CADTH

CADTH pCODR Expert Review Committee Terms of Reference

FEBRUARY 2018

CADTH

Record of Updates

Update	Version	Reported on CADTH website
Original	April 2011	April 19, 2011
1	February 2013	July 2013
2	May 2014	July 2014
3	May 2016	September 2016
4	February 2018	March 2018

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1 pCODR Expert Review Committee Purpose

The purpose of the pCODR expert review committee (pERC) is to make cancer drug funding recommendations to participating provincial/territorial Ministries of Health, provincial cancer agencies and federal drug programs that can be used by these jurisdictions to guide their cancer drug funding decisions. The pERC recommendations must consider the evidence-based reviews of the clinical effectiveness and cost effectiveness of cancer drug products conducted by pCODR and the input provided by patient advocacy groups and jurisdictions.

As of April 1, 2014, pCODR is a program of the Canadian Agency for Drugs and Technologies in Health (CADTH).

The pCODR Guiding Principles (Appendix A) and the pERC Deliberative Framework (Appendix B) should be used to guide and frame the work of pERC.

2 Mandate

The mandate of the pERC is to provide cancer drug funding recommendations, including conditions and/or criteria for coverage where appropriate, to the participating provincial/territorial Ministries of Health, provincial cancer agencies and federal drug programs, based on Submissions or Resubmissions.

Upon request, the pERC also provides advice to jurisdictions on cancer drug products, which may or may not result in a change to a previously issued pERC recommendation. A Request for Advice may be made by the CADTH pCODR Advisory Committee (PAC) or the Provincial Advisory Group (PAG).

3 Responsibilities

The responsibilities of the pERC include:

a) to establish, maintain, and apply standards and methodologies to evaluate the therapeutic value and cost effectiveness of cancer drug products for active disease management;

b) to consider Submissions and Resubmissions made by manufacturers, provincially-recognized clinician-based tumour groups and/or the PAG, and all related clinical reviews and economic reviews prepared and provided in accordance with the pCODR's standards;

c) to evaluate Submissions, Resubmissions and Requests for Advice in terms of therapeutic advantages and disadvantages, cost-effectiveness, patient perspective and PAG perspective on the impact of the cancer drug product under review, compared to accepted or existing therapies;

d) to recommend, after consideration of a Submission or a Resubmission, to the provincial/territorial Ministries of Health and provincial cancer agencies, those new cancer drug products for active disease management, which may be considered for funding and advise the Provincial/Territorial Ministries of Health, provincial cancer agencies and federal drug programs, of the conditions and/or criteria under which such products may be funded;

e) to provide reasons for every recommendation made to the provincial/territorial Ministries of Health and provincial cancer agencies, for public dissemination.

f) to provide advice and, if appropriate, a change to a previously issued recommendation, in response to every Request for Advice made by the PAC or PAG;

g) to consider feedback provided by Submitters, Manufacturers (if not the submitter), the PAG and patient advocacy groups, on an Initial Recommendation before issuing a Final Recommendation, unless there are instances where

the pERC determines an Initial Recommendation meets the criteria for early conversion to a Final Recommendation;

h) to deliberate on a Submission or Resubmission again, and, if appropriate, to change a Final Recommendation, in response to a Procedural Review submitted to pCODR and decided upon by the President and CEO of CADTH, on the advice of the pCODR Advisory Committee (PAC) Chair and Vice-Chair, who will determine if the grounds for a procedural review exist.

4 Accountability & Reporting

The pERC is an expert advisory committee that provides advice to the provincial/territorial Ministries of Health, provincial cancer agencies and federal drug programs. The pERC is accountable to the President and CEO of CADTH through the pERC chair. The pERC Chair shall report back to the President and CEO of CADTH at a minimum on a biannual basis in consultation with the pCODR Director.

5 Membership

5.1 Composition

The committee is composed of 13-17 members, including the Chair as follows:

- Five to seven cancer specialists (oncologists)
- One “non-oncology” physician
- Three health economists
- One to two pharmacists
- One hematologist
- Two patient representatives and a patient representative alternate

At least one of these members should also have expertise in health ethics.

If vacancies exist due to lack of available expertise, the overall composition of the pERC will be discussed with the President and CEO of CADTH to determine appropriate action, which may include but is not limited, to a temporary or permanent revision in the composition of pERC.

5.2 Requirements

All pERC members must meet all of the following requirements:

- currently not employed by any pharmaceutical manufacturer or related companies;
- able and willing to comply with Conflict of Interest and Confidentiality requirements of the pCODR;
- availability/commitment of time to participate fully in the pERC;
- knowledge of, experience with, and understanding of, issues related to cancer and its management (diagnosis, treatment and care);
- knowledge and understanding of pCODR’s mandate and the mandate of the committee, including their role in the broader cancer system as well as the healthcare system;
- willingness to work within the defined processes and parameters for reviewing cancer agents, including evidence-based medicine, cost-effectiveness and patient values;
- experience in committee and/or community work;
- ability to communicate effectively;

- ability to acquire the information and adopt the skills needed to successfully negotiate important issues;
- strong listening skills;
- ability to act with integrity and independence of specific interests;
- ability to relate to and respect a diverse range of values and beliefs;
- ability to gain respect and credibility within a diverse range of stakeholders and the wider public;
- ability to work constructively as a member of a team

pERC members representing a healthcare specialty must also meet the following requirements:

- a professional degree from a recognized institution in at least one of the following disciplines: medicine, pharmacy, pharmacology or health economics;
- be in active practice and/or research in either the community, hospital and/or academic setting;
- should have an understanding of the use and delivery of oncology drugs within the Canadian context.

pERC patient members must also meet the following requirements:

- Personal knowledge of, experience with, and understanding of issues related to cancer and its management (diagnosis, treatment and care);
- Demonstrated understanding and appreciation of patient needs and priorities;
- An overall understanding of other patient issues and health care concerns that may impact cancer patient communities on a broader scale.

More details on requirements for pERC members are set out in the pCODR Nomination/Application Information Package, which is available on the CADTH website.

