

<b>NAME OF DEPARTMENT</b>	OFFICE FOR RESEARCH
<b>NAME OF DOCUMENT</b>	<b>Handling Complaints in Research</b>
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<b>ASSOCIATED MELBOURNE HEALTH POLICY</b>	Research Policy
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<b>FUNCTIONAL GROUP</b>	Office for Research
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<b>EQUIP CRITERIA</b>	<p>Standard 15.10 – Corporate Systems and Safety.</p> <p>Criterion 15.10 – Fostering and encouraging clinical and health services research.</p> <p>Criterion 15.11 – Ensuring research integrity through governing body oversight.</p>
<b>SUMMARY</b>	<p>The Guidelines for Handling Complaints in Research have been developed to clearly set out the roles and responsibilities of Melbourne Health (MH) and its Human Research Ethics Committee (HREC) and the processes in place in relation to managing any complaints that may be received in relation to research undertaken at and/or by MH.</p> <p>These guidelines have been written in accordance with the <i>National Statement on Ethical Conduct in Human Research (2007)</i> and the <i>Australian Code for the Responsible Conduct of Research (2007)</i>.</p> <p>These guidelines should be read in conjunction with the MH Guidelines for Research Practice.</p>

#### 1. ASSOCIATED POLICY

MH Research Policy

#### 2. PURPOSE AND SCOPE

These Guidelines for Handling Complaints in Research have been developed to clearly set out the roles and responsibilities of MH and its Human Research Ethics Committees and the processes in place in relation to managing any complaints that may be received about research undertaken at and/or by MH. Complaints may be made about researchers or the conduct of research or about the conduct of a Human Research Ethics Committee (HREC) or other review body. Complaints may be made by research participants, researchers, staff or others. All complaints should be handled promptly and sensitively.

Melbourne Health's Research Policy requires that all research in which MH is involved complies with the *National Statement on Ethical Conduct in Human Research 2007* and the *Australian Code for the Responsible Conduct on Research 2007*. Where a complaint involves allegations of research misconduct, the procedures described in the MH Guidelines for Research Practice should be followed.

#### 3. DEFINITIONS

<b>Informal Complaint</b>	An informal complaint is a verbal expression of dissatisfaction that can be dealt with promptly and to the reporter's/complainant's satisfaction at the point of service. Informal complaints do not need to be recorded.
<b>Formal Complaint</b>	A formal complaint includes all written incident reports or complaints and any verbal complaints that cannot be dealt with as informal incidents/complaints. Formal complaints should be recorded by the Office for Research in the HREC Complaints Register and reported to the relevant HREC. A written file note of the complaint should also be placed in the relevant HREC file. Research related complaints are also reported to the NHMRC's Australian Health Ethics Committee as part of MH's Annual HREC report.

#### 4. GUIDELINES

- Complaint management must be sensitive towards the rights, need and concerns of reporters, complainants, patients, research participants and researchers.
- Complaint management must comply with the *Victorian Information Privacy Act 2000*, the *Health Records Act 2001* and the *Health Services (Conciliation and Review) Act 1987*
- All reporters, complainants, patients, research participants and investigators have a right to report or complain either in person or through a representative.
- All complaints should be managed in a timely and sympathetic manner and be treated confidentially.
- It is the responsibility both of the Office for Research and the HREC to ensure that the process is easily accessible to all concerned.
- The Office for Research will record details of complaints in the research complaints register.

The evaluation of complaints helps to inform the Office for Research and the HREC about areas where processes can be improved, particularly in relation to research management.

## 5. PROCEDURE

Complaints can be received in verbal or written formats.

In all cases, details of complaints will be recorded on the Research Complaints Register, held in the Office for Research. The register includes information to track the progress of the complaint and provide a history of all referrals and action taken, as well as dates of receipt and resolution of the complaint. Hard copies of the documents will be scanned and saved in the electronic project file. Original hard copies of complaint documents including where relevant meeting minutes, actions taken and outcomes will also be kept in the relevant HREC project file and the Office for Research Complaints file. It is important to identify either the HREC project number or project title when registering a complaint or enquiry.

The decision as to whether an incident/complaint is minor or serious will be made by the HREC Manager in consultation with the Chair of the HREC and, where necessary, the Executive Director of Research.

All research related complaints will be reported to the HREC and the NHMRC's Australian Health Ethics Committee as part of the HREC annual report.

### 5.1 Complaints from Research Participants

Formal complaints from research participants, most of whom will be MH patients, should also be notified to the MH Consumer Liaison Officer. This is usually done by telephone and followed up with an explanatory e-mail.

At MH, the first person designated to receive complaints from research participants is the HREC Manager. It is expected that most complaints from research participants will be able to be dealt with by the HREC Manager in conjunction with the relevant principal researcher.

Serious complaints, which cannot be readily resolved, will be referred for consideration by the HREC Manager, HREC Chair, Executive Director of Research and Consumer Liaison Officer.

In circumstances where a complaint cannot be resolved using MH's internal complaint resolution processes, external, independent advice will be sought. This may include consultation with the Office of the Health Services Commissioner or with senior staff from partner institutions in the Parkville Strip, such as the University of Melbourne's Dean of the Faculty of Medicine, Dentistry and Health Sciences or the Professors of Medicine or Surgery.

