GUIDELINE DEVELOPMENT AND CONFLICTS OF INTEREST
Identifying and Managing Conflicts of Interest of Prospective Members and Members of NHMRC Committees and Working Groups Developing Guidelines
1.1 Background

1.1.1 NHMRC views the identification and management of conflicts of interest as an issue of central importance in ensuring that there is no influence in decision making owing to a competing interest that could erode the integrity of decisions. Developing sound policies for the identification, declaration and management of conflicts of interest is a prerequisite of ensuring public confidence in the integrity of guidelines and other advice issued by NHMRC.

1.1.2 In creating this document, NHMRC is cognisant of international events such as failures to disclose interests and to publish negative results from industry-funded clinical trials; and of concerns that researchers and institutions may be compromised by undisclosed relationships with the private sector, for example, with drug and medical-device companies.

1.1.3 The policies in this document aim to ensure the integrity of the publications issued by NHMRC committees and working groups developing guidelines and to strike an appropriate balance between the existence of ‘interests’ in the topic under review and the expertise required to make sound and meaningful recommendations.

1.1.4 Guideline developers seeking approval under Section 14A of the National Health and Medical Research Council Act 1992 (NHMRC Act) are required to follow their own internal institutional procedures in relation to declaration, identification and management of interests and are required to comply with the principles about disclosure of interests contained in this document in order to meet Standard A6 of the NHMRC Procedures and requirements for meeting the 2011 NHMRC standard for clinical practice guidelines.

1.1.5 Under Section 42A of the NHMRC Act disclosures of interests are required for appointments to take place to committees and working groups. Failure to disclose an interest can lead to the termination of an appointment to a committee or working group (see 1.5.5).

1.2 Characteristics of membership of NHMRC committees and working groups

1.2.1 Guideline development, the provision of advice and peer review all require persons with expertise relevant to the topic under review. Situations will arise in which the pool of individuals able to provide a high level of specialist input is relatively small.

1.2.2 Guidelines, advice and peer review would be of lesser quality without relevant experts. Therefore judgements need to be made which balance the benefit of having persons with expertise against the risks of their interests biasing a process. By the same token, the focus on technical knowledge should not override or dominate all other considerations.

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1 Third party guideline developers should refer to Section 1.1.4 of this document.
1.2.3 Ideally, the individuals appointed to a committee or working group will reflect the diversity of pertinent expertise, perspectives and opinion on the topic under review; and in some areas it might be both feasible and appropriate to appoint a methodologist.

1.2.4 Efforts should be made to appoint members who have no conflicts, though, typically, expertise will coexist with involvement in the topic, personal circumstances and interests that need to be identified, declared and managed.

1.3 The disclosure of interests

1.3.1 The intent of the policy of disclosure of interests 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 by NHMRC 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.

1.4 Typical circumstances in which conflicts of interest arise

1.4.1 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.

1.4.2 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.

1.5 The Appointment of Members: guidance for the NHMRC CEO or their Delegate on assessment and management of interests

Under the NHMRC Act the CEO can delegate any or all of their powers to a committee or a member of NHMRC staff (Section 82(1C)).

1.5.1 The following serves as a guide to the circumstances in which a prospective committee or working group member may be appointed or precluded from appointment or may be appointed on condition of a suitable conflict of interest management strategy being put in place. The final decision on appointment will be a matter of judgement by the CEO 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 discussions; 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.

1.5.2 Disclosures could include but are not limited to the kinds of interests identified under 1.4.2 (a) to (h). Disclosures are required of all financial interests and prior to a determination on whether or not the dollar amounts involved constitute 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.

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2 The disclosure of interests of NHMRC staff is governed by Section 13 of the Public Service Act 1999, which imposes a legally binding Code of Conduct on all public servants covered by that Act (and this includes all NHMRC staff).

3 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.
1.5.3 The CEO 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
   or
   c) an appointment is precluded.

1.5.4 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 (see Section 3.1).

1.5.5 If members are found to have breached this interest policy, under Section 44B(3)(b) of the NHMRC Act, the CEO must terminate the appointment if the committee member fails to comply, without reasonable excuse, with an obligation to disclose an interest under Section 42A of the NHMRC Act.

1.5.6 As part of the oversight of decisions taken on disclosures of interests, there will be an Annual Report to the CEO of NHMRC on the decisions taken in relation to conflicts of interest.

1.5.7 Section 2.1 provides further detail on the internal process of disclosing and managing interests for prospective members of NHMRC committees and working groups developing guidelines.

2.1 Key Elements of the Process of Disclosing and Managing Interests

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

2.1.2 Appointment to a committee or working group developing guidelines is subject to approval by the CEO or their Delegate. The CEO or their 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 NHMRC’s decisions on means to manage any conflicts of interest and will confirm their consent for this information to be posted to the NHMRC web site. Exceptions to this requirement about the publication of interests will be made by the CEO in appropriate circumstances. Publication of this information will occur before work commences on the development of the guideline and as any further conflicts of interest arise. It will also be published in the final guideline.

2.1.3 When NHMRC has received completed disclosures from all prospective members, they will be invited to meet, face-to-face or by teleconference, in order to discuss the register of disclosures and any proposed management plans. This meeting will be presided by the prospective Chair of the committee or working group. Prospective members, including the Chair, will be afforded the opportunity to bring up-to-date their disclosure subsequent to these discussions and prepare a finalised disclosure for review. The meeting will provide all members with an opportunity to voice any concerns about interests relating to other prospective committee members.

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4 Third party guideline developers seeking NHMRC approval will need to appoint a person in accordance with their own institutional rules and codes. See Section 1.1.4 of this document.

5 It will 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.
2.1.4 The CEO or their Delegate will review each finalised disclosure and determine whether or not the disclosure of interests precludes an appointment to a committee or working group and, if an appointment is to go ahead, how a member’s interests will be managed.

2.1.5 In carrying out this review, the CEO or their Delegate will follow the process outlined under 1.5.1 (a) to (d).

2.1.6 The CEO or their 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 NHMRC repository and will inform the Annual Report to the CEO of NHMRC. If the CEO or their Delegate determines that a declared interest precludes the appointment of an individual to a committee or working group, the individual will be advised of the reasons for this determination.

2.1.7 Prospective members should be advised by letter or email of their appointment status and the details of any conflict of interest management plan.

3.1 The role of the Chair

3.1.1 In accordance with Section 42A(6)(b) of the NHMRC Act, the final decision to determine whether or not the member of a committee or working group can participate, as new disclosures of interest arise, must be made by the Chair of the committee or working group.6

3.1.2 In order to ensure consistency in decision-making, the Office of NHMRC must ensure that Chairs, as well 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.

3.1.3 If the Chair declares an interest, the CEO or their Delegate will determine the actions needed for action to manage a conflict of interest throughout the life of a committee or working group.

3.1.4 The Chair (or, when appropriate, the CEO or their 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.

3.1.5 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 updated on the website.

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6 Under Section 42A(5) of the NHMRC Act a member, who has disclosed an interest in a matter under subsection (3) or (4) must not: (a) be present when the Council or committee considers the matter; or (b) take part in any decision of the Council or committee in relation to the matter.