

# MELBOURNE HEALTH

## GUIDELINES FOR RESEARCH PRACTICE

**Version 5: September 2011**  
**Review Date: February 2013**  
**Number: 18.1**

### REVISION AND APPROVAL HISTORY

<b>Date</b>	<b>Rev No</b>	<b>Author and approval</b>
3 October 2007	1	Angela Gray, Assistant Manager Research Directorate
12 November 2007	2	Angela Watt, Manager Research Directorate
16 August 2010	3	Angela Watt, Director Research Governance and Ethics
16 February 2011	4	Angela Gray, Manager Human Research Ethics Committee
27 September 2011	5	Jessica Turner, Research Ethics and Communications Coordinator

### FURTHER INFORMATION

Contact the Office for Research on (03) 9342 8530 or email:

[research@mh.org.au](mailto:research@mh.org.au)

## TABLE OF CONTENTS

<b>1</b>	<b>INTRODUCTION.....</b>	<b>1</b>
<b>2</b>	<b>DEFINITIONS.....</b>	<b>2</b>
<b>2.1</b>	<b>DEFINING RESEARCH.....</b>	<b>2</b>
<b>2.2</b>	<b>DEFINING INSTITUTIONS IN WHICH RESEARCH IS CONDUCTED.....</b>	<b>2</b>
<b>2.3</b>	<b>RESEARCH GOVERNANCE: RESPONSIBILITIES AND ACCOUNTABILITIES .....</b>	<b>3</b>
<b>3</b>	<b>RELEVANT DOCUMENTS.....</b>	<b>4</b>
<b>4</b>	<b>INSTITUTIONAL AND RESEARCHER RESPONSIBILITIES....</b>	<b>5</b>
<b>4.1</b>	<b>THE INSTITUTION’S RESPONSIBILITIES.....</b>	<b>5</b>
<b>4.2</b>	<b>THE RESEARCHER’S RESPONSIBILITIES.....</b>	<b>6</b>
<b>5</b>	<b>SUPERVISION OF STUDENTS AND RESEARCH TRAINEES... </b>	<b>7</b>
<b>6</b>	<b>DATA AND RECORDS MANAGEMENT.....</b>	<b>8</b>
<b>6.1</b>	<b>RESPONSIBILITIES OF MELBOURNE HEALTH.....</b>	<b>9</b>
<b>6.2</b>	<b>RESPONSIBILITIES OF RESEARCHERS.....</b>	<b>10</b>
<b>6.3</b>	<b>RESPONSIBILITIES OF PARTICIPANTS IN RESEARCH.....</b>	<b>11</b>
<b>7</b>	<b>AUTHORSHIP.....</b>	<b>11</b>
<b>8</b>	<b>PUBLICATION.....</b>	<b>13</b>
<b>9</b>	<b>INTELLECTUAL PROPERTY .....</b>	<b>15</b>
<b>10</b>	<b>PEER REVIEW.....</b>	<b>15</b>
<b>11</b>	<b>DISCLOSURE OF POTENTIAL CONFLICT OF INTEREST.....</b>	<b>16</b>
<b>12</b>	<b>COLLABORATIVE RESEARCH ACROSS INSTITUTIONS</b>	<b>16</b>
<b>12.1</b>	<b>RESPONSIBILITIES OF INSTITUTIONS</b>	<b>17</b>
<b>13</b>	<b>RESEARCH MISCONDUCT.....</b>	<b>17</b>
<b>13.1</b>	<b>RESPONSIBILITIES .....</b>	<b>17</b>
<b>13.2</b>	<b>DEFINITION OF RESEARCH MISCONDUCT.....</b>	<b>18</b>
<b>13.3</b>	<b>RESPONSIBILITY TO REPORT RESEARCH MISCONDUCT.....</b>	<b>19</b>
<b>13.4</b>	<b>CHIEF EXECUTIVE OFFICER .....</b>	<b>20</b>
<b>13.5</b>	<b>PROTECTION OF INTERESTED PARTIES</b>	<b>20</b>
<b>13.6</b>	<b>ADVISORS ON INTEGRITY IN RESEARCH.....</b>	<b>20</b>
<b>13.7</b>	<b>LODGING A COMPLAINT .....</b>	<b>21</b>
<b>13.8</b>	<b>DESIGNATED PERSON TO RECEIVE ALLEGATIONS.....</b>	<b>21</b>
<b>13.9</b>	<b>THE PROCEDURE TO INVESTIGATE ALLEGED MISCONDUCT .....</b>	<b>22</b>
<b>13.9.1</b>	<b><u>Purpose</u>.....</b>	<b>23</b>
<b>13.9.2</b>	<b><u>The Research Misconduct Inquiry</u>.....</b>	<b>23</b>
<b>13.9.2.1</b>	<b>Sequestration of Research Records.....</b>	<b>24</b>
<b>13.9.2.2</b>	<b>Internal Research Misconduct Inquiry .....</b>	<b>24</b>
<b>13.9.2.3</b>	<b>Independent External Research Inquiry Report.....</b>	<b>24</b>

13.9.3	<b><u>Charge to the Internal or External Inquiry Panel</u></b> .....	25
13.9.4	<b><u>The First Meeting</u></b> .....	25
13.9.5	<b><u>The Investigation Process</u></b> .....	25
13.9.6	<b><u>The Inquiry Report</u></b> .....	26
13.9.6.1	<b>Draft Report - Comments</b> .....	26
13.9.7	<b><u>Melbourne Health’s Review and Decision</u></b> .....	26
13.10	<b>CONSULTATION WITH NHMRC, ORI OR OTHER FUNDING BODY, AS APPROPRIATE AND THE TRANSMISSION OF THE FINAL INQUIRY REPORT</b> .....	27
13.11	<b>TIMELINE FOR COMPLETING THE INQUIRY REPORT</b> .....	28
13.12	<b>ADMINISTRATIVE ACTIONS</b> .....	28
13.13	<b>TERMINATION OF EMPLOYMENT OR RESIGNATION PRIOR TO COMPLETING PRELIMINARY INQUIRY OR INVESTIGATION</b> .....	29
13.14	<b>RESTORATION OF THE ACCUSED PERSON’S REPUTATION</b> .....	29
13.15	<b>PROTECTION OF THE COMPLAINANT AND OTHERS</b> .....	29
13.16	<b>INTERIM ADMINISTRATIVE ACTIONS</b> .....	30
13.17	<b>RECORD RETENTION</b> .....	30
	<b>Appendix 1 – Advisors on Integrity in Research</b>	31

## 1 INTRODUCTION

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. These guidelines provide a framework of standards intended to guide researchers, and the institutions in which they work, in acceptable research practices. These guidelines have been developed in accordance and comply with the National Statement on Ethical Conduct in Human Research (2007), the Australian Code for the Responsible Conduct of Research (2007) and the Australian Code of Practice for the care and use of animals for research purposes (7<sup>th</sup> Edition 2004) issued jointly by the National Health and Medical Research RAC of Australia (NHMRC), the Australian Research Council RAC (ARC) and the Australian Vice-Chancellor's Committee (AVCC) and guidelines issued by the National Institute of Health and Public Health Service of the United States of America.

The broad principles that guide research have been long established. Central to these are the maintenance of high ethical standards and validity and accuracy in the collection and reporting of data. The responsibility of the research community to the public and to itself is acknowledged. This responsibility is particularly important where professional practice or public policy may be defined or modified in the light of research findings.

