



# Health Research South

## SCIENTIFIC PEER REVIEW: Guidelines for Dunedin School of Medicine Departments

### Introduction

Scientific peer review (hereafter referred to as peer review) in the context of human research refers to the scientific validity of the research project and is a vital step in research project development. Peer review is a requirement of ethical approval and can enhance research project development in a variety of ways through providing an objective perspective from an informed reader.

It is a requirement in the Dunedin School of Medicine (DSM) and the Southern District Health Board (Southern DHB) that all research projects involving human participants undergo peer review. This includes research carried out in the DSM, and the Southern DHB regardless of location or which organisation the researcher is from. The process below will also fulfil the requirement by the Health and Disabilities Ethics Committees (HDEC) that all research submitted for HDEC approval has undergone scientific peer review.

### Principles for Peer Review

- A peer review process should be commensurate with the type of proposal, the potential risk to participants and where the research will be undertaken (see “Levels of Peer Review” below).
- The type of peer review process that is used must be fit-for-purpose, efficient, justifiable and in confidence (see “Levels of Peer Review” below).
- Peer review should involve a process that leads to a consensus opinion about the quality of the research.

### Levels of Peer Review

All human research requires peer review of scientific validity, but the level of review should reflect the risk and intended purpose. The following describes the levels that will be used for research in the DSM and Southern DHB.

**Level A** is the level required for the HDEC and other ethics committee review, and reflects the level of ethics risk and need for sound scientific justification, methodology and feasibility. A higher level of review is also expected for any other research in humans where there is greater research complexity, resource investment and institutional risk.

Level A peer review requires one or more of the following:

- Approval by a Peer Review Committee is based on review by at least two peers, and must include review by a reviewer with an appropriate level of statistical expertise. The Peer Review Committee Chairperson has the role of determining the overall approval recommendation.
- Review by a recognized external peer reviewing body and judged to be of an acceptable standard (e.g. HRC funded projects)
- Review by a recognized internal peer reviewing body (e.g. UORG or other existing committee) and judged to be of an acceptable standard.

Where peer review has been carried out by an internal or external funding body, the Chair of the respective Peer Review committee must be satisfied that the peer review is of an appropriate standard.

**Level B** is the level required to confirm scientific validity for research not requiring HDEC review, and recognizes that some research involving humans has lower risk, complexity and investment of resource. Level B provides for a less demanding review.

Level B peer review requires

- Approval by a Peer Review Committee Chairperson based on review by at least two peers confirming scientific validity

**Level C** is the level required for confirming the validity of research carried out for the purpose of learning to do research, where there is no direct intent to gain new knowledge, and where the research does not require ethics committee review e.g. low risk observational.

Level C peer review requires

- Approval by a Peer Review Committee Chairperson based on review by one other peer confirming scientific validity

### **Standards for Peer Review**

The following are adapted from the *“Joint Health Research Council and NEAC guidance on features of robust peer review for assessing the scientific validity of research, 2012.”* While not strictly standards, they nevertheless describe the key areas of focus for determining scientific validity and provide a nationally recognised framework for scientific peer review.

- 1. The relative merit of the research:** consideration of whether the proposed work is important, worthwhile and justifiable. The research should address a health issue that is important for health and/or society. The aims, research questions and hypotheses should build on and address gaps in existing knowledge.
- 2. The design and methods:** consideration of the quality of study design and the robustness of the methods used. This might include study methodology, a description of sample recruitment and characteristics (including number, gender and ethnicity

where relevant) and proposed methods of data analysis. An indication of timelines for the research should be included.

- 3. *The feasibility of the research:*** consideration of whether the overall strategy, methodology and analyses are well reasoned and appropriate to achieve the specific aims of the project. The review will determine whether the research has the likelihood, on balance, of improving scientific knowledge, concepts, technical capacity or methods in the research field, or of contributing to better treatments, services, health outcomes or preventive interventions. The research should be achievable within the specified timeframe and the researcher/research team must have the appropriate experience and expertise to undertake the research.

In addition we have added a further standard to enhance the process of research communication.

- 4. *The presentation of the application:*** consideration of the overall presentation, including structure, 'understandability', clarity and readability of the research application. While not directly about the research, the way in which the application reads and gets the message across often reflects how well the research has been planned and conceived. Presentation is a strong determinant of whether the research will be understood, fundable and therefore whether it will be done at all.

## **Process of Peer Review in the Dunedin School of Medicine and the Southern DHB**

- 1. *Departmental Committees.***

Individual departments within the DSM should establish a committee for peer review. They should follow the guidelines set out below in ways that best work in their own context and for the type of research carried out.

Each Committee is responsible for ensuring peer review that conforms to the principles described, matches research projects with the appropriate level of peer review, and assesses the project against the standards for peer review. The structure should include a Chairperson responsible to the relevant Head of Department and a committee with "rotating" membership of regular reviewers. The number of members, the frequency and format of meetings is at the discretion of the department.

- 2. *Process level and timeframes***

A review process should be developed which is best suited to the area/discipline and characterised by efficient communications and short, agreed time-frames for turnaround. The process needs to state clearly, for each of the three levels of peer review, who is responsible for what, along with the required timeframes for each level.

- 3. *Standards of peer review for scientific validity***

Standards of peer review based at least on the “Standards for Peer Review” above should be in written form and widely available within the department. These are the standards that the reviewer will use in reaching a recommendation about the scientific validity and presentation of the research project.

