HREC Procedure
Administration of Ethical Review

Purpose:

To describe the administrative processes that support the ethical review of research projects submitted to the Royal Victorian Eye and Ear (Eye and Ear) Human Research Ethics Committee (HREC).

Scope:

This procedure applies to the preparation of HREC agendas, conduct of meetings, review of research applications, preparation of HREC minutes, notification of HREC decisions, maintenance of records of HREC decisions and activities and reporting requirements of HREC.

Procedure / Method:

The operation of the HREC is guided by the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research.

Preparation of HREC Agenda

1. The HREC Secretary is responsible for preparing the Agenda for each HREC meeting and forwarding to HREC members at least a week prior to the HREC meeting.
2. All complete submissions (new and resubmitted applications, extensions to approved projects (reapplications), progress reports and final reports) and relevant documents received by the Research Office (RO) by the submission closing date are included in the agenda for the HREC's consideration at its next meeting.
3. The HREC Chair may also add items for review to the Agenda.
4. Documentation received after the closing date can be included on the agenda and/or tabled at the meeting at the discretion of the HREC Chair.
5. Agenda items include at least the following items:
    i) Attendees and Apologies
    ii) Conflict of Interest by Members
    iii) Confirmation that all decisions are aligned with the principles of the National Statement
    iv) HREC Minutes (from the previous meeting)
    v) New Research Applications (Greater than Low Risk and Low Risk)
    vi) Renewal/Extension of approved projects
    vii) Amendments to existing projects
    viii) Training
    ix) Monitoring and Safety Reports
    x) Amendments reviewed out of session for ratification
    xi) Business Arising
    xii) Annual Reports
    xiii) Final Reports
    xiv) General Business and Correspondence
6. The agenda and all associated documentation are confidential and are marked and treated as confidential.

Conduct of HREC Meetings

1. The HREC meets at least 6 times per year at approximately bi-monthly intervals. Meeting dates and agenda closing dates are available on the Eye and Ear Research website.
2. Members attend HREC meetings in person. There is no provision for attendance by proxy.
3. The Chair may cancel a scheduled meeting if a quorum cannot be achieved. Should this occur, the HREC will reconvene, where possible, within 3 weeks of the cancelled meeting to ensure all agenda items are considered.
4. HREC meetings may be held in person or using a videoconference platform.
5. The HREC meeting is conducted in private, to ensure confidentiality and open discussion.
6. Notwithstanding paragraph 5, the HREC Chair may agree to the presence of observers to a meeting, providing any conflicts of interest declarations are made and a confidentiality agreement has been signed.
7. Notwithstanding paragraph 5, the HREC Chair may invite individuals to attend all or part of the meeting for presentations and discussion about specific projects or other matters related to the function of the HREC.
8. Members who are unable to attend a meeting are asked to contribute any review comments to the HREC Secretary by email prior to the meeting. Written comments, including any declarations of conflict of interest must be received prior to the meeting so that they can be discussed in the course of the meeting. The minutes record the submission of written comments. If the comments cannot be submitted prior to the meeting then their inclusion in the minutes and/or letter to researchers is at the discretion of the HREC Chair.

Review of Research Applications, Resubmissions, Amendments and Reapplications

1. The HREC assesses each submission for scientific merit and validity and ethical requirements in accordance with the National Statement and other relevant guidelines and legislation. The HREC must ensure that it is sufficiently informed on all aspects of a research protocol, including its scientific validity, in order to make an ethical assessment. New projects are allocated by the HREC Chair or Deputy Chair to relevant HREC members to undertake a scientific review and to present their findings at the HREC meeting.
2. The HREC considers research submissions being conducted at or under the auspices of the Eye and Ear and/or campus research partners submitted by either affiliated or non-affiliated researchers, and at other agreed upon sites under individual arrangements. . The HREC conducts review for eye and ear, nose and throat research and psychosocial research in these areas.
3. The HREC considers fully completed initial application and requests for proposed amendments to research projects that already hold HREC approval. Current versions of application, amendment and reapplication forms shall be available on the Eye and Ear research website.
4. All requests for amendments must outline the nature of the proposed change, the reason for the change and an assessment of ethical implications arising from the proposed changes. All amended documents such as protocols and Participant Information and Consent Forms (PICFs) must be provided in clean and tracked versions (including revised version numbers and dates) for the review.
5. HREC may delegate to an HREC subcommittee consideration of research projects assessed as low risk.
6. Similarly, amendments that are not complex in nature may be reviewed and approved by HREC Chair, followed by ratification by the full HREC Committee. In these cases, the Principal Investigator (PI) is notified of the approval and research can proceed from the date of the approval letter. No further correspondence is provided on the amendment unless the HREC requests additional information.