5.3 Officers

The pERC shall have a Chair and a Vice-Chair. The responsibilities of the pERC Chair and the pERC Vice-Chair are laid out in Appendix C.

5.4 Nomination/Appointment Process

The nomination and appointment process shall be as set out in the Nomination/Application Information Package, which is available on the CADTH website.

5.5 Term of Appointment

Of the first patient members appointed to the pERC, two patient members shall be appointed for a term of three years. The other patient member and/or the patient alternate shall be appointed for a term of two years. Thereafter all appointments of the patient members shall be for a term of three years.

All other pERC members' terms shall be for a term of two or three years.

The term of any pERC member, including a patient member, may be renewed at the discretion of the President and CEO of CADTH. Generally, pERC members will be limited to serving two consecutive terms, unless otherwise decided by the President and CEO of CADTH.

Notwithstanding anything set out in these terms of reference, the President and CEO of CADTH shall have the right to remove and/or replace a pERC member at or before the expiry of his/her term.

5.6 Withdrawal from Committee

An individual may resign as a pERC member at any time upon written notification to both the pCODR Director and the pERC Chair.

pERC members who are absent for more than three pERC meetings per year will automatically forfeit membership on the pERC. However, the pERC Chair has the discretion to approve, in advance, an extended absence of any pERC member.

5.7 Voting Rights

Each pERC member, including the pERC Chair and each patient member, shall be entitled to one vote on all matters coming before the pERC. However, in case of an equality of votes, the motion put forward would fail and a new motion would need to be proposed.

6 Committee Support

Secretariat and administrative support for the pERC is provided by pCODR staff.

7 Meetings

7.1 Frequency of Meetings

The pERC will meet in-person on a monthly basis on a pre-specified day of each month. Under exceptional circumstances, additional meetings may be called.

7.2 Notice of Meetings

Most meetings of the pERC shall be held in Toronto, Ontario, Canada. From time to time, meetings may be held at such locations and times as either the pCODR program or the pERC Chair may determine. If a meeting must be cancelled, notice of a meeting cancellation will be provided at least two weeks in advance of a scheduled meeting date.

7.3 Quorum

The quorum at pERC meetings shall be 50 percent + 1 of the voting membership.

7.4 Attendance

pERC members shall attend all pERC meetings. A pERC member who is unable to attend an in-person meeting may request permission from the Chair to participate in the meeting via such means as video conference, teleconference or other communications facilities. The Chair shall have sole discretion in deciding whether to grant permission to such member's request but shall only grant permission in exceptional circumstances.

7.5 Attendees

In addition to pERC members, only the following persons shall be entitled to attend pERC meetings:

a) PAC members and PAG members appointed by provincial/territorial Ministries of Health, provincial cancer agencies and federal drug programs participating in the pCODR.

b) Clinical and Economic Guidance Panel Members and experts by invitation only (see below)

c) pCODR staff (see below)

PAC members and PAG members appointed by provincial/territorial Ministries of Health and provincial cancer agencies participating in the pCODR shall attend as observers. At each meeting, PAG will be given the opportunity to provide its perspective on the Submission for consideration by the pERC, through the PAG Chair and/or a designated member of the PAG. PAG members shall not have the right to participate in the pERC deliberations or to vote (i.e., beyond the steps of information gathering and clarification).

Clinical and Economic Guidance Panel members and/or experts may attend the pERC meetings, by invitation of the pERC Chair only, in circumstances where the pERC has questions or requires clarifications regarding a Submission, a Resubmission, a Reconsideration of an Initial Recommendation, a Request for Advice or a pCODR guidance report. Panel members and experts, however, shall not participate in, or be present during, any pERC deliberations or vote.

The pCODR staff attending the meeting shall serve as a resource to the pERC. They provide administrative and secretariat support and may actively participate in the presentation of information, Requests for Advice, Submissions, Resubmissions and Reconsiderations of an Initial Recommendation at the request of the pERC Chair. They shall also assist in obtaining additional information and/or expert advice at the pERC's request. pCODR staff shall not have the right to vote.

Other individuals may be invited to attend as observers, at the discretion of the pERC Chair and the pCODR program, and in accordance with the *CADTH Confidentiality Guidelines* and the *CADTH Conflict of Interest Guidelines*, which are available on the CADTH website.

7.6 Agenda

The pERC's meeting agendas shall be developed by the pERC Chair in consultation with pCODR staff.

7.7 Conflict of Interest Disclosure

At the commencement of every meeting, the Chair shall ask pERC members and invited attendees if they have any conflicts of interest to disclose. Any pERC member or invited attendee with a conflict must disclose such conflict and comply with the *pCODR Conflict of Interest Guidelines*. These guidelines are available on the CADTH website.

7.8 Decisions

No decision can be made unless there is a quorum.

7.8.1 Review Standards

Every Submission, Resubmission and Reconsideration of an Initial Recommendation will be reviewed by the pERC having regard to the applicable review standard established by the pCODR.

7.8.2 Recommendations

Every Initial Recommendation or Final Recommendation shall be decided by a majority of votes. Every pERC member participating in the meeting must vote (i.e., for or against) on the motion for the adoption of a recommendation; a member cannot abstain from voting, unless they have been absent for a majority of the discussion. In the event of an equality of votes, the motion put forward would fail and a new motion would need to be proposed.

Deliberations based on a Submission or a Resubmission must result in a recommendation on the submitted drug.

Deliberations in response to a Request for Advice must result in advice for the requesting jurisdictions and may or may not result in a change to a previously issued pERC Final Recommendation.

If necessary, the pERC may defer providing a recommendation or advice pending further information. This information will be provided by the pCODR program.

7.8.3 Reasons for Recommendation

The pERC shall give reasons for recommendation in support of every Initial Recommendation and every Final Recommendation, and these reasons for recommendation will be distributed in accordance with the procedure established by the pCODR.

