


<p>The Royal Melbourne Hospital Human Research Ethics Committee</p> <p>TERMS OF REFERENCE</p>	 <p>The Royal Melbourne Hospital</p>
	<p>Tier 4 Committee</p>

Objectives

The Royal Melbourne Hospital Human Research Ethics Committee (RMH HREC) has been established by RMH in exercise of its commitment to the conduct of human research in accordance with the highest scientific and ethical standards. The RMH HREC is administered by the Ethics Office functional area of the RMH Office for Research.

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

- Proposals for human research to be undertaken at or under the auspices of RMH; and
- Proposals for human research received by the HREC in the exercise of its function as a certified HREC under the NHMRC National Certification Scheme for ethical and scientific review of multi-centre research under the National Mutual Acceptance (NMA) Scheme of Australia. NMA is designed to eliminate unnecessary duplication of ethics review of human research in accordance with the requirements of the National Statement on Ethical Conduct in Human Research (2023) as amended from time to time (National Statement) and in effect as of 1 January, 2024.

The RMH HREC has been certified by the NHMRC as compliant with the National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-centre Human Research throughout Australia. The RMH HREC is certified for review of the following categories of research:

- Clinical trials phase I, II, III & IV
- Clinical trials drugs and devices
- Clinical trials surgery
- Clinical trials other
- Clinical interventional research other than clinical trials
- Population health and/or public health
- Qualitative research
- Mental health
- Paediatric research
- Other health and medical research including basic research, epidemiological research, health service improvements and observational studies.

The impact on patient care and safety is always considered in discussions and decisions in the context of harm, discomfort, inconvenience and burden in accordance with the requirements of the National Statement. The members of this committee must adhere to the Melbourne Health Values of *People First, Lead with Kindness, Excellence Together*.

Roles

The RMH HREC roles are to:

- Ensure that the design and conduct of any human research that it reviews within the scope of its responsibilities conform with the National Statement and other relevant national codes of human research ethics, as well as with the ethical standards to which RMH is committed.
- Ensure that participants in any human research that the HREC reviews and approves are accorded the respect and protection that is due to them.
- Facilitate and foster human research that is of benefit to Australian communities.
- Ensure that any decision it makes complies with relevant Victorian and Australian laws.

In fulfilling these roles, the HREC will:

- Receive and review proposals for human research projects to determine whether they meet all relevant ethical standards.
- Ensure it is sufficiently informed on all aspects of a research proposal, including its scientific and statistical validity, before deciding whether a proposal is both acceptable on ethical grounds and that it conforms with the National Statement.
- Ensure that participants in all reviewed and approved human research projects are accorded the protection and respect that is due to them.

- Advise researcher applicants whether reviewed research proposals meet relevant ethical standards and whether the project has or has not been approved and provide reasons, linked to the National Statement, for those decisions.
- Determine, in relation to each reviewed and approved research project, that there will be mechanisms to monitor the conduct of the research and that the frequency and type of those mechanisms reflect the degree of risk and burden to participants.
- Offer relevant advice and assistance to other institutions without formally constituted HRECs.
- Implement systems adopted by RMH to promote the efficient ethical review of multicentre research projects in demand to minimise unnecessary duplication of ethical review of human research.
- Have the authority to delegate any of its activities that are capable of being delegated to assist in the expeditious and effective ethical review of research proposals. The HREC will remain responsible and accountable for the delegated activities and recommendations.
- Consider issues referred by the RMH Executive and, where appropriate, provide advice to RMH Executive especially on policy issues with ethical implications in any research endeavour.
- Provide a forum and due process in which [staff, patient, carer, student] concerns regarding ethical issues in research can be considered and investigated; and
- Promote a deeper understanding of ethical issues related to research within RMH through educational activities and forums as requested or necessary.

Membership

The RMH HREC will be constituted in conformity with the National Statement. The HREC will have at least eight (8) members and must include:

- a. a chairperson, with suitable experience, including previous membership of an HREC where possible, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement.
- b. two people who bring a broader community or consumer perspective and who have no paid affiliation with the institution.
- c. a person with knowledge of, and current experience in, the professional care or treatment of people; for example, a nurse, counsellor, or allied health professional.
- d. a person who performs a pastoral care role in a community including, but not limited to, an Aboriginal and/or Torres Strait Islander elder or community leader, a chaplain or a minister of religion or other religious leader.
- e. a qualified lawyer, who may or may not be currently practicing and, where possible, is not engaged to advise the institution on research-related or any other matters.
- f. two people with current research experience that is relevant to research proposals to be considered at the meetings they attend and
- g. additional members as required from time to time to assist with scientific review and ethical decision making.

