PROCEDURE

Handling Research Related Complaints

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 with procedural fairness.

Scope:

This procedure applies to:

- all research undertaken by and at the Eye and Ear;
- all staff, students, Honorary Researchers and members of a research team involved in research involving 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.

Procedure/Method:

Categories of complaints

Complaints will be identified to allow for analysis of trends and may include (amongst other things):

- breaches of the Code;
- 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 responsible conduct of research;
- non-compliance with relevant legislation;
- unethical behaviour; and
- research misconduct.

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, Eye and Ear staff or others. All complaints, from all sources, should be handled promptly and sensitively, with records kept as described below under Recording of Complaints.

Procedural fairness:

The Procedures to managing and investigating complaints will be:

- Proportional;
- Fair;
- Impartial;
- Timely;
- Transparent; and
- Confidential.

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 Eye and Ear's Managing Consumer Feedback Procedure, in which instance the CLO will liaise with the RO in consultation with the EDMS in the resolution of the complaint, and following the Eye and Ear's Managing Consumer Feedback Procedure.

  or

- via the Administrative Officer, RO 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's internal complaint resolution processes, external, independent advice will be sought. This may include consultation with the Office of the Health Complaints Commissioner or with senior staff from other organisations (eg. Victorian Managed Insurance Agency).

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 (PI).

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 EDMS, who has responsibility for the Eye and Ear's research portfolio, and will together liaise with the PI of the research in question to resolve the matter.

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 EDMS, will endeavour to resolve the problem directly with the complainant and/or the PI.

Complaints from Committee members

Complaints from Committee members should be directed in the first instance to the RO. The RO in consultation with the EDMS 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

The seriousness of complains will be determined by the following factors:

- the extent of the departure from accepted practice;
- the extent to which research participants, the wider community, animals and the environment are, or may have been, affected by the breach;
- the extent to which it affects the trustworthiness of research;
- the level of experience of the researcher;
- whether there are repeated breaches by the researcher;
- whether institutional failures have contributed to the breach; and
- any other mitigating or aggravating circumstances.

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 (CEO) for resolution.

If the complaint relates to an allegation of research misconduct, the procedures outlined in the Code will be followed.

Suspected Breaches of the Code

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

- Not meeting required research standards;

- Fabrication, falsification and misrepresentation;
- Plagiarism;
- Failure to maintain research records;
- Failure to provide adequate supervision;
- Failure to acknowledge contributions of authorship fairly;
- Failure to manage conflicts of interest; and
- Failure to conduct peer review responsibly.

The Eye and Ear will follow the procedures outlined in the 'Guide to managing and investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research' (2018)' (as amended or updated from time to time).

Complaints involving employees of other organisations

Where a complaint involves an employee of another organisation, the complaint will also be referred to the Designated Officer or CEO or equivalent of that organisation.

Recording of Complaints

In all cases, details of a complaint, actions taken and outcomes 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 the Research Office Reference Number and 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.

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:

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

Code: The Australian Code for the Responsible Conduct of Research (2018) (as amended and updated from time to time).

Designated Officer: A senior professional or academic institutional officer or officers appointed to receive complaints about the conduct of research or potential breaches of the Code and to oversee their management and investigation where required.

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: Research misconduct is defined in the Code as a serious breach of the Code which is also intentional or reckless or negligent.d

Standard:

NSQHS Standard 1: Clinical Governance

National Clinical Trials Governance Framework

Legislation:

Current Legislation may be sourced at: http://www.austlii.edu.au/ or Victorian legislation at: https://www.legislation.vic.gov.au/

- Health Records Act (Vic) 2001
- Privacy and Data Protection Act (Vic) 2014
- Health Complaints Act (Vic) 2016
- Privacy Act (Cth) 1988

Other regulations:

NHMRC National Statement on Ethical Conduct in Human Research (2007 and as amended)

NHMRC Australian Code for the Responsible Conduct of Research (2018 and as amended)

References:

Linked Policy & Procedure:

- P 18 Research Policy
- HR5.4 Employee complaints and Investigation Procedure
- RS 1.04 Monitoring and Safety Reporting for Research Projects Procedures
- LM 3.4 Managing Consumer Feedback Procedure – compliments, enquiries and complaints

Approval/Committees:

Research Committee

Responsible Executive:

Executive Director Medical Services

Review Officer:

Research Manager

Procedure Review:

This procedure will be reviewed every 5 years.

Key Words for Search:

Complaint, research, breach, misconduct

Contributors:

Name	Position	Service /Directorate
Dr Andrea Johannessen	Research Manager	Medical Services
Ms Kerryn Baker	Administrative Officer	Research Office
Dr Marc Sarossy	Chair, Human Research Ethics Committee	Medical Services
Ms Renee Chmielewski	Manager Planning and Patient Experience	Redevelopment, Planning and Infrastructure
Dr Sean Jespersen	Executive Director Medical Services/Chief Medical Officer	Medical Services
Mr Andrew Jaworski	General Counsel	CEO

Version Details:

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