The processes of research protect the truth. Communication between collaborators; maintenance and reference to research records; presentation and discussion of work at meetings of experts; publication of results, including the important element of peer review; and the possibility that investigations will be repeated or extended by other researchers, all contribute to the intrinsically self-correcting and ethical nature of research.

It is a basic expectation and requirement of Melbourne Health (MH) that its researchers are committed to high standards of professional conduct. Researchers have a duty to ensure that their work enhances the good name of MH and the profession to which they belong.

Researchers should only participate in projects that conform to accepted ethical standards and that they are competent to perform. Debate on and criticism of, research projects are essential parts of the research process. Researchers should consult with their colleagues and peers and participate in a transparent peer review process.

These guidelines contain specific procedures for responding to allegations of research misconduct. As required in the Australian Code for the Responsible Conduct of Research, where a complaint about research or researchers may raise the possibility of misconduct, these procedures should be followed. These guidelines should be read in conjunction with

the *Australian Code for the Responsible Conduct of Research 2007*. They also comply with the United States of America, Public Health Service (PHS) regulation Title 42 Code of Federal Regulations (CFR) Part 50, Subpart F, *Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought*. This regulation applies to any research, research-training or research-related grant or cooperative agreement with the United States of America, Public Health Service. Should allegations of possible misconduct be made, the guidelines of the funding body supporting the research in question should also be consulted for advice.

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.

## **2 DEFINITIONS**

For the purpose of these guidelines the following definitions have been reproduced as they appear in *The Australian Code for the Responsible Conduct of Research 2007*.

### **2.1 DEFINING RESEARCH**

The existence of many definitions of research demonstrates how difficult it is to define it comprehensively. This document adopts the following definition written for the broad audience involved in the *Research Assessment Exercise* for Britain's universities:

Research is original investigation undertaken in order to gain knowledge and understanding and make this widely available. It includes work of direct relevance to the needs of commerce and industry, as well as to the public and voluntary sectors; scholarship; the invention and generation of ideas, images, performances and artefacts including design, where these lead to new 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 analysis of materials components and processes, as distinct from the development of new analytical techniques. It also excludes the development of teaching materials that do not embody original research<sup>1</sup>.

### **2.2 DEFINING INSTITUTIONS IN WHICH RESEARCH IS CONDUCTED**

While the *Australian Code for the Responsible Conduct of Research* is written particularly for universities, research institutes, hospitals and other publicly funded organisations that undertake or sponsor research, it will also be relevant to other organisations involved in research. Such organisations may include market survey and public opinion polling companies, pharmaceutical corporations, government departments

---

<sup>1</sup> [House of Commons, Science and Technology Committee. Research Assessment Exercise: a re-assessment. Eleventh Report of Session 2003–04, p17](#)

and agencies, non-government agencies, community organisations, international agencies and product testing laboratories.

### 2.3 RESEARCH GOVERNANCE: RESPONSIBILITIES AND ACCOUNTABILITIES

Melbourne Health is accountable for the quality, safety and ethical acceptability of the research it sponsors or permits to be undertaken by its staff or within the institution. Good research governance has been 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<sup>2</sup>.

It is intended to improve research quality and, where research involves humans, foster participant safety by enhancing ethical and scientific quality, promoting good practice, reducing adverse events, ensuring lessons are learned and preventing poor performance and research misconduct.

In Australia there has been no single source of guidance either in law or in the form of guidelines to assist institutions to develop and maintain responsible governance in research. Where standards have existed, they have been based primarily on the expectations of the two peak funding bodies, the Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC). The *National Statement on Ethical Conduct in Human Research (2007)*<sup>3</sup> 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 for the Responsible Conduct of Research (2007)*<sup>4</sup> sets down the broad principles of responsible and accountable research practice and identifies the responsibilities of both institutions and researchers in areas including:

- data and records management;
- publication of findings;
- authorship;
- conflict of interest;
- supervision of students and research trainees;

together with the definition of research misconduct and how allegations of misconduct should be handled. The *Australian code of practice for the care and use of animals for scientific purposes (7th Edition 2004)*<sup>5</sup> describes the principles of responsible and accountable research practices in which animals are involved.

---

<sup>2</sup> United Kingdom Department of Health. Research Governance Framework for Health and Social Care. Second Edition 2005. [www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4108962](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962)

<sup>3</sup> NHMRC *National Statement on Ethical Conduct in Human Research* (2007). [www.nhmrc.gov.au/publications/synopses/e72.syn.htm](http://www.nhmrc.gov.au/publications/synopses/e72.syn.htm)

<sup>4</sup> NHMRC/AVCC [Australian Code for the Responsible Conduct of Research \(2007\)](#)

<sup>5</sup> NHMRC [Australian code of practice for the care and use of animals for scientific purposes](#) (7<sup>th</sup> Edition 2004)

In addition to these three key documents, there is a range of other sources of information about various aspects of the oversight and regulation of research. Not all of these will be pertinent to every institution. However they cover laws and regulations regarding research into unregistered pharmaceutical products, federal, state and territory privacy law and associated guidelines, laws and guidelines regarding the use of animals in research, and codes of conduct covering such matters as biosafety, radiation safety, consent and confidentiality and professional standards. Institutions also are expected to have procedures in place to deal with intellectual property and copyright issues, data storage and security, indemnity, insurance and induction of new researchers into methodology, research ethics and occupational health and safety.

The ARC and the NHMRC now state explicitly that all institutions that wish to receive or accept funding to support their research must have in place an effective and clearly documented system of research governance. The governance structure should clearly identify the roles, responsibilities and accountabilities of all those who play a role in research, namely sponsors, funding bodies, the host institution itself, senior and junior researchers and the employer (where this is not the host institution). Just as new members of the boards of governance of a research institution are inducted into and updated on such matters as academic governance, budget and finance, human resources issues and risk management, so too should these board members be inducted into and provided with regular reports about matters related to research governance.

### 3 RELEVANT DOCUMENTS

These guidelines have been developed in accordance with the principles and requirements of the following documents. The originating documents take precedence over the MH guidelines where any discrepancy occurs.

- [\*National Statement on Ethical Conduct in Human Research \(2007\)\*](#)
- [\*The Australian Code for the Responsible Conduct of Research \(2007\)\*](#)
- [\*The Australian code of practice for the care and use of animals for scientific purposes \(7th Edition 2004\)\*](#)
- [\*Code of Conduct for the Victorian Public Sector \(Victorian Government\)\*](#)
- [\*MH Whistleblowers Protection Procedures\*](#)
- [\*Staff Complaints and Internal Investigations Policy. Reference Number: HR4.11 MH Policies and Procedure Manual \(Volume 1\).\*](#)

- [MH Research Policy](#)
- [Guidelines for Data Management in Research](#)
- [Guidelines for the Use of Human Tissue Samples in Research](#)
- [Guidelines for Research Publications and Authorship](#)
- [Guidelines for Researchers' Qualifications](#)
- [Guidelines for Managing Conflict of Interest in Research](#)
- [Intellectual Property Policy 2010](#)
- [Guidelines for Handling Complaints in Research](#)
- [Guidelines for Monitoring and Reporting of Safety in Clinical Trials Involving Therapeutic Products and Other Clinical Research](#)
- [International Conference on Harmonisation / Good Clinical Practice \(ICH/GCP\) Guidelines](#)

## **4 INSTITUTIONAL AND RESEARCHER RESPONSIBILITIES**

These guidelines on research practice are designed to foster and maintain a research environment of respect, integrity, honesty and responsibility.

