

PROCEDURE
**HREC Procedure Independent
Expert Advice for High Risk
Research Projects**



Purpose:

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

Scope:

Hospital staff undertaking high risk research projects.

Risks/Precautions:

None have been identified at the time of last review.

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. In doing so, the HREC must apply the principles outlined in the NHMRC standard. These include ensuring that the research has "merit and integrity", that the "likely benefit must justify any risks" (1.6) and that the researcher is "designing the research to minimise the risks of harm" (1.7). The Committee must ensure that any risks are minimised and adequately explained as well as balanced against the potential benefits of the research.

In its risk assessment, the risk must be identified and assessed including the likelihood and severity or magnitude of the risk (2.1.1(b)). The statement explicitly states that:

In determining the potential benefits and the existence, likelihood and severity or magnitude of risks, researchers and those reviewing the research should base their assessments on the available evidence and should consider whether to seek advice from others who have experience with similar methodology, population and/or research domain. (2.1.2)

Notwithstanding the possibility that participants may decide to be recruited into very high risk studies, voluntarily consenting to the assumption of risks that have been disclosed, there may arise circumstances in which the hospital is not prepared to conduct such high risk research for operational reasons. 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 or merit of the research, 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

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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/Method:

Each new project is presented to the HREC by a member of the HREC that has no conflict of interest and who is appropriately scientifically qualified and experienced. As part of that presentation, a review of scientific merit is conducted. The HREC member who will conduct the review is selected by the chair, or in his/her absence, the deputy chair. The need for external review may arise if

- A. No member can be identified who has appropriate expertise to review the project prior to the meeting or
- B. If the HREC in its deliberations comes to the conclusion that the HREC lacks the ability to review the project.

Internal Independent Review

1. Where feasible, the HREC 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 must 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 reach a decision or if the internal review process is considered inconclusive, the HREC Chair shall commission independent external expert review.

External Independent Review

1. One reviewer will be selected where external independent expert review is required. The HREC 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 HREC 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 an external independent 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.

The external independent reviewer is required to be protected by insurance. If the reviewer is an employee of a VMIA insured agency, then they are covered under the VMIA Health Program. If the reviewer is not an employee of a VMIA insured entity, then they need to provide a certificate of currency for professional indemnity insurance policy (as per the VMIA Clinical Trials Risk and Insurance Guide).

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

Outcome:

Staff act in accordance with this document and best practice evidence at the time of review.

Definitions:

HREC : Human Research Ethics Committee

PI : Principal Investigator

Standard:



NSQHS National Standard 1: Clinical Governance

Legislation:

Current Legislation may be sourced at: <http://www.austlii.edu.au/> or Victorian legislation at: <https://www.legislation.vic.gov.au/>

None have been identified at the time of this review.

References:

Victorian Managed Insurance Agency - Clinical Trials, Risk and Insurance Guide 2023

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Linked Policy & Procedure:

Research Policy

Approval/Committees:

- Executive Director Medical Services and/or Director Medical Services
- Human Research Ethics Committee

Responsible Executive:

Executive Director Medical Services/Chief Medical Officer

Author:

Manager Research

Evaluation:

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

Procedure Review:

This procedure will be reviewed at least every 3 years.

Author/ Co-Authors:

Name	Position	Service / Program
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Version Details:

Details	
Procedure No:	RVEE0192159
Parent Policy:	Research Policy
National Standard(s)	Clinical Governance
Legislation Section:	E – Patient’s Rights F - Privacy
Review Date(s):	2011, 18/04/2013, 22/09/2016, 15/10/2020, 13/05/2024

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