



Framework for the Natural Therapies Working Committee on Disclosing Interests



August 2021

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1. Objectives and scope

This framework is intended to support members of the Natural Therapies Working Committee (NTWC) in disclosing and managing interests relevant to the Natural Therapies Review.

The framework outlines NTWC decisions to date about what constitutes a relevant interest in the context of the NTWC and provides information on:

- types of interests relevant to the work of the NTWC
- the level of detail expected for each interest
- processes NTWC follows when a new interest is disclosed
- assessing the significance of an interest
- options for management strategies

2. Background

Under Section 39 (s39) of the *National Health and Medical Research Council Act 1992* (NHMRC Act) working committees are established by the CEO to help carry out the functions of the CEO, Council or Principal Committees. A working committee comprises members appointed by the CEO and has functions determined in writing by the CEO.

NHMRC's *Policy on the Disclosure of Interests Requirements for Prospective and Appointed NHMRC Committee Members*¹ (the DOI Policy), outlines the key requirements of working committee members to disclose and document any interests related to matters being considered by the committee. The DOI Policy aligns with the NHMRC Act and the *Public Governance, Performance and Accountability Act 2013* (PGPA Act),

The NTWC has been appointed to oversee the evidence evaluations for the Commonwealth Government's *2019-20 Natural Therapies Review*² by advising on the research protocols, outcomes of interests, evidence evaluation reports and evidence statements for 16 natural therapies, excluded from private health insurance on 1 April 2019. The 16 therapies under review are: Alexander Technique, aromatherapy, Bowen Therapy, Buteyko, Feldenkrais, homeopathy, iridology, kinesiology, naturopathy, Pilates, reflexology, Rolfing, shiatsu, tai chi, Western herbal medicine and yoga.

This framework outlines the key steps for disclosing interests on Committee Centre, and includes decisions to date on the types of interests relevant to the work of the NTWC, including their management. The framework is intended as a supporting document to the DOI Policy¹.

¹ <https://www.nhmrc.gov.au/sites/default/files/documents/attachments/publications/policy-on-the-disclosure-of-interests-requirements.pdf>

² <https://www.health.gov.au/health-topics/private-health-insurance/private-health-insurance-reforms/natural-therapies-review-2019-20>

Interests in the context of the Natural Therapies Working Committee

Members of the NTWC have been appointed for their expertise and experience across a diverse range of professions and fields, including systematic review methods and the types of study designs commonly used in complementary medicine. It is anticipated that when people bring expertise to a committee, they will have interests that require disclosure and in some instances, management. Such interests do not necessarily preclude members' participation and involvement in deliberations, but must be carefully, robustly and transparently managed to safeguard decision-making processes.

Projects carried out by the Public Health Team receive significant scrutiny from stakeholders. This scrutiny often centres on the interests that committee members have, whether the interests have been disclosed, and how the interests have been managed.

Due consideration is applied to members' disclosed interests prior to appointment to NHMRC committees. In considering members' interests the delegate aims to balance the benefit of members' expertise along with any attendant interests, including assessing the risk that an interest may bias or introduce the perception of bias to decision making.

The process for disclosing interests is ongoing throughout the term of a committee and is a legislative requirement of all members of s39 committees. Details of the legislative requirement are outlined in the NHMRC's DOI Policy¹.

3. What is an interest? How are they disclosed?

What types of interests are relevant?

Guidance on what constitutes an interest is available in section 2.1 of the DOI Policy. In summary, an interest is defined in the policy as: *"any direct or indirect, pecuniary or non-pecuniary interest."*³

Whilst the DOI Policy aims to provide general guidance on the types of interests committee members must disclose, it is not exhaustive. **Figure 1** (below) provides examples of the types of interests NTWC members are required to disclose.