7.8.4 Reconsideration of an Initial Recommendation

After considering feedback on an Initial Recommendation, the pERC shall make a Final Recommendation that either upholds the Initial Recommendation or makes a change to the Initial Recommendation. Feedback may be provided by the Submitter, the manufacturer (if not the Submitter), the PAG or patient advocacy groups

In accordance with the procedure established by pCODR, in some circumstances an Initial Recommendation may proceed to a Final Recommendation without additional deliberation and reconsideration by the pERC.

7.8.5 Redeliberation on a Submission or Resubmission

In response to a request for Procedural Review and at the direction of the President and CEO of CADTH with input from PAC, pERC may deliberate on a Submission, Resubmission or Request for Advice again, and, if appropriate, change a Final pERC Recommendation.

7.9 Record of Meetings

The pCODR program shall keep permanent records of:

a) transcripts of all pERC meetings

b) a record of key decisions and actions from all pERC meetings

c) records of every Initial Recommendation and Final Recommendation made by the pERC

d) copies of all reasons for an Initial Recommendation or a Final Recommendation given by the pERC

A record of key decisions and actions from all pERC meetings shall be prepared by pCODR staff and, after their approval by the pERC members who participated, shall be sent to all pERC members and relevant pCODR staff.

A summary of the pERC deliberations for each Submission or Resubmission discussed at a pERC meeting shall be prepared by pCODR staff and subsequently reviewed by pERC members. The summary of the pERC deliberations is not a complete record of the proceedings of the pERC meeting at which the Submission or Resubmission was discussed. The summary will be posted on the CADTH website along with the Initial and Final Recommendations.

In all circumstances in which the pERC responds to a Request for Advice, the pERC advice given in reply thereto shall be given in writing (i.e., record of advice) and will be distributed in accordance with the procedure established by the pCODR. If the pERC changes a previously issued recommendation in response to a Request for Advice, the distribution of the changed recommendation will take place in accordance with the procedure established by the pCODR. A permanent record of the pERC's deliberations, including any change to the recommendation, shall be kept.

In all circumstances in which the pERC re-deliberates on a Submission in response to a Procedural Review approved by the President and CEO of CADTH, and if the pERC changes a previously issued recommendation as a result of the re-deliberation, the distribution of the changed recommendation will take place in accordance with the procedure established by the pCODR. A permanent record of the pERC's re-deliberation, including any change to the recommendation, will be kept.

7.9.1 Subcommittees

From time to time, pERC may form subcommittees and/or working groups to fulfill its mandate. Subcommittees and working groups will report back findings to the pERC for deliberation. The reimbursement of any expenses associated with the subcommittee work requires advanced approval by the pCODR Director.

8 Reimbursement of Expenses

A reasonable remuneration or honoraria for pERC members shall be provided by CADTH.

pERC members shall be entitled to be paid reasonable expenses incurred by them in the performance of their duties.

Expenses associated with meetings (teleconference calls, web meetings, etc) will be reimbursed by CADTH.

Travel expenses will be reimbursed for in-person meetings of pERC, in accordance with CADTH's Travel Policy.

CADTH offers a centralized travel service for all domestic travel related functions in place of using an external travel agent. Travel arrangements can be made via e-mail: travelcentral@cadth.ca.

The reimbursement of any additional expenses will require approval in advance from the Director of pCODR.

9 General Provisions

9.1 Code of Conduct

pERC members must abide by the *CADTH Code of Conduct.*

9.2 Code of Communications

pERC members must abide by the *CADTH Code of Communications.*

9.3 Conflict of Interest Guidelines

In addition to the provisions provided in Section 7.7, Conflict of Interest at pERC meetings, all pERC Members must undertake in writing to abide by the terms of the *CADTH Conflict of Interest Guidelines*.

9.4 Indemnification

pERC Members shall be indemnified by CADTH against personal civil liability incurred by reason of any act or omission within the scope of the members' activity.

10 Confidentiality

It is the responsibility of pERC members to know what information is confidential and to obtain clarification from the pCODR program when in doubt. Except as compelled by applicable legal process, a pERC member must, both while having and after ceasing to have that status, treat as confidential all information regarding the policies, internal operations, systems, business or affairs of the committee and of CADTH obtained by reason of his or her status as a committee and not generally available to the public. A pERC member shall not use information obtained as a result of his or her involvement on the committee for personal benefit. Each pERC member shall avoid activities which may create appearances that he or she has benefited from confidential information received during the course of his or her duties as a committee member.

More details on confidentiality are set out in the *Code of Communication* and the *Code of Conduct*, which are available on the CADTH website.

11 Terms of Reference

The Terms of Reference for the pERC will be reviewed every 2 years or as required.

Appendix A: pCODR Guiding Principles

The pan-Canadian Oncology Drug Review evolved from the interim Joint Oncology Drug Review (iJODR), which demonstrated the value that a national collaborative platform can provide to cancer care decision-making. The objective of both iJODR and pCODR is to build the foundation for a streamlined, national cancer drug review process that supports evidence-based decision-making. Ultimately, this will improve access to a more consistent standard of care across Canada, and bring clarity for patients, health professionals and industry about how, when and why drug funding decisions are made.

The guiding principles for pCODR arose from iJODR's foundational work. They have been developed in consultation with key stakeholders, most notably the patient advocacy community.

Governance

A review process with governance structures which are fair, objective, transparent and accountable to patients, payers and the public.

Health System Focus

Cancer treatment drugs are evaluated within a review process and decision making framework that are consistent with those used for drugs for other diseases.

Representation

A review process that is multidisciplinary, cross-jurisdictional and collaborative in nature with appropriate input from key stakeholders and linked to other key national initiatives.

Excellence

A review process that reflects an ongoing commitment to excellence through incorporation of best practices in a spirit of continuous quality improvement.

Evidence-based

A review process with capacity for rigorous and consistent evidence-based clinical and pharmacoeconomic reviews to support evidence-based decision-making.

Ethical Framework

A review process that includes an ethical framework.

Efficient and Effective

A review process that is cost-efficient, effective and streamlined (i.e. reduced duplication) to support timely decision-making.

