

TERMS OF REFERENCE

Human Research Ethics Committee

Peninsula Care Goal	Effective
Peninsula Care Goal	Safe
Peninsula Care Goal	Personal
Peninsula Care Goal	Connected

1. Introduction

The Human Research Ethics Committee operates under the authority of the Executive Sponsor Research, in exercise of its commitment to the conduct of human research according to the highest scientific and ethical standards and operates in accordance with the National Statement on Ethical Conduct in Human Research (NHMRC 2023) (National Statement) and other relevant national codes of human research ethics as amended from time to time and also with the ethical standards to which Peninsula Health is committed.

2. Purpose

Conduct scientific and ethical reviews of:

- proposals for human research to be undertaken at or under the auspices of Peninsula Health
- proposals for human research to be undertaken at local institutions without their own Human Research Ethics Committee

Facilitate and foster human research that is of benefit to Australian communities

Ensuring that:

- the design and conduct of any human research that it reviews is within the scope of its responsibilities conforms with the National Statement and other relevant national codes of human research ethics as amended from time to time and also with the ethical standards to which Peninsula Health is committed.
- participants in any human research that the Human Research Ethics Committee reviews and approves are accorded the respect and protection that is due to them.
- any decision it makes complies with relevant Victorian and Australian laws.

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3. Definitions

National Standards Committee	Governance of a National Standard
Committee	Same structural level as National Standards committees however do not align with a National Standard.
Implementation Committee	High level committee that requires authorisation from Executive and is time limited to implement a specific action/project
Project Group	Established by Committees and/or Standard Leads as required and are time limited to manage a specific task/project. Project Groups report to any of the above
Safe	We provide a physically and emotionally safe service for consumers and staff
Personal	Our care and services are focused on consumers' individual needs and preferences
Effective	We provide the right care in the right way
Connected	We provide a smooth, integrated pathway with no surprises

4. Functions and Responsibilities

The Human Research Ethics Committee (HREC) is responsible for:

- Conducting ethical and scientific review of research projects involving human participants in a timely fashion and to ensure that the proposed research project strikes an appropriate balance between protecting the rights and wellbeing of research participants and facilitating research.

Note: Peninsula Health HREC does not review single-site drug or device trials conducted under the CTN or CTA schemes submitted on behalf of external organisations or investigators

- Operating and acting at all times in accordance with the National Statement and other relevant NHMRC guidelines and legislation as amended from time to time.
- Deciding whether participants in all reviewed and approved human research projects will be accorded the protection and respect that is due to them.

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- Advising Peninsula Health and researcher applicants whether or not reviewed research proposals meet relevant ethical standards and have or have not been approved and provide reasons, linked to the National Statement, for those decisions.
- Determining, 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 to participants.
- Ensuring that they are 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 conforms with the National Statement.
- Receiving advice and reports including from Independent Expert reviewers to assist in determining if a research project is acceptable on ethical grounds and meets all necessary scientific, legal, insurance and regulatory requirements from organisational committees with relevant expertise eg seeking Drugs and Therapeutics with respect to research proposals as deemed appropriate by the HREC Chair.
- Offering relevant advice and a HREC Review Only Service to other institutions/researchers upon request.
- Implementing systems to promote the efficient ethical review of research projects including mutual acceptance in the case of multi-centre research or acceptance of single ethical review processes for approval of multi-site clinical trials in order to minimise any unnecessary duplication in the review of that research.
- Implementing and oversee systems that support expedited review of low risk research and post-approval amendments, without the necessity for review by the full Committee in accordance with the National Statement.
- Considering issues referred by the Executive Sponsor Research.
- Providing a forum in which staff, consumer, carer, student concerns regarding ethical issues in research can be considered and investigated.
- Promoting a deeper understanding of ethical issues related to research within Peninsula Health through educational activities.
- Notify the institution upon becoming aware that there may be a conflict of interest involving the institution for which it is providing HREC Review.
- The Human Research Ethics Committee may seek information internally and externally and, where necessary, obtain external legal and professional advice to assist in undertaking its responsibilities.
- The Human Research Ethics Committee may refer items to other committees as required.

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- The Human Research Ethics Committee may oversee a Low Risk Ethics Review Panel as a sub-committee as required.
- The Human Research Ethics Committee may receive reports for review, noting or action.

Reports to

The Executive Sponsor Research authorises the Human Research Ethics Committee to perform activities within these Terms of Reference.

