

المجلس الطبي السعودي  
Saudi Health Council



**National Center for Evidence Based Medicine**  
**CONFLICTS OF INTEREST POLICY**  
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# NCEBM CONFLICTS OF INTEREST POLICY

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## Introduction

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Content and other experts participating in guideline panels provide valuable input and unique insights during the development of clinical guidelines. However, conflicts of interest (COIs) can bias their recommendations, with the risk of potentially harmful outcomes for patients or the health system. The appropriate management of COIs and their disclosures are essential for producing high-quality, trustworthy clinical guidelines.<sup>1</sup>

Research has shown that COI management and methodology can heavily impact on the strength of recommendations.<sup>2</sup>

COIs are defined as “a divergence between an individual's private interests and his or her professional obligations such that an independent observer might reasonably question whether the individual's professional actions or decisions are motivated by personal gain, such as direct financial, academic advancement, clinical revenue streams, or community standing.”<sup>3</sup> They range from direct financial (financial relationships with entities that have investment in products or services directly relevant to the guideline topic) to indirect (nonfinancial), for example through a competing professional, academic, personal or political role related to issues such as academic advancement, clinical revenue streams, and community standing and reputation.<sup>4</sup>

This document outlines the

- NCEBM COI policy
- Role of the Guideline Advisory Board (via a nominated Responsible Officer) for managing COIs
- NCEBM rules for COIs and
- COI responsibilities of GDG members.

It also contains supporting materials and forms for the

- Responsible Officer:
  - Conflict of Interest assessment – description of steps (Appendix 1.)
  - Expanded guidance for the implementation of G-I-N principles (Appendix 2.)
  - Types of interests (Appendix 3.)
  - Checklist for assessing adherence to the G-I-N principles (Appendix 4.)
- GDG members:
  - NCEBM Declaration of Interest (DOI) Form (Appendix 5.)
  - Code of Conduct (Appendix 6.)

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<sup>1</sup> Traversy G, Barnieh L, Akl EA, et al. Managing conflicts of interest in the development of health guidelines. *CMAJ* 2021;193:E49-54.

<sup>2</sup> Agoritsas T, Neumann I, Mendoza C, Guyatt GH. Guideline conflict of interest management and methodology heavily impacts on the strength of recommendations: comparison between two iterations of the American College of Chest Physicians Antithrombotic Guidelines. *J Clin Epidemiol* 2017;81:141-143.

<sup>3</sup> Schünemann H, Osborne M, Moss J, et al. An official American Society policy statement: Managing Conflict of Interest in professional societies. *Am J Respir Crit Care Med* 2009;180:564-580

<sup>4</sup> Schünemann H, Al-Ansary LA, Forland F, et al. Guidelines International Network: Principles for disclosure of interests and management of conflicts in guidelines. *Ann Int Med* 2015; 163:548-553.

- Guidance for Completion of the NCEBM DOI Form (Appendix 7.).

These materials apply to the development of NCEBM Guidelines in the Kingdom of Saudi Arabia (KSA) and were approved by the NCEBM Advisory Committee in February 2021.

## NCEBM Conflict of Interest (COI) Policy

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In 2015, the Guidelines International Network (G-I-N), a global network of guideline developers that aims to promote best practices in the development of high-quality guidelines, conducted a review of the published literature and organizational policies, and based on its results developed a set of 9 guiding principles as a framework for the disclosure, assessment, and management of financial and nonfinancial COIs<sup>5</sup>.

NCEBM has adopted the 9 Guidelines International Network (G-I-N) Principles where No. 6 has been modified to our needs and standards:

1. **Principle 1:** Guideline developers should make all possible efforts to not include members with direct financial or relevant indirect COIs.
  - 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.
2. **Principle 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.
3. **Principle 3:** A guideline development group should use standardized forms for disclosure of interests.
4. **Principle 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.
  - As part of this disclosure, the guideline development group should disclose all specific monetary values because COIs may arise at different levels in different settings. Reporting of actual or approximate amounts, if known, increases transparency. Registries of disclosures could be used.<sup>[5]</sup>
5. **Principle 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).
6. **Principle 6:** Chairs of guideline development groups should have no direct financial or relevant indirect COIs.

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<sup>5</sup> Schünemann H, Al-Ansary LA, Forland F, et al. Guidelines International Network: Principles for disclosure of interests and management of conflicts in guidelines. *Ann Int Med* 2015; 163:548-553.

7. **Principle 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.
    - 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.
  8. **Principle 8:** No member of the guideline development group deciding about the direction or strength of a recommendation should have a direct financial COI.
    - 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.
  9. **Principle 9:** An oversight committee should be responsible for developing and implementing rules related to COIs.
    - 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 adviser.
- For the description of steps for the assessment of declarations of interest by a nominated Responsible Officer, see Appendix 1.
- For expanded guidance for the implementation of the G-I-N principles, see Appendix 2.
- For explanations of the different types of conflict, see Appendix 3.
- For a checklist for assessing adherence to the G-I-N principles, see Appendix 4.

## NCEBM Rules for COIs

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NCEBM sets the following rules for COIs:

1. Time Threshold for “Current Interests” : Current interests have been defined as those that have arisen during a period of 4 years preceding the NCEBM activity or work that an expert has been invited to participate in
2. Thresholds for Financial COIs:
  - Non-monetary support from a commercial entity or other organization with an interest related to the subject of the meeting or work (including equipment, facilities, research assistants, paid travel to meetings, etc.): Valued at more than US \$1,000 overall
  - Current investments in a commercial entity with an interest related to the subject of the meeting or work (including indirect investments such as a trust or holding company but excluding mutual funds, pension funds or similar investments that are broadly diversified and on which the GDG member exercises no control): Valued at more than US \$5,000 overall guidance.

## Role of the Guideline Advisory Board in the Management of COIs

The Guideline Advisory Board (GAB) oversees operational activities and is fully independent from the GDGs involved in clinical guideline development.

