

Reference Number	SOP002 v1	Date October 2024
Title	Ethical Review	
Purpose	The purpose of this SOP is to describe the process of ethical review 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 quality assurance activities right up to multi-centre 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
SOP001	Research at Eastern Health
SOP003	Human Research Ethics Committee (HREC)
SOP004	Lower Risk
SOP005	Quality Assurance and Clinical Audit
SOP006	National Mutual Acceptance (NMA)
SOP008	Monitoring of Approved Research
TOR	Human Research Ethics Committee Terms of Reference October 2024

4. Definitions

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 the National Statement. 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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Quality Assurance	Quality Assurance covers activities such as clinical audit, quality assurance and evaluation activities as well as projects that involves the potential for no more than lower risk.
Lower Risk Research	Research in which the only foreseeable risk is no greater than discomfort.
Research	An intellectual investigation aimed at discovering, interpreting and revising human knowledge.
Research Governance	A system for 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 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 at Eastern Health, to follow and adhere to the procedures set out in this SOP.

6. Procedure

6.1 Ethical Review at Eastern Health

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.

The HREC conducting the review may be the **Eastern Health Human Research Ethics Committee** (See below) or **an accredited HREC outside of Eastern Health**. (See Section 6.3)

Eastern Health Human Research Ethics Committee (HREC)

Eastern Health HREC is constituted to comply with the National Statement (2023). Its primary 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. Only research approved by the Eastern Health HREC (or an accredited Human Research Ethics Committee (HREC) – see section 6.3) can be undertaken at Eastern Health.

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

For more information on the review of post approval amendments, please refer to **SOP008 - Monitoring of Approved Research**

6.2 Review of lower risk projects at Eastern Health

As per the HREC Terms of Reference, 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. As such, the HREC delegates the review of **lower risk projects** to its sub-committee.

For more information regarding the review of Lower risk, please refer to **SOP004 - Lower Risk**.

The HREC remains responsible and accountable for the activities and recommendations of the sub-committee. The composition, role, functions and procedures of sub-committees of the HREC is approved by the HREC. The sub-committee reports to the HREC through their Chair. The HREC publishes the dates of its meetings and submission closing dates for applications. The responsibilities and entitlements applicable to the HREC members will also apply to sub-committee members.

Decisions by the sub-committee must also 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 meeting.

6.3 Accepting Ethical Review from an accredited HREC external to Eastern Health

The National Mutual Acceptance (NMA) scheme enables Eastern Health to accept an HREC review and approval from an external, accredited HREC under NMA.

The NMA scheme can apply to any form of human research as defined in the National Statement on Ethical Conduct in Human Research (2023), for which an application is made to an HREC for the purpose of being conducted at a public health organisation. This includes lower risk research review by a full HREC using a national ethics form (e.g. HREA). For more information please refer to **SOP006 - National Mutual Acceptance (NMA)**

6.4 Quality Assurance Activities

Quality Assurance/Evaluation Activities do not require ethical review by a Human Research Ethics Committee (HREC). Quality Assurance/Evaluation Activities must, however, be registered with the Eastern Health Office of Research and Ethics.

For more information please refer to **SOP005 - Quality Assurance and Clinical Audit**.

6.5 Site Specific Assessment

Any research project which has received ethics approval cannot commence at Eastern Health until an Eastern Health site specific assessment has been conducted. Please refer to **SOP007 Site Specific Assessment (SSA)** for information related to the submission and review of Site Specific Assessments.

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
3476	Clinical Quality Registries Guideline
SOP001	Research at Eastern Health
SOP003	Human Research Ethics Committee (HREC)
SOP004	Lower Risk
SOP005	Quality Assurance and Clinical Audit
SOP006	National Mutual Acceptance (NMA)
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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