Conflict of Interest Guidelines for CADTH Expert Committee and Panel Members

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 work undertaken by CADTH. The principles of transparency and disclosure are essential to achieving these objectives. By disclosing relevant personal, occupational, professional or financial relationships with, or interests in, a Party (all as defined in section 2.2), participants in CADTH activities will ensure that conflicts of interest are identified and resolved, thereby preserving the objectivity and credibility of CADTH's programs and processes.

2.0 Definitions

- 2.1 In these COI Guidelines, the word "Member" means, unless otherwise stated, a committee or panel member who is appointed in accordance with the specific Terms of Reference of a CADTH committee or panel. CADTH is not precluded from appointing experts, as Members of the Committee, who may have interactions and/or relationships with one or more Parties (as defined below).
- 2.2 In these COI Guidelines, the word "**Party**" means an individual, corporation, entity, association or organization, which has an interest in CADTH's recommendations. "**Parties**" has a corresponding meaning.

2.3 A Member has a "personal interest" where:

- a) the Member or a related person
 - i) has an affiliation or association with, or membership in, any group, organization or special interest group of relevance to the Committee's or Panel's mandate;
 - ii) has a non-arm's length relationship with any group, organization or special interest group of relevance to the Committee's or Panel's mandate;
- b) a related person has a financial, occupational or professional relationship with, or interest in a Party.
- 2.4 "Arm's length" means the relationship which exists between parties who are strangers to each other, and who bear no special duty, obligation or relation to each other.

- 2.5 A "**related person**" is a spouse, a partner or an immediate family member of the Member.
- 2.6 A person has an "occupational relationship" with a Party where the person is an employee of, or engaged by, such Party.
- 2.7 A person has a "**professional relationship**" with a Party including, without limitation, in situations where the person is providing advice to the Party, with or without remuneration.
- 2.8 A person has a "bias" when he/she has an inclination or prejudice for or against someone or something.
- 2.9 A person has a "**professional opinion**" when he/she has a view, judgment, or assessment about a particular matter formed on the basis of prior academic knowledge or an objective conclusion based on a research project.

3.0 Applicability

3.1 These COI Guidelines apply to all Members.

4.0 Scope of Conflict of Interest

- 4.1 A conflict of interest refers to situations in which personal, occupational, professional or financial considerations, either direct or indirect, may affect or compromise, or appear to affect or compromise, an individual's objectivity, fairness or professional judgment in carrying out his/her duties as a Member of a CADTH committee or panel.
- 4.2 A conflict of interest may be real, potential or perceived in nature.
 - a) A real conflict of interest arises where a Member has a bias, or a personal, occupational, professional or financial relationship with, or interest in, a Party, which may affect or compromise, or appear to affect or compromise, his/her work with CADTH.
 - b) A potential conflict of interest incorporates the concept of foreseeability: when a Member can foresee that a private or personal interest may someday be sufficient to influence his/her work with CADTH, but has not yet (for example, an identified future commitment with a Party).
 - c) A perceived or apparent conflict of interest may exist when there is a reasonable apprehension, which a reasonably well-informed person could properly have, that a conflict of interest exists, even if, in fact, there is neither a real nor a potential conflict.

- 4.3 It is acknowledged that individuals have varied backgrounds, ideas, biases and personal experiences and influences that may colour 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 of itself a disqualification on account of conflict of interest nor is the holding of tentative views on a matter of relevance to the Committee's mandate. However, a bias capable of unfairly affecting the outcome of the case will lead to a conflict of interest.
- 4.4 The following are meant to illustrate examples of conflicts of interest and are not meant to be exhaustive:
 - a) A Member has a pecuniary or financial interest in a decision when he/she stands to gain or lose by that decision, either in the form of money, gift, favour or other special consideration
 - b) A Member has a private or personal interest sufficient to impair, influence or appear to influence the objective exercise of his/her official duties as a Member;
 - c) A Member is a party to a claim, application or proceeding for or against CADTH;
 - d) A member uses CADTH confidential information for his/her own purpose or benefit or the benefit of a friend or family member or knowingly divulges CADTH confidential information to any person other than another Member, unless the disclosure is required by law.