In particular, the GAB

- Prior to confirming the appointment of GDG members, nominates a Responsible Officer to review nominees' answers provided via the declaration of Interest form (see section 5.).
- Decides whether any declared interests are such that a proposed GDG member should not be included, for example due to significant financial or personal ties with a company who has an interest in a product that is the subject of the guideline.
- Approves the appointment of GDG members for whom no potential conflict exists or any interest is irrelevant or insignificant.
- If a declared interest is determined to be potentially or clearly significant, applies one or more of the following three measures for managing the conflict of interest
  - (i) allows full participation, with public disclosure of the member's interest;
  - (ii) mandates partial exclusion (i.e., member will be excluded from that portion of the meeting or work related to the declared interest and from the corresponding decision-making process); or
  - (iii) mandates total exclusion (i.e., member will not be able to participate in any part of the meeting or work).
- See Appendix 1. for the detailed description of COI assessment steps.
- Ensures that Declarations of Interest are gathered, securely and confidentially stored and kept up-to-date.
- Responds promptly to enquiries and requests from Chairs of GDGs regarding new or changing conflicts of interest.
- Defines procedures for handling disputes in conflict of interest resolution and resolves any conflicts arising during the COI process.

## Who should complete a declaration of interests form?

Group or individual	DOI required?	Management of COI	Comments
Guideline development group	Yes	According to the processes outlined here	Chair must be free of all financial COI, and free of non-financial interests.



External review group	Yes if they are representing themselves; No if they represent an institution	By interpretation of their comments in the context of their COI	These individuals or organizations may be conflicted. Their DOI form (if they represent themselves as an individual) or institutional affiliation (when they represent an entity) should make their interests clear.
Systematic review team	Yes	According to the processes outlined here	The systematic review team members should have no financial or nonfinancial COI. They may have performed systematic reviews on the topic previously.
Methodologist	Yes	According to the processes outlined here	The methodologist should have no financial or nonfinancial COI.
Meeting observers	No	By interpretation of their comments in the context of their affiliation(s)	The role and interests of representatives of organizations must be made clear at GDG meetings if the observers participate in any way in the discussions.

## COI Responsibilities of the GDG Members

All GDG members agree to

- The conditions outlined in this guidance document.
- Review and sign the NCEBM Declaration of Interest (DOI) Form provided by NCEBM (see Appendix 5.).
- Review the Code of Conduct provided by NCEBM (see Appendix 6.) and adhere to it for all activities.
- Complete the NCEBM DOI Form (see Appendix 5.) electronically or in paper format as requested by the Guideline Support Team, and submit it to the Responsible Officer assigned by the GAB if possible, at least 4 weeks but no later than 2 weeks before the guideline scoping meeting. All experts must complete this form before their participation in guideline development can be confirmed.
- Disclose any circumstances that could represent a current potential conflict of interest (i.e., any interest that may affect, or may reasonably be perceived to affect, their objectivity and independence).



- Disclose on the NCEBM DOI form (see Appendix 5.) any current financial, professional or other interest relevant to the subject of the work or meeting in which they have been asked to participate in or contribute towards and any interest that could be affected by the outcome of the meeting or work.
- Declare relevant current interests (see definition in Section 2.) of their immediate family members and, if they are aware of it, relevant interests of other parties with whom they have substantial common interests and which may be perceived as unduly influencing their judgment (e.g., employer, close professional associates, administrative unit or department).
- If they are unable or unwilling to disclose the details of an interest that may pose a real or perceived conflict, disclose that a conflict of interest may exist.
- Promptly inform the GAB via the Responsible Officer and update their DOI if there is any change in this information prior to, or during the meeting or work (including through the period up to the publication of the final results or completion of the activity concerned).
- To disclose verbally their interests and any changes to previously reported interests to the other participants at the start of each activity, and for these interests/changes to be recorded in the meeting's minutes.
- Accept the decisions of the GAB (represented by the assigned Responsible Officer) on inclusion and exclusion as final and adhere to its measures relating to their DOIs.
- To be excused from discussions or decision-making on particular recommendations on which COIs bear.
- A summary of all declarations and actions taken to manage any declared interests to be published in resulting reports and work products including the final full guideline.

In addition, GDG Chairs agree to

- Review their GDG members' conflicts before each meeting and evaluate if the GAB needs to be involved based on new or changing COIs.
- Once the GDG is appointed, determine if specific GDG members should be excused from individual recommendations or part of the discussion.

## Reporting declarations of interest in the Guideline

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A summary of how declarations of interest were collected, assessed and managed must be included in the main guideline document. If no conflicts were disclosed, this needs to be stated as well. The interests disclosed and the way any conflicts of interest were managed can be presented in either tabular or narrative form. NCEMB will not approve a guideline document that does not contain this information.

The following are examples of how conflicts of interest should be reported in the guideline:

- Dr N.C. reported being an investigator on trials for company X and company Y, but not for any products or products related to those being considered in this guideline. She also reported holding shares in company Z (valued at more than US\$ 5000), which makes antiviral drug X. She was therefore excluded from all discussion of the use of antivirals in prevention and treatment and from the formulation of recommendations on antiviral agents.



- Dr M.R. reported having been a consultant for company X on drug research and development. He is currently a member of a data safety and monitoring board for it; receives royalties through the National Institutes of Health (United States) from the use of gossypol for cancer; and is a consultant to several start-up companies, none of which has products on the market. Since no products related to any of these items were under consideration in this guideline, no action was taken.
- Dr A.F. reported that his spouse is an employee of company X. He was therefore excused from the room during the review of the evidence and discussion of recommendations on drug X, made by company X.

The completed declaration of interests forms are kept confidential at NCEBM for at least 10 years, and must not be distributed or made public. The responsible technical officer can make available to people outside NCEBM a summary of the forms' contents, but the forms themselves can only be released into the public domain under the explicit direction of NCEBM's Director-General.

