Eastern Health

HUMAN RESEARCH ETHICS COMMITTEE

TERMS OF REFERENCE

1. Establishment

The Eastern Health Human Research Ethics Committee (HREC) has been established by the Board of Directors of Eastern Health to exercise its commitment to the conduct of human research according to the highest scientific and ethical standards and to protect the welfare and rights of participants in research.

The HREC is established in accordance with the policy framework of Eastern Health, and operates within the guidelines of the National Health and Medical Research Council (NHMRC).

The HREC exercises the authority delegated by the Board of Directors to fulfil the roles and carry out the functions as detailed in these Terms of Reference and in accordance with the Eastern Health Strategic Plan and Values. The HREC reports to the Board through the Executive Director Eastern Health Institute and Chief Executive.

The 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 HREC has been established to conduct scientific and ethical reviews of proposals for human research:

- to be undertaken at or under the auspices of Eastern Health; and
- received by the HREC in the exercise of review processes accepted, accredited or certified for the purposes of any other system designed to eliminate unnecessary duplication of ethics review of human research, including the National Mutual Acceptance Program operating in Australia.

When requested the HREC may also conduct ethical review of proposals for human research undertaken under the auspices of external organisations that, for example, do not have their own fully constituted HREC.

2. Function

The function of the HREC is to:

- ensure that the design and conduct of any human research that it reviews is within the scope of its responsibilities, and conforms with the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2023 – under rolling review) (National Statement) and other relevant national codes of human research ethics as amended from time to time, and with the ethical standards to which Eastern Health 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 and broader communities; and
- ensure that any decision it makes complies with relevant Victorian and Australian laws.

In fulfilling these responsibilities, the HREC will:

- receive and review proposals for human research projects to determine whether they meet all relevant ethical standards;
- ensure that it is sufficiently informed on all aspects of a research proposal, including its level of risk to participants and scientific and statistical validity, before deciding whether a proposal is acceptable on ethical grounds and that it complies with the National Statement;
- advise Eastern Health and researcher applicants whether or not the research proposals

reviewed meet relevant ethical standards and have or have not been approved and provide reasons, linked to the National Statement, for those decisions;

- determine, in relation to each reviewed and approved research project, the mechanisms in place to monitor the conduct of the research and ensure that the frequency and type of those mechanisms reflect the degree of risk to participants;
- offer relevant advice and assistance to other institutions without formally constituted HRECs;
- implement systems to promote the efficient ethical review of multi-centre research projects in order to minimise unnecessary duplication of ethical review of human research where able;
- establish and delegate to a sub-committee or sub-committees any of its powers and functions that are capable of being delegated by the HREC in accordance with the National Statement to assist in the timely and effective ethical review of both research proposals and research issues as may arise from time to time. The HREC will remain responsible and accountable for the activities and recommendations of any sub-committees;
- receive advice and reports to assist in determining whether a research project is acceptable on ethical grounds and meets all necessary scientific, legal, insurance and regulatory requirements, including from committees with relevant expertise e.g. Expert Advisory Committees or expert reviewers, with respect to research proposals;
- consider issues referred by the Executive Director Eastern Health Institute, Chief Executive or Board of Directors and, where appropriate, provide advice on policy issues with ethical implications;
- review research projects involving patients, employees, other parties external to Eastern Health, or resources;
- provide a forum in which the concerns of the Board of Directors, Chief Executive, Executive Director Eastern Health Institute, staff, students, researchers, patients and carers, and parties external to Eastern Health, regarding ethical issues in human research can be considered and investigated;
- promote a deeper understanding of ethical issues related to research across Eastern Health through educational activities;
- maintain records for all research activity reviewed by the HREC and its sub-committees including but not limited to higher-risk projects, and lower risk projects, registries, including audits and/or quality assurance activities, and staff surveys undertaken for the purpose of teaching and learning and/or internal Eastern Health use; and
- meet insurance obligations related to the conduct of HREC-approved activity.

3. Composition

The HREC will be constituted in accordance with the National Statement. The HREC will consist of at least eight (8) members appointed by the Board of Directors and will include:

a) a chairperson with suitable experience, including previous membership of a HREC, 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 Eastern Health and do not currently engage in medical, scientific, legal or academic work, and who are preferably from the community in which Eastern Health is located;

c) a person with knowledge of, and current experience in, the professional care or treatment of people, for example, a nurse, medical practitioner, 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, a minister of religion or other religious leader;

e) a qualified lawyer who may or may not be currently practising and, where possible, who is not engaged to advise Eastern Health on research-related or any other related matters; and

f) two people with current research experience that is relevant to research proposals to be considered at the meetings they attend.

The Board of Directors will appoint one member to serve as the Chair and up to two members to serve as Deputy Chairs.

The Board of Directors may appoint additional members if 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 required to consider.

