

Canadian Task Force on Preventive Health Care

Policy on disclosures of interests and management of conflicts of interest

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List of Abbreviations

COI = conflict of interest
CME = continuing medical education
ERSC = Evidence Review and Synthesis Centre
GIN = Guidelines International Network
GHGD = Global Health and Guidelines Division
PHAC = Public Health Agency of Canada
TFO = Task Force Office
WG = working group

1.0 Introduction and underpinning principles

This policy outlines procedures for the disclosure of interests and management of conflicts of interest (COIs) for the Canadian Task Force on Preventive Healthcare (“Task Force”; Figure 1).

This policy is informed by a scan of best practices in the international guideline community (1-12) and policies of medical journals (13-15), and adheres to the Guidelines International Network (GIN) Principles for Disclosure of Interests and Management of COIs (“GIN principles”) (10).

Another underpinning principle of this policy is that the Task Force distinguishes between declaration of interests and COI. The declaration of one or more interests does not necessarily indicate that a real or potential COI is present. The Task Force carries out an evaluation of declared interests to determine whether they represent a COI.

The Task Force’s Oversight Committee for COI (“Oversight Committee”) consists of the Task Force Chair and Vice-Chair, and the Director of the Global Health and Guidelines Division (GHGD) at the Public Health Agency of Canada (PHAC). The Oversight Committee is responsible for developing, approving, and ensuring implementation of policies related to COI in collaboration with other relevant parties, as appropriate.

2.0 Scope

This policy provides guidance that applies to all current and prospective members of the Task Force, regardless of the discipline(s) or stakeholder(s) that they may represent.

The policy also provides an overview of procedures followed for groups and individuals that provide external support to the Task Force (Section 8):

- Invited content experts (expert advisors)
- External stakeholders and peer reviewers
- GHGD staff at the PHAC
- Evidence Review and Synthesis Centres (ERSCs)
- Knowledge Translation Program, St. Michael’s Hospital

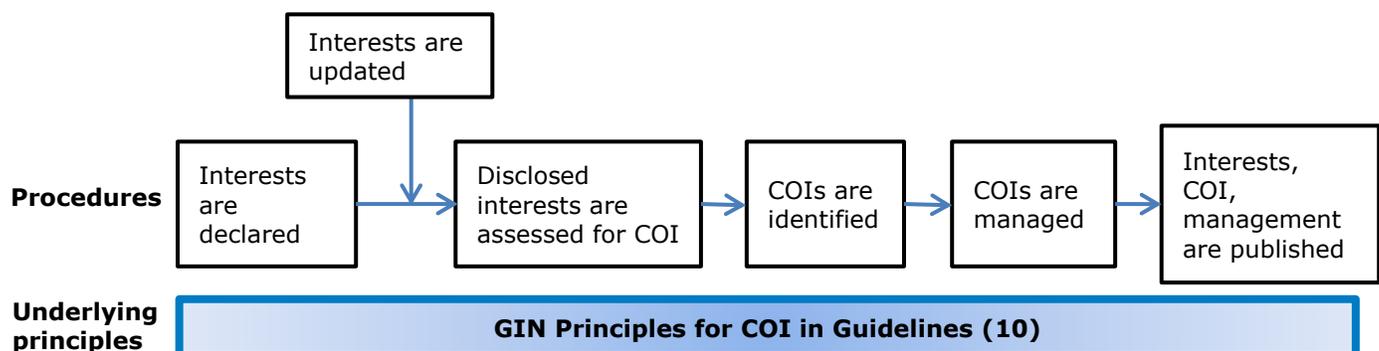


Figure 1. General overview of Task Force procedures for the disclosure of interests, and the assessment, identification, and management of COI.

3.0 Defining Interests

3.1 Financial interests

A financial interest is when an individual or organization (if an individual is participating on behalf of an organization) receives or could receive income or other form of monetary support or financial benefit that is related or relevant to, or could reasonably be perceived to be impacted by, the topic of the Task Force guideline process that the individual or organization is supporting.