Evaluation

A review process with capacity for data capture and ongoing evaluation (decision monitoring/ performance measurement) to support continuous process improvements. In addition, capacity for health outcomes and economic impact analysis to support decision-making and planning.

Appendix B: pERC Deliberative Framework

The pan-Canadian Oncology Drug Review (pCODR) was established by the provincial and territorial Ministries of Health to assess the clinical evidence and cost effectiveness of cancer drugs and to use this information to make recommendations to the provinces and territories to guide their drug funding decisions. A key aspect of this process is the work done by the pCODR Expert Review Committee (pERC). Committee members examine the clinical and economic information provided by the guidance panels, as well as patient advocacy group input and Provincial Advisory Group (PAG) input, to formulate to a recommendation.

To help guide the pERC's deliberations, the committee must follow a framework, (see Tables B1 and B2) which provides an outline of all the elements that should be considered by pERC during its review, and reinforces that no single element over-rides another, but rather that pERC uses the sum of all elements to formulate a funding recommendation. The framework can be applied to all oncology drugs and situations including situations such as rare cancers or end of life care. In addition, the framework reinforces that there is no threshold that must be met for any single element in the review; rather, it is the individual drug, disease and context that determine pERC's information needs for each element of the framework.

Table B1: Criteria Definitions and Sources of the pERC Deliberative Framework

Criteria	Definition	Sub-Criteria	Source
Overall Clinical Benefit	A measure of the **net health benefit** of using the drug to diagnose or manage a cancer related condition (e.g., lung cancer) or cancer care related issue (e.g., skeletal related events in metastatic disease)	• Effectiveness • Safety • Burden of Illness • Need	Clinical Guidance Report provided by Clinical Guidance Panel, which incorporates the pCODR systematic review
Alignment with Patient Values	An assessment made after considering information on patient values	• Patient values	Patient advocacy group input sought at beginning of the review
Cost Effectiveness	A measure of the **net efficiency** of the drug and companion technology compared to other drug and non-drug alternatives (no cut-off threshold)	• Economic evaluation • Costs, cost per QALY, cost per life year gained, cost per clinical event avoided • Uncertainty of net economic benefits	Economic Guidance Report, which incorporates the Economic Guidance Panel review of the pharmacoeconomic model.
Feasibility of Adoption into the Health System	An assessment of the ease with which the drug can be adopted into the overall health care and cancer care systems	• Economic Feasibility – Budget Impact Assessment • Organizational Feasibility	Provincial Advisory Group input Economic Guidance Report, which incorporates evaluation of budget impact assessment assumptions

Table B2: Detailed Description of Each Element of the pERC Deliberative Framework.

Criteria	Sub-Criteria	Sub-Criteria Definitions
Overall Clinical Benefit	Effectiveness (systematic review in the Clinical Guidance Report)	The **potential health impact** of the drug compared to the other drug and non-drug alternatives, measured in terms of **relevant patient outcomes** such as mortality, morbidity, quality of life. **Magnitude, direction and uncertainty** of effect should be considered.
	Safety (systematic review in the Clinical Guidance Report)	**Frequency** and **severity** of adverse effects associate with the new drug compared to other drug and non-drug alternatives.
	Burden of Illness (Clinical Guidance Report, patient advocacy group input)	Incidence, prevalence or other measure of **disease burden on the population**.
	Need (Clinical Guidance Report, patient advocacy group input)	**Availability of an effective alternative** to the drug technology.
Alignment with Patient Values	Patient Values (patient advocacy group input)	**Patient based values** which bear on the appropriate use and impact of the drug.
Cost effectiveness	Economic Evaluations (Economic Guidance Report and pharmaco- economic model review)	A measure of the **net cost** or efficiency of the drug and companion technology **compared to other drug and non-drug alternatives**. The **uncertainty** of results should be considered.
Feasibility of Adoption into Health Systems	Economic Feasibility (evaluation of budget impact assessment in Economic Guidance Report)	The **net budget** impact of the new drug on other drug and health system spending, including companion testing technology.
	Organizational Feasibility (Provincial Advisory Group input)	The **ease** with which the new drug can be adopted, with an assessment of health system **enablers** and **barriers** to implementation, inclusive of all elements: operational, capital, human resources, legislative and regulatory requirements

Appendix C: Responsibilities of pERC Chair & pERC Vice-Chair

pERC Chair Role & Responsibilities

The pERC Chair provides leadership to the committee, represents the pERC to the President and CEO of CADTH and pCODR program and acts as the sole spokesperson of the pERC.

Specifically, the Chair:

- Presides over all pERC meetings to ensure all members fully commit to fulfilling their responsibilities as outlined under pERC Terms of Reference and its appendices.
- Reports on committee activities to the President and CEO of CADTH in an open, positive and timely manner.
  - Will assist the President and CEO of CADTH and the pCODR Director in their evaluation of the Vice-Chair position on the pCODR Expert Review Committee after one year's time, to determine the requirement for the level of commitment outlined in the Vice-Chair's Roles and Responsibilities
- As the main liaison between the pERC and the pCODR program, maintains constructive and collaborative relationships to maximize the impact of the committee's work.
- Maintains the integrity of the committee and its work, by ensuring members follow the pERC Code of Conduct and Conflict of Interest Guidelines, in consultation with the pCODR program.
- Works with the pCODR program to develop the monthly pERC meeting agenda. The Vice-Chair will also assist with the development of the agenda.
- Works with the pCODR program to assign submissions to a tiered queue for review and placement on the pERC agenda. Consultation with the Provincial Advisory Group (PAG) will be sought as required.
- Considers requests from submitters for a priority review, as part of three-person panels, which could include the Vice-Chair and one additional pERC member.
- Works with the pERC Vice-Chair and pCODR Director to recruit Clinical and Economic Guidance Panel members with pan-Canadian representation, as required.
- Assists pCODR program in determining if additional expertise is required on a particular drug Review Team.
- Invites members of the Review Team, including Clinical Guidance Panel members or Economic Guidance Panel members and/or External Experts to provide in-person input at a pERC meeting, to assist in the committee's information gathering and clarification activities.
- During pERC deliberations, determines if committee deliberations should be deferred until additional, impactful information is sought out, from the Review Team, the Submitter, or from External Experts.
- Works with the pCODR program to review feedback provided by stakeholders on an initial recommendation. Feedback will be screened by the pCODR program, in consultation with the Chair.
- Works with the pCODR program and either Economic Guidance Panel members or Clinical Guidance Panel members to assess proposed new information when screening a resubmission.
- Responsibilities under procedural review to be added once finalized by PAC.

