

Requesting an exemption from HREC review for a Quality Assurance (QA) Activity

The following information is required for requests to the Far North Queensland Human Research Ethics Committee for exemption from Human Research Ethics Committee review for a Quality Activity with intent to publish (including conference presentations).

Required Documents

- **Cover letter** addressed to the Chair of the FNQ Human Research Ethics Committee which includes the following:
 - State that you are seeking 'an exemption from HREC review for a QA activity with intent to publish findings external to Queensland Health',
 - Project title,
 - Brief description of the activity including justification of the project it is a QA Activity and not a research project.
- **QA Application Form** completed and signed by the applicant and the relevant Head of Department. If the QA sites are within both the Cairns and Hinterland and Torres and Cape Hospital and Health Services, both application forms will need to be completed.
- **QLD Exemption Form generated in ERM.** Please note that there must be a reference number in the footer of the form (eg. QA/2021/QCH/xxxx).
- **Study Protocol/Plan.** The Protocol/Plan may be brief however should provide sufficient detail (e.g. 2 - 3 pages).
- **Data Collection Tool/s.** (Eg. Excel spreadsheet)
- **Information Sheet and Consent Form** (if relevant)
- **Email from the Data Custodian** as outlined on the QA Application Form if you require access to confidential patient information for your project.
- **CV** for each researcher participating in the study (maximum 2 pages).

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

Submitting a QA application in ERM

QA applications must be submitted via the Ethics Review Manager (ERM) system. The link to the ERM website is <https://au.forms.ethicalreviewmanager.com/>. If you previously had log in details for Ethics Online Forms, your log in details for ERM will be the same.



COMPASSION



ACCOUNTABILITY



RESPECT

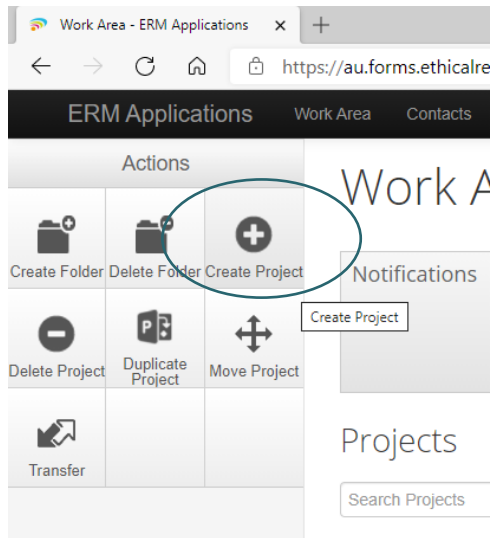


INTEGRITY



Queensland
Government

1. Log in to ERM and select create project.



2. Enter your project title, select Queensland Health as the jurisdiction and QLD Exemption Form the press create.

A screenshot of the 'Create Project' form. The form has a title 'Create Project' and a close button (X) in the top right corner. It contains three main input fields: 'Project Title* (Max 200 characters)' with the text 'FNQ HREC Test', 'Jurisdiction*' with a dropdown menu showing 'Queensland Health', and 'Form*' with a dropdown menu showing 'Please select...' and a list of options: 'Please select...', 'HREA', 'MDF', and 'QLD Exemption Form'. At the bottom right of the form, there is a blue 'Create' button and a grey 'Close' button, with the 'Create' button circled in red.

You will be directed to the overview page (below) to create your QLD Exemption Form.

Exemption Form_Test

Project Tree ▾

Action Required	Status	Review Reference	Date Modified	NMA
Yes	Not Submitted	N/A	07/04/2021 15:03	Project is not for NMA

Navigation Documents Signatures Collaborators Submissions Correspondence History

QLD Exemption Form Show In

Section **Questions** ←

Exemption Form Introduction Project Details Project Location Details Project Team Details Documents Applicant Signature Page

Select the Introduction tab – you will be taken to the Main page of the QLD Exemption Form.

Introduction

The purpose of this form is to facilitate the exemption review pathway. The form should be used when the following apply:

Non-Research Project:

Ethical consideration of non-research projects may be required in order for the results of the project to be published or presented outside of Queensland Health. Non-research activities may include:

- Quality Assurance (QA) Activity: An activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation. Terms such as 'peer review', 'quality assurance', 'quality improvement', 'quality activities', 'quality studies' and 'audit' are often used interchangeably and are considered part of a Quality Assurance program
- Clinical case studies involving no more than three cases.

OR

Research that may be exempted from HREC Review:

National Statement Chapter 5.1.22 – states that institutions may choose to exempt from ethical review research that:

- Is negligible risk research; and
- Involves the use of existing collections of data or records that contain only non-identifiable data about human beings.

It must be noted that research that involves the use of data that is stored in an identifiable form cannot be used in research that is exempt from ethical review (National Statement Chapter 5.1.22).

