Townsville Hospital and Health Service

Research Monitoring

Guide for reporting to the RGO

Research Governance Officers (RGOs) are responsible for monitoring research practice and assuring adherence to the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research (2007, updated 2018), Good Clinical Practice principles and the Australian Code for the Responsible Conduct of Research (2018).

All research approved by Townsville Hospital and Health Service (THHS) RGO is monitored, regardless of the level of the risk. Monitoring arrangements are appropriate and adaptive to the risk and complexity of the research.

More Information

- NHMRC Safety monitoring and reporting clinical trials involving therapeutic products
- Queensland Health Research Management Policy
- Research monitoring at Townsville Hospital and Health Service

Contact THHS RGO

(07) 4433 1351

TSV-RGO@health.qld.gov.au

Progress Reporting

Research Governance Officers (RGOs) review progress reports to verify that the conduct of research conforms to the approved proposal and safety issues are managed appropriated at their site. Principal Investigators (PI) must submit a progress report at least annually with an overview of the study activity including any difficulties faced, and a final progress report when the study is completed.

Notification of Commencement:

- Submit within 5 business days of study commencement at THHS.

Progress Report:

- Submitted annually, as soon as the PI has received the annual report acknowledgment from the HREC.
- Includes start date, site recruitment or data collection, adherence to study protocol, reporting any complaints, participant withdrawals, summary of findings to date and any publications or presentations.

Final Report:

- Submit after the study is completed (usually when results are available but can also be after data analysis is finalised and access to data source is no longer required).
- The final report should include a copy of the results and/or publication. If not available at the time of reporting these must be provided in a timely manner.

Submit online:

All reports must be submitted on the Ethical Review Manager (ERM) online platform. Select your project, then the ethics application and create a Sub-Form. Complete the details, upload report and any supporting documents, then sign electronically and submit.

- **download report template here**
- **submit report online here**

Version 1: January 2021

Queensland Government

External Study Sponsor Safety Reporting

Studies where THHS is not the study sponsor reporting requirements are:

Within 72 hours of becoming aware of event:

- Report all significant safety issues and urgent safety measures taken as a response to an event, including SUSARs arising from the local site.

N.B. Do not submit individual reports of AEs, SAEs, external SUSARs/USADEs or individual (including six-monthly) line listings.

Without undue delay and no later than 15 days of becoming aware of the event, report:

- Any action taken by the sponsor,
- Any protocol violations and deviations from the study protocol that involve THHS participants or data integrity,
- If the study is temporarily halted for safety reasons,
- If the study is terminated early for safety reasons.

Annually:

- Provide a safety report including a clear summary of the evolving safety profile of the trial. This can be included in the annual progress report for the study, or *Executive Summary* of safety information, or a DSUR.

  For **clinical trials**, the annual safety report must include:
  - a brief description and analysis of new and relevant findings.
  - for IMPs not on the Australian Register of Therapeutic Goods, a brief analysis of the safety profile of the IMP and its implications for participants taking into account all available safety data and the results of relevant clinical or non-clinical studies.
  - 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.
- Where applicable, include all industry safety monitoring, Investigator Brochures, and Data and Safety Monitoring Board (DSMB) reports.

Submit online:

All reports must be submitted on the Ethical Review Manager (ERM) online platform. Select your project, then the ethics application and create a Sub-Form. Complete the details, upload report and any supporting documents, then sign electronically and submit.

- **submit safety reports online here**

Definitions

Principal Investigator

An individual responsible for the overall conduct of a research study and ensures that the study complies Good Clinical Practice, the *Australian Code for the Responsible Conduct of Research* (2018) and any conditions of approval (either at one site or multiple sites, may also be called a Coordinating Principal Investigator).

Site Principal Investigator

Principal Investigator responsible for the conduct of the study at the THHS site.

Sponsor

An individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study. The sponsor, through their independent safety monitoring arrangements, has the primary responsibility for monitoring the ongoing safety of a study.

Significant Safety Issue

A safety issue that could adversely affect the safety of participants or substantially impact on the continued ethical acceptability or conduct of the research.

Urgent Safety Measure

A measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety.

Note: This type of safety measure can be instigated by either the investigator or sponsor and can be implemented before seeking approval from HRECs or institutions.

