
Identifying and managing conflicts of interest of prospective members of CRE WHiRL committees and working groups developing guidelines

This policy applies to the Centre for Research Excellence in Women's Health in Reproductive Life (CRE WHiRL) committees and groups developing guidelines.

The NHMRC Act 1992 defines a conflict of interest as 'any direct or indirect pecuniary or non-pecuniary interest'. A conflict of interest does not preclude an individual's involvement within a particular group; however, to ensure the independence and integrity of decision-making processes and for transparency, all relevant interests must be declared and managed appropriately.

For further information on conflicts of interest, please visit the NHMRC 'Guidelines for Guidelines website at <https://www.nhmrc.gov.au/guidelinesforguidelines/plan/identifying-and-managing-conflicts-interest>

1. Scope of COI policy

The Conflicts of Interest policy applies to all individuals who participate in the decision-making process as it relates to the development of guidelines within the CRE WHiRL guidelines projects. This includes but is not limited to members of the:

- CRE WHiRL Steering Committee
- Guideline International Advisory Committee
- Guideline Management Committee
- Guideline Reference Group
- Guideline Development Groups
- Guideline technical team, including project manager, methodologist, evidence reviewers

2. The process of disclosing COIs

Any individual who participates in decision making processes relating to work undertaken within the project is required to complete a 'Declarations of Interest' form and return it to the project manager of the project prior to attending their first meeting. Members need to disclose all relevant interests within the previous three (3) years.

3. Identifying conflicts of interest

The intent of this policy is to have the participants in guideline development disclose any interests relevant to any of the guidelines that are under consideration in order that:

- a) such interests can be assessed and managed appropriately
- b) the maximum pertinent expertise can be retained
- c) each participant can form their own judgement about the issue on which they are offering advice, while taking the interests of other group members into consideration.

Overall, this document seeks to provide guidance on (i) what might constitute conflicts of interests and the disclosure of such interests, (ii) the process by which a determination is made as to whether or not there is a conflict of interest and (iii) the kinds of procedures that need to be put in place in order to address or manage any conflicts of interest.

4. Typical circumstances in which conflicts of interest arise

There are two general circumstances under which conflicts of interest may arise, and there may be others:

- a) **Financial interests:** an interest must be declared as a potential conflict when benefits or losses either in money or in-kind have occurred or may occur at a level that might reasonably be perceived to affect a person's judgement in relation to fair decisions about evidence and their participation in group decision-making.
- b) **Other relationships:** an interest must be declared as a potential conflict when a strong position or prejudice or familial connection or other relationship held by a person could reasonably, or be perceived to, affect a person's judgement in relation to fair decisions about evidence and their participation in group decision-making including making an effort to arrive at a consensus.

In particular, conflicts of interest may involve but are not limited to:

- a) financial interests such as receipt by the prospective member or 'immediate family members' (partner and dependent children) of payments, gratuities, consultancies, honoraria, employment, grants, support for travel or accommodation, payment for meals and beverages or entertainment or educational event attendance (including registration fees) or gifts from an entity having a commercial interest in the guidelines
- b) any other direct or pecuniary interest considered relevant (for instance, having provided expert testimony on behalf of an entity with a commercial or other interest in the guidelines to be developed)
- c) relationships, including board membership, employment, stock ownership or consultancies between the prospective member or 'immediate family members' (partner and dependent children) and corporations whose products or services are related to the guideline topics or that have a commercial or other interest in the guidelines to be developed
- d) affiliations to or associations with any organisations or activities which could reasonably be perceived to be an influence due to a competing interest either for or against the issue for which a guideline is being developed
- e) institutional interests (that is, interests arising from an affiliation or association of an individual to an institution) – for example, when parties with an interest in the topic of the guideline have made gifts to the member's institution to endow chairs or fund the construction of research facilities or donate equipment to support a project in which the member is involved; or when research conducted within an institution could affect the value of equity that the institution holds in a company or the value of a patent that the institution licenses to a company
- f) a prospective member having been involved in the development of related guidelines, standards, educational materials or fact sheets, writing of publications, delivering speeches, or engagement in public debate on the topic related to the guidelines to be developed
- g) receipt of research funding by the prospective member or immediate family members from any entity that has a commercial interest in the prospective guidelines
- h) any other influences which might reasonably be considered likely to affect the expert judgement of the individual, or lead to the perception by others that the judgement of the individual is compromised.

