Reference Number	SOP004 v1	Date October 2024
Title	Lower Risk	
Purpose	The purpose of this SOP is to describe the process of review of new research applications that is considered lower risk.	

1. Scope

This SOP applies to all research proposals that fall into the category of lower risk.

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
SOP003	Human Research Ethics Committee (HREC) Review
SOP005	Quality Assurance and Clinical Audit
TOR	Eastern Health Human Research Ethics Committee – Subcommittee Jan 2015

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.
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 ethics committee, 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 procedures set out in this SOP.

6. Procedure

As per the Eastern Health HREC Terms of Reference, the Eastern Health HREC has the authority to delegate to a sub-committee any of its powers and functions. This delegation enables expeditious and effective ethical review of research proposals. Accordingly, the Eastern Health HREC has delegated the review of lower risk projects to the sub-committee.

The sub-committee is constituted in accordance with the National Statement (2023) and is governed by the Eastern Health Human Research Ethics Committee – Subcommittee Terms of Reference. Please refer to the **Eastern Health Human Research Ethics Committee – Subcommittee Terms of Reference**.

The composition, role, functions and procedures of sub-committee of the HREC is approved by the HREC. The sub-committee reports to the HREC through the Chair. The responsibilities and entitlements applicable to the HREC members also apply to sub-committee members.

Decisions made by the sub-committee/sub-committee delegate are consistent with the National Statement (2023), the terms of reference of the HREC and the terms of reference of the sub-committee. All decisions are ratified by the HREC at the next scheduled HREC meeting.

The HREC remains responsible and accountable for the activities and recommendations of the sub-committee, and publishes the dates of its meetings and submission closing dates for applications.

For information about dates of meetings and submission closing dates please refer to Office of Research and Ethics (ORE) website. Eastern Health Institute | Eastern Health

Any lower risk research project which has received ethics approval from a non-Eastern Health HREC 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
SOP002	Ethical Review
SOP003	Human Research Ethics Committee (HREC) Review
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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