

CADTH

pCODR

PAN-CANADIAN
ONCOLOGY DRUG REVIEW

Conflict of Interest Guidelines for the pCODR Expert Review Committee, Clinical and Economic Guidance Panel Members and Provincial Advisory Group Members

April 2015

INQUIRIES

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1 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 the pCODR program at 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 2.2), participants in pCODR activities will ensure that conflicts of interest are identified and resolved, thereby preserving the objectivity and credibility of pCODR processes.
- 1.2 Permanent and term employees must comply with the CADTH conflict of interest guidelines and disclose any conflicts, both at the start of employment and as conflicts arise. The Conflict of Interest Policy for CADTH employees is available at: <https://www.cadth.ca/about-cadth/how-are-we-doing/conflict-interest>
- 1.3 Contractors must also comply with the CADTH conflict of interest guidelines and complete the disclosure form annually before participating in CADTH activities, and as conflicts arise. The guidelines document for contractors is available at: <https://www.cadth.ca/about-cadth/how-are-we-doing/conflict-interest>

2 Definitions

- 2.1 In these COI Guidelines, the word “Member” means, unless otherwise stated, any pCODR Expert Review Committee (pERC), Clinical or Economic Guidance Panel members and Provincial Advisory Group members.
- 2.2 In these COI Guidelines, the word “Party” means a drug or health technology manufacturer (including such manufacturer’s parent corporation, subsidiaries, affiliates and associated corporations), or any other academic or professional organization which may fund clinical studies involving drugs or other health technologies, or any organization that may fund those drugs or other health technologies.

3 Applicability

- 3.1 These COI Guidelines apply to all Members.

4 Scope of Conflict of Interest

- 4.1 A conflict of interest 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 Members participating in a pCODR activity. A conflict of interest may be real, potential or perceived in nature.
- 4.2 A real conflict of interest arises where a Member has a financial or other personal interest with a Party which may compromise, or have the appearance of compromising, their work with pCODR (for example, a close family connection such as a spouse, or financial interest, with a Party).

- 4.3 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 their work with pCODR, but has not yet (for example, an identified future commitment with a Party).
- 4.4 A perceived (or apparent) conflict of interest may exist when there is a reasonable apprehension, which a reasonably well-informed person could reasonably have, that a Member has a conflict of interest, even if, in fact, there is neither a real nor a potential conflict.

5 Disclosures

- 5.1 Before a Member participates in any pCODR 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 pCODR.
- 5.2 All Clinical and Economic Guidance Panel Members must complete the COI Disclosure Form for each review conducted. All other Members (pERC members, Provincial Advisory Group (PAG) members must complete the COI Disclosure Form annually. **However, the obligation to disclose is ongoing and Members must inform pCODR of any conflict of interest that arises during the period of their commitment as soon as it is known to them.**

5.3 Schedule 1 Disclosures

- 5.3.1 Without limiting the generality of the foregoing, Members are required to disclose to pCODR all interests or activities that occurred during the past two 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:
 - a) receipt of gifts from a Party
 - b) receipt from a Party of funding for, or payment of, travel
 - c) receipt of funding or honoraria from a Party for speaking engagements
 - d) receipt of funding or honoraria from a Party for giving educational lectures
 - e) receipt of funding or honoraria from a Party for organizing conferences
 - f) receipt of funding or honoraria from a Party for writing articles or editorials
 - g) 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, Members are required to disclose to pCODR all interests or activities that occurred during the past two 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:
 - a) employment with a Party
 - b) receipt of payment as an advisor or consultant for a Party
 - c) receipt of funding or honoraria from a Party for research grants

- d) receipt of payment from a Party for academic appointments (including endowed chairs)
 - e) receipt of funding or honoraria from a Party for personal education
- 5.4.2 Members are required to disclose all of their currently owned stocks or stock options (related to a Party), excluding mutual funds.

5.5 Schedule 3 Disclosures

- 5.5.1 In addition to disclosures made under Sections 5.3 and 5.4, Members are required to disclose to pCODR any other activities or interests that affect or appear to affect the Member's objectivity or fairness.
- 5.5.2 Members 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.

6 COI Management

- 6.1 pCODR executive director and the CADTH President and CEO have the authority to determine if the circumstances or interests of a Member amount to a conflict of interest with respect to work being undertaken by pCODR.
- 6.2 pCODR executive director and the CADTH President and CEO have the authority to remove a Member temporarily from their role when it is deemed that the COI(s) impede the Member's objectivity (real or perceived) on the Committee, Panel, or Group to which they belong.
- 6.3 See Appendix 1 for management of COI declarations.
- 6.4 COI for Panel and PAG is assessed by pCODR staff before work is initiated on a submission. The pERC Chair assess pERC member COI before any pERC deliberations on a submission. The CADTH President and CEO assesses the pERC Chair's COI as required if specifically requested by a third-party.

