

Departmental Policy

Departmental Procedure Instructions/Forms

CUMMING SCHOOL OF MEDICINE

Disclosure and Management of Potential Conflicts of Interest in Relationships with Industry

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Latest Revision January 1, 2013		

Purpose

- An effective and principled partnership between Faculty Members, the faculty, and Industry is critical to realize fully the benefits of biomedical research and ensure continued advances in the prevention, diagnosis, and treatment of disease. Faculty members hold trust relationships with patients, research participants, students, funding partners and society. These trust relationships can be put at risk by potential Conflicts of Interest that may compromise independence, objectivity or ethical duties. The purpose of this policy is to present policies and procedures for disclosure of relationships with Industry with a goal of facilitating productive and ethical relationships to:
 - a) ensure that all Faculty Members disclose relationships with Industry;
 - b) promote a standard of conduct that will preserve and enhance public confidence in the integrity of the Faculty and assist its Faculty Members to identify, manage and resolve potential Conflicts of Interest;

- ensure that educational activities are designed to objectively address
 the learning needs of those for whom the program is intended and
 administered by organizers without influence from sponsors;
- d) ensure that research activities are designed with highest levels of academic standards and are not subject to inappropriate influence by industry sponsors;
- e) establish clear procedures for accepting funds and other donations, and for reporting and resolving potential and real Conflicts of Interest; and
- f) communicate expectations about Conflicts of Interest and disclosure that arise from accreditation bodies, key stakeholders (e.g., governments, health care organizations) and research funding agencies.

Scope 2 This policy applies to Faculty Members.

Definitions 3 In this policy

- a) "AHS" means Alberta Health Services.
- b) "Conflicts of Interest" occur when a Faculty Member or his/her immediate family have a significant financial or other personal consideration that may compromise or have the potential to compromise or have the appearance of compromising his or her professional judgment or integrity in clinical responsibilities, teaching, conducting or reporting research, or performing other obligations.
- c) "Educational Activities" include, but are not limited to, courses, lectures, seminars, symposia, workshops, simulation training, journal clubs, and rounds that are part of the formal or informal curriculum of a University educational program. Educational Activities offered through the Cumming School of Medicine include learners in the Bachelor of Health Sciences, Undergraduate Medical Education, Post Graduate Medical Education, Continuing Medical Education and Professional Development, and Graduate Science Programs.
- d) "Faculty Members" include full time and clinical/adjunct faculty members associated with the Cumming School of Medicine.
- e) "Faculty" means Cumming School of Medicine.
- f) "Family" means a Faculty Member's spouse or partner and dependent children or step-children.
- g) "Financial Interests" include interests in a business consisting of:

- a stock, stock option or similar ownership interest in such business, but excluding any interest arising solely by reason of investment in such business by a mutual, pension or other institutional investment fund over which the Member does not exercise control; or
- ii. receipt of, or the right or expectation to receive any income from, such business (or from an agent or other representative of such business) whether in the form of a fee (e.g., consulting), salary, allowance, forbearance, forgiveness, interest in real or personal property, dividend, royalty derived from the licensing of technology, rent, capital gain, real or personal property or any other form of compensation or any combination thereof.
- h) "Gifts" means items of any value that are given to a Faculty Member (or Family member) by a business or individual that does or seeks to do business with the Faculty Member and for which the Faculty Member has neither paid nor provided services.
- i) "Industry" includes private sector pharmaceutical, diagnostic, biotechnology, medical device, information communications, hospital and research equipment and supplies industries. It includes entities that do business with the intent of or possibility of commercial gain. It includes organizations such as banks, insurance companies and other financial institutions which may benefit from a relationship with the Faculty or Faculty Members. It does not include Alberta Health Services or government.
- j) "Ownership Interest" includes holding of stock, ownership or partownership or other financial interest in a business, including arrangements to receive royalties under institutional royalty-sharing policies.
- k) "Research Activities" include but are not limited to clinical trials, basic research, proof of concept and beta testing of processes and devices and other contracted services.
- "Research Sponsors" means Industries that sponsor research, training and instructional projects involving funds, materials, or other compensation from outside sources under agreements.
- m) "University" means the University of Calgary.

