

Purpose

The purpose of this guideline is to provide a transparent process to manage actual and potential conflicts of interest.

Target Audience

Researchers, members of the BH HREC committee and all individuals providing research review or advice.

Definition

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.

Guideline

Introduction

“A conflict of interest in the context of research exists where:

- A person’s individual interests or responsibilities have the potential to influence the carrying out of his or her institutional role or professional obligations in research; OR
- An institution’s interests or responsibilities have the potential to influence the carrying out of its research obligations.

While a conflict may relate to financial interests, it can also relate to other private, professional or institutional benefits or advantages that depend significantly on the research outcomes.

A conflict of interest may compromise the research process itself and/or the institutional processes governing research, and may lead researchers of institutions to base decisions about the research on factors outside the research requirements.

A perception that a conflict of interest exists can be as serious as an actual conflict, raising concerns about an individual’s integrity or an institution’s management practices.”

National Statement on Ethical Conduct in Human Research (2007) (Updated March 2014)
Chapter 5.4 <https://www.nhmrc.gov.au/book/chapter-5-4-conflicts-interest>

Disclosure:

- In each conflict of interest situation, there must be a full disclosure by those involved in the circumstances giving rise to concerns about the conflict of interest. This may sometimes involve information that people are unwilling to disclose publicly. An opportunity to make disclosures to a small group in confidence must 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 making processes. The most satisfactory approach is for complete withdrawal (e.g. 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.

Conflicts of interest should be documented using the [Disclosure of a Related Conflict of Interest Form](#).

Conflicts Of Interest Involving Researchers

Staff involved in research have a responsibility to disclose any potential for conflict of interest that may influence or be seen to influence any aspect of the conduct of the research, at the time of proposing and reporting 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 project, as well as information pertaining to personal, professional or institutional benefits that depend significantly on the research outcomes.

If researchers are invited to attend a committee meeting, they may be required to complete a [Disclosure of a Conflict of Interest Form](#).

The process for dealing with Disclosure of a conflict of interest is 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.

Conflicts Of Interest Involving Research Ethics Committee

Members of a Barwon Health HREC shall declare any conflict of interest related to the activities being considered by the committee to the Chair using the [Disclosure of a Conflict of Interest Form](#).

Additionally, committee member and Barwon Health staff shall annually sign a Privacy, Confidentiality and Security Agreement 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.

Independent/Expert Reviewers

Expert reviewers who provide the BH HREC and individuals who provide BH committees or BH staff and students with independent expert comments related to research shall be asked to complete a [Disclosure of a Conflict of Interest Form](#).

Experts invited to review a clinical trial under the First Time in Humans protocol developed by the Victorian Managed Insurance Authority process shall sign a VMIA "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.

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.

Evaluation

Regular document revision and periodic audit for conflict of interest as part of random research audit.

Key Aligned Documents

[Conflict of Interest Policy](#), PROMPT: Barwon Health \ Organisational Services \ Barwon Health Board of Directors

[Disclosure of a Conflict of Interest Form](#), PROMPT: Barwon Health \ Ethics & Research \ Research

[Privacy Confidentiality and Security Agreement Brochure](#), PROMPT: Barwon Health \ Knowledge and Information Services \ HIS

Key Legislation, Acts & Standards

The National Statement on Ethical Conduct in Human Research (2007) (Updated March 2014)
The Australian Code for the Responsible Conduct of Research

References

Australian Government, (NHMRC). (2014, March 27). Chapter 5.4: Conflicts of interest
Retrieved October 23, 2014 from <https://www.nhmrc.gov.au/book/chapter-5-4-conflicts-interest>

ARC Conflict of Interest and Confidentiality Policy - Version 2014.1

http://www.arc.gov.au/about_arc/COI/ARC_Conflict_of_Interest_and_Confidentiality_Policy_Version_2014.1.pdf

VMIA Expert reviewer agreement and FTIH Protocol and Proformas

<http://www.vmia.vic.gov.au/Risk-Management/Clinical-trials/Clinical-trials-tools-andresources.aspx>

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