Please contact your local HREC office for advice if you are not sure whether the exemption review pathway is appropriate for your project.

Select the 'Next' tile to begin entering details about your project. You can also save your progress at any time by selecting the 'Save' tile.

ERMs Applications Work Area Contacts Help Miss Jacey Douglas (Jacey.Douglas@health.qld.gov.au)

QLD Exemption Form

Introduction

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Once you press the 'Next' tile, you will be asked to enter preliminary details about your project. To continue, press the next tile.

ERMs Applications Work Area Contacts Help Miss Jacey Douglas (Jacey.Douglas@health.qld.gov.au)

QLD Exemption Form

Project Details

Question 1: What is the title of your project?

FNQ HREC Test

Question 2: Briefly describe your project in plain language.

Note: You should include the following in your description:

- Your plain language summary should be understandable by a layperson
- Outline what question you are trying to answer
- Describe what you are doing, why and how you will do it
- What you expect to achieve

Please also include information if you expect to present or publish your findings (for example at a conference or in a peer-reviewed journal)

This is a test to create a HREC exemption application in the ERM system

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Once you have entered details about your project, you will be asked which research office this exemption application will be submitted to. An example of the selections available is provided below.

The screenshot shows the 'QLD Exemption Form' interface. On the left is a sidebar with 'Actions' including Previous, Next, Navigate, View as PDF, Documents, Signatures, Save, Share, Roles, Collaborators, Completeness Check, and Submit. The main content area is titled 'QLD Exemption Form' and contains 'Project Location Details'. A section titled 'Question 3: To which Research Office will this exemption application be submitted to?' has a dropdown menu open. The dropdown list includes: 'Please Select...', 'Central Queensland Hospital and Health Service Human Research Ethics Committee (EC00173)', 'Children's Health Queensland Human Research Ethics Committee (EC00175)', 'Darling Downs Hospital and Health Service Human Research Ethics Committee (EC00182)', 'Far North Queensland Human Research Ethics Committee (EC00157)', 'Gold Coast Hospital and Health Service Human Research Ethics Committee (EC00160)', 'Metro South Health Service District Human Research Ethics Committee (EC00167)', 'Queensland Health Forensic and Scientific Services Human Ethics Committee (EC00305)', 'Royal Brisbane and Women's Hospital Human Research Ethics Committee (EC00172)', 'The Prince Charles Hospital and Health Service Human Research Ethics Committee (EC00168)', 'Townsville Hospital and Health Service Human Research Ethics Committee (EC00183)', and 'West Moreton Hospital and Health Service (EC00184)'. Below the list are notes: '***Multi-site: The project will be conducted at sites across multiple HHSs/Institutions.' and '***HINT ** If your project involves any of the following, please seek advice from your local Research Office on the appropriate ethics application form: Sites/Institutions outside of Queensland Health, Investigators external to Queensland Health, Access to data held by data custodians external to the site (e.g. Pathology Queensland)'. At the bottom, it says '© Infonetica Ltd 2021 Version 2.4.3.1' and 'Terms and Conditions | Data Controller/Privacy Policy | Data Processor/Privacy Policy'.

When conducting a project for HREC exemption within Cairns and Hinterland Hospital and Health Service ONLY - Please select Cairns and Hinterland HHS. Every Queensland Health site that falls within the geographical location of this HHS will then appear and be available for you to select your project site/s.

This screenshot shows the same 'QLD Exemption Form' interface. The 'Please select HHS/Institution:' dropdown is now set to 'Cairns and Hinterland HHS'. Below this, there is a section titled 'Please select site names for Cairns and Hinterland HHS' with a list of checkboxes next to various site names: All, Atherton Community, Allied and Mental Health, Atherton Hospital, Babinda Multipurpose Health Centre, Cairns Hospital, Cairns North Community Health, Chillagao Hospital, Croydon Primary Health Care Clinic, Cow Bay Primary Health Clinic, Dimbulah Hospital, Edmonton Community Health Centre, Forsyth Hospital, Georgetown Hospital, Gordonvale Hospital, Herberton Hospital, Innisfail Community Health Centre, Innisfail Hospital, Jumbun Community Health Care Centre, Lotus Glen Health Service, Malanda Primary Health Centre, Mareeba Hospital, Milaa Milaa Primary Health Centre, Mission Beach Community Health Centre, Mossman Multi Purpose Health Service, Mount Garnet OPD, Ravenshoe Primary Health Care Centre, Smithfield Community Health Centre, Tully Community Health Centre, and Tully Hospital.

Aboriginal Controlled Health Organisations

For our Aboriginal Controlled Health Organisation Partners who the FNQ HREC Chair considers HREC Exemptions for, there is the ability to enter the details of the Aboriginal Controlled Health Organisation/s of the project by selecting 'Other' then typing in the relevant organisation name.

