Human Research Ethics Committees

Terms of Reference

October 2026

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A. BACKGROUND

1. The Monash Health Human Research Ethics Committee A and Human Research Ethics Committee B (the Human Research Ethics Committees) operate under the authority of the Monash Health Research Strategy and Governance Group, in exercise of its commitment to the conduct of human research according to the highest scientific and ethical standards.

2. The Human Research Ethics Committees operate in accordance with the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2025) (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 Monash Health is committed.

B. PURPOSE AND ROLE

3. The purpose of the Human Research Ethics Committees is to conduct scientific and ethical reviews of:

   - proposals for human research to be undertaken at or under the auspices of Monash Health; and
   - proposals for human research received by the Human Research Ethics Committees in the exercise of their function as accredited Human Research Ethics Committees within the National Mutual Acceptance of multi-site research programme; and
   - proposals for human research received by the Human Research Ethics Committees 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.

4. The role of the Human Research Ethics Committees is to:

   (a) Ensure that the design and conduct of any human research that they review is within the scope of their responsibilities and 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 Monash Health is committed.

   (b) Ensure that participants in any human research that the Human Research Ethics Committees review and approve are accorded the respect and protection that is due to them.

   (c) Facilitate and foster human research that is of benefit to Australian communities.

   (d) Ensure that any decision they make complies with relevant Victorian and Australian laws.

C. SPECIFIC RESPONSIBILITIES

5. The Human Research Ethics Committees are responsible for:

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

   (b) 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.

(c) Deciding whether participants in all reviewed and approved human research projects will be accorded the protection and respect that is due to them.

(d) Advising Monash 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.

(e) 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.

(f) Ensuring that the Committees 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.

(g) 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 e.g., seeking Therapeutics Review and/or review by the Monash Health Technology Clinical Practice Committee and or Data Governance and Artificial Intelligence Committee with respect to research proposals as deemed appropriate by the Chair.

(h) Offering relevant advice and a HREC Review Only Service to other institutions upon request.

(i) 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.

(j) Implementing and overseeing systems that support expedited review of post-approval amendments, without the necessity for review by a full Committee in accordance with the National Statement.

(k) Considering issues referred by the Chief Medical Officer of Monash Health and, where appropriate, providing advice to the Chief Medical Officer especially on policy issues with ethical implications.

(l) Providing a forum in which staff, consumer, carer, and student concerns regarding ethical issues in research can be considered and investigated.

(m) Promoting a deeper understanding of ethical issues related to research within Monash Health through educational activities.

(n) Upon becoming aware that there may be a conflict of interest involving the institution for which they are providing HREC Review, notifying the institution.

D. AUTHORITY AND RELATIONSHIPS

6. The Monash Health Research Strategy and Governance Group authorises the Human Research Ethics Committees to perform activities within these Terms of Reference. The Monash Health Research Strategy and Governance Group reports directly to the Monash Health Research and Innovation

Council through the Chief Medical Officer. The reporting pathways of the Human Research Ethics Committees within the Monash Health Corporate Structure are depicted in Diagrams 1 and 2.

7. The Human Research Ethics Committees may seek information internally and externally and, where necessary, obtain external legal and professional advice to assist in undertaking their responsibilities.

8. The Human Research Ethics Committees may refer items to other committees as required.

9. The Human Research Ethics Committees will adhere to the Monash Health procedures for consumer complaints, research complaints and safety reporting. These procedures are to be made publicly accessible via: Forms Library | Monash Health.

E. MEMBERSHIP

E.1 Composition

10. The Human Research Ethics Committees membership will include a minimum of 8 members and include members from the following categories as stated in section 5.1.30 of the National Statement. Further, the membership composition will aim to reflect the diversity in the Australian community.

- 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;
- at least two (2) people who bring a broader community or consumer perspective and who have no paid affiliation with the institution;
- at least two (2) people with current research experience that is relevant to research proposals to be considered at the meetings they attend;
- at least one (1) person with knowledge of, and current experience in, the professional care or treatment of people; for example, a nurse, counsellor or allied health professional;
- at least one (1) 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;
- at least one (1) qualified lawyer, who may or may not be currently practicing and, where possible, is not engaged to advise Monash Health on research-related or any other matters;
- additional members as required from time to time to assist in ethical decision-making.

11. Monash Health may recruit members for the Human Research Ethics Committees in such manner and shall appoint them for such a period and on such terms and conditions as it determines, however in ordinary circumstances:

- Monash 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 one year, with continuity of membership from year to year to be encouraged;

- members are assessed by the Head, Research Operations in September each year against the Monash Health Key Performance Indicators for HREC members as amended from time to time;

- all members are provided with a copy of the 'Key Selection & Performance Criteria for Members of the Monash Health Human Research Ethics Committees' 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:

  (i) advise the alternate member accordingly;

  (ii) forward the documentation to the alternate member;

  (iii) advise the Head, Research Operations, HREC Executive Officers and Human Research Ethics Committee that the alternate member will be in attendance.

