

Quality Assurance (QA) Activity Decision Tool

Research support

Purpose

This work instruction describes the process for differentiating between quality activities and research activities, for the purpose of determining the requirement for ethical review.

Scope

This work instruction applies to all permanent, temporary, and casual employees, board members, executives, volunteers, students, visiting medical officers, contractors (their agents and assigns) in Cairns and Hinterland Hospital and Health Service (CHHHS).

Work Instruction

A quality 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 activities within CHHHS 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.

Purpose of the activity

The primary differentiation between research and quality activities is in the purpose of the activity. Regardless of the methods employed, if the purpose of an activity is not limited to the monitoring or evaluation of a CHHHS service or activity, then it is NOT a quality activity.

What is the purpose of your activity?

SECTION A. Purpose of the Activity			
Activity	Purpose	Yes	No
Research	To answer a question or test a hypothesis with application beyond the local unit / area in which the activity is conducted		
	To generate knowledge which can be generalised to the broader population		
Quality (includes clinical audit, service evaluation and service development)	To monitor or evaluate a Cairns and Hinterland Hospital and Health Service activity with the aim of improving service delivery or quality in Cairns and Hinterland Hospital and Health Service.		
	To answer a question specifically about the unit / area in which the activity is being conducted to monitor, evaluate, or improve the activity.		
	To gain information that may be of interest to similar services, but which cannot be appropriately generalised to those services.		

If you answered YES to either of the Research statements, your activity is not a quality activity. You may contact the HREC Coordinator to discuss options to progress your project.

If you answered NO to both Research statements, and YES to all Quality statements your activity is a quality activity, please continue to section B. Ethical review triggers for quality activities.



COMPASSION



ACCOUNTABILITY



RESPECT



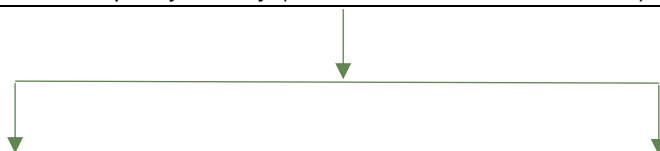
INTEGRITY



Queensland
Government

To determine whether a quality activity has research components which would trigger the requirement for ethical review, answer the following questions about your project.

SECTION B. Ethical Review Triggers for Quality Activities		
	Yes	No
Does the proposed activity pose any risks for patients beyond those of their routine care?		
Does the proposed activity impose a burden on patients beyond that experienced in their routine care?		
Is the proposed activity to be conducted by a person who does not normally have access to the patient's or their records?		
Does the proposed activity risk breaching the confidentiality of any individual's personal information, beyond that experienced in the provision of routine care?		
Will data be used or presented in such a way that it may be possible to identify individuals?		
Does the proposed activity involve any clinically significant departure from the routine clinical care provided to the patients?		
Does the proposed activity involve randomisation or the use of a control group or a placebo?		
Does the proposed activity seek to gather information about the patient beyond that collected in routine clinical care?		
Does the proposed activity potentially infringe the rights, privacy or professional reputation of carers, health care providers or institutions?		
Does the proposed project involve targeted analysis of data involving minority / vulnerable groups (eg. Aboriginal and Torres Strait Islander status), whose data is separated out of the data collected or analysed as part of the main quality activity (i.e. a sub-set of the main data)?		



If you answered **NO to ALL** of the triggers, your project is a quality activity, not requiring ethical review. **Go to section C.**

If you answered **YES to ANY** of the triggers, your project may be considered research, and is likely to require ethical review.

Please contact the HREC Coordinator to discuss options to progress your project.

SECTION C. Quality Activity with intent to publish or present
<p>Where your project is a quality activity, you are required to 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 you a letter stating the project is exempt from ethical review. This letter will allow you to publish your results in a journal or at a conference, despite not holding ethical approval. This is a mandatory requirement of any reputable journal.</p> <p><i>* The National Statement on Ethical Conduct in Human Research (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.</i></p>

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.

Definitions

Term	Definition
Research	A systematic and scientific investigation which generates new knowledge where there is no - or limited - research evidence available. Research is usually intended to be generalisable or transferable to other populations or locations.
Clinical Audit	Compares outcomes against evidence-based clinical standards. Answers the question: 'Does this service reach a predetermined, independently defined standard?'
Service Evaluation	Service / practice evaluation measures the effectiveness or efficiency of an existing or new service / practice that is evidence based, with the intention of generating information to inform local decision making. Measures current service.
Service Development	Service development introduces (or evaluates a recently introduced) change in service delivery or practice for which there is evidence derived from research or from other health/social care settings that have already introduced and evaluated the change. Comparison of one service model with another; possibly one redundant and one innovative; or two currently in use. Answers the question: 'Is this new service model better than the previous (or existing) model?'
Ethical approval	Approval granted by a Human Research Ethics Committee registered with the NHMRC, for the conduct of the reviewed research activity.