

Canada's Drug Agency
L'Agence des médicaments du Canada

Conflict of Interest Policy

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Effective/Revised Date: October 1, 2022

Review Period: Every 3 years

Version: 1.0

Conflict of Interest Policy

Definitions

In this policy document:

- **“bias”** means when an individual has an inclination or prejudice for or against someone or something (may be conscious or unconscious bias).
- **“contractor”** means, unless otherwise stated, any person that has entered into a contract for services with the organization to assist in its activities (e.g., lead reviewers, peer reviewers, researchers, economists, methods specialists, information specialists, copy editors, etc.).
- **“contributor”** means an individual who provides a particular perspective on a project as part of a prescribed process, and who is not remunerated (e.g., patient group, patient or caregiver, clinician or other stakeholder providing input on a project).
- **“entity”** means any organization that has legal capacity to enter into agreements or contracts, assume obligations, incur and pay debts, sue and be sued in its own right, and to be held responsible for its actions.
- **“guest speaker”** means an invited presenter who is not an employee.
- **“participant”** means an individual who has been invited on an ad hoc basis to attend a committee meeting or other meeting (e.g., subject matter expert).
- **“party”** means a drug or health technology company (including such manufacturer's parent corporation, subsidiaries, affiliates, and associated corporations).
- **“payment”** means a benefit, compensation, discharge or performance of an obligation, or reimbursement, by giving over something that is of satisfactory value to its recipient, such as money or its equivalent.
- **“project”** means the activity in which an individual is, or will be, engaged.

Conflict of Interest Policy

Applicability

1. This policy applies to the Canada's Drug Agency (CDA-AMC):
 - Board of Directors
 - Employees and candidates for employment
 - Members of advisory or expert committees or panels
 - Participants
 - Contributors
 - Contractors, consultants, and temporary agency personnel
 - Guest speakers.

Purpose

2. This policy supports our core value of transparency. We are transparent about the interests of those who are engaged and involved in our work and our governance so that the effect of interests is known, understood, and managed.
3. This policy describes the approach that the organization shall apply to the management of a conflict of interest; specifically, it sets out the responsibilities for identifying and managing conflicts of interest to promote high ethical standards and preserve the objectivity and credibility of the organization's work.

Policy Statement

4. This policy provides guidance on:
 - when a declared interest could represent a conflict of interest
 - what types of interests need to be declared and when
 - how conflicts may be managed.
5. Through the disclosure of relevant personal and non-personal interests (including both financial and non-financial), conflicts of interest can be identified and managed. This policy is intended to supplement but not replace any provincial and federal laws governing conflicts of interest, if applicable. For example, directors and officers are subject to additional rules under the organization's governing statute.
6. All interests must be declared if, in the view of a reasonable person, they are relevant, or could be perceived to be relevant to the organization's mandate, activity in question or anticipated future activity, as may be applicable.

Conflict of Interest Policy

Scope of Conflict of Interest

7. A conflict of interest is any situation in which an individual has or is perceived to have a personal, non- personal or other relevant interest sufficient to bias, influence, or appear to influence, the objective exercise of that individual's CDA-AMC-related duties, responsibilities, or decision-making.
 - A **personal interest** may be a benefit, in any form, to an individual by a party or entity whose business may be directly affected by CDA-AMC advice or other decisions taken by CDA-AMC. This benefit is interpreted broadly and means anything relating to an individual's interests (regardless of value) now or in the future. Personal interests usually fall into the following categories:
 - **Financial interests:** These may include any monetary interests gained like salary or other payments for services (e.g., stipends, honoraria, speaker's fees), or equity interests (e.g., stocks, stock options, intellectual property rights), and the like.
 - **Non-financial interests:** These cover other kinds of potential gain (e.g., increase in reputation if a former student receives an award).
 - **Loyalties:** These arise from a personal connection or duty to another person or organization (e.g., with a past employer, past student, family member, close colleague, or frequent collaborator).
 - A **non-personal interest** is where there is, or could be perceived to be, an opportunity for a third party closely associated with an individual to benefit as a result of that individual's role at CDA-AMC.
 - There may be a wide range of **other interests** with a party or entity that are relevant, depending on the circumstances and matters under consideration, and could include both financial and non-financial interests. Other relevant interests could include intellectual interests; for example, holding a strong view in a specific topic area that could interfere with one's role or duty to be objective.
8. A conflict of interest may be real, potential, or perceived in nature.
 - A **real conflict** arises where an individual involved in CDA-AMC's work has an interest that could compromise their objectivity or fairness.
 - A **potential conflict** incorporates the concept of foreseeability; for example, when an individual can foresee that an interest may someday be sufficient to influence their work at CDA-AMC, but has not yet influenced their work (e.g., an identified future commitment with a party or with another entity).

Conflict of Interest Policy

- A **perceived (or apparent) conflict** arises where a person's duties or responsibilities to CDA-AMC appear to be influenced by that person's interests, even if, in fact, there is neither a real nor a potential conflict.

