

Reference Number	SOP012 v1	Date October 2024
Title	Complaints Handling	
Purpose	The purpose of this SOP is to describe the complaints management process relating to research and registered quality assurance activities being conducted at Eastern Health.	

1. Scope

This SOP applies to all research carried out at any of the Eastern Health campuses. It applies to all types of research at Eastern Health, ranging from clinical quality audits, quality assurance activities right up to multicentre clinical trials.

2. Target Audience

The target audiences are Eastern Health researchers (including delegates and collaborators), sponsors, contract research organisations, research participants and members of the public.

3. Related Policies

2959	Ethical and Responsible Conduct of Research Standard
2961	Ethical and Governance Review of Research
2321	Research at Eastern Health Policy
SOP008	Monitoring of Approved Research
SOP009	Safety Reporting
G008	Suspension or Cessation of Approved Research

4. Definitions

Complaint	Complaints are considered any concern or grievance relating to research being conducted at Eastern Health. Complaints may relate to any aspects of research and could include - the conduct of the research, the impact of participation in the research, research personnel, any conduct of the Eastern Health Human Research Ethics Committee (HREC) or conduct of the Office of Research and Ethics.
Centre for Patient Experience	The Eastern Health Centre for Patient Experience Team is responsible for a range of functions including - Consumer Participation & Engagement, Patient Experience, Feedback (Complaints, Compliments and Suggestions), Diversity, Equity and Inclusion and Patient Information and Education Resources

Victorian Health Incident Management System (VHIMS)	The Victorian Health Incident Management System (VHIMS) is a standardised dataset for the collection and classification of clinical, occupational health and safety (OH&S) incidents, near misses and hazards.
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5. Responsibilities

It is the responsibility of all Eastern Health investigators, collaborators, Institutes and their delegates, Sponsors and Contract Research Organisations, conducting research or registered quality assurance activities at Eastern Health, to follow and adhere to procedures set out in this SOP.

6. Procedure

Complaints may be made by a variety of people, including research participants, their relatives and friends, research personnel, and personnel from departments impacted by the research. Complaints may involve a number of possible issues, including the conduct of the research, research personnel themselves, the conduct of the Human Research Ethics Committee or the administrative process. Research participants are provided with information as to how to make a complaint in the Participant Information and Consent Forms, on the Eastern Health Centre for Patient Experience website and the Office of Research and Ethics website.

Complaints received directly by the Office of Research and Ethics

- 6.1** Complaints received from participants directly by the Office of Research and Ethics, are directed to the HREC Chair in the first instance. All complaints are processed promptly and sensitively. Details of the complaint and complainant's contact details are recorded by the Office of Research and Ethics.
- 6.2** Complaints received via the Office of Research and Ethics must also be forwarded to the Centre for Patient Experience. The Centre for Patient Experience must enter all participant complaints into Victorian Health Incident Management System (VHIMS).
- 6.3** The HREC Chair investigates the complaint, with the assistance of the Office of Research and Ethics. The research team may be involved in the resolution of the complaint, as appropriate.
- 6.4** Depending on the nature of the complaint, advice may also be sought from senior personnel at Eastern Health, such as the Director of Research, Executive Director Eastern Health Institute, Department heads or line managers.
- 6.5** The HREC Chair may also refer the complaint to the full HREC or the HREC Sub-Committee, as appropriate.
- 6.6** Complaints directed at the administrative process or administrative personnel may be directed to the HREC Chair, the Manager of the Office of Research and Ethics, the Director of Research or/and the Executive Director Eastern Health Institute, as appropriate.
- 6.7** Complaints directed at the HREC's conduct should be referred directly to a senior person who is independent of the HREC, eg the Executive Director Eastern Health Institute.

- 6.8** Electronic records of all complaints, investigations and resolutions are kept on the Office of Research and Ethics sharepoint page. If necessary the complaint will also be recorded in VIHMS .

Complaints received by the Centre for Patient Experience

- 6.9** Complaints received via the Centre for Patient Experience will be forwarded to the Office of Research and Ethics. The Centre for Patient Experience must enter the participant complaint into Victorian Health Incident Management System (VHIMS) on behalf of the Office of Research and Ethics. The complaint is then managed by the Office of Research and Ethics as per points **6.1 – 6.8**.

7. Related Material

Consult the Eastern Health Office of Research and Ethics (ORE) website for advice and any forms required for submissions. [Eastern Health Institute](#) | [Eastern Health](#)

8. References

Internal References

2959	Ethical and Responsible Conduct of Research Standard
2961	Ethical and Governance Review of Research
2321	Research at Eastern Health Policy
SOP008	Monitoring of Approved Research
SOP009	Safety Reporting
G008	Suspension or Cessation of Approved Research

External References

NHMRC National Statement of Ethical Conduct in Human Research (2023) NHMRC
Australian Code for Responsible Conduct of Research (2018)
Australian Commission on Safety and Quality in Health Care, The HSQHS Standards available at <https://www.safetyandquality.gov.au/standards/nsqhs-standards> (accessed 28 November 2023)
AS 10002:2022 Guidelines for Complaint Management in organisations (ISO 10002:2018, NEQ), Published 25 March 2022.
Good Practice Guides, Victorian Ombudsman. Available at <https://www.ombudsman.vic.gov.au/learn-from-us/practice-guides/> (accessed 28 November 2023)

9. Further Information

For enquiries related to this Standard Operating Procedure please email ethics@easternhealth.org.au

10. Version History

Date	Version	Author	Authoriser	Summary of Changes	Next Revision Due
October 2024	1	Ms Sharon Reid – Research Governance Manager	Prof David Taylor – Director of Research	Not applicable – first version	October 2025