

# Requesting an exemption from Human Research Ethics Committee review for a Quality Assurance/Audit Activity

## Submitting a request

The following information is required for requests to the Royal Brisbane and Women's Hospital (RBWH) or The Prince Charles Hospital (TPCH) Human Research Ethics Committee for an exemption from Human Research Ethics Committee review for a Quality Assurance / Audit activity with intent to publish:

1. Cover letter addressed to the Chair of the RBWH or TPCH Human Research Ethics Committee containing the following:
  - a. Statement of what is being requested, e.g. "I am writing to seek an exemption from Human Research Ethics Committee review for the following Quality Assurance activity with intent to publish the findings";
  - b. Descriptive title of the activity;
  - c. Brief summary of the activity with justification of why this is a Quality Assurance / Audit activity rather than a research study and the ethical issues identified (refer to the National Statement on Ethical Conduct in Human Research 2007, pages 6 & 7 and Ethical Considerations in Quality Assurance and Evaluation Activities (2014);
  - d. Contact details (postal address, telephone number and e-mail address) of the applicant.
2. A separate proposal document containing the following:
  - a. Descriptive title of the activity;
  - b. Investigators involved (e.g. to the level of potential authorship on any resultant publication);
  - c. Literature review including standards of care and relevant indicators;
  - d. Aim and Background: Why is this activity being undertaken? What are the standards of care that apply in this case? If standards are not known, what is to be determined? How will the results be used?
  - e. Method: Details on participants, or data, to be included (inclusion / exclusion criteria, numbers involved, relevant time periods); what, if anything, participants will be asked to do; variables to be reported on, including outcomes of interest; method of data collection (e.g. chart review); methods used to maintain confidentiality / anonymity; the form the results will take (e.g. descriptive statistics); study timelines; how the exercise might be fed back into an audit or service improvement cycle; where the results are anticipated to be presented external to the institution; references (where relevant).

The proposal document may be brief but should provide sufficient detail (e.g. 2 - 3 pages). A research protocol template can be used and modified as appropriate (e.g. sample size calculations may not be relevant).
3. Any associated study materials (e.g. data collection tools, patient satisfaction questionnaires).

Submit one hard and one electronic copy of all documents to either of the following:

The Prince Charles Hospital	Royal Brisbane and Women's Hospital
Research, Ethics and Governance Unit Building 14 The Prince Charles Hospital Rode Road, Chermside, Qld 4032  Email: <a href="mailto:ResearchTPCH@health.qld.gov.au">ResearchTPCH@health.qld.gov.au</a> Phone: (07) 3139 4500	Human Research Ethics Office Level 7, Block 7 Royal Brisbane and Women's Hospital Butterfield Street, Herston, Qld 4029  Email: <a href="mailto:RBWH-Ethics@health.qld.gov.au">RBWH-Ethics@health.qld.gov.au</a> Phone: (07) 3646 5490

## Outcome

You will receive correspondence from the Chair or the HREC Coordinator with one of the following outcomes:

1. A letter of exemption from full HREC review;
2. A request for further information;
3. If considered not a Quality Assurance / Audit activity, a request to submit via the research pathway (i.e. completion of a Low or Negligible Risk Research Application for Ethics Review or a Human Research Ethics Application [HREA]).

## Submitting a request

Institutional approval procedures for Quality Assurance / Audit activities, where relevant, must be followed. However, a Site Specific Assessment application (which is only required for research studies) is not required.

Date	Version	Custodian
11/2015	1.0	HREC Coordinators, The Prince Charles Hospital and Royal Brisbane and Women's Hospital
11/2017	2.0	HREC Coordinators, The Prince Charles Hospital and Royal Brisbane and Women's Hospital