

# CUMMING SCHOOL OF MEDICINE GUIDE TO CONFLICT-OF-INTEREST REQUIREMENTS

## 1. INTRODUCTION

### 1.1. Background

At a high level, a conflict of interest (or “COI”) can be understood as a situation in which an individual is involved in or has multiple interests, (personal, family, financial, related entities, or others), and serving one interest could involve (or could *appear* to involve) working against the other, creating bias, or impacting objectivity and neutrality.

As a publicly-funded education and research institution, CSM/UCalgary and our faculty and staff are subject to a number of legislative, granting agency (e.g. Tri-Agency and U.S. Department of Health and Human Services), and accreditation requirements related to disclosing, managing, and eliminating conflicts of interest.

The primary governing documents related to COIs at UCalgary are:

- the Code of Conduct (“**Code**”) and Procedure for Conflict of Interest (created pursuant to Alberta’s *Conflict of Interest Act*); and,
- the Research Integrity Policy (created pursuant to the Tri-Agency Framework for the Responsible Conduct of Research) (effective date December 12, 2014).

These have been effective since 2015 and 2014, respectively, and approved by UCalgary’s Board of Governors and General Faculties Council (after having followed the formal UCalgary policy development and governance process for approval). The Code also required review and has been endorsed by Alberta’s Ethics Commissioner (most recently in 2019). **These policies apply equally across UCalgary to all faculties and units.** This guide provides additional guidance on CSM-specific resources for managing COIs in accordance with UCalgary policies (eg: CSM Legal Counsel and Conflicts Officer and CSM Conflicts Committee).

Although the term “conflict of interest” may have a negative connotation, **it’s important to note that UCalgary does not view the mere existence of a COI as negative, or as implying wrongdoing, impropriety or unethical conduct. COIs are about situations and perceptions, not behaviours.** UCalgary expects that COIs will exist and arise in pursuit of our academic mission, particularly given the complex roles and responsibilities of our faculty members. Many COIs can be reasonably managed – the key is transparency and documentation.

The goal of COI policies and procedures is to protect the integrity of the UCalgary, CSM, and its faculty and staff. To that end, COIs must be disclosed and, where possible, managed. COIs (real or perceived) that are undisclosed/undocumented or are improperly managed threaten the reputation and integrity of CSM/UCalgary, its research enterprise, and those involved. They can undermine the public’s confidence in UCalgary’s and the faculty or staff member’s ability to pursue and disseminate knowledge, devoid of bias and personal interests, and result in accreditation issues or the loss of research funding.

As required by the University’s Delegation of Authority Policy and Conflict of Interest Procedure, the Dean of CSM retains final decision-making authority on whether and how a COI may be managed, taking in to

account any advice provided by the CSM Conflicts Committee and the CSM Legal Counsel and Conflicts Officer, respectively. Neither the CSM Conflicts Committee nor the CSM Legal Counsel and Conflicts Officer set the conflict policies and procedures or make decisions on individual COI issues. Their role is to support and advise the Dean.

## **1.2. Purpose**

This Guide has been developed in the context of UCalgary's focus on encouraging entrepreneurship and innovation, with a view to facilitating these endeavors while promoting transparency and compliance with COI policies. This Guide is intended to:

- provide information and clarity to CSM management, faculty, and staff regarding identifying, disclosing, and managing COIs;
- provide details of how existing institutional COI requirements and procedures apply to CSM faculty and staff activities, including how and where to make disclosures; and
- promote efficiency in processes.

This Guide will be updated and communicated to CSM faculty and staff regularly, and at least annually, to ensure awareness and understanding.

## 2. RELEVANT POLICIES, APPLICATION, & DEFINITIONS

### 2.1. Governing Policy Requirements and Application

- UCalgary's [Code of Conduct](#)
- UCalgary's [Research Integrity Policy](#)
- [Tri-Agency Framework: Responsible Conduct of Research](#)
- Tri-Council Policy Statement 2 (2022) [Chapter 7 \(Conflicts of Interest\)](#) ("TCPS2")
- Accreditation standards by [Liaison Committee on Medical Education \(LCME\)/Committee on Accreditation of Canadian Medical Schools \(CACMS\)](#) (undergraduate) and [Committee on Accreditation of Continuing Medical Education \(CACME\)](#)
- Advanced Technical Skills Simulation Laboratory ([ATTSL Conflict of Interest Operating Standard](#))
- [NIH Grants Policy Statement: Financial Conflict of Interest.](#)
- Other funding agency or accreditation body COI requirements applicable to UCalgary faculty, instructors and staff that may be in place and required from time to time.

This Guide does not replace the above governing policies and requirements and is intended to supplement and provide clarity.