The above role and responsibilities will be re-evaluated by the President and CEO of CADTH and pCODR Director from time to time, as required.

Remuneration

- The Chair will receive a stipend in the range of $6,000 per month.
- Any reasonable travel costs for pERC or other pCODR meetings, in accordance with CADTH's Travel Policy.

Time commitment

- Up to 4 days per month. The Chair will be required to travel for up to once-monthly pERC meetings, which are expected to last a half day in duration.
- Once monthly pERC meetings are held in Toronto, Ontario.
- Additional travel may be requested for public/stakeholder meetings, which are generally held in Toronto, Ontario, but may be held in other cities across Canada, as required.

Term of appointment

- The appointment will be for a period of 2-3 years.
- The appointment can be renewable at the end of the appointment period, subject to satisfactory evaluation. There should be no expectation of automatic reappointment.

pERC Vice-Chair Role & Responsibilities

The pERC Vice-Chair provides assistance to the pERC Chair in carrying out the following duties:

- Is responsible for chairing meetings in the event that the pERC Chair is unable to attend a meeting. This will include any pre-meeting planning and preparatory work that would accompany chairing a specific meeting.
- Will assume the chairing of a meeting for a specific agenda item in the event that the Chair should declare a conflict of interest with regard to that specific item.
- Assists the pERC Chair with development of the monthly pERC meeting agenda.
- Facilitates the quality and efficient running of monthly pERC meetings, by assisting the pERC Chair and pCODR program in the following activities:
  - Over a 2-3 meeting period, presenting one submission or resubmission, to ensure appropriate standards are set and modeled for other pERC members.
  - Detailed review of draft recommendations prior to public posting.
  - Providing advice on policy and procedures to enhance quality of committee work.
- Assists with the recruitment of clinical and economic guidance panels with pan-Canadian representation.

Remuneration

- pERC Vice-Chair will receive $1000 per day, which is pro-rated on a hourly basis, using 7.25 hours/day.
- Any reasonable travel costs for pERC or other pCODR meetings, in accordance with CADTH's Travel Policy.

Time commitment

- Up to 3 days per month (2 days as with all pERC member responsibilities, which includes pERC meeting time and preparation for meeting, and one additional day for pERC Vice-Chair responsibilities). pERC members will be required to travel for up to once-monthly pERC meetings, which are expected to last a half day in duration.
- Once monthly pERC meetings are held in Toronto, Ontario.
- If additional time commitment is considered, this will be negotiated between the pERC Chair and the pCODR Director in advance of the activity.

Term of appointment

- The appointment will be for a period of two to three years, to be aligned with the appointment term for the pERC Chair.
- After one year, the President and CEO of CADTH, in consultation with the pERC Chair and pCODR Director, will evaluate the roles and responsibilities for a Vice-Chair position on the pCODR Expert Review Committee, to determine the requirement for the level of commitment outlined above.

- The appointment may be renewed at the end of the term of the appointment period, subject to satisfactory evaluation. There should be no expectation of automatic reappointment.
- The successful candidate will be required to subscribe to the CADTH Code of Conduct.
- All pERC members should note the requirement to declare any potential conflict of interest that might arise in the course of pCODR business.

CADTH

CADTH pan-Canadian Oncology Drug Review (pCODR) Expert Review Committee (pERC)

Members Roles and Responsibilities

- to establish, maintain, and apply standards and methodologies to evaluate the therapeutic value and cost effectiveness of cancer drug products for active disease management;
- to consider submissions made by manufacturers, and/or tumour groups, and all related clinical reviews and economic reviews prepared and submitted in accordance with the pCODR's standards;
- to evaluate submissions and pCODR Advisory Committee (PAC) or Provincial Advisory Group (PAG) requests for advice in terms of therapeutic advantages and disadvantages, cost-effectiveness, and patient perspective on impact of the cancer drug product under review, compared to accepted or existing therapies;
- to recommend, after consideration of a submission, to the provincial/territorial Ministries of Health and provincial cancer agencies, those new cancer drug products for active disease management, which should be considered for funding and advise the provincial/territorial Ministries of Health and provincial cancer agencies, of the conditions under which such products may be funded;
- to provide reasons for every recommendation made to the provincial/territorial Ministries of Health and provincial cancer agencies, for public dissemination;
- to provide advice and, if appropriate, a change to a previously issued recommendation, in response to every request for advice by the PAC or PAG;

Qualifications for all pERC members, including Chair

- currently not employed by any pharmaceutical or related companies;
- able and willing to comply with Conflict of Interest and Confidentiality requirements of the pCODR;
- availability/commitment of time to participate fully in the pERC;
- knowledge of, experience with, and understanding of, issues related to cancer and its management (diagnosis, treatment and care);
- knowledge and understanding of pCODR's mandate and the mandate of the committee, including their role in the broader cancer system as well as the healthcare system;
- willingness to work within the defined processes and parameters for reviewing cancer agents, including evidence-based medicine, cost-effectiveness and patient values;
- experience in committee and/or community work;
- ability to communicate effectively;
- ability to acquire the information and adopt the skills needed to successfully negotiate important issues; strong listening skills;

- ability to act with integrity and independence of specific interests;
- ability to relate to and respect a diverse range of values and beliefs;
- ability to gain respect and credibility within a diverse range of stakeholders and the wider public;
- ability to work constructively as a member of a team

Additional qualifications for professional members of pERC

- a professional degree from a recognized institution in at least one of the following disciplines: medicine, pharmacy, pharmacology or health economics;
- be in active practice and/or research in either the community, hospital and/or academic setting;
- should have an understanding of the use and delivery of oncology drugs within the Canadian context.