### **4.1 THE INSTITUTION'S RESPONSIBILITIES**

- 4.1.1 Responsible research governance requires that institutions promote awareness of relevant national guidelines relating to the conduct of research and monitor practices to ensure conformity with those guidelines.
- 4.1.2 The Office for Research is responsible for the review and approval and monitoring of all research conducted at MH.
- 4.1.3 The Executive Director of Research is responsible for all research undertaken under the auspices of MH. The Executive Director of Research is responsible to the Chief

Executive Officer, MH.

- 4.1.4 All research conducted within MH must 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. Where research requires approval by a human or an animal ethics committee, or by other safety or regulatory committees, research must not proceed without such approval.
- 4.1.5 It is the responsibility of each Department or Unit Head to ensure that all members of a research group are aware of these requirements and that appropriate approvals are obtained before any research project commences.

## **4.2 THE RESEARCHER'S RESPONSIBILITIES**

- 4.2.1 Researchers must be aware of and adhere to ethical principles of integrity, respect for persons, justice, beneficence and veracity. Responsible researchers demonstrate respect for the dignity, privacy and cultural differences of human participants, and avoid harming them. Respect also must extend to sentient and insentient animals and the environment used in research. Research must therefore comply with all relevant guidelines (see footnote ii) including this document and all relevant laws.
- 4.2.2 All research projects and proposed research grant applications are to be discussed with the appropriate Clinical Director or Department Head.
- 4.2.3 All staff, scientific visitors, and students are expected to maintain the highest standards of professional conduct in research:
- in planning and conducting experiments;
  - in recording and documenting observations with honesty, diligence and objectivity. Researchers have an obligation to society, funding agencies, their discipline/field, their colleagues and those whom they supervise or train, to maintain high standards of intellectual honesty and integrity in the conduct of their research, and in their dealings with other researchers;
  - in interpreting 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.
  - in fully and critically discussing all original results with colleagues and senior medical and scientific staff.
- 4.2.4 All research projects must be submitted to the Office for Research for review and approval by the appropriate Research and Ethics Committee, prior to commencement.
- 4.2.5 Researchers have a responsibility to ensure the safety of all those associated with the

- research.
- 4.2.6 Researchers must be alert to and avoid plagiarism, deception, and the fabrication or falsification of results, each of which is a serious departure from responsible research conduct. Researchers must report cases of suspected misconduct, and do so in a responsible, timely and appropriate manner as directed by institutional procedures. **Refer to: Chapter 8. “Publication” and Chapter 12. “Research Misconduct”.**
- 4.2.7 Researchers must act with respect for the truth and for the rights of those affected by their research, to ensure they are conducting their research with integrity. Personal ambition and expectation of economic gain or material advantage must not compromise ethical, societal or scholarly considerations.
- 4.2.8 Researchers must 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. **Refer to: Chapter 7. “Authorship”.**
- 4.2.9 Researchers must respect those affected by their research and be mindful of the consequences of their research, adhering strictly to ethical and legal principles.
- 4.2.10 Researchers must 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.
- 4.2.11 Confidentiality must be observed for data of a confidential nature, for example from individual patient records.
- 4.2.12 Secrecy may be necessary for a limited period in the case of research with commercial interest.

## **5 SUPERVISION OF STUDENTS AND RESEARCH TRAINEES**

- 5.1 All new researchers are to receive proper training appropriate to the discipline(s) involved, in research ethics, and governance. The distribution of written material is not to be substituted for such training. Researchers act as role models for trainee researchers and need to ensure that the model they provide is positive and conducive to a research culture of excellence, honesty, integrity and discipline.
- 5.2 Department or Unit Heads are responsible for and must establish clear lines of responsibilities for, and standards of, supervision and mentorship to be provided by staff.
- 5.3 The responsibility of supervision of each research student/junior researcher (including honours, masters, doctoral and junior postdoctoral research workers) should be assigned to a specific and appropriately qualified senior researcher in each research unit.

- 5.4 The ratio of students/junior researchers to supervisors should be appropriate to ensure effective intellectual interaction and effective oversight of the research at all times.
- 5.5 Research Supervisors are responsible for providing each trainee with written material on applicable government and institutional guidelines for the conduct of research, including those covering ethical requirements for studies on humans or animals, requirements for privacy and confidentiality, and occupational health and safety matters.
- 5.6 Researcher Supervisors must provide guidance in all matters of research conduct to those whom they supervise.
- 5.7 Research Supervisors must insist that training in research conduct, both formal and practical, is commenced as soon as possible in the career of a researcher. Training should encompass not only discipline-based research, but also industry research interactions, and skills relevant to working with diverse communities.
- 5.8 The Research Supervisor must seek to ensure the validity of research data obtained by a research trainee under his/her supervision. Research Supervisors must take responsibility for overseeing all stages of the research process, including developing an hypothesis or research objective, preparing applications for funding, selecting methods for research and data collection and recording, and summarising, analysing and reporting findings.
- 5.9 Research Supervisors must not exploit research students and junior colleagues.
- 5.10 Research Supervisors must not put research students or junior researchers at risk. Risks can include chemical hazard, infectious disease and psychological trauma.

## 6 DATA AND RECORDS MANAGEMENT

‘Data’ means different things to different researchers and in different disciplines. As with ‘research’ there are many possible definitions.

In the *Australian Code for the Responsible Conduct of Research*, data is used to describe sufficient information from the work to enable the published results to be defended, enable other researchers to follow what was done, and ascertain whether the findings were genuine, analysed appropriately, and not fabricated. Research methods also need to be described in sufficient detail to enable independent replication of findings.

While the original material – such as biological materials, questionnaires, or tape recordings – may not need to be kept (except as required by legislation or discipline convention), a durable record of the relevant information derived from them (e.g. assays, test results, electronically recorded responses, or transcripts) must be kept. In some cases, retention of the original material for others to use may be required.

## 6.1 RESPONSIBILITIES OF MELBOURNE HEALTH

- 6.1.1 The Head of Department or Unit conducting the research is responsible for the storage of data collected by their researchers, and for maintaining clear and durable records concerning the location of stored data. The original data must be able to be distinguished from all subsequent analyses and the preparation of material for publication.
- 6.1.2 Original data are the property of MH and should be retained for at least five years. An investigator may make copies of original data, within the constraints of confidentiality as set out in Sections 1.6, 3.3 and 3.4 of these guidelines. Data from on-going studies, e.g. registers of human disease, should be maintained securely and indefinitely. Researcher Responsibilities. Refer to: [Guidelines for Data Management in Research](#)
- 6.1.3 Whenever possible, original data should be retained in the research unit in which they were generated. In some cases, such as when data are obtained from limited-access databases, or in a contracted project, it may not be possible to hold them in this way. In such cases, a written indication of the location of the original data, or key information regarding the limited-access database from which it was extracted, must be kept in the research unit. Individual researchers should be able to hold copies of the data for their approved research use.
- 6.1.4 Confidential databases, e.g. Genetic registers or patient files, must be maintained in such a manner as to prevent unauthorised access.
- 6.1.5 MH has written guidelines and procedures for data ownership, processing and storage, including covering situations when researchers move between institutions/employers, or when data are held outside Australia. Refer to: [Guidelines for Data Management in Research](#).
- 6.1.6 MH has guidelines and procedures for the establishment and ownership of, and access to, databases/databanks containing confidential information. These procedures are consistent with legislation and other guidelines, including privacy guidelines. (Refer to: [Guidelines for Data Management in Research](#)).
- 6.1.7 MH has guidelines to advise researchers on matters concerning the ownership and use of samples and the confidentiality thereof. (Refer to: [Guidelines for the Use of Human Tissue Samples in Research](#)).
- 6.1.8 MH has policies to ensuring that computing systems, especially those that are accessible through networks, are secure. Security and confidentiality must be assured in a way that copes with use by multiple researchers and the departure of individual researchers. Institutions are responsible for providing appropriate long-term storage and retrieval facilities for digital data. (Refer to: [Guidelines for Data Management in Research](#))