Please note that the requirements listed above are not new and have been in place and applicable to CSM and the broader UCalgary community for several years. These policies continue to apply to all CSM Academic Staff Members, Clinical and Adjunct Appointees, and Employees, as set out in each policy.

### 2.2. Key Definitions. What is a Conflict of Interest?

"**Conflict of Interest**" means a conflict of interest as defined in the Code or as defined in the University's Research Integrity Policy. For ease of reference:

**2.2.1. Under the Code, a "Conflict of Interest" exists when, in the course of carrying out their University responsibilities, an individual takes any action where they know or ought to know that the action may result in an actual or perceived **Private Benefit** to them or to a **Related Person** or **Related Entity**, including:**

- a) the individual takes part in a decision in the course of carrying out their University responsibilities, where they know or ought to know that the decision may result in an actual or perceived Private Benefit to them or to a Related Person or Related Entity; or
- b) the individual uses their position with the University to influence or seek to influence a University decision which they know or ought to know may result in an actual or perceived Private Benefit to them or to a Related Person or Related Entity; or
- c) the individual communicates information that they know or ought to know is not available to the general public and is obtained by the individual in the course of carrying out their

University responsibilities or as a result of their University position in order to obtain or seek to obtain a Private Benefit for the individual or for a Related Person or Related Entity.

A **“Private Benefit”** means a personal benefit or furthering a private interest (including the avoidance of a negative consequence) but does not include a benefit or interest that is of general application, affects a person as a member of a broad class, or is inconsequential (i.e. de minimis).

A **“Related Entity”** means:

- a) a public corporation of which the individual is a director or officer or the beneficial owner of more than 5% of the outstanding shares of any class;
- b) a ‘for-profit’ private corporation of which the individual is a director or officer;
- c) a ‘for-profit’ private corporation of which the individual is the beneficial owner of shares in the corporation;
- d) a non-profit corporation or an association of which the individual is a director or officer; and
- e) a partnership of which the individual is a partner or of which one of the partners is a Related Entity of the individual by reason of clause (i),(ii), (iii) or (iv) above

A **“Related Person”** means an individual who is directly associated with another individual and includes:

- a) a parent, sibling and child of the individual;
- b) a spouse or domestic partner of the individual; and
- c) any other person who is directly associated with the individual.

**2.2.2. Under the Research Integrity Policy, “Conflict of Interest”** means activities or situations that may place an individual in a real, potential, or perceived conflict between their duties or responsibilities related to research on the one hand, and personal, University or other interests on the other. These interests include, but are not limited to, business, commercial or financial interests pertaining to the individual, their family members, friends, or their former, current or prospective professional associates. This definition of Conflict of Interest is as defined and interpreted by Tri-Council.

### 3. PROCESSES AND PROCEDURES

#### 3.1. Duty to Disclose. When, How, and What?

##### 3.1.1. Annual Disclosures

All individuals with the authority to approve expenditures (including purchasing/p-card), contracts, or the hiring of an individual on behalf of UCalgary are required to submit an annual disclosure, regardless of the existence of a COI.

In addition, as part of accreditation standards for the Cumming School of Medicine (CSM), Academic Staff Members and Clinical Appointees in CSM are also required to make an annual disclosure, regardless of the existence of any COI.

Annual disclosures must be made by no later than March 1 of each calendar year.

Disclosures can be made online on Peoplesoft as follows: **Navigate to myUCalgary > All about me > Employee Self Service > Conflicts of Interest and follow the steps to complete the disclosure.**

If the information in your disclosure has not changed from the prior year and is already subject to an approved Management Plan, please make note of that prior approval and approved Management Plan in the disclosure, as that will help expedite review and approval.

##### 3.1.2. Ongoing Duty to Disclose – As Conflicts Arise

CSM Academic Staff, Clinical/Adjunct faculty, and employees have an ongoing obligation to disclose any actual, potential or perceived COI as defined under the Code or Research Integrity Policy (see section 2 above) as soon as they identify that there may be a Conflict of Interest **and before** they enter into any proposed transaction or arrangement that may give rise to the COI. This requirement to disclose is ongoing and is required each time a new actual, potential, or perceived COI arises. This is not intended to duplicate the Annual Disclosure, but rather capture situations that arise after the Annual Disclosure that were not disclosed at that time.

##### 3.1.3. Other Specific Disclosure Requirements that may apply

REBs and TCPS2: Importantly, the Code and Research Integrity Policy disclosures referenced above do not replace the TCPS2 requirement to disclose research conflicts of interest to the CHREB or CFREB on ethics applications. These are separate disclosures that must be made in accordance with the requirements of the REBs.

