# Safety Reporting Guidelines

## Children's Health Queensland Hospital and Health Service

Safety Reporting for clinical trials must follow the 2018 NHMRC Guidance: Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods and the Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods

All Safety Reporting must be submitted via the ERM web portal for researchers, by creating a sub-form under the relevant project and application form.

**What should be reported to the Human Research Ethics Committee (HREC)?**

- Urgent Safety Measures (USMs) instigated by the Site or Sponsor within 72 hours of becoming aware of the event
- All other Significant Safety Issues (SSIs) should be notified within 15 calendar days of the sponsor instigating or being made aware of the issue
- An annual safety report including a clear summary of the evolving safety profile of the trial
- Investigator Brochure amendments
- Data Safety Monitoring Board (DSMB) reports
- Where CHQ HREC is Lead HREC, all safety reports for participants in in any Institution where CHQ HREC is the Lead HREC are to be submitted for review where it is thought the event is directly connected to the study treatment. This does not include expected events as per the Protocol/Information Sheet.
- Protocol deviations/violations if thought to affect the safety of the participant or study

**What should be reported to the Research Governance Office (RGO)?**

When the study has been approved by a non-CHQ HREC and when CHQ is the sponsor of the trial (i.e., Investigator Initiated studies), please submit the following to the CHQ Research Governance Office: Please note, any safety reports approved by CHQ HREC do not require re-submission to Research Governance Office.

- Urgent Safety Measures (USMs) instigated by the Site or Sponsor within 72 hours of becoming aware of the event
- Suspected Unexpected Serious Adverse Reactions (SUSARs) or Unanticipated Serious Adverse Device Effects (USADEs) arising from the local site, within 72 hours of becoming aware of the event or change in status from SAE to SUSAR
- All other SSI that result in temporary halt, amendment or early termination of a trial within 72 hours of becoming aware of the event
- An annual safety report including a clear summary of the evolving safety profile of the trial
- Investigator Brochure amendments
- Data Safety Monitoring Board (DSMB) reports
- Protocol deviations/violations if thought to affect the safety of the participant or study

## What should NOT be reported to the HREC or RGO?

- Individual Safety Reports that do not affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.
- External SUSARs or device/non-therapeutic good equivalents
- Six monthly line listings
- Protocol deviations, unless these affect the safety of the project/participants

For definitions of Terminology associated with safety reporting, please see page 4 of 2018 NHMRC Guidance: Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods.

**Document history**

| Version | Date | Changed by | Nature of amendment |
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| 1.0 | 20/08/2020 | Amanda Smith | |
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Previous versions should be recorded and available for audit.