This includes both personal financial interests and the interests of the individual's immediate family members (defined as the spouse, or partner with whom one has a close personal relationship, and children). Financial interests could include, but are not limited to, for example:

- personal financial gain such as paid work, board membership, consulting income, paid speaking engagements or lectures (including continuing medical education [CME] and other educational presentations), honoraria and travel support;
- monetary or other support for research, including donations of equipment, etc.;
- patents;
- financial support to the individual or to their institution including grants or fellowships;
- payments to participate in a study on a health technology that is or may be subject to a recommendation;
- stock shares, stock options, bonds, or other ownership in a commercial entity;
- gaining a significant proportion of one's clinical income from an intervention that may be subject to a recommendation.

3.2 Non-financial interests

A non-financial interest is when an individual or organization (if an individual is participating on behalf of an organization) has academic, professional, or other personal interests or relationships that are related or relevant to the topic of the Task Force guideline process.

This could include personal non-financial interests and the interests of the individual's immediate family members (defined as the spouse, or partner with whom one has a close personal relationship, and the children). These could include, but are not limited to, for example:

- prior publication of a study or review that is included in the guideline;
- prior public declaration of opinion or position (e.g., in public testimony, or an editorial in a journal);
- unpaid involvement in the delivery of CME or other educational sessions using industry-provided materials;
- affiliation with an organization advocating or lobbying for products or services related to the guideline topic;
- is themselves an advocate or lobbyist for particular products or services;
- holds a position of authority in a professional organisation such as a medical college, a university, charity, or advocacy group;
- unpaid board memberships for organizations.

Nonfinancial interest “are ubiquitous and not inherently bad. However, they must be identified and appropriately managed if an unbiased, credible guideline is to be produced” (3).

4.0 Declaring Interests

Before being appointed to the Task Force, prospective members must declare interests (as defined in Section 3) related to ongoing guideline topics, in addition to other significant interests that could impair the integrity of the Task Force (e.g., funding from industry) from the past 3 years, using a standardized form (Appendix I).

Task Force members must declare interests (as defined in Section 3) related to ongoing guideline topics from the past 3 years, by completing the same standardized disclosure form (Appendix I).

Task Force members are required to declare interests at the following times:

- When new topics are selected (annually)
- Before each in-person meeting of the Task Force (quarterly)
- When changes to interests arise between disclosures (ongoing).

The disclosure form is administered and collected by the Task Force Office (TFO) and reviewed by the Oversight Committee to determine whether COI is present (Section 5).

5.0 Defining and assessing COI

5.1 Defining COIs

A COI arises when one or more of the interests of an individual (or organization if an individual is participating on behalf of an organization) involved in the guideline process may impair or unduly influence, or reasonably be perceived to impair or unduly influence, their ability to provide advice or otherwise act in their role in the Task Force guideline process. COIs may be financial or non-financial depending on the nature of the interest that gives rise to the COI.

5.2 Assessing interests for COI

As mentioned above, the Task Force distinguishes between declared interests and COI, in that declared interests do not automatically imply a COI. An assessment is required to determine whether a declared interest is a COI. As noted in Section 1, the Task Force Chair, Vice-Chair, and GHGD Director constitute the Oversight Committee for this assessment process. Where interests are declared by members of the Oversight Committee, they will not be involved in assessing their own interests.

The Oversight Committee makes judgments on whether interests represent COI as per the definition above, the conclusion of which may be informed by the:

- Relevance of the interest to the guideline topic
- Proposed role of the individual in the guideline process
- Nature of the interest (e.g., financial versus non-financial)
- Recency or currency of the declared interest
- Frequency of the interest (for repeated activities)
- Duration of the interest
- Sources of funds, for financial interests (e.g., government versus industry)
- Nature of previous publications, where applicable (e.g., public opinion versus meta-analyses of published literature)
- Other factors as deemed relevant for the particular situation

If the information provided in the disclosure form is deemed to be insufficient to allow for a proper assessment, the Oversight Committee will seek additional information as need to complete the assessment. The results of the assessments are documented internally and inform the approach to management of COI.

