Reference Number	SOP010 v1	Date October 2024
Title	Auditing and Compliance	
Purpose	The purpose of this SOP is to describe project auditing and compliance activities at Eastern Health.	

1. Scope

This SOP applies to all research that is, or has been, carried out at Eastern Health.

This SOP describes the **Eastern Health Research Auditing Program.** This program was developed by the Office of Research and Ethics to satisfy the governance requirements of Eastern Health.

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
SOP008	Monitoring of Approved Research

4. Definitions

ICH Guideline for Good Clinical Practice (GCP)	An internationally accepted standard for the designing, conducting, recording and reporting of clinical trials.
Self-Audit Form	A form generated by the Eastern Health Office for Research, intended to be used as a tool for research teams to conduct a self-assessment of GCP Compliance.
In-person Audit	An audit involving an in-person interview with research staff, as well as an examination of any, or all, records associated with a research project. This may include completed consent forms and computer files.
Desk-Top Audit	An audit involving a single email request, requesting the research team to provide information about a chosen topic or aspect of their project.
Random Audit	Audit of a project, where the project has been selected at random, as part of the usual, on-going monitoring process.
Targeted Audit	Audit of a project, where the project has been specifically selected due to compliance-related concerns.

5. Responsibilities

It is the responsibility of 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

At any time throughout the life-cycle of a research project, an audit request may be sent by the Office of Research and Ethics to the research team. Audit requests may be random or targeted. Audits may be in-person audits or desk-top.

6.1 In-person audits

In-person audits may be either random or targeted.

In-person audit invitations will be sent via email. The email will identify the project to be audited, describe the reason for the audit, explain how long the audit will take and outline what will need to be made available for the auditor/s on the day of the audit. Researchers will be given at least 2 weeks' notice of an upcoming audit. The invitation will include a timeframe that the audit will need to be schedule within.

Researchers are asked to reply to the invitation email, nominating a suitable time for a member of the Office of Research and Ethics to perform the audit. A mutually convenient time is formalised upon their reply.

As preparation for the audit, researchers will be asked to complete and return an **Eastern Health Self-Audit Tool**. Completed forms should be returned to the Office of Research and Ethics **no later than 3 days** prior to the scheduled audit. This tool defines the scope of the audit and will assist with audit preparation.

On the day of the audit one nominated member of the study team should be present/available for the duration of the audit. The study team member won't need to be present for the entire duration of the audit. A brief meeting at the beginning of the audit and another brief meeting to close the audit will be sufficient.

The Principal Investigator will need to be available on the day of the audit (either in person or by phone) to answer any questions should they arise.

A formal Audit Report will be provided to the researchers following the audit.

If any compliance issues, or any other findings arise from the audit, the Office of Research and Ethics will work closely with researchers to resolve these as soon as possible.

6.2 Desk-top Audits

Desk-top audits may be either random or targeted.

Desk-top audit invitations will be sent via email. The email will identify the project, describe the reason for the audit, and outline what information the research team will need to provide to the Office of Research and Ethics.

Researchers will be given a specified timeframe to respond. This timeframe is **usually 7 days,** but may be negotiated to suit the research staff and Office of Research and Ethics staff.

Once all requested information has been received by the Office of Research and Ethics, it will be reviewed. A response/outcome will be communicated to the researchers.

If compliance issues, or any other matters of concern arise from the audit, the Office of Research and Ethics will work closely with the researchers to resolve these as soon as possible.

6.3 Other compliance activities

Eastern Health Office of Research and Ethics will continue to develop activities and initiatives that will support researchers, ensuring that research carried out at Eastern Health is compliant with all relevant regulatory requirements.

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
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