RESPONSIBLE EXECUTIVE	Angela Watt
PRIMARY AUTHOR	Sarah Rickard
IMPLEMENTATION STRATEGY	Email update to all employees and uploaded to the Office for Resea4rch website.
EVALUATION STRATEGY	Updated policy to be evaluated by Melbourne Health Office for Research Governance management team.
STANDARD/S (National, Aged Care, Disability Services)	NSQHS Clinical Governance Standard.
VERSION SUMMARY	The Research Integrity Guideline replaces the Guideline for Research Practice and has been developed to clearly set out the roles and responsibilities of Melbourne Health (MH) and persons involved in the management or conduct of research at MH. These guidelines have been written in accordance with the *Australian Code for the Responsible Conduct of Research (2018) and the Singapore Statement.*

EXECUTIVE SUMMARY

1. Melbourne Health (MH)H requires research practices conducted under its auspices to be ethically sound and have integrity.
2. The *Australian Code for the Responsible Conduct of Research, 2018* (Code) outlines core principles and responsibilities of institutions and researchers that characterise responsible conduct of research.
3. All research conducted at MH should hold appropriate approvals required to conduct the research project, including ethical and MH site specific research governance approval, prior to commencement of the research project.
4. All MH staff and affiliates, including students, who are involved in research associated with MH should conduct research in compliance with this guideline, MH policy and requirements and all relevant laws and guidelines including those for supervision of research staff, trainees and students, data and records management, authorship, publication and research communications, intellectual property, peer review, statistical review, disclosure of potential conflicts of interest and monitoring of research.
5. MH has appointed Research Integrity Advisors (RIAs) to provide guidance and advice to staff and students on responsible research practices as outlined in the Code, organisational policies and procedures, and other guidelines and legislation relevant to their disciplines.

1. ASSOCIATED MELBOURNE HEALTH POLICY

Research Policy MH 18

2. PURPOSE AND SCOPE

These guidelines and the associated procedures apply to all individuals paid by, under the control of, or affiliated with MH, such as scientists, trainees, technicians, other staff members, students, fellows, guest researchers, or collaborators who are engaged in research at MH.

3. DEFINITIONS

These guidelines use the definitions of *The Australian Code for the Responsible Conduct of Research 2018* (Code) which are reproduced in Appendix 1.

4. RESPONSIBILITIES

MH will promote good research practice and integrity, provide safe places of work and research training.

MH researchers have a responsibility to conduct research with integrity and in accordance with the Code and other applicable requirements including MH policy and procedure.

All MH staff and affiliates, including students, who are involved in research associated with the MH should be familiar with and should comply with this guideline and any other relevant guideline or requirements.

5. PROCEDURE/GUIDELINE/POLICY

5.1. INTRODUCTION

MH requires research practices conducted under its auspices to be ethically sound and have integrity.

Research integrity is a way of thinking and behaving that ensure that research undertaken is trustworthy.

Research plays a critical and beneficial role in our society. Those conducting research enter into a social contract requiring them to be responsible and accountable for their activities. The right to conduct research is a privilege which is conditional on the rights and wellbeing of human participants, other living creatures and the good of the community being put foremost, in conformity with long established broad principles guiding research practice.

MH is committed to supporting a research culture that encourages responsible research practices based on the principles of research integrity. Responsible research practices guide researchers in the conduct of their work as well as in their engagement with the practical, ethical and intellectual challenges inherent in research.

It is a basic expectation and requirement of MH that its researchers are committed to high standards of professional conduct.

Researchers should only participate in projects that conform to accepted ethical standards and that they are competent to perform.

Researchers have a duty to ensure that their work enhances the good name of MH and the profession to which they belong.

This guideline designed to foster and maintain a research environment of integrity, respect, honesty and responsibility and provide a framework of standards intended to guide researchers, and the institution in acceptable research practices.

5.2. RESEARCH GOVERNANCE

Research governance is a framework through which organisations are accountable for the scientific quality, ethical acceptability and safety of the research they allow to be conducted under their auspices.

Good research governance can be defined as a system that sets standards of research practice that:

- provides mechanisms to deliver those standards;
- provides for monitoring and assessment of research practice, improves research; and
- safeguards the public and applies to all professional groups involved in research.

Good research governance is an essential component of the responsible conduct of research and involves the organisation undertaking a feasibility review of all aspects of the study. It is intended to improve research quality, promote good research practice and accountability and, where research involves humans, foster participant safety by enhancing ethical and scientific quality, reducing adverse events and ensuring lessons are learned, thus preventing poor performance and breaches of the Code.

