

Aim

The Royal Victorian Eye and Ear Hospital (Eye and Ear) affirms its commitment to the highest standards of medical research, including the strict observance of relevant ethical principles and practices. To this end, the Eye and Ear shall appoint and maintain a Human Research Ethics Committee (HREC), which shall function with autonomy appropriate to its role and in accordance with the National Statement on Ethical Conduct in Human Research 2007 as amended (National Statement) and with these terms of reference.

Scope of responsibility

The HREC has been established to conduct scientific and ethical review of:

- a) proposals for human research to be undertaken at or under the auspices of the Eye and Ear and/or campus research partners submitted by either affiliated or non-affiliated researchers; and
- b) human research to be undertaken at other agreed upon sites under individual arrangements;

and endorse applications to the Therapeutic Goods Administration (TGA) for access to unapproved therapeutic goods via the Authorised Prescriber Scheme.

Research projects considered may include, but are not limited to, research involving medicines, medical devices, biologicals, medical radiation and imaging, surgical procedures, biological samples, access to health information, as well as epidemiological and psychosocial investigations.

The Eye and Ear shall appoint sufficient staff and provide sufficient facilities for a Secretariat (the Research Office (RO)) to act on behalf of the Committee.

Objectives

The objectives of the Human Research Ethics Committee are:

- a) ensure that the design and conduct of any human research that it reviews within the scope of its responsibilities, conforms with the National Statement as well as other relevant national codes of human research ethics and also with the ethical standards to which the Eye and Ear is committed;
- b) assess projects submitted to it for review in accordance with the National Statement and any relevant guidelines and legislation in order to determine their scientific and ethical acceptability;
- c) ensure that participants in any human research that the HREC reviews and approves are afforded the respect and protection that is due to them;
- d) facilitate and foster human research that is of benefit to Australian communities;
- e) ensure that any decision it makes complies with relevant Victorian and Australian laws.
- f) Impact on Patient Safety is considered in all Committee business making decisions.

Functions

In fulfilling these objectives, the HREC will:

- a) provide independent, competent and timely review of research projects involving humans in respect of their ethical acceptability and alignment with the National Statement;
- b) require that participants in all reviewed and approved human research projects will be afforded the protection and respect that is due to them;
- c) following review and consensus decision making, advise researchers whether or not reviewed research proposals meet relevant ethical standards and have or have not been approved and provide reasons for those decisions in terms of where they might not meet the National Statement;
- d) provide ethical oversight, monitoring and advice for research projects involving humans;
- e) implement systems to promote the efficient ethical review of multicentre research projects and associated research governance and site specific procedures in order to minimise unnecessary duplication of ethical review of human research;
- f) delegate to a subcommittee any of its powers and functions that are capable of being delegated in order to assist in the expeditious ethical review of research proposals. The HREC will remain responsible and accountable for the activities and recommendations of any subcommittees;
- g) consider issues referred by the CEO and/or Board and, where appropriate, provide advice on policy issues with ethical implications;
- h) promote a deeper understanding of ethical issues related to research within the Eye and Ear through educational activities;
- i) review and approve applications from individual medical practitioners to the TGA for access to unapproved therapeutic goods in conjunction with the Eye and Ear Pharmacy Department and Executive Director Medical Services.

Reporting relationships

The Human Research Ethics Committee shall function with autonomy appropriate to its role and in accordance with the National Statement and with these terms of reference.

The HREC acts by way of delegated authority of the Chief Executive Officer (CEO) of the Eye and Ear and via the CEO to the Eye and Ear's Board.

Membership

The membership of the HREC shall conform to the requirements of the National Statement and shall include, as far as possible, equal numbers of men and women, at least one-third of whom are not Eye and Ear employees.

