

Melbourne Health Guidelines Cover Sheet

NAME OF DEPARTMENT	OFFICE FOR RESEARCH
NAME OF DOCUMENT	Handling Conflicts of Interest in Research
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ASSOCIATED MELBOURNE HEALTH POLICY	Research Policy
DATE OF ISSUE	3 July 2017
REVISION NUMBER	3
FUNCTIONAL GROUP	Research
DIVISIONAL SPONSOR	Executive Director of Research
EQUIP NATIONAL STANDARDS	<p>Standard 15 Corporate Systems and Safety</p> <p>Criteria 4 The organisation's research program develops the body of knowledge, protects staff and consumers/patients and has processes to appropriately manage the organisational risk.</p>
SUMMARY	<p>The Guidelines for Handling Conflicts of Interest in Research have been developed to clearly set out the roles and responsibilities of Melbourne Health (MH), its Human Research Ethics Committees, advisors to those committees and research staff and the processes in place in relation to managing any potential or real conflicts of interest.</p> <p>These guidelines have been written in accordance with the <i>National Statement on Ethical Conduct in Human Research (2007)</i> and the <i>Australian Code for the Responsible Conduct of Research (2007)</i>.</p> <p>These guidelines should be read in conjunction with the Melbourne Health Guidelines for Research Practice.</p>

1. ASSOCIATED POLICY

Authorised by: Executive Director of Research

Handling Conflicts of Interest in Research

MH Research Policy

2. PURPOSE AND SCOPE

The Guidelines for Handling Conflicts of Interest in Research have been developed to clearly set out the roles and responsibilities of MH, its Human Research Ethics Committee, advisors to the committee and research staff and the processes in place in relation to managing any potential or real conflicts of interest.

A conflict of interest exists where there is a divergence between the individual interests of a person and their professional responsibilities such that an independent observer might reasonably conclude that the professional actions of that person are unduly influenced by their own interests. Conflicts of interest in research are common and it is important that they are disclosed and dealt with properly. A conflict of interest, in the context of research, exists where the interests or responsibilities of an individual or an institution have the potential to influence the way they carry out their institutional role or professional obligations in research. A conflict may relate to financial interests and/or private, professional or institutional benefits that depend significantly on the research outcome. In addition to affecting the integrity of a researcher, a conflict of interest may compromise the research process itself, as well as the institutional governance of research.¹

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,

There is a need for careful ethical scrutiny of research projects to ensure the well being of participants, the integrity of the researchers and the reputation of the institution.

To achieve these goals the key principles which should guide individuals are

1. Full disclosure; and
2. Avoidance of conflict of interest.

These guidelines have been developed to provide a framework for advising individuals involved in research activities on matters related to potential or real conflicts of interest.

3. DEFINITIONS

Conflict of Interest	A situation where there is a divergence between the individual interests of a person and their professional responsibilities such that an independent observer might reasonably conclude that the professional actions of that person are unduly influenced by their own interests.
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4. GUIDELINES

- In each conflict of interest case, there should be a full disclosure by those involved of the circumstances giving rise to concerns about the conflict of interest. This may sometimes involve information that people are unwilling to disclose publicly. A process involving disclosure to a small group in confidence should be provided.
- Where those involved in a conflict of interest situation are unable or unwilling to make any disclosure at all, they should withdraw from processes that could be influenced by conflicts.
- 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-

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making processes. The most satisfactory approach is for complete withdrawal (eg leaving the room while a matter is discussed).

- A record must be kept of how each conflict is managed in the proceedings, or minutes, of the meeting at which the matter is discussed, even if confidential information must be omitted. It is important that the possibility of a conflict is acknowledged in each case, along with an outline of how it was managed.

5. PROCEDURE

5.1 Conflicts of Interest Involving Researchers

Staff conducting research have a responsibility to disclose at the time of proposing and reporting research any potential conflict of interest that may influence or be seen to influence any aspect of the conduct of the research. This responsibility extends to matters related to research including investigations, publication, media reports, ethics and compliance applications, grant applications and applications for appointment or promotion.