PHS/NIH: The Code and Research Integrity Policy disclosures likewise do not replace PHS/NIH requirements to report COIs. The PHS/NIH requires all those responsible for the design, conduct, or reporting of research funded by the PHS/NIH (Principal Investigators and Co-Investigators, as well as any other Key Team Members responsible for the design, conduct, or reporting of the NIH research,

including honorary staff, students, technicians, external collaborators, or consultants) to report any Significant Financial Interests (SFI) and Financial Conflicts of Interest (FCOI), as defined by the PHS/NIH.<sup>1</sup>

At a minimum, SFIs must be disclosed:

- (1) **at the time of application** for PHS/NIH funding or through another institution as a sub-award;
- (2) **within 30 days** of a change of the terms and conditions of the grant or sub-award, updates or changes to Principal Investigator's or Key Team Members SFIs, and upon any sponsored travel within the terms of the existing grant or sub-award; and
- (3) **annually** for the life of the grant funding or sub-award.

Applications or subawards will not be processed by the Research Services Office or CSM Legal Unit (as applicable) until disclosures from the Principal Investigator and all Team Members have been submitted and reviewed. Failure to submit the annual disclosure during the term of the award or subaward by the Principal Investigator or a Key Team Member may result in suspension of the research account.<sup>2</sup>

**NIH/PHS FCOI disclosures are received by the Research Services Office. Disclosures can be made through SharePoint > Conflict of Interest Management and following the steps to complete the disclosure.**

**NOTE:** SFIs that do not directly and significantly affect the design, conduct or reporting of the PHS/NIH-funded research are not FCOIs for the purposes of PHS/NIH funding; however, they may still be considered an institutional COI under the Code and may be referred to the PeopleSoft Code disclosure process.

ATSSL: The ATSSL Conflict of Interest Operating Standard is related to the Code and follows the PeopleSoft disclosure process above. It addresses conflicts as they relate specifically to the use of the ATSSL and is required for accreditation purposes. For more information about when you need to make a disclosure related to use of the ATSSL, please see the ATSSL Operating Standard linked above.

LCME/CACMS & CACME: the Code and Research Integrity Policy address the national accreditation requirement that each faculty of medicine have a formalized institutional policy and procedure related to COI disclosure and management. Real, potential and perceived COI that occur in conjunction with one's UCalgary responsibilities (e.g., clinical, educational, research, administrative) are reported through the PeopleSoft disclosure process referenced above.

---

<sup>1</sup> "Significant Financial Interest (SFI)" is defined by the NIH as: (1) A financial interest consisting of one or more of the following interests of the investigator (and those of the investigator's spouse and dependent children) that reasonably appears to be related to the investigator's institutional responsibilities: (i) With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

#### **3.1.4. How do I know if my situation presents a conflict requiring me to disclose?**

It is acknowledged that there are situations sufficiently complex that judgments may differ as to whether there is or may be a COI, and individuals may inadvertently place themselves in situations where conflict exists. When in doubt as to whether a COI exists, you should disclose the arrangement as a potential conflict and a determination will be made in accordance with the applicable requirements.

#### **3.1.5. What should my disclosure include?**

You should disclose all material facts related to the COI and, where an actual, potential, or perceived COI exists, propose a Management Plan for review that either eliminates the COI or sufficiently separates the interests in conflict to remove the perception of improper influence, bias, or use of public resources for private benefit.

For example, a disclosure about a potential, perceived, or actual Private Benefit to a Related Entity (as defined above) might include the following information:

- Are you a consultant, employee, owner, director/officer, shareholder, board member etc., or is it a family member's company?
- What do you do with the Related Entity or what are you proposing to do and how, if at all, does it involve the University or your University position? Is there a risk of a perception it could involve the University or your University position, even if it does not? (In such case, best practice is simply to document it does not actually involve the University).
- Is there an intent to contract the Related Entity, or provide them with access to use University resources or employees?
- Are the activities of the Related Entity being funded by a grant through the University?
- Any involvement of the Related Entity in University research?
- Any relevant REB approvals and conflict management plans from the REB
- IP ownership arrangements with the Related Entity if applicable
- Data or information sharing arrangements with the Related Entity
- Nature of any financial arrangements (e.g., salary, consulting fees, value of equity ownership from the Related Entity, or proposed remuneration or contract to the Related Entity)
- High level estimate of commitment of time spent on activities for the Related Entity and description of those activities
- For spinoffs/start-ups, is the Related Entity actively commercializing (generating revenue, licensing or selling product, obtaining funding or investment from outside the University which does not flow through the University), or simply engaged in furthering applied research and development funded by grants through the University

- For spinoffs/start-ups, has a commercialization disclosure been made as required by the IP Policy?

### **3.2. Information on Management Plans**

CSM faculty and staff are asked to propose a potential management plan in their disclosure for the Dean's consideration, as it is expected that the faculty or staff member may have already considered or put in place mitigations to address the COI. However, whether and how a COI is manageable remains in the Dean's discretion.