5.3. PRINCIPLES OF RESEARCH INTEGRITY

Principles of responsible and accountable research practice include:

- 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.

The Code outlines core principles and responsibilities of institutions and researchers that characterise responsible conduct of research.

The Code is supported by a number of guides that detail how to comply with the principles and responsibilities of the code including:

- Guide to Managing and Investigating Potential Breaches of the Code, 2018 (the Investigation Guide). This guide outlines a model process for institutions to use to manage and investigate potential breaches of the 2018 Code.
- Authorship (2019)
- Management of Data and Information in Research (2019)
- Peer Review (to be released in 2019)
- Conflicts of Interest (to be released in 2019)
- Research Supervision (to be released in 2019)
- Dissemination of Research (to be released in 2019)
- Collaborative Research (to be released in 2019)

NOTE: until such time as the individual guides under development are issued, institutions and researchers should refer to the advice set out in the 2007 version of the Code.

The *National Statement on Ethical Conduct in Human Research (2007- updated 2018)* sets the ethical standards for research involving humans and outlines the responsibilities of institutions, review bodies and researchers for the ethical design, conduct and dissemination of results of human research.

The *Australian code of practice for the care and use of animals for scientific purposes* describes the principles or responsible and accountable research practices in which animals are involved.

5.4. INSTITUTIONAL RESPONSIBILITIES

MH is committed to supporting a research culture that encourages responsible research practices based on the principles of research integrity.

The Executive Director of Clinical Governance and Medical Services is responsible for all research undertaken under the auspices of MH. The Executive Director of Clinical Governance and Medical Services is reports to the Chief Executive Officer, MH.

MH will:

i. Promote responsible research practice and integrity, and awareness of relevant national guidelines relating to the conduct of research.

ii. Monitor practices to ensure conformity with relevant national guidelines relating to the conduct of research.

iii. Provide safe places of work.

iv. Provide research training opportunities.

v. Manage review and approval of ethical and site-specific research governance applications via The Office for Research.

5.5. RESEARCHER RESPONSIBILITIES

All MH staff and affiliates, including students, who are involved in research associated with the Melbourne Health should:

i. Conduct research in compliance with this guideline, MH policy and requirements and all relevant laws and guidelines.

ii. Discuss all research projects and proposed research grant applications with, and obtain support from, the appropriate Clinical Director or Department Head.

iii. Obtain all approvals required to conduct the research project, including ethical and MH site specific research governance approval, prior to commencement of the research project.

iv. Be aware of, and adhere to, ethical principles of integrity, respect for persons, justice, beneficence and veracity.

v. Ensure that personal ambition and expectation of economic gain or material advantage must not compromise ethical, societal or scholarly considerations.

vi. Contribute to the monitoring of research by MH through processes, which include provision of regular reports as required by the institution, and through the prompt notification of adverse or untoward events.

vii. Ensure that data is entered into the iPM research participation tab for all patients that are consented into research proposals.

viii. Ensure that the evidence of participation (participant information and consent forms and relevant visit data) are included in the participants medical record.

ix. In addition to the researcher responsibilities outlined in the Code, all MH staff and affiliates, including students, who are involved in research associated with the MH should:

a) Conduct research safely.

b) Adhere with ethical standards.

c) Respect the dignity, privacy and cultural differences of human participants, animal used in research and the environment and avoid harming them.

d) Participate in ongoing training programs including in research integrity.

e) Provide mentoring, training and support of fellow researchers including new researchers.

f) Be aware of, and appropriately manage, actual or potential conflicts of interest, whether financial or non-financial. This will generally require open disclosure and discussion, with the involvement of supervisors, managers and colleagues**.**

g) Employ appropriate methods and use a high level of rigour and objectivity in research activities.

h) Manage research data responsibly including making and securely storing complete, clear, attributable, accurate and enduring records of all research. Confidentiality must be observed for data of a confidential nature, for example from individual patient records. Secrecy may be necessary for a limited period in the case of research with commercial interest.

i) Interpret results cautiously. In general, research results and methods should be open to scrutiny by colleagues within MH and through appropriate publications and conference presentation, to the wider scientific profession.

j) Share findings and data openly, honestly and promptly, as soon as they have established provenance, ownership claims and if there are any barriers to sharing the data such as legal requirements of contracts, intellectual property claims, or the uniqueness of the data may lead to privacy issues.

