Townsville Hospital and Health Service

Research Monitoring

Guide for reporting to the HREC

Human Research Ethics Committees (HRECs) 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 HREC is monitored, regardless of the level of the risk.

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 HREC

(07) 4433 1440

TSV-Ethics-Committee@health.qld.gov.au

Townsville Hospital and Health Service

Progress Reporting

Human Research Ethics Committees (HRECs) review progress reports to verify that the conduct of research conforms to the approved proposal. Monitoring arrangements are appropriate and adaptive to the risk and complexity of the research. Principal Investigators 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. Depending on the nature and level of risk anticipated in the study additional intervals of reporting can be requested by the HREC.

Progress Report:

- Submitted annually on 30th April.
- 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:

- Submitted 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**

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Queensland Government

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).

Sponsor

An individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance 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.

Contact THHS HREC

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Safety Reporting

The sponsor, through their independent safety monitoring arrangements, has the primary responsibility for monitoring the ongoing safety of a study. The HREC need only be informed about urgent issues which **adversely affect the safety of participants** or materially **impact on the continued ethical acceptability** or conduct of the research. Reporting requirements are:

Within 72 hours of becoming aware of event:

- Report all significant safety issues and urgent safety measures taken as a response.

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

- Any unforeseen events that might affect the ethical acceptability of the project,
- Any protocol violations and deviations from the study protocol that involve participant consent, participant safety or data integrity,
- If the project is discontinued at a site before the expected date of completion,
- Where applicable, include all industry safety monitoring, Investigator Brochures, and Data and Safety Monitoring Board (DSMB) reports.

Within 15 days of a sponsor's decision to:

- Temporarily stop a study for safety reasons; or
- Early termination of a study 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 *Development Safety Update Report* (DSUR).

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**