³ The word 'pecuniary' is defined in Macquarie Dictionary as an adjective meaning:

1. consisting of or given or exacted in money
2. of or relating to money
3. (of an offence, etc.) entailing a money penalty

Figure 1. Examples of relevant interests

Professional Affiliations
•e.g. employment, board appointments, consultancies, business ownership, professional relationships with entities with an interest in the work of NTWC or with contractors for the 2019-20 Natural Therapies Review
Institutional Affiliations
•e.g. where an entity with an interest in the work of the NTWC has made gifts to the members' institution to fund academic positions, scholarships, the construction of research facilities, or equipment to support a project in which the member is involved
Publications & Presentations
•e.g. journal articles, opinion pieces, textbooks, conference presentations, expert testimony (paid or unpaid)
Research Funding
•e.g. grants, industry funding and receipt of funding by the member or immediate family members from an entity with a commercial interest in the work of the NTWC or from NHMRC
Relationships
•e.g. immediate family members (including spouses) with a related interest, working and personal relationships including board membership, employment at the same organisation, shares and/or ownership or consultancies between the member and entities that have a commercial or other interest in the work of the NTWC
Other Financial
•e.g. patents, royalties, honoraria, 'in kind' payments (such as travel, accommodation, conference registration, meals, beverages, entertainment)
Other Non-Financial
•e.g. gifts from an organisation or entity having a commercial interest in the issues being considered
Social & Other Interests
•e.g. the practice of yoga or Pilates in your spare time

Institutional donations

Members must disclose donations or funding that are provided:

- directly to their individual research group, and
- by a donor/funder with an interest in natural therapies (including private health insurers), and
- for:
 - research into one or more of the 16 natural therapies under review, or
 - educational positions relevant to one (or more) of the 16 natural therapies under review, including (but not limited to) academic positions and scholarships, or
 - research facilities to support a project in which the member is involved

NHMRC understands that depending on the size of a research group and a member's role in it, members may not always be aware of all of the donations/funding received by their research group. However, NHMRC expects members to disclose these donations/funding where they are aware of them or where they would be reasonably be expected to be aware of them (e.g. when they have a senior role in the research group).

What level of detail should be provided?

When disclosing an interest in Committee Centre, it is essential that members provide sufficient information to support NTWC in assessing the significant of the interest and whether a management strategy is required. **Table 1** (below) outlines the types of information that should be provided and examples.

Table 1. Information to provide when disclosing interests

Information Type	Key information to include	Examples
The nature of the interest	This should document the type of interest (e.g. is it direct or indirect, pecuniary or non-pecuniary) as well as providing context about the interest	<p>"I hold a direct, pecuniary interest through my employment with Albury Complementary Medicine Practice, where I practice as a kinesiologist."</p> <p>"I hold an indirect, pecuniary interest through my relationship with my spouse, who owns a 30% share in 'Mind-Body Worx', a physical therapy studio offering yoga, Tai Chi and Pilates"</p> <p>"I hold a direct, non-pecuniary interest through my previously expressed opinions on iridology. See www.theconversation.com.au/joe-bloggs-opinion-article in which I expressed the view that iridology should not be used in conventional naturopathic practice – or funded by Private Health - due to my personal concerns about its diagnostic validity".</p>
The value of the interest	This should describe the monetary (or non-financial, e.g. in-kind) value of the interest. For research grants, separate amounts should be reported for each individual grant provided by each entity.	<p>"I am a recipient of the following grants:</p> <ul style="list-style-type: none"> • 'Title of grant', awarded by XXXX organisation, 2015-2020; \$375,000 • 'Title of grant', awarded by YYY organisation; 2019-2022; \$225,000" <p>"I am an author on a Bowen Therapy textbook for which I receive approximately \$5,000 in royalties per annum. The textbook is prescribed for some Bowen Therapy training courses in Australia."</p> <p>"I received support from ZZZ organisation for travel, accommodation, and conference registration to attend..."</p>
The timeframe for the interest	This should clearly specify the time period during which an individual holds or held an interest.	<p>'From 2015 to 2020...'</p> <p>'On 23 June 2020...'</p>

Information Type	Key information to include	Examples
Who was involved	This should include sufficient detail about the parties involved, and any additional information about the significance of the interest. This includes information about the roles, remit or objectives of any third parties as well as any expectations associated with the relationship.	<p>"I received funding from X organisation which is a manufacturer of a range of naturopathic and homeopathic products"</p> <p>"I was a co-author on a research paper with my colleague and close friend Jane Doe- a prominent researcher and homeopathy proponent - evaluating the effectiveness of homeopathy"</p> <p>"I co-authored an opinion piece on the value of evidence-based medicine with John Smith - a vocal critic of complementary and alternative medicines"</p> <p>"I am a member of association X, which advocates for government funding of some natural therapies treatments. I have provided input to position papers in relation to this in 2019 and 2020."</p>

Timeframe for disclosure of interests

The DOI Policy does not set a specific time limit for disclosures. Disclosures for the last five years are most likely to be relevant. However, members are encouraged to consider the relevance and significance of any interest, regardless of timeframe, that may be relevant to the work of NTWC. For example, a position held a number of years ago (e.g. in a complementary medicine company or lobby group) may be relevant because of the significance of the position or the prominence of the organisation. Similarly, activities undertaken, or positions held recently, may have no relevance to a member's participation in NTWC because of the remoteness or distance from the work of NTWC.

