

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

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Submitting a request

The following information is required for requests to the Royal Brisbane & Women's Hospital (RBWH) Human Research Ethics Committee (HREC) for an exemption from HREC review for a Quality Improvement / Audit activity with an intent to publish:

1. Cover letter addressed to the Chair of the RBWH HREC 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 Improvement activity with an 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 Improvement / Audit activity rather than a research study (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 email address) of the applicant.

2. A separate proposal document (Protocol) 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).

Submission Requirements

Please submit the request for exemption on the Exemption Form accessed via ERM (<https://au.forms.ethicalreviewmanager.com/>). Please upload all supporting documentation for the exemption request into the Exemption Form. Once the application is complete, please sign the application and press 'Submit'.

Outcome

You will receive correspondence from the Chairperson 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 Improvement / Audit activity, a request to submit via the research pathway (i.e. completion of the Human Research Ethics Application [HREA]).

Submitting a request

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