As far as is practicable, the Chair should ensure that:

a) the HREC membership at each meeting has diversity, including gender diversity; and

b) at least one third of those participating in each meeting are from outside of the institution. (NS 5.1.36)

4. Appointment

The Executive Director Eastern Health Institute will recommend one member to serve as Chair and two members to serve as Deputy Chairs for appointment by the Board on such terms and conditions and for such a period as the Board determines.

The appointment of the Chair and Deputy Chair(s) from among the members will be reviewed annually by the Board of Directors.

In recruiting members to the HREC Eastern Health will adopt open and transparent processes including advertising for applications for membership and making appointments of members.

Members will be appointed for a term of up to three years and may be eligible for re-appointment by the Board subject to a review of performance and expertise at the end of each term, with continuity of membership to be encouraged.

All appointments to the HREC will be recommended to the Board by the Executive Director Eastern Health Institute and the Chief Executive. All members will be appointed for their expertise as individuals and not in a representative capacity.

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

No remuneration is payable to members.

Members who are absent from three successive meetings of the HREC without leave from the Chair will have their membership reviewed.

Members may resign their membership at any time by written notice to the Chair, who will notify the Board of Directors.

The appointment of any member may be terminated by the Board of Directors on the recommendation of the Chief Executive or Executive Director Eastern Health Institute, if that person considers it necessary for the proper and effective functioning of the HREC or that the person is not a fit and proper person to serve on the HREC.

5. Members' Responsibilities and Entitlements

Each member is responsible for deciding whether, in their judgment, a proposal submitted to the HREC meets the requirements of the National Statement and other relevant guidelines 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 to be assisted by a current HREC member as a mentor.

Each member has a responsibility to:

- sign a Committee Member confidentiality agreement annually;
- become and remain familiar with the National Statement, and consult other guidelines and

information relevant to the review of specific research proposals;

- disclose immediately to the Chair of the HREC any conflicts of interest that may impact the HREC's review of a research proposal;
- protect the confidentiality of information received in the exercise of their duties;
- remain up to date with the National Statement and other relevant codes, guidelines and legislation;
- prepare for and attend HREC meetings or, if unavailable, provide opinions on the ethical acceptability of research proposals; and
- undertake continuing education in human research ethics at least once every three years.

6. Chair and Deputy Chair Responsibilities and Entitlements

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

- 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 at the meetings or through the receipt and consideration of comments from those members who cannot be present (NS 5.2.5).
- 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 or consensus, 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. Some decisions may not be unanimous and a dissent will be recorded in the minutes of the meeting. Where requested by a dissenting member, the reasons for the dissent will also be recorded in the minutes of the meeting (NS 5.2.8).

The Chair is responsible for guiding the manner in which the HREC communicates with investigators (NS 5.2.13–14) and the decisions about inviting investigators to attend HREC meetings (NS 5.2.6).

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

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.

7. Meetings

The HREC will normally meet each month, with the exception of January, and will publish the dates of its meetings and submission closing dates for applications.

Meeting documentation, including the agenda, minutes of the previous meeting and other relevant documents, will be distributed to the committee members and attendees no less than 10 days prior to the meeting.

The proceedings of all meetings and all decisions will be minuted to reflect the work done by the HREC and these minutes will be confirmed by the HREC at the following meeting.

The members of the HREC will undertake their work in accordance with the National Statement, relevant legislation, including the Charter of Human Rights & Responsibilities Act 2006, and Eastern Health policies, including the Eastern Health Values and Code of Conduct.

8. Achieving a quorum

The quorum at each HREC meeting shall be the 8 members required to fulfil the minimum membership requirements set out in the National Statement (Sections 5.1.30), including at least one member from each of categories (a), (c), (d) and (e) and two members from categories (b) and (f), present either in person or by electronic means. No individual may represent more than one of the categories listed in 5.1.30 at any individual meeting, but may fill a different category at a separate meeting, so long as all minimum membership categories are represented at each meeting. Where there is less than full attendance of members from the minimum membership categories at a meeting, the chairperson must be satisfied that the views of the members who are not present have been received and considered by all members of the HREC participating in the meeting, before a decision is made. (Section 5.2.5).

9. Disclosure of Interest

Any member who has a direct or indirect interest, financial or otherwise, in a proposal or other matter considered by the HREC must declare that interest as soon as practicable. The member must withdraw from the discussion of the proposal unless invited by the Chair to attend the meeting. All declarations of interest and the absence of the member from the discussion of the matter must be recorded in the minutes of the meeting.

10. Observers in attendance at the meeting

The HREC welcomes the attendance of investigators and other visitors as observers to its meetings.

All visitors wishing to attend a meeting of the HREC as an observer are required to notify the HREC Chair of their request in advance and in writing and must declare any interest they may have in the matters being considered. The HREC Chair will review the request to attend a meeting and approve or reject the request. All visitors to a HREC meeting will be asked to sign a confidentiality agreement prior to attendance at the meeting. The attendance of visitors and the duration of their attendance must be recorded in the minutes of the relevant HREC meeting.

