

**DOCUMENT TITLE:- TPCHF Conflict of Interest Guidelines containing specific reference to grant application processes**

## **Introduction**

This document is to be used in conjunction with [TPCHF Conflict of Interest Policy](#).

[TPCHF's Conflict of Interest Guidelines](#) have been drafted for use by TPCHF with specific reference and thanks to the *Australian Code for the Responsible Conduct of Research (2007)*,<sup>1</sup> *The Canadian Council for International Co-operation Code of Ethics*, and the *NHMRC Training Fellowships Peer Review Guidelines for Funding commencing in 2009*.

TPCHF has specific responsibilities regarding the assessment and funding of medical research grant applications so the TPCHF's Conflict of Interest Guidelines contains both general guidelines for Foundation use and guidelines specific to research application situations. This document has drawn from the above sources in order to leverage industry best practice and contemporary methods.

## **Part 1: General Guidelines**

### **1. Declare it: a Duty to Disclose**

In connection with any actual or possible conflict of interest, an interested person has a duty to disclose and must disclose the existence of an interest, financial or otherwise. He/she will be given opportunity to disclose all material facts to the directors /members of committees with governing board delegated powers considering the proposed transaction or arrangement. The actual or possible conflict of interest issue will be recorded with names, issue in questions and documentation lodged with the Foundation office.

### **2. Discuss it: Determining Whether a Conflict of Interest Exists**

After disclosure of the (financial) interest and all material facts, and after any discussion with the interested person, he/she shall leave the governing board or committee meeting while the determination of a conflict of interest is discussed and voted upon. The remaining Board/ committee members, and /or Chair of the Board/ committee shall decide if a conflict of interest exists. The outcome of this discussion will be recorded in the minutes of the meeting, and a copy of the minutes must be lodged with the Foundation office.

### **3. Dealing with it: Procedures for managing a Conflict of Interest situation**

- a. An interested person may present their point of view at the governing board or committee meeting, especially if they believe that no conflict of interest or potential conflict of interest exists
- b. After stating their view, he/she shall leave the meeting during the discussion of, and if necessary, the vote on, the transaction or arrangement involving the possible conflict of interest.

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<sup>1</sup> This Code has been jointly developed by the National Health and Medical Research Council, the Australian Research Council and Universities Australia, and has broad relevance across all research disciplines. This Code replaces the *Joint NHMRC/AVCC Statement and Guidelines on Research Practice (1997)*. The Code has been written specifically for universities and other public sector research institutions. It is a reference for people outside the research community who require information on the standards expected in the responsible conduct of research within Australia. Compliance with this Code is a prerequisite for receipt of National Health and Medical Research Council and Australian Research Council funding.





- c. The chairperson of the governing board or committee shall, if appropriate, appoint a disinterested person or committee to investigate alternatives to the proposed transaction or arrangement.
- d. After exercising due diligence, the chairperson and/or governing board or committee members will determine whether the organisation can obtain a more advantageous arrangement or transaction from a person that would not give rise to a conflict of interest
- e. If a more advantageous transaction or arrangement is not reasonably possible under the circumstances, the governing board or committee shall determine by a majority vote of the disinterested directors whether the transaction or arrangement is in the Foundation's best interest, for its own benefit, and whether it is fair and reasonable. In conformity with the above processes, it shall make its decision as to whether to enter into the transaction or arrangement.
- f. The following will be recorded:
  - a) The names of the persons who disclosed or otherwise were found to have an interest in connection with an actual or possible conflict of interest,
  - b) the nature of the interest
  - c) any action taken to determine whether a conflict of interest was present, and
  - d) the governing board's or committee's decision as to whether a conflict of interest in fact existed
- g. The minutes of the governing board and all committees with board delegated powers shall contain:
  - a) The names of the persons who were present for discussions and votes relating to the transaction or arrangement,
  - b) the content of the discussion, including any alternatives to the proposed transaction or arrangement, and
  - c) a record of any votes taken in connection with the proceedings

**4. When a conflict of interest situation is perceived by someone else**

- a. If the governing board or committee has reasonable cause to believe a member has failed to disclose actual or possible conflicts of interest, it shall inform the member of the basis for such belief and afford the member an opportunity to explain the alleged failure to disclose.
- b. If, after hearing the member's response and after making further investigation as warranted by the circumstances, the governing board or committee determines the member has failed to disclose an actual or possible conflict of interest, it shall take appropriate disciplinary and corrective action.



