Australian code for the responsible conduct of research: revision of the Joint NHMRC/AVCC Statement and Guidelines On Research Practice / Australian Government, National Health and Medical Research Council, Australian Research Council, Universities Australia.

Contributors

Australia National Health and Medical Research Council (Australia) Australian Research Council Universities Australia

Publication/Creation

[Canberra, Australia]: Australian Government: National Health and Medical Research Council: Australian Research Council: Universities Australia, [2007]

Persistent URL

https://wellcomecollection.org/works/sqftxcze

License and attribution

Conditions of use: it is possible this item is protected by copyright and/or related rights. You are free to use this item in any way that is permitted by the copyright and related rights legislation that applies to your use. For other uses you need to obtain permission from the rights-holder(s).



Wellcome Collection 183 Euston Road London NW1 2BE UK T +44 (0)20 7611 8722 E library@wellcomecollection.org https://wellcomecollection.org



Australian Government

National Health and Medical Research Council

Australian Research Council

Universities Australia

AUSTRALIAN CODE FOR THE RESPONSIBLE CONDUCT OF RESEARCH



REVISION OF THE JOINT NHMRC/AVCC
STATEMENT AND GUIDELINES ON RESEARCH PRACTICE

AUSTRALIAN CODE FOR THE RESPONSIBLE CONDUCT OF RESEARCH

Paper-based publications

This work is copyright. Apart from any use as permitted under the *Copyright Act 1968*, no part may be reproduced by any process without prior written permission from the Commonwealth available from the Attorney General's Department. Requests and inquiries concerning reproduction and rights should be addressed to the Commonwealth Copyright Administration, Attorney General's Department, Robert Garran Offices, National Circuit, Canberra, ACT, 2600 or posted at: http://www.ag.gov.au/cca.

ISBN print 1864964324

C Australian Government 2007

Electronic documents

This work is copyright. You may download, display, print and reproduce this material in unaltered form only (retaining this notice) for your personal, non-commercial use or use within your organisation. Apart from any use as permitted under the *Copyright Act 1968*, all other rights are reserved. Requests for further authorisation should be directed to the Commonwealth Copyright Administration, Attorney General's Department, Robert Garran Offices, National Circuit, Canberra, ACT, 2600 or posted at: http://www.ag.gov.au/cca

ISBN online 1864964383

To obtain details regarding National Health and Medical Research publications contact:

Email:

nhmrc.publications@nhmrc.gov.au

Phone:

toll free 1800 020 103 extension 9520

Internet:

http://www.nhmrc.gov.au/

To obtain details regarding Australian Research Council publications contact:

Email:

communications@arc.gov.au

Phone:

+61 2 6287 6716

Internet:

http://www.arc.gov.au

To obtain details regarding Universities Australia¹ publications contact:

Email:

contact@universitiesaustralia.edu.au

Phone:

+61 2 6285 8200

Internet:

http://www.universitiesaustralia.edu.au

Secretariat

Rhonda Stilling March 2004 to June 2005
Rhonda Stilling June 2005 to July 2006
Miranda Crean July 2006 to March 2007
Robyn Weare March 2007 to July 2007

Technical writing and editing

Biotext Margaret Heaslop and Janet Salisbury

This Australian Code for the Responsible Conduct of Research has been jointly issued by the National Health and Medical Research Council, the Australian Research Council and Universities Australia.



Formerly known as the Australian Vice-Chancellors' Committee

CONTENTS

ABOUTTHE	CODE	1
	Structure of the Code	1
	Development of the Code	1
	Defining research	1
PART A	PRINCIPLES AND PRACTICES TO ENCOURAGE RESPONSIBLE RESEARCH CONDUCT	1.1
Section 1	General principles of responsible research	1.3
	Introduction	1.3
	Responsibilities of institutions	1.3
	Responsibilities of researchers	1.4
	Special responsibilities	1.5
Section 2	Management of research data and primary materials	2.1
	Introduction	2.1
	Responsibilities of institutions	2.1
	Responsibilities of researchers	2.2
Section 3	Supervision of research trainees	3.1
	Introduction	3.1
	Responsibilities of institutions	3.1
	Responsibilities of researchers and supervisors of research trainees	3.1
	Responsibilities of research trainees	3.2
Section 4	Publication and dissemination of research findings	4.1
	Introduction	4.1
	Responsibilities of institutions	4.1
	Responsibilities of researchers	4.2
Section 5	Authorship	5.1
	Introduction	5.1
	Responsibilities of institutions	5.1
	Responsibilities of researchers	5.1
Section 6	Peer review	6.1
	Introduction	6.1
	Responsibilities of institutions	6.1
	Responsibilities of peer reviewers	6.1
	Responsibilities of researchers	6.1

Section 7	Conflicts of interest	7.1
	Introduction	7.1
	Responsibilities of institutions	7.1
	Responsibilities of researchers	7.2
Section 8	Collaborative research across institutions	8.1
	Introduction	8.1
	Responsibilities of institutions	8.1
	Responsibilities of researchers	8.2
PART B	BREACHES OF THE CODE, RESEARCH MISCONDUCT, AND THE FRAMEWORK FOR RESOLVING ALLEGATIONS	9.1
Section 9	Breaches of the Code and misconduct in research	9.3
Section 10	Concepts and definitions	10.1
Section 11	Responsibilities	11.1
Section 12	The framework for resolving allegations	12.1
APPENDICES		
Appendix 1	Process report	A1.1
Appendix 2	Joint Working Group membership	A2.1
Appendix 3	References	A3.1

ABOUT THE CODE

The purpose of the Australian Code for the Responsible Conduct of Research (the Code) is to guide institutions and researchers in responsible research practices. In describing good practice, this Code promotes integrity in research for researchers and explains what is expected of researchers by the community. In providing advice on how to manage departures from best practice, this Code assists researchers, administrators and the community in this important matter.

STRUCTURE OF THE CODE

This Code consists of two main parts:

- · Part A describes the principles and practices for encouraging the responsible conduct of research, for institutions and researchers.
- · Part B provides a framework for resolving allegations of breaches of this Code and research misconduct, addressing the responsibilities of both institutions and researchers.

DEVELOPMENT OF THE CODE

This Code has been jointly developed by the National Health and Medical Research Council, the Australian Research Council and Universities Australia, and has broad relevance across all research disciplines. This Code replaces the Joint NHMRC/AVCC Statement and Guidelines on Research Practice (1997).

This Code is a guide for responsible research conduct in Australia, providing a basic reference for the development of appropriate policies and procedures. It is written specifically for universities and other public sector research institutions. Compliance with this Code is a prerequisite for receipt of National Health and Medical Research Council and Australian Research Council funding.

This Code is a reference for people outside the research community who require information on the standards expected in the responsible conduct of research within Australia.

This Code does not incorporate all the laws, regulations, guidelines and other codes of practice that apply to the conduct of research within Australia. Key guidelines that should be read in conjunction with this Code are listed in Appendix 3.

DEFINING RESEARCH

The meaning of 'research', as used in this Code, is original investigation undertaken to gain knowledge, understanding and insight. It is a broad concept and there is no simple, single way to define research for all disciplines.

A definition of research based on the Research Assessment Exercise for universities in the United Kingdom is provided in Box A.1. This definition has been used successfully for many years, and is useful for illustrating what the term 'research' can cover.

Box A.I Definition of research used in the United Kingdom Research Assessment Exercise

Research is defined as that which:

'... includes work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors; scholarship; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction.

It excludes routine testing and routine analysis of materials, components and processes such as for the maintenance of national standards, as distinct from the development of new analytical techniques. It also excludes the development of teaching materials that do not embody original research.⁵²

Here the term 'scholarship' has the particular meaning:

'... the creation, development and maintenance of the intellectual infrastructure of subjects and disciplines, in forms such as dictionaries, scholarly editions, catalogues and contributions to major research databases.'

RAE (2005). RAE 2008 Research Assessment Exercise: Guidance on Submissions, RAE 03/2005. See Annex B 'Definition of research for the RAE'. http://www.rae.ac.uk/pubs/2005/03/rae0305.pdf

PART A

PRINCIPLES AND PRACTICES TO ENCOURAGE RESPONSIBLE RESEARCH CONDUCT

PARTA

PRINCIPLES AND PRACTICES TO ENCOURAGE RESPONSIBLE RESEARCH CONDUCT

1 GENERAL PRINCIPLES OF RESPONSIBLE RESEARCH

INTRODUCTION

Responsible research is encouraged and guided by the research culture of the organisation. A strong research culture will demonstrate:

- · honesty and integrity
- · respect for human research participants, animals and the environment
- · good stewardship of public resources used to conduct research
- · appropriate acknowledgment of the role of others in research
- · responsible communication of research results.