5. Membership

Minimum membership is prescribed by NHMRC (National Statement 2023, Section 5.1.30) and detailed below. Additional members at Peninsula Health are

Member/Role	Responsibilities
Executive Sponsor Research	Provides Executive oversight of the operations of the Human Research Ethics Committee
Pharmacist	Provides specific advice in relation to research involving medication

- The Human Research Ethics Committee shall be constituted as prescribed by the National Statement and will include at least eight (8) members, both men and women, namely:
 - a chairperson with suitable experience, including previous membership of an HREC, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement;
 - two people who bring a broader community or consumer perspective and who have no paid affiliation with the institution;
 - 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;
 - 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;
 - 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; and
 - two people with current research experience that is relevant to research proposals to be considered at the meetings they attend.
- additional members as required from time to time to assist in ethical decision-making.

Recruitment

- Peninsula Health will adopt open and transparent processes including advertising for applications for membership and making appointments of members;
- members are appointed for a term of three years, with continuity of membership be encouraged, with a maximum of 3 terms unless specifically approved by the Executive Sponsor

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- members contributions are assessed by the Executive Sponsor Research at the end of each calendar year against the Peninsula Health Key Performance Indicators for HREC members as amended from time to time;
- all members be provided with a copy of the Role Statement for HREC Members as amended from time to time;
- members will receive a formal notice of appointment that will include an assurance by the institution of legal protection for any liability that may arise in the course of the bona fide conduct of their duties;
- where a member has suggested an alternate member ('the alternate member') to attend those Committee meetings that the principal member is unable to attend, it is the responsibility of the principal member to:
 - advise the alternate member accordingly;
 - forward the documentation to the alternate member;
 - advise the Manager, Office for Research and Human Research Ethics Committee that the alternate member will be in attendance;
- It is the responsibility of the Chair to appoint alternate members in consultation with the absent member
- All nominations to the Human Research Ethics Committee will be made to and ratified by the Executive Sponsor Research on the recommendation of the Manager Office for Research
- Peninsula Health shall appoint Human Research Ethics Committee members personally, for their expertise and not in a representative capacity.
- Peninsula Health may add to the membership such other persons as is necessary to ensure that the Human Research Ethics Committee 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.
- Members who are absent from three successive meetings of the Human Research Ethics Committee without the approval of the Chair will undergo a review of membership status.
- Members may resign their membership by written notice to the Manager, Office for Research
- The appointment of any member may be terminated if the Executive Sponsor Research is of the opinion that:
 - it is necessary for the proper and effective functioning of the Human Research Ethics Committee; or
 - the person is not a fit and proper person to serve on a Human Research Ethics Committee

Members Roles and Responsibilities

- 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 is responsible to:
 - disclose to the HREC any conflicts of interest that may affect the HREC's review of a research proposal;

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- protect the confidentiality of information received in the exercise of his or her duties;
- become familiar with the National Statement and other relevant guidelines;
- prepare for and attend HREC meetings or, if unavailable, provide opinions on ethical acceptability of research proposals;
- undertake continuing education in human research ethics once every three years.
- The Manager and Office Coordinator Office for Research, are required to attend meetings of the Human Research Ethics Committee but are not members of the Human Research Ethics Committee and do not have voting rights.
- Other attendees at a meeting of the Human Research Ethics Committee may include staff of the Office for Research and such other persons as the Human Research Ethics Committee requests (including researchers who have a study under consideration) to attend. Any such attendees are not members of the Human Research Ethics Committee and do not have voting rights.

6. Term of Position / Appointment

Members are appointed for a term of three years, with continuity of membership encouraged, with a maximum of 3 terms unless specifically approved by the Executive Sponsor.

7. Chair

Substantive role

- Provide effective leadership
- Approve agenda prior to circulation
- Approve minutes prior to circulation
- The Executive Sponsor Research will also appoint from the appointed members one member to serve as Chair and another member to serve as Deputy Chairperson on such terms and conditions and for such a period as the Executive Sponsor determines.
- In addition to the responsibilities and entitlement 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.
- The Chair is responsible to ensure that Human Research Ethics Committee decisions are informed by an exchange of views from those members who comprise the minimum membership along with other members whether in full attendance or through the receipt and consideration from some of those members who cannot be present.
- As the Human Research Ethics Committee 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 and the decisions about inviting investigators to attend HREC meetings.

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Deputy Chair

- Takes on responsibility of chair at all times chair not available
- 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

8. Secretariat

Substantive role

- Prepare the agenda and relevant supporting documentation and notify members no less than 7 days prior to each meeting
- Minute taker
- Provide feedback to reporting clinical work groups regarding adoption of recommendations
- Ensure policy, procedure, guidelines are uploaded onto PROMPT
- The Office for Research provides Secretariat support to the Committee. The Manager, Office for Research is the Executive Officer to the Committee.