6.1.9 It is the responsibility of all Principal Investigators and/or Department or Unit Heads to ensure that all research staff are fully informed of any confidentiality agreements applying to any research project and that the researchers are informed of their obligations in respect of such agreements.

## **6.2 RESPONSIBILITIES OF RESEARCHERS**

6.2.1 Researchers have primary responsibility for the appropriate and secure management of data and records, including security of confidential material.

6.2.2 Researchers should keep clear and accurate records of the procedures followed (including any approvals granted) before, during and after the research process.

6.2.3 Researchers must accord primary research records such as laboratory notebooks the same level of care and protection as data.

6.2.4 Researchers must retain data, including electronic data, in a durable, appropriately indexed and retrievable form.

6.2.5 Researchers must manage their data so as to comply with relevant privacy legislation and protocols.

6.2.6 Researchers must make available for discussion data that form the basis of publications of any kind. Where confidentiality provisions apply (for example, where the researchers or institution have given undertakings to third parties, such as the participants of the research), it is necessary for data to be kept in a way that reference to them by third parties can occur without breaching such confidentiality.

6.2.7 When researchers are given access to information of value to others, such as in the peer review process, strict confidentiality must be maintained.

6.2.8 Researchers must be cognisant of professional standards, legal requirements and contractual arrangements in determining how long data must be retained.

6.2.9 Researchers must hold data for sufficient time to allow reference to them by other researchers and interested parties. For published data, this may be for as long as interest and discussion persists following publication. It is recommended that the minimum period for retention is 5 years from the date of publication but for specific types of research, such as clinical research and clinical trials, 15 years or more may be required. Management of clinical trials data must comply with ICH/GCP guidelines.

6.2.10 Researchers must retain all relevant material while there is any likelihood that results from the work may be challenged. Data that have been subjected to challenge (and all relevant material) must be retained until any matter is resolved.

6.2.11 Researchers must retain data that are the basis for publications in a durable form and under the control of the institution where all or most of the work was undertaken.

- 6.2.12 Researchers must enquire whether confidentiality agreements apply to any given research project.
- 6.2.13 Researchers must make known to the head of the research institution (or nominated representative), details of any confidentiality agreement before such agreement is signed.

### 6.3 RESPONSIBILITIES OF PARTICIPANTS IN RESEARCH

To ensure their own safety and the validity of the research results, research participants have a 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.

## 7 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. Authorship should honestly reflect the contribution to the work being published. No person who is an author, consistent with this definition, may be excluded as an author without his or her permission in writing.

- 7.1 Researchers must comply with authorship criteria appropriate to their discipline, and/or according to the requirements of the journal in which their work is to be published<sup>6</sup>. The *Australian Code for the Responsible Conduct of Research* usually relates to work published in scholarly-refereed journals. It is also intended to cover non-refereed publications, such as in web pages and publication in other media. Similarly, the policies outlined here should also be adhered to in relation to grant applications. The following paragraphs should be read in conjunction with Chapter 8. “Publication”. See also [Guidelines for Research Publications and Authorship](#).
- 7.2 Collaborating researchers must discuss authorship of a publication or other research output at an early stage in the conception of the research project, and must review their decisions on authorship whenever there are changes in author participation.
- 7.3 The right to authorship is not tied to either position or profession, and does not depend on

---

<sup>6</sup> There are a number of published guidelines for authorship including:

[The Vancouver Protocol:](#)

[Committee on Publication Ethics \(COPE\) Guidelines on Good Publication Practice \(2002\)](#)

[Nature: Publication Polices](#)

whether the contribution was paid or voluntary. A researcher's name would not normally warrant inclusion as an author in situations where their participation related solely to the acquisition of data, the acquisition of funding or where their role in the research related only to general overall supervision.

**7.4** Researchers must ensure that others who have made substantial contributions to the research and those individuals and organisations who have provided facilities or material are acknowledged.

**7.5** The criteria for authorship are that each person listed as an author should have participated actively and significantly to the research. An author, as defined by the International Committee of Medical Journal Editors (ICMJE) Statement of Authorship, is a person who has:

1. Made substantial contribution to (a) conception and design, or acquisition of data; or (b) analysis and interpretation of data;
2. Participated in (a) drafting the article, or (b) revising it critically for important intellectual content; and
3. Participated in final approval of the version to be published.

Authors must meet at least one criteria of each of the three above conditions. All those listed as authors must have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

**7.6** Researchers must not deviate from acceptable execution of duties and responsibilities of authorship. Expressly unacceptable are:

- **Guest authorship** - the inclusion of an individual as an author solely to improve the chances of the manuscript being published or to improve the status of the publication.
- **Gift authorship** - the inclusion of an individual as an author solely based on an association with the study. E.g. Inclusion based on an individual's position as the head of the department in which the research was conducted.
- **Ghost authorship** - a failure to identify and disclose a contribution to the research and/or manuscript that meets the requirements of authorship.
- Omission from authorship of those who have made substantial intellectual contributions.

**7.7** One author should be nominated as the "responsible author" who can accept responsibility for the entire work. In the case of a publication that is the result of collaboration between different institutions, each institution should nominate a person as the "nominated author" for the part of the work emanating from that institution.

At least one author must accept responsibility for each part of an article critical to its main conclusion. An author's role in a publication or other research output must be sufficient for that person to take public responsibility for at least that part of the output to

which that person contributed.

- 7.8** A written acknowledgment of authorship signed by each co-author should be completed for each manuscript accepted for publication (Melbourne Health Research Publications and Authorship form – Appendix A of MH Guidelines for Research Publications and Authorship). The documents must be readily available in the department of the executive or senior author, at the time of submission or resubmission of the research paper for publication, and must remain in safe keeping in that department.
- 7.9** Department and Divisional Heads along with Principal Investigators must establish procedures to help prevent conflicts arising from disputes about authorship and to help resolve them if they arise. Complaints may be directed to the Office for Research where they will be handled in accordance with the relevant MH policies.
- 7.10** Names of sponsors of research must be disclosed.

## **8 PUBLICATION**

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. Although the formal publication of the results of research will usually take place in academic journals or books, this may not always be the case. This Chapter should be read in conjunction with **Chapter 7. “Authorship.”**

Peer review is also an integral part of publication. This Chapter should be read in conjunction with **Chapter 9. “Peer Review.”**

MH is committed to promoting an environment of honesty, integrity and accuracy in publishing.

