



Australian Government
National Health and Medical Research Council
Australian Research Council



Disclosure of interests and management of conflicts of interest

A guide supporting the *Australian Code for the Responsible Conduct of Research*

Publication details

Publication title:	Disclosure of interests and management of conflicts of interest: A guide supporting the <i>Australian Code for the Responsible Conduct of Research</i>
Published:	2019
Publisher:	National Health and Medical Research Council
NHMRC Publication Reference:	R41E
ISBN Online:	978-1-86496-040-2
Suggested citation:	Disclosure of interests and management of conflicts of interest: A guide supporting the <i>Australian Code for the Responsible Conduct of Research</i> . National Health and Medical Research Council, Australian Research Council and Universities Australia. Commonwealth of Australia, Canberra

Copyright

© Commonwealth of Australia 2019



All material presented in this publication is provided under a Creative Commons Attribution 4.0 International licence (www.creativecommons.org.au), with the exception of the Commonwealth Coat of Arms, NHMRC logo and content identified as being owned by third parties. The details of the relevant licence conditions are available on the Creative Commons website (www.creativecommons.org.au), as is the full legal code for the CC BY 4.0 International licence.

Attribution

Creative Commons Attribution 4.0 International Licence is a standard form license agreement that allows you to copy, distribute, transmit and adapt this publication provided that you attribute the work. The NHMRC's preference is that you attribute this publication (and any material sourced from it) using the following wording:
Source: National Health and Medical Research Council.

Use of images

Unless otherwise stated, all images (including background images, icons and illustrations) are copyrighted by their original owners.

Contact us

To obtain information regarding NHMRC publications or submit a copyright request, contact:

E: nhmrc.publications@nhmrc.gov.au

P: (02) 6217 9000

Contents

1. Introduction	1
2. Disclosure of interests	2
2.1 What interests should be disclosed?	2
2.2 What is a conflict of interest?	3
2.3 Identifying and managing conflicts of interest	3
3. Responsibilities of institutions	4
3.1 Develop and promote institutional policy	4
3.2 Provide training for researchers	4
3.3 Manage institutional interests	5
4. Responsibilities of researchers	5
4.1 Disclose interests and comply with relevant policies	5
4.2 Engage in relevant training	6
5. Resolution of disputes	6
6. Breaches of the Code	6
Additional resources	6

1. Introduction

This guide supports the implementation of the *Australian Code for the Responsible Conduct of Research* (the Code), which articulates the broad principles and responsibilities that underpin the responsible conduct of Australian research.

In particular, this guide is intended to assist institutions and researchers to adhere to relevant principles of the Code, including:

- Principle 3, ‘Transparency in declaring interests...’, which includes the responsibility to disclose interests and manage conflicts of interest.

This guide aims to assist institutions to develop and maintain policies that facilitate the disclosure of interests and the identification and management of conflicts of interest.

These policies are necessary in order to:

- maintain the integrity and reliability of the conduct and outcomes of research
- mitigate the risks associated with the complex relationships between researchers and public and private organisations
- ensure public trust in individuals and organisations involved in research.

This guide also aims to assist those involved in research to understand and apply best practice in disclosing interests and in managing any conflicts that may arise, or may be perceived to arise, from those interests.

The Code and this guide apply to all research conducted under the auspices of Australian institutions. These institutions vary in size, maturity, experience and organisational structure. They range from large and complex universities to small privately funded institutes.

Accordingly, it is acknowledged that different institutional policies and processes are capable of fulfilling the aim of this guide and attempts have been made to ensure that there are appropriate options for flexibility in its application.

2. Disclosure of interests

2.1 What interests should be disclosed?

The Code requires researchers to disclose to an institution all interests that are relevant, or could appear to be relevant, to proposed or ongoing research. Where required, relevant interests may also need to be disclosed to funding bodies, research participants, publishers and journal editors, collaborators and the public.

Institutions may also have interests that are relevant to individual research projects or research programs that may merit disclosure to researchers, funding bodies, research participants, publishers and journal editors, collaborating institutions or the public.