As a general rule, if a member is in doubt about whether an interest is relevant or not, they should disclose the interest. This aids transparency and vests decision making about the relevance of an interest, which would otherwise remain unknown, to NHMRC and the NTWC.

Institutional donations

The following information should be provided when disclosing institutional donations:

- the organisation providing the donation/funding
- the monetary value (\$)
- the size of the donation/funding relative to the overall budget of the research group
- the purposes the donation/funding are allocated to (e.g. the salary of the member, staff salaries, research facilities)

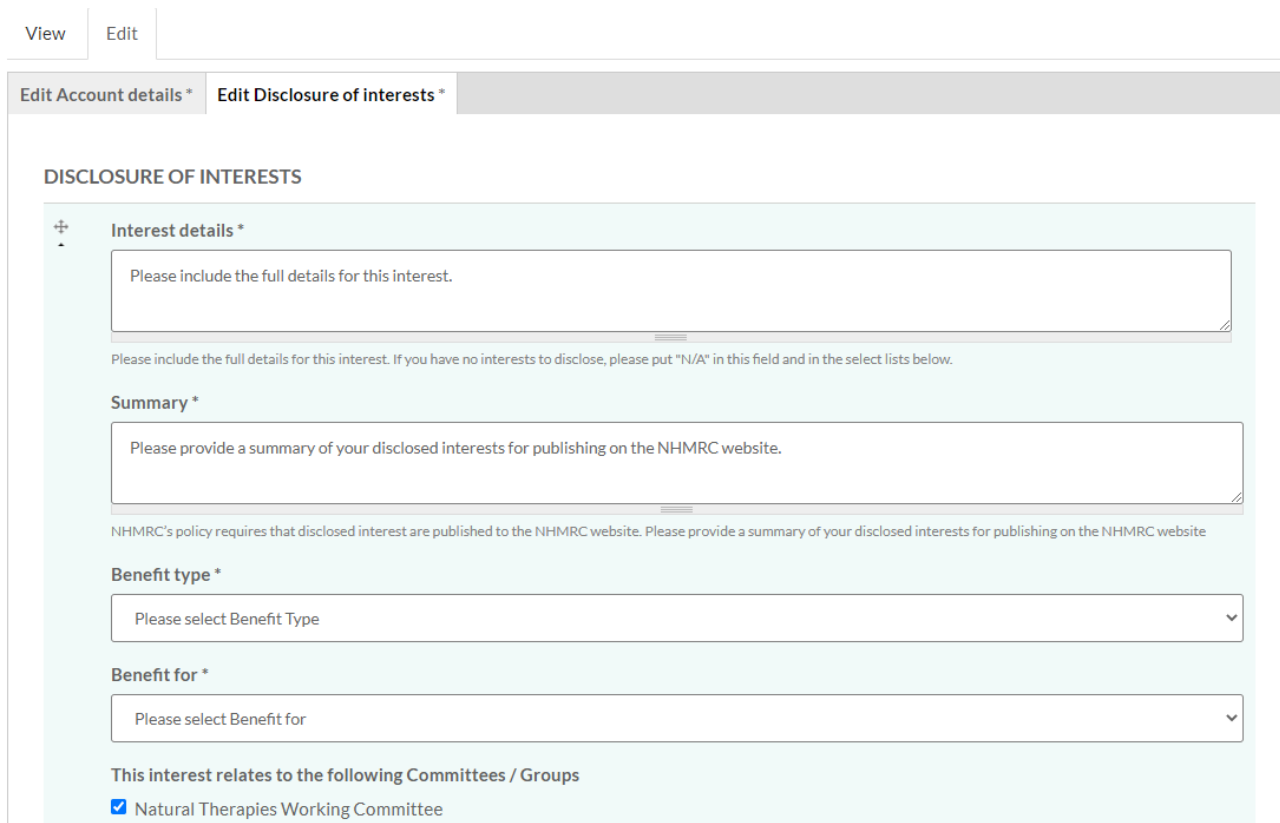
Recording interests in Committee Centre

Members of s39 committees, including NTWC, are required to document their interests in Committee Centre, available from <https://committeecentre.nhmrc.gov.au/>.

