



Safety Reporting Guidelines

This summary is in line with the most recent [NHMRC safety monitoring guidelines](#). The following must be reported utilising the [WA Health Safety Report Form](#).

Report Type	Office	Who	Time frame
Serious breach	RG Office at the site the breach occurred	PI	72 hours
	Lead HREC	CPI	7 days
Significant safety issue	RG Office at any site the issue will impact	PI	72 hours
	Lead HREC	CPI	72 hours – 15 days
Local Suspected Unexpected Serious Adverse Reaction (SUSAR)/ Unanticipated Serious Adverse Device Effect (USADE)	RG Office at the site the event occurred	PI	72 hours
Annual safety report	Lead HREC	CPI	Annual
Updated Investigator Brochure (no protocol/ consent form change)	Lead HREC	CPI	When received from sponsor

No longer required to report

- Adverse events which do not meet the definition of a local SUSAR/USADE
- SUSAR line listings
- Full DSUR or DSMB reports (executive summaries may be used as the annual safety report)

Who should sign the safety report form?

- **If the safety issue originates from the site:** the PI should complete and sign and submit the report.
- **If the safety issue originates from the whole project:** the CPI should complete and sign the report. If a SSI is involved, this report should be copied to the PI who should submit to the RG Office.

How is a serious breach reported?

- A serious breach of the protocol or Good Clinical Practice that is likely to significantly affect:
 - the safety or rights of a participant; or
 - the reliability and robustness of the data generated in the project.
- The PI must notify the RG Office at which the breach occurred within 72 hours of the breach occurring. The RG Office does not need to be notified of breaches occurring at other sites.
- Through the CPI, the sponsor must notify the HREC of a serious breach within 7 days.

How is a significant safety issue reported?

- A significant safety issue is an issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability of the trial. They often require action such as the reporting of an urgent safety measure, an amendment, a temporary halt or early termination of a trial.
- The PI must report any significant safety issues which impact the site to the RG Office within 72 hours.
- Through the CPI, the sponsor must report to the HREC:
 - Any urgent safety measure within 72 hrs of the measure being taken.
 - An Amendment within 15 days of becoming aware of the issues.
 - Temporary halt/early termination within 15 days of the decision.

How are local SUSARs or USADEs reported?

- Adverse events should be reported when they are serious, unexpected and believed to be a direct result of trial participation. This means that hospitalisation, injury or sickness in trial participants not related to the study no longer need to be reported.
- The PI must notify the RG Office at which the event occurred within 72 hours.
- Local SUSARs do not need to be reported to the HREC.
- **SUSAR line listings:** SUSAR line listings no longer need to be submitted to the HREC or the RG Office. SUSARs dated after this will no longer be acknowledged.

How are annual safety reports or Investigator Brochures reported?

- Through the CPI, the sponsor must submit a brief, lay language safety report to the HREC.
- This report should summarise the evolving safety profile of the project and may be aligned with the annual progress report.
- The annual safety report should generally include:
 - a brief description and analysis of new and relevant findings
 - a brief discussion of the implications of the safety data to the trial's risk-benefit ratio
 - a description of any measures taken or proposed to minimise risks
 - The Executive Summary of a Development Safety Update Report or Data and Safety Monitoring Board report may be used. The full report is not required and these should be submitted annually.
- Updated Investigator Brochures (IB) should be provided to the lead HREC when received by the sponsor.
- IBs that have resulted in an amendment to the Protocol and/or to the Participant Information Sheet/Consent Form (PICF) must be submitted on the [WA Health Amendment Form](#).

Further Information

If you have any queries please feel free to email SMHS.RGO@health.wa.gov.au or phone (08) 6152 2646 for further clarification.