Conflict of Interest Reporting Requirements

9. It is the responsibility of each individual to declare any conflicts of interest in accordance with this policy. Each individual has the responsibility to identify and manage conflicts of interest by:
 - Disclosing any interests that could give rise to a conflict of interest so that the organization is aware of these in advance.
 - Working with the organization to determine whether a situation gives rise to a conflict of interest before being involved in any decision or project on behalf of CDA-AMC.
 - Working with the organization to manage any conflicts as they arise, in a manner that protects the integrity of CDA-AMC's work and decision-making while allowing the individual to give the right level of input to enable the best decision to be made.
10. Before an individual engages with or participates in any CDA-AMC activity, the individual must disclose any real, potential, or perceived conflict of interest by completing and submitting a Conflict of Interest Declaration Form in the form and manner prescribed by the organization.
11. All individuals described in the section on Applicability must:
 - Complete the declaration form and update the declaration as soon as new conflicts are identified. Where new conflicts are identified, declaration forms must be updated immediately, and no later than 15 calendar days after the conflict arises.
 - Review the information previously declared, yearly at a minimum. Contributors, contractors, guest speakers, and participants must complete or verify and update the declaration form for each CDA-AMC project or activity that the individual is involved in within the organization.
12. In addition to updating the declaration form, members of the Board of Directors and members of advisory committees, expert committees and panels are required, at the commencement of every meeting, to disclose any new conflicts of interest.

General Principles for Assessing Conflicts

13. The organization is not precluded from obtaining advice from experts who may have interactions and or relationships with individuals who have a vested interest in a CDA-

Conflict of Interest Policy

AMC project. It is recognized that, in many cases, there may be a small pool of experts who have the relevant expertise and who are able to effectively advise CDA-AMC on these matters.

14. It is acknowledged that individuals have varied backgrounds, ideas, personal experiences and influences that may affect how they view or react to someone or something. In certain instances, it may be advisable, or even essential that individuals contribute their experience, expertise and/or knowledge to the resolution of the issues at hand. Expertise in an area, or familiarity with the relevant issues, is not in and of itself a disqualification on account of conflict of interest nor is the holding of tentative views on a matter of relevance to a committee's or panel's mandate; however, a bias capable of unfairly affecting the outcome of the case is considered a conflict of interest.
15. Where a conflict is identified, the organization will work with the individual to assess the conflict. This will involve assessing all the relevant factors on a case-by-case basis, including:
 - The role of the individual in a decision-making process (e.g., if the individual is an observer with no right to vote, the conflict is less material than if the individual is a committee member or chair).
 - The nature of the conflicting interest (e.g., a conflict based on a relationship to a past employer is less material than a conflict that could lead to a direct financial gain).
 - The closeness of the conflicting interest to the individual (e.g., if it relates to a grant co-applicant, it is less material than to a principal applicant).
 - The value and nature of any benefit the individual could receive from the proposal being considered (e.g., a conflict involving a large financial gain relating to advice on a relevant product will be more material than one involving an honorarium for travel to a conference).

General Principles for Managing Conflicts

16. In general, the organization will not engage in an activity where there is a material conflict unless it can be managed or structured to avoid the conflict, or the decision can be made by the Board or a committee that has sufficient members without the individual being involved.
17. Dependent on both the nature of the conflict and structure of the activity, the organization may consider measures including, but not limited to:
 - Having the individual abstain from participation in discussions or deliberations.

Conflict of Interest Policy

- Recusing the individual from voting or decision-making.
 - Requesting that the individual conclude involvement in the conflicting matter.
 - Using a different service provider.
18. Exceptions may be made in situations where the organization believes a particular activity is sufficiently compelling (e.g., meets a pressing health system need or is in the best interest of the organization).

Publication of Conflict of Interest Declarations

19. As part of the organization's commitment to enhance transparency of its processes and operations, conflict of interest declarations may be made publicly available on the CDA-AMC website if such public disclosure is not prohibited by law, and CDA-AMC determines, in its sole discretion, that such public disclosure is in the best interest of the organization and the person or persons to whom the conflict relates. Such information may include the individual's title, name, organization (if applicable), nature of their affiliation with the organization (e.g., Board of Directors, advisory committee, expert committee or panel members, contributors, contractors, etc.), and the nature of declared conflicts of interest.
20. If an individual has contributed expertise or authored a CDA-AMC publication, a summary of the individual's expertise, experience, affiliations, and the nature of the conflict of interest may be included in that publication.

Monitoring

21. There may be situations when interests will not be identified, declared, or managed appropriately and effectively. This may happen innocently, accidentally or because of deliberate actions. Anyone who is aware of a contravention with this policy, or who is concerned that there has been, or may be, an issue of non-compliance, should follow the steps as set out in the Supplemental Conflict of Interest Guidance document, and may report these concerns via email at requests@cda-amc.ca if there is not a satisfactory resolution.
22. The organization will examine each reported instance of potential contravention according to its specific facts and merits and will provide relevant parties the opportunity to respond and amend the declaration, as appropriate.

Conflict of Interest Policy

Related Forms and References

23. Related documents:

- [Supplemental Conflict of Interest Guidance document](#)
- Conflict of Interest Declaration Form

Board of Directors

24. Amendments to this policy are subject to approval of the Board of Directors. Amendments to and clarifications of the Policy and all related documents will be posted on the website.

Policy Owner and Review Period

25. The Vice-President, Corporate Strategy and Services is responsible for overseeing the implementation of this policy. The policy will be reviewed every 3 years unless an earlier review is needed.

Corporate Contact

Please direct any questions or requests for changes to this policy to the Director, Strategy and Governance, at jocelyn.chisamore@cda-amc.ca.

Conflict of Interest Policy

Revision History Table

Section	Description of Changes	Prepared/ Updated By	Date
All	New Harmonized Policy Introduced Note: This policy replaces 5 policies (Board Conflict of Interest, Conflict of Interest Policy for Employees, Conflict of Interest Guidelines for Expert Committee and Panel Members, Conflict of Interest Guidelines for Contractors, Patient Group Conflict of Interest Declaration).	Governance	October 1, 2022
	Approved by the Board.		June 16, 2022
All	Policy template updated.	Governance	December 19, 2023
All	Policy template updated.	Governance	July 1, 2024