## APPENDICES

### Appendix 1. Conflict of Interest (COI) Assessment - Description of Steps

*Adapted from Guidelines for Declarations of Interests (WHO Experts)*

- <http://www.emro.who.int/images/stories/polio/doi-guidelines.pdf?ua=1>

#### **STEP 1. The Initial Review - Relevance and Significance of the Interest**

1. Upon receipt of a completed NCEBM DOI Form from an expert, an Initial Review is conducted by the GAB, to determine whether an interest has been declared, and if so, whether it is insignificant or whether it is potentially significant. The GAB will assign the task of the Initial Review to a nominated person ("Responsible Officer").
2. A declared interest is insignificant or minimal if it is unlikely to affect or be reasonably perceived to affect, the expert's judgment. Normally, insignificant or minimal interests are:
  - unrelated or are only tangentially related to the subject of the activity or work and their outcome;
  - nominal in amount or inconsequential in importance;
  - expired and are unlikely to affect current behavior.
3. If, after the Initial Review, the Responsible Officer determines that no relevant interest has been declared or such interest is insignificant or minimal, then he/she must record this in writing, e.g. in a note for the record or a memorandum to the GAB. Only at this point is an invitation issued to the expert to participate in the GDG meeting or activity. In case of doubt or uncertainty, the Responsible Officer should consult with the other members of the GAB.
4. However, if the Initial Review indicates that the declared interest is significant or potentially significant, no further action may be taken until the Responsible Officer undertakes a full assessment, as described in the next step, of the potential conflict of interest.

#### **STEP 2. The Conflict of Interest Assessment - Factors to Consider**

The purpose of this assessment is to determine whether the expert may participate in the activity at all or whether the expert may do so only under certain conditions. The following actions should be undertaken to ensure that an appropriate and robust assessment takes place:

1. After the Initial Review, the Responsible Officer should convene a meeting with the GAB and relevant technical staff to discuss and review all the NCEBM DOI Forms in which a relevant interest has been declared. In case of doubt or uncertainty, the Responsible Officer should consult with the NCEBM Lead, as appropriate. All relevant interests should be individually discussed, and any decisions or follow-up actions agreed. In this regard, the following non-exhaustive and indicative list of issues should be considered:
  - The nature and value of the interest e.g. intellectual property (e.g. patents), financial and/or investment, the value of which exceeds US \$5,000;
  - Academic \ intellectual vs. financial;
  - Number of relevant interests declared on the DOI Form;
  - Personal vs. non-personal (department or institution) nature of the declared interest;



- If non-personal, the position and role of the expert in the department or institution;
  - Relationship of the expert's institution with NCEBM;
  - The relevance and specificity of the declared interest in view of the subject matter of the meeting or work to be undertaken;
  - The timeliness of the interest. Is it still current i.e. has it occurred within a period of 4 years from the foreseen GDG meeting or activity;
  - Whether the interest relates to an expert's immediate family member;
  - Whether the interest could be attributed to a professional bias reflected repeatedly as part of expert testimony in a regulatory or judicial proceeding or by reason of the expert's office; and
  - Whether the participation of the expert in the meeting or work provides, or may provide him or her, with clear actual and direct financial or pecuniary benefit or enable him or her to obtain access to a competitor's or potential competitor confidential proprietary information.
2. A further investigation should always be undertaken if the Responsible Officer or GAB has any concerns about any aspect of the information provided. Further information or clarifications may be required from the expert concerned.

### STEP 3. The Conflict of Interest Assessment - The Balancing Test

A conflict of interest assessment essentially involves carrying out a "balancing test". In carrying out such a balancing test, the Responsible Officer and/or GAB, while fully considering the contribution, tasks and function of the expert as well as the availability of alternative experts with the required expertise, must weigh:

- the nature, type and magnitude of the expert's interest and therefore the degree to which the interest may be reasonably expected to influence the expert's judgment

#### against

- the adequacy of measures/options available to protect the independence and integrity of the decision-making process.

### STEP 4. The Conflict of Interest Assessment - Possible Options

1. If it is concluded that a declared interest is potentially significant, one of the following three options, or a combination of those options, may be considered to determine under what conditions, if any, the expert may participate in the activity or meeting.
2. The Responsible Officer and/or GAB should always consult the Chair of the GDG meeting prior to making a public disclosure of an expert's interest to other meeting participants or considering any of the measures described below.
  - a. **Conditional Participation:** Under this option, the Responsible Officer would decide to continue the expert's involvement in the GDG meeting or work and publicly disclose the expert's interest at the start of the meeting to all meeting participants and in the report of the meeting and/or relevant publications or work products. This approach is especially appropriate where the expert's interest is relatively minor.



- b. **Partial Exclusion:** In this alternative, the Responsible Officer would limit the expert's involvement, either (a) by excluding the expert from that portion of the GDG meeting or work where a conflict of interest has been identified and/or (b) excluding the expert from participating in the decision making process relating to the development of, for example, guidelines or recommendations. In both cases, and after consulting the Chair of the meeting (if applicable), the reported interest must also be publicly disclosed to other meeting participants and must be recorded and disclosed in the report of the meeting and/or relevant publications or work products. Partial exclusion must be carefully monitored. It may only be used to enable other members to listen to the results of research or views held by the best-qualified experts, while bearing in mind the expert's potential bias.
  - c. **Total Exclusion:** In this case, the expert is excluded from the GDG meeting or work altogether, where the nature of the conflict of interest is too significant vis-à-vis the overall objective, or where limiting the expert's involvement to only a portion of the meeting or work is not feasible (because, for example, the expert's participation in the remainder of the meeting would have little or no value). A decision to exclude an expert should always be taken in consultation with the Co-Chairs of the relevant GDG.
3. As a general matter, a **useful approach** is to assess the situation through the eyes of a hypothetical **"reasonable person on the street"**. If an appropriately well informed person might reasonably conclude that the work or proceedings as a whole were tainted, or were unfair or were unduly influenced by the expert's interest in the outcome, then the expert's involvement should be excluded or limited (rather than merely disclosed).
4. If the Responsible Officer, after meeting with the GAB, is unable to determine which action should be taken in an individual case, the DOI responses should be reviewed with the NCEBM Lead, as appropriate.
5. It is recommended that the GAB also personally contact the expert whenever considering partial or full exclusion, both as a courtesy towards the expert and in order to confirm its understanding of the interests declared as such an exchange may yield additional information that may be pertinent to a conflict of interest analysis.