Protocol Deviation

Accidental or unintentional changes to, or non-compliance with the research protocol that do not increase risk or decrease benefit or; do not have a significant effect on the participant's rights, safety or welfare; and/or on the integrity of the data.

Protocol Violation

Serious non-compliance with the research protocol that involves participant consent, participant safety or data integrity and which compromises the ethical acceptability of the project. For example, inadequate informed consent, unreported serious adverse events, incorrect or missing tests, inappropriate dosages, mishandled samples, inadequate record keeping, intentional deviation from protocol or good clinical practice, repeated participant non-compliance.

Abbreviations

AE Adverse Event

CPI Coordinating Principal Investigator

CTA Clinical Trial Approval

CTN Clinical Trial Notification

DSM Data Safety Monitoring

DSUR Development Safety Update Report

IMP Investigational Medicinal Product

PI Principal Investigator

RGO Research Governance Officer

SAE Serious Adverse Event

SUSAR Suspected Unexpected Serious Adverse Reaction

THHS Townsville Hospital and Health Service

TGA Therapeutic Goods Administration

USADE Unanticipated Serious Adverse Device Effects

USM Urgent Safety Measure

Contact THHS RGO

(07) 4433 1351

TSV-RGO@health.qld.gov.au

Submit online:

All reports must be submitted on the Ethical Review Manager (ERM) online platform. Select your project, then the ethics application and create a Sub-Form. Complete the details, upload report and any supporting documents, then sign electronically and submit.

- **download SAE report template here**
- **download progress report template here**
- **submit reports online here**

THHS Study Sponsor Safety Reporting to THHS

Studies where THHS is the study sponsor reporting requirements are:

Within 24 hours of becoming aware of event, report:

- 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, report:

- 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.

Annually:

- Provide a safety report including a clear summary of the evolving safety profile of the trial. This can be included in the annual progress report for the study, or *Executive Summary* of safety information, or a *Development Safety Update Report* (DSUR).

  For **clinical trials**, the annual safety report must include:

  - a brief description and analysis of new and relevant findings.
  - for IMPs not on the Australian Register of Therapeutic Goods, a brief analysis of the safety profile of the IMP and its implications for participants taking into account all available safety data and the results of relevant clinical or non-clinical studies.
  - 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.

- Where applicable, include all industry safety monitoring, Investigator Brochures, and Data and Safety Monitoring Board (DSMB) reports.

Regulation of Medicine & Medical Device Clinical Trials

Clinical trials of medicines and medical devices conducted in Australia are regulated by the Therapeutic Goods Administration.

Clinical trials of unapproved therapeutic goods are conducted under either the Clinical Trial Approval (CTA) Scheme and the Clinical Trial Notification (CTN) Scheme, where that use involves:

- **any new product** not entered on the Australian Register of Therapeutic Goods, including any new formulation of an existing product or any new route of administration, or in the case of an existing medical device, new technology, new material or a new treatment modality; or
- **use of a product beyond the conditions of its marketing approval**, including new indications extending the use of a medicine to a new population group and the extension of doses or duration of treatments outside the approved range.

More Information

- www.tga.gov.au/clinical-trials
- www.australianclinicaltrials.gov.au/

Contact TGA

1800 020 653

clinical.trials@health.gov.au

THHS Study Sponsor Safety Reporting to TGA

For clinical trials, where THHS is the study sponsor, being conducted under the CTN/CTA schemes THHS has delegated the sponsor responsibilities for reporting to the Therapeutic Goods Agency to the Coordinating Principal Investigator. Reporting requirements are:

Within 24 hours of becoming aware of event, report:

- All urgent safety measures taken in response to significant safety issue/s,
- All SUSARs occurring in Australian participants.

Within 72 hours of becoming aware of event, report:

- All significant safety issues that adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial and require an USM.

Immediately, but no later than 7 days after becoming aware of the event, report:

- All fatal or life threatening Australian SUSARs, with any follow-up information within a further 8 calendar days.

Within 15 days of becoming aware of the event, report:

- All other significant safety issues,
- All other Australian SUSARs,
- If the study is temporarily halted for safety reasons,
- If the study is terminated early for safety reasons.

Submit online:

These reports can be submitted via TGA Business Services Account using the Adverse Event Management System.