

<b>Reference Number</b>	<b>SOP001 V1</b>	<b>Date</b> October 2024
<b>Title</b>	<b>Research at Eastern Health</b>	
<b>Purpose</b>	The purpose of this SOP is to describe the role of research at Eastern Health.	

## 1. Scope

This SOP applies to all research, including registered quality assurance activities, 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 and Contract Research Organisations.

## 3. Related Policies

2959	Ethical and Responsible Conduct of Research Standard
2961	Ethical and Governance Review of Research
2321	Research at Eastern Health Policy
3476	Clinical Quality Registries Guideline
SOP002	Ethical Review
SOP003	Human Research Ethics Committee (HREC)
SOP004	Low Risk
SOP005	Quality Assurance and Clinical Audit
SOP006	National Mutual Acceptance (NMA)
SOP007	Monitoring of Approved Research

## 4. Definitions

<b>Research</b>	an intellectual investigation aimed at discovering, interpreting and revising human knowledge.
<b>Research Governance</b>	refers to the processes used by institutions to ensure that they are accountable for the research conducted under their auspices - including overseeing and ensuring that research is conducted legally, efficiently and ethically in compliance with the parameters set by the local and, if appropriate, the central approving Human Research Ethics Committee (HREC), community standards and the law.

## 5. Responsibilities

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

## 6. Procedure

**6.1** Research is undertaken at Eastern Health to maximise the health, quality of care and wellbeing of the communities it serves. This is achieved by increasing knowledge and understanding of health and health-related matters, and translating research evidence into clinical practice. Research enables Eastern Health to achieve its strategic goal of optimising care and patient experience.

**6.2** The National Clinical Trials Governance Framework (NCTGF) was implemented in May 2023 across all Australian jurisdictions. Its purpose is to enhance the governance arrangements for clinical trials within health services. Eastern Health has implemented the NCTGF, and as such, prioritise patient safety, ethical treatment, and access to cutting-edge therapies. By adhering to the framework, Eastern Health enhances healthcare outcomes for all. This involves strong governance, transparent processes, and community engagement, ensuring that clinical trials are conducted with integrity and benefit both patients and the broader healthcare system.

**6.3** Eastern Health is committed to supporting research across the organisation through timely ethical review and sound governance, overseen by the Office of Research and Ethics. Eastern Health strongly encourages the dissemination of and application of research findings. Eastern Health promotes research across the organisation through providing forums for presentation of research findings and preparation of research activity reports overseen by the Office of Research and Ethics.

**6.4** Research must be undertaken ethically and be scientifically justifiable. Research participants must be informed, participate voluntarily and, on balance, not be exposed to greater health risk than if they had not participated.

**6.5** Research at Eastern Health must be conducted in accordance with and comply with:

- The National Statement on Ethical Conduct in Human Research (NHMRC, 2023);
- The Australian Code for the Responsible Conduct of Research (NHMRC, 2018);
- Relevant Commonwealth and State legislations;
- University partnership agreements and affiliations;
- The requirements of relevant regulatory and professional bodies; as amended from time to time.

These standards and codes govern ethical review and approval of research and research governance. To ensure patient safety, only research approved by an accredited Human Research Ethics Committee (HREC) can be undertaken at Eastern Health. The Eastern

Health HREC, in accordance with the above Codes, is able to terminate research for reasons of non-compliance or safety.

**6.6** Eastern Health conducts research by funding it directly and through funding from the Eastern Health Foundation, universities, research granting bodies, government agencies, industry, not-for-profit organisations and philanthropic agencies.

**6.7** Eastern Health partners with Deakin, La Trobe, Monash and other universities to enhance research performed within and involving Eastern Health. Eastern Health facilitates these linkages through the Office of Research and Ethics. As well as providing evidence that helps to optimise patient care and experiences, research informs teaching. Together with universities and other training partners, Eastern Health aims to provide quality healthcare and be a training ground for the workforce of the future.

## **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
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3476	Clinical Quality Registries Guideline
SOP002	Ethical Review
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SOP007	Monitoring of Approved Research

### **External References**

NHMRC National Statement of Ethical Conduct in Human Research (2023) NHMRC  
Australian Code for Responsible Conduct of Research (2018)  
NMHRC Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (November 2016 and updates)  
TGA Australian clinical trial handbook V2.4 August 2021  
TGA NOTE FOR GUIDANCE ON GOOD CLINICAL PRACTICE (CPMP/ICH/135/95) Annotated with TGA comments (2000)

## **9. Further Information**

For enquiries related to this Standard Operating Procedure please email [ethics@easternhealth.org.au](mailto:ethics@easternhealth.org.au)

## 10. Version History

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