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NHMRC’s Public Consultation of Identifying and Managing Conflicts of Interest: Draft Policies for NHMRC Committees and Working Groups Developing Guidelines

Dear Professor Anderson,

I am pleased to take this opportunity to provide feedback on the NHMRC’s Public Consultation of Identifying and Managing Conflicts of Interest: Draft Policies for NHMRC Committees and Working Groups Developing Guidelines (October 2011) on behalf of the University of Sydney.

We recognise the importance of managing real and perceived Conflicts of Interest (CoI) to ensure the integrity of the NHMRC guideline-writing process, and commend the NHMRC for taking this initiative to protect the excellent reputation of Australian health and medical research here and overseas and to ensure the user community can be confident that NHMRC guidelines provide the best possible advice, that is, advice informed by the best available expertise and which is current, accurate and impartial.

We support the Go8 submission to this public consultation and reinforce their recommendations for procedural transparency, that NHMRC should draw upon international expertise where appropriate, and that NHMRC have processes to manage CoIs for NHMRC Officials making decisions on appointments to guideline-writing working groups and committees. In addition, we have included general observations and detailed feedback on specific items in the draft policy in the answers below to the NHMRC public consultation questions.

Public Consultation questions
Section 1 – Policies Document:

1. Are there any gaps in the issues addressed in this document?

We have identified a number of issues the consideration of which would strengthen the guidelines.

Selection of Prospective Members. NHMRC processes to select and invite prospective committee and working group members are absent from the guidelines and flowchart. Where the NHMRC sees the selection of prospective members as prerequisite to, rather than part of, the CoI process, we would suggest that initial panel selection is integral to the overall integrity of the process and should be included in the CoI guidelines.
Bias and Prejudgement. The guidelines currently conflate two issues which are, and should be, conceptually separate; “conflict of interests” and “pre-judgement or bias.” The former focuses on relationships, duties or personal interests being at odds with one another; the latter requires only a known intellectual or personal position. While there is no real “interest” or duty in conflict in prejudgement or bias, there is a real risk that such an individual will not consider the issues at hand in an open minded way or strive to achieve consensus. Consequently, we would recommend that the notion of “prejudgment and bias” be borne in mind when reviewing the guidelines – e.g., 1.4.2(d), and to some extent 1.4.2(e), deal with pre-judgement rather than with conflict of interests, and this could be made more explicit here and included elsewhere in the guidelines as appropriate.

Reasonableness. We would encourage the NHMRC taking the outsiders’ perspective of “reasonableness” when assessing the likely impact of a disclosed interest. This means considering the reasonable effect or impact of something from the point of view of someone external to the situation (i.e., objectively) rather than from the point of view of a person with knowledge of, or confidence in, the particular individuals involved (i.e., subjectively). The important question is whether an outsider, with the information at hand, would be likely to think that there was some undue influence. It should be clear that there is no room for considerations such as “an outsider who didn’t know Fred might think that, but I know he is a person of the utmost integrity therefore there is no conflict”.

2. Given the difficulties that may arise in finding suitably qualified experts, does the document strike the right balance between ensuring adequate expertise is available to be deployed on the committee and creating a framework to ensure conflicts are managed appropriately?

The overall balance is appropriate. We would, however, like to emphasise the following.

1.5.1(d), 2.1.4(d) and 2.2 flowchart. We believe the requirement that committee chairs should have “no major conflicts” sets the bar too high. While it may not be possible to ensure that a chair with the necessary expertise has no major conflicts, it should be possible to find someone with no “significant” conflicts. If this really is a concern, it would be better to provide that the chair should have no significant conflicts but a senior NHMRC officer (e.g., the CEO) may make an exception to this in appropriate cases if satisfied that it would not otherwise be possible to appoint an appropriate chair. We point to the Go8 suggestion that NHMRC consider international expertise where appropriate.

3. Do you have any suggestions for further guidance on matters to be declared?
4. Is there anything that should be declared which has not been included in this section?

We have identified a number of issues the consideration of which would strengthen the guidelines.

1.3.1. Ensuring public confidence in the outcomes of the NHMRC guideline-writing process is one of the key objectives of the CoI policy. This clause would be strengthened by adding at 1.3.1(c) “the community can have confidence that their interest in the outcome of these groups’ work is properly protected.”

1.4.2 (a) “Equipment” should be explicitly included. This is a fertile area for overlooked conflicts as people may assume that they don’t have a conflict because equipment has been provided to a group or a project rather than to them personally, or they just don’t think to consider whether the provision of equipment might create an inappropriate perception.

1.4.2(b) As noted by the Go8, the definition of “immediate family members” as “partner and dependent children” is too narrow to achieve adequate transparency and should be broadened to include “siblings and their partners, and parents.”
1.5.2. All references in this clause to “an entity” should read “an entity or an individual”. Individuals can own patents, operate as individual traders and engage in commerce just as a company can, whether alone or in partnership and individuals can give gifts or gratuities, employ, etc. In some cases individuals may be used to confer benefits to ensure that payments made are not reflected in corporate accounts or other accessible documents.

One respondent has noted several inconsistencies between (1.4) Typical Considerations about potential conflicts of interest and their translation into (1.5) Guidance for the responsible Senior Officials. For example, 1.4.2(d) includes “related guidelines, standards, education material, and fact sheets” whereas 1.5 does not mention these but includes at 1.5(g), “publications, delivering speeches, engagement in public debate on the topic of concern in the guidelines to be developed”. He suggested the document could be reframed entirely as a guide for NHMRC Officials by collapsing 1.4 into 1.5 thus avoiding potential inconsistencies and overlap.

Finally, we would seek clarification about the nature and extent of the disclosure of CoIs by prospective members and about arrangements at the NHMRC to insure the security of the information provided and the NHMRC’s subsequent assessment. NHMRC should not overburden prospective panel members with Col reporting, and prospective members should have confidence that systems are in place for secure storage of data and its disposal when appropriate. Ideally, a coherent standard for reporting CoIs could be introduced across NHMRC, with Col data stored securely for reuse, so that researchers would not be required to resupply Col information as they fulfill different roles in the NHMRC system (e.g., reviewer, guideline writer, etc.). Otherwise, CoI reporting may act as a disincentive for NHMRC experts.

5. Is the amount to trigger a declaration of interests reasonable?
Yes.

Section 2 – Key Elements and Flow Chart:

1. Are there any gaps in this section in relation to the guidance for the responsible Senior Officials at the Office of NHMRC to apply their judgement in how to manage any conflicts?
No.

2. Is the flow chart an adequate representation of the proposed process?
Yes.

Please do not hesitate to get in touch should you wish to clarify any aspect of this submission or discuss this matter further.

Yours sincerely

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