

## **1.0 Purpose of the Guidelines**

- 1.1 These *Conflict of Interest (COI) Guidelines* are intended to ensure the highest ethical standards and maintenance of the integrity of the research undertaken by and/or sponsored by CADTH. The principles of transparency and disclosure are essential to achieving these objectives. By disclosing relevant personal, occupational, or financial connections or interests with a Party (defined in section 2.3), Participants in CADTH activities will ensure that conflicts of interest are identified and resolved, thereby preserving the objectivity and credibility of CADTH programs and processes.

## **2.0 Definitions**

In these *COI Guidelines*:

- 2.1 “HTA agency” means, unless otherwise stated, a not-for-profit organization that evaluates health technologies, including drugs, for the betterment of health outcomes. The agency can reside in any country in the world.
- 2.2 “Participant” means, unless otherwise stated, contractors, reviewers, patient representatives, committee members, panel members, and any experts and consultants retained to assist in CADTH activities.
- 2.3 “Party” means a drug or health technology manufacturer (including such manufacturer’s parent corporation, subsidiaries, affiliates, and associated corporations).
- 2.4 “Project” means the CADTH activity in which the Participant is, or will be, engaged.
- 2.5 “CADTH Scientific Advice Program” means a voluntary, fee-for-service consultation for pharmaceutical companies. Through this Program, CADTH offers advice on early drug development plans from a health technology assessment perspective.

## **3.0 Applicability**

- 3.1 These *COI Guidelines* apply to all Participants.

## **4.0 Scope of Conflict of Interest**

- 4.1 A COI refers to situations in which personal, occupational, or financial considerations, either direct or indirect, may affect, or appear to affect, the objectivity or fairness of Participants in a CADTH Project. A COI may be real, potential or perceived in nature.

- 4.2 A real COI arises where a Participant in the CADTH Project has a financial or other personal interest with a Party that may compromise, or have the appearance of compromising, their work on the Project (for example, a close family connection such as a spouse or child, or financial interest, with a Party).
- 4.3 A potential COI incorporates the concept of foreseeability; i.e., when a Participant in the CADTH Project can foresee that a private or personal interest may someday be sufficient to influence their work on the Project, but has not yet influenced their work (for example, an identified future commitment with a Party).
- 4.4 A perceived (or apparent) COI may exist when there is a reasonable apprehension, which a reasonably well-informed person could reasonably have, that a Participant has a COI, even if, in fact, there is neither a real nor a potential conflict.

## 5.0 Disclosures

- 5.1 Before a Participant undertakes any Project on behalf of CADTH, the Participant must disclose any COI, as described in section 4.0, by completing and submitting a *Conflict of Interest Disclosure Form* in the form and manner prescribed by CADTH.
- 5.2 All Participants must complete the *COI Disclosure Form* annually. **However, the obligation to disclose is ongoing and Participants must inform CADTH of any COI that arises during the period of their engagement with CADTH as soon as it is known to them.**

### 5.3 Schedule 1 Disclosures

- 5.3.1 Without limiting the generality of the foregoing, Participants are required to disclose to CADTH all interests or activities that occurred during the past two (2) years in which they, their immediate family members, or the department or organization for which they have managerial responsibility, benefited. Information shared may pertain to:
- i) receipt of gifts from a Party
  - ii) receipt from a Party of funding for, or payment of, travel
  - iii) receipt of funding or honoraria from a Party for speaking engagements
  - iv) receipt of funding or honoraria from a Party for giving educational lectures
  - v) receipt of funding or honoraria from a Party for organizing conferences
  - vi) receipt of funding or honoraria from a Party for writing articles or editorials
  - vii) receipt of any other financial support or honoraria from a Party.

## 5.4 **Schedule 2 Disclosures**

5.4.1 Without limiting the generality of the foregoing, Participants are required to disclose to CADTH all interests or activities that occurred during the past five (5) years in which they, their immediate family members, or the department or organization for which they have managerial responsibility, benefited. Information shared may pertain to:

- i) employment with a Party
- ii) receipt of payment as an advisor or consultant for a Party
- iii) receipt of funding or honoraria from a Party for research grants
- iv) receipt of payment from a Party for academic appointments (including endowed chairs)
- v) receipt of funding or honoraria from a Party for personal education.

