

Reference Number	SOP003 v1	Date October 2024
Title	Human Research Ethics Committee (HREC)	
Purpose	The purpose of this SOP is to describe the Human Research Ethics Committee (HREC) at Eastern Health	

1. Scope

This SOP applies to all research required to be reviewed by the Eastern Health Human Research Ethics Committee (HREC).

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
SOP001	Research at Eastern Health
SOP002	Ethical Review
SOP004	Lower Risk
SOP005	Quality Assurance and Clinical Audit
SOP006	National Mutual Acceptance (NMA)
TOR	Eastern Health Human Research Ethics Committee Terms of Reference October 2024

4. Definitions

Research	an intellectual investigation aimed at discovering, interpreting and revising human knowledge.
Human Research Ethics Committee (HREC)	is an NHMRC registered committee which undertakes to provide review and approval of research projects. Its composition and conduct is governed by guidelines in particular in the National Statement on Ethical Conduct in Human Research (2023). Its function is to protect the welfare and rights of participants involved in research by reviewing research proposals

	involving humans, monitoring the conduct of research and dealing with complaints that arise from research.
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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 at Eastern Health, to follow and adhere to the procedures set out in this SOP. External investigators may also submit an ethics application for ethical review by the Eastern Health HREC. In that case it is the external party that accepts the ethical review outcome.

6. Procedure

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 and donors; as amended from time to time.

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

Eastern Health HREC is constituted to comply with the National Statement (2023).

The membership of the Eastern Health HREC must include people external to Eastern Health. The HREC shall comprise the following:

- Chairperson.
- Lawyer
- At least two laypeople as described in the National Statement.
- Person with knowledge and current experience in the professional care, counselling or treatment of people.
- Person who performs pastoral role in the community.
- People with current research experience.

The HREC Terms of Reference list the membership requirements of the Eastern Health HREC as well as outlining the responsibilities, scope and processes for the HREC members.

For further information please refer to the **Eastern Health Human Research Ethics Committee Terms of Reference October 2024**.

Delegation of Authority to Sub-committees/Delegates

The HREC has the authority to delegate to a sub-committee any of its powers and functions that are capable of being delegated in order to assist in the expeditious and effective ethical review of research proposals.

The HREC may delegate review of **post approval amendments** and **lower risk projects** to appropriate sub-committee members and/or delegates.

The HREC will remain responsible and accountable for the activities and recommendations of any sub-committees/delegates. The composition, role, functions and procedures of sub-committees of the HREC shall be approved by the HREC. HREC will publish the dates of sub-committee meetings and the submission closing dates for applications.

These committees report to the HREC through their Chair. The responsibilities and entitlements applicable to the HREC members will also apply to sub-committee members.

Decisions by a sub-committee/delegate must be consistent with the National Statement, the terms of reference of the HREC and the terms of reference of the sub-committee. All decisions must be ratified by the HREC at the next scheduled HREC meeting.

For more information please refer to **SOP004 - Lower Risk** and **SOP008 - Monitoring of Approved Research**

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

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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

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