6.0 Management of COI

6.1 Prior to appointment

If COI are identified among prospective members of the Task Force related to ongoing topics, or if prospective members have significant interests of concern (e.g., industry funding), the COI Oversight Committee will notify the selection committee (see methods manual, Section 1.5). The Task Force endeavors to avoid the inclusion of individuals with COI as members. The selection committee may

therefore vote against appointment of the prospective member if COI or interests that could impair the integrity of the Task Force are present.

6.2 Current Task Force members

For every guideline topic selected by members of the Task Force, a working group (WG) is formed, consisting of two to five Task Force members who volunteer to join the WG (one of whom is selected as the WG Chair). The approach to management of COI will differ slightly depending on whether the individual with a COI is a proposed member of a topic-specific WG, or a non-WG Task Force member (see Table 1, Appendix 3). Management options generally fall into the categories of 'full involvement', 'limited involvement', and 'full exclusion'.

The management approach is largely determined by the nature and significance of the COI, as well as the availability of other members without COI to participate in a given topic (there must be a minority of members with COI participating in a given topic). The management approach is determined and approved by the Oversight Committee, reported to the affected member, and kept on file.

Even if the recommended action allows the member to participate in discussions and vote on certain elements of the topic, the member may withdraw from discussions or voting on a topic at any time they feel it is appropriate to do so.

Table 1. Options for the management of COI among Task Force members (when part of a WG or when non-WG members)

Option 'category'	Working group members*	Non-WG Task Force members
	Action	Action
Full involvement	<p>No action other than the process of open declaration – the person can engage in all aspects of the committee’s work and can serve as WG chair.</p> <p>This is usually because nothing declared is considered by the Oversight Committee to represent a conflict of interest.</p>	<p>Non-WG Task Force members do not attend regular meetings of the WG but are often present for discussions at Task Force in-person meetings, and provide input on and approval of various documents throughout the guideline process.</p> <p>Non-WG Task Force members may:</p> <ul style="list-style-type: none"> • Be present as necessary for all discussions on the topic (e.g., at in-person meetings) • Provide input on and approve the final recommendations/guideline • Be listed as a contributing or Task Force group author.
Limited involvement	<p>The Task Force will make use of this option for cases of non-financial COI.</p> <p>Task Force member with COI and rationale for including in the guideline process will be designated as a clinical expert and serve as an advisor to the WG.</p> <p>Expert advisors to the Task Force</p> <ul style="list-style-type: none"> • May: <ul style="list-style-type: none"> ○ attend and provide input during early-stage discussions (e.g., scoping) that precede recommendation development ○ review and provide input on early documents related to guideline (e.g., scoping documents) ○ review and provide input on wording of draft/final recommendations/guidelines (but not direction or strength) ○ provide expertise/input to specific questions from the WG on an ad-hoc basis during the recommendation development process • May not: <ul style="list-style-type: none"> ○ be chair of WG ○ be present for discussions on the direction, strength of recommendations ○ provide input or vote on direction or strength of recommendations ○ approve draft/final recommendations/guidelines. 	<p>Non-WG Task Force members do not attend regular meetings of the WG but are often present for discussions at Task Force in-person meetings, and provide input on and approval of various documents throughout the guideline process.</p> <p>The Task Force will make use of this option for cases of non-financial COI.</p> <p>In such cases, non-WG Task Force members:</p> <ul style="list-style-type: none"> • May: <ul style="list-style-type: none"> ○ attend and provide input during early-stage discussions (e.g., during in-person meetings) that precede recommendation development ○ review and provide input on early documents related to guideline (e.g., scoping documents) as part of Task Force review processes ○ review and provide input on wording of draft/final recommendations/guidelines (but not direction or strength) as part of Task Force review processes ○ provide expertise/input to specific questions from the WG on an ad-hoc basis during the recommendation development process • May not: <ul style="list-style-type: none"> ○ be present for discussions on the direction, strength of recommendations ○ provide input or vote on direction or strength of recommendations