5.4.2 Participants are required to disclose all of their stocks or stock options (related to a Party) totalling more than \$10,000 (excluding mutual funds).

## 5.5 **Schedule 3 Disclosures**

5.5.1 In addition to Disclosures made under sections 5.3 and 5.4, Participants are required to disclose to CADTH any other activities or interests that affect or appear to affect the Participant's objectivity or fairness.

5.5.2 Participants are required to disclose all potential or pending future commitments with a Party. The information to be disclosed relates to all interests and activities as described in Schedule 1 and Schedule 2 Disclosures outlined in sections 5.3 and 5.4.

## 5.6 **Schedule 4 Disclosures**

5.6.1 Participants are also required to disclose any activity with the CADTH Scientific Advice Program or any similar international programs. This disclosure is required for any work that CADTH may perform in the future related to drugs that have received advice from these programs. This disclosure includes all past, potential and/or pending future commitments.

## 6.0 **COI Resolution**

6.1 The CADTH executive have the authority to determine if the circumstances or interests of a Participant amount to a COI with respect to work being undertaken by CADTH.

6.2 The CADTH executive have the authority to remove a Participant from the Project when it is deemed that the COI(s) impede the Participant's objectivity (real or perceived) on the Project.

## **7.0 Confidentiality of Conflict of Interest Declarations**

7.1 Unless the Participant has been advised of, and agreed in advance to, a planned exception to this policy, the content of each completed Conflict of Interest Disclosure Form, and the declaration of conflicts disclosed to CADTH, shall remain confidential to:

- i) the CADTH executive or their designates
- ii) the Chair of the CADTH Board
- iii) members of CADTH Committees and Panels.

7.1.1 If the Participant has contributed expertise or acted in an authorship role to a CADTH publication, a summary of the Participant's COI declaration may be included in that publication. The Participant will be advised in advance of CADTH's intention to publish this information.

## **8.0 Amendment to the COI Guidelines**

After appropriate consultation, the COI Guidelines may be amended at any time by CADTH.

By email: [patrickc@cadth.ca](mailto:patrickc@cadth.ca) or fax #: 613 226 5392, Attention: Contracts

## **Conflict of Interest Disclosure Form (CADTH Contractor)**

I have read and understood the *Conflict of Interest (COI) Guidelines* and I agree to be bound by the obligations contained therein. I understand that it is my responsibility to report to CADTH any real, potential, or perceived conflicts of interest as defined in the *CADTH COI Guidelines*, and to disclose the information requested in the *COI Guidelines*.

I understand that this information may be shared with:

- i) the CADTH executive or their designates
- ii) the Chair of the CADTH Board
- iii) members of CADTH Committees and Panels.

I also understand that the information disclosed will not be made public unless otherwise agreed to (see section 7.0), and will be retained on file by CADTH.

I have reviewed my activities and interests as they relate to the matters itemized in the Disclosures section (section 5.0) of the *COI Guidelines*. Attached in Schedules 1, 2, 3, and 4 is a list of those activities and interests.

I hereby certify that I have disclosed all relevant information, with respect to any matter involving a Party, that may place me in a real, potential, or perceived COI situation. Except as otherwise disclosed in Schedules 1, 2, 3, and 4 attached, I declare that I have no COI to report, as defined in the *COI Guidelines*.

I promise to inform CADTH of any change in circumstances that may create a COI as soon as it is known to me.

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Date

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Print Name

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Signature

## Conflict of Interest Disclosure Form — Schedule 1

(Reference: COI Guidelines Section 5.3)

Disclosures are required under section 5.3 of the *Conflict of Interest Guidelines* for those activities or interests involving any Party during the past **two (2)** years that benefited the Participant, their immediate family members, or the department or organization for which they have managerial responsibility, particularly as the activities relate to the following areas (add pages, as necessary):

*For each Party and drug, technology, or topic, identify the type of funding or benefit received and indicate the total value (dollar range).*

Name of Party <i>(see section 2.3 for definition)</i>	Drug, technology, or topic involved, and year of funding	Check (✓) type of benefit, as appropriate						Check (✓) dollar range, as appropriate			
		Gifts	Travel funding or payment	Funding or honoraria for:				Value of funding or benefit			
				Speaking engagements	Educational lectures	Organizing conferences	Writing articles or editorials	Other* (see below)	\$0 to \$5,000	\$5,001 to \$10,000	\$10,001 to \$50,000

\*OTHER GIFTS/FUNDING/HONORARIA: PLEASE PROVIDE DETAILS


I do not have any declarations for Schedule 1.

