Reference Number	SOP008 v1	Date October 2024
Title	Monitoring of Approved Research	
Purpose	The purpose of this SOP is to describe the process of post-approval monitoring of approved research. It describes ongoing reporting requirements.	

1. Scope

This SOP applies to all research carried out at Eastern Health. It describes the process for post-approval monitoring and reporting as per local, national and international requirements.

This SOP is consistent with NHMRC National Statement of Ethical Conduct in Human Research (2023) and NHMRC Australian Code for Responsible Conduct of Research (2018), and other relevant national and international guidelines and standards.

2. Target Audience

The target audiences are Eastern Health researchers (including delegates and collaborators), sponsors and Contract Research Organisations who may be directly or indirectly involved in research at Eastern Health.

3. Related Policies

2959	Ethical and Responsible Conduct of Research Standard
2961	Ethical and Governance Review of Research
2321	Research at Eastern Health Policy
SOP006	National Mutual Acceptance (NMA)
SOP009	Safety Reporting
SOP010	Auditing and Compliance
SOP012	Complaints Handling
G002	Change in Personnel
G008	Suspension or Cessation of Approved Research

4. Definitions

Reviewing HREC	The HREC responsible for the original ethics review of a given research project. This HREC is also responsible for all subsequent post-approval ethical reviews.
Single-Site Review	An ethics review which has been carried out by the Eastern Health HREC on behalf of the Eastern Health site.
Multi-Site Review	An ethics review carried out by an external HREC under the National Mutual Acceptance (NMA) Scheme.
ICH Guideline for Good Clinical Practice (GCP)	An internationally accepted standard for the designing, conducting, recording and reporting of clinical trials.

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 the procedures set out in this SOP.

Failure to comply with post-approval reporting requirements may result in suspension or withdrawal of HREC approval and/or site authorisation to conduct the research project.

6. Procedure

Once a research project has been approved by an HREC (either the Eastern Health HREC, or another approved HREC for example under NMA) and given site authorisation by Eastern Health, ongoing project reporting is required. Reporting obligations to both the reviewing HREC and the Eastern Health Office of Research and Ethics apply.

For instructions on how to submit post-approval submissions, please refer to the Eastern Health Office of Research and Ethics (ORE) website Eastern Health Institute | Eastern Health

6.1 Amendments

The Eastern Health Office of Research and Ethics must be notified of the following –

1. Any proposed amendment to an ethically approved research project which was originally reviewed by the Eastern Health HREC, and
2. Any HREC-approved amendment to an authorised project which has been reviewed by an external HREC.

In both cases outlined above, a full explanation of the scope of the amendment and a rationale for the amendment should be given. Tracked and clean copies of all the amended documents should be submitted.

The amendment should be submitted by the principal investigator (or delegate) at Eastern Health.

Amendments requests that require Eastern Health HREC review will be reviewed by the Eastern Health HREC (or appropriate delegates). Amendments that have already received HREC approval by an approved HREC such as under the National Mutual Acceptance scheme, will be reviewed administratively by a member of the Eastern Health Office of Research and Ethics.

Change of research personnel amendments (excluding a change of Principal Investigator) and all administrative amendments will be reviewed by a member of the Eastern Health Office of Research and Ethics.

Any queries arising from an amendment review will be sent to the principal investigator (or delegate).

Upon approval, all amendments will receive a formal approval email (or acknowledgement email where appropriate)

6.2 Safety Reporting

Throughout the life of a research project, Safety Reports need to be submitted as per **SOP009 – Safety Reporting.**

Clinical Trials involving therapeutic goods must also comply with the reporting requirements in the NMHRC Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (November 2016 and updates)

6.3 Serious Breaches

A **serious breach** is a breach of Good Clinical Practice or the protocol that is likely to affect to a significant degree the safety or rights of a research participant or the reliability and robustness of the data generated in the research project.

Serious breaches must be notified to the reviewing HREC by the sponsor of the project (or delegate). Notification of the reviewing HREC should be done **within 7 days** of the breach occurring.

Where the reviewing HREC is an external HREC such as under the National Mutual Acceptance scheme, the Eastern Health Office of Research and Ethics should also be notified of the Serious Breach by the site Principal Investigator.

Once received and reviewed, the Office of Research and Ethics will issue a formal acknowledgement.

6.4 Non-serious Breaches

A **non-serious breach** is any deviation, breach, divergence or departure from the requirements of Good Clinical Practice (GCP) or the protocol that **does not** have a significant impact on the continued safety or rights of participants or the reliability and robustness of the data generated in the research project.

Non-serious breaches are required to be submitted to the Eastern Health Office of Research and Ethics, irrespective of the HREC which has reviewed the project.

Non-serious breaches do not need to be submitted within a specific timeframe. Non-serious breaches are permitted to be compiled and submitted quarterly.

Once received and reviewed, the Office of Research and Ethics will issue a formal acknowledgement.

6.5 Progress Reports

A progress report must be submitted to the Eastern Health Office of Research and Ethics, annually for all authorised projects at Eastern Health.

Progress reports are due annually in the month of **February.**

Once received and reviewed, the Office of Research and Ethics will issue a formal acknowledgement.

Failure to submit the progress report may result in suspension of the approved project by the Eastern Health Office of Research and Ethics.

6.6 Final Reports

Once a project has completely closed at Eastern Health, a final report is required to be submitted.

Once received and reviewed, the Office of Research and Ethics will issue a formal acknowledgement.

The status of the project will then be 'closed' in the Office of Research and Ethics records.

6.7 Complaints

Any complaints regarding the conduct of a research project or the conduct of the Eastern Health HREC in the ethical review of a research project should be promptly reported to the Eastern Health Office of Research and Ethics.

Information about complaints and complaints handling can be found in **SOP012 - Complaints Handling**

6.8 Auditing

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.

Audits are carried out as per **SOP010 - Auditing and Compliance**

6.9 Suspension or Cessation of Approved Research

Failure to comply with post-approval reporting requirements outlined throughout this SOP may result in suspension or withdrawal of HREC approval and/or site authorisation.

In the event of serious deficiencies in the conduct of a research project, deficiencies in reporting, or other non-compliance with the conditions of HREC approval and/or site authorisation, HREC approval and/or site authorisation may be withdrawn.

Withdrawal may also occur if it is believed a participant's welfare is compromised in any way.

For further details about the suspension or cessation of approved research please refer to **G008 - Suspension or Cessation of Approved Research.**

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
SOP006	National Mutual Acceptance (NMA)
SOP009	Safety Reporting
SOP010	Auditing and Compliance
SOP012	Complaints Handling
G002	Change in Personnel
G008	Suspension or Cessation 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
Oct 2024	1	Ms Sharon Reid – Research Governance Manager	Prof David Taylor – Director of Research	Not applicable – first version	Oct 2025