Please note: If you are *not an employee of an Aboriginal Controlled Health Organisation* – this pathway is unavailable to you.

The screenshot shows the 'ERM Applications' interface. On the left is a sidebar with 'Actions' (Previous, Next, Navigate, View as PDF, Documents, Signatures, Save, Share, Roles, Collaborators, Completeness Check, Submit). The main area displays a list of health organisations with checkboxes. The 'Other' option is selected and circled in red. Below the list, a text input field contains the name 'Apunipima Cape York Health Council, Wuchopperen Health Service, Gurriny Yealamucka, Mulungu etc etc'.

Once you have entered your project sites, press the 'Next' tile. Remember to save your work as you go by pressing the 'Save' tile. The new page will ask for project team details.

The screenshot shows the 'QLD Exemption Form' interface. The 'Project Team Details' section is highlighted in green. The 'Add Another' button is circled in red. The form fields are filled with: Title: Miss, Name: Jacey Douglas, Department: Research Administration, Organisation: Queensland Health, Telephone: (07) 42265513, Email: Cairns_Ethics@health.qld.gov.au, Role on the project: Lead Investigator. Below this, there are empty form fields for additional team members.

There is the option to enter more than one team member by selecting 'Add Another' as above.

Once you have entered your project team details, press the 'Next' tile. The new screen will ask why you believe your project meets the HREC review exemption criteria. You will have two options to select from.

An example on how this section may be completed is provided below. It is recommended to always select the 'Exempt not research' option and ensure your rationale does not include any of the Triggers for HREC review as outlined in the [NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities](#) document (bottom of page 3, top of page 4).

The screenshot shows a web browser window with the URL <https://au.forms.ethicalreviewmanager.com/Project/Page/14904/305738>. The page title is 'QLD Exemption Form' and the version is '75469 Version: V2.11'. The user is identified as 'Miss Jacy Douglas (Jacy.Douglas@health.qld.gov.au)'. The form is titled 'QLD Exemption Form' and contains the following sections:

- Question 6: Why do you believe this project meets the exemption criteria for:**
 - Please consider the following information when selecting one of the options below:
 - Exempt Research – Not requiring HREC Review [National Statement chapter 5.1.22](#)
 - Exempt not research [QA, Clinical Audit and Evaluation of current practice](#)
 - This submission is to assess the ERM system to enable the submission of a QA, Clinical Audit and Evaluation of current practice by applicants who wish to publish their results external to Queensland Health.
- Question 7: Please upload supporting documents**
 - Further information, for example, CV's or budgets, may be requested from some sites in order to appropriately assess your project for site suitability.
 - Upload Protocol/Project Outline of Description
 -
 - Upload evidence of department support (e.g. Quality registration/Heart of Department)*
 -
 - ***HINT*** Please note evidence of department support is always required to demonstrate endorsement and may include an email or a letter of support***
 - Upload and any other supporting project documents (If required)

This section of the ERM form enables you to upload all required documents.

Completeness check

Before you submit your online form, press Completeness Check to ensure you haven't missed anything.

ERM Applications Work Area Contacts Help Miss Jacey Douglas (Jacey.Douglas@health.qld.gov.au) 75469 Version: V2.17

QLD Exemption Form

Declaration by the Applicant

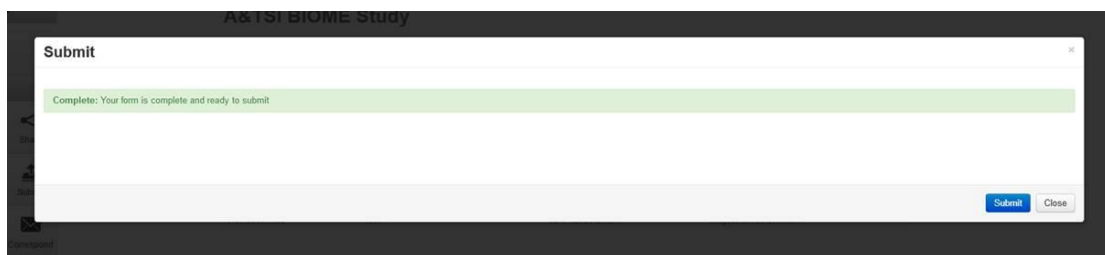
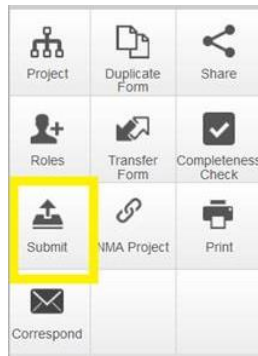
- I declare the information in this form is truthful and accurate to the best of my knowledge and belief and I take full responsibility for the sites for the conduct of the project.
- I declare I am signing this form on behalf of the project team and I confirm any named person on this application is aware of and agree to their involvement in the project.
- I have had access to and read the NHMRC "National Statement on Ethical Conduct in Human Research" 2007 (Updated 2018) and Ethical considerations in quality assurance and evaluation activities: 2014.
- I have consulted all relevant legislation and regulations and the project will be conducted in accordance with these;
 - I will immediately report to the reviewing body any issue which might warrant review of the project.
 - I have attempted to identify all the risks related to the project that may arise in conducting this project and acknowledge my obligations and the rights of participants;
 - I will not continue the project if endorsement is withdrawn and will comply with any special conditions required by the reviewing body.
 - I have the appropriate qualifications, training, experience and facilities to conduct the project set out in the attached application and to deal with any emergencies and contingencies related to the project that may arise.

