FNQ HREC *(EC00157)*

# CHHHS Quality Assurance (QA) Application

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| QA Activities should pose negligible or no risk to the CHHHS. This application is a decision support tool to assist in differentiating those activities that carry an element of risk and/or fall into the category of research.  Quality Activities are defined as assessing current practice to see whether or not it is working or assessing current practice against a standard or guideline. Quality Activities can involve consenting, non-consenting participants or a combination of both. Research is defined as the seeking of new knowledge.  Applicants should make initial contact with the HREC Coordinator to receive the QA submission requirements prior to completing this form. Please contact the FNQ HREC Coordinator by emailing [FNQ\_HREC@health.qld.gov.au](mailto:FNQ_HREC@health.qld.gov.au)  The application process is the responsibility of the person proposing a new clinical audit or the person responsible for conducting an established clinical audit that has not been through this application process.  All applications are to be signed off by the Head of Department for the Main Investigator or Director prior to submission. | |
| Applicant / Contact Person: | |
| Name: |  |
| Position: |  |
| Department: |  |
| Telephone: |  |
| Email: |  |
| Process: | |
| 1. View how to apply information under the Research tab on QHEPS. It is advisable to contact the HREC Coordinator on 4226 5513 prior to completing the application documents if you have any queries. | |
| 1. Create and complete an QLD Exemption Form in the [Ethics Review Manager (ERM)](https://au.forms.ethicalreviewmanager.com/), upload all the required documents and submit the form in ERM. | |
| 1. Email a copy of all the required documents to [FNQ\_HREC@health.qld.gov.au](mailto:FNQ_HREC@health.qld.gov.au). | |
| QA Activity Details: | |
| Title: |  |
| Description: |  |
| Aim: |  |
| Dates:  *(approx. start to finish)* |  |
| Outcomes / Results: |  |
| Declarations: | |
| This section is to be completed by the *Investigator*  Please tick each statement below:  I agree that the information provided in this application is accurate at the time of seeking an exemption from HREC review and that any amendments to the project after exemption is granted will be submitted to the Chair for the FNQ HREC prior to implementation.  I have made contact with the Data Custodian and have been advised there are costs / no costs *(circle one)* associated with the retrieval of records / data for this project. The contact email for the Cairns Hospital data custodian is: [CBH\_health\_information\_services@health.qld.gov.au](mailto:CBH_health_information_services@health.qld.gov.au)  I have notified the Clinical Department Head of the outcome of my discussion with the Data Custodian.  Applicant Signature: ................................................................... Date: ….../….../……… | |
| This section is to be completed by the Clinical Director of the *Investigator*  *(e.g Director of Medicine, Director of Surgery, Director of Anaesthetics, Director of Nursing, Director of Allied Health etc)*  Please tick each statement below:  I have reviewed the project plan and discussed the nature of the activity with the applicant.  I support the proposed project being conducted within my Clinical Department.  Conducting this project will not impact negatively on patient care in any way.  Staff FTE (including non-clinical) will not be compromised as a result of data being collected for this project.  I agree that the project is a negligible risk Quality Assurance Activity and the outcomes will be beneficial to patients, medical professionals and the department.  I agree, if there are costs associated with the retrieval of medical records / data, the following cost centre can be utilized \_\_ \_\_ \_\_ \_\_ \_\_ \_\_.  Name of Clinical Director: ………………………………………………………..  Department Name: …………………………………………………………………  Signature of Clinical Director: .………………………………………………….. Date: ……/……/…… | |
| This section is to be completed by the Chair of the FNQ HREC.  This application *meets the requirements* to be exempt from HREC Review, as per the National Statement on Ethical Conduct in Human Research, sections 5.1.22 & 5.1.23.  The application does not fall within the definition of research as described on page 7 of the National Statement on Ethical Conduct in Human Research.  A Quality Activity HREC Acknowledgement Letter will be formulated and provided to the applicant advising them of my decision.  FNQ HREC Chair Name:…………………………………………………...  FNQ HREC Chair Signature:………….…………………………………… Date: ……/……/……  -or-  This application *does not meet the requirements* for exemption and requires review by the HREC. Please contact the HREC Administrator on 4226 5513 for further advice.  FNQ HREC Chair Name:…………………………………………………...  FNQ HREC Chair Signature: ………….…………………………………… Date: ……/……/…… | |