5.0 Disclosures

5.1 Before a Member participates in any CADTH activity, the Member must disclose any conflict of interest, as described in section 4.0, by completing and submitting a Conflict of Interest Disclosure Form in the form and manner prescribed by CADTH. All Members must complete the COI Disclosure Form at least annually. However, the obligation to disclose conflicts of interest is ongoing and Members must inform CADTH of any conflict of interest that arises during the period of their Committee or Panel commitment as soon as it is known to them. The Member is required to forward an updated COI Disclosure form to CADTH immediately following such notification.

5.2 In addition to the foregoing, Members will be required, at the commencement of every Committee or Panel meeting to disclose any conflict of interest, as described in section 4.0.

5.3 Schedule 1 Disclosures

- 5.3.1 Without limiting the generality of the foregoing, Members are required to disclose to CADTH, by completing the attached Schedule 1, all interests or activities that occurred during the past three (3) years in which they or a related person benefited. Information to be disclosed includes, but is not limited to:
 - i) receipt of gifts, favours or hospitality 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, honoraria or gift from a Party.

5.4 Schedule 2 Disclosures

- 5.4.1 In addition to other disclosures made under these Guidelines, and without limiting the generality of the foregoing, Members are also required to disclose to CADTH, by completing the attached Schedule 2, all interests or activities that occurred during the past three (3) years in which they or a related person benefited. Information to be disclosed includes, but is not limited to:
 - i) employment or engagement 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;
 - 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.

- vi) receipt of funding from a Party for an unrestricted grant.
- vii) other financial interests which include securities (including stocks, shares, stock options and warrants, but excluding mutual funds managed by a person or persons with whom the Member deals at arm's length) or ownership interest held in a Party.

5.5 Schedule 3 Disclosures

- 5.5.1 In addition to disclosures made under these Guidelines, and without limiting the generality of the foregoing, Members are required to disclose to CADTH, by completing the attached Schedule 3, any other activities, affiliations or interests in the past three (3) years that affect or compromise, or may appear to affect or compromise, the Member's objectivity, fairness or professional judgment in carrying out their duties as a Member of a CADTH Committee or Panel.
- 5.5.2 The interests to be listed in Schedule 3 include, but are not limited to:
 - i) advice to, or close association with, a Party;
 - ii) professional relationship with a Party,
 - iii) the Member's participation as investigator in clinical trials of relevance to the Committee's or Panel's mandate;
 - iv) professional opinions (as defined in section 2.9) expressed publicly by the Member of relevance to the Committee's or Panel's mandate;
 - v) the Member's involvement in the promotion of a product of relevance to the Committee's or Panel's mandate;
 - vi) papers written by the Member of relevance to the Committee's or Panel's mandate;
 - vii) the Member providing expert testimony in Court in regard to a matter of relevance to the Committee's or Panel's mandate;
 - viii) the Member's affiliation with, association with, or membership in, any group, organization or special interest group of relevance to the Committee's or Panel's mandate;
 - ix) lobbying activities on the part of the Member of relevance to the Committee's mandate:
- 5.5.3 In addition, Members are required to disclose in Schedule 3 all potential or pending future commitments with a Party.

6.0 Principles for Dealing with COI

- 6.1 If the Member is not certain whether he/she is in a conflict of interest position, the matter may be brought to the attention of Committee Chair or the CADTH Executive Team member responsible for the Committee or Panel for advice and guidance.
- 6.2 If there is any question or doubt about the existence of a conflict of interest, the Committee Chair in conjunction with a CADTH Executive Team member shall determine whether a conflict exists. Such determination shall be final.
- 6.3 A number of committee or panel governance models may be used to facilitate the work of a Committee or Panel. In the event that a Committee or Panel uses a Chair and Vice Chair model, section 6.3.a) shall apply. Should the Committee or Panel use a co-Chair model, 6.3.b) shall apply.
 - a) Chair and Vice Chair Model: The Chair of committee or panel meetings should have no conflict of interest in connection with any matter relevant to the Committee's or Panel's mandate. Except as otherwise provided herein, the Committee or Panel Chair chairs all meetings of the Committee or Panel. In the absence of the Chair, the Vice Chair shall act in his/her stead. The determination of whether the Chair or Vice Chair, as applicable, has a conflict of interest shall be determined by the CADTH President and CEO. If it is determined that the Chair or Vice Chair, as applicable, has a conflict of interest on a matter relevant to the Committee's or Panel's mandate, he/she shall not participate in any deliberation or vote in respect of such matter. In the event that both the Chair and Vice Chair have a conflict of interest, the CADTH President and CEO shall appoint the chair of the meeting.
 - b) Co-Chair MODEL: The Co-chair(s) of meetings should have no conflict of interest in connection with any matter relevant to the Committee's mandate. Except as otherwise provided herein, the Co-Chairs chair all meetings of the Committee. In the absence of one Co-Chair, the other Co-Chair shall be the sole chair of the meeting. The determination of whether a Co-Chair has a conflict of interest shall be determined by the CADTH President and CEO. If it is determined that a Co-Chair has a conflict of interest on a matter relevant to the Committee's or Panel's mandate, he/she shall not participate in any deliberation or vote in respect of such matter. In the event that both Co-Chairs have a conflict of interest, the CADTH President and CEO shall appoint the chair of the meeting.
- 6.4 In determining whether a Member or the Committee Chair has a conflict of interest, the Member, Committee Chair and CADTH shall be guided by these COI Guidelines and the COI Flowchart set out in Schedule 4 (the "COI Flowchart"). The following terms used in the COI Flowchart have the meaning set out below.