Financial interests are foremost in the public mind, but other interests may also be relevant, including personal, familial, professional and organisational.

Financial interests requiring disclosure include, but are not limited to:

- direct payments to the researcher, such as salary, consultancy payments, speaking fees, panel memberships
- indirect payments to the researcher, for example funding of travel, accommodation, professional development, hospitality
- payments to support research, such as funding from an industry or interest group
- company shares or options
- royalties
- directorships
- some scholarships
- operational or infrastructure support.

Disclosure may also be required when a financial interest of the kind listed above is held by a member of the researcher's immediate family. Financial interests also exist where there is a future expectation of a benefit, for example, proceeds from the sale of intellectual property arising from a project or the promise of shares in a spin-off company.

When disclosing financial interests, researchers and institutions should consider the significance of the financial interest, including:

- the monetary value of the payment, gift, or interest
- the significance that a reasonable, independent observer would attach to the payment, gift or interest
- the circumstances under which a gift or payment is made, for example, if the gift or payment is a regular payment or a single instance.

Non-financial interests that require disclosure include, but are not limited to:

- board membership (even if unpaid) or other affiliation with an organisation that could stand to benefit from or be affected by the research
- personal or social relationships and current and past professional relationships, where relevant
- recent employment with, or role in, organisations with financial links or affiliations with industry groups that could stand to benefit from or be affected by the research.

2.2 What is a conflict of interest?

Under the Code, a conflict of interest exists in a situation where an independent observer might reasonably conclude that the professional actions of a person are or may be unduly influenced by other interests. The perception that a conflict of interest exists is a serious matter and can raise concerns about the integrity of individuals or the management practices of the institution, potentially undermining community trust in research.

The design and conduct of research often requires consultation or expert advice. Particularly in Australia, the pool of experts in a research field can be so small that all the relevant individuals from whom a researcher might seek advice or guidance have some link with the design, sponsorship or conduct of the research project or with related research projects. Whether these activities or relationships give rise to a conflict of interest is a determination to be made by the appropriate decision maker.

In making this determination, it should be recognised that having multiple interests does not necessarily constitute a conflict of interest.

2.3 Identifying and managing conflicts of interest

Having a conflict of interest does not, in itself, imply improper motivation or individual wrongdoing. However, it is important that any conflict of interest is properly identified and managed. After an individual discloses their interests, an appropriate decision maker (e.g. an authorised institutional officer, a committee Chair, or a committee) must determine whether a conflict of interest exists.

If a conflict of interest is identified, the appropriate decision maker must determine what measures, if any, are most appropriate to manage that conflict of interest. These measures should be tailored to the individual circumstances and could include one or more of the following:

- requiring the public disclosure of the interests, for example when presenting or publishing the research
- involving an appropriate individual to oversee some or all of the research activity
- requiring the researcher to absent themselves from any deliberative decision making regarding the research
- requiring the researcher to play a different or reduced role in some or all of the research
- requiring the researcher to relinquish financial or other interests.

3. Responsibilities of institutions

This section provides guidance on the responsibilities that institutions have in relation to disclosure of interests and identification and management of conflicts of interest.

3.1 Develop and promote institutional policy

Institutions that conduct research must have a policy for the disclosure and management of interests that is clearly written and readily accessible to all staff, researchers and other interested parties, including the public. The policy should detail the parties who are responsible for each component of the process.

Under the Code, institutions have the responsibility to:

R3 Develop and maintain the currency and ready availability of a suite of policies and procedures which ensure that institutional practices are consistent with the principles and responsibilities of the Code.

The policy should be consistent with this guide and should:

- a) require that researchers disclose all relevant interests to the institution
- b) guide those involved in research in making appropriate disclosures of relevant interests to research participants, other relevant parties and the public, and to funding bodies, where required
- c) describe the processes that are involved in the identification and management of conflicts of interest, including who is responsible and accountable for these processes
- d) require that a record of interests in relation to current research grants is maintained
- e) require that a record be kept of how each identified conflict was managed, with appropriate consideration of confidentiality requirements
- f) include an expectation that researchers and staff will comply with the disclosure of interest policies and procedures of relevant external bodies
- g) be reviewed regularly to take into account new professional standards or regulatory developments.