12. It is the responsibility of the Chair to appoint alternate members in consultation with the absent member.

13. All nominations to the Human Research Ethics Committees will be made to and ratified by the Chief Executive on the recommendation of the Director, Research and Innovation and Chief Medical Officer.

14. Monash Health shall appoint Human Research Ethics Committee members personally, for their expertise and not in a representative capacity.

15. Monash Health may add to the membership such other persons as is necessary to ensure that the Human Research Ethics Committees have access to the expertise necessary to enable them to address the ethical issues arising from the categories of research they are likely to consider.

16. Members who are absent from three successive meetings of the Human Research Ethics Committees without the approval of the Chair will undergo a review of membership status.

17. Members may resign their membership by written notice to the Head, Research Operations.

18. The appointment of any member may be terminated if the Chief Medical Officer of Monash Health is of the opinion that:

    - it is necessary for the proper and effective functioning of the Human Research Ethics Committees; or

    - the person is not a fit and proper person to serve on a Human Research Ethics Committee.

E.2 Members Responsibilities and Entitlements

19. 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.

20. 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.

21. Each member is responsible to:

    - disclose to the HREC any conflicts of interest that may affect the HREC's review of a research proposal;
    - protect the confidentiality of information received in the exercise of their 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.

22. Members who are not staff members of Monash Health may be offered an honorarium for each attendance at a committee meeting. The value of the honorarium will be determined from time to time by the Chief Medical Officer of Monash Health.

E.3 Chair

23. The Chief Medical Officer of Monash Health 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 Chief Medical Officer determines.

24. In addition to the responsibilities and entitlement as members, the Chair and Deputy Chair will have the following responsibilities.

25. 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.

26. 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, whether in full attendance or through the receipt and consideration from some of those members who cannot be present.

27. As the Human Research Ethics Committees endeavour 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.

28. 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.

29. 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.

E.4 Secretary

30. The Research Support Services Unit of Monash Health will provide Secretariat support to the Committees. The Head, Research Operations will have oversight of the secretariat support to the Committees.

F. OPERATIONAL PROCEDURES

F.1 Meetings

31. Meetings will be held monthly with the exception of January. Additional meetings may be scheduled as determined by the Chair to meet urgent requests for Human Research Ethics Committee review.

32. 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.

33. The quorum at Monash 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 membership.

34. Meetings of the Human Research Ethics Committees may be held or participated in by conference call or similar means, as determined by the Chair.

35. Any member or guest of the Human Research Ethics Committees 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 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.

36. The Human Research Ethics Committees 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.

37. 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 Monash Health website and revised no less than on a quarterly basis, to ensure accuracy and ease of accessible information for researchers.

F.2 Access and attendance

38. The Head, Research Operations, HREC Executive Officers and Human Research Ethics & Site Authorisation Coordinator are required to attend meetings of the Human Research Ethics Committees but are not members of the Human Research Ethics Committees and do not have voting rights.

39. Other attendees at a meeting of the Human Research Ethics Committees may include staff of Research Support Services and such other persons as the Human Research Ethics Committees request (including researchers who have a study under consideration) to attend. Any such attendees are not members of the Human Research Ethics Committees and do not have voting rights.

F.3 Decisions

40. The Human Research Ethics Committees 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 Monash Health Research Strategy and Governance Group for resolution.

41. In the event the Human Research Ethics Committee wishes to suspend or withdraw the ethical approval of a study, this will be communicated with the researcher in person/virtually and will then be documented in writing. The suspension or withdrawal of ethical approval will then be reported to the Monash Health Research Strategy and Governance Group.

42. Decisions of the Human Research Ethics Committees 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.

F.4 Meeting documentation

43. 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.

44. The proceedings of each meeting must be minuted and the minutes must accurately reflect the work and resolutions of the Human Research Ethics Committee. A draft of the minutes of a meeting must be prepared and promptly provided to the Chair for review (within 2 working days of the meeting). The draft minutes of a meeting must be considered and approved by the Human Research Ethics Committee at the next meeting following and signed by the Committee Chair. Draft minutes (or final signed minutes if available) must be provided to the Monash Health Research Strategy and Governance Group for noting upon request.

45. Written advice on the review outcome is to be provided to the researcher via email, following approval of the draft minutes within 4 working days of the meeting.