7. Where an urgent protocol amendment is required for safety reasons, the Chair may review and approve the request (with the help of an expert reviewer, if necessary). In such circumstances, the modification or renewal information is tabled at the next HREC meeting.
8. The submissions are reviewed by the HREC. Decisions on the acceptability or otherwise of the submission are made by consensus. Unanimity is often achieved but is not an absolute for approval to be granted.
9. The HREC may also choose to refer the submission to an internal or external expert reviewer(s), ensuring no conflicts of interest exist and that a confidentiality agreement is in place.
10. The Chair and/or HREC must consider whether an advocate for any participant or group of participants should be invited to the HREC meeting to ensure informed decision-making. Any attendance is limited to the proposal in question and attendance is reflected in the minutes.
11. The HREC, after consideration of a submission, makes one of the decisions outlined below. The Ethics Secretariat advises PIs of the HREC decision, stating compliance with or inconsistency in terms of the National Statement.

Applications

a. to approve the project as being ethically acceptable, with or without conditions; or
b. to request modifications, this may then be reviewed for final approval by the HREC Chair and/or subset of the HREC membership; or
c. to defer making a decision on the project until the clarification of information or the provision of further information to the HREC; or
d. to reject the project.

Amendments

a. to approve the amendment as being ethically acceptable, with or without conditions; or
b. to request modifications to the amendment, this may then be reviewed for final approval by the HREC Chair alone for minor amendments, a subset of the HREC membership or the full HREC Committee for more substantial changes; or
c. to defer making a decision on the amendment until the clarification of information or the provision of further information to the HREC; or
d. to reject the amendment.

Reapplications (time extension to a current project with approval)

a. to approve the reapplication as being ethically acceptable, with or without conditions; or
b. to request modifications, this may then be reviewed for final approval by the HREC Chair and/or subset of the HREC membership; or
c. to defer making a decision on the project until the clarification of information or the provision of further information to the HREC; or
d. to not extend the approval period for the project.

12. For projects where the HREC has requested clarification, the provision of further information, or amendment to the project, the HREC may choose to delegate the authority to review that information and approve the project between meetings to one of the following:

    i. Chair or Deputy Chair alone;

    ii. Chair and/or Deputy Chair, in verbal or written consultation with one or more named members that were present at the meeting or who submitted written comments on the application;

    In such circumstances, the HREC is informed at the next meeting, of the final decision taken on its behalf.

Preparation of HREC Minutes

1. The HREC Secretary is responsible for preparing and maintaining minutes of all HREC meetings.
2. The format of the minutes includes at least the following items:
   - i) Attendance and apologies
   - ii) Conflicts of Interest by members
   - iii) HREC Minutes (from the previous meeting)
   - iv) New Research Applications
   - v) Renewal of approved protocols
   - vi) Amendments to approved protocols
   - vii) Safety and Monitoring Reports
   - viii) Amendments reviewed out of session for ratification
   - ix) Business Arising
   - x) Annual Reports
   - xi) Final Reports
3. The minutes include a record of decisions made by the HREC. This includes reference to views expressed by any absent members.
4. In relation to the review of new applications or amendments, the minutes record a summary of the main ethical issues considered, including any requests for additional information, clarification or amendment to the project.
5. To encourage free and open discussion, particular views are not attributed to particular individuals in the minutes, except in circumstances where a member seeks to have his/her opinions or objections recorded.
6. Declarations of conflicts of interest by any member of the HREC and the absence of the member concerned during the HREC consideration of the relevant application are minuted (refer to HREC Procedure for Handling Conflict of Interest in Ethical Review of Research).
7. The minutes are finalised within 10 working days following the relevant meeting including review by the HREC Chair (or delegate) for accuracy.
8. The minutes are forwarded to all members of the HREC as an agenda item for the next meeting. All members will be given the opportunity to seek amendments to the minutes prior to their finalisation.
9. From January 2016, all minutes are stored electronically. Hard copies of minutes prior to 2016 have been archived and can be retrieved by the HREC Secretary, if needed.