On appointment

Remuneration

- pERC members receive $1000 per day, which is pro-rated on a hourly basis, using 7.25 hours/day
- Any reasonable travel costs for pERC or other pCODR meetings, in accordance with the CADTH Travel Policy.

Time commitment

- Up to 2 days per month. pERC members are required to travel for up to once-monthly pERC meetings, which are expected to last a full day in duration.
- Once monthly pERC meetings are held in Toronto, Ontario.

Term of appointment

- The appointment is for a period of 2 to 3 years.
- The appointment can be renewable at the end of the appointment period, subject to satisfactory evaluation. There should be no expectation of automatic reappointment.
- The successful candidates will be required to subscribe to the CADTH Code of Conduct.
- Candidates should note the requirement to declare any potential conflict of interest that might arise in the course of pCODR business.

CADTH pan-Canadian Oncology Drug Review (pCODR) Expert Review Committee (pERC) Patient Member

The CADTH pan-Canadian Oncology Drug Review (pCODR) Expert Review Committee (pERC) is looking for a Patient Member who has first-hand experience with the treatment and care of cancer or is the family member of a cancer patient and has developed a deep understanding of the treatment and care of cancer.

Background

The role of pERC is to assess the clinical evidence and cost-effectiveness of cancer drugs in order to make recommendations to the provinces and territories to help guide their drug funding decisions.

Composed of up to 17 members, pERC makes recommendations and provides advice to the Ministries of Health and provincial cancer agencies and federal drug programs.

Desired Qualifications

The successful candidate will have personal knowledge of, experience with, and understanding of issues related to cancer and its management (diagnosis, treatment, and care). They will also have a demonstrated understanding and appreciation of patient needs and priorities and an overall understanding of other patient issues and health care concerns that may impact cancer patient communities.

Successful candidates should also possess the following:

- Strong communication and interpersonal skills to be able to work constructively as a member of a team
- Ability to act with integrity and independence from specific interests and gain respect and credibility within a diverse range of stakeholders
- Open-minded approach and diplomacy skills, with the ability to relate to and respect a diverse range of values and beliefs

Members of pERC are expected to prepare for and attend up to 12 meetings per year in Toronto, and comply with pCODR's Conflict of Interest and Confidentiality requirements. No person currently employed by any pharmaceutical or related company will be considered.

Members of pERC receive a modest remuneration.

To request materials in an accessible format, please contact us at 613-226-2553 or by email at requests@cadth.ca.

CADTH

CADTH 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:

a) receipt of gifts, favours or hospitality 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, 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:

a) employment or engagement 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;
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.
f) receipt of funding from a Party for an unrestricted grant.
g) 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:

a) advice to, or close association with, a Party;
b) professional relationship with a Party,
c) the Member's participation as investigator in clinical trials of relevance to the Committee's or Panel's mandate;
d) professional opinions (as defined in section 2.9) expressed publicly by the Member of relevance to the Committee's or Panel's mandate;
e) the Member's involvement in the promotion of a product of relevance to the Committee's or Panel's mandate;
f) papers written by the Member of relevance to the Committee's or Panel's mandate;
g) the Member providing expert testimony in Court in regard to a matter of relevance to the Committee's or Panel's mandate;
h) 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;
i) 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.

Discussion: 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.

Deliberation: 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.

Decision: 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.

Direct Impact: 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.

CADTH

CADTH 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:

a) receipt of gifts, favours or hospitality 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, 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:

a) employment or engagement 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;
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.
f) receipt of funding from a Party for an unrestricted grant.
g) 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:

a) advice to, or close association with, a Party;
b) professional relationship with a Party,
c) the Member's participation as investigator in clinical trials of relevance to the Committee's or Panel's mandate;
d) professional opinions (as defined in section 2.9) expressed publicly by the Member of relevance to the Committee's or Panel's mandate;
e) the Member's involvement in the promotion of a product of relevance to the Committee's or Panel's mandate;
f) papers written by the Member of relevance to the Committee's or Panel's mandate;
g) the Member providing expert testimony in Court in regard to a matter of relevance to the Committee's or Panel's mandate;
h) 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;
i) 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.

Discussion: 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.

Deliberation: 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.

Decision: 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.

Direct Impact: 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.

CADTH

Appendix A: 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.

Date	Print Name	Signature

Name of Committee/Panel

CADTH

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):

Name of Party (see section 2.2 for definition)	**Drug, technology or topic involved and year of funding**	*Check (√) type of benefit as appropriate*							*Check (√) type of benefit as appropriate*			
				Funding or honoraria for:					**Value of funding or benefit**			
		Gifts, etc.	**Travel funding or payment**	**Speaking engagements**	**Educational lectures**	**Organizing conferences**	**Writing articles or editorials**	**Other* (see below)**	**$0 – $5,000**	**$5,001 – $10,000**	**$10,001 – $50,000**	**Over $50,000**
		☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
		☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
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		☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
		☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

***Other gifts/funding/honoraria: please provide details:**

☐ **I do not have declarations for Schedule 1.**

Date _____ Print Name _____ Signature _____

CADTH

Conflict of Interest Disclosure Form – Schedule 2

(Reference: COI Guidelines Section 5.4)

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):

Name of Party (see section 2.2 for definition)	**Drug, technology or topic involved and year of funding**	*Check (√) type of benefit as appropriate*							*Check (√) type of benefit as appropriate*			
				Funding or honoraria for:					**Value of funding or benefit**			
		Employment or engagement	**Payment as advisor or consultant** (see below)**	**Research funding or grants**	**Payment for academic appointment (endowed chairs)**	**Personal education funding**	**Unrestricted grants**	**Securities**	**$0 – $5,000**	**$5,001 – $10,000**	**$10,001 – $50,000**	**Over $50,000**
		☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
		☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
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		☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
		☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

****Payments as advisor/consultant: please provide details:**

☐ **I do not have declarations for Schedule 2.**

Date _____ Print Name _____ Signature _____

Conflict of Interest 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.

