



Health Human Research Ethics Committee (HREC) Committee Terms of Reference

Chair	HREC Chair
Secretary	Ethics and Governance Advisor, Discovery & Innovation Unit
Terms of reference approval date	16 August 2024
Terms of reference review date	16 August 2025

1. PURPOSE

The Austin Health Human Research Ethics Committee (HREC) is a National Mutual Acceptance (NMA) HREC. This means the Austin Health HREC can provide ethics services to any Health Care provider covered under the NMA scheme. Austin Health HREC is managed by Discovery & Innovation Unit (DIU) at Austin Health and is supported by the Victorian Translational Research Institute (VicTRI). Austin Health makes a case-by-case decision on whether its HREC can and will review any study based on expertise of HREC members and their capacity to conduct the review in necessary timeframes.

The Austin Health HREC is registered with the National Health and Medical Research Council (NHMRC) and constituted under its [National Statement on Ethical Conduct in Human Research \(2023\)](#).

Austin Health charges fees to conduct its reviews. Any funds surplus to operational costs are directed back to the Austin Health DIU.

This document outlines the scope of the Austin Health HREC.

Acronyms:

Acronym	Definition
AH	Austin Health
CMO	Chief Medical Officer
COO	Chief Operations Officer
DIU	Discovery & Innovation Unit
HDR	Higher Degree Research
HREC	Human Research Ethics Committee
NHMRC	National Health and Medical Research Council
OPPIC	Organisational Policy, Procedure and Information for Consumers
SAE	Serious Adverse Event
SOPs	Standard Operating Procedures

SUSAR	Suspected Unexpected Serious Adverse Reaction
TGA	Therapeutic Goods Administration
VicTRI	Victorian Translational Research Institute

Related documents

- a. [Australian Code for the Responsible Conduct of Research 2018](#)
- b. [National Clinical Trials Governance Framework](#)
- c. National Statement on Ethical Conduct in Human Research (2023)
- d. [Privacy and Data Protection Act 2014](#) (Victoria)
- e. [Privacy Act 1988](#)
- f. [Public Records Act 1973](#) (Vic)

2. FUNCTIONS AND RESPONSIBILITIES

2.1 HREC Objectives

The Austin Health HREC exists to:

- a. Provide independent, competent, and timely review and monitoring of research projects;
- b. Ensure all research projects are reviewed in accordance with the [National Statement on Ethical Conduct in Human Research \(2023\) \(the National Statement\)](#), the [National Clinical Trials Governance Framework](#), the [NMA Accreditation Requirements](#), the [NHMRC Responsible Code of Conduct for Research \(2018\)](#) (the Code) and the Declaration of Helsinki ethical principles and in a manner consistent with good clinical practice.
- c. Protect the welfare, dignity, rights, safety, and well-being of research participants.

2.2 HREC functions

- a. Assess proposals submitted to them to identify whether they meet the National Statement principles of:
 - Respect for human beings and their welfare
 - Research merit and integrity
 - Justice
 - Beneficence
- b. The HREC, where appropriate will consider the scientific validity of research.

2.3 HREC member role and responsibilities

- a. Austin Health HREC members and operational staff in the DIU are responsible for maintaining familiarity with Austin Health's policies and procedures, the documents described in section 2.1.b, and other relevant guidelines. Austin Health's operational staff will ensure all relevant policies and procedures are available on the website and internally on Austin Health's OPPIC system. All submissions, deliberations and decisions are handled in strict confidence.
- b. Each member of an ethical review body is responsible for deciding whether, in their judgement, a proposal submitted to the review body meets the requirements of the [National Statement](#) and the [Code](#), and other appropriate guidelines and legislation as required.
- c. To fulfil that responsibility, each member of a review body should:
 - Become familiar with the National Statement, and consult other guidelines relevant to the review of specific research proposals.
 - Prepare for and attend scheduled meetings of the review body or, if unavailable, provide opinions on the ethical acceptability of research proposals before meetings, subject to institutional policies on absences.
 - Attend continuing education or training programs in research ethics; where possible, this training will be included as a standing agenda item.
 - Sign an agreement to maintain confidentiality regarding the content of applications, deliberations, correspondence between the HREC and any other party/institution.

