Cairns and Hinterland
Hospital and Health Service

Reporting and Monitoring factsheet

Unless otherwise stipulated in your ethics approval or site authorisation letter, the NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods applies to all clinical trials conducted at the Cairns and Hinterland Hospital and Health Service.

Please note: If the research study/project has not been ethically approved by the Far North Queensland Human Research Ethics Committee (FNQ HREC), please contact the approving HREC for their reporting and monitoring requirements. Each HREC has their own reporting and monitoring requirements.

All submissions made to the FNQ HREC and Research Governance Office/r (RGO) must be submitted in Ethics Review Manager (ERM).

Progress Reporting for all research projects

- FNQ HREC annual progress and final report templates can be found on the CHHHS intranet site or on the external website.

Item
Notification of Study Commencement to be submitted within 10 days.
Annual Progress Report: • HREC – Submitted annually on the 30th April. • RGO – Submitted once HREC acknowledgement has been received.
Final Report: • HREC – Submitted annually on the 30th April. • RGO – Submitted once HREC acknowledgement has been received.

Safety reporting to the RGO for CHHHS sponsored research projects and clinical trials

Within 24 hours of becoming aware of event

- All SAEs, except those that are identified in the protocol as not needing immediate reporting,
- All significant safety issues and urgent safety measures taken as a response,
- All SUSARs,
- Any occurrences of congenital anomaly/birth defect arising from any pregnancy of a participant (or partner): clinical trials only with IMP.

Within 15 days of becoming aware of the event:

- Any protocol violations and deviations from the study protocol,
- If the study is temporarily halted for safety reasons,
- If the study is terminated early for safety reasons.

Report as specified in the protocol

- All safety critical events,
- Any additional requested information relating to reported deaths.

Safety Reporting for externally sponsored Clinical Trials

What should be reported to the HREC?

- Urgent Safety Measures (USM) instigated by the Site or Sponsor within 72 hours of becoming aware of the event.
- All other Significant Safety Issues (SSI) 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.
- Amended CTN/CTX.

What should be reported to the RGO?

- Urgent Safety Measures (USM) 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 (USADE) 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 results 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 study.
- Data Safety Monitoring Board (DSMB) reports.
- Amended CTN/CTX.

What should NOT be reported to the HREC or REGO?

- Single Serious Adverse Events (SAE), Serious Adverse Reactions (SAR) and Adverse Events (AE) 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

Summary Tables:

Table 1: Investigator Reporting – flow and timing of safety reports for externally sponsored clinical trials

	Individual SAE *(Except those identified in the Protocol as not requiring reporting)*	**Congenital Anomaly / birth defect** from participant / partner pregnancy	**Individual SAE's deemed SUSAR / USADE** by the investigator, arising from the local site	**Urgent Safety Measures (USM)** instigated by the site	**Other USM instigated** by the Sponsor	**All other SSI** *(Including temporary halt/early termination of a trial)*	**Annual Sponsor Safety Report**
Sponsor	Within 24 hours of becoming aware of the event.	Within 24 hours of becoming aware of the event.		Within 24 hours of becoming aware of the event.			
To RGO			Within 72 hours of becoming aware of the event.	Within 72 hours of becoming aware of the event.	Within 72 hours of becoming aware of the event.	No later than 15 calendar days of the Sponsor becoming aware of the issue.	Annually once HREC acknowledgement is received.

Table 3: Sponsor Reporting – flow and timing of safety reports for externally sponsored clinical trials

	SUSAR / USADE (Occurring in Australian Participants)		**Significant Safety Issues (SSI)**		**Annual Safety Report**
	Fatal / Life Threatening SUSARs	All Other SUSARs	Urgent Safety Measure	All other SSI (including, temporary halt/early termination of a trial)	
To Investigators			Without undue delay and no later than 72 hours of the Sponsor becoming aware of the issue	No later than 15 calendar days of the Sponsor becoming aware of the issue.	Annually
To TGA	Immediately but no later than 7 calendar days after being aware; follow up information within a further 8 calendar days	15 calendar days after being made aware of the case	Without undue delay and no later than 72 hours of the Sponsor becoming aware of the issue	No later than 15 calendar days of the Sponsor becoming aware of the issue.	Annually
To HREC			Without undue delay and no later than 72 hours of the Sponsor becoming aware of the issue	No later than 15 calendar days of the Sponsor becoming aware of the issue.	Annually