#### **STEP 5.** Note for the Record

At the end of the meeting(s) during which the DOI Forms are reviewed and assessed, the Responsible Officer should prepare minutes of the meeting(s) or a memo to file to record the decisions made and, in brief, the reasoning behind such decisions. The minutes or memo to file should be approved by the GAB.



## Appendix 2. Expanded guidance for the implementation of G-I-N principles

Adapted from Appendix 2. of Reference [4] - <https://www.cmaj.ca/content/cmaj/suppl/2021/01/05/193.2.E49.DC1/200651-ana-2-at.pdf>

G-I-N Principles	Challenges and considerations for implementation	Questions to ask
<p>Principle 1: Guideline developers should make all possible efforts to not include members with direct financial or relevant indirect COIs.</p> <p>Although the G-I-N recognizes the need for exceptions when this is not practical, such issues should not diminish the importance of this principle. 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>Implementation of this principle requires identifying all participants to whom it applies. At a minimum, this principle should be implemented for panel members; applying the principle to other parties involved (e.g., organization secretariat) should also be considered. Standing panels that make recommendations on many different topics cannot say a priori that they will exclude all members with COI. Such a group may instead implement this principle each time a topic-specific panel is assembled, and exclude members deemed to have significant COI for that particular topic.</p> <p>Implementation of this principle will require clear guidance about what constitutes a COI and how this is assessed (see Principle 2). While groups may not use the exact same terminology (i.e., direct financial and indirect) as the GIN principles to describe types of COI, this principle is meant to encompass all types of COI. A structured and consistent framework for assessing interests for the presence of COI and the severity of said COI may help. Developers may choose to implement this principle by ensuring less than 50% of panelists have COI, while others may strive not to include any members with COI.</p>	<p>Who comprises the guideline panel?</p> <p>Can this principle feasibly be applied when members are appointed to the panel, or should it apply only to topic- specific subgroups?</p> <p>Is there a rationale for including a member who has a COI?</p> <p>Will inclusion of a member with COI result in more than 50% of panel members having COI?</p> <p>What mechanism will be used to make decisions transparent to readers (see Principle 4)?</p>



<p>Principle 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>Developers should explicitly and clearly define the primary accountability of the guideline development group and the types of interests that may constitute COI, which therefore must be disclosed. It is important that interests and COI not be conflated, as not all interests will necessarily represent COI. The definition of COI should be applied consistently to all members of the guideline panel. Guideline groups without specific definitions may look to the published definitions from other major developers. Definitions and procedures for management of COI should be determined before the panel is constituted. For existing guideline groups who wish to update their COI policies/procedures to be GIN-compliant, groups may consider implementing these principles prior to assigning new topics for a given guideline cycle</p>	<p>How is COI defined? How are the different types of interest (e.g. financial, non-financial) defined? What interests or relationships might pose a competing obligation? Who comprises the guideline panel?</p>
<p>Principle 3: A guideline development group should use standardized forms for disclosure of interests.</p>	<p>Developers should ensure that standardized forms are used to gather disclosures of interests for all members of the guideline panel. Forms should properly capture all elements of a given interest that are required to determine if that interest is a COI. Such elements may include: relevancy to the given topic, recency of the interest, frequency of the interest (e.g., one-time payment versus recurring), duration of the interest, dollar amount (if relevant, see principle 4), and the proposed role of the individual in the guideline process.<sup>1</sup></p>	<p>Does the organization have a standardized disclosure of interest form? Is the form consistently used by all members? Does the form collect adequate information to assess the disclosed interests for COI?</p>



<p>Principle 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 at different levels in different settings. Reporting of actual or approximate amounts, if known, increases transparency. Registries of disclosures could be used.[5]</p>	<p>Developers should publicly disclose two elements:</p> <p>(1) Interests disclosed by panelists: All interests, regardless of COI, declared by panel members should be made publicly available either on a dedicated webpage (either the forms themselves, or a summary of the information on the form) or included as a supplement when publishing guidelines.</p> <p>(2) The existence of COI among members and an explanation of how the COI was managed (if applicable): This information can be shared either in a 'competing interests' section within the published guideline, as part of the methods section, or in the authorship/acknowledgement section. To fully implement principle 1, information on why a member with COI was included in the panel rather than excluded should also be explained.</p>	<p>What will be the forum for publishing disclosed interests (e.g., webpage, within guideline, etc.)?</p> <p>With what level of detail will disclosed interests be published?</p> <p>What will be the forum for publishing COI identified among members of the panel and how they were managed?</p>
<p>Principle 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>Panelists should fill out the standardized disclosure of interests form on a regular basis to ensure that any changes in interests are captured in a timely fashion. Developers should balance the desire to capture COI in a timely manner and the resources required to collect, assess, determine and manage declarations from members.</p> <p>Full declarations or only updates may be done and this may be done at the start of meetings, or by e-mail when meeting invitations are sent out.</p>	<p>Who comprises the guideline panel?</p> <p>At which meetings will panelists be required to fill out disclosure of interest forms?</p> <p>Are there other re-occurring milestones within the guideline cycle that warrant disclosures of interests (e.g., an annual topic selection process)?</p>
<p>Principle 6: Chairs of guideline development groups should have no direct financial or relevant indirect COIs.</p>	<p>Guideline chairs should not have any COI (though they may have interests). This may be implemented at the level of the panel writ-large,</p>	<p>Can this principle be feasibly applied when members to the panel are appointed, or should it apply only to topic- specific subgroups?</p>