## Part 2: Guidelines specific to TPCHF Grant Application Processes

### Relevant recommendations from industry best practice

Section 7 of The *Australian Code for the Responsible Conduct of Research (2007)* makes the following points regarding managing conflicts of interest situations with specific reference to research:

- Conflicts of interest in the research area are common and it is important that they are disclosed and dealt with properly.
- Conflicts of interest have the potential to compromise judgments and decisions that should be made impartially.
- The perception that a conflict of interest exists is also a serious matter and raises concerns about the integrity of individuals or the management practices of the institution.
- Where the circumstances constitute a conflict of interest, or may lead people to perceive a conflict of interest, the person concerned must not take part in decision-making processes.
- A full disclosure is required by those involved, of the circumstances giving rise to concerns about the conflict of interest.
- Where those involved are unable or unwilling to make any disclosure at all, they should withdraw from processes that could be influenced by conflicts.
- The most satisfactory approach is for complete withdrawal (eg leaving the room for the item being discussed), but some bodies allow some general discussion of the matter before the person withdraws. It is preferable that the person concerned does not remain in the room, even if silent, while the matter is debated and decided.

### ***Guidelines for the TPCHF Research Committee***

1. TPCHF is committed to fair review of all grant applications ensuring any conflicts of interest are dealt with consistently, transparently and with rigour.
2. The likely principal areas where conflicts may arise in the course of TPCHF Research Committee undertaking its duties on behalf of the Foundation, are:
  - a) direct involvement in an application by a member of the Research Committee who is the Chief Investigator or an Associate Investigator of a grant application;
  - b) a working involvement of a Research Committee member in the department or the operational area pertaining to the submitted grant application
  - c) potential or future involvement as a scientific, or departmental or institutional colleague with the researchers named in the grant application
  - d) direct or potential involvement of a Research Committee member due to a personal financial interest in the outcome of the granting process
  - e) perceived special involvement with the researchers named in the grant application due to a family/ or out-of work hours social and personal relationship, either currently or during the past five years and/or any other perceived conflicts.





3. Potential and actual situations of conflict of interest will be managed as follows;
  - a) The Foundation Office under direction of the TPCHF CEO, will provide the Chair of the Research Committee and all Research Committee members with the names of all investigators and institutes involved in applications being reviewed including external assessors. This will usually occur through provision of the application forms.
  - b) TPCHF Research Chair and all Research Committee members are to review this information and provide the Foundation Office, via the CEO with a list of all applications with which they have, or may have, a conflict of interest and a description of the nature of that conflict. This needs to be achieved well in advance of the Research Committee meeting at which applications are reviewed.
  - c) The list of all applications with the notification of Research Committee members' conflicts of interest will be reviewed by the Chair of the Research Committee and the CEO. If the number of voting members of TPCHF Research Committee declaring a conflict of interest on the same application, leaves 2 or less members of the research committee without a conflict of interest, then a suitably qualified person from outside TPCH should be requested to work with the remainder of the Research Committee to assess the application.
  - d) All conflicts of interest will be recorded in a document and will be used by the Research Committee Chair during the application review process.
  - e) Prior to discussing each application, the following steps are to be taken:
    - i. the TPCHF Research Committee Chair will announce the application reference number and the name of the applicant to be discussed;
    - ii. the TPCHF Research Committee Chair will refer to the conflicts of interest guidelines provided by the Foundation Office, via the CEO, and announce the committee members that have already identified conflicts of interest with the application;
    - iii. TPCHF Research Committee Members will then be given the opportunity to disclose any conflicts of interest not previously identified;
    - iv. all conflicts of interest will then be discussed by the Research Committee;
    - v. the TPCHF Research Committee Chair will recommend the action to be taken;
    - vi. TPCHF Research Committee Members will discuss the recommended action;
    - vii. after discussion, the TPCHF Research Committee Chair will make the final decision on the action to be taken regarding the conflict of interest;
    - viii. if necessary the TPCHF Research Committee Chair can refer the matter to the Chairman of the Board





- ix. the TPCHF CEO will record the final action on each conflict of interest, as announced by the TPCHF Research Committee Chair as well as the name/s and reasons for any member of the TPCHF Research Committee who disagrees; and
- x. only then may the Research Committee commence discussion of the application.
- xi. At the end of the meeting the Research Committee Chair will check that the record of conflicts of interest final actions is correctly recorded and sign that the COI documentation returning to the Foundation office is correct

A TPCHF Research Committee member may withdraw from discussion of any application if they wish, despite the Chair's decision about the nature of any conflict of interest.