1.1 The Committee shall include the following members:

- a) Chair with suitable experience, appointed by the CEO;
- b) at least two members who are lay people, one man, one woman, who have no affiliation with the Eye and Ear and are not currently involved in medical, scientific, academic or legal work;
- c) at least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people, a nurse or allied health professional;

- d) at least one member who performs a pastoral care role in a community - for example a Minister of Religion or Aboriginal elder;
 - e) at least one member who is a lawyer, and who is not engaged by the Eye and Ear; and
 - f) at least two members with current research experience, that is relevant to the type of research to be considered at the meetings they attend.
- 1.2 Wherever possible, one or more of the members listed above should be experienced in reflecting on and analysing ethical decision making.
- 1.3 Where required, the HREC may seek advice and assistance from appropriate Expert Reviewers to assist with the review of a project. However, the HREC must be satisfied that such experts have no conflicts of interest, or have declared any conflicts of interest, in relation to the project under consideration arising from any personal involvement or participation in the project, any financial interest in the outcome or any involvement in competing research. Such person(s) is required to provide an undertaking of confidentiality and is not entitled to decide on any matter.
- 1.4 Appointment of Members
- The Eye and Ear may recruit members for the HREC and shall appoint them on such terms and conditions as it determines and will:
- a) adopt open, fair and transparent processes, for applications and appointments of members;
 - b) oversee the appointment of one or more Deputy Chair positions, who will be a current HREC member appointed by the CEO. In the absence of the Chair or if the Chair is conflicted, one or more of the Deputy Chair performs the role and duties of the Chair;
 - c) convene a selection committee, consisting of at least two, of the following; HREC Chair, Executive Director Medical Services, Research Manager and an HREC member and will review the prospective applicant's Curriculum Vitae, and may consult with the HREC members in order to make a recommendation to the Eye and Ear CEO;
 - d) invite prospective members to attend a meeting of the HREC as an observer before the recommendation is made;
 - e) ensure members are appointed by the CEO, for a term of between one and three years with the option of future terms. However, future terms are not guaranteed. Appointments shall allow for continuity, the development of expertise within the HREC, and the regular input of fresh ideas and approaches;
 - f) ensure the Chair is nominated for appointment by the Executive Director of Medical Services and appointed by the CEO;
 - g) members may resign their membership by written notice to the Research Office, at least 3 months in advance; and
 - h) manage the appointment of any member that may be revoked if the CEO is of the opinion that:
 - i. it is necessary for the proper and effective functioning of the HREC; or
 - ii. the person is not a fit and proper person to serve on an HREC.

Members are appointed to a single category of membership. Additional members may be appointed to ensure the HREC has the expertise required to assess the applications submitted for consideration.

1.5 Conditions of Appointment

Members other than the Chair and Deputy Chair (if required to take on obligations of Chair) are not remunerated for their contribution to the Committee.

Members shall receive a formal notice of appointment that includes:

- a) the date of appointment;
- b) length of tenure;
- c) assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of their duties as a HREC member; and
- d) conditions of their appointment including:
 - i. familiarising themselves with National Statement and other guidelines as provided;
 - ii. preparing for and attending scheduled meetings; or if unavailable, providing comments;
 - iii. attend continuing education or training in research ethics at least every 3 years;
 - iv. an assurance of confidentiality on undertaking their appointment (all matters of which they become aware during the course of their work on the HREC will be kept confidential). A copy of the Eye and Ear confidentiality agreement will be required to be signed and dated and returned to the HREC Secretary; and
 - v. declaration of any conflicts of interest, which exist at the time or may arise during their tenure on the HREC. These may be made to the Chair, HREC Secretary or at an HREC meeting if the conflict of interest relates to a specific research project. A Conflict of Interest Declaration will be required to be signed and updated annually and returned to the HREC Secretary. If any member announces a conflict of interest, he/she may be required to leave the room during the discussion and decision making process relating to the conflict of interest.

Upon appointment, members are provided with the following documentation:

- a) HREC Terms of Reference;
- a) National Statement on Ethical Conduct in Human Research;
- b) list of HREC members' names and contact information for the RO and HREC Secretary;
- c) Relevant information including web links to HREC processes, state and national guidelines and legislation;
- d) Confidentiality Agreement;
- e) Conflict of Interest Declaration; and
- f) Privacy Statement.

Members must agree to their name and category of Committee membership being made available to the public, including publication on the Eye and Ear website research page.

5.7 Chair and Deputy Chair Responsibilities

The Chair must not have other responsibilities that impair the HREC's capacity to fulfil its obligations under the National Statement and fulfil roles and carry out the functions set out in these Terms of Reference.