The Office for Research and the Human Research Ethics Committee (HREC) require full disclosure of all aspects of the funding of research projects, as well as information pertaining to personal, professional or institutional benefits that depend significantly on the research outcomes.

If the research involves commercial entities the parties (commercial entity and MH) must agree that the purpose of the support (funding and / or study drug/ equipment) is for scientific research and not to promote, influence the sale or purchase of any company product and that any agreement relating to a research project is not part of any other arrangement pursuant to which the institution (MH) is obliged to buy or prescribe any company product. Accordingly, each party should represent and warrant to the other that the support provided under any agreement (i) has not been determined in any manner that takes into account the volume or value of any referrals, reimbursements or business between the institution and company, and (ii) is not offered or provided, in whole or in part, with the intent of, directly or indirectly, implicitly or explicitly, influencing or encouraging the recipient to purchase, prescribe, refer, sell, arrange for the purchase or sale, or recommend favorable placement of a company product or as a reward for past behavior. This or similar wording should be in an agreement or other documentation signed by the parties.

If researchers are invited to attend a committee meeting, they may be required to sign a "Confidentiality and Conflict Declaration Form".

Disclosure of a conflict of interest shall be handled as follows:

- The Committee must discuss the matter and agree on a conflict of interest management or elimination plan.
- A record of a conflict of interest shall be made and the minutes shall include details of how the conflict is managed.
- Where relevant, conflicts of interest should be disclosed to research participants in the Participant Information and Consent Form.

5.2 Conflicts of Interest Involving Committee Members

Members of the MH HREC shall declare any conflict of interest related to the activities being considered by the committee to the chair.

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Additionally, members shall annually sign a “Confidentiality and Conflict Declaration Form” to declare any potential conflicts with the deliberations of the Committee.

Members of the committee shall refrain from involvement in the decision making process in matters in which they have a conflict of interest and absent him/herself from the relevant deliberations.

A record of a conflict of interest shall be made and the minutes shall include details of how the conflict is managed.

5.3 Independent / Expert Reviewers

Expert reviewers who provide a HREC with independent expert comments either through the MH Expert Scientific Review Panel shall be asked to sign a Confidentiality and Conflict Declaration Form. Experts invited to review a clinical trial under the First Time In Humans protocol developed by the Victorian Managed Insurance Authority processed shall sign an “Agreement for the conduct of expert review of a clinical trial”. These agreements shall be signed before a protocol is reviewed and /or before an expert reviewer attends a meeting of a HREC.

5.4 Multi-Centre Research

The Committee must discuss the matter and agree on a conflict of interest management or elimination plan.

A record of a conflict of interest shall be made and the minutes shall include details of how the conflict is managed.

Where applicable, this plan shall include written notification to all relevant bodies of the conflict of interest.

6. ENQUIRIES CONCERNING CONFLICTS OF INTEREST

Any enquiries regarding the handling of conflicts of interest in research should be directed, in the first instance, to:

Dr Angela Watt

Manager Office for Research

Royal Melbourne Hospital city campus

Grattan Street

Parkville, Victoria 3050

Telephone: 61 3 9342 8530

Fax: 61 3 9342 8548

E-mail: angela.watt@mh.org.au

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7. REFERENCES

- Melbourne Health Research Policy
- Melbourne Health Guidelines for Research Practice
<https://www.thermh.org.au/research/researchers/about-research/policies-guidelines-regulations>
- National Statement on Ethical Conduct in Human Research 2007
- Australian Code for the Responsible Conduct of Research 2007
- Guidelines for Accreditation of Organisations v. 2.2; Office of the Gene Technology Regulator 2012
- Australian code for the care and use of animals for scientific purposes 8th edition (2013). Melbourne Health Procedure MH09.08.08 - Conflict of Interest Procedure 2015)

8. FURTHER INFORMATION

Contact the Office for Research on (03) 9342 8530.

9. REVISION AND APPROVAL HISTORY

Date	Rev No	Author and approval
22/03/2010	1	Angela Watt, Manager Office for Research
23/6/2015	2	Sarah Rickard, Manager of Research Governance
03/07/2017	3	Sarah Rickard, Manager Research Governance and Audit