	<ul style="list-style-type: none"> • Reasons for being included in the process as an expert will be outlined in the guideline, and recusal from discussions/voting noted • Individual is not listed as contributing author on the guideline (clinical experts are not included as authors on Task Force guidelines) but may be acknowledged 	<ul style="list-style-type: none"> ○ approve draft/final recommendations/guidelines. • Recusal will be noted in guideline • Individual is not listed as contributing author on the guideline (unable to meet all ICMJE criteria)
<p>No involvement (complete exclusion)</p>	<p>The Task Force will make use of this option for cases of financial COI and may make use of this option for certain cases of non-financial COI.</p> <p>The severity of the COI precludes the Task Force member from being a member of the relevant working group (see options for non-WG TF members)</p>	<p>The Task Force will make use of this option for cases of financial COI and may make use of this option for certain cases of non-financial COI.</p> <p>In such cases, non-WG Task Force members:</p> <ul style="list-style-type: none"> • May not <ul style="list-style-type: none"> ○ be present for any discussions on the guideline (will leave room for in-person meetings) ○ review or provide input on early documents related to guideline or ○ review/approve draft/final recommendations/guidelines • Recusal will be noted in guideline and individual is not listed as contributing author

*The Task Force endeavors not to include members with relevant COI as members of a topic working group unless there is a rationale for including them such as relevant topic expertise

7.0 Publication of interests and COI

Declaration forms for all Task Force members are made public on the Task Force website (<https://canadiantaskforce.ca/about/members/>).

The Task Force also publishes, in each guideline, a summary of relevant interests disclosed and any COIs identified, reasons for including individuals with COIs in the guideline process, and how COIs were managed.

The GIN principles recommend publicly disclosing specific monetary values for financial COI (10), however the Task Force takes a strict approach to all financial COI (see Table 1), regardless of value.

8.0 External support to the Task Force

8.1 Content Expert Advisors to Working Groups

Clinical and content experts are invited to serve as external advisors to guideline topic WGs; they attend WG meetings, review documents for accuracy, and review final guidelines but are not members of the WG and do not have input into or vote on the direction or strength of recommendations.

Upon joining a project, each new content expert advisor to the WG must complete a Disclosure Form (Appendix I) to declare interests related to the guideline topic. They are also asked to update the disclosure form on an annual basis.

Interests declared by content expert advisors to WGs are assessed for COI by the Oversight Committee as described in Section 5.

Content experts who have received industry funding in a related area, or who have other COI, may be allowed to take part in the guideline process in their role as external advisors to the WG. This is more likely to be considered if the COI is deemed manageable and not so extensive as to potentially impair the credibility of their input, if the COI is non-financial, and if highly knowledgeable reviewers without such conflicts are unavailable (10). In these cases, efforts will be made to ensure an appropriate balance of opinion from those who provide feedback (e.g., other experts without COI may be invited to participate) and to be aware of COI in reviewing input received. In other cases, the Task Force may seek involvement of alternate experts.

8.2 External Stakeholders and Peer Reviewer

Upon joining a project, each new stakeholder and peer reviewer must sign a disclosure form (Appendix I) to report any relevant interests that could give rise to a COI (Section 3). Disclosure forms expire after one year and they are asked to sign a subsequent form if necessary. Interests declared by stakeholders and peer reviewers are assessed for COI by the Oversight Committee as described in Section 5.

