Reference Number	**SOP006 v1**	**Date** October 2024
Title	**National Mutual Acceptance (NMA)**	
Purpose	The purpose of this SOP is to describe the process of the National Mutual Acceptance Scheme (NMA)	

1. Scope

This SOP applies to all eligible multi-centre health and human research that is conducted at multiple sites within one or more Australian State and/or Territory public health system.

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)
SOP004	Lower Risk
SOP005	Quality Assurance and Clinical Audit
SOP007	Site Specific Assessment (SSA)
TOR	Eastern Health Human Research Ethics Committee Terms of Reference October 2024

4. Definitions

Certified Human Research Ethics Committee (HREC)	An HREC which has been assessed and certified by a NHMRC certification committee to conduct the scientific and ethical review of multi-centre human research projects.
Coordinating Principal Investigator (CPI)	The individual who takes overall responsibility for the research project and submits the project for scientific and ethical review. The CPI is responsible for ongoing communication with the HREC and passing on any outcomes from this to the Principal Investigators.

Multi-centre Human Research	Human research that is conducted at multiple sites within more than one State and Territory public health system.
Principal Investigator (PI)	The individual who takes responsibility for the overall conduct, management, monitoring and reporting of research conducted at a site and submits the research project for site authorisation.
Public Health Organisation	Publically funded health service.
Research Governance Officer (RGO)	The individual appointed within a Public Health Organisation who is responsible for the management of applications for site authorisation and oversight of authorised research projects.
Site	A facility, location or service where the research is being conducted.
Site Specific Assessment (SSA)	A review undertaken to examine the suitability of a multi-centre research study to take place at a particular site. The SSA will be undertaken in accordance with the relevant standard SSA form developed by each jurisdiction.

5. Responsibilities

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

6. Procedure

The National Mutual Acceptance (NMA) scheme can apply to any form of health and 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 (referred to a sub-committee) using a national ethics form (e.g. HREA). In the state of Victoria, the only exception is research projects involving access to coronial material (these must be referred to the Victorian Institute for Forensic Medicine HREC) and research projects involving persons in custody. (These require review by the Justice HREC of Victoria.)

The NMA single ethical review process applies to public health organisations; however, private health organisations may accept the review of a NMA proposal reviewed by a NHMRC certified HREC. Some jurisdictions may have certain requirements to provide ethical approval for private health organisations. Investigators should contact the respective State or Territory health department representatives and ensure these requirements are followed.

HREC review under National Mutual Acceptance (NMA)

The single ethical review/approval of a multi-centre human research project is to be conducted by an appropriately NHMRC Certified HREC (reviewing HREC) in a participating jurisdiction. There are different areas of certified review. The majority of reviewing HRECs are certified to review adult research projects. Some HRECs are certified to review paediatric research projects and some are certified to review both adult and paediatric research projects.

For a list of all participating HRECs, RGOs and organisations, please refer to the following link - Participating Organisations and Ethics Committees - Clinical Trials and Research

Eastern Health Site Specific Assessment (SSA)

Research projects ethically approved under NMA cannot commence at Eastern Health until an Eastern Health Site Specific authorisation has been issued. Please refer to **SOP007 Site Specific Assessment (SSA)** for information related to the submission and review of Site Specific Assessments.

Responsibilities under National Mutual Acceptance (NMA)

Coordinating Principal Investigator (CPI)

- Takes overall responsibility for developing the HREC application in consultation with accepting sites (participating PIs).
- Takes overall responsibility for the research project and submits the project for scientific and ethical review;
- Is responsible for the ongoing communication with the reviewing HREC and passing on information from the HREC to the sponsor and the PI at each site conducting the research; and
- Takes on the responsibilities as the PI at their own site (as outlined below).

Principal Investigator (PI)

- Takes responsibility at their own site for the conduct, management, monitoring and reporting of the research project;
- Is responsible for submitting the site specific assessment documents for site authorisation and liaises with the site Research Governance Officer (RGO) throughout the life of the research project; and
- Is responsible for relevant communication with and reporting to the CPI with respect to all information related to the research that requires submission to the reviewing HREC.

Please note - The CPI and PI may delegate some responsibilities to research staff and / or other relevant persons (including sponsors) to manage communication during the project.

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)
SOP004	Lower Risk
SOP005	Quality Assurance and Clinical Audit
SOP007	Site Specific Assessment (SSA)
TOR	Eastern Health Human Research Ethics Committee Terms of Reference October 2024

External References

National Mutual Acceptance Single Ethical Review of Multi-centre Human Research Projects - NMA Standard Principles for Operation, version: March 2024
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)
National Mutual Acceptance (NMA) Data Linkage Guide - State of Victoria, Australia, Department of Health, March 2024
Guidelines for the Victorian Specific Module - State of Victoria, Australia, Department of Health, October 2021

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