k) Appropriately cite and, where applicable, obtain permission for the use of all published and unpublished work.

l) Acknowledge in research outputs all contributors and contributions to the research described in the research output.

m) Be listed as an author of a research output only when they have made a significant intellectual or scholarly contribution that they are willing to be accountable for and agree to be listed as an author.

n) Participate in the peer review process. Give fair, prompt and rigorous evaluations, and respect confidentiality when participating in peer review.

o) Respect Aboriginal and Torres Strait Islander heritage in ways that promote Aboriginal and Torres Strait Islander cultures and understanding and respect between indigenous and non-indigenous Australians in the conduct of research in Australia.

p) Provide complete and accurate information in all research applications including ethical, governance and funding applications and related documents.

q) Use funds for research in accordance with relevant funding agreements.

r) Ensure future use of research results are in accordance with applicable requirements and permissions.

s) Seek advice and discuss any concerns about the conduct of research with research integrity advisers and report any suspected research misconduct.

These principles and responsibilities are influenced by the Australian Code for the Responsible Conduct of Research (2018) and the Singapore Statement.

5.6. RESPONSIBILITIES OF PARTICIPANTS IN RESEARCH

To ensure their own safety and the validity of the research results, research participants should be reminded of their responsibility to provide information truthfully and to act in accordance with the agreement they have made in consenting to their involvement in a research study.

5.7. SUPERVISION OF RESEARCH STAFF, TRAINEES AND STUDENTS

It is the responsibility of staff in supervisory positions to ensure that staff, trainees and students involved in research projects at MH have the appropriate education, training, experience, mentoring and support to conduct quality research, safely and responsibly.

For further information refer to MH SOP - Supervision of research staff, trainees and students for further information and MH requirements.

5.8. RESEARCH APPROVALS

All research and quality assurance projects undertaken at MH or involving MH staff, patients or resources should be submitted to the Office for Research for review and approval prior to commencement.

The research should comply with current regulations governing occupational health and safety, conditions of use of hazardous materials including ionizing substances, toxic chemicals, gene technology and waste disposal.

5.8.1 Site-specific research governance approval

Research projects should not commence at MH until after written approval of the site-specific research governance application has been issued by the Office for Research.

For more information on research governance or to submit a MH site-specific research governance application go to the Research Governance webpage.

5.8.2 Approval of studies involving human research

The National Statement on Ethical Conduct in Human Research 2007 (updated 2018 - National Statement), requires each project involving human research to have ethical approval prior to starting. This is consistent with the principles of international ethical statements; the Declaration of Helsinki (1964) and the Nuremberg Code (1947).

All projects involving human research should be reviewed and approved by the MH Human Research Ethics Committee (HREC) or other National Health and Medical Council (NHMRC) National Mutual Acceptance (NMA) review accredited HREC before approval of the site-specific research governance can be finalised.

Note: Any projects involving human participants and genetically modified organisms (GMOs) should also be reviewed by an accredited Institutional Biosafety Committee (IBC).

For more information on ethics processes or to submit an application for ethical review go to the Ethics Webpage.

For the process to submit an application for quality assurance review go to the Quality Assurance webpage.

5.8.3 Approval of studies involving research with Genetically Modified Organisms

All projects involving genetically modified organisms that require regulation should be reviewed by an accredited Institutional Biosafety Committee (IBC) before approval of the site-specific research governance can be finalised.

The IBC should be registered with the Office of the Gene Technology Regulator (OGTR) and have experience and technical expertise to review a specific application.

For more information on using genetically modified organisms or to submit a MH site-specific GMO research governance application go to the Gene Technology webpage.

5.8.4 Approval of studies involving animal research

All projects involving animals should be reviewed and approved by an accredited Animal Ethics Committee (AEC) before approval of the site-specific research governance can be finalised.

The AEC should be constituted and operated in accordance with the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes and have experience and technical expertise to review the application.

For more information on using genetically modified organisms or to submit a MH site-specific Animal research governance application go to the Animal Ethics webpage.

5.9. DATA AND RECORDS MANAGEMENT

MH recognises that data are a valuable product of research that should be appropriately managed.

Good data management practices are essential to support data integrity and should be followed throughout the research data lifecycle.

Research data and metadata should be collected, stored, retained, used, shared and disposed of in a manner that protect the privacy, rights, safety, and well-being of the research participants and the wider community, maintains data integrity and is in accordance with all applicable requirements (including MH, legislative, guidelines, legal, ethical, and funding bodies', study agreements etc.) at each stage of the data lifecycle.