This section discusses the responsibilities of institutions and researchers to maintain an environment that fosters responsible research.

RESPONSIBILITIES OF INSTITUTIONS

1.1 Promote the responsible conduct of research

Institutions are expected to:

- promote awareness of all guidelines and legislation relating to the conduct of research
- · provide documents setting out clearly the policies and procedures based on this Code
- actively encourage mutual cooperation with open exchange of ideas between peers, and respect for freedom of expression and inquiry
- · maintain a climate in which responsible and ethical behavior in research is expected.

1.2 Establish good governance and management practices

Good institutional governance and management practices encourage responsible conduct by researchers. Such practices promote quality in research, enhance the reputation of the institution and its researchers, and minimise the risk of harm for all involved.

- 1.2.1 Each institution should provide an appropriate research governance framework through which research is assessed for quality, safety, privacy, risk management, financial management and ethical acceptability. The framework should specify the roles, responsibilities and accountabilities of all those who play a part in research.
- 1.2.2 The research governance framework should demand compliance with laws, regulations, guidelines and codes of practice governing the conduct of research in Australia (see Appendix 3). Common law obligations also arise from the relationships between institutions, researchers and participants, while contractual arrangements may impose further obligations.
- 1.2.3 Each institution must ensure the availability of the documents that help guide good research governance, conduct and management.

- 1.2.4 There must be a clear policy on collaborative research projects with other organisations, which requires arrangements to be agreed before a project begins. As a minimum, these arrangements should cover financial management, intellectual property, authorship and publication, consultancies, secondments, ethics approval, and ownership of equipment and data.
- 1.2.5 Each institution must have a well-defined process for receiving and managing allegations of research misconduct.
- 1.2.6 There must be a process for regular monitoring of the institution's performance with regard to these guidelines.

1.3 Train staff

It is important that institutions provide induction, formal training and continuing education for all research staff, including research trainees. Training should cover research methods, ethics, confidentiality, data storage and records retention, as well as regulation and governance. Training should also cover the institution's policies regarding responsible research conduct, all aspects of this Code, and other sources of guidance that are available. Institutions may make arrangements for joint induction and training with other institutions.

1.4 Promote mentoring

Institutions should promote effective mentoring and supervision of researchers and research trainees. This includes advising on research ethics, research design and methods, and the responsible conduct of research.

1.5 Ensure a safe research environment

Each institution must ensure a safe working environment in which to conduct each research project.

RESPONSIBILITIES OF RESEARCHERS

1.6 Maintain high standards of responsible research

Researchers must foster and maintain a research environment of intellectual honesty and integrity, and scholarly and scientific rigour. Researchers must:

- · respect the truth and the rights of those affected by their research
- manage conflicts of interest so that ambition and personal advantage do not compromise ethical or scholarly considerations
- · adopt methods appropriate for achieving the aims of each research proposal
- · follow proper practices for safety and security
- cite awards, degrees conferred and research publications accurately, including the status of any publication, such as under review or in press
- promote adoption of this Code and avoid departures from the responsible conduct of research
- conform to the policies adopted by their institutions and bodies funding the research.

1.7 Report research responsibly

Researchers should ensure that research findings are disseminated responsibly.

1.8 Respect research participants

Researchers must comply with ethical principles of integrity, respect for persons, justice and beneficence.

Written approval from appropriate ethics committees, safety and other regulatory bodies must be obtained when required.

The National Statement on Ethical Conduct in Human Research and Values and Ethics — Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (or any replacement documents) sets out principles for protecting human participants in research (see Appendix 3).

1.9 Respect animals used in research

Researchers must respect the animals they use in research, in accordance with the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* (see Appendix 3).

1.10 Respect the environment

Researchers should conduct their research so as to minimise adverse effects on the wider community and the environment.

1.11 Report research misconduct

A researcher who considers that research misconduct may have occurred must act in a timely manner, having regard to the institution's policies.

SPECIAL RESPONSIBILITIES

1.12 Aboriginal and Torres Strait Islander peoples

It is acknowledged that research with Aboriginal and Torres Strait Islander peoples spans many methodologies and disciplines. There are wide variations in the ways in which Aboriginal and Torres Strait Islander individuals, communities or groups are involved in, or affected by, research to which this Code applies.

This Code should be read in conjunction with Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (NHMRC 2003) and the Guidelines for Ethical Research in Indigenous Studies (Australian Institute of Aboriginal and Torres Strait Islander Studies 2002).

1.13 Consumer and community participation in research

Appropriate consumer involvement in research should be encouraged and facilitated by research institutions and researchers. This Code should be read in conjunction with the *Statement on Consumer and Community Participation in Health and Medical Research* (NHMRC and Consumers' Health Forum of Australia Inc., 2002).

2 MANAGEMENT OF RESEARCH DATA AND PRIMARY MATERIALS

INTRODUCTION

Policies are required that address the ownership of research materials and data, their storage, their retention beyond the end of the project, and appropriate access to them by the research community.

The responsible conduct of research includes the proper management and retention of the research data. Retaining the research data is important because it may be all that remains of the research work at the end of the project. While it may not be practical to keep all the primary material (such as ore, biological material, questionnaires or recordings), durable records derived from them (such as assays, test results, transcripts, and laboratory and field notes) must be retained and accessible.

The researcher must decide which data and materials should be retained, although in some cases this is determined by law, funding agency, publisher or by convention in the discipline. The central aim is that sufficient materials and data are retained to justify the outcomes of the research and to defend them if they are challenged. The potential value of the material for further research should also be considered, particularly where the research would be difficult or impossible to repeat.

RESPONSIBILITIES OF INSTITUTIONS

2.1 Retain research data and primary materials

Each institution must have a policy on the retention of materials and research data. It is important that institutions acknowledge their continuing role in the management of research material and data. The institutional policy must be consistent with practices in the discipline, relevant legislation, codes and guidelines.

- In general, the minimum recommended period for retention of research data is 2.1.1 5 years from the date of publication. However, in any particular case, the period for which data should be retained should be determined by the specific type of research. For example:
 - for short-term research projects that are for assessment purposes only, such as research projects completed by students, retaining research data for 12 months after the completion of the project may be sufficient
 - for most clinical trials, retaining research data for 15 years or more may be necessary
 - for areas such as gene therapy, research data must be retained permanently (eg patient records)
 - if the work has community or heritage value, research data should be kept permanently at this stage, preferably within a national collection.
- 2.1.2 A policy is required that covers the secure and safe disposal of research data and primary materials when the specified period of retention has finished.

Provide secure research data storage and record-keeping facilities

Institutions must provide facilities for the safe and secure storage of research data and for maintaining records of where research data are stored.

- 2.2.1 There must be a policy on research data ownership and storage. This policy must cover all situations that arise in research, including when researchers move between institutions or employers and when data are held outside Australia. Agreements covering ownership and storage of research data should be reviewed whenever there is movement or departure of research staff.
- 2.2.2 Wherever possible and appropriate, research data should be held in the researcher's department or other appropriate institutional repository, although researchers should be permitted to hold copies of the research data for their own use. Arrangements for material held in other locations should be documented.
- 2.2.3 In projects that span several institutions, an agreement should be developed at the outset covering the storage of research data and primary materials within each institution.
- 2.2.4 Research data and primary materials must be stored in the safe and secure storage provided.

2.3 Identify ownership of research data and primary materials

Each institution must have a policy on the ownership of research materials and data during and following the research project. The ownership may also be influenced by the funding arrangements for the project. As a general rule, the most satisfactory arrangement will be that the materials and data retained at the end of a project are the property of the institution that hosted the project, another institution with an interest in the research, or a central repository.

2.4 Ensure security and confidentiality of research data and primary materials

Each institution must have a policy on the ownership of, and access to, databases and archives that is consistent with confidentiality requirements, legislation, privacy rules and other guidelines.

- 2.4.1 The policy must guide researchers in the management of research data and primary materials, including storage, access, ownership and confidentiality.
- 2.4.2 The processes must ensure that researchers are informed of relevant confidentiality agreements and restrictions on the use of research data.
- 2.4.3 Computing systems must be secure, and information technology personnel must understand their responsibilities for network security and access control.
- 2.4.4 Those holding primary material, including electronic material, must understand their responsibilities for security and access.

RESPONSIBILITIES OF RESEARCHERS

2.5 Retain research data and primary materials

When considering how long research data and primary materials are to be retained, the researcher must take account of professional standards, legal requirements and contractual arrangements.

2.5.1 Researchers should retain research data and primary materials for sufficient time to allow reference to them by other researchers and interested parties. For published research data, this may be for as long as interest and discussion persist following publication.