- Before any deliberations of the HREC, declare any interests that could influence the objectivity of their decision making. The procedure for managing conflicts of interest is:
 - Conflicts of interest and how each was managed will be recorded in the meeting minutes.
 - Members must recuse themselves from the HREC's decision making on matters that relate to the conflict of interest.
 - In the case where the member is an Investigator, the member concerned is required to leave the room (or be sent to a breakout room or equivalent if using videoconferencing). The committee member with the conflict of interest may be asked to respond to questions directed to them upon returning to the room. This member will not participate in voting and voting occurs before the member returns to the meeting.
- d. The following processes are applicable to the function of the HREC:
 - HREC may request the advice of an expert to help assess applications.
 - The HREC will monitor research projects to ensure they continue to conform to the conditions of approval.
 - The HREC may delegate authority to the Chair, to a sub-committee comprised of members with specific expertise of the operational staff in the Discovery & Innovation Unit.
 - The HREC will reach its decisions by consensus per the National Statement.

2.4 Chair responsibilities

The Chair/s of the HREC will:

- a. Lead the HREC and provide vision to meet its stated objectives.
- b. Direct discussions to effectively use the time available to review research proposals.
- c. Ensure minutes accurately reflect the Committee's decisions.

2.5 Discovery & Innovation Unit responsibilities

- a. Act as Ethics, Integrity and Governance Advisors to provide operational and advisory support on best practice to the HREC. The Ethics, Integrity and Governance Advisors will be the first point of contact for HREC members and for institutions or investigators wishing to access the HREC.
- b. Provide prior review to ensure proposals meet the acceptable quality level before being placed on the HREC agenda.
- c. Circulate confidential HREC agendas, along with all required documents, no less than 10 calendar days before the meeting.
- d. Maintain confidential minutes as a formal record of each meeting. The minutes will be circulated no later than two working days after a meeting and will identify decisions to be formally accepted as correct at the following meeting.
- e. Where relevant, ensure any objections to consensus decisions are formally documented.
- f. Ensure distribution of meeting papers in a confidential manner to the members prior to each meeting, as well as maintaining records of HREC business. Records of applications and associated documents will be maintained indefinitely to meet record retention requirements.
- g. Coordinate and draft policies and procedures in accordance with the Code and other relevant legislation and codes of practice for review by the HREC.
- h. Foster open communication between the committee and researchers to facilitate the review process as per the National Statement (Section 5.2.14).
- i. Develop documentation per the National Statement (Section 5.1.5) and coordinate and conduct annual reviews of the operation of the HREC.
- j. Prepare an annual report of HREC activities and function to the Austin Health Board.

2.6 Accountability of the Austin Health HREC

- a. The responsibilities of Austin Health, acting as an institution that conducts research involving human subjects, are defined in the National Statement ([Section 5.1](#)), the NHMRC Responsible Code of Conduct for Research and the Austin Health Clinical Trials & Research Governance Framework.
- b. The Austin Health HREC is accountable to the Austin Health Board, through the Chief Executive Officer (CEO) via the Chief Medical Officer (CMO).
- c. Reports on activity and procedural changes will be provided to Austin Health Board and to the NHMRC annually, or as required. Reports will be on:
 - Membership/membership changes.