- 8.1** Researchers have responsibilities to their colleagues and the wider community to publish the results of their research.
- 8.2** MH has an obligation to oversee confidentiality agreements to protect intellectual property rights between MH, the researcher and the sponsor of the research. MH will work with researchers and the sponsor 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.

Researchers are required to submit all confidentiality agreements to the Office of Research for review and approval before they are signed.

- 8.3** Where confidentiality is involved, the Principal Investigator must ensure that all parties to the research are aware of the nature of the confidentiality provisions.

- 8.4** MH is committed to ensuring that sponsors of research understand the nature of academic freedom and that sponsors do not discourage publication or the dissemination of research findings for longer than the minimum time required.

The MH Human Research Ethics Committee has adopted the ICMJE policy on registration of clinical trials. The ICMJE requires as a condition of consideration for publication, registration of the clinical trial in a public trials registry. This policy applies to any clinical trial starting recruitment on or after 1 July 2005. The goal of the ICMJE in introducing this policy is to foster a comprehensive, publicly available database of clinical trials.

- 8.5** Publication of multiple papers based on the same set(s) or subset(s) of data is improper unless full cross-referencing occurs within the papers. Simultaneous submission of papers based on the same set(s) or subset(s) of data to more than one journal or publisher should be disclosed to each journal or publisher at the time of submission.
- 8.6** Researchers must not re-publish without full disclosure and cross-referencing, and must have received permission to do so from the original publisher.
- 8.7** Researchers must take all reasonable steps to ensure that published reports, statistics and public statements about research activities and performance are accurate and unambiguous.
- 8.8** Researchers must be cognisant that integrity and accuracy in publication of results also extends to the accurate listing of publications in applications (for positions, research grants, awards etc), curricula vitae and public statements. This also applies to accurately describing the state of any publication (“in preparation”, “submitted”, “accepted”) of research funding (“applied for”, “granted”, “funding period” etc) and of awards conferred, including where any of these relate to more than one researcher.
- 8.9** Researchers must correct the record in cases where misleading or inaccurate statements have been made as soon as they are aware of the error.
- 8.10** Publications must include information on the sources of financial support for the research, and must include a disclosure of any potential conflicts of interest. An altruistic sponsor will not have a ‘financial’ conflict of interest.
- 8.11** Researchers must take great care when reporting research findings to the media. It would be preferable for such findings to have been subjected to peer review before reporting. The status of research findings, whether preliminary, complete, peer reviewed or otherwise must be explicitly disclosed.
- 8.12** Where there is confidential reporting or use of research that has not been subjected to peer review, researchers have an obligation to fully explain the status of the work to the sponsor and the scrutiny to which it will be subjected.

## 9 INTELLECTUAL PROPERTY

Melbourne Health 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 2010. Researchers should liaise with the Director of Business Development at an early stage in the development of research that may have potential Intellectual Property or Patents.

## 10 PEER REVIEW

Peer review is accepted by the research community as an essential element of quality assurance in a range of processes from assessing grant applications, to reviewing performance, to the selection of staff. Peer review supports honesty and integrity in research and can help detect departures from the principles of the *Australian Code for the Responsible Conduct of Research* (eg double publication, errors and misleading statements). However, it cannot act as the sole overseer of research integrity as peer reviewers rarely have access to all relevant information.

MH encourages and supports researchers to participate in peer review processes.

**10.1** Researchers have a responsibility to participate in peer review processes for research when asked. In particular, researchers who are in receipt of substantial public funding support have a clear obligation to become involved in assessments of grant applications for public funds and the review of submitted publications.

**10.2** Researchers involved as peer reviewers of research applications and/or publications must:

- act in confidence and must not disclose any matter regarding the application or publication without the express permission of both the author(s) and the agency;
- be fair, impartial and not introduce irrelevant considerations;
- disclose all real or potential conflicts of interest, and any other relevant matters that may affect the judgement of the application or publication;
- not disclose to an outside party the outcome of any process in which they are involved;
- ensure that they are informed about the policies and selection criteria to be applied.

**10.3** Researchers applying for research support or submitting papers for publication must:

- ensure that their applications/publications are accurate and honest;
- not omit relevant material or make claims not capable of verification;
- not approach any person involved as a peer reviewer in an attempt to influence the decision making process (Contact with peer reviewers via

normal research practice including presentations at meetings, participation in seminars etc, is not precluded);

- disclose all other sources of research support for all applicants;
- disclose all sources of funding in regard to any publication.

## **11 DISCLOSURE 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 must be treated as though the conflict exists.

- 11.1** Researchers have a responsibility to disclose at the time of proposing and of reporting research any potential conflict of interest that may influence or be seen to influence any aspect of the conduct of the research. This responsibility extends to matters related to research including investigations, publication, media reports, grant applications, and applications for appointment or promotion.
- 11.2** Disclosure of affiliation with, or financial involvement in, any organisation with a direct commercial interest in the research of any staff must be forwarded in writing to the Director Research Governance and Ethics, on an annual basis. Details of any benefits should be included.
- 11.3** The NHMRC requires disclosure of all affiliations with, or financial involvement in, any organisation with a direct commercial interest in research that is also being funded by NHMRC grants.
- 11.4** The Office of Research conducts an annual audit of all members of its research and ethics committees with regard to disclosure of potential conflicts of interest.

## **12 COLLABORATIVE RESEARCH ACROSS INSTITUTIONS**

Research can involve a wide range of collaboration 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.

## 12.1 RESPONSIBILITIES OF INSTITUTIONS

In accordance with the [Australian Code for the Responsible Conduct of Research](#), organisations involved in a joint research project should ensure that agreement is reached with the partners on the management of the research. This agreement should be in writing. Researchers may use the template developed by Melbourne Health for this purpose (MH Research Collaboration Agreement) or may use an agreement developed by a collaborating partner.

For all externally sponsored CTN clinical trials, one of the Clinical Trial Research Agreement templates, developed by VMIA (Insurer of public hospitals in Victoria) together with Medicines Australia should be completed.

The agreement 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 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.

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

## 13 RESEARCH MISCONDUCT

### 13.1 RESPONSIBILITIES

A number of people have responsibility for resolving allegations of research misconduct and breaches of the *Australian Code for the Responsible Conduct of Research*, the MH Guidelines for Research Practice, and Melbourne Health Research Policies and Procedures, including:

- The CEO, who has overall responsibility for the process, although certain aspects are delegated to the Executive Director of Research;
- The Designated Person, who conducts a preliminary investigation to assess the allegations and provide advice to the Executive Director of Research;
- Advisors on Integrity in Research, appointed by Melbourne Health to advise those making or considering making allegations;
- The Head of Department where the research is being or was conducted;
- Research supervisors;
- Researchers.

It is important that all parties are aware of their responsibilities, Melbourne Health

---

policies that govern research and the process for receiving and resolving allegations as described herein.

Anyone who forms a reasonable suspicion that research misconduct has occurred must act in a timely manner in accordance with the procedure described herein.

