PROCEDURE

HREC Lower Risk Research Review

Purpose:

To define the process of research review by the Lower Risk Research Subcommittee of The Royal Victorian Eye and Ear Hospital (Eye and Ear) Human Research Ethics Committee (HREC).

Scope:

Research conducted at the Eye and Ear and/or reviewed by the Eye and Ear HREC that is considered to be of minimal risk as described in the *National Statement on Ethical Conduct in Human Research* (2023 and as amended) (National Statement) as "research in which there is no risk of harm or discomfort, but which includes a potential for minor burden or inconvenience" or low risk research described as "research in which there is no risk of harm, but there is a risk of discomfort and in which there may also be a foreseeable burden."

Where the risk, even if unlikely, is more than lower risk then the application must be reviewed by the HREC.

Risks/Precautions:

None have been identified at the time of this review.

Procedure/Method:

Lower Risk Research applications can be reviewed and approved without the need for consideration by a fully constituted HREC.

An expedited review is provided by the Lower Risk Research Subcommittee of the HREC consisting of the members detailed in the Terms of Reference.

The procedure:

1. If the planned project falls within the lower risk research category, the researcher needs to complete the Research Office Application Cover Sheet and LNR VIC application form (available on the Ethical Review Management (ERM) Platform which can be accessed on the Research website). It is the responsibility of the Principal Investigator (PI) to**:**
    - ensure that the information provided on the form is accurate and detailed sufficiently to enable review;

- approach the relevant departments for approval to access sources of information and provide Head of Unit signature on a Head of Supporting Department form (available on the Research internet site);
- approach supporting departments for approval to provide the necessary resources (including staff, time, and facilities) and capturing agreement on a Head of Supporting Department form (available on the Research internet site); and
- inform all those involved in the activity of their responsibilities.

2. Submit the application via ERM.
3. There are no submission deadlines for low risk research applications as they are reviewed out of session on a continuous basis.
4. When an application is received, the Research Office checks the application is in order to identify any preliminary issues that might need addressing in order to facilitate thorough review. e.g., failure to attach Consent Form.
5. All projects will be allocated a Research Office Reference Number. Any correspondence in relation to the project must always make reference to this Research Office Reference Number.
6. Once the application is considered complete, the application is sent to the members of the Lower Risk Research Subcommittee for review. Ideally, a response will be provided within 14 days.
7. Any queries, clarification or comments will be emailed to the PI.
8. The Lower Risk Research Subcommittee will refer any project to the full HREC if the project is found to be outside the scope of the Lower Risk Research Subcommittee.
9. The Lower Risk Research Subcommittee will refer any project to the full HREC if the project description involves collection, use and/or disclosure of personal or health information without consent of the individual whose information it is for the HREC to consider approving a waiver of the requirement for consent, as per *s95, 95A and 95AA of the Privacy Act (Cth) or the Statutory Guidelines for Research of the Health Records Act (Vic).*
10. The Research Office advises the PI, of the outcome, which can be:
    a. approval of the application; or
    b. approval of the application subject to conditions that need to be met before approval can be granted; or
    c. referral of the application to the HREC to consider; or
    d. declining the application.
11. Approval for lower risk research projects is for a period of up to three years.
12. The PI is obligated to provide an Annual Report to the Lower Risk Research Subcommittee summarising project progress. At completion of the project, the

PI is also required to provide a comprehensive final report of the outcome(s) of the research to the Lower Risk Research Subcommittee and detail any changes to clinical practice that might arise from the research.

a. All Reports will be listed on Lower Risk Research Report for the HREC meeting Agenda. HREC members can request to review a Progress or Final Report of any lower risk research project.

b. All projects are archived by the Research Office upon receipt of a comprehensive Final Report.

13. A record of all decisions made in relation to lower risk research is kept by the Research Office and a summary of these decisions will be incorporated into the agenda and the minutes of the next scheduled meeting of the HREC for its noting.

The Application Form and Supporting Documents

All sections of the application must be completed accurately with sufficient detail to allow a clear picture of what the project involves.

A project description/protocol is the document that outlines the study plan for a human research project. The study plan must be carefully designed to safeguard the health and safety of the participants, as well as answer specific research questions. A project description/protocol gives written evidence for the necessity and feasibility of a research study. It should provide a full and detailed description of the objectives, design, methodology, statistical considerations and organisation of the study, including specific details on how the research will be conducted and evaluated. A complete, detailed project description/protocol allows the reviewers to make a judgement about the scientific and ethical aspects of the study.

Approval will only be granted to studies with an adequate study planl.

Following approval by the Lower Risk Research Subcommittee, the project description/protocol becomes the definitive document for the study conduct, evaluation and reporting. Once a project description/Protocol is approved, it is essential that the study is carried out in accordance with the details in the document, as the investigators only have approval to do the research as described in the protocol.

Outcome:

Lower Risk Research conducted at the Eye and Ear is reviewed and approved to ensure high quality ethical review by the Lower Risk Research Subcommittee.

Standard:

NSQHS Standard 1: Clinical Governance

- National Statement on Ethical Conduct in Human Research (NHMRC; 2023 and as amended)

Legislation:

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

- *Privacy Act 1988 (Cth)*
- *Health Records Act 2001 (Vic)*

References:

None have been identified at the time of this review.

Linked Policy & Procedure:

- Research Policy

Approval/Committees:

Human Research Ethics Committee

Responsible Executive:

Executive Director Medical Services/Chief Medical Officer

Author:

Research Manager

Evaluation:

Processes and procedures are evaluated within the context of organisation risk management accreditation and legislative standards.

Procedure Review:

Lower Risk Research Review procedures will be reviewed every three years by the HREC Chair and RO to ensure the process continues to be robust and consistent with the National Statement.

Author/ Co-Authors:

Name	Position	Service /Directorate
Dr Chris Tan	Director Medical Services	Medical Services
Dr Marc Sarossy	Chair, Human Research Ethics Committee	Medical Services
Assoc Professor Peter Keller	Research Manager	Research Office

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Details	
Procedure No:	RVEE0192161
Parent Policy:	Research Policy
National Standard:	Clinical Governance
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