- Research data should be made available for use by other researchers unless this 2.5.2 is prevented by ethical, privacy or confidentiality matters.
- 2.5.3 Research data should be retained for at least the minimum period specified in the institutional policy.
- 2.5.4 If the results from research are challenged, all relevant data and materials must be retained until the matter is resolved. Research records that may be relevant to allegations of research misconduct must not be destroyed.
- 2.5.5 The institutional policy on the secure and safe disposal of primary materials and research data must be followed.

2.6 Manage storage of research data and primary materials

Researchers must manage research data and primary materials in accordance with the policy of the institution. To achieve this, researchers must:

- Keep clear and accurate records of the research methods and data sources, including any approvals granted, during and after the research process.
- 2.6.2 Ensure that research data and primary materials are kept in safe and secure storage provided, even when not in current use.
- Provide the same level of care and protection to primary research records, such 2.6.3 as laboratory notebooks, as to the analysed research data.
- 2.6.4 Retain research data, including electronic data, in a durable, indexed and retrievable form.
- 2.6.5 Maintain a catalogue of research data in an accessible form.
- 2.6.6 Manage research data and primary materials according to ethical protocols and relevant legislation.

Maintain confidentiality of research data and primary materials 2.7

Researchers given access to confidential information must maintain that confidentiality. Primary materials and confidential research data must be kept in secure storage. Confidential information must only be used in ways agreed with those who provided it. Particular care must be exercised when confidential data are made available for discussion.

3 SUPERVISION OF RESEARCH TRAINEES

INTRODUCTION

All research trainees must receive training on research ethics, this Code and the research policies of the institution concerned. This should have high priority for completion early in their careers. Researchers and supervisors must ensure that the role model they provide to junior colleagues is positive and conducive to a research culture of excellence, integrity, professionalism and mutual respect.

In return, research trainees must understand that in undertaking research they are joining an endeavour that requires dedication and accountability. Thus, research trainees also have responsibilities under this section.

RESPONSIBILITIES OF INSTITUTIONS

3.1 Set standards for supervision and mentorship

Institutions must ensure that each research trainee, whether part of the institution or from elsewhere, has an appropriately qualified and trained supervisor. It follows that the ratio of research trainees to supervisors must be low enough for effective intellectual interaction.

Induct research trainees 3.2

Institutions must ensure that research trainees understand the importance of responsible research conduct.

- Each institution must provide induction and training for all research trainees. This training should cover research ethics, occupational health and safety, and environmental protection, as well as technical matters appropriate to the discipline.
- The institution must maintain the ready availability of key documents on the responsible conduct of research, including this Code, institutional guidelines on the conduct of research, requirements for research involving humans and animals, privacy and confidentiality, and the institution's mechanisms for dispute resolution.

RESPONSIBILITIES OF RESEARCHERS AND SUPERVISORS OF RESEARCH TRAINEES

3.3 Ensure training

Supervisors of research trainees should ensure that training starts as soon as possible in the career of a researcher. Training should encompass discipline-based research methods and other relevant skills, such as the ability to interact with industry and to work with diverse communities.

3.4 Mentor and provide support

The research supervisor should guide the professional development of research trainees. This involves providing guidance in all matters relating to research conduct and overseeing all stages of the research process, including identifying the research

objectives and approach, obtaining ethics and other approvals, obtaining funding, conducting the research, and reporting the research outcomes in appropriate forums and media.

Ensure valid and accurate research 3.5

Supervision includes oversight of the research outcomes from those under supervision. A supervisor must be satisfied that the research methods and outcomes of researchers and research trainees under their supervision are appropriate and valid.

3.6 Ensure appropriate attribution

Researchers and supervisors must ensure that research trainees receive appropriate credit for their work.

RESPONSIBILITIES OF RESEARCH TRAINEES

3.7 Seek guidance

A research trainee must demonstrate a professional attitude towards the research. Frequent sessions with the supervisor are important, requiring the cooperation of both parties. The trainee should not wait until approached by the supervisor but should play an active part in maintaining an appropriate schedule of meetings.

3.8 Undertake induction and training

A research trainee should complete all induction and training courses as soon as practical after starting research in an institution.

4 PUBLICATION AND DISSEMINATION OF RESEARCH FINDINGS

INTRODUCTION

Dissemination of research findings is an important part of the research process, passing on the benefits to other researchers, professional practitioners and the wider community. Research activities supported by public funding are rarely complete until the results have been made widely available. However, research is expensive and often cannot be undertaken without the support of commercial sponsors, who seek rewards in the form of rights to commercial exploitation of the research outcomes. In such cases, sponsors may seek to delay or otherwise restrict the release of research results. In publications and dissemination in such instances, the general principles of responsible research set out in Section 1 of this Code apply.

There are many ways of disseminating research findings. Formal publication of the results of research will usually take place in academic journals or books, but this is not always the case. This section of the Code applies to all forms of dissemination, including non-refereed publications, such as web pages, and other media such as exhibitions or films, as well as professional and institutional repositories.

This section should be read in conjunction with Sections 5 (Authorship) and 6 (Peer review).

RESPONSIBILITIES OF INSTITUTIONS

Promote responsible publication and dissemination of research findings 4.1 Institutions must promote an environment of honesty, integrity, accuracy and

4.2 Protect confidentiality and manage intellectual property

responsibility in the dissemination of research findings.

- Institutions must ensure that all parties to the research are made aware of the nature and scope of confidentiality agreements (see also paragraph 2.7).
- Institutions must maintain a policy that protects the intellectual property rights 4.2.2 of the institution, the researcher, research trainees and sponsors of the research, as appropriate.
- 4.2.3 Institutions must ensure that the sponsors of research understand the importance of publication in research and do not delay publication beyond the time needed to protect intellectual property and other relevant interests.
- Institutions must ensure that researchers are aware of contractual arrangements that restrict, delay or limit publication.

Support communication of research findings to the wider public 4.3

- Institutions should make available assistance, such as through a media relations or a science communication officer, to researchers when communicating research findings through the media.
- When reporting research results for publicity purposes, institutions must make 4.3.2 every effort to acknowledge partner institutions and sponsors involved in collaborative research.

RESPONSIBILITIES OF RESEARCHERS

4.4 Disseminate all research findings

Researchers have a responsibility to their colleagues and the wider community to disseminate a full account of their research as broadly as possible.

- 4.4.1 The account should be complete, and, where applicable, include negative findings and results contrary to their hypotheses.
- 4.4.2 Publication activities must take account of any restrictions relating to intellectual property or culturally sensitive data.
- 4.4.3 Researchers must, where feasible, also provide research participants with an appropriate summary of the research results; see, for example, the Statement on Consumer and Community Participation in Health and Medical Research (see Appendix 3).

4.5 Ensure accuracy of publication and dissemination

Researchers must take all reasonable steps to ensure that their findings are accurate and properly reported. If they become aware of misleading or inaccurate statements about their work, they must correct the record as soon as possible.

4.6 Cite the work of other authors fully and accurately

Researchers must ensure that they cite other relevant work appropriately and accurately when disseminating research findings. Use of the work of other authors without acknowledgement is unethical.

4.7 Multiple submissions of research findings

It is not acceptable to include the same research findings in several publications, except in particular and clearly explained circumstances, such as review articles, anthologies, collections, or translations into another language. An author who submits substantially similar work to more than one publisher, or who submits work similar to work already published, must disclose this at the time of submission.

4.8 Obtain permission for republishing

Researchers must take all reasonable steps to obtain permission from the original publisher before republishing research findings.

4.9 Disclose research support accurately

A publication must include information on all sources of financial and in-kind support for the research and any potential conflicts of interest. Researchers must acknowledge the host institution and funding sources of the research.

4.10 Register clinical trials

Researchers must register clinical trials with a recognised register to promote access to information about all clinical trials.

4.11 Manage confidentiality

Sometimes the confidentiality requirements of a sponsor can prevent or delay peer review until after the research results are delivered to the sponsor. In such cases, the researcher must explain to the sponsor that the work has not been subject to peer

review. The importance of peer review in the research process is discussed in Section 6. Whenever a sponsor's confidentiality requirements prevent peer review of a research report before its delivery to the sponsor, the researcher must inform the sponsor.

