

1 PURPOSE

This document sets out the ethics committee standards and requirements with respect to conflicts of interest that may arise from proposals to conduct research at the Peter MacCallum Cancer Centre. It is intended to complement the organisational conflict of interest policy (Refer Policy 1.1.1.22) that applies to a broad spectrum of activities of Peter Mac employees and adopts the relevant definitions, principles, policy statements and procedures described in that policy.

This procedure defines conflict of interest as a situation in which financial or other personal considerations may compromise, or have the appearance of compromising, a researchers' or committee members' professional judgement. It encompasses actual, potential and perceived conflicts of interest, as defined in the institutional policy.

The document also describes committee processes regarding committee member conflicts of interest in order to comply with national standards and in order to respect the expectations of the community and other stakeholders in the process by which research is reviewed by Human Research Ethics Committees. This SOP satisfies the requirements set out in the *National Statement on Ethical Conduct in Human Research (2007, and amendments)*.

2 SCOPE

This SOP applies to researchers and all other staff members involved in research activities at the Peter Mac. It applies to all Peter Mac Human Research Ethics Committee members, sub-committee members, panels and invited experts involved in the review of research proposals at Peter Mac.

This SOP also applies to conflict of interest for multi centre research.

3 RESPONSIBILITY

It is the responsibility of researchers and all other staff involved in research at Peter Mac, all committee sub-committee members, all invited experts involved in research review and all Ethics Committee Secretariat staff to follow and comply with the information set out in this SOP.

Researchers must be aware of potential conflict of interest in the conduct of research and appropriately disclose perceived, potential and actual conflicts of interest during the project review process.

Committee and sub-committee members must disclose perceived, potential and actual conflicts of interest and abstain from participating in decision-making in relation to those projects in which the conflict (potentially) arises. Similarly, invited experts are also required to disclose perceived, potential and actual conflicts.

4 PROCEDURE

The Ethics Committee must ensure that a conflict of interest, whether actual, potential or perceived, in no way influences:

- The rigour of the processes used to review and approve proposed research projects
- The selection of participants in a research project
- The protection of the privacy and other rights of research participants
- The interpretation and use of the data, outcomes and results of a research project

4.1 Conflicts of Interest Involving Researchers

All researchers at all sites for which the Ethics Committee is responsible must disclose the following to the relevant committees/sub-committees:

- All aspects of the funding and other support of the project that would be pertinent to the committee's deliberations regarding the project. In a multi-centre situation, this extends to notification to the reviewing HREC.
- Provision of details about former or recent relationships with research sponsors.
- Any financial or other interests in any entity contributing to the funding or other support of the project.
- Any significant change in either the funding or other support of the research project or in the nature or extent of the interests of the researcher during the course of the project. This requirement applies to any stage of the project up to and including the last publication or data, outcomes or results derived from the project.
- Any other matter that could lead to an actual, potential or perceived conflict of interest.

Conflict of Interest shall be managed as follows:

- All aspects of funding/support must be disclosed.
- The Ethics Committee shall determine the extent of disclosure of interests required to research participants.
- The Ethics Committee shall then inform the researcher of the extent of disclosure of interest required to be included in any participant information and consent forms.

4.2 Conflicts of Interest Involving Committee and Sub Committee Members

Any member of the committee or its sub-committees must disclose the following:

- Any actual, potential or perceived conflict of interest, in any research project that is submitted for consideration by the committee. These interests may include any personal involvement or participation in the research, any financial interest in the outcome of the research or any involvement in competing research.

Disclosure of Conflict of Interest shall be handled as follows:

- The chair of the committee, or sub-committee, shall determine whether a member's interests constitute a conflict of interest at the time the research is considered by the committee or sub-committee.
- If those interests are deemed to create a conflict of interest, then the member must abstain from participating in the process by which the committee makes a determination in relation to that research.
- A member who has a conflict of interest may be asked questions and may be present for discussion concerning the research, but must be excluded from the deliberative discussions and decision-making of the committee or sub-committee concerning the research.
- A record of a conflict of interest shall be made and the minutes shall include details of how the conflict is managed.
- An abstention letter may be sent to communicate the handling of the conflict of interest. In addition, Ethics Committee and sub-committee members shall annually sign a "Declaration of Interest Form" to declare any potential conflicts with the deliberations of the Committee. All completed forms are kept in the Ethics Committee Secretariat office.

4.3 Conflicts of Interest Involving Independent/Expert Reviewers

Expert reviewers who provide the HREC with independent expert comments must:

- Sign a Review Contract which contains a "Declaration of Interest Form" to declare any potential conflicts prior to participating in the review.


5 RELEVANT DOCUMENTS

POLICY 21.1.1 Responsible Conduct of Research

POLICY 1.1.1.22 Declaration of Private Interests

POLICY 1.1.1.24 Conflict of Interest

FORM 1.1.19 Declaration of Private Interests Form

Peter Mac 

ETHICS COMMITTEE

**STANDARD OPERATING PROCEDURE
SOP003**

**TITLE: Handling Conflict of Interest in
Ethical Review of Research**

END OF DOCUMENT