

## Purpose

To define conflict of interest and outline disclosure responsibilities relating to researchers, to avoid any actual, perceived or potential conflicts of interest as per chapter 5.4 of the *National Statement on Ethical Conduct in Human Research (2007, incorporating all updates)* and the *Australian Code for the Responsible Conduct of Research (2018)*.

## Definitions

**Conflict of interest** is defined in the context of research as:

- a person's individual interests or responsibilities that 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 that have the potential to influence the carrying out of its research obligations.

A conflict of interest may be defined as:

- **actual:** a situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity.
- **perceived:** one in which a reasonable person would think that the professional's judgment is likely to be compromised by financial or other personal considerations.
- **potential:** involving a situation that may develop into an actual conflict of interest.

**Immediate family:** parents, spouse and dependent children.

**Financial interest related to the research:** financial interest in the sponsor, product or service being tested.

## Guidance

The Principal Investigator is responsible for ensuring the conflict of interest declaration is completed in the eProtocol application regarding any actual, perceived or potential conflicts of interest. The declaration is inclusive of the Principal Investigator's conflicts and members of the study team. A conflict may relate to the researcher or their immediate family's financial interests, other private, professional or institutional benefits or advantages that depend significantly on the research outcomes or other financial interest related to research.

For example, a researcher must disclose any financial involvement the researcher may have with a sponsoring company, such as shares, or other ownership interest, consulting fees, stock options, intellectual property rights, scholarships or funded travel. An example of a non-financial relationship include if a researcher or a member of a researcher's family has close ties to the owner of a company that is involved, or to a competitor.

Bellberry undertakes careful ethical review of research applications and requires disclosure of any actual, perceived or potential conflict of interest. Once identified, Bellberry can assess whether any such relationship or connection might influence, or be seen to influence, any aspect of the study.

## Declaring a conflict

The Principal Investigator is responsible for submitting a notification to the HREC via an amendment within 30 days if a conflict, or change to a relationship, or other source of potential conflict is discovered

with any member of the research team. The Principal Investigator is also responsible for conducting a conflict of interest review annually. This is reported to the HREC via the progress report.

The declaration requires that the Principal Investigator identify any relationship or connection that could, or could be seen to:

- bias the analysis and/or reporting of results
- influence the selection of research participants
- affect the rigour of the review process.

Bellberry recommends that in considering what may be a conflict, the Principal Investigator err on the side of caution – that is, anything that might be considered relevant be identified, even if the Principal Investigator does not believe it will be assessed as being a conflict.

After assessing the declaration, the relevant Human Research Ethics Committee (HREC) may request more information, including steps being taken or planned to manage and minimise any potential impact.

Where a conflict of interest is disclosed, the Committee will determine the best course of action as per the National Statement Chapter 5.4. For example, the Committee may ask the Principal Investigator to provide a plan for the management of the conflict.

If a conflict of interest is not disclosed but is subsequently discovered, Bellberry may undertake a further review, and ethical approval may be withdrawn.

## **References**

[National Statement on Ethical Conduct in Human Research \(2007 incorporating all updates\)](#)

[The Australian Code for the Responsible Conduct of Research \(2018\)](#).