Stakeholders are representatives of organisations who are asked for their perspective on Task Force products. COIs among stakeholders are anticipated, particularly where they represent advocacy organizations. Their unique perspectives are sought to ensure Task Force has considered a range of views and implications when developing its scientific reviews and recommendations. COIs among stakeholders do not exclude them from reviewing Task Force products. Stakeholders do not vote on recommendations and their declared interests and COIs are taken into consideration when interpreting the input received.

Peer reviewers are acknowledged experts in the topic who have not participated in the WG and do not vote on recommendations. COIs among peer reviewers are possible as recommendations may impact on their professional and other opportunities; however, their unique perspective provides the Task Force with

a range of viewpoints in developing recommendations. As with stakeholders, declared interests and COI of peer reviewers are taken into consideration when interpreting the input that they provide.

The input received from stakeholders and peer reviewers and a summary of their declared interests are published along with each guideline.

8.3 Science Team from the Global Health and Guidelines Division at the Public Health Agency

Staff of the GHGD, as employees of PHAC, are governed by the Values and Ethics Code for the Public Sector (17) and the Policy on Conflict of Interest and Post-Employment (18). PHAC employees are required to report to the PHAC COI Secretariat, “all outside activities, assets, liabilities and interests that might give rise to a real, apparent or potential conflict of interest in relation to their official duties,” within 60 days of appointment, and regularly thereafter as personal situations or official duties change (18). If it is determined by the PHAC COI Secretariat that a COI exists, the employee must comply by:

1. avoiding or withdrawing from circumstances which give rise to COI;
2. selling assets or putting assets into a blind trust where the ownership of such assets constitutes a COI (19).

When COI are identified among GHGD staff, the employee will work with their Manager, the Director of the GHGD, and the COI Secretariat, as needed, to ensure the COI is resolved in the public interest (18,19). The GHGD Director will also inform the Task Force Chair or Vice-Chair about the COI and how it will be managed.

8.4 Evidence Review and Synthesis Centre Staff

The Task Force does not assume responsibility for developing, approving, or implementing policies for the disclosures of interests and COI management for ERSC staff. However, the Task Force requires that ERSCs that carry out evidence reviews for Task Force guidelines have their own policy in place on COI, that they follow, from a major institution (e.g., government, hospital, university) or that of the Cochrane Collaboration (16).

When COI are identified among ERSC staff, ERSC direction will inform the Task Force chair or Vice-Chair about the COI and how it will be managed.

8.5 Knowledge Translation Program, St Michaels Hospital

As with ERSCs, the Task Force does not assume responsibility for developing, approving, or implementing policies for the disclosures of interests and COI management for KT team staff. However, the Task Force requires that the KT team have their own policy in place on COI, that they follow, from a major institution (e.g., government, hospital, university).

When COI are identified among KT team staff, KT team direction will inform the Task Force chair or vice-chair about the COI and how it will be managed.

9.0 References

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10.0 Appendices

Appendix I Disclosure Form

Canadian Task Force on Preventive Health Care

Disclosure Form

Preamble:

The Canadian Task Force on Preventive Health Care (Task Force) Disclosure Form will be completed by Task Force members prior to each in-person meeting to provide information on **financial, business/professional, and intellectual interests related to the topics addressed that could potentially be construed or seen as giving rise to conflicts of interest (COI).**

Task Force members are expected to provide full disclosure for new topics, and an updated disclosure, reflecting changes in their situation since the form was last completed, for continuing topics.

Task Force Disclosure Form will also be completed by new Task Force members prior to their participation. Completed Disclosure Forms will be kept on file by the Project Lead and posted on the Task Force website.

