Far North Queensland HREC *(EC00157)*

Completing Progress and Final Reports

A guide for researchers

This guide is intended to help researchers complete the FNQ HREC Annual Progress Report / Final Report form with enough detail for the HREC to determine the current status of the study, whether it is continuing as approved, and whether any follow-up is required. Please use the current FNQ HREC Annual Progress Report / Final Report template. Annual Progress Reports must be submitted at least annually by 30 April and should report on the previous calendar year activity (for example, 1 January to 31 December). Final Reports must be submitted at the completion of the project. Progress reports help the HREC monitor whether the study is continuing as approved and identify any issues or changes since approval. Final reports allow the HREC to consider project outcomes, key findings and any publications arising from the study. Please complete each applicable section with enough detail for the HREC to assess the current status of the study and whether any follow-up is required.

Further information on submitting progress and final reports can be found on the Ethics - post approval submission requirements | Cairns and Hinterland Hospital and Health Service webpage.

Section-by-section guidance

Section 1 – Project details

Provide the HREC reference number, project title, report type, reporting period, Principal Investigator (PI) details, contact details, sponsor details if applicable, and any changes to approved sites since the last report. Ensure the reporting period and other key project details are accurate and current.

Section 2 – Study status

State whether the study is in progress at all approved sites. If not, identify which sites are active and explain whether any sites are on hold, not yet commenced, inactive, completed, or discontinued. Include enough detail for the HREC to understand the current status of the study and whether it is continuing as approved.

If the study has multiple approved sites, clearly report the status of each approved site. Ensure study status, commencement information, and any recruitment information are accurate and consistent throughout the report.

If any approved site is inactive, on hold, not yet commenced, or experiencing delays, briefly explain the reason and provide an update on any progress toward resolution.

Section 3 – HREC approved documentation

List any approved documents currently in use that have changed since the last report, including version numbers and dates where relevant. If there have been changes to documents that affect the consent process or participant information, ensure these have been submitted as amendments where required. If document versions are listed, ensure they reflect the approved versions relevant to the reporting period.

Section 4 – Changes to the approved study

Report any amendments since the last progress report, including changes to the research team. If amendments have not yet been submitted to the HREC and relevant RGO, they should be submitted as soon as possible. Only include amendments relevant to the reporting period, including changes to the research team where applicable.

Section 5 – Management of risks

Report any complaints regarding the conduct of the study since approval or since the last progress report, and provide enough detail for the HREC to understand the issue and any action taken.

Section 6 – Safety monitoring

If safety monitoring is required for the study, provide the relevant details and attach any required Data Safety Monitoring Committee or Board recommendations, reports, or executive summaries. If a DSMC/B or other independent safety monitoring process applies to the study, include the relevant monitoring documentation with the report where applicable.

Section 7 – Other considerations

Report any concerns you wish to draw to the attention of the HREC and RGO, such as barriers or obstacles encountered in the research project, difficulties with recruitment or data collection, or any other issues affecting study conduct. Also confirm whether there are sufficient funds to complete the study as approved.

Section 8 – Security of project-related data and information

Describe how project-related data and records are being protected, including how paper and electronic records are stored, where they are stored, who has access, how long they will be retained, and whether any security breaches have occurred since the last report. Describe the actual storage, access, retention and disposal arrangements for the study data and records in enough detail for the HREC to assess whether they are appropriate to the study. Statements such as “records are stored securely” are not enough on their own. The HREC needs enough detail to understand the actual storage and security arrangements. If the study has not yet commenced, describe the proposed arrangements for protecting project-related data and records once the study begins.

Data storage and retention arrangements should be consistent with applicable institutional and site requirements.

Section 9 – Progress to date / Final report information

Provide a brief summary of progress or findings to date, including any publications accepted or in press and any presentations given during the reporting period. For final reports, summarise the results, explain how the results have been shared with the appropriate parties in accordance with the approved protocol, and attach all related publications, presentations, reports, or dissemination materials. Where applicable, attach final publications, presentations, reports, or other dissemination materials relevant to the reporting period.

Important: If the project has been published or presented, copies of all publications, presentations, reports, or dissemination materials must be attached to the final report.

For clinical trials, separate annual safety reporting requirements may also apply.

Questions about this guide? Contact the HREC Coordinator: FNQ_HREC@health.qld.gov.au

Our values
COMPASSION ACCOUNTABILITY INTEGRITY RESPECT