7 Publication of Conflict of Interest Declarations

- 7.1 A summary of the conflict of interest declaration for each pERC Member will be posted annually and publicly available on the pCODR website.
- 7.2 If the Member has contributed expertise or acted in an authorship role to a pCODR publication, a summary of the Member's conflict of interest declaration will be posted annually and publicly available on the pCODR website.

8 Amendment to the COI Guidelines

The COI Guidelines may be amended at any time by pCODR.

APPENDIX A: pCODR Conflict of Interest Management

General Guidance:

If you are taking part in a pCODR drug review process (i.e., as a pCODR Expert Review Committee member or Clinical or Economic Guidance Panel member), you must consider whether or not you have any interests that could conflict with your role. The following chart gives an overview of what may constitute a conflict of interest, and what you need to do. It is only intended as a general guide and should be used in conjunction with the full policy [please refer to the applicable Terms of Reference and pCODR Conflict of Interest Guidelines].

pCODR will assess conflict of interest before any Committee, Panel or Group initiate work on a review. In the event of a COI, pCODR shall make a determination of management of the COI for these members:

- The lead of the Panel and the lead author from the Methods Team should have no financial or professional conflicts; however, this requirement may be waived by the pCODR executive director in situations where the expertise pool is limited, is essential to the review and all efforts have been made to find a suitable replacement with no conflicts.
- pCODR staff will disclose a summary of all conflicts of interest at an initial Panel meeting.

COI for pERC members is determined and managed by the pERC Chair, in consultation with pCODR as required, and give the member directions that he or she considers appropriate to address the actual, potential or perceived COI. Directions may include, among other requirements:

- A requirement that the member absent himself/herself from all discussions and voting on the matter in question; or
- A requirement that a member absent himself/herself from the voting only.

The pERC Chair should have no financial, professional or other conflicts. COI for the pERC Chair is determined by the CADTH President and CEO on an annual basis. If there is an additional request from a Third Party to make specific considerations of the pERC Chair's COI for a specific submission, the CADTH President and CEO will review this request taking into consideration the recommendation from the pCODR Advisory Committee Chair and Vice-Chair. As such, specific requests for managing pERC Chair COI will result in the delay of the review of that submission; this delay may be between 3-6 months in duration. The request must provide sufficient details to assess cause for the request.

Where COI is determined to exist for the pERC Chair, the Vice Chair will be requested to Chair the meeting and the Chair will not be present for deliberation or vote.

In the situation where a Third Party requests that a pERC member (excluding pERC Chair) not be allowed to participate in deliberation or vote, this will be assessed by the pERC Chair in collaboration with the pCODR executive director. Additional consultation with the CADTH President and CEO may be required. These assessments may cause a delay in the review of a submission. The request must provide sufficient details to assess cause for the request.

pCODR is not precluded from obtaining advice from experts who may have interactions and or relationships with parties who have a vested interest in pCODR recommendations relating to drug funding . It is recognised that, in many cases, there may be a small pool of

experts who have the relevant technical expertise and who are able to effectively advise pCODR on these matters.

Do you have a conflict of interest you need to declare?

Management

A1. Do you have a personal financial interest?

In the last 2 years have you received, or do you plan to receive, any financial payment or other benefit from either the manufacturer or the owner of the product under consideration (or comparator), or the industry or sector from which the product comes). This could include:

- Ownership in any relevant company or other business entity
- Payments such as salary, consultation fees, or fee paid work
- Have stock and stock options (excluding mutual funds)
- Received honoraria, gifts, trips, personal education grants, expenses and hospitality over and above what would be reasonably expected

A2. Payments such as research grants, academic appointments (endowed chairs) and education, lead investigator, advisory board member, travel expenses for independently sponsored scientific meetings

Committee: If the payment relates specifically to the product under consideration/ comparator for the specific indication under review, you will have to be absent from all discussions & voting unless ruled otherwise.

Panel: Lead author and participants should have no financial interest, unless ruled otherwise.

Committee: You will still be able to participate (vote and discussions), unless ruled otherwise.

Panel: Lead author and participants should have no financial interest, unless ruled otherwise.

B1. Do you have a personal family financial interest?

In the last 2 years has a close family member (spouse/partner or children residing in your home) received, or do they plan to receive, any financial payment or other benefit from either the manufacturer or the owner of the product under consideration (or comparator), or the industry or sector from which the product comes?