<p>A relevant COI exists if it influences the direction or strength of a recommendation. An example of a co-chair without such conflicts is a methodologist who has no interest related to the direction or strength of the recommendation.</p>	<p>or at the level of topic-specific working groups depending on the group's needs.</p> <p>In the event a new potential COI emerges for an appointed chair (e.g. if a panel's scope is expanded), another member could be assigned as the chair for the purposes of addressing that topic only. In all cases where COI among a chair is deemed 'unavoidable' it should be explained why this was the case.</p> <p>This principle implies that 'cannot be chair' or 'cannot be topic chair' should be included as options for management of identified COI.</p>	<p>Do the circumstances of the panel make COI among the chair unavoidable?</p> <p>Who can be assigned as non-conflicted co-chair?</p>
<p>Principle 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>As per principle 1, &lt;50% of panelists (including experts) should have a COI. Guideline developers may consider balancing conflicted experts with those that do not have COI, being mindful that this may not always be possible in practice (e.g., due to particularly strong personalities or power imbalances).</p> <p>As developers may worry that strictly following the GIN principles could make it difficult to constitute panels with relevant expertise, they may alternatively invite experts with COI to participate as 'advisors' who are not members of the panel. Panels may invite these expert advisers to attend certain meetings, provide input on specific questions, or provide input on specific documents.</p> <p>Another option for getting the input of experts is to include them as peer reviewers of the guideline</p>	<p>Is there a rationale for including a member who has a COI?</p> <p>Will inclusion of a member with COI result in more than 50% of members having COI?</p> <p>Can conflicted individuals whose input is desired be appointed as advisors or informants?</p> <p>Can the input of a conflicted panelist(s) be appropriately balanced by panelists without COI?</p>





	<p>drafts. Experts or peer reviewers who are invited should still fill out disclosure of interest forms.</p> <p>Contributions of experts should be interpreted in the context of their potential COI.</p>	
<p>Principle 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.</p> <p>They should be physically absent from the discussion about the direction and strength of the recommendation.</p>	<p>Implementation of this principle requires a clear definition for what constitutes a financial COI.</p> <p>Participants with financial COI may be involved in early stages of the guideline process (e.g. initial scoping), but must be excluded once the panel reaches the stage of developing recommendations.</p> <p>Operationalization of this principle may require some planning. For example, at face-to-face meetings, individuals with financial COI can leave the room when required, whereas at teleconferences, the relevant agenda items could be placed at the end of a call so that those with COI can leave the call early.</p>	<p>At what point does the process of recommendation development begin?</p> <p>How to exclude individuals with financial COI from various forms of meetings that the panel may undertake?</p>



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### Appendix 3. Types of Interests

Adapted from *Guidelines for Declarations of Interests (WHO Experts)* - <http://www.emro.who.int/images/stories/polio/doi-guidelines.pdf?ua=1>

- **Direct Interest:**
  - A conflict of interest is usually financial and arises where the expert receives income or support that is related to or could be affected by the outcome of the GDG meeting or activity involved.
  - The conflict could involve personal financial gain, such as consulting income or honoraria, a business interest, such as a partnership or joint venture; an investment, such as stocks or bonds; financial support for research from the private sector given directly to the expert or to his university or research institution; or an intellectual property interest, such as a patent or copyright. A conflict of interest could also arise where an expert's participation in an activity accords him or her access to proprietary information or gives the expert a commercial competitive advantage.
- **Interests of Others:**
  - A conflict of interest usually relates to the expert's own interests. However, it could also be created by interests of others who may, or may be perceived to, unduly influence the expert's views.
  - A typical example is where an expert's work could affect or be affected by interests held by the expert's family, rather than the expert personally. Accordingly, relevant interests of the expert's immediate family members must be declared. Under these Guidelines, the term "immediate family member" includes the expert's spouse and children. "Spouse" includes a partner with whom the expert has a similar close personal relationship.
  - In addition, if the expert is aware that the outcome of the activity would benefit or adversely affect other parties with whom the expert has substantial common interests—whether personal, professional or financial—disclosure of those affected interests is also necessary. Examples of other parties include the expert's siblings, parents, employer, close professional colleagues, administrative unit or department.
- **Bias**
  - Expert GDG members or other individuals providing technical or normative advice to NCEBM may have some degree of "intellectual bias" in relation to a particular topic. Experts are expected to have and assert their own views and opinions on the topics under review, and in a sense that is why NCEBM wishes to invite them; what should be considered for the purpose of these guidelines are views and opinions that could be perceived as affecting the impartiality of the expert. Evidence of such bias could, for example, be identified through public statements made and positions held as part of a regulatory or judicial process. Whereas it could be important for other advisory body members to be aware of such public statements or positions, the potential bias may, but does not necessarily, constitute conflict of interest. However, in situations

where there is a significant directly related interest or duty of the individual, for example, as the head or as part of the leadership of an organization or other professional society that has publicly and repeatedly taken a fixed public position on an issue that is under review by NCEBM, then a bias in such a situation may constitute an interest to be disclosed and managed. This would be the case because such a person could be expected to represent or defend the interests and the position espoused by the organization.

- **Unfair or competitive advantage**

- Information that is disclosed or deliberated upon in the context of NCEBM body meetings will in most cases be confidential and occasionally proprietary to NCEBM or to third parties working with it. In this respect, a conflict of interest would arise if the disclosure of such information to an expert would give him or her a clear actual and direct financial or pecuniary benefit. Such a benefit could be in the form of information that would give the expert an unfair or competitive advantage, for example, in a product development or commercialization setting. Depending on the specific circumstances and taking into account information disclosed on the DOI Form, the participation of an expert may need to be limited to avoid such an unfair advantage being given which in turn would expose NCEBM to public criticism and be a basis for protest or challenges by third parties.