NTWC members can access their disclosure of interest through "My Account" >> "Update Details" >> "Edit Disclosure of Interest". Alternatively, the Natural Therapies Project Team can draft text

and upload for a NTWC member, with their permission. **Figure 2** (below) is a screenshot of the relevant page for disclosing interests on Committee Centre.

Figure 2. Details for disclosure of interests on Committee Centre



The screenshot shows the 'Edit Disclosure of interests' form. At the top, there are tabs for 'View' and 'Edit'. Below the tabs, there are two main sections: 'Edit Account details *' and 'Edit Disclosure of interests *'. The 'Edit Disclosure of interests *' section is active and contains the following fields:

- DISCLOSURE OF INTERESTS** (Section Header)
- Interest details *** (Section Header)
 - A text area with the placeholder: 'Please include the full details for this interest.'
 - A note: 'Please include the full details for this interest. If you have no interests to disclose, please put "N/A" in this field and in the select lists below.'
- Summary *** (Section Header)
 - A text area with the placeholder: 'Please provide a summary of your disclosed interests for publishing on the NHMRC website.'
 - A note: 'NHMRC's policy requires that disclosed interest are published to the NHMRC website. Please provide a summary of your disclosed interests for publishing on the NHMRC website.'
- Benefit type *** (Section Header)
 - A dropdown menu with the placeholder: 'Please select Benefit Type'.
- Benefit for *** (Section Header)
 - A dropdown menu with the placeholder: 'Please select Benefit for'.
- This interest relates to the following Committees / Groups** (Section Header)
 - A checkbox labeled 'Natural Therapies Working Committee' which is checked.