RMH will ensure that one or more of the appointed members are experienced in reflecting on and analysing ethical decision-making.

The RMH Executive will appoint one member to serve as the Chairperson and at least one member to serve as Deputy Chairperson on such terms and conditions as the RMH Executive determines.

RMH may add to the membership such other persons as is necessary to ensure that the HREC has access to the expertise necessary to enable it to address the ethical issues arising from the categories of research it is likely to consider. In addition, and as far as practicable, the RMH HREC will ensure the HREC membership has diversity and that a minimum of one third of the HREC are from outside the RMH.

Appointment

RMH uses open and transparent processes including advertising for membership and appointing members.

All appointments to the HREC will be made by the Chief Executive (CE) in consultation with the Executive Director responsible for the Research portfolio and endorsement by the Director, Office for Research (or delegate). All HREC members will be nominated and appointed personally for their expertise and not in a representative capacity.

Members are appointed for terms, each of three years, and are eligible for reappointment at the end of each 3-year term.

Where a member is appointed to fill a casual vacancy ('the casual member') that appointment shall expire at the time when the previous member's term would have expired. The casual member shall then be eligible for appointment for the following term.

Members will receive a formal notice of appointment that will include an assurance by RMH of legal protection for any liability that may arise during the *bona fide* conduct of their duties. Professional indemnity insurance is provided by RMH for all HREC members in relation to liabilities that arise during *bona fide* conduct of their duties as HREC members.

No fees are payable to members, but approved out of pocket expenses, such as car parking costs, are met by RMH.

Members who are absent from three successive meetings of the HREC without notification to the Chair or the Office for Research Ethics Office will be subject to review of their membership.

Members may resign their membership by written notice to the Chair. The appointment of any member may be terminated if any member of The RMH Executive is of the opinion that the termination is necessary for the proper and effective functioning of the HREC.

Members Responsibilities and Entitlements

Each member is responsible for deciding whether, in his or her judgment, a proposal submitted to the HREC meets the requirements of the National Statement and is ethically acceptable.

Each member will be provided with an induction and orientation to the functions of the HREC and be offered the opportunity of being assisted by a current HREC member as a mentor.

Each member has a responsibility to:

- a. disclose at any time to the HREC any conflicts of interest that may impact the HREC's review of a research proposal.
- b. protect the confidentiality of information received in the exercise of their duties.
- c. remain up to date with the National Statement and other relevant codes, guidelines and legislation.
- d. prepare for and attend HREC meetings or, if unavailable, provide opinions on the ethical acceptability of research proposals and
- e. undertake continuing education in human research ethics throughout their tenure.

Chair and Deputy Chair Responsibilities and Entitlements

In addition to the responsibilities and entitlements as members, the Chair and Deputy Chair will have the following responsibilities:

- The Chair must not have other responsibilities that will impair the HREC's capacity to fulfil the obligations under the National Statement and fulfil roles and carry out the functions set out in these Terms of Reference.
- Appropriate modest remuneration shall be paid to the Chair in recognition of their significant responsibility in overseeing the operations of the HREC.
- The Chair is responsible for ensuring that 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 from some of 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.

As the HREC endeavours to reach decisions by general agreement, which need not involve unanimity, 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 general agreement has been reached.

The Chair is responsible for guiding the manner in which the HREC communicates with investigators. They are also responsible for the decision to conduct individual meetings with investigators as well as inviting investigators to attend HREC meetings.

The Deputy Chair should support the Chair in the performance of, and be capable of fulfilling, the responsibilities of the Chair whenever the Chair cannot attend meetings or perform any other function.

Meetings

The HREC will meet at least once per month, except for January. The dates of submission closing and meeting dates are published on the RMH publicly facing website.