Policy Statement

4 Principles

- **4.1** Faculty Members will act in the best interests of learners, patients, research participants and the University.
- **4.2** Faculty Members will not exercise their duties and functions if they have Conflicts of Interest unless those Conflicts have been disclosed, mitigated, and/or managed appropriately.

- **4.3** Faculty Members will ensure that their participation in collaborative efforts with Industry is in keeping with their primary obligation to their patients, students and society. They will declare and manage Conflicts of Interest in accordance with the policy and guidelines in this document.
- **4.4** Faculty members will not accept gifts from Industry.
- **4.5** Faculty Members are responsible for the content of their scholarly work (e.g., presentations, lectures, posters, social media, abstracts, publications).

Duties of Faculty Members

- **4.6** Faculty Members have a duty to:
 - a) disclose potential Conflicts of Interest;
 - b) mitigate and/or manage any circumstances that could give rise to potential Conflicts of Interest.

Disclosure

- **4.7** Faculty Members will disclose potential Conflicts of Interest in accordance with the procedures.
- **4.8** The disclosure will include the sources of all Financial Interests or ownership interests in Industry in areas related to practice, education, research or other professional activity.
- **4.9** Department Heads, Institute Directors, Associate Deans and others who receive funding on behalf of the University (e.g., grants for educational activities, educational programs, equipment, renovations etc.) will submit a list of funds received and the purpose for which they were received to the Dean annually.

Management Committee on Conflicts of Interest

- **4.10** The Dean will appoint a Management Committee on Conflicts of Interest with representatives from clinical, education, administrative, and research sectors of the Faculty and other groups as appropriate.
- **4.11** Faculty members, Department Heads or the Dean may consult the Management Committee on Conflicts of Interest on matters relating to disclosure, management and resolution of Conflicts of Interest.

Violations

4.12 Violators of this policy may be subject to penalties under University regulations, collective agreements, and provincial and federal law.

Responsibilities

- 5 Approval Authority (Dean, Cumming School of Medicine)
 - Ensure appropriate rigor and due diligence in the development or revision of this policy.

Faculty Member

- Read and apply the Policy, Guides, and act accordingly.
- Provide disclosure information.

Implementation Authority

- Ensure that Faculty Members are aware of and understand the implications of this policy and related procedures;
- Collect and maintain annual disclosure statements;
- Monitor compliance with the policy and related procedures;
- Regularly review the policy and related procedures to ensure consistency in practice; and
- Sponsor the revision of this policy and related procedures when necessary.

Appendices

- **6** Appendices
 - 1. Management Committee on Conflicts of Interest
 - 2. Guide to Disclosure of Conflicts of Interest and Educational Activities
 - 3. Guide to Disclosure of Conflicts of Interest and Research
 - 4. Guide to Meetings with Industry Representatives
 - 5. Guide to Authorship and Use of Industry Materials

Instructions/Forms

7 Conflict of Interest Disclosure Form

Parent Policy

8 University of Calgary Code of Conduct

Related Policies

9 Intellectual Property Policy

Policy on Outside Professional Activity

Faculty of Graduate Studies Conflict of Interest Policy

<u>Conflict of Interest: Instructions for US Public Health Services Funding Disclosure of FCOI</u>

References

- 10 Provincial, National and International
 - Association of American Medical Colleges (AAMC), Industry Funding of Medical Education: Report of an AAMC Task Force. June 2008
 - College of Physicians and Surgeons of Alberta, Relationships with Industry, Standard 38, January 2010
 - <u>Tri Council Policy Statement concerning Ethical Conduct for Research</u> involving Humans, (Dec 2010)
 - <u>Canadian Association for Graduate Studies (CAGS)</u>, A guide to intellectual property for graduate students and postdoctoral scholars
 - CMA Policy, Guidelines for physicians in interactions with Industry, 2007

History

11 Approved: Executive Faculty Council, November 14, 2012

Approved: Cumming School of Medicine Council, December 12, 2012

Effective: January 1, 2013

Minor modifications to conform with University policy structure. February 11, 2014

The electronic version is the official version of this policy. February 11, 2014