4.12 Responsibly communicating research findings in the public arena

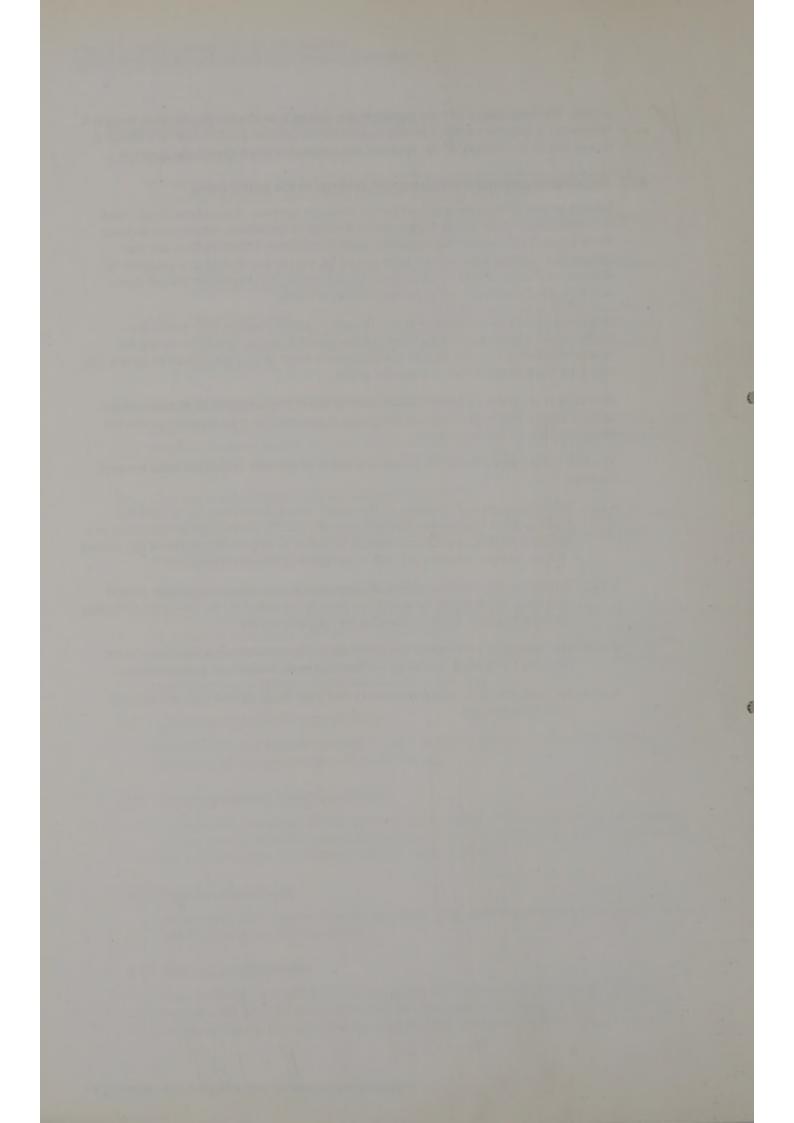
Subject to any conditions imposed by the research sponsor, researchers should seek to communicate their research findings to a range of audiences, which may include the sponsor, professional organisations, peer researchers, policy makers and the community. Researchers may be interviewed by the media, invited to participate in debates, and approached by individuals for comment. It is important that all these activities are considered and supported where possible.

However, while it is straightforward to discuss research findings with peers, it is harder to do so effectively with other groups and the media, where the scope for misunderstanding is much greater and frequently there is no opportunity to review the report of discussions before it becomes public.

Researchers should seek opportunities and be ready to participate in workshops and other activities where professional assistance is provided in communicating with the media and the wider community.

The following points should be noted in relation to publicly communicating research findings:

- 4.12.1 Discussing research findings in the public arena should not occur until the findings have been tested through peer review. In discussing the outcomes of a research project, special care should be taken to explain the status of the project - for example, whether it is still in progress or has been finalised.
- 4.12.2 To minimise misunderstanding about research outcomes, researchers should undertake to promptly inform those directly impacted by the research, including interested parties, before informing the popular media.
- 4.12.3 The outcomes of research with a strong commercial element may have to be presented to a stock exchange or financial body before any public release.
- 4.12.4 Any restrictions on communications that have been agreed with the sponsor must be honoured.



5 AUTHORSHIP

INTRODUCTION

The outcomes of research may be disseminated in a variety of ways but enduring forms, such as journal articles, are particularly important and to be an author for such a form is meritorious. To be named as an author, a researcher must have made a substantial scholarly contribution to the work and be able to take responsibility for at least that part of the work they contributed.

Attribution of authorship depends to some extent on the discipline, but in all cases, authorship must be based on substantial contributions in a combination of:

- · conception and design of the project
- · analysis and interpretation of research data
- · drafting significant parts of the work or critically revising it so as to contribute to the interpretation.

The right to authorship is not tied to position or profession and does not depend on whether the contribution was paid for or voluntary. It is not enough to have provided materials or routine technical support, or to have made the measurements on which the publication is based. Substantial intellectual involvement is required.

A person who qualifies as an author must not be included or excluded as an author without their permission. This should be in writing, and include a brief description of their contribution to the work.

Sometimes the editor of a significant collective work or anthology has responsibilities analogous to those listed above for authorship and, in such cases, similar criteria apply to 'editor' as to 'author'. However, the term 'editor' should be applied only to a person who has played a significant role in the intellectual shaping of a publication.

RESPONSIBILITIES OF INSTITUTIONS

Have criteria for authorship

Institutions must have a policy on the criteria for authorship consistent with this Code, seeking to minimise disputes about authorship and helping to resolve them if they arise.

Where a work has several authors, one should be appointed executive author to record authorship and to manage communication about the work with the publisher.

RESPONSIBILITIES OF RESEARCHERS

Follow policies on authorship

Researchers should adhere to the authorship criteria of this Code and their institution's policies.

Agree on authorship 5.3

Collaborating researchers should agree on authorship of a publication at an early stage in the research project and should review their decisions periodically.

5.4 Include all authors

Researchers must offer authorship to all people, including research trainees, who meet the criteria for authorship listed above. Those offered authorship must accept or decline in writing.

5.5 Do not allow unacceptable inclusions of authorship

Authorship should not be offered to those who do not meet the requirements set out above. For example, none of the following contributions, in and of themselves, justifies including a person as an author:

- being head of department, holding other positions of authority, or personal friendship with the authors
- providing a technical contribution but no other intellectual input to the project or publication
- providing routine assistance in some aspects of the project, the acquisition of funding or general supervision of the research team
- providing data that has already been published or materials obtained from third parties, but with no other intellectual input.

5.6 Acknowledge other contributions fairly

Researchers must ensure that all those who have contributed to the research, facilities or materials are properly acknowledged, such as research assistants and technical writers. Where individuals are to be named, their written consent must be obtained.

5.7 Extend the authorship policy to web-based publications

Authors of web-based publications must be able to take responsibility for the publication's content and must be clearly identified in the publication.

5.8 Maintain signed acknowledgments of authorship for all publications

The department of the executive or senior author must retain the written acknowledgment of authorship discussed above in the form of an original hand-written signature. Where it is not practical to obtain an original signature, it is acceptable to use faxed or emailed consent. This also applies to published conference abstracts and similar publications. If an author is deceased or cannot be contacted, the publication can proceed provided that there are no grounds to believe that this person would have objected to being included as an author.

6 PEER REVIEW

INTRODUCTION

The term 'peer review' is used here to describe impartial and independent assessment of research by others working in the same or a related field. Peer review has a number of important roles in research and research management, in the assessment of grant applications, in selecting material for publication, in the review of performance of researchers and teams, and in the selection of staff.

Participation in peer review processes should be encouraged. Peer review provides expert scrutiny of a project, and helps to maintain high standards and encourage accurate, thorough and credible research reporting.

Peer review may also draw attention to deviations from the principles of this Code, such as double publication, errors and misleading statements. Peer review has been important in the detection of fabrication and fraud in research. However, on its own, it cannot ensure research integrity.

RESPONSIBILITIES OF INSTITUTIONS

6.1 Encourage participation in peer review

Institutions should recognise the importance of the peer review process and encourage and support researchers to participate.

RESPONSIBILITIES OF PEER REVIEWERS

6.2 Conduct peer review responsibly

It is important that participants in peer review:

- · are fair and timely in their review
- act in confidence and do not disclose the content or outcome of any process in which they are involved
- · declare all conflicts of interest, do not permit personal prejudice to influence the peer review process, and do not introduce considerations that are not relevant to the review criteria
- · do not take undue or calculated advantage of knowledge obtained during the peer review process
- · ensure that they are informed about, and comply with, the criteria to be applied
- · do not agree to participate in peer review outside their area of expertise
- · give proper consideration to research that challenges or changes accepted ways of thinking.

RESPONSIBILITIES OF RESEARCHERS

Do not interfere during the peer review process

Researchers whose work is undergoing peer review must not seek to influence the process or outcomes.

6.4 Participate in peer review

Researchers in receipt of public funding have a responsibility to participate in peer review processes.

6.5 Mentor trainees in peer review

Supervising researchers have a responsibility to assist trainee researchers in developing the necessary skills for peer review and understanding their obligation to participate.

6.6 Declare conflicts of interest

Peer reviewers must declare all relevant conflicts of interest.