Achieving a quorum

The quorum at each HREC meeting shall be 8 members, including at least one member from each of categories (a), (c), (d) and (e) and two members from categories (b) and (f) above, present either in person or via electronic/technical means. Where there is less than full attendance of the minimum membership at a meeting, the Chair should be satisfied, before a decision is reached, that the views of those absent who belong to the minimum membership have been received and considered. Those absent that belong to the minimum membership will be provided with a copy of the meeting agenda and a set of the meeting papers.

Observers to the Meeting

The HREC welcomes the attendance of investigators and other visitors as observers to its meetings. Anyone wishing to attend a meeting of the HREC as an observer is required to notify Ethics Office Management of their request in advance and in writing. The Ethics Office Manager will discuss the request with the Chair before approval is granted for the visitor in question. All visitors to a HREC meeting will be asked to sign a Confidentiality Agreement prior to attendance at the meeting and will be provided with electronic access to the meeting papers. The attendance of visitors is noted on the minutes of the relevant HREC meeting.

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 the member's views.

The HREC will endeavour to reach decisions by general agreement, which need not involve unanimity.

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

The members of the committee will undertake their work in accordance with relevant RMH policies, including the RMH Values and Mission.

Record Keeping

The RMH retains electronic copies of all research submissions and HREC meeting minutes. Copies of the electronically signed HREC meeting minutes are kept in the Office for Research Shared Drive with restricted access indefinitely. Electronic copies of HREC meeting minutes and individual complete research project applications are stored on the Office for Research Shared Drive as provided by RMH. This drive is only accessible to authorised staff members of the Office for Research.

Reporting

The HREC is accountable to the RMH Executive for the exercise of its functions and the fulfilment of its roles. The HREC will regularly provide copies of the minutes of its meetings to the RMH Executive and Governing Body in accordance with National Standard requirements.

The HREC will report to the RMH Executive as requested. The report will contain a summary account of:

- a. the number of research ethics proposals received, reviewed, approved.
- b. any complaints received from either researchers about the conduct of the HREC or from participants or others about the conduct of research approved by the HREC.
- c. any changes in membership of the HREC.
- d. any changes in the procedures used for the performance of its functions and
- e. any changes in staffing levels and personnel who provide administrative support to the HREC.

This annual report will also include an evaluation of the performance of the HREC identifying any factors, including the level of administrative support that have affected or in the next year may affect the integrity and efficiency of the HREC's performance.

The Chair of the HREC will review and approve any reports of activities of the HREC, whether to RMH, to the NHMRC or to Safer Care Victoria.

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

Administrative Support

Administrative support for the HREC will be provided by the Office for Research.

Committee Terms of Reference and Evaluation

Terms of reference to be reviewed every two years and notified to the Non-Clinical Policy Committee for endorsement and upload to RMH electronic document libraries consistent with the RMH Quality Framework.

Alignment with RMH Strategic Goals and National Safety and Quality Healthcare Standards

RMH Strategic Goals (Select the relevant area)		NSQHS (2nd Ed.) National Standards (Select the relevant standard only)	
<input checked="" type="checkbox"/> A great place to work, a great place to receive care <input checked="" type="checkbox"/> Realising the potential of the Melbourne Biomedical Precinct <input type="checkbox"/> Becoming a digital health service <input type="checkbox"/> Remain sustainable (Financial and Environmental) <input type="checkbox"/> Home First		<input checked="" type="checkbox"/> Standard 1 - Clinical Governance <input checked="" type="checkbox"/> Standard 2 - Partnering with Consumers <input type="checkbox"/> Standard 3 - Preventing and Controlling Infections <input type="checkbox"/> Standard 4 - Medication Safety <input type="checkbox"/> Standard 5 - Comprehensive Care <input type="checkbox"/> Standard 6 - Communicating for Safety <input type="checkbox"/> Standard 7 - Blood Management <input type="checkbox"/> Standard 8 - Recognising and Responding to Acute Deterioration <input checked="" type="checkbox"/> The National Clinical Trials Governance Framework	
Select Clinical Governance Domain to which applies to your Committee			
<input checked="" type="checkbox"/>	Clinical Practice	<input checked="" type="checkbox"/>	Risk Management
<input checked="" type="checkbox"/>	Consumer Partnership	<input checked="" type="checkbox"/>	Workforce
<input checked="" type="checkbox"/>	Leadership and Culture		
Reviewer:	Ethics Office Manager	Last review date:	September 2024
Authoriser:	RMH Executive Director of Research	Next review date:	September 2026

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