46. Research Support Services maintains a repository with all Human Research Ethics Committee meeting agendas and minutes. On this repository, an electronic file is maintained for each study received and reviewed by the Human Research Ethics Committees and Research Governance Office, containing all demographic information about the study as required under chapter 5.2 of the National Statement, and all of the study documents (such as Participant Information Sheets and Consent Forms and relevant correspondence). The repository is maintained in accordance with the Monash Health Records Management Operational Policy and are considered corporate records, subject to the Public Records of Victoria (PROV) requirements.

47. Prior to September in a given year:

    (a) the Human Research Ethics Committees are responsible for reporting on a regular basis to the Monash Health Research Strategy and Governance Group on all aspects of their operations, including new proposals for human research, proposed updates to policies and procedures, and any external reporting such as the HREC Annual Report to NHMRC. The Monash Health

Research Strategy and Governance Group will also request information as required for reporting to the Research and Innovation Council and the Clinical Governance Report.

(b) an annual meeting schedule for the following year must be distributed to all members of the Human Research Ethics Committees and required attendees.

F.5 Conflicts of interest

48. Each proposal for human research received by the Human Research Ethics Committees is required to address both actual or perceived conflicts of interest, and where there is a disclosure, the researcher must demonstrate a plan for managing the conflict of interest and informing participants.

49. For proposals where a member of the Human Research Ethics Committees has an actual or perceived conflict of interest, the member will either excuse themselves from the meeting for discussion of the proposal or will be an apology for the meeting. The conflict of interest will be documented in the meeting minutes.

50. The Human Research Ethics Committees will adhere to the Monash Health People and Culture Conflict of Interest Procedure.

51. Each member of the Human Research Ethics Committees will also be required to declare any conflicts of interest on an annual basis.

F.5 Fees for ethical review

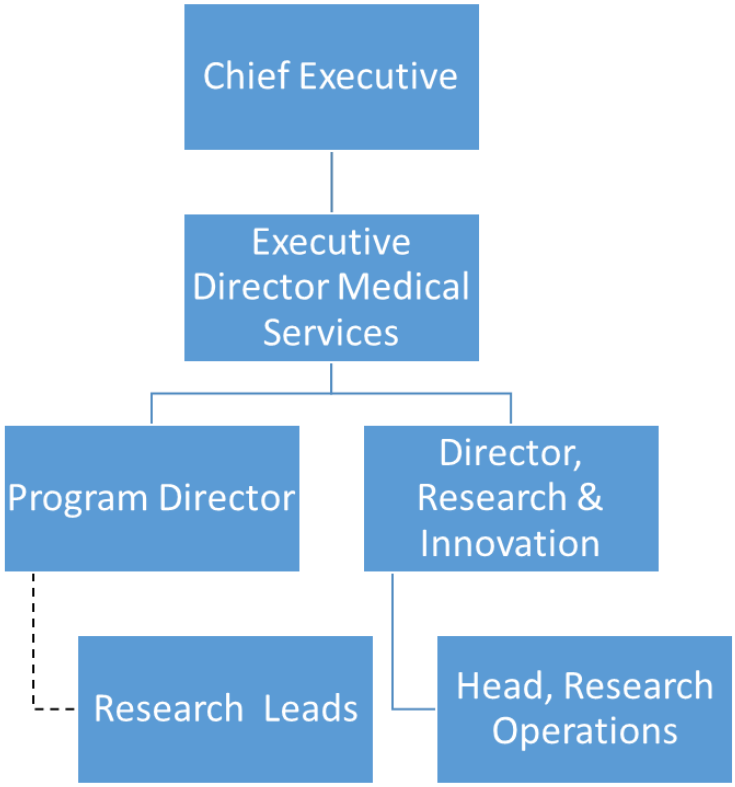
52. Fees for ethical review, where applicable, are set out in the Monash Health Human Research Ethics & Governance Fee Schedule memorandum dated 21 December 2021, effective from 1 February 2022, reproduced in Appendix H.3. Applicants must submit the relevant New Fee Form or Amendment Fee Form. The applicable schedule will be made publicly available https://monashhealth.org/research/resources/ and with these Terms of Reference. Any superseding approved schedule must be reflected in Appendix H.3.