From time to time, investigators may be invited by the HREC Chair to attend the relevant part of a HREC meeting. Investigators may request the Chair's permission to attend the relevant part of a meeting.
All observers must leave the meeting at the request of the Chair if any matters are to be considered in closed session.

11. Decision Making

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 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 written or electronic form, with reasons for those decisions linked to the relevant sections, chapters or paragraphs of the National Statement.

The minutes of the HREC meeting are confirmed, or amended and confirmed, as a true record of proceedings and decisions made at the previous meeting of the HREC. The Chair of the HREC may consider and authorise actions arising from the draft minutes of a meeting to enable timely communication of outcomes to applicants.

12. Record Keeping

Eastern Health retains electronic copies of all research submissions and HREC meeting agendas and minutes. Electronic copies of HREC meeting minutes and each research project application are stored on the Office of Research and Ethics SharePoint Drive. This drive is accessible to

authorised staff members of the Office of Research and Ethics.

The retention and disposal of all HREC records, including email and electronic documents, shall be in accordance with the relevant legislation and Public Record Office of Victoria (PROV) standards and Eastern Health policy.

All HREC records shall be secured against tampering, unauthorised access and unlawful deletion.

The identity of the Chair, the administrative support person from the Office of Research and Ethics (as so called) and all members and their respective categories of membership shall be specified on the agenda and minutes of every meeting.

13. Reporting

The HREC is accountable to the Board of Directors for the exercise of its functions and the fulfilment of its roles.

The Chair of the HREC will review and approve any reports of activities of the HREC, whether to the Eastern Health Board of Directors; the Executive Director Eastern Health Institute; the Chief Executive; the NHMRC; or the Office of the Health Complaints Commissioner in Victoria.

All adverse events arising from any clinical trial or other research shall be reported to the Quality & Safety Committee at least quarterly.

The HREC will provide an annual report to the Board of Directors including a summary of:

- the number of research ethics proposals received, reviewed, approved;
- the nature of any adverse events reported to HREC under NHMRC Safety Guidelines 2016, the outcome and the action taken;
- any complaints received from researchers, participants or others about the conduct of research approved by the HREC;
- 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;
- any recommendations for changes to the HREC Terms of Reference;
- 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.

Through the Chief Executive or Executive Director Eastern Health Institute, the HREC Chair may at any time bring to the attention of Eastern Health any issues of concern that merit consideration and attention.

14. Administrative Support

Administrative support for the HREC will be provided by the research support team in the Office of Research and Ethics, Eastern Health Institute.

15. Procedures

In carrying out its functions, the HREC shall at all times:

- ensure that enquiries are made to researchers in a courteous and supportive manner, so as to develop mutual respect and regard for sound ethical practice;
- provide notice of the decisions of the HREC to the person/s nominated in the proposal in writing and in a reasonable time;
- determine the method of monitoring that is appropriate for each project;
- monitor projects that have received ethical approval to ensure that they conform to the approved protocol and that the researcher/s submits an application for approval of any amendments to the approved protocol.

16. Establishment of HREC Sub-Committees

The HREC has the authority to delegate to a sub-committee any of its powers and functions that are capable of being delegated in order to assist in the expeditious and effective ethical review of research proposals. The HREC will remain responsible and accountable for the activities and recommendations of any sub-committees, and will publish the dates of its meetings and submission closing dates for applications.

The composition, role, functions and procedures of sub-committees of the HREC shall be approved by the HREC. These committees report to the HREC through their Chair.

The responsibilities and entitlements applicable to the HREC members will apply to sub-committee members (refer Section 5).

Decisions by a sub-committee must be consistent with the National Statement, the terms of reference of the HREC and the terms of reference of the sub-committee. All decisions must be ratified by the HREC at the next scheduled meeting.

17. Expedited Review

The review of proposals where involvement in the research carries no more than low risk to participants, as defined by the National Statement, including the review of amendments to approved research protocols, may be considered through a review process conducted outside the normal scheduled HREC meetings. The review may occur at a sub-committee meeting or at an out-of-session review at the discretion of the Chair, who may seek advice from HREC members or others with relevant expertise before reaching a decision.

If a review of a proposal occurs through this review process, the decision must be considered and ratified by the HREC at the next scheduled meeting.

18. Suspension or Withdrawal of Ethical Approval

The HREC may suspend or withdraw ethical approval in accordance with the NHMRC Guidelines, Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods 2018 if:

- a research project is not, or cannot be, conducted in accordance with the approval; or
- the rights, safety or welfare of participants may be compromised.

If the withdrawal or suspension of ethical approval is being considered or if ethical approval is suspended or withdrawn, the Chair or Deputy Chair of the HREC will inform the investigator(s) and the relevant institution(s) or organisation(s) of such withdrawal or suspension and the reasons for the decision, and when appropriate, recommend to the relevant institution(s) or organisation(s) that the project approval be reinstated, suspended, or discontinued, or that other steps are taken.

Document History

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