9. Frequency / Schedule

Monthly, or as otherwise arranged. From time to time issues may arise that require immediate consideration by the group. These issues may be addressed via email discussion, or by extraordinary meeting.

10. Duration

Approximately 2 hours.

11. Quorum

Attendance of 8 members as described in the National Statement.

12. Attendance and Proxies

Attendance:

Committee members should notify the secretariat if that are unable to attend their rostered meeting. A proxy may not attend unless they have had formal approval.

13. Meeting Procedure

- Meetings will be held monthly with the exception of January and November. Additional meetings may be scheduled as determined by the Chair to meet urgent requests for Human Research Ethics Committee review.
- If the Chair is absent from a meeting and no acting chair has been appointed, the members of the Human Research Ethics Committee present may choose one of them to act as chair for that meeting.
- The quorum at the Peninsula Health Human Research Ethics Committee meetings is 8 members present either in person or via other electronic/technical means and is inclusive of all categories of required membership.
- Meetings of the Human Research Ethics Committee may be held or participated in by conference call or similar means, as determined by the Chair.
- Any member or guest of the Human Research Ethics Committee who has a direct or indirect pecuniary interest in a matter being considered, or about to be considered, by the Human Research Ethics Committee at a meeting must, as soon as practicable after the relevant facts

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come to the person’s knowledge, disclose the nature of that interest and, unless the Human Research Ethics Committee agrees otherwise, recuse themselves from that meeting and, where relevant, not vote on the matter. The disclosure of interest must be recorded in the minutes of the meeting.

- The Human Research Ethics Committee 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.
- Guidance for researchers, including submission requirements and application submission, which are an integral component of the Human Research Ethics review process will be available to researchers on the Peninsula Health website and revised no less than on a yearly basis, to ensure accuracy and ease of accessible information for researchers.
- **Researchers may be invited for interview at the request of allocated reviewers or Chair.**
- The Human Research Ethics Committee will endeavour to reach decisions by consensus. In the absence of consensus, a resolution of the Human Research Ethics Committee must be supported by a simple majority of those Committee members present and voting. The Committee Chair does not have an additional casting vote. In the event of a tied vote, the matter will be referred to the Executive Sponsor Research for resolution.
- Decisions of the Human Research Ethics Committee may be made by circular or written resolution. A proposed circular resolution of the Human Research Ethics Committee is passed when a majority of those entitled to vote on the matter have voted in favour of the proposed resolution. The resolution is taken to be passed on the date, and at the time, when the last vote in favour to satisfy the majority threshold is passed.

14. Documentation

- The agenda and meeting papers shall be prepared and distributed by the Secretariat at least one week prior to the meeting
- Meeting documentation (including the agenda, minutes of the previous meeting and all other relevant documents) will be distributed to the members of the Human Research Ethics Committee and all attendees at least 7 days prior to each meeting.
- The proceedings of each meeting must be minuted and the minutes must accurately reflect the work and resolutions of the Human Research Ethics Committee.
- Written advice on the review outcome is to be provided to the researcher via email, following approval of the draft minutes within 7 days of the meeting.
- Prior to November in a given year: an annual meeting schedule for the following year must be distributed to all members of the Human Research Ethics Committee and required attendees.

15. Communication Plan

Feedback is provided to researchers within 1 week of the meeting.

16. Performance Evaluation

The Human Research Ethics Committee will conduct an annual review of these Terms of Reference and of its performance and provide a report arising from each review to Executive Sponsor Research for their consideration no later than November each year. Meeting attendance, approval times and communication of meeting feedback timelines will be included.

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17. Relevant National Standards

Standard 1: Clinical Governance
Standard 2: Partnering with Consumers
National Clinical Trials Governance Framework

18. Relevant Aged Care Quality Standards

Standard 1: Consumer Dignity and Choice
Standard 2: Ongoing Assessment and Planning with Consumers

19. Affiliated Audits / Reviews

Project audits may be undertaken as required

20. Mandatory or recommended training

For non-Peninsula Health members, volunteer mandatory training is required.

Document management	Position
Executive Sponsor:	Executive Director Medical Services and Clinical Governance
Document Owner:	Manager Office for Research
Document Author	Manager Office for Research
Approved by:	Executive Director Medical Services and Clinical Governance
Date Approved:	
Date created/revised in archived system:	

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