G. REVIEW OF TERMS OF REFERENCE AND COMMITTEE PERFORMANCE

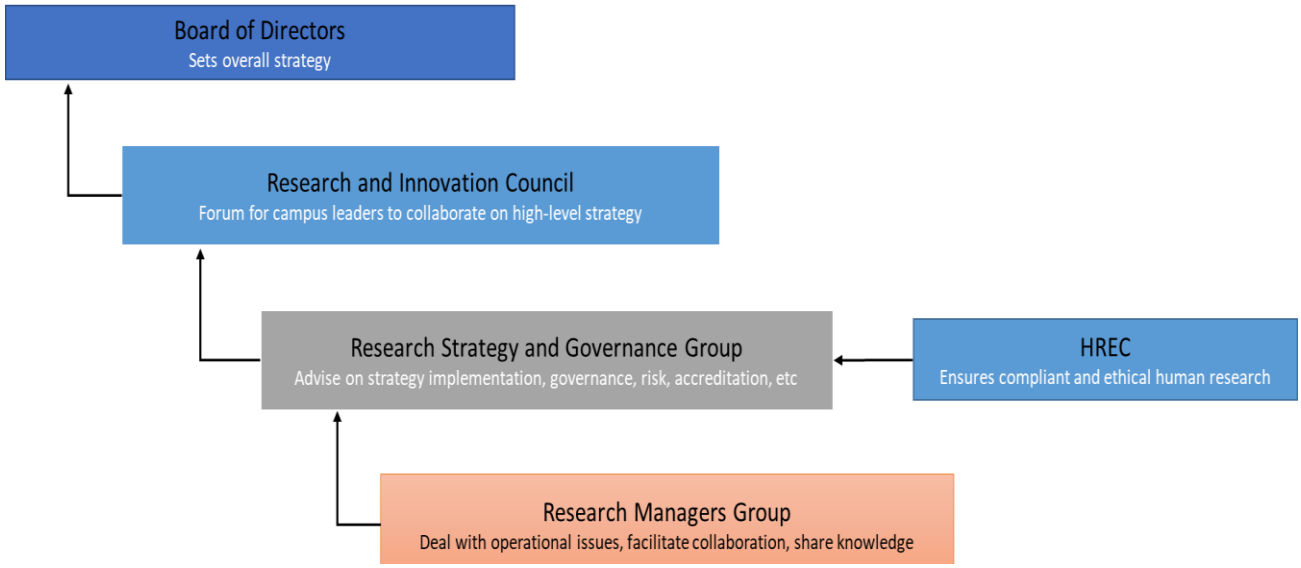
53. The Human Research Ethics Committees will conduct an annual review of these Terms of Reference and of their performance and provide a report arising from each review to the Monash Health Research Strategy and Governance Group for its consideration no later than September each year.

H. APPENDICES

H.1 Diagram 1: Monash Health Research Program Structure



H.2 Diagram 2: Monash Health Research Governance Reporting Structure



H.3 Human Research Ethics and Governance Fee Schedule

Source: Monash Health Human Research Ethics & Governance Fee Schedule memorandum, 21 December 2021. Fees effective from 1 February 2022.

New research project	Amount incl. GST
Commercially sponsored study - Phase I single site study	$7,700
Commercially sponsored study - Phase I multiple site study (+ charge per site)	$7,700
Commercially sponsored study - single site study	$6,600
Commercially sponsored study - multiple site study (+ charge per site)	$6,600
Commercially sponsored study - additional sites	$550 per site
Commercially sponsored - sub studies	$3,300
Non-commercial external sponsor - e.g. collaborative group studies	$605
External studies (non-clinical trials) - for profit entity	$605
External studies (non-clinical trials) - not for profit entity	$550
In-house studies (including clinical research studies, low risk research studies conducted by Monash Health staff, which are funded)	$220

Fees are cumulative. For a commercially sponsored trial with two sites, the memo gives an example of $6,600 plus $550 for one additional site, totalling $7,150 including GST.

Each study is charged once, for either ethics submission or governance submission. For a multicentre study submitted for both HREC and governance approval at Monash Health, the HREC review fee applies and no governance fee applies.

H.3 Fee schedule continued

Post-approval item	Amount incl. GST
HREC & governance review of protocol amendments and changes to Participant Information and Consent Form as part of the protocol amendment - commercially sponsored studies	$880
Governance review only of protocol amendments and changes to Participant Information and Consent Form as part of the protocol amendment - commercially sponsored studies	$440
HREC & governance review of administrative changes, updated Investigator Brochure, addition of investigator only, updated Participant Information and Consent Form - commercially sponsored studies	$220
Governance review only of administrative changes, updated Investigator Brochure, addition of investigator only, updated Participant Information and Consent Form - commercially sponsored studies	$220
Addition of a site to an existing commercially sponsored study (charge per additional site)	$550
Addition of a site to a collaborative/investigator-initiated study following HREC approval (charge per additional site)	$110
Post-approval amendments to collaborative group, investigator-driven studies and external studies for not-for-profit entities	No fee
External practitioner requests for HREC endorsement of Authorised Prescriber	$110
Changes to the Clinical Trial Research Agreement initiated by the commercial sponsor	$110

Payment requirements

Fees are payable in full at the time of initial submission of a project or amendment and are non-refundable. Payments submitted to Research Support Services must use the New Fee Form or Amendment Fee Form.