The declaration of one or more interests will not be taken to indicate that a real or potential COI is present. The Task Force will carry out an evaluation of declared interests to determine whether or not they represent a COI. **To facilitate assessment of the interests for COI, for each entry, please include a brief explanation of the relevance of the declared interest to the guideline topic and why it could be construed or seen as giving rise to COI.**

Name:

I have reviewed my current activities and those of the past 3 years for interests that could potentially be construed or seen as giving rise to COI, or that could otherwise impair the scientific integrity of the work of the Canadian Task Force on Preventive Health Care, particularly as they relate to the attached *Affiliations and Interests Checklist*, including financial and/or intellectual affiliations or memberships in associations, research funding, payments, gifts, gratuities, honoraria, advocacy, consulting or other conflicts.

I have also considered the activities of my spouse/common-law partner and immediate family members insofar as they could be viewed to affect my impartiality.

I hereby certify that I do not have any relevant interests to disclose that could potentially be construed or seen as a COI except as disclosed above.

I undertake to inform the Chair and the Project Lead of any changes in circumstances that may place me in a position of real, potential or apparent conflict of interest.

Signature _____ Date _____

Affiliations and Interests Checklist

In reviewing your activities (and those of your spouse/common-law partner and immediate family members), to determine whether they affect your impartiality or create a real, potential or apparent conflict of interest, among other things, consider the following:

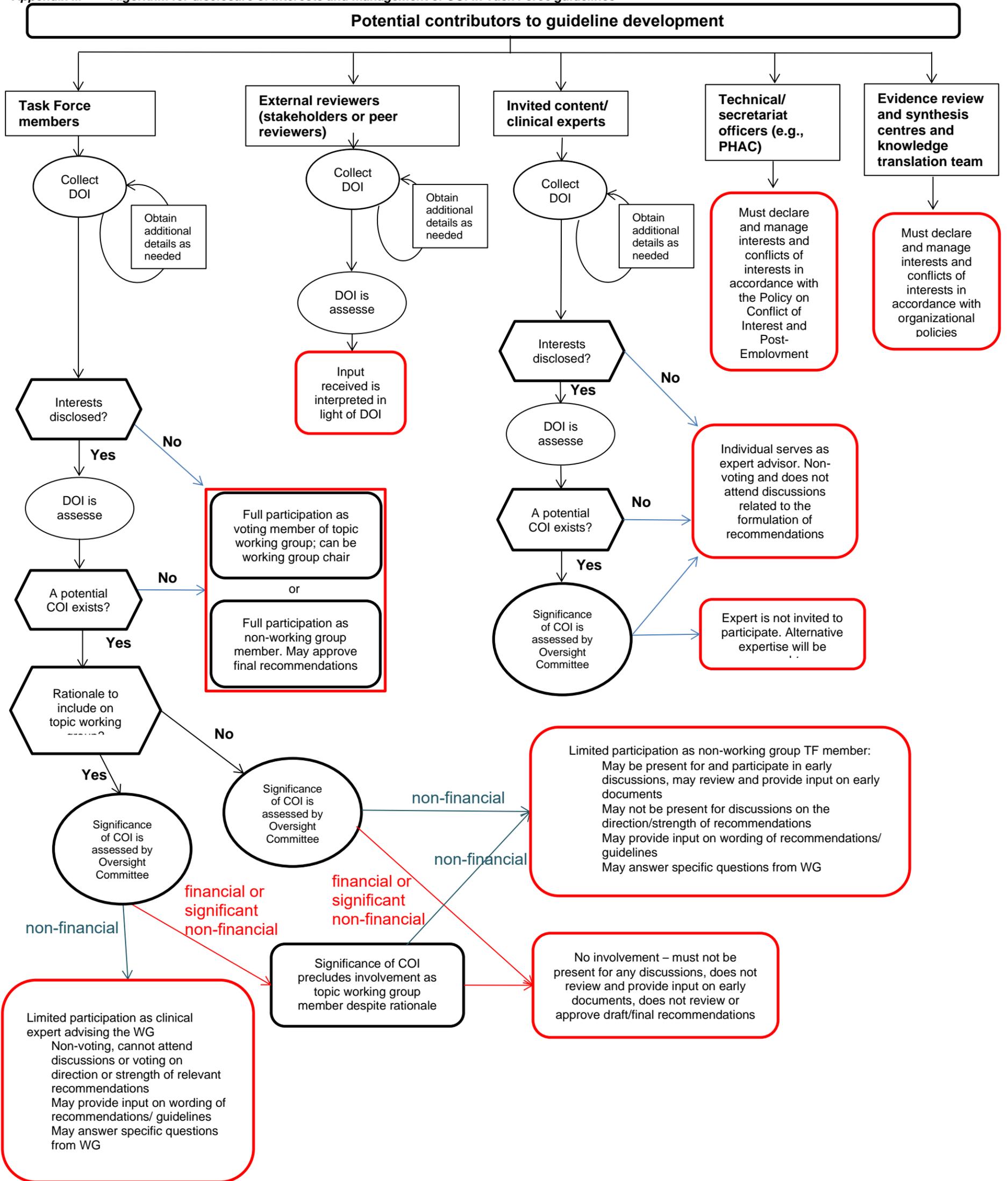
- Investments in a business enterprise (other than mutual funds or Registered Retirement Savings Plans that are not self-directed);
- Patents;
- Paid speaking engagements (including continuing medical education);
- Participation as investigator in clinical trials of relevance to the Task Force's mandate;
- Previous, present and potential Contracts, Grants and/or Contributions;
- Pending negotiations regarding potential contracts;
- Honoraria and other sources of personal income;
- Advice to or close association with international organizations;
- Gifts and hospitality of significant value;
- Travel sponsorship;
- Promotion of a product(s) of relevance to the Task Force's mandate;
- Publications;
- Public statements;
- Lobbying activities;
- Membership in associations or special interest groups;
- Expert testimonies in court;
- Access to confidential information; and
- Any interest or activity that may create a reasonable apprehension of bias.