The key responsibilities of the Chair are to ensure that:

- a) HREC decisions are informed by an exchange of views from those members who comprise the minimum membership, whether in full attendance or through the receipt and consideration of submissions from those members who cannot be present. Achieving such decisions requires that the Chair actively engages all members, elicits their views, and communicates their responses to other members;
- b) the HREC endeavours to reach decisions by general agreement. Accordingly, the Chair will need to facilitate the expression of opinion from all members, identify points of agreement and of disagreement and judge when a sufficient degree of agreement has been reached;
- c) the manner in which the HREC communicates with investigators and decisions about inviting investigators to attend HREC meetings are appropriate; and
- d) members of the committee undertake ongoing training and continuing education related to research ethics.

The Chair is remunerated for time spent on administrative work performed out of session that supports the Committee. In the absence of the Chair, the Deputy Chair may also be remunerated.

5.8 HREC Member Responsibilities

All HREC members must:

- develop familiarity with the National Statement;
- prepare for, attend and contribute to meetings;
- decide, in his or her own judgment, whether proposals meet requirements of the National Statement and are ethically acceptable;
- provide opinions in advance if not attending an HREC meeting;
- attend continuing education/training; and
- disclose all actual, real or perceived conflicts of interest.

5.9 Orientation of HREC Members

New HREC members are provided with orientation following their appointment.

Orientation involves some or all of the following:

- a) introduction to other HREC members prior to the HREC meeting;
- b) informal meeting with HREC Chair to explain their responsibilities as an HREC member, the HREC processes and procedures;
- c) an opportunity to sit in on HREC meetings before their appointment takes effect;
- d) 'partnering' with another HREC member in the same category; and
- e) priority given to participate in training sessions.

Meetings

A quorum shall consist of eight members representing all categories of membership, where possible.

The HREC will meet at least six times per year and will publish the dates of its meetings and submission closing dates for applications.

The HREC Secretary will attend all HREC meetings and will record the discussion and resolutions of the committee in the minutes.

HREC Members are expected to give at least 3 weeks' notice prior to non-attendance at a meeting. If the member is one of the eight core members, they should still expect to receive all the relevant meeting papers and take the opportunity to contribute their views so that these can be recorded and considered.

Decisions at meetings must be made following an exchange of opinions from each of the members who constitute the minimum membership, whether at a face to face meeting, by teleconference or videoconference or where one of those members is absent, by the receipt and consideration of that member's views.

The HREC Secretary will record decisions about approval, amendment or rejection of proposals, with reasons for those decisions linked to the relevant sections, chapters or paragraphs of the National Statement where possible.

Procedures

The HREC shall establish, implement and document its working procedures concerning:

- frequency of meetings;
- attendance at meetings;
- conduct and structure of meetings and deliberations;
- preparation of agendas and minutes;
- timely distribution of papers prior to meetings;
- presentation of applications for ethical review:
- timely consideration and review of applications;
- managing conflicts of interest;
- communicating with researchers, including face to face, by telephone and in writing (including email);
- reporting on its activities to the Institution;
- methods of decision making;
- prompt notification of decisions;
- record keeping;
- monitoring of approved research;
- reporting and handling of adverse occurrences;
- receiving and handling of complaints;
- advising institution(s) or organisation(s) of decisions to withdraw ethical approval of a research project;
- attendance, as observers, of people other than members or researchers;
- fees, if any, to be charged; and
- confidentiality of the content of protocols and of Committee proceedings.

Subcommittees

To assist the HREC in its work, the following subcommittees may provide advice, recommendations and/or decisions:

- Low Risk Research Subcommittee
- Such other subcommittees as deemed necessary by the HREC

The HREC Secretariat shall establish procedures for the workings of these subcommittees and submit their Terms of Reference to the HREC for approval.

9. Reports Communications and Records

The HREC shall report to the Eye and Ear Board twice per year via the CEO.

The Chair of the HREC will review and approve any reports of activities of the HREC, whether to the Eye and Ear, the NHMRC or to the Health Complaints Commissioner (HCC) in Victoria.

The HREC, through the Chair, may at any time bring to the attention of the CEO any issues of significant concern that merit prompt consideration and attention.

The HREC shall report at least annually to the NHMRC information relevant to its ethical review processes as required under section 5.7.4 of the National Statement.

Evaluation shall focus on the Committee's performance against its Terms of Reference, with particular emphasis on achievements against the Committee's purpose and objectives and the National Safety and Quality Health Service Standards (standard 1), the Clinical Governance Standard.

10. Review

Last Reviewed: April 2020

Next Review: April 2022