Original data and metadata should not be removed from MH and should be accessible at all times.

Researchers should not remove copies of any data from MH without approval from the Principal Investigator (PI), Head of Department (HOD) and Director Research Governance and Ethics (except where the movement of data described in the ethically approved study protocol and agreements). Appropriate agreements should be in place prior to movement of data. This requirement includes when researchers leave the organisation.

Research staff should plan data management requirements and processes for each study as part of the study planning activities i.e. with the start of protocol development or on approach to participate in a research study by an external party (i.e. collaborator or commercial sponsor).

A data management and data access plans should be developed and included in research the project protocol or other research documentation.

For details of requirements refer to:

- MH Research Policy MH 18
- MH Intellectual Property Policy MH12
- MH Data Management in Research Guideline
- MH Data Storage and Security Guideline
- MH Agreements, Ownership and Intellectual Property Guideline
- MH Databanks and Registries Guideline
- MH Research Publications and Authorship Guideline
- MH Archiving retention and disposal of data Guideline
- MH OFR SOP Data Management Plan
- MH OFR SOP Data Access Plan
- Management of Data and Information in Research: A guide supporting the Australian Code for the Responsible Conduct of Research, 2019

5.10. AUTHORSHIP

Authors are responsible for the publication of the results of research.

To claim to be an author requires that a person is directly involved in the creation of the work – conceiving it, analysing and interpreting the data on which it is based, writing or revising its intellectual content, and taking responsibility for it once published.

Authors should ensure that:

i. Authorships honestly reflects the contribution to the work being published.
ii. Ensure that authors of research outputs are all those, and only those, who have made a significant intellectual or scholarly contribution to the research and its output
iii. All authors agree to be listed as an author.
iv. No person who is an author, consistent with the above definition, may be excluded as an author without his or her permission in writing.
v. All of those who have contributed to the research are acknowledged.
vi. All other relevant work is appropriately and accurately cited and acknowledged.

For further information refer to the:

- MH Research Publications and Authorship Guideline
- Authorship: A guide supporting the Australian Code for the Responsible Conduct of Research, 2019

5.11. PUBLICATION AND RESEARCH COMMUNICATIONS

Publication is an essential part of the research process. It informs other researchers, professional practitioners and the wider community of the results of the research.

The principles underpinning responsible research communication are honesty, accuracy, transparency and openness. This may include reporting results contrary to hypotheses and where necessary, take action to correct the record in a timely manner.

Redundant publication, where the publication of work that overlaps substantially with that already published, or that is intentionally subdivided into smaller units to increase scholarly productivity, is not acceptable, except where each subsequent publication fully cross-references and acknowledges the earlier work.

Researchers should be aware of and abide by responsibilities associated with publication and communication of research.

Refer to the MH Research Publications and Authorship Guideline for details.

5.12. INTELLECTUAL PROPERTY CONSIDERATIONS

MH is committed to advancing its research. In the current climate, commercialisation and exploitation of scientific discoveries or inventions will add significantly to MH's reputation as a leading research institution.

Researchers should be aware that Patents and Intellectual Property are important components of research. Researchers should be familiar with the MH Intellectual Property Policy MH12 2017. Researchers should liaise with the Office for Research and the Director of Business Development at an early stage in the development of research that may have potential Intellectual Property or Patents.

Where external bodies are involved, MH has an obligation to oversee confidentiality agreements to protect intellectual property rights between MH and the external body. MH will work with researchers and the external body to ensure that where such agreements limit free publication and discussion, an approved process is instigated to ensure that limitations and restrictions are explicitly agreed.

For details refer to:

- MH Research Policy MH 18
- MH Intellectual Property Policy MH12
- MH Research Publications and Authorship Guideline
- MH Data Management in Research Guideline

5.13. PEER REVIEW

Peer review is the independent and impartial evaluation of work by one or more people with similar competences and discipline. It is an important aspect of assurance of scientific merit of the research protocol and functions as a form of self-regulation by qualified members of a profession within the relevant field of study.

Peer review of the research protocol should occur:

- Before the study application is submitted to the reviewing committee and provides a useful opportunity to improve quality, performance and provide credibility.
- Prior to submission of grant proposals and publication of Research Outputs.

Researchers have a responsibility to take part in the peer review process including peer review of applications ethical for ethical approval, grant proposals and publications.

