Pre-Submission Peer Review: Process and Guidelines

INTRODUCTION

The National Statement on Ethical Conduct in Human Research requires each institution to be satisfied that human research receives ethical approval meets relevant scholarly or scientific standards. An important aspect of this assurance is evidence of peer review. Peer review aims to assess the scientific and methodological basis of research prior to submission for ethical review. The process is a key indicator of quality assurance and is a useful opportunity to improve the quality of a project.

The Barwon Health Research Development Unit (RDU) requires that **all high-risk research and student research** undergo peer review before submission to RDU. RDU cannot issue approval for high risk or student projects without submission of a completed Peer Review Pro Forma.

The purpose of the pre-submission peer review is to determine if the proposed research is scientifically and methodologically sound, has merit, and contains all elements required for ethical review. Research must be designed to both answer the research question and to safeguard the health and safety of the participants. 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.

The following guidelines summarise the process of pre-submission peer review and provide some guidance as to how to conduct a peer review of a research project. These guidelines primarily address the scientific rather than ethical or regulatory aspects of the project.

WHAT IS 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 investigators; however the reviewer must not be in a dependent relationship (i.e. must not report to the Principal Investigator) and should be sourced from another department if the Principal Investigator is the Head of Department.

- _**Expert**_: in terms of research experience, understanding of the research methodology and outcomes of the proposed study.

- _**Documented**_: clear, written evidence of the review and the researcher response to any reviewer comments is to be submitted with the research application.

WHEN SHOULD PEER REVIEW TAKE PLACE?

Peer review of a project should be undertaken for **all high-risk projects and student projects**. The Peer Review Pro Forma should be completed once the scientific protocol has been developed and must occur before the application is submitted for ethical review. The investigators must allow sufficient time to find a reviewer, allow the reviewer to conduct the peer review and to address the reviewer's comments adequately, prior to submission to the RDU office.

A pro forma for pre-submission peer review is provided on the RDU website. 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 that 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:

- Research projects that do not form part of a student's education (e.g. Honours, Masters, PhD, clinical placement).

- Low risk research projects.

- 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.

- Applications by another accredited HREC under the National Mutual Acceptance (NMA) Scheme.

- Protocols reviewed by advisory groups. However, evidence of the review and a response to any queries raised must be submitted with the initial submission to RDU.

PEER REVIEW PROCESS

The protocol and associated ERM form (e.g. HREA, QA form) must undergo peer review. The researchers must arrange for a peer review of their project by an independent & expert person (see section 'What is Peer Review?'). The reviewer's recommendations must be addressed appropriately.

The RDU Unit can be contacted for advice on the pre-submission peer review process or the sourcing of possible reviewers: **RDU@barwonhealth.org.au**

The process for Pre-submission Peer Review:

1. Investigators source an appropriate peer reviewer and send to them the final research protocol, ERM form, and Pre-Submission Peer Review Pro Forma.

2. The peer reviewer documents their review of the Protocol on the Peer Review Pro forma

3. The peer reviewer returns the completed pro forma to the investigators

4. The investigators respond appropriately to the review comments

    NB: 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 pro forma should be completed to document the review of the amended protocol

5. The principal investigator completes the remainder of the ethics application and submits via ERM to the RDU office. The review pro forma and any responses to the review should be included in the submission.

Note: Head of department signoff is still required in addition to peer review. You should show evidence of peer review to your head of department when obtaining signoff.

GUIDANCE FOR REVIEWERS

Below are some questions that reviewers should consider when performing their review.

- Is the study designed in a way that will answer the research question?
- Are measures in place to safeguard the health and safety of participants?
- Is the protocol clear and detailed enough for all members of the research team to understand what is required and permitted?
- Do researchers need to provide more information in the protocol to improve clarity?
- Are there fundamental problems that need to be addressed?

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 novelty, relevance and internal validity of the project and the overall quality of the research protocol.

The Pre-Submission Peer Review Pro Forma must be completed as it lists criteria against which a protocol should be reviewed. As you review the project, try to identify if any of the key elements listed in the pro forma are not included in sufficient detail.