7 CONFLICTS OF INTEREST

INTRODUCTION

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 the research area are common and it is important that they are disclosed and dealt with properly. Conflicts of interest have the potential to compromise judgments and decisions that should be made impartially. Such compromise could undermine community trust in research.

Financial conflicts of interest are foremost in the public mind but other conflicts of interest also occur in research, including personal, professional and institutional advantages.

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 broad range of actual and potential conflicts of interest in the research environment, and institutions need to have a comprehensive policy in place to cover the likely range of circumstances.

RESPONSIBILITIES OF INSTITUTIONS

7.1 Maintain a policy

Institutions must have a policy for managing conflicts of interest. A range of responses is required, depending on the nature of a conflict, to prevent researchers from influencing decisions unfairly and to avoid unwarranted perception that a conflict of interest has been ignored.

Advice on managing conflicts of interest is readily available from organisations such as law societies and institutes of company directors. In relation to policy, the following points should be observed:

- Ensure that the policy is clearly written and readily available to all staff. 7.1.1
- 7.1.2 In each conflict of interest case, encourage a full disclosure by those involved of the circumstances giving rise to concerns about the conflict of interest. This sometimes involves information that people are unwilling to disclose publicly, and a process involving disclosure to a small group in confidence should also be provided. Where those involved 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 (eg leaving the room for the item), but some bodies allow some general discussion of the matter before the person withdraws. It is preferable that the person concerned does not remain in the room, even if silent, while the matter is debated and decided.

- 7.1.4 A record must be kept of how each conflict is managed in the proceedings, 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.
- The policy should aim to cover the full range of possible conflicts of interest, and the policy must be reviewed regularly to enable amendment informed by experience and legislative and regulatory developments.

RESPONSIBILITIES OF RESEARCHERS

Disclose conflicts of interest 7.2

Researchers frequently have a conflict of interest that cannot be avoided. Decisionmaking processes in research often need expert advice, and the pool of experts in a field can be so small that all the experts have some link with the matter under decision. An individual researcher should therefore expect to be conflicted from time to time, and be ready to acknowledge the conflict and make disclosures as appropriate.

- Researchers should use the following approach to manage conflicts of interest:
 - · read and understand the policy of the institution
 - · maintain records of activities that may lead to conflicts, for example: consultancies; membership of committees, boards of directors, advisory groups, or selection committees; and financial delegation or in receipt of cash, services or equipment from outside bodies to support research activities
 - · when invited to join a committee or equivalent, review current activities for actual or apparent conflicts and bring possible conflicts of interest to the attention of those running the process
 - disclose any actual or apparent conflict of interest as soon as it becomes apparent.
- While there is no requirement to disclose the details of a conflict of interest, for example, because of a confidentiality agreement or for personal reasons, the existence of the conflict must be declared, followed by withdrawal from the situation.

8 COLLABORATIVE RESEARCH ACROSS **INSTITUTIONS**

INTRODUCTION

Research can involve a wide range of collaborations within institutions, between institutions, and internationally. Collaborative research has increased markedly in recent times and this raises specific issues, such as sharing intellectual property, managing research findings, managing conflicts of interest, and commercialising research outcomes.

Research practices differ between countries, but researchers supported by Australian public funding should make every effort to comply with this Code even when conducting research outside Australia. Any need to deviate from this Code must be submitted for institutional approval.

RESPONSIBILITIES OF INSTITUTIONS

Establish agreements for each collaboration

Organisations involved in a joint research project should ensure that an agreement is reached with the partners on the management of the research. Such an agreement should follow the general principles of this Code, including integrity, honesty and a commitment to excellence.

The agreement should be in writing. It must cover intellectual property, confidentiality and copyright issues; sharing commercial returns, responsibility for ethics and safety clearances; and reporting to appropriate agencies. It should address the protocols to be followed by the partners when disseminating the research outcomes, and the management of primary research materials and research data.

The agreement may take various forms, including a legal contract signed by the chief executive officer, an exchange of letters, or a research management plan signed by all parties, or management plans signed by appropriate representatives from all parties.

Each organisation must ensure that its researchers are aware of, and understand, the policy and agreements governing the joint research collaboration.

8.2 Manage conflicts of interest

Institutions must have a policy for managing conflicts of interest that arise in collaborative research (see Section 7).

8.3 Manage access to research materials

The collaborating parties should each identify a person to be involved in the management of research data, primary materials and other items to be retained at the end of the project.

RESPONSIBILITIES OF RESEARCHERS

8.4 Comply with multi-institutional agreements

Researchers involved in joint research must be aware of, and comply with, all policies and written agreements affecting the project, particularly those relating to the dissemination of research findings and the management of research data and primary materials.

8.5 Declare conflicts of interest

When establishing a research collaboration, researchers must disclose as soon as possible any actual or apparent conflicts of interest relating to any aspect of the project.

PART B

BREACHES OF THE CODE,
RESEARCH MISCONDUCT,
AND THE FRAMEWORK
FOR RESOLVING ALLEGATIONS

PARTE

RESEARCH MISCONDUCT,
AND THE FRAMEWORK
FOR RESOLVING ALLEGATIONS

9 BREACHES OF THE CODE AND MISCONDUCT IN RESEARCH

Part A of this document describes principles and practices for encouraging the responsible conduct of research. Part B addresses how to respond to an allegation that research has not been conducted responsibly.

Allegations of deviations from this Code and of misconduct in research will be made from time to time. A prompt and effective response is required in each case. All affected parties must be treated fairly and the situation remedied, and appropriate steps taken to maintain public confidence in the research endeavour. In Australia, minor matters have been handled entirely within institutions. However, more serious matters have been treated in various ways, lacking consistency and public acceptance. Recent studies in Australia, the United States and the United Kingdom (see Appendix 3) indicate a higher rate of unreported offences than expected. Commentators have suggested that growth in the rate of serious offences is real and is the result of commercial and other pressures for success, particularly in areas such as biotechnology and medicine.

A complaint that a researcher has not acted responsibly requires a response that may include the following steps:

- · a discreet investigation
- · a formal inquiry
- · the imposition of a sanction or penalty
- · actions to remedy the situation
- · advice to expert groups and public statements as appropriate.

In most cases the response will not require all these steps, for example when the complaint cannot be sustained or when the researcher concedes. However, an allegation of serious misconduct that may attract a significant penalty, if proven, will require all the steps and great care.

The process outlined above resembles the process for almost all complaints of misconduct. However, research is complex and requires great care to get it right because of the number of interested parties and the extent to which a serious offence may lead to collateral damage. Interested parties range from the employing institution to professional journals and funding bodies; those affected by the offence range from colleagues and students to the professions and public confidence in research.

The number of serious misconduct cases may be increasing, but it is still small, and so is the number of people with experience in managing such cases. Therefore, it is important that processes are consistent and that there is a repository of experiences and advice to guide future cases.

Many commentators have called for serious research misconduct cases to be investigated by an independent statutory tribunal to maximise experience, simplify avoiding conflicts of interest, and achieve transparency and accountability. There is much to recommend such a body but many steps are required to create it, and complex issues in the Australian constitutional and other legal environments must first be addressed. However, this Code does require institutions to establish independent external research misconduct inquiries to evaluate allegations of serious research misconduct that are contested.

MISCONDUCT IN RESEARCH

10 CONCEPTS AND DEFINITIONS

This Code establishes a framework for dealing with allegations of research misconduct and establishing inquiries to determine whether research misconduct has occurred. The penalties for research misconduct will be contained in institutional policies for employment. Serious misconduct in research can lead to serious penalties, including termination of employment, and people who are the subject of such complaints must be entitled to appeal to a higher body through institutional disciplinary processes. For this and other reasons, it is important that definitions are clear and processes demonstrate procedural fairness.

BREACHES OF THE CODE AND RESEARCH MISCONDUCT

In addressing the process for responding to allegations, it is useful to distinguish between minor issues that can clearly be remedied within the institution and more serious matters where the involvement of people who are independent of the institution is desirable. The boundary between minor and serious issues is not sharp, and those determining a particular case will find it helpful to consider the penalties that might be applied by the employing institution if the allegations are true, the steps needed to ensure procedural fairness to all concerned, the extent to which there are consequences outside the institution, and the standing of the research community in the eyes of the general public.

Here, the term breach is used for less serious deviations from this Code that are appropriately remedied within the institution. The term research misconduct is used for more serious or deliberate deviations.

Research misconduct

A complaint or allegation relates to research misconduct if it involves all of the following:

- · an alleged breach of this Code
- · intent and deliberation, recklessness or gross and persistent negligence
- · serious consequences, such as false information on the public record, or adverse effects on research participants, animals or the environment.