5. The appointment of members: guidance for the Directors of the CRE or their delegate on assessment and management of interests

The following serves as a guide to the circumstances in which a prospective committee or working group member may be appointed on condition of a suitable conflict of interest management strategy being put in place. The final decision will be a matter of judgement by the Director(s) or their Delegate. This judgement will take into account the information declared in a written disclosure of interests and will:

- a) consider whether or not there are factors that could, or could be perceived to, affect a person's expert judgement in relation to fair decisions about evidence and their participation in group decision-making
- b) consider whether there could exist real, perceived or potential competing interests that could influence a person's expert judgement or erode the integrity of a group decision
- c) determine whether or not the disclosed interests will be managed by a range of measures (e.g. exclusion from certain discussions¹; divestment of financial interests; resignation from membership of entities whose interests could be affected by any recommendations; a peer review or public consultation process)
- d) ensure the committee or working group is chaired by someone who has no conflicts of interest that could, or could be perceived to, erode the integrity of a group decision.

Disclosures are required of all financial interests and prior to a determination on whether or not the disclosure constitutes a low or high level of conflict of interest. Disclosure is required in relation to disbursements over the three years preceding, and any anticipated disbursements in the twelve months following appointment to the committee or working group.

The Director or their Delegate will determine whether or not, on the basis of the declaration of interests:

- a) an appointment may proceed and participation can occur without any constraint
- b) an appointment may proceed and interests can be managed with constraints – in other words, how a management plan will be put in place which may include measures to mitigate the conflict

In addition to the disclosure of interests both prior to and at the time of appointment, members are required, during their term on the committee or working group, to declare any relevant interests to the Chair if they arise or become evident.

If members are found to have breached this interest policy, the Director must terminate the appointment if the committee member fails to comply, without reasonable excuse, with an obligation to disclose an interest.

As part of the oversight of decisions taken on disclosures of interests, there may be a report included in the guideline on the decisions taken in relation to conflicts of interest.

6. Key elements of the process of disclosing and managing interests

Completion of the disclosure is a prerequisite for consideration of an appointment to a committee or working group developing guidelines.

Appointment to a committee or working group developing guidelines is subject to approval by the Director(s) or Delegate. The Director(s) or Delegate will invite prospective members to complete a form for disclosure of information in relation to interests which may impact on development of the guideline. This form will also record the prospective members' willingness to accept the CRE's decisions on means to manage any conflicts of interest and will confirm their consent for this information to be published in the final guideline or as required by

¹ A conflict of interest may only apply to a specific task within a committee's mandate. For example, an individual may contribute their expertise to a discussion or be able to answer questions from other members but not vote on a final outcome or the crafting of a final recommendation.

NHMRC for guideline approval².

Disclosures of interest will be a standing agenda item at each meeting. Meetings will be presided by the Chair of the committee or working group. Members, including the Chair, will be afforded the opportunity to bring up-to-date their disclosures and voice any concerns about interests relating to other prospective committee members.

The Director(s) or Delegate will be required to create a record of all decisions in relation to appointments to a committee or working group. The record of these decisions will be held in a central CRE repository and on the CRE website.

Prospective members should be advised by letter or email of the details of any conflict of interest management plan.

7. The role of the Chair

- The final decision to determine whether or not the member of a committee or working group can participate in discussion, as new disclosures of interest arise, must be made by the Chair of the committee or working group³
- In order to ensure consistency in decision-making, the CRE must ensure that Chairs, as well as members of committees or working groups receive advice and guidance on the principles contained in this document and on whether or not disclosures of interests may trigger the need for action to manage a conflict of interest throughout the life of a committee or working group.
- If the Chair declares an interest, the Director(s) or Delegate will determine the actions needed for action to manage a conflict of interest throughout the life of a committee or working group.
- The Chair (or, when appropriate, the Director(s) or Delegate) must ensure that a record be kept of the actions taken to manage conflict of interest throughout the life of the committee or working group. The record must include the updating of declarations of interest before each meeting and any actions taken (e.g. a member was asked to leave the meeting while a recommendation was made, or a member was present during discussions but did not take part). If no action was necessary this must also be noted in the record of the meeting.
- Members must also be advised that, at the beginning of every meeting, they will be asked to declare any changes not already stated in their disclosure of interests. Any changes will also be recorded and updated in a register of interests, which will be uploaded to the CRE website.

² It may also be necessary in some circumstances to obtain a family member's direct consent to the disclosure in a manner that is consistent with the requirements of the Information Privacy Principles contained in the Privacy Act 1988.

³ Where a member has disclosed an interest, the Chair and guideline development group members determine whether the disclosure represents no conflict, a low or high conflict. Where there is high conflict, the member must abstain from voting or decision on relevant recommendations. Where there is low conflict, the Chair and Committee are reminded of the nature of the conflict at the commencement of each meeting.