- Number of meetings held each year.
 - Number of protocols presented, approved and rejected.
 - Monitoring procedures in place and any problems encountered.
 - Complaints procedures and number of complaints received.
 - Timeliness of protocol reviews.
- d. To support the separation of executive functions and the HREC, the CEO and CMO will not attend the HREC meetings. Instead, they will be attended by Senior Representatives of the DIU. Reports will be provided to the CMO and CEO per our research governance reporting lines.
- e. The HREC may bring issues of significant concern to the CMO and CEO, through the research governance reporting lines.
- f. The CEO will provide regular reports to the Austin Health Board.
- g. The DIU, acting on behalf of Austin Health, is responsible for:
- Ensuring any human research is designed and conducted in accordance with the Australian Code for the Responsible Conduct of Research 2018 ([the Code](#)); and is ethically reviewed and monitored in accordance with the National Statement and National Clinical Trials Governance Framework.
 - Creating and managing research governance processes as outlined in Section 5.1 of the National Statement and the Austin Health Clinical Trials & Research Governance Framework.
 - Managing conflicts of interest.
 - Monitoring the conduct of research.
 - Handling complaints.
 - Ensuring accountability.
 - Promoting clearly documented, accessible and current policies and procedures for research governance and ethical review.
 - Ensuring these Terms of Reference are available for access by the general public.
 - Providing adequate resources to allow proper function of the HREC.
 - Facilitating education of HREC members and assisting in conflict of interest resolution as necessary.
 - Conducting an annual review of the function of the HREC.
 - Appointing a chairperson and deputy chairperson to the HREC.
 - Providing advisory support to the HREC.

3. EXPECTED OUTCOMES

3.1 Review and approval of pre- and post-approval documents

- a. Activities associated with research conducted with or about people, or their data or tissue must not start before written approval is given ([National Statement 5.2.26\(h\)](#))
- The HREC may only approve applications that comply with The National Statement and other relevant legislation.
- b. Applications are to be submitted for review in accordance with the website instructions. Guidelines to assist applicants as well as document templates and policies and procedures will be made available on the website.
- c. New proposals must be considered and approved only at quorate meetings of the HREC and meet the requirements outlined in The National Statement (Section 5.1.30).
- d. The HREC may request the applicant to supply further information in relation to an application to clarify issues that may arise during review.
- e. The HREC may request an applicant attend a meeting to facilitate review of a research protocol, which may include providing information to, and answering questions from, HREC members.
- f. Following consideration of each application, the HREC may decide that an application to commence a project or activity is approved with or without conditions, deferred to the next meeting, approved subject to satisfactory clarifications for review by the Discovery & Innovation Unit, or not approved.
- g. Applicants will be notified of HREC decisions within five (5) business days from the date of the meeting.
- h. The HREC may establish a HREC Executive from the available members at any time. The HREC Executive must include the Chair and if deemed appropriate any other membership category as required.
- i. The HREC Executive:
- May approve modifications to approved projects or activities for ratification at the next quorate committee meeting.

- May specify urgent action required in response to reports of adverse events or emergencies.
- Consistent with HREC meetings, must declare if they have a conflict of interest with an item and another member must be appointed for consideration of the item.
- Must distribute agenda items in a safe and confidential manner.

4. REPORTING

4.1 Reporting

The Austin Health HREC is accountable to the Austin Health Board, through the Chief Executive Officer (CEO) via the Chief Medical Officer (CMO).

Reports on activity and procedural changes will be provided to Austin Health Board and to the NHMRC annually, or as required. Reports will be on:

- Membership/membership changes.
- Number of meetings held each year.
- Number of protocols presented, approved and rejected.
- Monitoring procedures in place and any problems encountered.
- Complaints procedures and number of complaints received.
- Timeliness of protocol reviews.

4.2 HREC monitoring and reporting requirements

- The HREC will monitor approved projects in accordance with the National Statement Section 5.5 and the Austin Health Clinical Trials Governance Framework to verify that the conduct of the research conforms to the approved proposal.
- Mechanisms for reporting include:
 - Annual progress reports from researchers. If a project is deemed to be of considerable risk to participants, researchers may be requested to provide more frequent progress reports.
 - Reports from safety or other monitoring boards.
 - Review of adverse event reports; Risk Based Monitoring and/or Auditing of Research.
 - Other forms in accordance with the [National Statement](#) and Austin Health Clinical Trials & Research Governance Framework.
- Researchers will be advised in the letter of final approval that they are required to submit reports as a condition of approval.
- The DIU will send reminders to the Principal Investigator when a report is due.
- The HREC will require, as a condition of final approval, that investigators immediately report any of the following:
 - Proposed changes to the protocol or project in the form of a request for modification.
 - Other unforeseen events that may affect the continued ethical acceptability of the project, including compliance with the approved protocol, conduct of research investigators, emerging conflict of interest or changes to conditions of the approval.
 - If the project is discontinued for any reason.