Research misconduct includes fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting the results of research, and failure to declare or manage a serious conflict of interest. It includes avoidable failure to follow research proposals as approved by a research ethics committee, particularly where this failure may result in unreasonable risk or harm to humans, animals or the environment. It also includes the wilful concealment or facilitation of research misconduct by others.

Repeated or continuing breaches of this Code may also constitute research misconduct, and do so where these have been the subject of previous counselling or specific direction.

Research misconduct does not include honest differences in judgment in management of the research project, and may not include honest errors that are minor or unintentional. However, breaches of this Code will require specific action by supervisors and responsible officers of the institution.

Box B.1 contains some examples of research misconduct.

Box B.1 Examples of research misconduct

There are many ways in which researchers may deviate from the standards and provisions of this Code, including but not limited to:

- · fabrication of results
- · falsification or misrepresentation of results
- · plagiarism
- · misleading ascription of authorship
- · failure to declare and manage serious conflicts of interest
- · falsification or misrepresentation to obtain funding
- conducting research without ethics approval as required by the National Statement on Ethical Conduct in Research Involving Humans and the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes
- · risking the safety of human participants, or the wellbeing of animals or the environment
- · deviations from this Code that occur through gross or persistent negligence
- · wilful concealment or facilitation of research misconduct by others.

Relationship to other forms of misconduct

The framework in this part of the Code is designed to investigate and make findings on the veracity of allegations about research misconduct. The need for a framework specifically for the investigation of research misconduct arises because of the complex and technical issues commonly associated with research; because third parties, such as collaborators, publishers, and potential beneficiaries of the research, will usually be from outside the institution; and because of the need to assure the public that researchers and their institutions regard research misconduct as a serious matter.

The research misconduct framework contained in this Code is designed to determine findings of fact and what, if any, research misconduct has occurred. This research misconduct framework does not address disciplinary issues.

Employing institutions have agreements with their employees on other forms of misconduct, such as harassment, bullying or financial misconduct. This Code introduces additional processes that are to be applied when the allegations involve research misconduct. The processes in this Code are not for the investigation of other forms of misconduct, although sometimes research misconduct may be associated with other forms of misconduct.

The findings of fact and any determinations of research misconduct reached through processes that comply with this Code must then be used within the institution's separate procedures regulating employment conditions.

Misconduct unrelated to the research process is not research misconduct and falls outside the scope of this Code.

The processes of resolving research misconduct should be progressively incorporated into the institution's instruments regulating employment conditions when these are next negotiated. Responsibility for decisions on employment or sanctions of employees found to have committed research misconduct remains with the employing institution.

Chief executive officer (CEO)

The CEO is the chief executive officer of the institution where a departure from this Code or misconduct in research is alleged to have taken place. In an Australian university, for example, the CEO is the vice-chancellor.

Designated person

The role of the designated person is to advise the CEO or their delegated officer whether allegations appear to be justified and whether a prima facie case exists. The designated person should be a senior member of the institution's management structure who is experienced in research and research management.

The designated person receives a written allegation, conducts a preliminary investigation, and provides advice to the CEO or their delegated officer. The designated person must maintain full records of all matters that relate to allegations of research misconduct. In most university settings, for example, the designated person will be the deputy vice-chancellor (research) or similar. The designated person must not be the CEO.

When undertaking a preliminary assessment of allegations, the designated person should take into account the requirements of this Code and the institution's policy on research misconduct. He or she should also consider whether any immediate action should be taken, such as referral of allegations not related to research to other institutional disciplinary processes. Where necessary, the designated person must ensure that arrangements in the local workplace are fair to all parties until the allegations are resolved. The designated person must have authority to secure all relevant documents and evidence so that they are available if it is decided that the allegations are to be investigated.

The designated person must advise the CEO or their delegated officer whether the allegations should be dismissed, dealt with under misconduct provisions unrelated to research misconduct, referred back to the departmental level with instructions as to how they are to be handled, or investigated further through a research misconduct inquiry. If the advice is to investigate the matter further, the designated person should also advise how the inquiry should be constituted. After providing advice to the CEO or their delegated officer, the designated person should not play any further role in the matter, except that he or she may be called to give evidence or expert opinion.

Adviser in research integrity

Institutions must appoint one or more senior staff members as advisers in research integrity. Each adviser will be able to advise a staff member who is unsure about a research conduct issue and may be considering whether to make an allegation. Advisers should be people with research experience, wisdom, analytical skills, empathy, knowledge of the institution's policy and management structure, and familiarity with the accepted practices in research. An adviser should not be involved in a case if he or she has a relevant conflict of interest.

The adviser in research integrity should explain the options open to the person considering, making, or having made an allegation. These options include:

- referring the matter directly to the person against whom the allegation is being made
- · not proceeding or withdrawing the allegation if discussion resolves the concerns
- · referring the allegation to a person in a supervisory capacity for resolution at the local or departmental level
- making an allegation of research misconduct in writing to the designated person.

The adviser's role does not extend to investigation or assessment of the allegation.

The adviser must not make contact with the person who is the subject of the allegation, and he or she must not be involved in any subsequent inquiry.

Procedural fairness

When an institution establishes a panel of people to conduct an inquiry that may lead to disciplinary action, the person who is the subject of the inquiry must be granted a fair hearing under the legal principle of procedural fairness³, also known as 'natural justice'. To ensure procedural fairness, the allegations of research misconduct must be stated clearly in writing, the person facing the allegations has a right to be heard, and the members of the panel must be free from bias or preconception and must conduct themselves in a manner that demonstrates this.

In addition, the panel should provide its findings, and the reasons for those findings, in writing. There should also be an avenue for the findings to be appealed.

See Forbes (2002), Justice in Tribunals, (3rd ed) for a more detailed discussion of procedural fairness and natural justice

11 RESPONSIBILITIES

A number of people have responsibilities for resolving allegations of breaches of this Code and research misconduct, including:

- · the CEO, who has overall responsibility for the process, although certain aspects may be delegated as agreed by the governing body of the institution
- · the designated person, who conducts a preliminary investigation to assess the allegations and provides advice to the CEO or their delegated officer
- · advisers in research integrity, appointed by the institution to advise those making, or considering making, allegations
- · the head of department or research centre
- · research supervisors
- researchers.

It is important that all are aware of their responsibilities, the institutional policies that govern research, and the process for receiving and resolving allegations.

Anyone who forms a reasonable suspicion that research misconduct has occurred must act in a timely manner in accordance with the institution's policy.

RESPONSIBILITIES AT THE INSTITUTIONAL LEVEL

Policies on allegations

Institutions must have a written policy on receiving complaints or allegations related to research. Approaches may range from tentative inquiries about whether breaches have occurred, through to documented allegations of apparent research misconduct. The range of complaints and allegations from minor to serious, the technical elements, and different practices between disciplines mean that a flexible framework to handle the allegations is needed. An allegation of research misconduct may be linked with other types of misconduct, such as bullying, harassment or financial irregularities, adding other dimensions of employer-employee relationships. For these reasons, complaints about research conduct should be directed to a person in a responsible position with experience in considering them, such as the leader of the research group, the head of department, or a senior person in the administration.

The policy on receiving allegations and complaints about research misconduct should recognise the following categories:

- · Failure to implement the Code Failure to take responsibility for achieving the standards aspired to in Part A of this Code.
- · Breaches of the Code Specific actions or omissions that constitute breaches of this Code, but lack the seriousness of consequence or wilfulness to constitute research misconduct. Such breaches should be remedied by counselling or advice. Their repetition or continuation may, however, lead to more serious consequences and may constitute research misconduct.
- Research misconduct Serious breaches of the Code that are sufficiently substantial to warrant formal allegation, investigation, and denial or admission. If proven, such misconduct would be expected to lead to disciplinary action by the institution in accordance with its instruments of employment.

All allegations must be addressed appropriately. Breaches of this Code that are readily admitted and corrected do not automatically represent research misconduct, because they may occur through inexperience, honest error in the design or execution of the research, or the interpretation of research results. However, allegations of a minor nature that are contested can become major issues if they are not handled appropriately.

A person who is the subject of an allegation must be treated fairly and provided with opportunities to respond to allegations in writing.

A person who makes an allegation must also be treated fairly and according to any legislative provisions for whistleblowers during and following investigation of the allegations.

Reviewing employer-employee agreements

The process for handling research misconduct must not only be consistent with the framework established by this Code but must also accord with relevant workplace agreements and the law. This process will in all likelihood be distinct from those for other forms of misconduct in the workplace, such as sexual harassment, bullying and discrimination, because different approaches from their investigation are needed.

The National Health and Medical Research Council and the Australian Research Council expect that institutions in receipt of public research funds will progressively include this framework for handling research misconduct in relevant instruments regulating employment conditions.