Notification of HREC Decisions

1. The HREC Secretary reports the HREC decision in writing to the PI within 10 working days of the meeting, unless otherwise notified.
2. If the HREC determines that further information, clarification or modification is required, the correspondence to the PI clearly articulates the reasons for this determination and outlines the information that is required. Requests for additional information, clarification and/or modification refer to the National Statement or relevant pieces of legislation.
3. The HREC endeavours to communicate openly with researchers to resolve outstanding requests for further information, clarification or modification of projects relating to scientific and ethical issues. The HREC may nominate one (or more) of its members to communicate directly with the applicant or by inviting the applicant to attend the relevant HREC meeting.
4. The HREC Secretary notifies the PI of the ethical approval of a project only when all outstanding requests for further information, clarification or modification have been satisfactorily resolved.

Notification of ethical approval is by email, and contains the following information:

i. Title of project
ii. Name of the Principal Investigator
iii. Unique HREC project identification number
iv. The version number and date of all documentation reviewed and approved by the HREC including Clinical Protocols, Participant Information and Consent Forms, Advertisements, Questionnaires etc.
v. Date of HREC approval and date of HREC expiry.
vi. Conditions of HREC approval.
vii. Statement of compliance of the HREC decision with the National Statement

5. If the HREC determines that a project is not ethically acceptable, the notification of the HREC's decision will include the grounds for rejecting the project with reference to the National Statement or other relevant pieces of legislation. HREC member(s) or RO staff may be nominated to work with the researcher to assist in re-submission.
6. The status of the project is recorded by the HREC Secretary on its database.

Record Keeping

1. The HREC Secretary prepares and maintains records of the HREC activities, including agendas and minutes of all meetings of the HREC. From 2016, all records are being stored electronically, on an Eye and Ear Drive with restricted access that is backed up and with disaster recovery processes in place.
2. The HREC Secretary prepares and maintains a confidential record for each project, received and reviewed, and amended, including the following information:

- the institution for whom the HREC is reviewing
- unique HREC project identification number
- Principal Investigator(s) and Associate Researchers
- title of the project
- ethical approval or non-approval correspondence with date
- approval or non-approval of any changes to the project
- conditions, if any, of approval of the project
- whether approval was by the Retrospective Review pathway
- duration of the approval
- action taken by the HREC to monitor the conduct of the research.

From 2016, electronic files are maintained for each individual research project.

3. The project file contains a copy of the submission, including signatures, relevant correspondence (including that between the applicant and the HREC), all approved documents and other material used to inform potential research participants.
4. All documents provided to HREC members are electronic files, which are stored in a dropbox account. Only the most recent HREC agenda will be available within dropbox. If members require access to previous versions, then they can be requested via the Research Office..
5. HREC records are stored and upon completion of a project and acceptance of the final project report, the project file is closed and archived (pre 2016).

Access to Records

1. Access to records held by the HREC Secretary is restricted to Research Office staff.
2. Investigators who are named on an HREC application may request access to HREC records relating to that application. Such requests must be made in writing and directed to the HREC Secretary.
3. Requests for HREC records from anyone not associated with an application need to be approved by the relevant Principal Investigator and the HREC Chair.
4. Requests for access to minutes from HREC meetings must be made in writing to the HREC Chair. The request must clearly describe and justify the reasons for requesting such access, and will be considered within the context of the National Statement and the Victorian Freedom of Information Act (1982).

Reporting Requirements

1. The Research Office staff shall notify the Executive Director Medical Services/Chief Medical Officer of any HREC membership changes as they occur. New members are appointed on the approval of the Eye and Ear CEO prior to membership commencement.
2. The HREC shall provide an annual report and a 6 monthly report to the Eye and Ear Board including:
    - number of meetings
    - number of projects reviewed, approved and rejected
    - categories of research (eg drug/device, psychosocial)
    - monitoring procedures for ethical aspects of research in progress and any problems encountered by the HREC in undertaking its monitoring role
    - description of any complaints received and their outcome
    - description of any research where ethical approval has been withdrawn and the reasons for withdrawal of approval
    - any emerging issues
3. The HREC will provide reports to the Australian Health Ethics Committee (AHEC) in accordance with the requirements of the NHMRC.
4. The HREC will provide reports to the Health Complaints Commissioner in accordance with the requirements of the Health Records Act 2001 (Vic).
5. The HREC will provide reports to the Australian Bureau of Statistics in accordance with the requirements of the Australian Government.
6. The HREC Membership, Meeting Dates, Terms of Reference and Standard Operating Procedures will be posted on the Eye and Ear website as a minimum.