Departments may elect to develop checklists or other “tools”, within the framework of standards above, to ensure review is as focussed and straightforward as possible.

Ethical aspects of the research may be commented on but decisions regarding the ethics of the research will be covered by Ethics Committee Review; in most cases this will be either Health and Disabilities Ethics Committees (HDEC) or the University of Otago Human Ethics Committee (Health) (UOHEC).

#### **4. *The Ethos of Peer Review***

As well as systematically using the standards of peer review as a guide for the review process, the ethos of peer review must be one of researcher encouragement that is, collegial collaboration with the researcher to develop and present their research project with high quality and integrity.

#### **5. *Final Approval***

Final approval that peer review has been completed should be provided by Head of Department or their delegated authority (e.g the Chair of the Peer Review Committee.)

#### **6. *Selecting Reviewers***

Selection of reviewers is pivotal to this process. It is the task of the respective Chairs of the Peer Review Committees to select reviewers who have sufficient experience while maintaining a degree of pragmatism about the nature of the role. While most reviewers may be internal to a large department, use of peer reviewers external to the Department (and the University) is encouraged and will be required more often in smaller departments. Overuse of reviewers is to be avoided and quality monitored. Researchers may be asked to suggest suitable persons who might be approached to provide peer review. Reviewers should not directly be part of the investigating team.

The Heads of Departments will need to ensure that all appropriate staff members are well informed of the need to take their share in this role.

#### **7. *Informing staff***

Each Department will be responsible for ensuring staff members are informed about the requirement and the Departmental process for peer review. Health Research South will provide support by incorporating the requirement for peer review into Clinical Research Approval and providing assistance in training and setting up systems as required.

## 8. *A system for administration*

Each department should develop a **system for recording decisions**. This can be in the form of a simple spread-sheet and should include at least:

- Name of researcher
- Researcher contact details
- Name of project
- Date received
- Date for completion of review
- Date of reviewer responses
- Date researcher informed of decision,
- Level of review
- Reviewer name/s, and contact details
- Final decision
- Comments (as required)

Health Research South will provide an electronic template for this

**A system of storage for records** should also be developed. Records that should be kept include a copy of the submitted draft research project, a copy of the completed and signed reviewer sheet, a copy of the final letter to the researcher. Samples of records will be required for moderation and quality improvement purposes and therefore should be easily accessible.

**Administrative support** may be required. Larger departments may need to consider some dedicated hours to support their peer review process.

## 9. *Chairperson's role*

- The Chairperson receives project draft, sets level of review, assigns reviewers, monitors responses, receives reviews and provides feedback to the researcher.
- The Chairperson may request of the researcher that the recommendations be considered, the required changes be made, further advice be sought, or resubmission be carried out to achieve peer review approval.
- In consultation with the reviewers, the Chairperson has responsibility for determining the overall approval decision/recommendation.
- The Chairperson may choose to expedite approval at Levels B and C by taking on the role of a reviewer.
- The Chairperson should not participate in the review of his/her own research projects but should seek another suitable person to deputise.
- The Chairperson makes the recommendation for approval to the Head of Department or may approve with delegated authority from the Head of Department. Delegated authority for the Chairperson to make the final decisions must be clearly recorded including under what conditions this can

occur e.g. all the time, for level B and C decisions only, some other set of circumstances.

- The Chairperson should report regularly to the Department on the status of the peer review process and recommend improvements.
- The Chairperson is a member of the DSM Peer Review Committee which reports to the School and HRS Board on a regular basis.

#### **10. Administrative templates**

These are provided by Health Research South to facilitate the process of peer review and to ensure the requirements for external agencies (e.g. HDEC) are met and can be efficiently processed (see Appendix 1)

#### **11. Applicants**

All researchers in DSM and SDHB will be expected to obtain peer review through the academic departmental committees with which the principal Investigator is associated. An additional Committee will be established where the research is not readily aligned with an academic department. In particular this will provide for researchers in nursing, midwifery and allied health. Southern DHB researchers should seek assistance from the Health Research South office as to which departmental committee to work with.

#### **12. Other peer review options**

Peer review of a comparable standard carried out through other approved external and internal bodies, if deemed to be for funding or fundable, should also be acknowledged as approved by the departmental committee.

#### **13. Moderation**

To ensure that the peer review is fair and valid and that consistent judgements are being made within a Department, the Chairperson should report regularly on this to the Head of the Department and to the Department. Where moderation is required this is the responsibility of the Head of Department.

Researchers may seek assistance from the Board of Health Research South when there is unresolved moderation.

#### **14. Monitoring quality, compliance and development of Peer Review**

Health Research South will establish a Peer Review Quality Committee with the Chairpersons from each Department's Peer Review Committee. The purpose is to provide uniformity of practice and consistency of judgements. This committee will initially meet at least twice each year and will provide a forum for refining the processes and expectations, setting standards and comparing approaches. Quality and compliance will be monitored and improvements developed as required. If

needed this committee may assist in moderating peer review decisions in departments.

**15. Process of Peer Review for other organisations carrying out research in Southern District Health Board or Dunedin School of Medicine research environment**

All research to be carried out in the Dunedin School of Medicine and Southern District Health Board must undergo peer review.

Peer review from organisations outside the DSM/Southern DHB environment for research to be done in this environment must meet the requirements described above. Assistance to achieve this may be offered through Health Research South.