## Appendix 4. Checklist for assessing adherence to the G-I-N principles

Adapted from Adapted from Appendix 3. of Reference [4] - <https://www.cmaj.ca/content/cmaj/suppl/2021/01/05/193.2.E49.DC1/200651-ana-3-at.pdf>

Guideline title: \_\_\_\_\_

Please indicate the names of the guideline panel members: \_\_\_\_\_

G-I-N Principles	Checklist item(s)		Provide an explanation of how this item is met (or why ' not applicable)	Page reported
Principle 1: Guideline developers should make all possible efforts to not include members with direct financial or relevant indirect COIs.	1a	The guideline or published methods of the guideline panel indicates that the group endeavors not to include members with COI when assigning members to the panel, when assembling topic-specific working groups, or both.	•	
	1b	The guideline or published methods of the guideline panel provide an indication of how many members have COI. Less than half (i.e., a minority) of guideline panel members have a COI	•	Please indicate the proportion of panelists with COI for this guideline:
	1c	The guideline or published methods of the guideline panel indicates the reasons for including conflicted members on the panel.	•	
	1d	The guideline or published methods of the guideline panel indicates how COI were managed among members.	•	
Principle 2: The definition of COI and its management applies to all members of a guideline development	2a	The guideline or published methods of the guideline panel provides definitions for the types of interests collected from members, and what constitutes a COI.	•	



group, regardless of the discipline or stakeholders they represent, and this should be determined before a panel is constituted.	2b	The guideline or published methods of guideline panel indicates the factors that are consistently assessed for all members to determine if a disclosed interest is in fact a COI	•		
	2c	The guideline or published methods of the guideline panel indicates how COI will be managed among members when identified.	•		
	2d	The guideline or published methods of the guideline panel indicates that the above factors (definitions, and how COI will be managed) applies to all members of the guideline panel consistently.	•		
Principle 3: A guideline development group should use standardized forms for disclosure of interests.	3a	The group clearly indicates and/or demonstrates that the same form is used for disclosure of interests among all members.	•		
Principle 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.	4a	a The guideline or published methods of the guideline panel indicates where disclosed interests of the guideline panel can be accessed by readers of the guideline (e.g., website url, disclosure registry, etc.).	•		
	4b	The published guideline document includes a section outlining COIs identified among members, the rationale for including those with COI, and how COI were managed.	•		
	4c	The guideline panel discloses monetary values of financial interests (range or specific amount).	•		
Principle 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,	5a	The guideline or published methods of the guideline panel indicates the specific regular instances at which guideline panelists will be required to declare interests (e.g., annually when new topics are selected, at quarterly meetings, before each teleconference, etc.).	•		



annually for standing guideline development groups).	5b	The guideline or published methods of the guideline panel indicates that the panel will also be required to complete a declaration of interests any time interests change.	•		
Principle 6: Chairs of guideline development groups should have no direct financial or relevant indirect COIs.	6a	The guideline or published methods of guideline panel indicates that members with COI will not be or were not permitted to chair guideline panels where possible.	•		
	6b	(If applicable) The guideline indicates that the panel chair had a COI, and that a non- conflicted co-chair was appointed for all meetings/discussions (including name of the co- chair).	•		
Principle 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.	7a	The guideline or published methods of the guideline panel clearly indicates how experts on the panel with COI were balanced by those without COI (e.g., by having them represent a minority on the panel, or including additional non-conflicted experts). Or How they were designated as expert advisors who are not voting nor non-voting panel members.	•		
	7b	(If applicable) The guideline or published methods of the guideline panel indicates how the panel will assess the interests of external advisors providing input (as neither voting nor non-voting members) for the presence of COI.	•		
	7c	(If applicable) The guideline or published methods of the guideline panel indicates how the panel will manage the input of external experts with COI, where identified.	•		
Principle 8: No member of the guideline development group deciding about the direction or strength of a	8a	The guideline or published methods of the guideline panel indicates that when financial COI is identified (in accordance with the definition set out in 2a) for a	•		



recommendation should have a direct financial COI.		particular guideline, that the individual with financial COI will, at the minimum, be absent for discussions and voting on the direction and strength of recommendations.			
	8b	The guideline document clearly indicates (if applicable) members who have financial COI (in accordance with the definition set out in 2a), and how their involvement was managed (e.g., by having them absent from discussions and voting on direction and strength of recommendations). Specific individual instances of recusal need not be noted, but it should be specified exactly how exclusion from discussions and voting was carried out (e.g., the member did not call in to teleconferences, and left the room during relevant in-person discussion).	•		
Principle 9: An oversight committee should be responsible for developing and implementing rules related to COIs	9a	The group clearly indicates in the guideline or methods documents who is responsible for reviewing DOI forms to determine if COI is present (i.e., who comprises the oversight committee).	•		
	9b	The group clearly indicates in the guideline or methods documents who is responsible for determining the management of COI, when identified.	•		
	9c	The group clearly indicates under which circumstances the oversight committee addresses the COI of panelists (e.g., for all cases vs. issue of dispute only).	•		

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## Appendix 5. NCEBM Declaration of Interest Form

Adapted from WHO DOI Form - <https://www.who.int/about/ethics/doi-form-EN.pdf?ua=1>

### DECLARATION OF INTERESTS

The work of NCEBM requires the assistance of experts who may have interests related to their expertise. To ensure the highest integrity and public confidence in its activities, NCEBM requires that experts disclose any circumstances that could give rise to a potential conflict of interest related to the subject of the activity in which they will be involved.

