

# Far North Queensland HREC (EC00157)

## Form of Indemnity (HREC Review Only) – Guidance for Completion

This guidance is specific to the Cairns and Hinterland Hospital and Health Service (CHHHS) and the Far North Queensland Human Research Ethics Committee (FNQ HREC, EC00157). It is to be used when an external sponsor or institution is required to indemnify the HREC for providing ethical review only, where CHHHS is not the responsible institution.

The Form of Indemnity for HREC Review Only template can be accessed on the [Indemnity & Compensation Guidelines – Medicines Australia](#) webpage. Please ensure you use the **Form of Indemnity – HREC Review Only** template, not the Standard Form of Indemnity.

### When is this form required?

This form is required when:

- FNQ HREC is providing ethical review for a project where CHHHS is not the responsible institution (sponsor), including projects conducted at non-QH sites (e.g., universities, ACCHOs, private facilities) or involving non-QH participants or data
- An amendment is submitted to add new non-QH sites to an existing FNQ HREC approved project

### Mandatory Attachments

The following must be uploaded to ERM alongside the completed form:

- Certificate of Currency (Insurance): Required for commercially sponsored clinical trials only. A current certificate from the Sponsor confirming clinical trial indemnity insurance must accompany this form. This certificate must be valid at the time of submission to the HREC.

Note: For non-commercially sponsored research (e.g., university or ACCHO-sponsored studies), a Certificate of Currency is not required.

- A brief (2–3 page) CV for the Principal Investigator (PI) at each external site must be uploaded to ERM. For initial HREA submissions, include CVs with the HREA. For amendments adding a new non-QH site, include CVs with the amendment submission.

### Completing the Form

**To:** Cairns and Hinterland Hospital and Health Service, Far North Queensland Human Research Ethics Committee (FNQ HREC, EC00157) providing HREC review only (“the Indemnified Party”)

**From:** [Name, registered address and ABN of sponsoring organisation] (“the Sponsor”)

**Re:** **HREC Reference:** [insert ERM HREC reference number]

**Project Title:** [insert project title exactly as it appears on the HREA]

## Section 1 – Study Details

- **Participants:** Where it states *'involving [{patients of [name of hospital(s), institution(s) or site(s)]} {non-patient volunteers}] ('the Participants)'*:
  - Insert the name of the non-Queensland Health site, external database, or organisation/s (e.g., Wuchopperen Health Service Limited, Apunipima Cape York Health Council).
  - If adding multiple external sites as part of the initial HREA application or via amendment: You must list ALL participating external sites. If part of an amendment, you must include the original approved external sites plus the new external sites being added to ensure continuous coverage.
- **Investigators:** Where it states, 'to be conducted by [name of investigator(s)] ('the Investigator)':
  - Insert the name(s) of the Principal Investigators conducting the research at each listed site.

## Execution and Submission

- **Signatures:** The Sponsor must enter the date on Page 3 and ensure a Sponsor Delegate signs the form.
- **Submission:** Upload the signed Form and external site PI CVs to the ERM amendment/HREA form. For commercially sponsored clinical trials, also attach the Certificate of Currency.
- **Final Execution:** The HREC Coordinator will arrange for the form to be executed by the CHHHS Chief Executive (or delegate).

**Important: The HREC approval letter cannot be released until the Form of Indemnity has been fully executed by the HHS Chief Executive (or delegate). Allow sufficient time for this process.**

## Need Help?

If you have questions regarding the indemnity process or completing this form, please contact the HREC office:

- **HREC Coordinator**
- **Email:** [FNQ\\_HREC@health.qld.gov.au](mailto:FNQ_HREC@health.qld.gov.au)
- **Phone:** 07 4226 5513