Appendix II Adherence to GIN principles

GIN principles	Corresponding procedure for the Task Force
<p>1. Guideline developers should make all possible efforts to not include members with direct financial or relevant indirect COIs.</p> <p>In situations in which panel members have COIs, conflicted members should represent a minority on a guideline panel and the guideline developer should be transparent about the reasons for including conflicted members and the management of COIs.</p>	<p>Section 6.1: “If COI are identified among prospective members of the Task Force related to ongoing topics, or if prospective members have significant interests of concern (e.g., industry funding), the COI Oversight Committee will notify the selection committee (see methods manual, Section 1.5). The Task Force endeavors to avoid the inclusion of individuals with COI as members. The selection committee may therefore vote against appointment of the prospective member if COI or interests that could impair the integrity of the Task Force are present.”</p> <p>Sections 6.2 and Table 1 outline how this principle is respected for current Task Force members. If there is a rationale for including an individual with a non-financial COI, they will be designated as an external advisor to the working group (i.e., not a voting member of the panel). Those with financial COI will not be included in guideline working groups.</p> <p>Section 7: Reasons for involving individual with COI are summarized in the guideline manuscript.</p>
<p>2. The definition of COI and its management applies to all members of a guideline development group, regardless of the discipline or stakeholders they represent, and this should be determined before a panel is constituted.</p>	<p>Section 2: “This policy provides guidance that applies to all current and prospective members of the Task Force, regardless of the discipline(s) or stakeholder(s) that they represent.”</p> <p>Sections 3 and 5 outline the definitions of interests, and COI, respectively, and Section 6 outlines the management procedures.</p>
<p>3. A guideline development group should use standardized forms for disclosure of interests.</p>	<p>Section 4: “Before being appointed to the Task Force, prospective members must declare interests (as defined in Section 3) related to ongoing guideline topics, in addition to other significant interests that could impair the integrity of the Task Force (e.g., funding from industry) from the past 3 years, using a standardized form (Appendix I).</p>

