

## Far North Queensland HREC (EC00157)

# Post Approval Submission Requirements

Below are the submission requirements for amendments, progress / final reports, study updates, change of investigators, extension of HREC approval etc.

A Post Approval Reporting Form must be submitted via Ethics Review Manager (ERM). The Researcher's Quick Guide and training presentation can be found under the [Templates section](#) of the Help menu. There is a comprehensive [FAQ section](#) under the HELP page on the website which should answer any of your questions.

### To create a Post Approval Reporting Form:

1. Log in to ERM and click on the relevant project.
2. Once the project has loaded, click the "Create sub form" button located in the Action pane on the left-hand side of the screen. Select Queensland Health as the Jurisdiction and select the appropriate form (Eg. HREC Amendments, Project Progress Report, Project Final Report etc).
3. Complete the questions, upload the required documents as listed below, sign the form and click the submit button.

Once the form has been submitted in ERM, please provide an electronic copy via email and hard copies (if the submission over 10 pages) to the address outlined below.

### Required Documents for Study Amendments:

- **Cover Letter** including the research title, reference number and a brief description of the amendment and a list of all the documents provided including the version numbers and version dates.
- **HREC Amendments Form** generated in ERM. The reference number must be in the footer of the form.
  - Please include an amendment reference number (eg. AM01, AM02 etc) as part of the purpose of the form submission.
- Upload the amended study documents (e.g. Study Protocol/Plan, Information Sheets, Consent Forms, Data collection tool etc.). *Please provide both clean and tracked changed versions of each document – this is a mandatory requirement.*

**N.B.** All study documents MUST include relevant logos, version numbers, document dates and page numbers in the footer of each document.

- **One electronic copy** of the entire submission to be provided to [FNQ\\_HREC@health.qld.gov.au](mailto:FNQ_HREC@health.qld.gov.au).
- If the submission is over 10 pages, **one hard copy** of the submission is also required.

### Required Documents for Change of Investigator / Study Personnel:

- **Cover Letter** including the research title, reference numbers and details of the investigator changes.
- **HREC Amendments Form** generated in ERM. The reference number must be in the footer of the form.
  - Please include an amendment reference number (eg. AM01, AM02 etc) as part of the purpose of the form submission.
- Upload the Investigator's / Study Personnel's CV (maximum of two pages).
- Amended Protocol/Project Plan (only required if the investigators are listed on the Protocol/Project Plan).  
*Please provide both clean and tracked changed versions of each document – this is a mandatory requirement.*
- **One electronic copy** of the entire submission to be provided to [FNQ\\_HREC@health.qld.gov.au](mailto:FNQ_HREC@health.qld.gov.au).
- If the submission is over 10 pages, **one hard copy** of the submission is also required.



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### *Required Documents for Request for extension of HREC approval:*

- **Cover Letter** including the research title, reference numbers and details of the extension request.
- **HREC Amendments Form** generated in ERM. The reference number must be in the footer of the form.
  - Please include an amendment reference number (eg. AM01, AM02 etc) as part of the purpose of the form submission.
- **One electronic copy** of the entire submission to be provided to [FNQ\\_HREC@health.qld.gov.au](mailto:FNQ_HREC@health.qld.gov.au).
- If the submission is over 10 pages, **one hard copy** of the submission is also required.

### *Required Documents for Progress Reports:*

- **Project Progress Report** generated in ERM. The reference number must be in the footer of the form.
- Upload the completed **FNQ HREC Progress Report Form** signed by the Principal Investigator.
- **One electronic copy** of the entire submission to be provided to [FNQ\\_HREC@health.qld.gov.au](mailto:FNQ_HREC@health.qld.gov.au).
- If the submission is over 10 pages, **one hard copy** of the submission is also required.

### *Required Documents for Final Reports:*

- **Project Final Report Form** generated in ERM. The reference number must be in the footer of the form.
- Upload the completed **Final Report Form** signed by the Principal Investigator.
- Upload any relevant documents and publications/journal articles/presentations etc.
- **One electronic copy** of the entire submission to be provided to [FNQ\\_HREC@health.qld.gov.au](mailto:FNQ_HREC@health.qld.gov.au).
- If the submission is over 10 pages, **one hard copy** of the submission is also required.

### *Submitting to the FNQ HREC*

Once the Post Approval Form has been submitted via ERM, please provide the following:

- An electronic copy of the form as submitted in ERM and the relevant documents via email to [FNQ\\_HREC@health.qld.gov.au](mailto:FNQ_HREC@health.qld.gov.au).

**N.B.** Please provide the electronic copies in PDF format.

- Hard copies can be posted to the following address:

**FNQ HREC Coordinator  
Research Ethics and Governance Unit  
William McCormack Place, Building 2  
Level 7, 5B Sheridan Street, Cairns QLD 4870**