All experts must disclose any circumstances that could represent a potential conflict of interest (i.e., any interest that may affect, or may reasonably be perceived to affect, the expert's objectivity and independence). You must disclose on this Declaration of Interest (DOI) form any financial, professional or other interest relevant to the subject of the work or meeting in which you have been asked to participate in or contribute towards and any interest that could be affected by the outcome of the meeting or work. You must also declare relevant interests of your immediate family members (see definition below) and, if you are aware of it, relevant interests of other parties with whom you have substantial common interests and which may be perceived as unduly influencing your judgment (e.g., employer, close professional associates, administrative unit or department). Please note that not fully completing and disclosing all relevant information on this form may, depending on the circumstances, lead NCEBM to decide not to appoint you to NCEBM functions in the future.

Please complete this form and submit it to the GAB if possible, at least 4 weeks but no later than 2 weeks before the first guideline meeting. All experts must complete this form before participation in meetings or work can be confirmed. You must also promptly inform the GAB if there is any change in this information prior to, or during the meeting or work. Please note that depending on the circumstances, not fully completing and disclosing all relevant information on this form may lead the NCEBM to decide not to appoint you to NCEBM functions in the future.

Answering "Yes" to a question on this form does not automatically disqualify you or limit your participation in meetings or work. Your answers will be reviewed by the GAB to determine whether you have a conflict of interest relevant to the subject at hand. One of the outcomes listed in the next paragraph can occur depending on the circumstances (e.g., nature and magnitude of the interest, timeframe, and duration of the interest).

The GAB may conclude that no potential conflict exists or that the interest is irrelevant or insignificant. If, however, a declared interest is determined to be potentially or clearly significant, one or more of the following three measures for managing the conflict of interest may be applied. The GAB (i) allows full participation, with public disclosure of your interest; (ii) mandates partial exclusion (i.e., you will be excluded from that portion of the meeting or work related to the declared interest and from the corresponding decision making process); or (iii) mandates total exclusion (i.e., you will not be able to participate in any part of the meeting or work).

All potentially significant interests will be disclosed to the other participants at the start of the activity and you will be asked if there have been any changes. A summary of all declarations and actions

taken to manage any declared interests will be published in resulting reports and work products. Furthermore, if the objectivity of the work or meeting in which you are involved is subsequently questioned, the contents of your Declaration of Interest form may be made available by the GAB to persons outside NCEBM if the NCEBM Lead considers such disclosure to be in the best interest of the NCEBM, after consulting with you. Completing this Declaration of Interest form means that you agree to these conditions.

If you are unable or unwilling to disclose the details of an interest that may pose a real or perceived conflict, you must disclose that a conflict of interest may exist and the GAB may decide that you be totally recused from the meeting or work concerned, after consulting with you.

Name:

Institution:

Email:

Date and title of meeting or work, including description of subject matter to be considered (if a number of substances or processes are to be evaluated, a list should be attached by the organizer of the activity):

Please answer each of the questions below. If the answer to any of the questions is "yes", briefly describe the circumstances on the last page of the form.

The term "you" refers to yourself and your immediate family members (i.e., spouse (or partner with whom you have a similar close personal relationship) and your children). "Commercial entity" includes any commercial business, an industry association, research institution or other enterprise whose funding is significantly derived from commercial sources with an interest related to the subject of the meeting or work. "Organization" includes a governmental, international or non-profit organization. "Meeting" includes a series or cycle of meetings.



NCEBM DECLARATION OF INTERESTS FORM		Yes	No
<b>EMPLOYMENT AND CONSULTING</b> Within the past 4 years, have you received remuneration from a commercial entity or other organization with an interest related to the subject of the meeting or work?			
1a	Employment	<input type="checkbox"/>	<input type="checkbox"/>
1b	Consulting, including service as a technical or other advisor	<input type="checkbox"/>	<input type="checkbox"/>
<b>RESEARCH SUPPORT</b> Within the past 4 years, have you or has your research unit received support from a commercial entity or other organization with an interest related to the subject of the meeting or work?			
2a	Research support, including grants, collaborations, sponsorships, and other funding	<input type="checkbox"/>	<input type="checkbox"/>
2b	Non-monetary support valued at more than US \$1000 overall (include equipment, facilities, research assistants, paid travel to meetings, etc.)  Support (including honoraria) for being on a speakers bureau, giving speeches or training for a commercial entity or other organization with an interest related to the subject of the meeting or work?	<input type="checkbox"/>	<input type="checkbox"/>
<b>INVESTMENT INTERESTS</b> Do you have current investments (valued at more than US \$5 000 overall) in a commercial entity with an interest related to the subject of the meeting or work? Please also include indirect investments such as a trust or holding company. You may exclude mutual funds, pension funds or similar investments that are broadly diversified and on which you exercise no control.			
3a	Stocks, bonds, stock options, other securities (e.g., short sales)	<input type="checkbox"/>	<input type="checkbox"/>
3b	Commercial business interests (e.g., proprietorships, partnerships, joint ventures, board memberships, controlling interest in a company)	<input type="checkbox"/>	<input type="checkbox"/>
<b>INTELLECTUAL PROPERTY</b> Do you have any intellectual property rights that might be enhanced or diminished by the outcome of the meeting or work?			
4a	Patents, trademarks, or copyrights (including pending applications)	<input type="checkbox"/>	<input type="checkbox"/>
4b	Proprietary know-how in a substance, technology or process	<input type="checkbox"/>	<input type="checkbox"/>



<b>PUBLIC STATEMENTS AND POSITIONS (during the past 3 years)</b>			
5a	As part of a regulatory, legislative or judicial process, have you provided an expert opinion or testimony, related to the subject of the meeting or work, for a commercial entity or other organization?	•	•
5b	Have you held an office or other position, paid or unpaid, where you represented interests or defended a position related to the subject of the meeting or work?	•	•
<b>ADDITIONAL INFORMATION</b>			
6a	If not already disclosed above, have you worked for the competitor of a product that is the subject of the meeting or work, or will your participation in the meeting or work enable you to obtain access to a competitor's confidential proprietary information, or create for you a personal, professional, financial or business competitive advantage?	•	•
6b	To your knowledge, would the outcome of the meeting or work benefit or adversely affect interests of others with whom you have substantial common personal, professional, financial or business interests (such as your adult children or siblings, close professional colleagues, administrative unit or department)?	•	•
6c	Excluding NCEBM, has any person or entity paid or contributed towards your travel costs in connection with this meeting or work?	•	•
6d	Have you received any payments (other than for travel costs) or honoraria for speaking publicly on the subject of this meeting or work?	•	•
6e	Is there any other aspect of your background or present circumstances not addressed above that might be perceived as affecting your objectivity or independence?	•	•