Complaints which highlight problems warranting amendments to the research protocol will be reviewed by the HREC who will provide written advice to the principal researcher.

### 5.2 Complaints from Researchers

Complaints from researchers about any aspect of the management of their research project by the Office for Research or the HREC should be directed in the first instance to the HREC Manager.

The HREC Manager will liaise with the principal researcher and, where necessary, the HREC Chair and the HREC itself to resolve the matter to the satisfaction of all parties.

Serious complaints which cannot be resolved using the process outlined above will be referred to the Executive Director of Research and, if necessary, the MH Chief Executive Officer. In some circumstances, external independent advisors, such as the University of Melbourne's Dean of the Faculty of Medicine, Dentistry and Health Sciences, Professors of

Medicine or Surgery, or the Dean of the University of Melbourne's Clinical School at the Royal Melbourne Hospital may be consulted to provide assistance and advice.

#### 5.3 Complaints from HREC Members and Other Interested Persons

Complaints from HREC members or other interested persons should be directed in the first instance to the HREC Manager. Other interested persons may include heads of departments whose services are required by researchers to support their research project and staff in wards or service departments whose assistance or support is required to facilitate the research. The HREC manager will endeavour to resolve the problem directly with the complainant and/or the principal researcher (as applicable) and, where necessary (and if appropriate), with the chair of the HREC.

Serious complaints will be referred to the Executive Director of Research, and, in the case of the Mental Health Research and Ethics Committee, to the Executive Director of North Western Mental Health. Consultation with the MH Chief Executive Officer and external independent advisors, as outlined above, will be sought if required.

#### 6. CATEGORIES OF COMPLAINTS

Complaints will be identified as relating to research activities or to review of research proposals by the HREC and will be categorised to allow analysis of trends. Categories may include:

- breaches of privacy/confidentiality;
- misappropriation/falsifying data/dubious authorship/plagiarism/misrepresentation;
- careless or inappropriate collection, analysis, use or disclosure of information;
- conflicts of interest;
- coercion/failure to appropriately obtain consent;
- departures from good research practice;
- other.

#### 7. SERIOUSNESS OF COMPLAINTS

Complaints will be rated on a scale for seriousness when they are first received by the Office for Research and again, when they are closed, in order to help with more accurate assessment of seriousness. The level of seriousness does not reflect the amount of resources that may go into the management of a particular complaint. It is not uncommon for less serious complaints to consume large amounts of time and other resources and for more serious incidents to be resolved comparatively quickly. A complaint can often raise several issues with different levels of seriousness:

- **Low Rated Complaints** - are those that ought to be easily resolved by a phone call or letter and an explanation. These may include misunderstandings or misconceptions where a detailed investigation is unwarranted.
- **Medium Rated Complaints** - are those involving incidents such as misunderstandings, access to records, disputes about costs, discourtesy, protocol violations, breaches of privacy, and diagnostic or treatment errors without serious consequences.
- **High rated complaints** - are those involving significant quality assurance implications, practices that need changing to avoid recurrence of the event, such as amendments to

the study protocol, or development of new policy. In addition, they include complaints about protocol violations, breaches of privacy, personal injury, professional misconduct, fraud, unlawful or unethical acts, lack of informed consent and diagnostic or treatment errors with serious adverse outcomes.

#### 8. POST-COMPLAINT ENQUIRIES

Any enquiries regarding the handling of incidents or complaints related to research activities should be directed to:

Manager Human Research Ethics Committee

Office for Research

Royal Melbourne Hospital city campus

Grattan Street

Parkville, Victoria 3050

Telephone: 61 3 9342 8530

Fax: 61 3 9342 8548

E-mail: [jessica.turner@mh.org.au](mailto:jessica.turner@mh.org.au)

#### 9. REFERENCES

These guidelines should be read in conjunction with:

- Melbourne Health Research Policy
- Melbourne Health Guidelines for Research Practice  
<https://www.thermh.org.au/research/researchers/about-research/policies-guidelines-regulations>
- [Melbourne Health Privacy and Confidentiality Policy](#)
- [Melbourne Health Code of Conduct 2007](#)
- [Melbourne Health Whistleblowers Protection Procedures](#)
- [Melbourne Health Staff Complaints and Internal Investigations Policy 2007](#)
- [Melbourne Health Grievance Procedure 2007](#)
- [Melbourne Health Workplace Bullying and Occupational Violence 2007](#)
- Melbourne Health Consumer Feedback Management 2005
- National Statement on Ethical Conduct in Human Research 2007
- Australian Code for the Responsible Conduct of Research 2007
- TGA Note for Guidance on Good Clinical Practice

#### 10. LEGISLATION

- Health Records Act (Vic) 2001
- Information Privacy Act (Vic) 2000
- Health Services (Conciliation and Review) Act (Vic) 1987
- Privacy Act (Commonwealth) 1988

#### 11. FURTHER INFORMATION

Contact the Office for Research on (03) 9342 8530.

#### 12. REVISION AND APPROVAL HISTORY

Date	Rev No	Author and approval
20/11/2007	1	Angela Watt, Manager Research Directorate
24/3/11	2	Jessica Turner, Research Ethics and Communications Coordinator, Office for Research
21/4/2016	3	Sarah Rickard, Manager of Research Governance