

Purpose:

The purpose of this procedure is to ensure that all complaints relating to the conduct of research undertaken at and/or by the Royal Victorian Eye and Ear Hospital (Eye and Ear) are undertaken in a confidential, appropriate, timely and sympathetic manner.

Scope:

This procedure applies to:

- all research undertaken at the Eye and Ear that is governed by the National Statement on Ethical Conduct in Human Research (2007 and as amended);
- all staff, students and Honorary Researchers involved in research at the Eye and Ear; and
- all reporters, complainants, patients, research participants and investigators who have a right to report or complain either in person or through a representative;

It is the responsibility of the Research Office (RO) to ensure that the procedure for research related complaints is easily accessible to all concerned.

Procedure:

Complaints may be made about researchers or the conduct of research, or about the conduct of a research-related committee or other review body. Complaints may be made by research participants, their carers or family, other researchers, hospital staff or others. All complaints, from all sources, should be handled promptly and sensitively, with records kept as described below under Recording of Complaints.

Formal complaints received from research participants will be entered into the Riskman/Victorian Health Incident Management System (VHIMS) by the person receiving the complaint eg Research Office, Research Administrative Officer or the Hospital's Consumer Liaison Officer (CLO). This system 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.

The decision as to the severity of a research incident/complaint will be made by the Research Manager in consultation with the Executive Director Medical Services/Chief Medical Officer and the Chair, HREC where the complaint is relevant to ethics approval.

For human research, information regarding the contact person for complaints should be included in Participant Information and Consent Forms.

Formal Complaints from Research Participants

Where the research participant is also an Eye and Ear patient, complaints are likely to be received through the following channels:

- via the Hospital's Patient Experience Feedback Procedure, in which instance the Hospital's CLO will liaise with the Research Office in consultation with the Executive Director Medical Services/Chief Medical Officer in the resolution of the complaint, and following the Eye and Ear's Patient Experience Feedback Procedure – Compliments and Complaints.
- or
- via the Research Administrative Officer, Research Office who is designated on Patient Information Consent Forms (PICFs) to receive complaints from research participants.

In circumstances where a complaint cannot be resolved using the Eye and Ear 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 other organisations (eg. Victorian Managed Insurance Agency).

Procedure for Handling Research Related Complaints

Complaints which highlight problems warranting amendments to the research protocol will be reviewed by the Chair, HREC and other HREC members as needed, who will provide written advice to the Principal Investigator

Complaints from researchers

Complaints from researchers about any aspect of the management of their research project should be directed in the first instance to the PI on their research project and if unresolved the, Research Office. The RO will advise the Executive Director Medical Services/Chief Medical Officer, who has responsibility for the Hospital's research portfolio, and will together liaise with the Principal Investigator of the research in question to resolve the matter.

Serious complaints which cannot be resolved using the process outlined above may be referred to external independent advisors for advice and/ or the Eye and Ear's Chief Executive Officer for resolution.

If the complaint relates to an allegation of research misconduct, the procedures outlined in the NHMRC Australian Code for the Responsible Conduct of Research (2007) will be followed.

Complaints from staff members relating to conduct of research or researcher

Complaints from staff members relating to the conduct of research or a researcher should be directed in the first instance to the RO. The RO, in consultation with the Executive Director Medical Services, will endeavour to resolve the problem directly with the complainant and/or the Principal Investigator.

Serious complaints which cannot be resolved using the process outlined above may be referred to external independent advisors for advice and /or the Eye and Ear's Chief Executive Officer for resolution.

If the complaint relates to an allegation of research misconduct, the procedures outlined in the NHMRC Australian Code for the Responsible Conduct of Research (2007) will be followed.

Complaints from Committee members

Complaints from Committee members should be directed in the first instance to the RO. The RO in consultation with the will endeavour to resolve the problem directly with the complainant and/or the Principal Investigator as applicable, and, where necessary, and if appropriate, with the Chair of the relevant committee.

Serious complaints which cannot be resolved using the process outlined above may be referred to external independent advisors for advice and / or the Eye and Ear's Chief Executive Officer for resolution.

If the complaint relates to an allegation of research misconduct, the procedures outlined in the NHMRC Australian Code for the Responsible Conduct of Research (2007) will be followed.

Recording of Complaints

In all cases, details of a complaint will be recorded by RO staff and held in the RO. Details of the complaint, actions taken and outcomes will also be recorded. It is important to identify either the project number or project title, if known, when registering a complaint or enquiry related to a specific project.

A summary of complaints involving human research will be reported to the NHMRC's Australian Health Ethics Committee (AHEC) as part of the HREC Annual Reporting requirement.

Categories of complaints

Complaints will be identified to allow for analysis of trends and 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;
- non-compliance with relevant legislation;
- unethical behaviour;
- other.

Severity rating of complaints

The severity of complaints will be monitored and an incident severity rating that aligns with Incident Severity Ratings (ISR) used for clinical complaints will be allocated and recorded in consultation with the Quality and Risk Manager.

Follow Up

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

Research Manager, Research Office

t. (03) 9929 8348

e. ethics@eyeandear.org.au

Outcome:

To ensure that research conducted at the Eye and Ear is done so appropriately, and that any complaints relating to research are dealt with in a timely manner and in accordance with the severity of the complaint.

The evaluation of complaints helps to inform the RO about areas where processes can be improved.

All complaints received by the RO will be evaluated for risk mitigation strategies, lessons learnt and to prevent recurrence.

Definitions:

Informal Complaint: 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 necessarily need to be recorded.

Formal Complaint: A formal complaint includes all written incident reports or complaints and any verbal complaints that cannot be dealt with as informal incidents/complaints due to their nature.

Research Misconduct: *The Australian Code for the Responsible Conduct of Research 2007* defines research misconduct as follows:

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

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

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

Standard:

NSQHS National Standard 1.1

NHMRC [National Statement on Ethical Conduct in Human Research \(2007 and as amended\)](#)

NHMRC [Australian Code for the Responsible Conduct of Research \(2007 and as amended\)](#)

Legislation:

Current legislation may be sourced at <http://www.austlii.edu.au>

Health Records Act (Vic) 2001

Information Privacy Act (Vic) 2000

Health Services (Conciliation and Review) Act (Vic) 1987

Privacy Act (Cth) 1988

References:

NHMRC [National Statement on Ethical Conduct in Human Research \(2007 and as amended\)](#)

NHMRC [Australian Code for the Responsible Conduct of Research \(2007 and as amended\)](#)

Linked Policy & Procedure:

Research Policy

LM 3.4 Patient Experience Feedback Procedure - Compliments and Complaints

Approval / Committees:

Executive Director Medical Services/Chief Medical Officer

Evaluation:

Complaints are responded to, investigated and resolved in a timely manner.

Review:

The procedure will be reviewed in six months to align with review of the Eye and Ear's Compliments and Complaints procedure review.

Author / Contributors:

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Policy / Procedure Details:

Details		
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