4. What happens once an interest is disclosed?

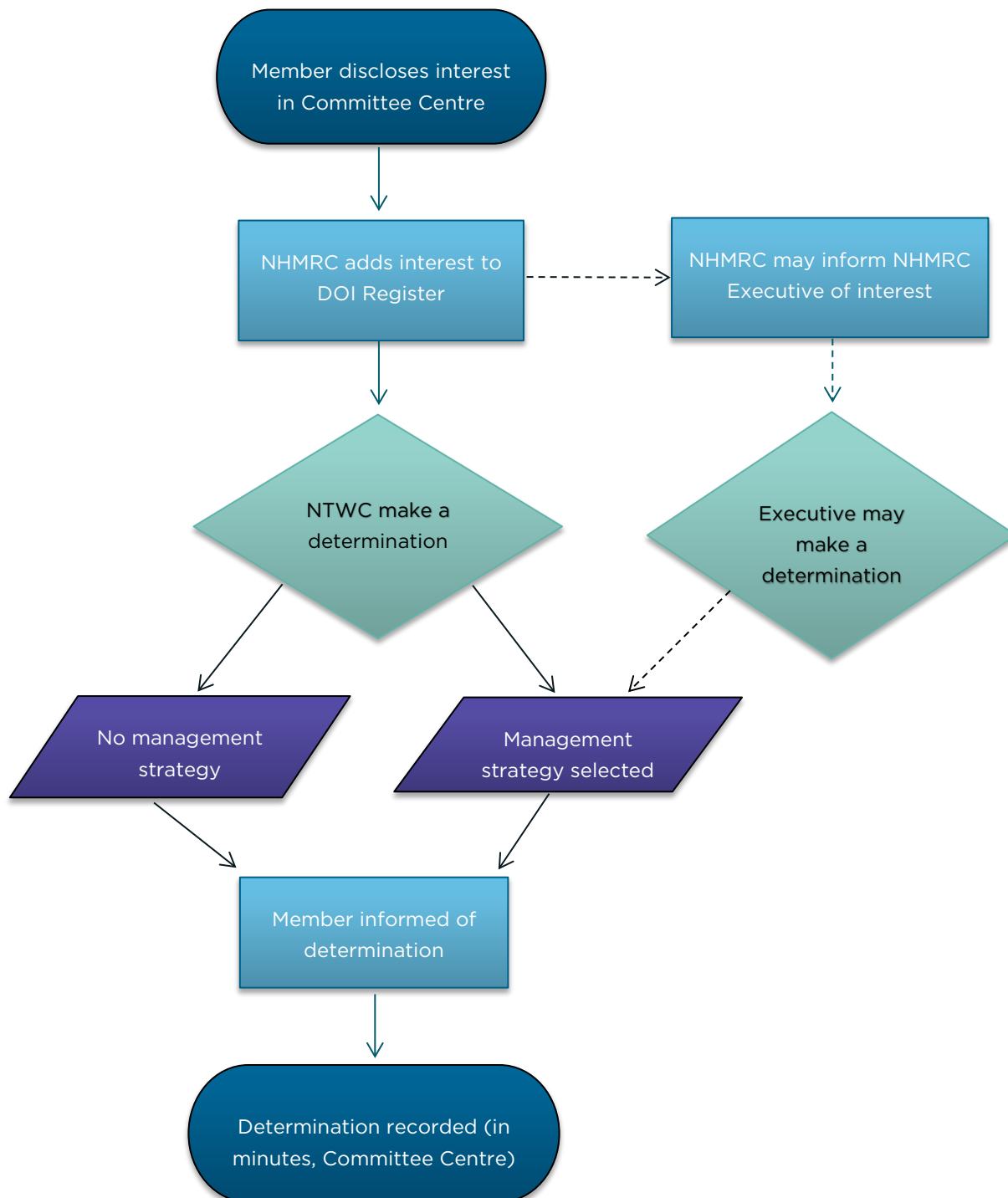
Members should regularly review their disclosure of interests on Committee Centre to identify whether any additional interests need to be disclosed or to clarify or expand on previously disclosed interests. At a minimum, members must review their interests with reference to the agenda for any upcoming meeting (including working group and full NTWC meetings), and identify those agenda items for which they may have relevant interests.

Figure 3, below, shows the process that is followed once a new interest is disclosed in Committee Centre.

NTWC are responsible for considering new interests and making determinations on whether they warrant a management strategy. Any new interests will be added to the Disclosure of Interest Register (circulated ahead of each meeting) and discussed at the start of NTWC meetings.

For more significant interests, NHMRC may also inform NHMRC Executive who may decide a management strategy is required.