### 13.2 DEFINITION OF RESEARCH MISCONDUCT

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

- An alleged breach of the *Australian Code for the Responsible Conduct of Research*;
- 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 any conduct that jeopardises research integrity and erodes the trust and confidence of the public in research. Research misconduct involves serious deviation from the *Australian Code for the Responsible Conduct of Research*. It includes fabrication, falsification, plagiarism, misleading ascription of authorship including the listing of authors without their permission, attributing work to others who have not in fact contributed to the research, the lack of appropriate acknowledgment of work primarily produced by a research student/trainee or associate, ignoring conflicts of interest and abusive supervision. It also includes deliberate, negligent or reckless deviation from accepted research practice, including conducting a research project without the approval from the appropriate Research and Ethics Committee or deliberate deviation from approved research protocols.

Research misconduct does not include honest errors or honest differences in interpretation of, or judgements about data. Ongoing carelessness in record keeping or in the preparation of grant applications or publications may, constitute misconduct, if it is of gross degree or repeated after admonishment. However, it does include the facilitation of misconduct in research by collusion in, or the concealment of, such actions by others. It also includes any plan or conspiracy or attempt to do any of the above. Undertaking research that is clearly outside the researcher's area of competence or without the necessary resources may also constitute research misconduct.

Procedures for reporting possible research misconduct or detrimental action by an institution or its employees are essential. The alleged misconduct may be reported internally via an established grievance procedure if the misconduct is detrimental to the person bringing the allegation or via some other procedure if the improper conduct has potential detrimental effects beyond the person bringing the allegation.

Examples of research misconduct include but are not limited to the following:

**Misappropriation:** A researcher or reviewer shall not intentionally or recklessly:

- Plagiarise, which shall be understood to mean the presentation of the documented words or ideas of another as his or her own, without attribution appropriate for the medium of presentation;
- Make use of any information in breach of any duty of confidentiality associated with the review of any manuscript or grant application; or
- Intentionally omit reference to the relevant published work of others for the purpose of inferring personal discovery of new information.

**Inference:** A researcher or reviewer shall not intentionally and without authorisation take or sequester or materially damage any research-related property of another, including without limitation the apparatus, reagents, biological materials, writings, data, hardware, software, or any other substance or device used or produced in the conduct of research.

**Misrepresentation:** A researcher or reviewer shall not with intent to deceive, or in reckless disregard for the truth:

- State or present a material or significant falsehood; or
- Omit a fact so that what is stated or presented as a whole states or presents a material or significant falsehood.

### 13.3 RESPONSIBILITY TO REPORT RESEARCH MISCONDUCT

Allegations of misconduct in research may originate inside MH, from other institutions, in learned journals or in the press. At the outset for collaborative projects involving other institutions a primary partner should be nominated to be responsible for investigations of any alleged deviation from these Guidelines.

- 13.3.1 All employees or individuals associated with MH should report observed, suspected or apparent misconduct in research. Persons bringing allegations do not have a role in deciding whether misconduct has occurred.
- 13.3.2 An individual suspecting possible misconduct should first seek advice in confidence from their institution's advisers on research integrity. Individuals should be aware that they are at liberty and encouraged to seek advice from the persons identified within this document as MH's Advisors on Research Integrity (Section 12.6).
- 13.3.3 Individuals must be aware of 'whistleblower' legislation (as applicable) in situations where the person bringing the allegation is alleging research misconduct via the media or another authority outside their institution.
- 13.3.4 Researchers should be aware of the possibility of misconduct in research, both their own and that of others. Researchers must acknowledge their responsibility to bring alleged

cases of research misconduct to the attention of the designated person. (Section 12.8)

13.3.5 Researchers should be aware of the research governance framework within which they work and in particular the provisions relating to research misconduct.

#### **13.4 CHIEF EXECUTIVE OFFICER (CEO)**

The CEO is the chief executive officer of the institution where a departure from these Guidelines or misconduct in research is alleged to have taken place. At Melbourne Health the CEO has delegated responsibilities for the investigation of research misconduct to the Executive Director of Research.

#### **13.5 PROTECTION OF INTERESTED PARTIES**

Allegations of research misconduct require very careful handling. When an allegation is made, the protection of all interested parties is essential. Any investigations that take place must do so in accordance with natural justice and procedural fairness. Such fair dealing must consider the protection of persons making allegations in good faith, and, of the person accused of misconduct.

Interested parties may include:

- The person bringing the allegation (the Complainant);
- The person against whom a complaint is made (the Accused Person);
- A research participant/s;
- Research students and staff working with persons making an allegation, or with persons against whom our allegation is made,
- Journals and other media reporting research subject to suspected, alleged, or found research misconduct,
- Other collaborative groups such as The University of Melbourne and The Walter and Eliza Hall Institute;
- Bodies financially supporting the research or the accused person; and
- In some cases the public - for example, if a drug is involved.

Adequate protection of the complainant and the accused person demands absolute confidentiality and urgency in the early stages of the investigation. On the other hand, the protection of other parties may involve some disclosure. The designated person who has received the complaint should make such judgements.

#### **13.6 ADVISORS ON INTEGRITY IN RESEARCH**

MH has appointed individuals with expertise in research, to the role of Advisors on Integrity in Research (Advisor). The role of an Advisor is to ensure that the interests of both complainant and the accused person are addressed. An Advisor should not be involved in a case if he or she has a relevant conflict of interest.

Advisors on Integrity in Research are expected to be familiar with the literature and

guidelines on research misconduct and able to give confidential advice to staff and students about what constitutes misconduct in research and the responsibilities of a potential complainant and the procedures for dealing with allegations.

Confidential discussions with the Advisor do not constitute a formal allegation.

The Advisor should explain the options open to the person considering, making, or having made the 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 discussions resolve 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.

If the circumstances described by the individual do not meet the definition of research misconduct, the Advisor on Integrity in Research will refer the individual or allegation to an appropriate senior member of staff with responsibility for resolving the problem.

Advisors on Integrity in Research will not be involved in investigating or adjudicating any allegation.

The current list of members of the MH staff designated as Advisors on Integrity in Research appears as Appendix 1 to these guidelines.

### 13.7 LODGING A COMPLAINT

All employees or individuals associated with MH should report observed, suspected, or apparent misconduct in research. A formal allegation of research misconduct must be referred in person or in writing to the person designated to receive allegations (see section 12.8).

All allegations must be addressed appropriately. Breaches of these guidelines and/or the *Australian Code for the Responsible Conduct of Research*, 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 in 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.

### 13.8 DESIGNATED PERSON TO RECEIVE ALLEGATIONS

MH has appointed the Director, Research Governance and Ethics as the Designated Person to receive allegations. The role of the Designated Person is to advise the Executive Director of Research regarding whether allegations appear to be justified and whether a prima facie case exists.

The Designated Person will receive a written allegation, conduct a preliminary investigation and provide advice to the Executive Director of Research. The Designated Person must maintain full records of all matters that relate to allegations of research misconduct.

When undertaking a preliminary assessment of allegations, the Designated Person will take into account the requirements of the *Australian Code for the Responsible Conduct of Research* and Melbourne Health's Guidelines for Research Practice. He/she will 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 has the 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 will advise the Executive Director of Research 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 will also advise how the inquiry should be constituted. After providing advice to the Executive Director of Research, the Designated Person will not play any further role in the matter, except that he or she may be called to give evidence or expert opinion.