Name of Party (see section 2.2 for definition)	**Nature or description of activities or interests** (see Section 5.5.2)	*Check (√) type of benefit as appropriate* **Financial value of benefit or internal (if any)**			
		$0 – $5,000	**$5,001 – $10,000**	**$10,001 – $50,000**	**Over $50,000**
		☐	☐	☐	☐
		☐	☐	☐	☐
		☐	☐	☐	☐
		☐	☐	☐	☐
		☐	☐	☐	☐

List those activities, affiliations or interests involving a Party with whom the Member has a potential or pending future commitment (as outlined in Section 5.5.3). Provide details on the nature of the commitment.

Name of Party (see section 2.2 for definition)	**Nature and timing of the future commitment**	*Check (√) type of benefit as appropriate* **Financial value of benefit or internal (if any)**			
		$0 – $5,000	**$5,001 – $10,000**	**$10,001 – $50,000**	**Over $50,000**
		☐	☐	☐	☐
		☐	☐	☐	☐
		☐	☐	☐	☐
		☐	☐	☐	☐
		☐	☐	☐	☐

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

Date _____ Print Name _____ Signature _____

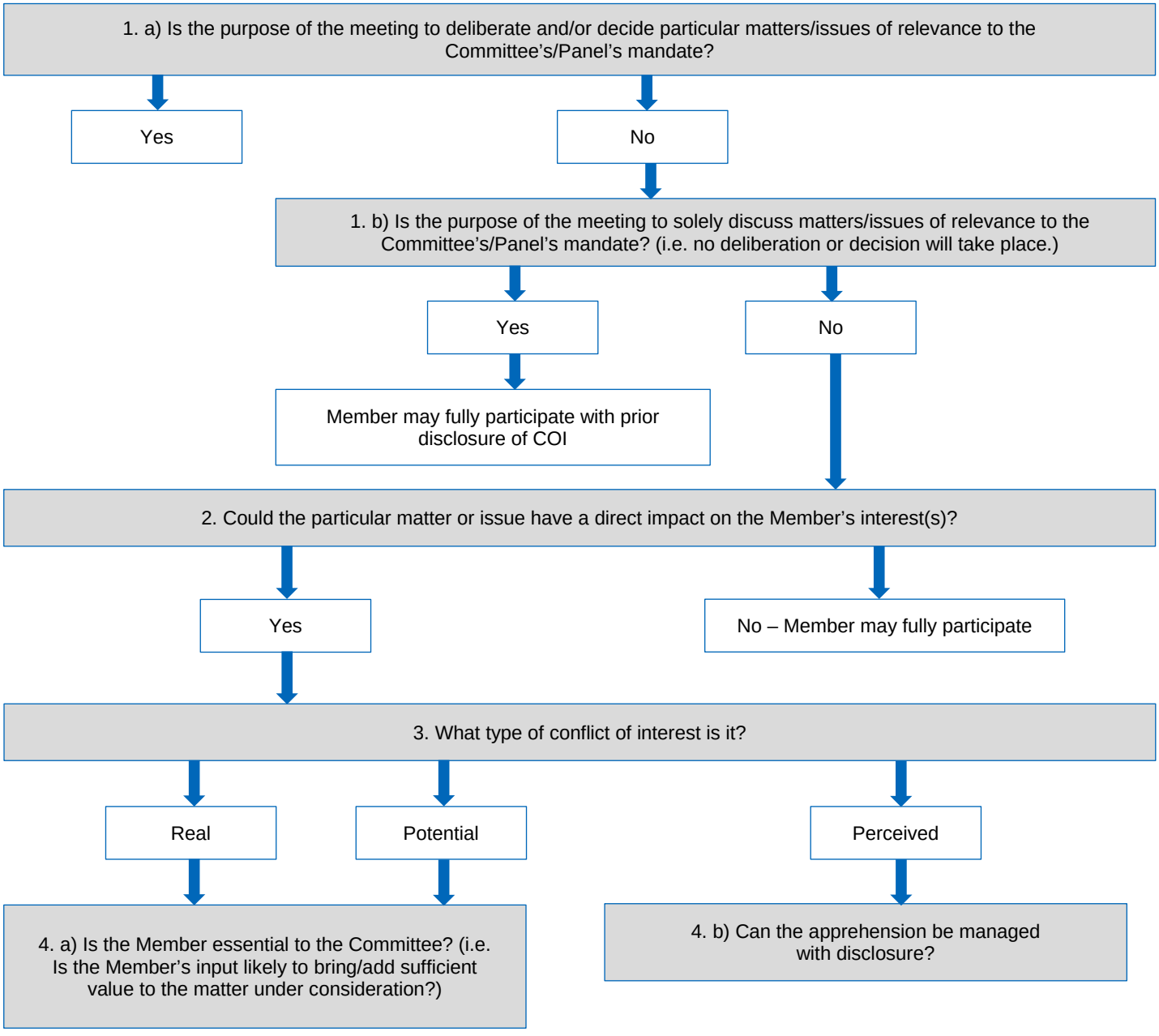
CADTH

Schedule 4

(Reference: COI Guidelines Section 6.0)