Figure 3. Flow chart for interests disclosed after appointment



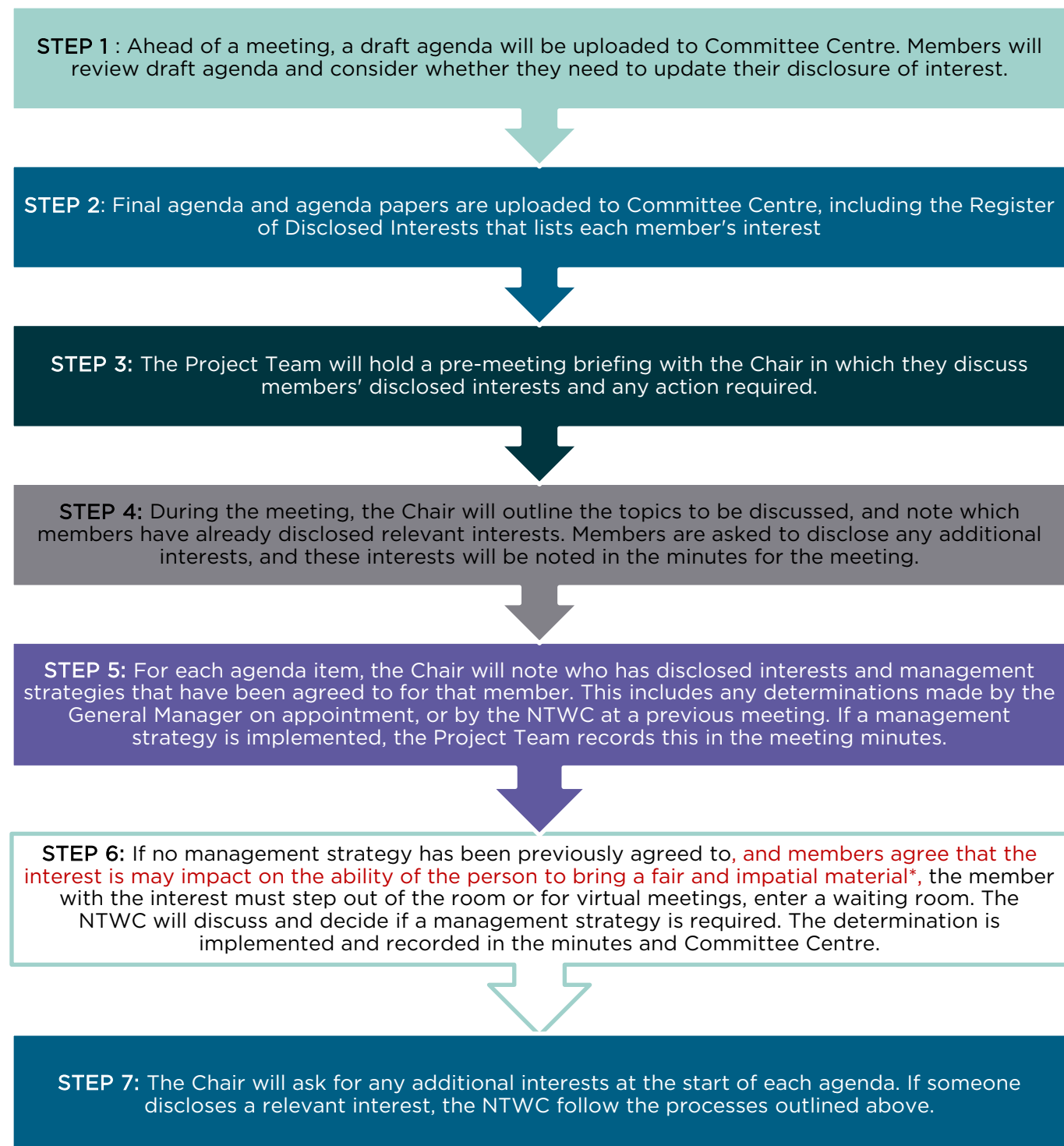
Meeting procedures

At meeting seven (held 29 November 2020) of the NTWC, members agreed to a list of meeting procedures (see **Figure 4** below).

The purpose of these procedures is to:

- ensure interests are disclosed as soon as they become evident
- provide NTWC with sufficient time to discuss and make determinations on interests
- ensure any determinations are implemented and recorded.

Figure 4. Meeting procedures for interests



Information on the types of management strategy that NTWC can select from when making a determination is provided in section 5 *Interest Risk Matrix and Management strategy options*.

Dealing with interests of interests at a meeting

On occasion, one member may have an interest in another's disclosure of interest. For example, Member A's organisation has received a gift from an organisation with an interest in the Natural Therapies Review and Member B has a position on a group that advises how the funding from the gift should be allocated. In this case, Member B has an interest in Member A's interest. If the committee needs to make a decision on Member A's interest, they first need to decide whether Member B can be involved in the decision making.

The process is as follows:

1. Member A and Member B leave the room (or are put in a videoconference waiting room).
2. The remaining members then determine whether to include or exclude Member B from making a determination on Member A's interest.
3. The committee either bring Member B back into the room to make a determination on Member A's interest, OR Member B remains out of the room.
4. The committee agrees on a determination on Member A's interest.
5. Member A is brought back into the room and informed what the determination is.

Reporting of interests

NHMRC records and reports members' interests for a number of purposes, which include but are not limited to:

- enabling the CEO of NHMRC, or delegate, to consider a member's interests when appointing people to NTWC
- supporting NTWC to manage interests, including decision making about whether disclosed interests constitute an actual or perceived conflict, and to determine appropriate management strategies
- documenting members' interests for internal audit and risk management purposes
- ensuring transparency by publishing a public summary of members' interests on NHMRC's website

NOTE: Interests can be found on the [Natural Therapies Working Committee](#) page on the NHMRC website.

