Far North Queensland HREC (EC00157)

Quality Assurance (QA) Activity Review Guide

A Quality Assurance (QA) Activity is one where the primary purpose is to monitor or improve the current quality of service delivered by an individual, group or an organisation. Quality assurance activities within Cairns and Hinterland Hospital and Health Service (CHHHS) and Torres and Cape Hospital and Health Service (TCHHS) seek to measure the quality or efficacy of a service provided by the Hospital and Health Service (HHS) and may include clinical audit, service evaluation or service development. Clinical audit and service evaluation evaluate business as usual; service development identifies a gap, introduces a change, and evaluates the outcome to determine whether the change has improved the service.

Applying the QA Activity Decision Tool (Derived from <u>Ethical Considerations in Quality Assurance and Evaluation Activities – NHMRC</u>) will assist in determining the extent of ethical review required.

Quality Assurance Activity Decision Tool

Activity	Yes	No
The activity is being undertaken by an employee of the CHHHS or TCHHS. (The activity may be undertaken by a student or trainee whilst on academic placement or rotation within the CHHHS or TCHHS)		
The activities associated with the QA Activity do not pose any significant additional risk or burden to participants beyond those routinely experienced in the environment where the activity is being conducted.		
Risks may include physical, psychological, spiritual and social harm or distress (e.g. stigmatisation or discrimination) and may involve people associated with participants. Burdens may include intrusiveness, discomfort, inconvenience or embarrassment, e.g. persistent phone calls, additional hospital visits or lengthy questionnaires. Careful consideration must be given to whether the proposed QA Activity poses any such risk or burden beyond what would be routinely experienced by the participant.		
Where applicable, appropriate informed consent is being sought from participants to engage in interviews, focus groups or other procedures related to the activity.		
The activity does not involve testing of a non-standard protocol or equipment.		
The activity does not involve a comparison of cohorts.		
The activity does not involve randomisation or the use of control groups or placebos.		
The activity does not involve targeted analysis of data involving minority/vulnerable groups whose data is to be separated out of that data collected or analysed as part of the main QA Activity.		
The activity is not supported by a competitive research grant. If yes, please specify.		
The activity is not seeking to establish a registry/databank.		











Data	Yes	No
The data being collected and analysed is coincidental to standard operating procedures with standard equipment and/or protocols.		
The collection and analysis of data is expressly for the purpose of maintaining standards or identifying areas for improvement in the environment from which the data was obtained.		
The data being collected and analysed is not linked to individuals.		
Data will be stored for at least 5 years following the activity and in accordance with the CHHHS Research/QA Data Guide.		
Data will only be accessed by a CHHHS or TCHHS employee who would normally have access to this data in the course of their work, or in the case of a student, during their placement within the CHHHS or TCHHS.		
Data will not be obtained from external sources or organisations.		
There is no secondary use of data - the data or analysis from this activity, will not be used for another purpose.		
The data being collected from participants is not beyond standard practice. This may include biospecimens or additional investigations.		

Dissemination	Yes	No
The privacy of participants will be protected in any presentation or publication arising from the activity. No information or characteristics which have the potential to reveal a participant's identity will be included in any dissemination of the results of the activity.		

If the response to all statements is "yes", the activity is likely to be a QA Activity and an application can be made to the FNQ HREC via the QA Activity application pathway. If the response to any statements is "no", the activity may not be exempt from full ethical review, and we advise you to contact the Research Ethics Team to clarify the most appropriate pathway for the application.

The intended use of the findings of a QA Activity determines the level of review required:

- 1. Findings of QA Activities which are for internal presentation or dissemination only do not require ethical review. They do need to be registered with the Quality Improvement (QI) register of the work area to which they apply.
- 2. If findings of a QA Activity are to be presented or disseminated outside of CHHHS and/or TCHHS, the QA Activity must be considered by the Chair of the Human Research Ethics Committee.

Please apply to the Chair of the Human Research Ethics Committee for an exemption* from ethical review to proceed with your project. If approved, the HREC Chair will issue a letter stating the project is exempt from ethical review. This letter will allow you to publish your results in a journal or present at a conference. This is a mandatory requirement of most reputable journals.





* The NHMRC <u>National Statement on Ethical Conduct in Human Research 2023</u> (paragraphs 5.1.22 and 5.1.23) defines research that can be exempted from ethics review as **negligible** risk research that involves the use of existing collections of data or records that contain only non-identifiable data about human beings.

Regardless of the type of project you undertake, you are encouraged to contact the Cairns and Hinterland Hospital and Health Service Research Ethics Team on 4226 5513 or via email FNQ_HREC@health.qld.gov.au for advice and assistance with designing your project.

