Reference Number	**SOP009 v1**	**Date** October 2024
Title	**Safety Reporting**	
Purpose	The purpose of this SOP is to describe the process of safety reporting	

1. Scope

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

This SOP is consistent with NHMRC National Statement of Ethical Conduct in Human Research (2023) and NMHRC Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (November 2016 and updates) 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.

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)
SOP008	Monitoring of Approved Research

4. Definitions

Investigational Product (IP) **Investigational Medicinal Product (IMP)**	A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, a new patient group or when used to gain further information about an approved use.
Adverse Events (AE)	Any untoward medical occurrence in a patient or clinical trial participant administered a medicinal product and that does not necessarily have a causal relationship with this treatment.
Adverse Reactions (AR)	Any untoward and unintended response to an investigational medicinal product related to any dose administered.

Serious AE/AR	Any adverse event/adverse reaction that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect.
Significant Safety Issues (SSI)	A safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.
Suspected Unexpected Serious Adverse Reactions (SUSAR)	An adverse reaction that is both serious and unexpected.
Urgent Safety Measures (USM)	A measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety.
Annual Safety Reports	A safety report that provides a brief description and analysis of new and relevant findings, a brief discussion of the implications of safety data to the risk-benefit ratio for the trial and a description of any measures taken or proposed to minimise risks.

5. Responsibilities

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

6. Procedure

The seriousness of the event and who is the sponsor will determine how the report is submitted.

All studies sponsored by Eastern Health (such as Eastern Health investigator initiated) are required to report all safety events. All externally sponsored studies are required to report any serious events that are related to the Investigational Product (IP). -

EXTERNALLY SPONSORED STUDIES – All serious events that are related to the Investigational Product (IP) are to be reported on the internal Eastern Health Safety Report Form. These are to be submitted directly to the Office of Research and Ethics via email to the following address - ethics@easternhealth.org.au.

EASTERN HEALTH INVESTIGATOR INITIATED STUDIES – All Adverse Events (AE), Adverse Reactions (AR) and Serious AE/AR are to be reported on the internal Eastern Health Safety Report Form. These are to be submitted directly to the Office of Research and Ethics via email to the following address - ethics@easternhealth.org.au.

Significant Safety Issues (SSI), Suspected Unexpected Serious Adverse Reactions (SUSAR), Urgent Safety Measures (USM) and Annual Safety Reports

- Significant Safety Issues (SSI), Suspected Unexpected Serious Adverse Reactions (SUSAR), Urgent Safety Measures (USM) and Annual Safety Reports are all to be submitted to the Office of Research and Ethics via ERM.
- For Ethics applications which have been submitted using an HREA form, the Safety Report form located under 'sub-forms' must be used.
- For Research governance applications which have been submitted using an SSA form, the Site Notification Form located under 'sub-forms' must be used. The reviewing HREC acknowledgement of the event must also be submitted.

Safety Reporting to the Eastern Health BoardThe Office of Research and Ethics is required to provide a quarterly safety report to the Eastern Health Board. As per the National Health and Medical Research Council (2016) Guidance on safety monitoring and reporting in clinical trials involving therapeutic goods, Principal Investigators are only required (as a minimum requirement) to report to the institution all significant safety issues and SUSARs (Suspected Unexpected Serious Adverse Reaction) arising from the local site. In addition to this, Eastern Health require all adverse events arising from an Eastern Health site be reported.

The report to the Board is to incorporate the following details –

- Risk Management Background
- Safety and Quality Implications
- Analysis of Safety Events
- Conclusion

Prior to submission to the Board, the safety report requires endorsement by the Executive Director Eastern Health Institute.

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)
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