As the central registry, Committee Centre is expected to hold comprehensive information about members' interests. The 'interest details' field captures comprehensive details about the interest; and the 'Summary' captures information about a members' interest for the purposes of public reporting on NHMRC's website. The 'Interest details' version of a disclosed interest is typically provided directly from Committee Centre to NTWC members to facilitate decision making about members' interests at each full NTWC meeting and as required.

For further guidance and information about privacy, refer to section 7 *Record of Interests* in the DOI Policy.

5. Interest Risk Matrix and management strategy options

Interest Risk Matrix

NHMRC has developed the following interest risk matrix (see Table 2) to assist members in:

- determining the level of risk of an interest, using a consistent approach
- determining:
 - a) if a management strategy is warranted, and
 - b) an appropriate management strategy to apply based on the level of risk

The Interest Risk Matrix outlines the factors that determine the level of risk of different interests. For each level of risk, the Interest Risk Matrix suggests appropriate management strategies. Examples of interests are provided for each level of risk.



Table 2. Interest Risk Matrix

RISK	CONSIDERATIONS	MANAGEMENT	EXAMPLE
MED-HIGH	<p>Relevant, Personal, Financial – large amount, long duration or significant control (includes family member⁴)</p> <p>Reputational risk</p>	<p>Restrictions on participation in committee (level of restriction agreed by General Manager or committee). E.g. exclusion from the videoconference during discussion <i>and</i> decision making about relevant therapies.</p> <p>Exclusion from relevant working groups</p> <p>Cannot be chair of committee</p> <p>Eliminate interest</p>	<p>Significant income tied to any of the 16 natural therapies or from private health insurance (e.g. working as a practitioner, company employee, long term consultant)</p> <p>Board member for an organisation with a significant interest in the Review (including private health insurance)</p> <p>Spouse earns income from any of the 16 natural therapies or health insurance</p> <p>Responsible for allocating large amount of funding from an organisation with a significant interest in the Review to researchers (where responsibility is solely on member, or shared with only one other person)</p>
MEDIUM	<p>Relevant, Personal or Financial – small amount, short duration or minimal control (includes family member⁴)</p> <p>Reputational risk</p>	<p>Restrictions on participation in committee (level of restriction agreed by committee). E.g. present for discussion but excluded from decision making)</p> <p>Restrictions on participation in relevant working groups (level of restrictions agreed by General Manager or committee). E.g. exclusion from decision making, meetings and correspondence unless input sought from other members.</p> <p>Dilution of interest within working groups</p> <p>Cannot be chair of committee</p> <p>Eliminate interest</p>	<p>Current consultancies or grants with organisations with an interest in the Review</p> <p>Support for speaking engagements, travel, or honoraria from organisations with a significant interest in the Review</p> <p>Royalties from patents related to any of the 16 natural therapies</p> <p>Child works as clerk for an organisation with an interest in the Review</p> <p>Publically expressed opinions that may be perceived to limit the ability of a member to examine evidence in an unbiased way</p> <p>Board member for an association with a position for or against a natural therapy</p> <p>Responsible for allocating funding from an organisation with a significant interest in the Review to researchers (where responsibility is shared with at least two other people OR amount of funding is small)</p>
LOW	<p>No personal or (or minimal) financial relationships, no control</p> <p>Non-financial professional/academic relationships</p>	<p>Full participation or some restriction (level of restriction agreed by General Manager or committee). E.g. full participation in discussion but exclusion from some decision making.</p>	<p>Co-authored publications or supervised personnel on evidence evaluations or methodological reviews</p> <p>Testified before government committees</p> <p>Member of an association that has a public position on a natural therapy</p> <p>Academic royalties from publication related to any of the 16 natural therapies</p> <p>Unpaid board member for a research organisation focused on natural therapies</p>
NONE	As above	Full participation	Academic publications only – examples of expertise, not conflicts of interest

⁴ Family member is defined as: partner and or dependent children.

When deciding on a management strategy, the NTWC should consider management strategies for:

- meetings
- out-of-session decision making (e.g. via email)
- working group membership

In addition to the level of risk of the interest, the NTWC should also consider:

- whether the absence of the member would substantially impede NTWC's consideration of the matter (i.e. the loss of significant expertise or experience from the Committee)
- the effect of the member's presence on public confidence in NTWC's decision-making processes (i.e. the perception of a conflict of interest)
- whether the member can be appropriately involved in certain discussions or decisions (e.g. 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
- the decision-making context and whether the composition of NTWC dilutes or mitigates any potential conflict of interest
- if the member can take action to divest themselves of financial interests or resign from membership of entities whose interests could be affected by NTWC's consideration.