A COI may be permitted where it can be managed in a way that withstands reasonable and independent scrutiny, is compliant with applicable law and UCalgary policies, and protects the interests and reputation of UCalgary and the disclosing individual.

The purpose of a Management Plan is to enhance transparency, create accountability and create separation between the competing/conflicting interests. It serves as valuable protection for both UCalgary and the discloser and assists in clearly defining respective roles, responsibilities and boundaries.

A helpful way to consider whether a management plan appropriately creates separation between conflicting interests is to consider the "newspaper test", viewing the arrangement from the eyes of the public. For example, consider:

- Given the University is a publicly funded institution and donor funded charity, would a reasonable person external to the University have concerns about the arrangement?
- Would you be comfortable sharing the arrangement with the public? Could you justify the arrangement as being fair and reasonable and in the interests of the University if asked about it by the media? What would you say?

A Management Plan may be required by ethics bodies, granting agencies or business units within UCalgary before certain steps can be undertaken.

Individual Management Plans are case specific and will necessarily vary depending on the specific circumstances of the individual COI. Considerations that may result in variation include level of financial interest, whether and how UCalgary or outside employees or students are involved, flow of funds, time involved, IP ownership, data sharing, level and type of University resources involved, nature of outside relationships, intersection with various UCalgary policies, and legal implications for UCalgary of the proposed arrangement. Notwithstanding, every effort will be made to ensure that Management Plans reflect a consistent and fair application of applicable policies to all CSM faculty and staff.

### **3.3. Review and Approval Process**

#### **3.3.1. Review by CSM Legal Counsel & Conflicts Officer**

Once a disclosure has been submitted, it is routed to the CSM Dean for review. Prior to the Dean's review, the CSM Legal Counsel & Conflicts Officer will review the disclosure and:

- connect with the faculty or staff member to obtain any further information or documentation that may be required to help with the review and determination of whether and how a COI may be managed



- assess the disclosure based on applicable policy and law and provide recommendations to the Dean as to whether and how the conflict may be managed
- identify to the Dean whether the disclosure would benefit from additional review and feedback from the CSM Conflict Committee

### **3.3.2. CSM Conflict Committee Referral & Review**

The CSM Conflicts Committee (the “**Committee**”) is an advisory committee established under the authority of the CSM Dean for the purposes of assisting the Dean in assessing complex COI disclosures made by CSM faculty and staff under applicable University policies.

The Committee is comprised of four senior academic staff members from CSM appointed by the Dean. The Committee contributes their academic, research, clinical, and commercialization expertise and provides further recommendations to the Dean on whether a COI can be managed or if it must be disallowed/eliminated.

The CSM Dean has discretion to refer a matter to the Committee for further consideration. Without limitation, the Dean may do so where it involves a novel or complex situation such that larger consultation and other types of expertise (e.g., academic/clinical/research/commercial) would be beneficial to a determination of the matter. This might include matters that involve multiple interested parties (internally or externally), activities that carry significant reputational, financial, or legal risk for UCalgary, or new activities, relationships or ventures that have not been explored at UCalgary.

In making its recommendations, the Committee will apply relevant COI policies in a manner that preserves the integrity of UCalgary, its education and research enterprises, and its faculty and staff, maintains compliance with applicable laws and other UCalgary policies, while also respecting academic freedom and considering UCalgary’s goals of encouraging and facilitating innovation and entrepreneurship.

The Committee [Terms of Reference](#) provides additional information regarding the Committee’s mandate and function.

Neither the Conflicts Officer nor the Committee make final decisions regarding COI disclosures of CSM faculty and staff. As noted above, decision-making authority rests with the CSM Dean. The decision of the CSM Dean is final, binding and is not subject to further review.

### **3.3.3. Final Approval**

After considering feedback and advice from the CSM Conflicts Officer and Committee (as applicable), the Dean will either issue an approval with a documented management plan, or a direction that the conflict be eliminated. The faculty or staff member will be required to sign and acknowledge the management plan or direction to eliminate the conflict.

#### **4. PRIVACY & CONFIDENTIALITY**

Personal information collected by the University as part of its COI disclosure processes is collected under the authority of section 33 of Alberta's *Freedom of Information and Protection of Privacy Act*. Personal information collected under a COI disclosure process shall only be used or disclosed for the purpose of assessing and managing the COI in accordance with applicable policies, and for administering the employment relationship in accordance with the applicable collective agreement or employment contract.

The CSM Dean, Conflicts Officer and the Committee shall maintain the confidentiality of any COI disclosures and related information and documentation and will limit access to same in accordance with UCalgary privacy policies and all applicable privacy and access legislation. Information about a disclosure or plan will only be shared on a need-to-know basis with those who have responsibilities under the applicable COI disclosure process and policies as part of their employment with UCalgary.