Appointing a designated person and advisers in research integrity

Institutions must appoint a designated person, other than the CEO, to whom allegations of research misconduct must be directed, and one or more persons as advisers in research integrity.

RESPONSIBILITIES AT THE DEPARTMENTAL OR RESEARCH CENTRE LEVEL

Establishing a responsible research environment is the most effective way of preventing research misconduct and other breaches of this Code. It also provides a sound basis for detecting and dealing with research misconduct should it arise. Thus, research groups should agree on how they will implement this Code and cooperate in maintaining high standards of research practice.

Wherever possible, supervisors and heads of departments should be the first point of contact when concerns arise. They are required to establish and maintain a high standard of behaviour in the environment in which the concerns have arisen. If a conflict of interest may exist for the supervisor or head of department, the first point of contact should be an experienced but independent senior mentor, such as an adviser in research integrity.

Breaches of this Code that do not constitute research misconduct should, as far as possible, be handled at the departmental level. However, even where alleged breaches are technical or minor, they should be handled fairly and in a manner that provides the maximum opportunity for improvement. Full records of the process must be kept. Supervisors and heads of departments must comply with institutional policy, including referral of the issues to the designated person when required. Failure by supervisors or heads of departments to address issues properly may in itself represent misconduct.

12 THE FRAMEWORK FOR RESOLVING ALLEGATIONS

COMPLAINTS AND ALLEGATIONS

Copies of the institution's policy setting out how to complain or make allegations of breaches of this Code and research misconduct must be readily accessible to all who work in the institution.

The framework for receiving and resolving allegations is outlined in Box B.2.

Box B.2 Framework for complaints and allegations

- Anyone who is concerned that a researcher has not acted responsibly must take action in a timely manner in accordance with this Code and the institution's policy.
- The institution has appointed a number of senior staff to act as advisers in research
 integrity. An adviser can be approached in confidence to discuss the issue of concern.
 The adviser will discuss the matter, the Code and the policies of the institution, and
 explain the options for taking action.
- It is preferable that, in the first instance at least, complaints and allegations are dealt with at the departmental level. However, if circumstances make this difficult or not possible, the adviser will suggest other approaches.
- If the complaint cannot be handled to everyone's satisfaction at the departmental level, a formal complaint or allegation must be made in writing to the designated person appointed to this role by the institution.
- The designated person must advise the CEO or their delegated officer whether a prima facie case exists, and how to proceed. Options include:
 - dismissing the allegations
 - instructing the department on how to deal with the allegations
 - dealing with the complaint under provisions unrelated to research misconduct
 - investigating the matter further through a research misconduct inquiry.
- If the CEO or their delegated officer decides that a research misconduct inquiry is needed, he or she must decide whether to use an internal institutional research misconduct inquiry or an independent external research misconduct inquiry.
- Upon completion of its tasks, the research misconduct inquiry must advise the CEO of its findings of fact and what, if any, research misconduct has occurred.
- · The CEO must then determine the actions to be followed, according to institutional policy.
- Subsequent actions may, as appropriate, include informing relevant parties of the outcome and correcting the public record of the research.

Sometimes it is not possible to deal with allegations of breaches of this Code at the departmental level, although this is the preferred route. People who feel unable to raise the matter with the supervisor or head of department must be able to go directly to an experienced senior mentor, such as an adviser in research integrity or an appropriate senior officer of the institution. This will be necessary when an allegation concerns the supervisor or head of the department.

Ignorance, poor judgment or inexperience may lead some researchers to breach inadvertently the provisions of this Code. Provided the alleged breaches do not constitute research misconduct as defined above, the researcher acknowledges the breach, the consequences of the breach are remedied and appropriate steps are taken to prevent recurrence, the matter can rest at the departmental level.

Allegations of research misconduct as defined earlier must be referred to the designated person, either directly or by the head of the department.

THE RESEARCH MISCONDUCT INQUIRY

The role of the CEO

Upon receiving the designated person's advice, the CEO (or their delegated officer, if this has been formally agreed to by the institution's governing body) must decide whether to accept the advice and how to proceed. At this stage, in the event of an admission of research misconduct, the issue may be resolved to the satisfaction of all parties. If the CEO or their delegated officer does not proceed to a research misconduct inquiry, he or she must notify in writing those making the allegation, the person who is the subject of the allegation, and the designated person.

If the CEO or their delegated officer decides to proceed to a research misconduct inquiry, he or she must provide this decision in writing to those making the allegation, the person who is the subject of the allegation, the designated person, and any other parties as required under any agreement, such as funding bodies and collaborating institutions.

In making a decision to proceed to an *internal* institutional research misconduct inquiry or an independent *external* research misconduct inquiry, the CEO or their delegated officer must take into consideration the advice received from the institution's *designated person*. The CEO or their delegated officer must also take into account the potential consequences for the accused, the accuser, other parties and institutions in the event that the allegation(s) were to be upheld, and the need to maintain public confidence in research. If, in his or her judgment, these are likely to be serious, the CEO or their delegated officer must establish an independent external research misconduct inquiry.

In the event that the CEO or their delegated officer makes a decision to conduct an internal institutional research misconduct inquiry, and later discovers the potential consequences of the allegation(s) are more serious than originally anticipated, it may be necessary to disband the internal inquiry and make new arrangements for an external independent research misconduct inquiry.

Internal institutional research misconduct inquiry

An internal institutional research misconduct inquiry is established by appointing appropriate members, including at least one member with knowledge and experience in the relevant field of research and at least one member who is familiar with the responsible conduct of research. At least one member should have experience on similar panels or have relevant experience or expertise. To achieve this membership, institutions may draw on their own staff or externally as required. All members must be free from bias or conflicts of interest.

Legal representation of parties should not be allowed, but a person appearing before the research misconduct inquiry may be accompanied by a support person.

The independent research misconduct inquiry will report findings of fact to the CEO or their delegated officer and what, if any, research misconduct has occurred. Where adverse findings have been made, the CEO will decide what disciplinary actions are required within the agreed disciplinary processes of the institution.

Independent external research misconduct inquiry

Panel members who conduct an independent external research misconduct inquiry must not be employed by the institution, have other current or recent dealings with the institution, or otherwise be subject to a reasonable perception of bias.

The panel should normally be constituted with a minimum membership of three people. At least one member should be legally qualified or have extensive experience as a member of a tribunal or similar body. At least one member should have knowledge and research experience in a relevant, related field of research, but not directly in the research area of the

allegations. Procedural fairness demands that the person subject to the inquiry be able to hear and respond to any and all material to be used by the panel in its decision-making process. Therefore, it is preferable that any expert knowledge that may be required is provided to the inquiry by witnesses rather than members of the panel. This will allow the witnesses to be questioned by both the panel and the person subject to the inquiry. If a panel member has relevant expert knowledge, it must be put to the defendant.

To be consistent with the general practice of tribunals, there are standard practices that should be followed. The panel should normally be assisted by a legally qualified person acting as 'counsel assisting', whose role it is to prepare the material to be put to the tribunal and to examine (question) witnesses on behalf of the panel. This person is not a member of the inquiry panel but may provide the panel with legal advice during the hearing. The person facing the allegations should be entitled to legal representation. The inquiry is not bound by the rules of evidence but its procedures must be consistent with the principles of natural justice and due process. In making findings, the inquiry should apply the civil standard of proof, although the standard of proof in serious cases will be higher than the mere balance of probabilities. Counsel assisting the inquiry will normally advise on this issue, as there is long-standing legal precedent based on a case before the Australian High Court in 1938.

Whether an external research misconduct inquiry by people external to the institution is open to the public or conducted in private should be determined by the panel itself on the basis of public interest. The panel has the responsibility to hear the views of all parties on this matter before such a decision is made.

Upon completion of its tasks, the independent external research misconduct inquiry must advise the CEO or their delegated officer of its findings of fact, and what, if any, research misconduct has occurred. The CEO or their delegated officer must, in due course, inform the governing body of the outcome of the inquiry. The research misconduct inquiry findings must be considered by the CEO or their delegated officer and appropriate actions must be taken in accordance with institutional instruments regarding employment conditions. Appropriate actions must also be taken when the allegations of misconduct are shown to be unfounded. The findings of an independent, external research misconduct inquiry should be made available to the public.

When conducting an independent external research misconduct inquiry, the person subject to the inquiry may have an entitlement to appeal to a higher authority, most usually the courts.

