

Purpose:

To describe the procedure for seeking independent expert advice for high risk research projects.

Guidelines:

The Royal Victorian Eye and Ear Hospital (Eye and Ear) Human Research Ethics Committee (HREC) considers proposed research projects which may have minimal, moderate or substantial risk to participants. The Committee must ensure that any risks are minimised and adequately explained as well as balanced against the potential benefits of the research.

The Committee also has a role in advising the Hospital whether the risks are too severe to allow the project to proceed. In making its decision about the risks, the Committee may consider existing analysis provided with the application from other expert bodies. The Committee may also consider that it has sufficient expertise amongst its members who do not have a direct involvement in the particular project. Occasionally, the Committee will conclude that it does not have sufficient expertise or information to make a judgement and must seek additional opinion.

Procedure:

Internal Independent Review

1. Where feasible, the Chair will select two members of the Hospital's senior staff, who are independent of the project and the HREC, with appropriate qualifications and experience to review the project from a risk perspective. The briefing to the reviewers may request a general review of the risks or may include specific questions about aspects of the project; for example the nature of inclusion and exclusion criteria. The reviewers will act anonymously in the fashion of peer-review journals. The reviewers will not have any perceived or actual conflict of interest in the research and will be asked to direct all questions to the researcher via the HREC Chair so that anonymity is maintained. The opinions from the reviewers shall be in writing.

As a staff member, the internal independent reviewer will have professional indemnity cover via the Hospital's insurer, the Victorian Managed Insurance Agency (VMIA) policy.

2. The opinions of the expert reviewers shall be reported back to the next HREC meeting for consideration. If the HREC still cannot decide or if the internal review process is considered inconclusive, the HREC Chair shall commission independent external expert review.

External Independent Review

1. Where external independent expert review is required, the Chair and the relevant members of the HREC without involvement in the specific project shall prepare a list of potential external reviewers.
2. The proposed external reviewers shall be approached by the Chair about their preparedness to conduct such a review, to adhere to the conditions of anonymity and to provide a quotation on the cost of preparing such a review.
The PI shall be notified of the cost to obtain the review. If the PI wishes to proceed, the Eye and Ear will invoice the cost to the PI and shall, on receipt of the payment, commission the review process from the reviewers.
3. An agreement will be entered into by the Eye and Ear and the reviewer including details of the responsibilities of the reviewer, insurance and indemnity arrangements, confidentiality and conflict of interest clauses and fee details.

See below for indemnity information for reviews relating to a First Time in Human drug or device study.

4. The results of the review shall be presented at the next HREC meeting.

First time in human studies

If the review by the independent external adviser relates to a First Time in Human drug or device study; before any review takes place, it must be ensured that the independent reviewer holds adequate professional indemnity insurance. If the proposed reviewer has inadequate or no professional indemnity insurance, the VMIA must be contacted to seek coverage for the independent reviewer. The VMIA will advise on the underwriting information it requires for the request to be considered.

Definitions:

HREC Human Research Ethics Committee

PI Principal Investigator

Standard:

NSQHS National Standard 1.1 Implementing a governance system that sets out the policies and procedures and/or protocols

Victorian Managed Insurance Agency - Clinical Trials, Risk and Insurance Guide 2015

Linked Policy & Procedure:

Research Policy

Approval / Committees:

This procedure was approved by the Human Research Ethics Committee and Executive Director Medical Services/Chief Medical Officer.

Evaluation:

Cases where an independent expert was engaged will be reviewed to ensure compliance.

Procedure Review:

This procedure will be reviewed triennially or earlier if legislative or insurance requirements change.

Key Words for Search:

HREC, expert, independent review, indemnity, high risk

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Policy / Procedure Details:

Details		
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