5. MEMBERSHIP

5.1 Committee membership

- The Austin Health HREC will consist of at least eight members with diversity, including gender diversity, as far as practicable per National Statement Sections 5.1.30 & 5.1.36.
- Membership will include:
 - 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 broader community or consumer perspective and who have no paid affiliation with Austin Health.
 - A person with knowledge of, and current experience in 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 practising, and where possible, who is not engaged to advise Austin Health.
- At least two people with current research experience relevant to the research proposals being considered at the meetings they attend. These two members may be selected, according to need, from an established pool of inducted members with relevant expertise.
- No individual may represent more than one of the membership categories at the same meeting. They may fill a different category at a separate meeting, if the minimum membership is maintained (National Statement, section 5.1.40).
- Members are appointed to the Austin Health HREC using open and transparent processes in accordance with the National Statement.
- Each member will receive a formal notice of appointment and assurance that Austin Health will provide legal protection for their activity as a member of the Austin Health HREC.
- Austin Health will maintain a core group of members appointed as individuals for their knowledge, qualities and experience, and not as representatives of any organisation, group or opinion per National Statement (Section 5.1.41). Each member will be required to sign a confidentiality agreement and conflict of interest statement. In addition, each member will be required to declare all conflicts of interest and affiliations upon identification that a conflict exists, in order that conflicts are appropriately managed. Any member with an affiliation to the proposed research under consideration will not be assigned to review the proposal.
- Members should attempt to attend all scheduled meetings. Where a member is absent for a meeting, they will provide an apology via the DIU. Apologies should be given as early as possible to ensure meetings are quorate. Where necessary, a proxy member will attend the meeting to ensure the quorum requirement is met (National Statement, section 5.2.3 (b)). Should a proxy member not be available, the absent Member should expect to receive all the relevant meeting papers and take the opportunity to contribute their views via written comments, which will be recorded and considered at the meeting (National Statement, section 5.2.4-5).

5.2 Appointment of members

- a. Austin Health may recruit new HREC members by calling for Expressions of Interest, and will provide a Duty Statement in the form of an Ethics Committee Position Description. Applicants must respond to the Expressions of Interest by providing a covering letter and current curriculum vitae. Internal applicants must also provide written approval from their Head of Area, supporting their application.
- b. All applicants (except for the Chair) will be interviewed at a minimum by the Manager of the DIU (or delegate), the Chair of the HREC and any other stakeholders as deemed appropriate.
- c. Members will be appointed by the DIU Manager on the advice of the interview panel.
- d. New members will be provided with an orientation package and will be required to attend an induction session.
- e. Before appointment, all members of the HREC must acknowledge in writing their acceptance of the terms of reference of the HREC and will be asked to sign a Confidentiality Agreement.
- f. Members are appointed for one-, two- or three-year terms. A member may be reappointed for an additional term or terms with the agreement of the DIU in consultation with the CMO, CEO and HREC Chair.

5.3 Varying and replacing members

Austin Health, on the advice of the Discovery & Innovation Unit may elect to vary membership or replace members at any time per the terms of the member's appointed letter.

5.4 Absenteeism, termination and resignation of members

- a. Where a member fails to attend three consecutive meetings of the HREC without providing an apology or acceptable reason, or has demonstrated an inability to maintain an adequate level of participation or meet their responsibilities to the HREC, this member will be replaced by a new appointee of the same category.
- b. The DIU will notify the member in writing prior to any termination of membership.
- c. Austin Health may terminate the appointment of any member if there is good reason to believe:
 - It is necessary for the proper and effective functioning of the HREC.

- The person is not fit and proper to serve on a HREC.
 - The person has failed to carry out their duties.
- d. A member can resign in writing to the DIU at any stage during their term.

