must be addressed appropriately.

Scope

- This policy applies to all Schulich faculty, staff and learners. The term “faculty” includes all those with a Schulich academic appointment, including adjunct and part-time faculty members and those at distributed sites. The term “learners” includes all undergraduate graduate, postdoctoral, and professional (MD and DDS) students, as well as residents and fellows.
- When in affiliated institutions, faculty and learners will abide by the relevant guidelines of those institutions or, where no such guidelines apply, by the standards set in this document.
- Where two policies or guidelines exist (including this policy), faculty and learners must abide by the higher standard of the two.
- All medical faculty are required to abide by the CMA Guidelines for Physicians Interactions with Industry: <https://policybase.cma.ca/en/permalink/policy14454>
- All dental faculty are required to abide by the CDA Code of Ethics.
- All faculty, whether full time or adjunct, must follow these guidelines whenever and wherever they are engaged in teaching responsibilities for Schulich or using their Schulich credentials.
- This policy is to be applied in conjunction with and does not supersede Western University policies and procedures governing conflicts of interest (www.uwo.ca/univsec/pdf/policies_procedures/section3/mapp34.pdf) and, for faculty who fall under the UWOFA collective agreement, does not supersede the *Conflict of Interest and Conflict of*

Commitment Article of the UWOFA collective agreement

- 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; that is, 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 Schulich credentials in such contracts.
- If a faculty member is unsure about a situation, it is recommended they contact the WORLDiscoveries office of the University.
- Interactions between faculty, students and staff and industry that are prohibited within the Schulich School of Medicine and Dentistry and its affiliated teaching hospitals are also prohibited off-site.

Specific Guidelines

This policy addresses the following types of interactions with Industry:

1. *Fees, gifts etc to individuals*
2. *Pharmaceutical samples*
3. *Site access by pharmaceutical representatives*
4. *Site access by Device Manufacturer Representatives*
5. *Continuing Professional Development/Continuing Medical Education/Continuing Dental Education*
6. *Industry funding for educational Undergraduate, Graduate, and Postgraduate programs*
7. *Participation in Industry-Sponsored Programs*
8. *Industry-Sponsored Scholarships and other Educational Funds for Trainees*
9. *Food*
10. *Professional Travel*
11. *Ghostwriting*
12. *Purchasing*
13. *Consulting Relationships*
14. *Educational Materials*
15. *Philanthropic Gifts*

1. Fees, gifts etc to individuals

Other than consulting arrangements permitted below, staff, practicing physicians and dentists, as well as medical and dental learners, must not accept a fee, personal gift or equivalent benefit of any value from industry. Physicians, dentists and learners should be aware that acceptance of gifts of any value has been shown to have the potential to influence clinical decision-making.

2. 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, dentist or learner. This may be achieved by an arm's length arrangement with an individual in a physician's or dentist's office or by a centrally managed system. Voucher systems, where available, are preferred.

3. Site access by pharmaceutical representatives and dental supply representatives

Access by pharmaceutical representatives to individual physicians and dentists 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.

4. Site access by device manufacturers' representatives

Site access by sales and marketing representatives are not permitted in patient care areas where such exist at Schulich, 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 is a role in device preparation or implementation that is critical to proper patient care and with 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.

5. Continuing Professional Development/Continuing Medical Education/Continuing Dental Education

All CPD/CME/CDE programs offered/endorsed by Schulich are subject to audit to ensure compliance with the standards for accreditation by the Committee on 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 Schulich, to an individual Department/Division, or to the CPD Office, but must not be given to an individual faculty member, staff, student or trainee. 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 scientific planning committee.

In the case of CPD/CME/CDE activities, the organization of events must comply with policies of the CPD Office 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. At no time will a faculty or staff member make available a list of students or CPD/CME/CDE participants with contact information to any external individuals or organizations.

6. Industry funding for educational Undergraduate, Graduate and Postgraduate programs

All funding accepted from Industry for educational programming must be provided in the form of an unrestricted educational grant. Schulich's Undergraduate, Graduate and Postgraduate medical and dental education programs 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 & Dentistry or to an individual department or division, but must not be given to an individual faculty member, staff, student or trainee.

7. Participation in industry-sponsored programs

Faculty and learners are prohibited from attending non-CPD/CME accredited events 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 and/or their faculty supervisors. There must be no overt or covert advertising or marketing taking place during these activities. Further, faculty and learners are

prohibited from accepting payment for simply attending a CPD/CME event or accepting gifts at such as covering fees for events. With the exception of presenting research results from industry-sponsored projects faculty should not participate in 'speaker's bureaus' which are often more about marketing than education. A speaker's bureau is defined as an arrangement whereby a speaker is under contract to a company, and thus acts as an agent of the company, AND the speaker does not have editorial control of the content.