When participating in peer review:

i. Researchers should provide fair, unbiased, prompt and rigorous evaluations.
ii. All potential conflicts of interest should be declared to ensure the process is transparent, independent and impartial.
iii. Respect confidentiality of all information under review and not use or disclose the information.

For further information refer to the Office for Research website for the Peer review process.

5.14. STATISTICAL REVIEW

The purpose of the statistical review is to determine if the proposed research is well designed by ensuring that the methods proposed can answer the research question.

Human research project protocols may require statistical review before submission to the MH Human Research Ethics Committee (HREC). Where applicable, investigators should:

i. Allow sufficient time to find a reviewer
ii. Allow the reviewer to conduct the statistical review
iii. Address the reviewer's comments adequately, prior to submission to the HREC
iv. Provide evidence of the statistical review in the HREC submission.

For further information refer to the Office for Research website for the Statistical review process

5.15. MONITORING OF RESEARCH

The requirement for monitoring is embedded into research legislation and guidelines as well as MH policy and guidelines including:

- MH policy and requirements
- Australian Code for the Responsible Conduct of Research (2018)
- National Statement on Ethical Conduct in Human Research (2018)
- The Therapeutic goods Act
- ICH Good Clinical Practice

Monitoring research involves keeping up to date with the progress of a research study. It includes verifying that the conduct of research:

i. Conforms to the approved proposal and any applicable requirements
ii. Conforms to ethical approvals and guidelines
iii. Is undertaken in a manner that protects the rights, safety and well-being of participants
iv. Results in credible study data
v. Is keeping to timelines
vi. Is keeping within the approved budget.

Researchers should contribute to research monitoring through processes, which include:

i. Self-audit
ii. Implementation of a study monitoring plan
iii. Provision of regular reports as required by the institution
iv. Provision of regular reports as required by the reviewing ethics committee
v. Provision of regular reports as required by funding bodies
vi. Prompt notification on adverse or unwanted events

Findings arising from monitoring should be used to develop corrective and preventative actions where required, to ensure compliance, the rights and well-being of participants are protected, and the study data are credible.

For further information refer to:

- MH Research Policy MH 18
- MH Data Management in Research Guideline
- MH OFR SOP Research Study Monitoring and Monitoring Plans (non-clinical trials)
- MH OFR SOP Clinical Trial Monitoring Plans and Monitoring Visits
- Office for Research website audit information

5.16. DISCLOURE OF POTENTIAL CONFLICTS OF INTEREST

A conflict of interest exists where there is a divergence between the individual interests of a person and their professional obligation to the institution such that an independent observer might reasonably question whether their own interests influence the professional actions or decisions of that person.

Conflict of interest is a serious issue in research as it can compromise the validity of the research process by influencing impartial judgement. While financial conflicts of interest are foremost in the public mind, other potential conflicts of interest include political or philosophical commitments, private benefits significantly dependent on research outcomes and significant personal or professional advantage.

A perception that a conflict of interest exists can be as serious as an actual conflict, raising concerns about the integrity of individuals or the management practices of the institution. For this reason, the possibility of a perceived conflict of interest should be treated as though the conflict exists.

Researchers are responsible for identifying, disclosing and managing potential or perceived conflicts of interest that may influence or be seen to influence any aspect of the conduct of the research at the time of proposing and of reporting research. This responsibility extends to matters related to research including investigations, publication, media reports, grant applications, and applications for appointment or promotion.

For further information refer to:

- MH Handling Conflict of Interest in Research Guideline
- MH Research Publications and Authorship Guideline
- MH Conflict of Interest and Managing Gifts, Benefits and Hospitality Obligations Policy

5.17. RESEARCH INTEGRITY ADVISORS

A Research Integrity Advisor (RIA) is someone nominated by the organisation that you can ask for help if you have questions about research integrity or if you have concerns about the conduct or in collaboration with of research at MH.

RIAs are appointed to provide guidance and advice to staff and students on responsible research practices as outlined in the Code, organisational policies and procedures, and other guidelines and legislation relevant to their disciplines.

For further information on Research Integrity or to contact a RIA refer to the Office for Research, Research Integrity webpage.

5.18. BREACHES OF THE AUSTRALIAN CODE FOR THE RESPONSIBLE CONDUCT OF RESEARCH

Under the Code, Institutions are required to manage concerns or complaints and investigate potential breaches of the Code related to research for which they are responsible.

A breach is defined as a failure to meet the principles and responsibilities of the Code and may refer to a single breach or multiple breaches.