This could include:

- Ownership in any relevant company or other business entity
- Payments such as salary, consultation fees, or fee paid work
- Have stock and stock options (excluding mutual funds)
- Received honoraria, gifts, trips, or personal education grants
- Receiving expenses and hospitality over and above what would be reasonably expected to attend meetings or conferences

B2. Payments such as research grants, academic appointments (endowed chairs) and educational, lead investigator, advisory board member, travel expenses for independently sponsored scientific meetings

Committee: If the payment relates specifically to the product/comparator under consideration, you will have to be absent from all discussions & voting unless ruled otherwise.

Panel: Lead author and participants should have no financial interest.

Committee: You will still be able to participate, unless ruled otherwise.

Panel: Lead author and participants should have no financial interest.

C. Do you have a non- personal financial interest?

Do you have managerial responsibility for a department or organization that has received a financial payment, or other benefit, in the last 2 years relating to either the product under consideration, or the manufacturer or the owner of the product. This could include:

- A grant or fellowship or other payment to sponsor a post, or contribute to the running costs of the department
- Commissioning of research or other work

Or do you plan to receive such a payment or other benefit in the future?

Committee: You may still be able to participate, unless ruled otherwise.

Panel: Lead author and participants should not have financial interests, unless ruled otherwise.

D1. Do you have a personal non-financial interest?

Have you expressed a clear opinion on the matter under consideration which has been:

- Expressed as a public statement, such as testifying in court
- Expressed a strong personal or religious belief about a product under consideration

Or are you part of a professional organization or advocacy group with a direct interest in the matter under consideration?

Or is there another reason why people might think you could be biased when giving advice or considering the evidence?

D2. Have you expressed a clear opinion:

- Reached as a conclusion of a research project
- Suffer from a condition which may be treated by the product under consideration?

Or where a funding request being evaluated for a funding recommendation was submitted by you (either alone or with others within an organization to which you belong)

Committee: You may still be able to participate, unless ruled otherwise.

Panel: Lead author and participants should no personal interest, unless ruled otherwise.

Committee: You will still be able to participate in the discussions but must be absent from the voting, unless ruled otherwise.

Panel: Lead author should have no personal interest, unless ruled otherwise. Panel members are not precluded from participation.

E. Do you have a personal family non-financial interest?

Has a close member of your family (spouse/partner, or children residing in the home)

- Suffer from a condition with may be treated by the product under consideration?
- Expressed a strong personal or religious belief about a product under consideration

Committee: You will still be able to participate in the discussions but must be absent from the voting, unless ruled otherwise.

Panel: Lead author should have no personal interest, unless ruled otherwise. Panel members are not precluded from participation.

Examples of Conflict of Interests

Example 1

Drug X” is on the agenda for discussion at the Expert Review Committee meeting. A committee member’s COI declaration includes recent involvement in planning and presenting at an educational session related to the launch of the drug. The member’s expenses for attending the session were covered and he received a \$2,500.00 honorarium for his work in organizing and presenting at the session.

Under these circumstances, a member may be excluded from meeting discussions regarding “Drug X” and/or comparator(s) to “Drug X” (See A1 above), regardless of the monetary value of the honorarium. Acceptance of an honorarium from the manufacturer of “Drug X” would likely be considered a “private or personal” interest and be perceived to affect the member’s objectivity regarding discussions on “Drug X” and/or its comparators.

Example 2

“Drug X” is on the agenda for discussion at the Expert Review Committee meeting. A committee member’s COI declaration includes their attendance at an educational session related to the launch of “Drug X”. The member’s expenses for attending the session were covered, however, they didn’t receive an honorarium for attending the meeting.

Under these circumstances, the member may or may not be excluded from meeting discussions regarding “Drug X” and/or comparator(s) to “Drug X” (see A2 above). Even though the member didn’t accept an honorarium from the manufacturer of “Drug X”, the payment of her expenses to attend an educational session specific to “Drug X” may be perceived to affect the member’s objectivity regarding discussions about the drug and/or their comparators. On the other hand, only reasonable expenses were covered.

In making the determination, other related conflicts may be examined (e.g. if the member has also participated in “Clinical Drug Trials” regarding “Drug X”, the combination of the two potential COIs may be sufficient to exclude the member from participating in meeting discussions on “Drug X” and/or its comparators; if the member has no other declared conflicts with “Drug X” or its manufacturer, they may be allowed to participate in the discussion)

Example 3

“Drug X” is on the agenda for discussion at the Expert Review Committee meeting. A committee member’s COI declaration includes that her son works for the company that manufactures “Drug X”. Upon further discussion with the member, it is determined her son works in the shipping department at the Company’s head office. Her son does not live with her and share no expenses related to the cost of living.