Appealing an HREC Decision

Principal Investigators can appeal a decision of HREC. In doing so, the PI must state the grounds on which the appeal is being made (ie. scientific merit or ethical review).

In the first instance, a request for reconsideration of an HREC decision should be made to the HREC Chair. The HREC shall reconsider the decision and the researcher shall have the opportunity to personally present his or her case and bring supporting documents to the next scheduled HREC meeting. If after reconsideration, the researcher still wishes to appeal the decision the following procedure shall be followed:

1. Appeals must be made in writing by the PI to the HREC Chair within 30 days of notification of the decision and include the grounds on which the appeal is being made.

2. On receipt of an appeal, the HREC Chair shall supply all relevant material to the CEO of the hospital.
3. The CEO shall convene an appeals panel, which shall consist of the CEO, two appointees of the CEO reflecting the principles of broad inclusion in decision making outlined in the National Statement on Ethical Conduct in Human Research (2007 and as amended) and a researcher expert in the discipline of research under consideration and independent of the decision under review.
4. The appeals process is not a court of law and neither the hospital nor the appellant shall have legal representation. It is desirable however that a member of the appeals committee be or have been a legal practitioner.
5. Any costs of the appeals committee shall be shared equally between the hospital and the appellant.
6. The appellant shall appear before the appeals Committee and state his or her case. Members of the Committee shall be able to ask questions of the appellant.
7. Once the appellant has stated his/her case and answered questions of the committee, the appellant shall leave the room. The Committee shall deliberate and may have up to 14 days to reach a final decision. The panel will make a recommendation to the HREC Chair following the review. This recommendation will be considered by the HREC at the next meeting. The appellant will be formally notified of the final decision, including the reasons. The possible outcomes include:

   a. The appeal is dismissed; or

   b. The appeal is upheld and the panel makes recommendation to resolve the issues based on the findings of the panel. The panel does not have the authority to approve an ethics application, but may choose to refer an ethics application to an independent ethics committee for re-review. If the panel requests that a second ethical review is required as a recommendation of the investigation, an alternative HREC with suitable expertise and no prior involvement in the matter will be invited to undertake this review. The panel or CEO cannot reverse the final determination of any HREC.

Outcomes:

To ensure that the Eye and Ear HREC meetings are conducted in compliance with the National Statement and other meeting protocols, the paperwork and outcomes are notified to researchers in a timely fashion, and the record keeping provides a full and accurate picture of HREC decisions and activities.

Definitions:

HREC Human Research Ethics Committee

RO Research Office

PI Principal Investigator

Standards:

National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (2007 and as amended)

Public Record Office Victoria (PROV) Public Record Office Standard (PROS) 12/05 (2012)

National Standard 1 – Governance (NSQHS)

Legislation:

Current legislation may be sourced at http://www/austlii.edu.au

Health Records Act 2001 (Vic)

Freedom of Information Act 1982 (Vic)

Linked Policy & Procedure:

Research Policy

HREC Procedure for Handling Conflict of Interest in Ethical Review of Research

HREC Terms of Reference

Approval / Committees:

Executive Director Medical Services and/or Director Medical Services

Chair, Human Research Ethics Committee

Responsible Executive:

Executive Director Medical Services/Chief Medical Officer

Evaluation:

This procedure will be reviewed to ensure adherence to the National Statement.

Procedure Review:

This procedure will be reviewed triennially.

Key Words for Search:

HREC, research, record keeping,

Authors / Contributors:

Name	Position	Service / Program
Dr David Marty	Director Medical Service	Medical Services
Dr Marc Sarossy	Chair, Human Research Ethics Committee	Medical Services
Kerryn Baker	Administrative Officer	Research Office
Dr Andrea Johannessen	Research Manager	Research Office

Policy / Procedure Details:

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