SUBSEQUENT ACTIONS

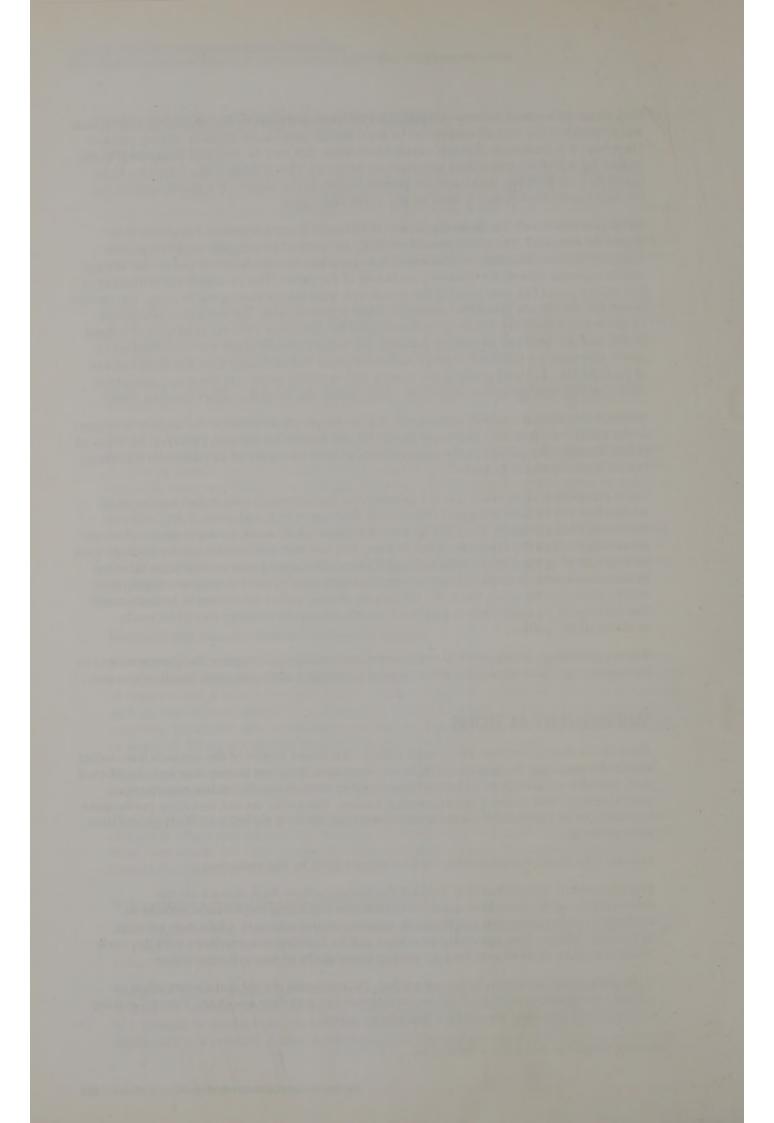
The CEO or their delegated officer must inform all relevant parties of the research misconduct inquiry findings and the actions taken by the institution. Relevant parties may include affected staff, research collaborators including those at other institutions, all funding organisations, journal editors, and professional registration bodies. The public record, including publications, may need to be corrected if research misconduct has affected the research findings and their dissemination.

Persons who made the allegations must be treated fairly by the institution.

Proven research misconduct may warrant disciplinary action. Such actions are the responsibility of the institution under its instruments regulating employment conditions. Institutions must ensure that employment agreements and contracts, when they are next negotiated, address how research misconduct will be handled in accordance with this Code. There should be defined penalties for people found guilty of research misconduct.

If the allegations are shown to be unfounded, the institution should make every effort to reinstate the good reputation of the accused researcher and their associates. Persons making mischievous complaints should face disciplinary action.

Briginshaw v Briginshaw (1938). 60 CLR 336 at 361-62



APPENDIX 1: PROCESS REPORT

BACKGROUND

In developing and issuing guidelines, the National Health and Medical Research Council is obliged under the *National Health and Medical Research Council Act 1992* (Section 13) to release draft guidelines for public consultation. To develop draft guidelines, the National Health and Medical Research Council establishes working parties that include some members of the relevant principal committee and others with relevant expertise.

In 2003, the National Health and Medical Research Council Research Committee appointed a working group to review the *Joint NHMRC/AVCC Statement and Guidelines on Research Practice* 1997 (the Joint Statement), now called the *Australian Code for the Responsible Conduct of Research 2007* (this Code). The Joint Working Group (JWG) included representatives from the National Health and Medical Research Council, the Australian Research Council and the Australian Vice-Chancellors' Committee (now Universities Australia).

PROCESS

The JWG undertook extensive consultation with two rounds of public consultation. The first consultation concluded in April 2005. The JWG conducted a workshop on managing allegations of research misconduct in August 2005. After considering the issues raised by the workshop, a second draft of this Code was released for public consultation; this round closed in May 2006.

The National Health and Medical Research Council, the Australian Research Council and Universities Australia have endorsed this Code.

APPENDIX 2: JOINT WORKING GROUP MEMBERSHIP

REVIEW OF JOINT NHMRC/AVCC STATEMENT AND GUIDELINES ON RESEARCH PRACTICE JOINT WORKING GROUP

The Joint Working Group (JWG) was established in September 2003, to review the Joint NHMRC/AVCC Statement and Guidelines on Research Practice. The JWG comprised the following members:

CHAIR

Professor Warwick Anderson

NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL

Professor Anthony Jorm Dr Kerry Breen

AUSTRALIAN RESEARCH COUNCIL

Dr Andrew Smith (September 2003–August 2004) Dr Mandy Thomas (September 2004–October 2006)

UNIVERSITIES AUSTRALIA5

Professor Pip Hamilton Professor Elspeth McLachlan

⁵ Formerly the Australian Vice-Chancellors' Committee

OPPEENDIX 2: JOINT WORKING GROUP MEMBERSHIP

REFERENCE FORT NIHARCIAVOC STATEMENT AND GUIDELINES ON REPEARCH PRACTICE JOINT WORKING GROUP

WATERWALL HEALTH AND MEDICAL RESEARCH CORNER

JOHUODHORAJCH MALIAMENA

AUDITEUR SETTEMBURG

APPENDIX 3: REFERENCES

AIATSIS (2000). Guideline for Ethical Research in Indigenous Studies, (Australian Institute of Aboriginal and Torres Strait Islander Studies).

http://www.aiatsis.gov.au/_data/assets/pdf_file/2290/ethics_guidelines.pdf

NHMRC (1997). Joint NHMRC/AVCC Statement and Guidelines on Research Practice, Commonwealth of Australia, Canberra.

http://www.nhmrc.gov.au/funding/policy/researchprac.htm

NHMRC (2002, 2005). Statement on Consumer and Community Participation in Health and Medical Research (the Statement on Participation), Commonwealth of Australia, Canberra. http://www.nhmrc.gov.au/publications/synopses/r22syn.htm

NHMRC (2003). Values and Etbics: Guidelines for Etbical Conduct in Aboriginal and Torres Strait Islander Health Research, Commonwealth of Australia, Canberra. http://www.nhmrc.gov.au/publications/synopses/e52syn.htm

NHMRC (2004). Australian Code of Practice for the Care and Use of Animals for Scientific Purposes, 7th edition (the Code of Practice), Commonwealth of Australia, Canberra. http://www.nhmrc.gov.au/publications/synopses/ea16syn.htm

NHMRC (2007). National Statement on Ethical Conduct in Human Research (the National Statement), Commonwealth of Australia, Canberra. http://www.nhmrc.gov.au/publications/synopses/e72syn.htm

Examples of published guidelines for authorship

APS Guidelines for Professional Conduct, American Physical Society. http://www.aps.org/statements/02_2.cfm

Authorship Guidelines, The British Sociological Association http://www.britsoc.co.uk/Library/authorship_01.doc

Guidelines on Good Publication and the Code of Conduct, Committee on Publication Ethics. http://www.publicationethics.org.uk/guidelines

Publication Policies, Nature. http://www.nature.com/nature/submit/policies/index.html

Uniform Requirements for Manuscripts Submitted to Biomedical Journals, International Committee of Medical Journal Editors.

http://www.annals.org/cgi/content/full/126/1/36?ck=nck

Statement on biosecurity

IAP (2005). IAP Statement on Biosecurity, InterAcademy Panel on International Issues. http://www.nationalacademies.org/morenews/includes/IAP_Biosecurity.pdf

Surveys of research misconduct

Geggie D (2001). A survey of newly appointed consultants' attitudes towards research fraud. Journal of Medical Ethics 27(5):344–346.

Henry DA, Kerridge IH, Hill SR, McNeill PM, Doran E, Newby DA, Henderson KM, Maguire J, Stokes BJ, Macdonald GJ, and Day RO (2005). Medical specialists and pharmaceutical industry-sponsored research: a survey of the Australian experience. *Medical Journal of Australia* 182:557.

Martinson BC, Anderson MS and de Vries R (2005). Scientists behaving badly. Nature 435:737-738.

APPENDIX 3: REFERENCES