### 13.9 THE PROCEDURE TO INVESTIGATE ALLEGED MISCONDUCT

Sometimes it is not possible to deal with allegations of research misconduct 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 should go directly to an experienced senior mentor, such as one of the Advisors on Integrity in Research. This will be necessary when allegations concern the supervisor or head of the department.

Allegations of research misconduct must be referred to the Designated Person, either directly or through the head of the department.

### 13.9.1 **Purpose**

The purpose of the inquiry is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged misconduct involves clinical trials or potential harm to human participants or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation will be set forth in an investigation report.

### 13.9.2 **The Research Misconduct Inquiry**

Upon receiving the designated person's advice, the Executive Director of Research 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 Executive Director of Research does not proceed to a research misconduct inquiry, he/she must notify in writing those making the allegation, the person about whom the allegation has been made, and the Designated Person.

If the Executive Director of Research decides to proceed to a research misconduct inquiry, he/she must convey 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 on or before the date the inquiry begins. At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation as it relates to the *Australian Code for the Responsible Conduct of Research*/PHS definition of research misconduct, and the NHMRC, PHS, or other funding agency applications or grant number(s) involved.

The Executive Director of Research must decide whether to proceed to an internal inquiry or an independent external inquiry. The Executive Director of Research will consider the advice received from the Designated Person. The Executive Director of Research will also take into account the potential consequences for the accused person, the complainant, other parties and institutions in the event that the allegations were upheld, and the need to maintain public confidence in research. If in his or her judgment, these are likely to be serious, the Executive Director of Research must establish an independent external research misconduct inquiry.

Other considerations that may need to be addressed by the Executive Director of Research at this stage are:

- the sequestration of relevant research records and or physical evidence;
- whether the misconduct might involve a criminal act that is required to be reported to the appropriate authority;
- the nature and gravity of the allegation and whether it may be necessary to limit the activities of the person accused of misconduct. Under some circumstances it may

require the accused person to be stood down from their position while the investigation is pursued.

The research misconduct inquiry will be conducted in accordance with the *Australian Code on the Responsible Conduct of Research*, as described below.

**13.9.2.1 Sequestration of Research Records**

The Executive Director of Research will immediately sequester any additional pertinent research records that were not previously sequestered during the preliminary inquiry by the Designated Person. This sequestration should occur before or at the time the accused is notified that an investigation has begun. The need for additional sequestration of records may occur for any number of reasons, including a decision to investigate additional allegations not considered during the preliminary inquiry stage or the identification of records during the preliminary inquiry process that had not been previously secured.

**13.9.2.2 Internal Research Misconduct Inquiry**

The Executive Director of Research will appoint an internal inquiry panel of three 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 will have experience on similar panels or have relevant experience or expertise. One member of the panel will be appointed Chair. To achieve the membership Melbourne Health will draw on its own staff or externally as required. All members must be free from bias or conflicts of interest.

Legal representation of parties is not allowed, but a support person may accompany a person appearing before the research misconduct inquiry.

The internal research misconduct inquiry will report findings of fact to the Executive Director of Research and what, if any, research misconduct has occurred. Where adverse findings have been made, the Executive Director of Research will decide what disciplinary actions are required within the agreed disciplinary processes of Melbourne Health.

**13.9.2.3 Independent External Research Misconduct Inquiry**

In the event of serious misconduct allegations, the Executive Director of Research may appoint a panel to conduct an independent external research misconduct inquiry. The members must not be employed by Melbourne Health, have other current or recent dealings with Melbourne Health, or otherwise be subject to a reasonable perception of bias.

The panel will 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 person accused.

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 panel but may provide the panel with legal advice during the hearing. The person facing the allegations is entitled to legal representation.

### 13.9.3 **Charge to the Internal or External Inquiry Panel**

An Internal or External Inquiry will be conducted according to the following procedures:

The Executive Director of Research will define the subject matter of the investigation in a written charge to the panel that describes the allegations and related issues identified during the preliminary inquiry, defines research misconduct and identifies the name of the accused person. The charge will state that the committee is to evaluate the evidence and testimony of the accused person, the complainant, and key witnesses to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.

During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional persons may be involved, the panel will notify the Executive Director of Research, who will determine whether it is necessary to notify the accused person of the new subject matter or to provide notice to additional people against whom allegations are made.

### 13.9.4 **The First Meeting**

The Executive Director of Research will convene the first meeting of the panel to review the charge, the preliminary inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The panel will be provided with a copy of these instructions, the *Australian Code for the Responsible Conduct of Research* and/or PHS regulation, where funding for the research is from the PHS, and any other relevant documents e.g. laws, codes, and regulations.

### 13.9.5 **The Investigation Process**

The panel will be appointed and the process initiated within 30 business days of the completion of the preliminary inquiry by the Designated Person, if findings from that preliminary inquiry indicate that the allegations appear to be justified and/or a prima facie case exists.

The investigation will normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls. Wherever possible, the panel should interview the complainant, the accused person, and other individuals who might have information regarding aspects of the allegations. Interviews of the accused person should be tape recorded or transcribed. All other interviews should be transcribed, tape recorded or summarised. Summaries or transcripts of the interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.

#### 13.9.6 **The Inquiry Report**

The panel will prepare a draft report for comment. At the conclusion of receipt of comments on the draft report, the panel will compile a final report, including comments made by the accused person and the complainant. The final report will be submitted to the Executive Director of Research.

##### 13.9.6.1 **Draft Report - Comments**

- The Executive Director of Research will provide the accused person with a copy of the draft investigation report for comment and rebuttal. The accused person will be given 7 days to review and comment on the draft report. His/her comments will be attached to the final report. The findings of the final report should take into account the comments of the accused person in addition to all the other evidence.
- The Executive Director of Research will provide the complainant, if he or she is identifiable, with those portions of the draft investigation report that address the complainant's role and opinions in the investigation. The report should be modified, as appropriate, based on this person's comments.
- The Executive Director of Research will provide a copy of the draft investigation report to MH's legal counsel for a review of its legal sufficiency. Comments should be incorporated into the report as appropriate.

In distributing the draft report, or portions thereof, to the accused person and the Complainant, the Executive Director of Research will inform the recipient of the confidentiality under which the draft report is made available. Confidentiality will be maintained in accordance with the conditions prescribed in the MH Whistleblowers Protection Policy and Procedures Policy, Section 10. For example, the Executive Director of Research may ask the recipient to sign a confidentiality statement or to come to his or her office to review the report.

#### 13.9.7 **Melbourne Health's Review and Decision**

Based on a preponderance of the evidence, the Executive Director of Research will make the final determination whether to accept the inquiry report, its findings, and the recommended institutional actions.

Where the Executive Director of Research's determination varies from that of the panel,

the Executive Director of Research will explain in detail the basis for rendering a decision different from that of the panel in the report to any agency currently funding the research.

The Executive Director of Research's explanation should be consistent with the *Australian Code for the Responsible Conduct of Research* and the US Public Health Service's definition of research misconduct, MH's policies and procedures, and the evidence reviewed and analysed by the panel. The Executive Director of Research may also return the report to the panel with a request for further fact-finding or analysis. The Executive Director of Research's determination, together with the panel's report, constitutes the final investigation report for purposes of funding agency review.

If, after the inquiry, the Executive Director of Research determines that a charge of research misconduct is established, those findings must be reported forthwith to any funding agency that supported work in respect of which such misconduct occurred, or any agency which is currently supporting the person found to have engaged in research misconduct.