4. After discussing any conflicts of interest, the Research Committee Chair may decide that:
  - a) the member with conflicts must not be present during any discussion of the application;
  - b) the Member has unique knowledge of the research area of the application and may only be present to answer direct questions relating to scientific issues, and is not to be present, or take any further part in the application review process. Note that questions are to be directed after the conflicts of interest have been identified and prior to discussion of the application; or
  - c) no action is deemed necessary.

It is an important fundamental of the peer review process that people within the field have access to other grant applications. This is a privilege not to be abused and reviewers must act in accord with these guidelines and accepted international practices in peer review.

It is possible that TPCHF may receive complaints relating to various forms of alleged conflicts of interest from dissatisfied applicants. Members of TPCHF Research Committee need to be aware that guidelines should be followed. It is therefore necessary that the grant review process is diligently monitored and documented regarding potential and real conflicts of interest. In rare instances the Board may require alternative actions to the Research Committee's assessment if due process is not followed.

5. When agreeing to serve on the TPCHF Research Committee, an incoming Research Committee member is required to sign a document agreeing to abide by the policies and guidelines of TPCHF.



## **Guidelines for Researchers**

**NHMRC Recommend the following Guidelines for Researchers and these are guidelines are adopted by TPCHF as part of the Guidelines for involvement with TPCHF either as an applicant to the grant process or in the course of serving on the TPCHF Research Committee.**

Researchers frequently have a conflict of interest that cannot be avoided. Decision-making processes in research often need expert advice, and the pool of experts in a field can be so small that all the experts have some link with the matter under decision. An individual researcher should therefore expect to be conflicted from time to time, and be ready to acknowledge the conflict and make disclosures as appropriate.

Researchers should use the following approach to manage conflicts of interest:

1. read and understand the policy of the institution
2. maintain records of activities that may lead to conflicts, for example:  
consultancies; membership of committees, boards of directors, advisory groups, or selection committees; and financial delegation or in receipt of cash, services or equipment from outside bodies to support research activities when invited to join a committee or equivalent, review current activities for actual or apparent conflicts and bring possible conflicts of interest to the attention of those running the process
3. disclose any actual or apparent conflict of interest as soon as it becomes apparent.



## Examples of Conflicts of Interest

### Some examples of conflicts of interest and appropriate Grant Review Panel (GRP) decisions:

**Example 1:** A GRP is required to review an application where Prof Brown is an applicant. Dr Smith, a member of the GRP, is also a member of Prof Brown's research unit.

**GRP Action:** Dr Smith is not to be present when Prof Brown's application is being reviewed by the GRP.

**Example 2:** A departmental colleague of Dr Jones (a member of the GRP) has submitted an application for funding for a research area related to hypogeniology. The GRP is required to review this application.

**GRP Action:** Dr Jones has exceptional knowledge in this particular field and her exclusion from discussions may result in the application not receiving fair representation. The GRP decision should be that Dr Jones be directed to answer only specific scientific questions related to the application, and not be present for or take part in general discussions, nor cast a vote on the final ranking of the application.

**Example 3:** Prof Walker, from the Department of Science, University of X, is a Member of a GRP. Dr Johnson, who is from a different Department at the same university, has submitted an application that the GRP is to review. Prof Walker and Dr Johnson are not well acquainted, as their departments are in different locations.

**GRP Action:** Prof Walker should be allowed to participate fully in the review of Dr Johnson's application.

**Example 4:** Last year Prof Thompson transferred from University '1' to University '2'. As a member of a GRP, Prof Thompson will be required to review several applications that have been submitted from University '1'.

**GRP Action:** Provided that Prof Thompson has not been a co-author within the past five years, and has no other Conflicts of Interest regarding the applications, he should be allowed to take full part in the review of applications from University '1'.

**Example 5:** Prof Wilson is a Head of Department at the University X and is also a member of a GRP. Prof Wilson's Department has submitted several applications for the peer review process, some of which will be reviewed by the GRP.

**GRP Action:** If one or more of the applications from Prof Wilson's Department are successful, Prof Wilson could receive financial gain, and therefore should not be present whilst those particular applications are being reviewed.