**EXPLANATION OF "YES" RESPONSES:** If the answer to any of the above questions is "yes", check above and briefly describe the circumstances on this page. **If you do not describe the nature of an interest or if you do not provide the amount or value involved where relevant, the conflict will be assumed to be significant.**

Nos. 1 - 4: Type of interest, question number and category (e.g., Intellectual Property 4.a copyrights) and basic descriptive details.	Name of company, organization, or institution	Belongs to you, a family member, employer, research unit or other?	Amount of income or value of interest (if not disclosed, is assumed to be significant)	Current interest (or year ceased)
<p><b>Nos. 5-6: Describe the subject, specific circumstances, parties involved, time frame and other relevant details</b></p>				

**CONSENT TO DISCLOSURE.** By completing and signing this form, you consent to the disclosure of any relevant conflicts to other meeting participants and in the resulting report or work product.

**DECLARATION.** I hereby declare on my honor that the disclosed information is true and complete to the best of my knowledge.

Should there be any change to the above information, I will promptly notify the responsible staff of NCEBM and complete a new declaration of interests form that describes the changes. This includes any change that occurs before or during the meeting or work itself and through the period up to the publication of the final results or completion of the activity concerned.

Date: \_\_\_\_\_

Signature \_\_\_\_\_

## Appendix 6. Code of Conduct for GDG Members

Adapted from Code of Conduct for WHO Experts - [https://cdn.who.int/media/docs/default-source/pvq/global-vaccine-safety/doi-a-b-en-form.pdf?sfvrsn=5ce3d14a\\_4](https://cdn.who.int/media/docs/default-source/pvq/global-vaccine-safety/doi-a-b-en-form.pdf?sfvrsn=5ce3d14a_4) (Annex B)

### Code of Conduct for Experts

NCEBM values and relies upon the normative and technical advice that is provided by leading subject matter experts in the context of its GDGs, meetings and other similar processes. Such advice contributes to the formulation of national guidelines that are disseminated and implemented by NCEBM for the benefit of the whole Kingdom. In order to ensure the integrity of such processes, thereby contributing to their credibility in the eyes of stakeholders, it is critical that experts appointed by NCEBM to render technical or normative advice

1. fully and honestly disclose all relevant interests and biases on the DOI Form that may give rise to real or perceived conflicts of interest. Such disclosure must also be made orally to all fellow GDG, meeting or group members at the outset i.e. unless this is done by the Chairperson or Guideline Advisory Board.
2. spontaneously report any material changes to their disclosed interest on an on-going basis during the period in which the expert serves the Organization;
3. respect the confidential nature of GDG or meeting deliberations or of the advisory function assigned by NCEBM and not make any public statements regarding the work of the committee or meeting or regarding the expert's advice without prior consent from NCEBM;
4. undertake not to engage in activities that may bring reputational harm to the NCEBM process that they are involved in;
5. undertake to represent their views in a personal and individual capacity with the best interest of NCEBM in mind as opposed to representing the views of their employers, other institutions or governments.
6. actively and fully participate in discussions and deliberations within the relevant GDG or meeting.

## Appendix 7. Guidance for the Completion of NCEBM DOI Forms

Adapted from *Guidance to Experts for Completion of WHO DOI Forms* -

[https://cdn.who.int/media/docs/default-source/pvg/global-vaccine-safety/doi-a-b-en-form.pdf?sfvrsn=5ce3d14a\\_4](https://cdn.who.int/media/docs/default-source/pvg/global-vaccine-safety/doi-a-b-en-form.pdf?sfvrsn=5ce3d14a_4) (Annex A)

The following table provides guidance to experts as to the type and extent of information that experts should disclose as they complete NCEBM Declaration of Interests Form.

Type of Interest in Relation to subject of meeting or work	Examples of Information Required
Expert's employment or that of an immediate family member	Indicate: a. name of employer b. title and function c. period of employment
Consulting work	Indicate: a. name of contracting party b. period of consultancy c. nature / subject of consultancy d. amount of income earned per consultancy
Research support	Indicate: a. source of the support b. amount of support c. whether support provided to expert personally, immediate family member or institution to which the expert is affiliated d. subject matter of research supported e. expert's role in the conduct of the research supported (e.g. head of research team, director of programme, scientist part of a larger team)
Investments	Indicate whether investment in any single company is valued at: a. the nature of the investment (e.g. stock, bonds, partial or total ownership interest etc) b. more than US \$5,000 c. provide the name of the company
Intellectual Property (IP)	Describe: a. nature and object of the IP b. whether IP is still protected c. relevant licensing arrangements relating to the IP d. whether royalties are being paid
Public Statements and Positions	Describe: a. forums in which public position taken (e.g. court, parliamentary committee etc.) b. year concerned



	<p>c. in brief, the position held</p> <p>d. the capacity in which the statement was made or position taken (e.g. Mr. Smith in his capacity as president of ABC society)</p> <p>e. indicate for how long approximately the position taken has been held or defended, if applicable e. whether there is a public record of the position held</p>
<p>Unfair or Competitive Advantage</p>	<p>a. state whether information obtained as a result of participation in the NCEBM body or activity could provide you with an unfair competitive advantage and/or a clear actual and direct financial or pecuniary benefit.</p> <p>b. Explain how you would propose to mitigate this concern.</p>