8. *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 Schulich or an affiliated hospital and it must be clear that there is no *quid pro quo* (a favour for a favour) 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.

9. *Food*

Unless attending an approved CPD/CME/CDE event faculty, staff, or learners should not accept Industry-provided food or meals within Schulich or off-site. An approved event is one which has received CPD/CME/CDE accreditation, or is compliant with section #8: *Industry sponsored scholarships and other educational funds for trainees*. Grants for in-services can be received to provide simple refreshments. Within affiliated institutions, the relevant institutional policies will apply.

10. *Professional travel*

Unless for legitimate reimbursement for contractual services, Industry funding for travel by faculty, staff, and learners is not acceptable.

11. *Ghostwriting*

Ghostwriting occurs when a paid professional writer, whether or not medically or dentally trained, writes something that is credited to someone else. All Schulich personnel must take responsibility 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.

12. *Purchasing*

Decisions relating to the purchasing of equipment and services must be free of bias. If Schulich personnel, or their direct family members, have financial interests in the pharmaceutical, device, or medical or dental equipment industry, 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, these conflicts of interest must be declared to those responsible for making the final decision.

13. *Consulting relationships*

Faculty members have special knowledge and competencies and it is a reasonable expectation that they will share this knowledge and skill with others, including with Industry. Consulting contracts may only be entered

into after discussion with the faculty member's Dean, Chair, or their delegate and completion of any other applicable process required under the UWOFPA collective agreement or *Conditions of Appointment for Physicians (2018)* or successor documents. Such contracts must provide details on specific tasks and deliverables, and the payment must be commensurate with tasks assigned. Arrangements that pay faculty or other Schulich personnel without clearly defined associated duties are considered gifts and are prohibited. Schulich reserves the right to require faculty and employees to amend their consulting agreements to bring them into line with this policy. These relationships are to be declared on the annual COI form.

14. Educational materials

Faculty may wish to enter into agreements with Industry to develop educational materials. The content of any materials produced must not give the impression that Schulich approves of or endorses a specific product, service or treatment.

If the faculty member is covered by the UWO Collective Agreement (UWOFPA) 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 Schulich student to defend their thesis.

15. Philanthropic gifts

Gifts of a philanthropic nature from Industry to a faculty member, Department or Division must be made through the Schulich Development Office or that of an affiliated hospital. There must be no possibility of a *quid pro quo* arrangement.

Research

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

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 consult with the WORLD Discoveries Office, Chair or institute director for guidance.

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, is not permitted.

Before commencing an Industry-funded research study, the researcher must 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. Any funding associated with that

industry project must be used specifically for that project until such time as the work is complete.

Professional Development

Schulich commits to developing educational programs for faculty and learners at all levels 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 decanal leader who will be accountable for them. This is in keeping with Schulich's commitment to a culture of professionalism.

Reporting

All faculty relationships with Industry must 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. Each Department Chair will then provide an annual Conflict of Interest (COI) report to the Dean that summarizes the disclosures for their department.

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, workshops, and other educational activities. This disclosure will encompass current relationships and those within the past 5 years, and must include the name of the commercial interest and the nature of the relationship. Information that an individual has no relevant financial relationship must also be disclosed. Faculty and learners will abide by the disclosure rules of sponsoring organizations at national and international meetings and in publications.

Procedures for Known or Suspected Policy Breaches

1. Any known or suspected breach of this policy should be reported to the Department Chair (in relation to faculty), Vice Dean (students), Program Director (residents) or staff leader (staff).
2. The Department Chair will include, in their annual COI report to the Dean, a summary of suspected breaches and of actions taken to address them.
3. For issues that cannot be resolved at the Department level, or if the Department Chair is directly involved in the suspected breach of this policy, the Dean's Office must be notified.
4. Suspected breaches of this policy may be investigated and, where appropriate, addressed through the applicable disciplinary processes for the faculty member, staff or learner based on the applicable collective agreement, *Conditions of Appointment (2018)* or other applicable process.

Enforcement of this policy will require a flexible approach, given the variability in context, circumstances, and seriousness of breaches that may occur. Generally, the initial approach should be educational, and enforcement should only proceed to greater sanctions if educational approaches have failed.

Approved by Joint Schulich Council, May 5, 2022.