



ADVANCED TECHNICAL SKILLS SIMULATION LABORATORY (ATSSL) CONFLICT OF INTEREST OPERATING STANDARD

Pursuant to the University of Calgary's Code of Conduct and Research Integrity Policy

1. BACKGROUND & PURPOSE

1.1. Background

The Advanced Technical Skills Simulation Laboratory ("ATSSL") is a medical simulation center in the Cumming School of Medicine at the University of Calgary ("UCalgary"). As part of a publicly funded education and research institution, the ATSSL and its faculty, instructors 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 (or "COIs"). UCalgary's <u>Code of Conduct</u> ("Code") pursuant to Alberta's <u>Conflict of Interest Act</u> and its <u>Research Integrity Policy</u> pursuant to the <u>Tri-Agency Framework for the Responsible Conduct of Research are the primary governing documents related to COIs.</u>

At its simplest, a COI is a situation in which an individual is involved in multiple interests, financial or otherwise, and serving one interest could involve (or could *appear* to involve) working against the other. In order to protect the integrity of the ATSSL and its curricula, COIs must be disclosed and, where possible, managed. COIs (real or perceived) that go unnoticed or are improperly managed threaten the reputation and integrity of UCalgary, the ATSSL and of those involved. They can undermine the public's confidence in UCalgary's and the affected individual's ability to pursue and disseminate knowledge, devoid of bias and personal interests. In addition, failure to comply with accreditation or granting agency COI requirements may result in accreditation issues or the loss of substantial sources of research funding.

1.2. Purpose

This Operating Standard is intended to provide details of how institutional COI obligations, rules, and procedures apply as it relates to the ATSSL and its activities. This includes managing business relationships with private sector pharmaceutical, diagnostic, biotechnology, medical device, information communications, hospital and research equipment and supplies industries or other entities that do business with the intent or possibility of commercial gain (collectively, "Industry"). It is also intended to provide information, clarity, and guidance to ATSSL faculty, instructors, and staff regarding identifying, disclosing, and managing COIs.

2. SCOPE, APPLICATION & DEFINITIONS

2.1. Governing Policy Requirements

This Operating Standard is intended to provide a COI identification, disclosure, and management procedure consistent with the following:

UCalgary's <u>Code of Conduct</u>





- UCalgary's Research Integrity Policy
- Tri-Agency Framework: Responsible Conduct of Research
- Tri-Council Policy Statement 2 (2022) <u>Chapter 7 (Conflicts of Interest)</u> ("TCPS2")
- Accreditation standards by the Royal College of Physicians and Surgeons of Canada
- 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 Operating Standard supplements, but does not replace, the above governing policies and requirements. It should be read together with these requirements, and in the event of conflict, the applicable policies prevail. Importantly, it does not replace the TCPS2 requirement to disclose research conflicts of interest to the CHREB on ethics applications.

This Operating Standard may be amended and updated from time to time in UCalgary's sole discretion, in which case those to whom this Operating Standard applies will be notified.

2.2. Application

2.3. This Operating Standard applies to all persons connected with ATSSL to whom UCalgary's Code also applies. In brief, that includes academic staff members, clinical and adjunct appointees, and employees(collectively, an "Interested Person"). It also applies to those who are not Interested Persons, but who are involved in the design or implementation of simulation or educational activities in the ATSSL, as set out herein. Conflict of Interest Definition

As the Code definitions and requirements are inclusive of many of the other policy requirements and definitions listed in section 2.1 and are the most stringent and broadly applicable, all capitalized terms used in this Operating Standard shall have the same meaning as defined in the Code.

For the purposes of this Operating Standard, "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:

2.3.1. 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.

A "Private Benefit" means a personal benefit or furthering a private interest (including the avoidance of a negative consequence), but <u>does not</u> 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:

- i. 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;
- ii. a 'for-profit' private corporation of which the individual is a director or officer;





- iii. a 'for-profit' private corporation of which the individual is the beneficial owner of shares in the corporation;
- iv. a non-profit corporation or an association of which the individual is a director or officer; and
- v. 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:

- i. a parent, sibling and child of the individual;
- ii. ii. a spouse or domestic partner of the individual; and
- iii. iii. any other person who is directly associated with the individual.
- 2.3.2. 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. PROCESS AND PROCEDURE

3.1. Duty to Disclose - Ongoing

Any Interested Person must disclose the existence of any actual, potential, or perceived Conflict of Interest as soon as the Interested Person identifies that there may be a Conflict of Interest <u>and</u> before UCalgary or the Interested Person enter into any proposed transaction or arrangement that may give rise to the Conflict of Interest. This requirement to disclose is ongoing and is required each time a new actual, potential, or perceived Conflict of Interest arises. Each Interested Person using the ATSSL facilities will also be required to attest to their compliance with this Operating Standard upon booking.

Organizations or individuals who are not Interested Persons, but who are involved in the design or implementation of simulation or educational activities in the ATSSL, will be required upon booking to attest that they do not have a relationship with an Interested Person and are not aware of any Conflict of Interest; OR, that they are aware of a Conflict of Interest and confirm it has been disclosed by the appropriate Interested Person who has received an approved Conflict Management Plan as per the Operating Standard, and which has been shared with the Manager, ATSSL.