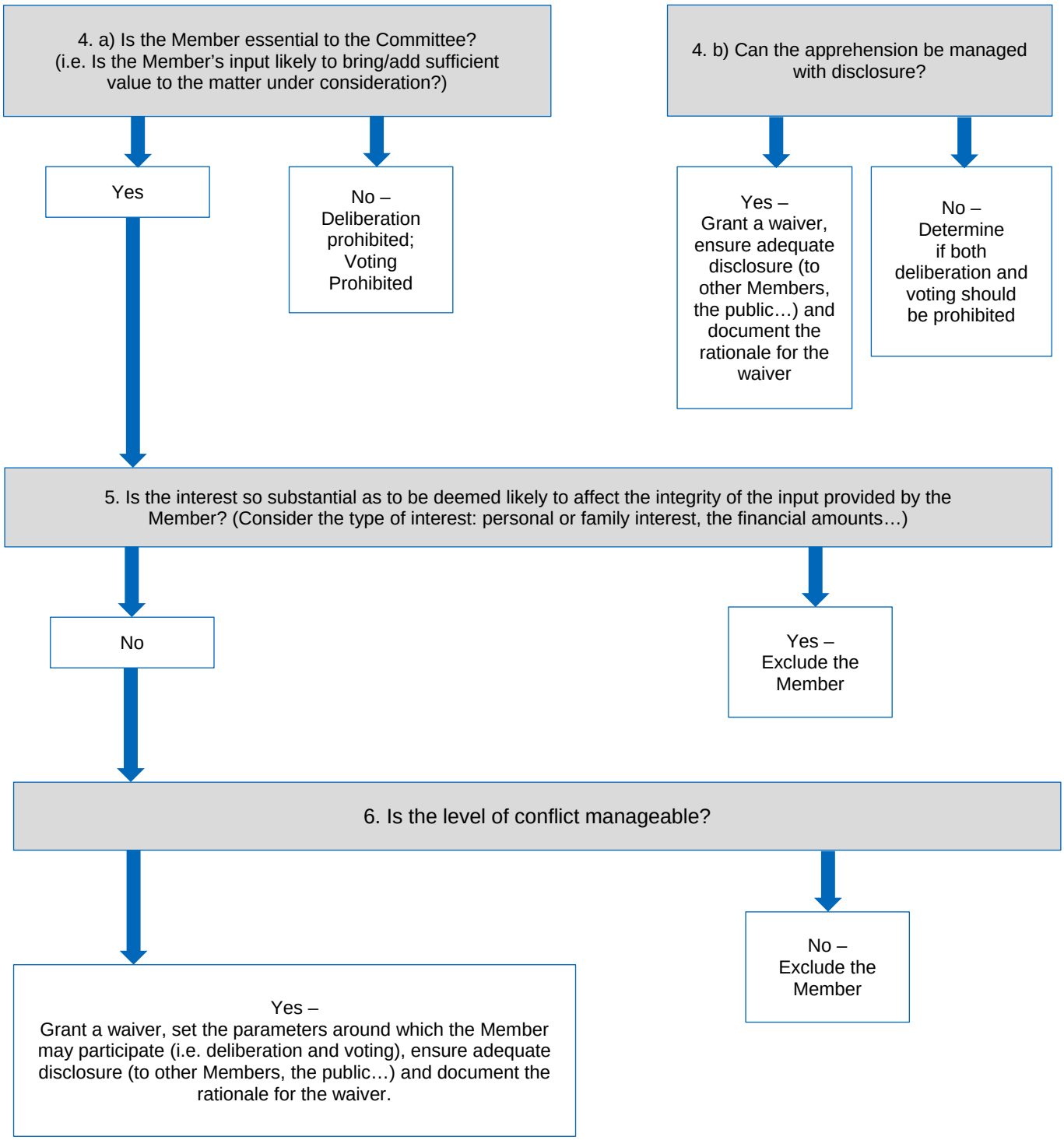
COI Flowchart

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



Continued on next page

Schedule 4


4. a) Is the Member essential to the Committee? (i.e. Is the Member's input likely to bring/add sufficient value to the matter under consideration?)
Yes
No – Deliberation prohibited; Voting Prohibited
4. b) Can the apprehension be managed with disclosure?
Yes – Grant a waiver, ensure adequate disclosure (to other Members, the public…) and document the rationale for the waiver
No – Determine if both deliberation and voting should be prohibited
5. Is the interest so substantial as to be deemed likely to affect the integrity of the input provided by the Member? (Consider the type of interest: personal or family interest, the financial amounts…)
No
Yes – Exclude the Member
6. Is the level of conflict manageable?
Yes – Grant a waiver, set the parameters around which the Member may participate (i.e. deliberation and voting), ensure adequate disclosure (to other Members, the public…) and document the rationale for the waiver.
No – Exclude the Member

CADTH

Statement of Interest and Qualifications

CADTH pan-Canadian Oncology Drug Review (pCODR) Expert Review Committee (pERC) Member Role

Nominees are asked to describe why they are interested in the role (up to 250 words).

Nominees are asked to describe their relevant qualifications and experience.

Nominee holds a professional degree from a recognized institution in at least one of the following disciplines: medicine, nursing, pharmacy, pharmacology, or health economics (up to 150 words).

Nominee is in active practice and/or conducts research in a community, hospital, or academic setting (up to 150 words).

Nominee has an understanding of the use and delivery of oncology drugs within the Canadian context (up to 150 words).

Nominee has knowledge of, experience with, and an understanding of issues related to cancer and its management (diagnosis, treatment, and care) (up to 150 words).

Nominee has knowledge and an understanding of CADTH's mandate and the mandate of the pERC committee, including their roles in the broader cancer system as well as the health care system (up to 150 words).

Nominee has experience in committee and/or community work (up to 150 words).

Nominee has the ability to relate to and respect a diverse range of values and beliefs (up to 150 words).

CADTH

Statement of Interest and Qualifications

CADTH pan-Canadian Oncology Drug Review (pCODR) Expert Review Committee (pERC) Patient Member Role

Nominees are asked to describe why they are interested in the role (up to 250 words).

Nominees are asked to describe their relevant qualifications and experience.

Nominee has personal knowledge of, experience with, and an understanding of issues related to cancer and its management (diagnosis, treatment, and care) (up to 150 words).

Nominee has demonstrated an understanding and appreciation of patient needs and priorities (up to 150 words).

Nominee has an overall understanding of other patient issues and health care concerns that may impact cancer patient communities on a broader scale (up to 150 words).

Nominee has experience in committee and/or community work (up to 150 words).

Nominee has the ability to work constructively as a member of a team (up to 150 words).