GIN principles	Corresponding procedure for the Task Force
	Task Force members must declare interests (as defined in Section 3) related to ongoing guideline topics from the past 3 years, by completing the same standardized disclosure form (Appendix I)."
<p>4. A guideline development group should disclose interests publicly, including all direct financial and indirect COIs, and these should be easily accessible for users of the guideline.</p> <p>As part of this disclosure, the guideline development group should disclose all specific monetary values because COIs may arise as different levels in different settings. Reporting of actual or approximate amounts, if known, increases transparency. Registries of disclosures could be used.</p>	<p>Section 7: "Declaration forms for all Task Force members are made public on the Task Force website (https://canadiantaskforce.ca/about/members/).</p> <p>The Task Force also publishes, in each guideline, a summary of relevant interests disclosed and any COIs identified, reasons for including individuals with COIs in the guideline process, and how COIs were managed.</p> <p>The GIN principles recommend publically disclosing specific monetary values for financial COI (10), however the Task Force takes a strict approach to all financial COI (see Table 1), regardless of value."</p>
<p>5. All members of a guideline development group should declare and update any changes in interests at each meeting of the group and at regular intervals (for example, annually for standing guideline development groups).</p>	<p>Section 4: Task Force members are required to declare interests at the following times:</p> <ul style="list-style-type: none"> - When new topics are selected (annually) - Before each in-person meeting of the Task Force (quarterly) - When changes to interest arise between disclosures (ongoing)
<p>6. Chairs of guideline development groups should have no direct financial or relevant indirect COIs. When direct or indirect COIs of a chair are unavoidable, a co-chair with no COIs who leads the guideline panel should be appointed.</p>	<p>TF members with COI cannot be guideline working group chairs. See Table 1.</p>

GIN principles	Corresponding procedure for the Task Force
<p>7. Experts with relevant COIs and specific knowledge or expertise may be permitted to participate in discussion of individual topics, but there should be an appropriate balance of opinion among those sought to provide input.</p> <p>In some settings, persons who fulfill this role may be considered expert advisers who are neither voting nor nonvoting members of the guideline development group.</p>	<p>Section 8.1: “Clinical and content experts are invited to serve as external advisors to guideline topic WGs; they attend WG meetings, review documents for accuracy, and review final guidelines but are not members of the WG and do not have input into or vote on the direction or strength of recommendations.”</p> <p>Although invited experts are designated as advisors, there may still be cases where they have COIs that preclude their involvement, and where alternate expertise will be sought. In cases where expert advisors are allowed to participate despite COI, “efforts will be made to ensure an appropriate balance of opinion from those who provide feedback (e.g., other experts without COI may be invited to participate) and to be aware of COI in reviewing input received.” (Section 8.1)</p>
<p>8. No member of the guideline development group deciding about the direction or strength of a recommendation should have a direct financial COI.</p> <p>These members should not participate in this phase of guideline development. They should be physically absent from the discussion about the direction and strength of the recommendation.</p>	<p>Task Force members with financial COI are not permitted to be involved in guideline processes relevant to their COI (Table 1).</p>
<p>9. An oversight committee should be responsible for developing and implementing rules related to COIs.</p> <p>The oversight committee should address issues of dispute and advise the chair of the guideline development group on determining who is a voting or nonvoting member and who should be designated as an expert advisor.</p>	<p>Section 1: “The Task Force’s Oversight Committee for COI (Oversight Committee) consists of the Task Force Chair and Vice-Chair, and the director of the Global Health and Guidelines Division (GHGD) at the Public Health Agency of Canada (PHAC). The Oversight Committee is responsible for developing, approving, and ensuring implementation of policies related to COI in collaboration with other relevant parties, as appropriate.”</p>



Adapted from: World Health Organization. WHO handbook for guideline development (2nd Edition); Chapter 6 Declaration and management of interest. WHO 2014. Available: <https://apps.who.int/medicinedocs/en/m/abstract/Js22083en/> (accessed May 8 2019).