3.2. Form and Routing of Disclosure

The Interested Person must make all disclosures in accordance with the Code and <u>Procedure for Conflict of Interest</u>, which are routed to the Dean of CSM to review, and the Interested Person must also inform the Manager, ATSSL.

Disclosures for employees and appointees with PeopleSoft access can be made online as follows: Navigate to myUCalgary > All about me > Employee Self Service > Conflicts of Interest and follow the steps to complete the disclosure. Disclosures for those without online access can be made in writing and submitted to the Manager, ATSSL, who will forward to the Dean or delegate for review.

The Interested Person must disclose all material facts related to the Conflict of Interest and, where an actual, potential, or perceived Conflict of Interest exists, propose a plan that either eliminates the Conflict of Interest or sufficiently separates the interests in conflict to withstand reasonable and independent scrutiny ("Management Plan"). Management Plans must be compliant with all Code requirements, including guidelines on Concurrent Employment, Conflict of Commitment, Acceptance of Gifts, Use of University Resources, and Supervising Related Persons.

Once the disclosure is made, the Dean or his delegate will consult with ATSSL to review the proposed Management Plan, and will either approve, make edits to the Plan, or deny (in which case, the Interested Person will be directed to eliminate the Conflict of Interest). The Dean holds the ultimate authority to approve or deny proposed arrangements presenting a Conflict of Interest, based on whether the Conflict of Interest can be appropriately managed in accordance with Code requirements.

For more information regarding the Procedure and making a disclosure, please see these FAQs.

3.3. Management of a Conflict of Interest (Elements of a Management Plan Created by Dean or Delegate)

Conflicts of Interest will be managed in accordance with the Code and <u>Procedure for Conflict of Interest</u>, and in accordance with approved Management Plans. This means that when a disclosure is made, if the Dean or delegate determines the conflict can be managed, they will agree with the Interested Party on a Management Plan that may include steps or elements as set out below:

- 3.3.1. Educating Interested Persons about appropriate and inappropriate relationships with Industry in relation to ATSSL activities.
- 3.3.2. Informing ATSSL learners of a Conflict of Interest involving an Interested Person acting as an instructor or speaker at the beginning of any course or program.
- 3.3.3. Advising learners not to attend courses or programs sponsored by industry unless its primary purpose is for education or research, not to meet with representatives of industry unless accompanied by an instructor, and not to accept gifts from industry.





- 3.3.4. Altering the focus or topic of a course or program to address a Conflict of Interest, up to and including eliminating a topic, instructor, or speaker from the agenda. The ATSSL planning committee may ask for a peer review of the content of any course or program to ensure that the principles of scientific integrity, objectivity and balance have been respected.
- 3.3.5. Requiring ATSSL courses or programs supported financially by Industry to meet certain criteria, including but not limited to:
 - a) Requiring funding to be obtained through an unrestricted educational grant; and.
 - b) Requiring disclosure of the source of funding to learners in advance.
- 3.3.6. Requiring ATSSL courses or programs supported with equipment from Industry (on loan or in-kind donations) to meet certain criteria, including but not limited to:
 - a) Requiring disclosure of the source of the equipment to learners in advance;
 - b) Inviting all available providers of reasonably comparable equipment to participate to ensure a balanced presentation;
 - c) Asking learners to complete a post-session evaluation form which asks about the perceived biases from instructors in the session; and
 - d) Placing restrictions on the participation of Industry representatives in the course or program, including but not limited to:
 - i. Industry representatives may only assist in education or research activities relating to the equipment where no one else with expertise is available (e.g., to provide a demonstration on how to use the equipment); and,
 - ii. Industry representatives may never use the course or program as a venue for the sale or marketing of the equipment;

4. CONFIDENTIALITY

4.1. Confidentiality

The Interested Person and ATSSL shall maintain the confidentiality of any disclosures made in connection with this Operating Standard and limit access to the information in accordance with the UCalgary's privacy policies and all applicable privacy and access legislation.

The Interested Person and ATSSL shall exercise care not to use, publish or disclose confidential information acquired in connection with disclosures of actual, potential or perceived Conflicts of Interest during or subsequent to their employment with UCalgary.





5. VIOLATIONS OF OPERATING STANDARDS

5.1. Violations

If anyone has reasonable cause to believe that an Interested Person has engaged in a breach of this Operating Standard, or the governing policy documents as applicable (a "Wrongdoing"), a known or suspected Wrongdoing may be disclosed to the Protected Disclosure Advisor or an independent party in accordance with the Procedure for Protected Disclosure set out under the Code. The allegation of Wrongdoing will be investigated in accordance with that Procedure.

Where a finding of Wrongdoing is made, the Interested Party may be subject to discipline and remedial action. The Dean or Vice-Dean of CSM have authority to determine disciplinary or remedial action in accordance with the applicable Collective Agreement and any applicable governing policy requirements on remedial action required.