<u>Discussion</u>: With proper disclosure of interest, a Member with a conflict of interest can participate in discussions with other Members of the Committee or Panel. A discussion will occur when the purpose of the meeting is to consider a matter in an open and informal setting, and where ideas are shared liberally (e.g. brainstorming, identifying options...), but where there is no deliberation or decision.

<u>Deliberation</u>: A deliberation will occur when the purpose of the meeting is to consider the reasons for and against certain options (e.g evaluating the options and potential recommendations...). Refer to the COI Flowchart to determine when a Member may participate in deliberations.

<u>Decision</u>: A decision will occur when the purpose of the meeting is to arrive at a determination usually by way of a consensus or a vote (e.g. voting on which option will be recommended). Refer to the COI Flowchart to determine when a Member may participate in decision making or voting.

<u>Direct Impact</u>: When considering if a particular matter or issue could have a direct impact on the Member's financial or personal interest, one must consider what benefit may result and if it is a benefit contemplated by Section 4. If it is, then one must answer "yes" and move on to the next question in the COI Flowchart. If the interest is not one that falls within the scope of Section 4, then it is not a benefit, thus not a direct impact on the Member's financial or personal interests.

Essential: A member will become essential to the Committee or Panel when expertise is limited and, as a result, the Member is required in order for CADTH to fulfill its mandate.

- 6.5 Except as otherwise provided herein or in the COI Flowchart, the Member who has a conflict of interest must abstain from participation in any discussion on the matter, shall not attempt to personally influence the outcome, shall refrain from voting on the matter and, unless otherwise decided by the Committee Chair, must leave the meeting room for the duration of any such discussion or vote.
- 6.6 When a conflict of interest exists, the Committee Chair has the authority to exclude a Member from the Committee or Panel meeting. In circumstances where the expertise pool is limited, and a Member's participation is essential to the work of the Committee and reasonable efforts have been made without success to find a suitable replacement with no conflicts, the Chair may grant a waiver in order to allow the Member to participate, and/or to limit his/her participation in the meeting, whether this participation be his/her right to vote or his/her right to participate in discussions or deliberations.
- 6.7 The disclosure and decision as to whether a conflict exists, and the Chair's or the President and CEO's, as applicable ruling on any matter relating to a

- conflict of interest, shall be duly recorded in the minutes of the meeting. The time the Member left and returned to the meeting shall also be recorded.
- 6.8 It is the responsibility of every Member who is aware of a conflict of interest on the part of another Member to raise the issue for clarification, first with the Member in question and, if still unresolved, with the Committee Chair.

7.0 Publication of Conflict of Interest Declarations

- 7.1 A summary of the Member's expertise, experience, affiliations and conflict of interest declaration will be posted and publicly available on the CADTH website.
- 7.1.1 If the Member has contributed expertise or acted in an authorship role to a CADTH publication, a summary of the Member's expertise, experience, affiliations and conflict of interest declaration will be included in that publication.

8.0 Amendment to the COI Guidelines

After appropriate consultation, the COI Guidelines may be amended at any time by CADTH, subject to approval of the President and CEO.

Conflict of Interest Disclosure Form CADTH Expert Committee and Panel Members

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 COI Guidelines, and to disclose the information requested in the COI Guidelines.

As a member of a CADTH Committee or Panel, I also understand that a summary of my expertise, experience, affiliations and conflict of interest declaration will be publicly available on the CADTH website and in all CADTH publications to which I have contributed in an advisory (i.e. have made recommendations) or authorship role.