Under these circumstances, the member may be allowed to participate in the meeting discussions regarding “Drug X”. Although the COI Guidelines “family member” definition includes spouse and child as examples, the employment of the member’s son is remotely related to “Drug X” (i.e. packing and shipping it). In his position with the company, the son is also unlikely to derive any benefit from a positive listing recommendation of “Drug X”.

Example 4

“Drug X” is on the agenda for discussion at the Expert Review Committee meeting. A committee member’s COI declaration includes that her husband is a sales representative for a company that manufactures a product in direct competition with “Drug X”.

Under these circumstances, the member will likely be excluded from meeting discussions regarding “Drug X” (see B1 above). COI Guidelines “family member” definition includes spouse. Since the company the member’s husband works for manufactures a comparator product to “Drug X”, the member may benefit directly from supporting a negative recommendation for “Drug X”.

Example 5

“Drug X” is on the agenda for discussion at the Expert Review Committee meeting. A committee member’s COI includes that the Medical Department he is Director of recently received a \$250,000 research grant from the company that manufactures “Drug X”. The grant is funding research being conducted by other physicians in his Department. The research work does not relate to “Drug X”

Under these circumstances, the member may be excluded from meeting discussions regarding “Drug X” (See C above). Even though the member may not appear to be benefiting directly from the research grant, his role as Director of a Medical Department that has received such a large grant may be perceived to affect his objectivity in discussions related to “Drug X” and/or comparators to “Drug X”.

Example 6

“Drug X” is on the agenda for discussion at the Expert Review Committee meeting. A committee member declares to the Chair prior to the meeting that they suffer from the disease for which “Drug X” is used. Upon further discussion with the member, it is determined he does not use “Drug X” himself currently, but may be possible that he will need to do so in the future.

Under these circumstances, the member may be able to participate in the Committee discussions but they will likely be excluded from voting (see D2 above). Committee deliberations (i.e., beyond information gathering and clarification) must be protected from potential personal or professional gain. The member having the specific disease for which the drug under consideration is used may be perceived to affect the member’s objectivity regarding a recommendation on that drug and/or its comparators.

APPENDIX B: Conflict of Interest Disclosure Form

For pCODR Expert Review Committee, Clinical and Economic Guidance Panel members and Provincial Advisory Group 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 pCODR any real, potential or perceived conflicts of interest as defined in the pCODR COI Guidelines, and to disclose the information requested in the COI Guidelines.

As a member of a pCODR Committee, Panel or Group, I also understand that a summary of my conflict of interest declaration will be publicly available on the CADTH website and updated from time to time, generally on an annual basis. This summary will include benefit type but will not provide specific monetary values.

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

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

Date: _____ Name: _____ Signature: _____

For Panel Members (please complete):

Name of Panel: _____ (name of drug)

Role on Panel (Lead or otherwise): _____

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 years which benefited the Member, 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 2.2 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 allowment	Funding or honoraria for:				Value of funding or benefit			
				Speaking engagements	Educational lectures	Organizing conferences	Writing articles or editorials	Other	\$0 - \$5,000	\$5,001 - \$10,000	\$10,001 - \$50,000

I do not have any declarations for Schedule 1.

Date: _____ 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 two years which benefited the Member, 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 2.2 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	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 - \$5,000	\$5,001 - \$10,000	\$10,001 - \$50,000	Over \$50,000

I do not have any declarations for Schedule 2.

Date: _____ 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 Member's objectivity or fairness (as outlined in Section 5.5.1); for example, employment of spouse/partner or child; financial interest or investment in business enterprise or corporation; lobbying or promotional activities; have you publicly testified or made other public statements, or any other interest, relationship or activity that may create a reasonable apprehension of a conflict of interest, etc.

Name of Party (see section 2.2 for definition)	Nature or description of activities or interests	Check (✓) as appropriate			
		Financial value of benefit or interest (if any)			
		\$0 - \$5,000	\$5,001 - \$10,000	\$10,001 - \$50,000	Over \$50,000

List those activities or interests involving a Party with whom the Member has a potential or pending future commitment (as outlined in Section 5.5.2).

Name of Party (see section 2.2 for definition)	Nature and timing of the future commitment details	Check (✓) as appropriate			
		Financial value of benefit or interest (if any)			
		\$0 - \$5,000	\$5,001 - \$10,000	\$10,001 - \$50,000	Over \$50,000

I do not have any declarations for Schedule 3.

Date: _____ Name: _____ Signature: _____