3.2 Provide training for researchers

Institutions must provide ongoing training and education that promotes and supports responsible research conduct and that assists researchers and those in other relevant roles to understand and comply with the institution's disclosure of interests policy.

Under the Code, institutions have responsibilities to:

R4 Provide ongoing training and education that promotes and supports responsible research conduct for all researchers and those in other relevant roles.

R5 Ensure supervisors of research trainees have the appropriate skills, qualifications and resources.

3.3 Manage institutional interests

It is good institutional practice to maintain a record of institutional interests that may be perceived to affect the design, review, conduct and dissemination of research carried out at that institution. Examples of specific interests include intellectual property rights or licence revenue (existing or potential); industry or government funding of individual research projects, programs or infrastructure; or shares or options held by the institution in any spin-off enterprises.

If an institutional conflict of interest is identified, a determination must be made about the most appropriate measures for managing that conflict of interest.

In accordance with the principle of transparency, institutions are encouraged to respond to reasonable requests about the sponsorship of research and how any related competing interests or conflicts of interest were managed.

4. Responsibilities of researchers

This section provides guidance on the responsibilities that researchers have in relation to disclosure of interests and management of conflicts of interest.

4.1 Disclose interests and comply with relevant policies

Researchers must refer to and comply with their institutional policies and disclose interests in accordance with established processes. These processes should ensure that researchers:

- a) maintain records of activities that may be relevant to the assessment of whether a conflict of interest exists (e.g. consultancies; membership of boards of directors, advisory groups, or committees; or receipt of or delegation to receive funds, services or equipment from outside bodies to support research activities)
- b) disclose any new interest in a timely fashion
- c) comply with the disclosure of interests policies and procedures of external bodies that the researcher or staff member engages or is affiliated with, for example funders, conference sponsors or organisers and publishers. Relevant roles may include, but not be limited to: company director, not-for-profit board member, scientific advisor or editor
- d) update any disclosures of interest as circumstances change, and at least annually during the period during which the research remains active.

Under the Code, institutions have the responsibility to:

R24 Disclose and manage actual, potential or perceived conflicts of interest.

4.2 Engage in relevant training

Researchers should engage in relevant training about their institution's policy and procedures for the disclosure of interests and the identification and management of conflicts of interest, and should seek out other relevant training opportunities when they perceive a knowledge gap.

Under the Code, researchers have the responsibility to:

R16 Undertake and promote education and training in responsible research conduct.

5. Resolution of disputes

The institutional disclosure of interests policy should include a description of a mechanism for raising concerns and the fair and timely resolution of disputes about any identification or management of a conflict of interest. The policy should include guidance on managing disputes involving researchers from multiple institutions.

Researchers should follow their institution's process to resolve any disputes that arise between them. The parties to the dispute should maintain records of agreements reached through direct dialogue or mediation.

6. Breaches of the Code

Institutions should investigate, assess and manage concerns or complaints related to conflict of interest that may constitute breaches of the Code in accordance with the *Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research* (the Investigation Guide).

Examples of breaches of the Code that are related to the disclosure of interests (see also Section 2.1 of the Investigation Guide) include, but are not limited to:

- failing to disclose a relevant interest in a timely manner
- failing to abide by any decisions as to the management of a conflict of interest.

Additional resources

- [National Statement on Ethical Conduct in Human Research](#) (see Chapter 5.4)
- [ARC Conflict of Interest and Confidentiality Policy](#)
- NHMRC disclosure and management of interests policies and guidance
 - [Identifying and managing conflicts of interest](#)
 - [Guide to NHMRC Peer review 2018](#)
 - [Policy on the Disclosure of Interests requirements for prospective and appointed NHMRC Committee members](#)

