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| Office for Research Governance and Development |

Pre-submission (Peer) review process

[Introduction](#Heading)

[What is a peer review?](#What_is_a_peer_review)

[When should peer review take place?](#When_should_peer_review_take_place)

[When is a Pre-submission (peer) review not required?](#Pre_submission_peer_review_NR)

[Pre-submission (Peer) review process](#Internal_Peer_Review_Process)

[Guidance for Reviewers: What comments are useful?](#Guidance_for_reviewers)

Introduction

The [*National Statement on Ethical Conduct in Human Research, 2007 (Updated 2018)*](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018) by the National Health and Medical Research Council (NHMRC) requires that each institution be satisfied that human research receiving ethical approval meets relevant scholarly or scientific standards. Peer review is seen as a key indicator of quality assurance in research and promotes the undertaking of relevant and scientifically sound research. Peer review should also be seen as a useful opportunity to improve the quality of the project, and the provision of pre-submission (peer) review should be seen as a facilitator of, not a barrier to, research at Gold Coast Hospital and Health Service (GCHHS).

The primary function of the pre-submission (peer) review is to determine if the proposed research has merit. Each research project must be carefully designed to both answer the research question/s and to safeguard the health and safety of the participants. Whilst Human Research Ethics Committees (HRECs) can, and do, assess scientific validity, members may not be content experts. Review of the proposed project by a peer can identify technical flaws of such magnitude that without modification the project is scientifically invalid and therefore unethical. Peer reviewers may take the opportunity to suggest changes that will improve the methodology and/or conduct of the project. Peer reviewers may also assist the ethical review process by identifying ways to minimise participant risk or burden.

Pre-submission (peer) review is not mandatory at GCHHS, but it is strongly encouraged.

What is a peer review?

Peer review is a system for review of research. Adequate peer review is:

* ***Independent:*** the reviewer must be independent of the project. The reviewer may be internal and may be a member of the same department as the investigator/s; however, the reviewer must not be in a dependent relationship (i.e., must not report to the Principal Investigator (PI)) and should be sourced from another department if the PI is the Head of Department.
* ***Expert:*** in terms of research experience, understanding of the research methodology and outcomes of the proposed study. Please also consider the appropriateness of the chosen expert for the research field.
* ***Documented:*** clear, written evidence of the review and the researcher response to any reviewer comments is to be submitted as a supporting document with the research application via [Ethical Review Manager (ERM).](https://au.forms.ethicalreviewmanager.com/Account/Login?ReturnUrl=%2fProject%2fPage%2f4692%2f154352)

When should peer review take place?

Peer review of a project should be undertaken once the scientific protocol has been developed and should always occur before the application is submitted for HREC approval. The researchers must allow sufficient time to find a reviewer, allow the reviewer to conduct the peer review, and then sufficient time to address the reviewer’s comments adequately, prior to submission via ERM.

A proforma for pre-submission (peer) review is provided [here](https://www.publications.qld.gov.au/dataset/gold-coast-health-research-documents/resource/8ae52211-6f9f-4c27-bf96-3826aa3e85c9). This is the recommended format for documentation of the reviewer’s comments on the protocol and contains all the required elements for documentation of the review.

When is a Pre-submission (Peer) review not required?

Projects which have already had a rigorous independent review conducted on the final version of the research protocol do not need to undergo additional peer review prior to submission. Circumstances where this has occurred may include:

* Commercially sponsored projects to be carried out on behalf of the sponsor where the protocol has been subjected to rigorous independent peer review processes organised by the sponsoring organisation

(Note: commercially funded projects involving significant academic/intellectual input from the local researchers are, in effect, research partnerships. Evidence of independent peer review should be considered for such projects)

* Multicentre trials conducted by cooperative groups with processes for rigorous independent peer review of research protocols. In some circumstances this may include evidence of scientific review which was part of an HREC approval by another institution
* Applications for GCHHS Governance Authorisation only i.e., HREC approval provided for this site by another accredited HREC under the National Mutual Acceptance (NMA) Scheme
* Protocols reviewed by advisory groups do not require further peer review. However, evidence of the review and a response to any query raised must be submitted with the initial submission to the HREC

*Note: Abridged protocols included in a successful peer reviewed grant application (such as NHMRC project grants) do not usually contain the same degree of detail that is required in a full research protocol and therefore successful grant applications are rarely regarded as evidence of rigorous peer review.*

Pre-submission (Peer) review Process

To complete a pre-submission (peer) review, researchers must arrange review of their protocol by an independent and expert person (as above). The reviewer’s recommendations should then be addressed appropriately.

The Office for Research Governance and Development (ORDG) may be contacted for advice on the pre-submission (peer) review process [GCHResearch@health.qld.gov.au](mailto:GCHResearch@health.qld.gov.au). Similarly, the ORGD may direct researchers to complete this process if it is felt the scientific merit of a protocol could benefit from evaluation and comment prior to HREC review.

**The process for pre-submission (peer) review:**

1. The PI sources an appropriate peer reviewer and sends them the (to date) final research protocol and Pre-submission (Peer) review Proforma
2. The peer reviewer documents their review of the protocol on the Pre-submission (Peer) review Proforma
3. The peer reviewer returns the completed proforma to the PI
4. The PI responds appropriately to the review comments

*Note: If the reviewer has indicated that the amended protocol requires re-consideration by the peer reviewer (or an alternative reviewer) before submission, the investigators must arrange this. An additional review proforma should be completed to document the review of the amended protocol.*

1. The PI submits their research application via ERM, including the completed Pre-submission (Peer) review Proforma, along with a written response to the peer reviewer comments and queries, and the project documents for HREC review.

*Note, where pre-submission (peer) review has been completed, the PI’s Line Manager (in signing the research application) is providing their assurance that the peer review has been conducted by a person with appropriate expertise*

**Please note:** The HREC may request another peer review be obtained for the following circumstances:

* the peer reviewer is not independent and has a dependent relationship with the PI
* the peer reviewer doesn’t have the appropriate research experience and/or expertise in the research field
* if significant changes have been made to the protocol following the initial peer review.

Guidance for Reviewers: What comments are useful?

The study must be carefully designed to answer both the research question/s and to safeguard the health and safety of the participants. The protocol is to be followed strictly by the Investigators throughout the duration of the study, so the final protocol must be clear and provide enough detail for all those involved in the study to understand what is required and/or permitted.

It is useful to introduce the written review with a very brief summary describing the project to confirm that your understanding of the research question is the same as the authors. It may also be useful to make a few general comments about the overall originality, relevance and internal validity of the project, and the overall quality of the research protocol.

The current version of the Pre-submission (Peer) review Proforma must be completed as it lists criteria against which a protocol should be reviewed. As you review the protocol try to identify if any of the key elements listed in the proforma are not included in sufficient detail.

**Please ensure the Conflict-of-Interest Declaration section is completed.**

During or following completion of the checklist, list any questions or comments you have about the research protocol in the space provided at the end of the proforma. For each listed point, please make it clear to the investigators what is being suggested or required. For example:

* Do researchers need to provide more information in the protocol to improve clarity?
* Are there fundamental problems which need to be addressed?
* Is the comment a suggestion to improve the science which is possibly useful but not essential?

Please be constructive in your comments: personal, sarcastic, or derogatory comments are never acceptable.

**Following review, please sign and return the completed review proforma to the Investigators for their response.**