When the final decision on the case has been reached, the Executive Director of Research will notify the CEO of Melbourne Health and appropriate senior staff, including the person to whom the accused person reports, and to the accused person and the complainant in writing. In addition, the Executive Director of Research will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case. The Executive Director of Research is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

### **13.10 CONSULTATION WITH NHMRC, ORI, OR OTHER FUNDING BODY, AS APPROPRIATE AND TRANSMISSION OF THE FINAL INQUIRY REPORT**

The Executive Director of Research will notify the NHMRC, the ORI or other funding body of the intent to conduct a research misconduct inquiry.

The final report, where required will be submitted to the NHMRC, the ORI or other funding body, or the TGA, and will describe the policies and procedures under which the inquiry was conducted, describe how and from whom information relevant to the inquiry was obtained, state the findings, and explain the basis for the findings. The report will include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct as well as a description of any sanctions imposed and administrative actions taken by the institution.

If MH plans to terminate an inquiry for any reason without completing all relevant requirements of the *Australian Code for the Responsible Conduct of Research* / PHS regulations, the Executive Director of Research will submit a report of the planned termination to the funding agency, including a description of the reasons for the proposed

termination.

If MH determines that it will not be able to complete the investigation in 120 days, the Executive Director of Research, will submit to the relevant funding agency a written request for an extension that explains the delay, reports on the progress to date, estimates the date of completion of the report, and describes other necessary steps to be taken. If the request is granted, the Executive Director of Research will file periodic progress reports as requested by the funding agency.

When NHMRC / PHS or other funding agency funding or applications for funding are involved and an admission of research misconduct is made, the Executive Director of Research will contact the funding agency for consultation and advice. Normally, the individual making the admission will be asked to sign a statement attesting to the occurrence and extent of misconduct. When the case involves government agency funds, such as NHMRC / PHS, MH cannot accept an admission of research misconduct as a basis for closing a case or not undertaking an investigation without prior approval from the relevant funding agency.

The Executive Director of Research will notify the funding agency at any stage of the inquiry or investigation if:

- There is an immediate health hazard involved;
- There is an immediate need to protect Government or equipment;
- There is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;
- It is probable that the alleged incident is going to be reported publicly;
- The allegation involves a public health sensitive issue, e.g., a clinical trial; or
- There is a reasonable indication of possible criminal violation. In this instance, the institution must inform the funding agency within 24 hours of obtaining that information.

### **13.11 TIME LIMIT FOR COMPLETING THE INQUIRY REPORT**

The inquiry should ordinarily be completed within 120 days of its initiation, with the initiation being defined as the first meeting of the panel. This includes conducting the inquiry, preparing the report of findings, making the draft report available to the subject of the inquiry for comment, submitting the report to the Executive Director of Research for approval, and submitting the report to the relevant government and funding authorities.

### **13.12 ADMINISTRATIVE ACTIONS**

MH will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated. If the Executive Director of Research determines that the alleged misconduct is substantiated by the findings, a decision on the appropriate

actions to be taken will be made, with reference to MH Human Resources Policy, section 4. “Employee Relations” - sections 4.1 “Grievance Procedure”, 4.2 “Disciplinary Procedure”, 4.3 “Termination of Employment”, and 4.11 “Staff Complaints and Internal Investigations”. The actions may include:

- Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;
- Removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;
- A review and/or monitoring of the current research activities of the individual;
- Restitution of funds as appropriate.

The funding agency must also be notified of the final outcome of the inquiry.

### **13.13 TERMINATION OF INSTITUTIONAL EMPLOYMENT OR RESIGNATION PRIOR TO COMPLETING PRELIMINARY INQUIRY OR INVESTIGATION.**

The termination of the accused person’s institutional employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the misconduct procedures.

If the accused person, without admitting to the misconduct, elects to resign his or her position prior to the initiation of a preliminary inquiry, but after an allegation has been reported, or during a preliminary inquiry or investigation, the preliminary inquiry or investigation will proceed.

If the accused person refuses to participate in the process after resignation, the inquiry panel will use their best efforts to reach a conclusion concerning the allegations, noting in their report the accused person’s failure to cooperate and its effect on the panel’s review of all the evidence.

### **13.14 RESTORATION OF THE ACCUSED PERSON’S REPUTATION**

If the institution finds no misconduct and the funding agency concurs, after consulting with the accused person, the Executive Director of Research will undertake reasonable efforts to restore the accused person’s reputation. Depending on the particular circumstances, the Executive Director of Research, will consider notifying those individuals aware of or involved in the investigation of the final outcome, publicising the final outcome in forums in which the allegation of research misconduct was previously publicised, or expunging all reference to the research misconduct allegation from the accused person’s personnel file. Any institutional actions to restore the accused person’s reputation must first be approved by the Executive Director of Research.

### **13.15 PROTECTION OF THE COMPLAINANT AND OTHERS**

Regardless of whether MH or the funding agency determines that research misconduct occurred, the Executive Director of Research will undertake reasonable efforts to protect the complainant who made allegations of research misconduct in good faith and others who cooperate in good faith with inquiries and investigations of such allegations. Upon completion of an investigation, the Executive Director of Research, will determine, after consulting with the complainant, what steps, if any, are needed to restore the position or reputation of this person. The Executive Director of Research will also take appropriate steps during the preliminary inquiry and the formal inquiry to prevent any retaliation against the complainant.

### **13.16 INTERIM ADMINISTRATIVE ACTIONS**

The Executive Director of Research will also take interim action to ensure the safety of research participants, experimental animals, research staff and students.

The Executive Director of Research will take interim administrative actions, as appropriate, to protect research funds and ensure that the purposes of the financial assistance are carried out as appropriate.

### **13.17 RECORD RETENTION**

After completion of a case and all ensuing related actions, the Executive Director of Research will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the Executive Director of Research or inquiry panels. The Executive Director of Research will keep the file for seven years after completion of the case to permit later assessment of the case. The funding agency or other authorised personnel will be given access to the records upon request.

## APPENDIX 1

### MH ADVISORS ON INTEGRITY IN RESEARCH, effective 16 August 2010

- Professor Peter Colman - Director of Diabetes and Endocrinology, and Chairman, Human Research Ethics Committee.
- Professor Stephen Davis - Director of Neurosciences.
- Professor Duncan Blake – Consultant Anaesthetist, Human Research Ethics Committee Member.
- Professor Michael Green - Director of Medical Oncology – Western Hospital, Deputy Director Medical Oncology - Royal Melbourne Hospital, Human Research Ethics Committee Member
- Professor Bruce Mann – Director Infection and Cancer Medicine, Melbourne Health, and Past Human Research Ethics Committee member.
- Professor Alex Cockram, Director North West Mental Health.
- Mrs Susan Sherson – Chair Clinical Ethics Committee, Clinical Nurse Educator, Undergraduate Coordinator and Human Research Ethics Committee Member.
- Professor Ian Everall, Cato Professor of Psychiatry, The University of Melbourne.
- Professor John Wark – Head of Bone and Mineral Service, The Royal Melbourne Hospital.
- Professor Nick Santamaria, Professor of Nursing Research, Translational Research, The University of Melbourne.
- Professor Terry O’Brien – Head of Department, Department of Medicine, The University of Melbourne.