Will the applicant sign this document electronically through this website, provide an email or letter of support specifically referencing this correspondence?

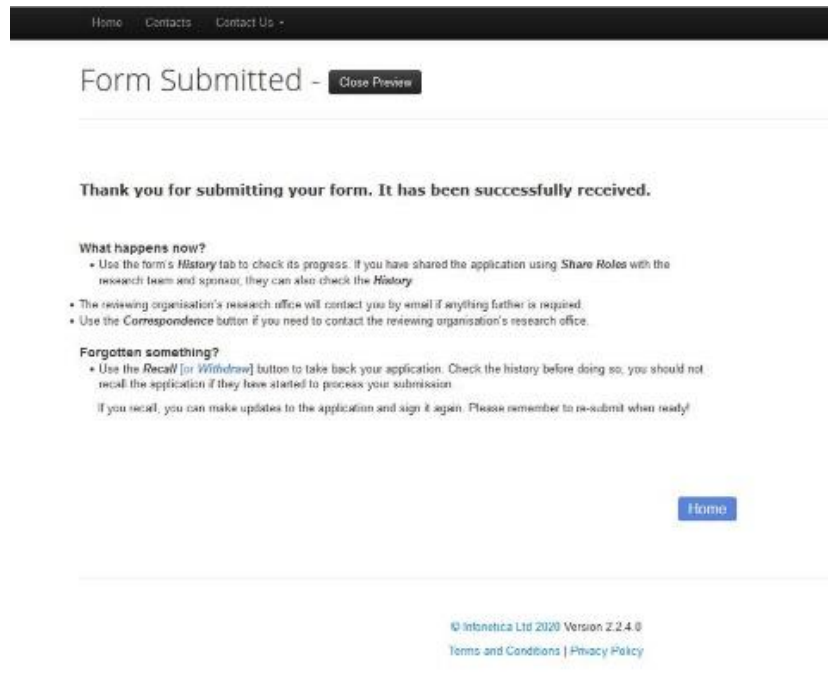
Electronic signature
 Upload email or letter of support / Wet Ink Signature

Application Complete

Once you have completed the QLD Exemption Form and uploaded your document/s, select Electronic signature or Upload email or letter of support / Wet Ink Signature option - *then* press the submit button.



You will know you have successfully submitted your sub-form if you see this screen:



Home Contacts Contact Us

Form Submitted - [Close Preview](#)

Thank you for submitting your form. It has been successfully received.

What happens now?

- Use the form's **History** tab to check its progress. If you have shared the application using **Share Roles** with the research team and sponsor, they can also check the **History**
- The reviewing organisation's research office will contact you by email if anything further is required.
- Use the **Correspondence** button if you need to contact the reviewing organisation's research office.

Forgotten something?

- Use the **Recall** [or **Withdraw**] button to take back your application. Check the history before doing so, you should not recall the application if they have started to process your submission

If you recall, you can make updates to the application and sign it again. Please remember to re-submit when ready!

[Home](#)

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Once you have submitted the QLD Exemption form in email, please email a copy of the entire application to FNQ_HREC@health.qld.gov.au and send one hard copy to the address below.

Need help with the ERM system?

Please contact the ERM helpdesk support team on:

Tel: 07 3708 5081 | Email: ERMhelpdesksupport@health.qld.gov.au

Contact details

Office / Internal mail address: HREC Coordinator, William McCormack Place 2, Level 7, 5b Sheridan Street, Cairns

Postal address: HREC Coordinator, PO Box 902, Cairns QLD 4870

Tel: 07 4226 5513 | E: FNQ_HREC@health.qld.gov.au

Resources

Ethical considerations in Quality Assurance and Evaluation Activities, March 2014

<https://www.nhmrc.gov.au/guidelines-publications/e111>

National Statement on Ethical Conduct in Human Research 2007

<https://www.nhmrc.gov.au/guidelines-publications/e72>

FNQ HREC's Jurisdiction

This HREC covers all sites that fall within the Cairns and Hinterland Hospital and Health Service and Torres and Cape Hospital and Health Service.