Peer Review Process

Introduction

The National Statement on Ethical Conduct in Human Research (NHMRC 2007) requires each institution to be satisfied that human research receiving ethical approval meets relevant scholarly or scientific standards. An important aspect of this assurance is evidence of peer review of the scientific basis of a research protocol. Peer review is seen as a key indicator of quality assurance in research and is an essential process to ensure that relevant and scientifically sound research is undertaken. Peer review should also be seen as a useful opportunity to improve the quality of the project.

All human research protocols require peer review before submission to the RMH Office for Research, and evidence of this review must be submitted with the application. The RMH Human Research Ethics Committee (HREC) cannot give approval for projects that do not fulfil peer review requirements.

The purpose of the peer review is to determine if the proposed research has merit. Each research project must be carefully designed to both answer the research question and to safeguard the health and safety of the participants. The primary purpose of the peer review is to 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. As the research protocol must be followed strictly by the researcher team throughout the duration of the study, the final protocol must be clear and provide enough details for all those involved in the study to follow it.

The following guidelines attempt to clarify the process of peer review and provide some guidance as to how to conduct a peer review of a research protocol. 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 once the scientific protocol has been developed and must always occur **before the application is submitted for HREC approval**.

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 HREC.

A proforma for peer review is provided on the RMH Office for Research website. This is the required 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 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/supported projects involving significant academic/intellectual inputs from the local researchers are, in effect, research partnerships. Evidence of independent peer review is required for such projects)
- Multicentre trials run by cooperative groups/clinical trials networks 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. For example, studies run by the Australasian Leukaemia & Lymphoma Group, Australasian Kidney Trials Network, etc.
- Applications for Melbourne Health Governance Authorisation only i.e. HREC approval provided by another accredited HREC under the National Mutual Acceptance (NMA) Scheme.
- Protocols approved by the Orygen, Research Review Committee (RRC). The Orygen RRC query letter, Researchers response to queries cover letter & the final Orygen RRC Approval Certificate should be submitted with the initial ethics application.

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

If your project falls into one of the above categories:

- Include a statement in your Peer Review Proforma explaining why peer review was not sought; and
- Attach documentation to support the explanation, where appropriate.

Internal Peer Review Process

The protocol for each research project must be subject to peer review; therefore unless an appropriate peer review has already been completed (see above) the researchers must arrange for a peer review of their protocol by an independent and expert person (as above). The reviewer's recommendations must then be addressed appropriately.

The process for Peer Review:

1. Investigators source an appropriate peer reviewer and send to them the (to date) final research protocol and Peer Review Proforma
2. The peer reviewer documents their review of the Protocol on the Peer Review Proforma
3. The peer reviewer returns the completed proforma to the investigators
4. The Principal Investigators to complete the 'Principal Investigator declaration' section of the proforma confirming if they accept/disagree with the Peer Review and completes any other required actions i.e. amendments to protocol and any other subsequent documentation / provides comments/justification etc.

   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 Proforma should be completed to document the review of the amended protocol
5. The principal investigator submits the completed Peer Review Proforma, along with a written response to the reviewer comments and queries, and the project documents for HREC review

Guidance for Reviewers: What comments are useful?

The study must be carefully designed to both answer the research question 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 validity of the project and the overall quality of the research protocol.

The current version of the 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.

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, 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?

It is important to be constructive in your comments: personal, sarcastic or derogatory comments are never acceptable.

Following review, sign and return the completed Review Proforma to the investigators for their response.