\_\_\_\_\_ Date

\_\_\_\_\_ Print Name

\_\_\_\_\_ Signature

## Conflict of Interest Disclosure Form — Schedule 2

(Reference: COI Guidelines Section 5.4)

Disclosures are required under section 5.4 of the *Conflict of Interest Guidelines* for those activities or interests involving any Party during the past **five (5)** years that benefited the Participant, their immediate family members, or the department or organization for which they have managerial responsibility, particularly as the activities relate to the following areas (add pages as necessary):

*For each Party and drug, technology, or topic, identify the type of funding or benefit received, and indicate the total value (dollar range).*

Name of Party <i>(see section 2.3 for definition)</i>	Drug, technology, or topic involved, and year of funding	Check (✓) type of benefit/interest, as appropriate						Check (✓) dollar range, as appropriate			
		Employment	Payment as Advisor or Consultant** (see below)	Research funding or grants	Payment for academic appointments (endowed chairs)	Personal education funding	Stocks or stock options of more than \$10,000 (excluding mutual funds)	Value of benefit or interest			
								\$0 to \$5,000	\$5,001 to \$10,000	\$10,001 to \$50,000	Over \$50,000

\*\*PAYMENTS AS ADVISOR/CONSULTANT: PLEASE PROVIDE DETAILS


I do not have any declarations for Schedule 2.

\_\_\_\_\_ Date

\_\_\_\_\_ Print Name

\_\_\_\_\_ Signature

## Conflict of Interest (COI) Disclosure Form — Schedule 3

*(Reference: COI Guidelines Section 5.5)*

List those activities or interests involving a Party (not already listed in Schedules 1 and 2) that may affect or appear to affect the Participant's objectivity or fairness (as outlined in Section 5.5.1); for example, employment of spouse or child; financial interest or investment in business enterprise or corporation; lobbying or promotional activities; or any other interest, relationship, or activity that may create a reasonable apprehension of a COI.

Name of Party <i>(see section 2.3 for definition)</i>	Nature or description of activities or interests	<i>Check (✓) as appropriate</i>			
		Financial value of benefit or interest (if any)			
		\$0 to \$5,000	\$5,001 to \$10,000	\$10,001 to \$50,000	Over \$50,000

List those activities or interests involving a Party with whom the Participant has a potential or pending future commitment (as outlined in Section 5.5.2). Provide details on the nature of the commitment.

Name of Party <i>(see section 2.3 for definition)</i>	Nature and timing of the future commitment	<i>Check (✓) as appropriate</i>			
		Financial value of benefit or interest (if any)			
		\$0 to \$5,000	\$5,001 to \$10,000	\$10,001 to \$50,000	Over \$50,000

**I do not have any declarations for Schedule 3.**

\_\_\_\_\_ Date

\_\_\_\_\_ Print Name

\_\_\_\_\_ Signature



By email: [patrickc@cadth.ca](mailto:patrickc@cadth.ca) or fax #: 613 226 5392, attention: contracts

## Conflict of Interest Disclosure Form — Schedule 4

(Reference: COI Guidelines Section 5.6)

CADTH considers it to be a perceived COI for a Participant or CADTH staff member who has participated in developing Scientific Advice for a given drug to later participate in a review for the same drug when submitted to CADTH through the Common Drug Review (CDR) program.

Activities that are considered in conflict are:

- attendance at the face-to-face Scientific Advice meeting
- viewing the written Scientific Advice produced for a drug.

**There is no time limit for having performed these activities. This includes all past, potential, and/or pending future commitments.**

Year participated	<i>Check (✓) as appropriate</i>	
	Participated in Scientific Advice Program of:	
	CADTH	International HTA Agency

I do not have any declarations for Schedule 4.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Signature