Reference Number	SOP007 v1	Date October 2024
Title	Site Specific Assessment (SSA)	
Purpose	The purpose of this SOP is to describe the process of Site Specific Assessment (SSA)	

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

4. Definitions

Research	An intellectual investigation aimed at discovering, interpreting and revising human knowledge.
Research Governance	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.

Site Specific Assessment (SSA)	A review undertaken to examine the suitability of a research study to take place at a particular site.
Site Authorisation	Formal authorisation that permits a research project to be conducted at Eastern Health.

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

a. Research projects ethically approved by the Eastern Health HREC (or its sub-committee)

All research projects ethically approved at Eastern Health by the Eastern Health HREC (or its sub-committee) also need to undergo a Site Specific Assessment (SSA). An SSA review focuses on the research governance matters related to the conduct of the proposed research. Governance matters considered during this review include, but not limited to the following –

- Clinical Trial Research Agreements
- Confidentiality agreements
- Insurance arrangements
- Indemnity documents
- Researcher qualifications and training
- Funding and resources
- Clinical Trial Notifications (CTN)

Once it has been established that all governance matters have been adequately addressed, the Office of Research and Ethics will issue a Site Authorisation letter.

Research or quality assurance activities cannot commence at Eastern Health until a Site Authorisation letter has been received.

Please refer to **SOP002 Ethical Review, SOP003 Human Research Ethics (HREC) Committee** and **SOP004 Lower Risk** for more information about ethics review and approval at Eastern Health.

b. Research projects ethically approved under NMA or by another non-Eastern Health HREC

Research projects ethically approved under NMA or by another non-Eastern Health HREC also require an Eastern Health SSA to be conducted. These research projects cannot commence at Eastern Health until an Eastern Health Site Authorisation has been issued.

The SSA review focuses on the same research governance items outlined in **Section 6.a.** above, with the following extra requirements:

- All associated lead HREC approval letter(s) from the reviewing Human Research Ethics Committee (HREC)
- A lead HREC approval letter listing Eastern Health as a participating site under the HREC approval
- All project documents which have been ethically approved by the lead HREC. (This includes all master documents – eg. Master PICFs)
- Eastern Health site specific versions of all ethically approved master documents – eg. Eastern Health site specific PICFs)

Once all governance matters have been adequately addressed, the Office of Research and Ethics will issue a Site Authorisation letter.

Please refer to **SOP006 National Mutual Acceptance (NMA)** for information about the NMA scheme.

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)
SOP008	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

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