I understand that the information disclosed will be retained on file by CADTH.

I have reviewed my investments, affairs, affiliations, activities and interests and have accurately completed the attached Schedules 1, 2 and 3.

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 conflict of interest situation. Except as otherwise disclosed in the attached Schedules 1, 2 and 3, I declare that I have no conflict of interest to report, as defined in the COI Guidelines.

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

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 three years which benefited the Member or related person, 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	otal valu	e (dollai	rang	e).								
			Check (√) type of benefit as appropriate						Check (√) dollar range as appropriate				
				Fu	ınding	or hon	oraria 1	for:	Va	lue of t	•	g or	
				ints	,	ces					nefit		
			_	Jeme	iures	erer	or	(wa			0		
Name of Party	Drug, technology or topic involved and		ing c	ngaç	lec E	conf	cles	pelc		000′	00'00	9	
(see section 2.2 for definition)	year of funding	<u> </u>	und	ig ei	ona	ing	artic Is	(see	\$5,000	. \$10	- \$5	00'00	
		Gifts. etc	Travel funding or payment	Speaking engagements	Educational lectures	Organizing conferences	Writing articles or editorials	Other* (see below)	- \$5,	\$5,001 - \$10,000	\$10,001 - \$50,000	Over \$50,000	
			Tra	Sp	Ed	ő	Wr) to	0\$	\$5,	\$1(ò	
		╢							\vdash				
		1											
*OTHER GIFTS/FUNDING/HONORARIA: PLE	ASE PROVIDE DETAILS												
I do not have any declarations for Sc	hedule 1.												
Data D	iint Nome												
Date Pr	rint Name S	gnature											

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 three years which benefited the Member or their immediate family members, particularly as the activities relate to the following areas (add pages as necessary):

For each Party and drug, technology or topic, identif	ly the type of funding or benefit received and indicate the	e tot	tal va	alue (do	llar ran	ge).								
						enefit / inte	erest a	as approp	oriate	Ched	ollar ran opriate	llar range as oriate		
			ent		ıts	chairs)	ing			Va	lue of		t or	
Name of Party (see section 2.2 for definition)	Drug, technology or topic involved and year of funding		Employment or engagement	Payment as Advisor or Consultant** (see below)	Research funding or grants	Payment for academic appointments (endowed chairs)	Personal education funding	Unrestricted Grants	Securities	\$0 - \$5,000	\$5,001 - \$10,000	\$10,001 - \$50,000	Over \$50,000	
		Į												
**PAYMENTS AS ADVISOR/CONSULTANT -	- PLEASE PROVIDE DETAILS		•	•			•							
I do not have any declarations for S	chedule 2.													
Date F	Print Name	Sigr	natur	e										

Conflict of Interest (COI) Disclosure Form – Schedule 3

(Reference: COI Guidelines Section 5.5)

List those activities, affiliations or interests involving a Party in the past three years (not already listed in Schedules 1 and 2) that may affect or compromise, or appear to affect or compromise the Member's objectivity, fairness or professional judgment (as outlined in Section 5.5.1). See list of examples in Section 5.5.2.

			Finar	ncial val	s appropri lue of ber st (if any)	nefit
Name of Part	ty (see section 2.2 for definition)	Nature or description of activities or interests (see Section 5.5.2)	000'5\$ - 0\$	\$5,001 - \$10,000	\$10,001 - \$50,000	Over \$50,000
se activities, affiliations o	r interests involving a Party with whom	the Member has a potential or pending future commitment (a	s outli	ned ir	n Sect	on 5
details on the nature of t	the commitment.		Finar	ncial val	s appropri	ate nefit
	the commitment. ty (see section 2.2 for definition)	Nature and timing of the future commitment	Finar	ncial val	s appropri lue of ber st (if any) 000'05\$ - 100'01\$	over \$50,000
		Nature and timing of the future commitment	Finar 0	r interes	ue of ber st (if any)	efit
		Nature and timing of the future commitment	Finar 0	r interes	ue of ber st (if any)	efit
Name of Part		Nature and timing of the future commitment	Finar 0	r interes	ue of ber st (if any)	efit

Schedule 4

(Reference: COI Guidelines Section 6.0)

COI FLOWCHART

All Members are required to disclose COI's in accordance with the COI Guidelines.