Management strategies for meetings

Based on the level of risk of an interest, members can choose from the management strategies for meetings outlined in **Figure 5** (below).

Figure 5. Management strategies for meetings

The member sits out of the room for items relating to their interest

The member remains in the room, but does not participate in discussion or decision making

The member remains in the room and answers question from other members, but does not otherwise participate in discussion or decision making

The member remains in the room and participates in discussion, but not decision making

The member remains in the room and can participate fully in discussion and decision making (i.e. no management strategy required)

Under the PGPA Act, a member who has disclosed an interest must leave the room (or videoconference) when matters that relate to the interest are discussed unless the members of NTWC determine otherwise. In other words, the default management strategy for an interest is the first listed in **Figure 5**. If NTWC wish for the member to remain in the room when matters related

to the interest are discussed they need to make a determination on a management strategy that will permit this.

Management strategies for out-of-session decision making

Members may also consider management strategies for discussion or decision making that occur outside of full NTWC meetings. For example, members may decide that a member with an interest in an organisation conducting an evidence review will not provide comments on a draft research protocol circulated out of session. See **Figure 6**, below, for options for management strategies that can be implemented for out-of-session decision making.

Figure 6. Management strategies for out-of-session decision making

The member is precluded from accessing documents related to their interest and is excluded from correspondence for out-of-session decision making

The member has access to documents related to their interest, but is excluded from correspondence for out-of-session decision making

The member has access to documents related to their interest, and is included in correspondence for out-of-session decision making, but does not participate

The member has access to documents related to their interest, is included in correspondence for out of session decision making and can participate in decision making (i.e. no management strategy required)

Management strategies for working groups

Working groups can include members with an interest related to the therapy the working group is responsible for. However, there must be more members in the working group without a significant interest related to that therapy (to dilute the perceived or real effect a member with an interest may have on the review process). Where a member has a medium-high risk interest in a therapy, they are to be excluded from decision making and correspondence for the relevant working group. If a working group requires specific content expertise, that member can be called upon for expert input and feedback, but will be excluded from decision making.

Management strategies for authors of studies

NTWC members are required to disclose if they are an author on a study that may be included in an evidence evaluation related to natural therapies.

NHMRC have used the recommendations by Cochrane in the *Conflict of Interest Policy for Cochrane Library Content 2020*, to develop guidance for managing interests related to authorship. In contrast to Cochrane Review authors, NTWC members are not normally involved in conducting key elements of the evidence evaluations, as independent evidence reviewers are responsible for these. However, as a best practice approach, the guidance will ensure members are:

1. aware of the possible conflicts that may arise as a result of authorship
2. aware of best practice management strategies for where an interest arises from authorship
3. transparent about authorship to provide assurance to external stakeholders

Guidance for managing interests related to authorship

Where a member of the NTWC is an author of a study eligible for inclusion in an evidence evaluation, the member:

- will **not** be involved in discussions about the inclusion and exclusion criteria for the relevant therapy
- will **not** be involved in making a decision about the eligibility of the study

In addition, where the independent evidence reviewers have included a study authored by a member, the member will **not** be involved in any of the following for that study:

- data extraction
- risk of bias assessment
- GRADE assessment

Where a member believes that aspects of a study they have authored have been misreported or incorrectly assessed in an evidence evaluation, they can raise this with the overall NTWC. The NTWC (excluding the member that is the author) will determine how (if at all) the reporting or assessment of the study in the evidence evaluation should be edited.

6. Further resources on interests

The following information is available under 'Member Resources' on Committee Centre, to guide members in the disclosure of their interests:

- [NHMRC Policy on the Disclosure of Interests Requirements for Prospective and Appointed NHMRC Committee Members](#) – provides detailed advice on 'what is an interest' and general guidelines for making a disclosure.
- [DOI User Guide for Committee Members](#) – provides step by step instructions for adding or revising a disclosure using the NHMRC Committee Centre

For further information, or for further assistance about disclosing interests, please contact the NHMRC Project Team via ComplementaryMedicine@nhmrc.gov.au.