Breaches of the Code may fall into the following categories:

i. Not meeting required research standards
ii. Fabrication, falsification, misrepresentation
iii. Plagiarism
iv. Research data management issues
v. Supervision
vi. Inappropriate Authorship
vii. Failure to disclose and manage conflicts of interest
viii. Failure to conduct peer review responsibly

Breaches can be minor (less serious) or major (more serious, including intentional or reckless or negligent behaviour).

Repeated or persistent breaches will likely constitute a serious breach.

For further information refer to:

- Investigating Breaches of the Code for the Responsible Conduct of Research Guideline
- Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research (2018).

6. ASSOCIATED POLICIES/PROCEDURES/GUIDELINES

- MH Research Policy MH18
- Intellectual Property Policy MH12
- Documentation and Records Management MH 05
- Data Management in Research Guideline
- Data Storage and Security Guideline
- Agreements, Ownership and Intellectual Property Guideline
- Archiving retention and disposal of data Guideline
- Guidelines for the Use of Human Tissue Samples in Research
- Research Publications and Authorship Guideline
- Guidelines for Managing Conflict of Interest in Research
- Guidelines for Handling Complaints in Research
- Investigating Breaches of the Code for the Responsible Conduct of Research Guideline

7. REFERENCES

- Australian Code for the Responsible Conduct of Research (2007 updated 2018)
- Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research (2018)
- Authorship - A guide supporting the Australian Code for the Responsible Conduct of Research
- Management of Data and Information in Research - A guide supporting the Australian Code for the Responsible Conduct of Research
- Conflicts of Interest (to be released in 2019)
- Research Supervision (to be released in 2019)

- Dissemination of Research (to be released in 2019)
- Collaborative Research across Organisations (to be released in 2019)
- National Statement on Ethical Conduct in Human Research (2007updated 2018)
- Therapeutic Goods Act (1989)
- Access to unapproved therapeutic goods – Clinical Trials in Australia (2004)
- The Australian Clinical Trial Handbook – A simple practical guide to the conduct of clinical trials to international standards of Good Clinical Practice (GCP) in the Australian Context (2018)
- Safety monitoring and reporting in clinical trials involving therapeutic goods
- Code of Conduct for the Victorian Public Sector (Victorian Government)
- ICH Good Clinical Practice (GCP) - Integrated Addendum to ICH E6 (R1) Guideline for Good Clinical Practice E6 (R2) (formerly adopted by the TGA with annotations on 8 February 2018)
- International Conference on Harmonisation / Good Clinical Practice (ICH/GCP) Guidelines
- Australian code for the care and use of animals for scientific purposes 8th edition (2013)
- Gene Technology Act (2000)
- Gene Technology Regulations (2001)
- The Office of the Gene Technology Regulator (OGTR) requirements
- Singapore Statement.

8. FURTHER INFORMATION

Contact the Office of the Office for Research on 9342 8530 or email: research@mh.org.au

9. DOCUMENTATION

9.1. Associated forms and charts (including IP/OP numbers)

10. REVISION AND APPROVAL HISTORY

Date	Version	Author* and contributors
26/8/2019	1	Sarah Rickard, Manager Research Governance and Audit

APPENDIX 1: Definitions from *The Australian Code for the Responsible Conduct of Research 2018*.

3Rs

The 3Rs are three principles that underpin a systematic framework to achieve the goal of humane experimental techniques. The principles are: Replacement of animals with other methods; Reduction in the number of animals used; and Refinement of techniques used to minimise the adverse impact on animals.

Balance of probabilities

The civil standard of proof, which requires that, on the weight of evidence, it is more probable than not that a breach has occurred.

Breach

A failure to meet the principles and responsibilities of the Code. May refer to a single breach or multiple breaches.

Conflict of interest

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. This refers to a financial or non-financial interest which may be a perceived, potential or actual conflict of interest.

Institution

Includes universities, independent research institutes, hospitals or any other organisation that conducts research. May refer to one or multiple institutions.

Peer review

The impartial and independent assessment of research by others working in the same or a related field.

Research

The concept of research is broad and includes the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies, inventions and understandings. This could include synthesis and analysis of previous research to the extent that it is new and creative.

Research Integrity Advisor (RIA)

An RIA is someone in the organisation that you can ask for help if you have questions about research integrity or if you have concerns about the conduct or in collaboration with of research at Melbourne Health.

Research misconduct

A serious breach of the Code which is also intentional or reckless or negligent.

Researcher

Person (or persons) who conducts or assists with the conduct of research.