5.5 Member education and remuneration

- a. To comply with NHMRC certification assessment, members must engage in continuous training opportunities. At Austin Health, members must complete mandatory ATLAS training and any HREC specific training provided by the DIU, and provide evidence of training by external providers.
- b. A record of HREC member training will be maintained by the DIU.
- c. Austin Health HREC members not employed by Austin Health are remunerated.

5.6 Quorum

- a. Per the National Statement, section 5.2.3, each HREC meeting must be quorate. A quorum can be achieved via videoconference and receiving written comments from members who are unable to attend the meeting. The Chair must be satisfied the views of those who are absent are received and considered (National Statement, Section 5.2.5).
- b. If a quorum is lost during the meeting, decisions can be finalised out of session.

5.7 Provision of member details

Austin Health does not issue the names of individual HREC members to external parties.

5.8 Insurance

Austin Health HREC members are covered under the Austin Health Victorian Medical Insurance Assurance (VMIA) indemnity policies in respect to liabilities that may arise while conducting their HREC duties for Austin Health.

Membership will be by the person's role as agreed by the committee. The Committee may invite any person to attend a committee meeting in order to facilitate its business.

Members will:

- Actively contribute to the work of the Committee – including reviewing any papers prior to meetings, representing the views of relevant staff groups and participating in decision-making.
- Provide feedback to staff they are representing on the work and outcomes of the Committee.
- Arrange for a proxy to attend a meeting in their place should they be unable to attend.
- Attend a minimum of 50% of meetings per year. Should a member be unable to attend at least 50% of meetings and have not provided a delegate to represent them, the member will be asked to resign their membership on the Committee and a replacement will be nominated.

The committee will seek input from suitable consumers as required.

6. MEETINGS

Meetings will be conducted in accordance with operating procedures established by the DIU.

Meetings will be conducted in such a way as to encourage discussion, debate, and the exchange of ideas.

6.1 Frequency

- a. The HREC meetings will be conducted at least once a month between February and December.
- b. The HREC meeting dates, and closing dates for the receipt of applications, will be advertised on the website.
- c. The Committee may elect to conduct special meetings, if circumstances or the nature of business is urgent or extraordinary.

6.2 Quorum

- a. The HREC must have a quorum of members in attendance to conduct meetings. Such quorum must comprise at least one member from each category.
- b. The HREC will not make decisions unless a quorum is in attendance. A non-quorate meeting of the HREC may discuss matters for future approval by a quorate meeting.
- c. Attendance at quorate meetings may be facilitated by submission of written comments, video linking or teleconferencing of some members.
- d. Any duly convened meeting at which a quorum is in attendance shall be able to consider and resolve any business of the HREC and shall have and may exercise all the functions of the HREC.

6.3 Conflict of Interest

Any member of the HREC who has a conflict of interest associated with a proposal or other related matter being considered by the HREC should declare such an interest at the earliest opportunity. The member shall remove themselves from the meeting or being a reviewer when the project is the subject of consideration. Once the HREC has considered the matter and a decision has been reached, the member will be asked to return to the meeting. All declarations of interest and their management and absences of members will be minuted. Where there are no declarations of interest, this will also be minuted.

6.4 Agenda and minutes

- a. The Discovery & Innovation Unit will manage the agenda and meeting outcomes.
- b. Circulate confidential HREC agendas, along with all required documents, no less than 10 calendar days before the meeting.
- c. The Discovery & Innovation Unit will create and share written minutes of the meeting. The minutes will be circulated no later than two working days after a meeting and will identify decisions to be formally accepted as correct at the following meeting.

6.5 Record keeping

- d. The DIU will prepare and maintain an official file for each application received. This may be electronic, and will include a copy of the application, any relevant correspondence including that between the applicant and the HREC or HREC Executive in accordance with the Public Records Act 1973 (Vic). Meeting minutes will be retained in a Minutes file in accordance with the Public Records Act 1973 (Vic).
- e. The DIU will also maintain the following records ([The Code 2.2.30 and 2.3.22](#)):
 - A register of all applications to the HREC, including the outcomes of deliberations.
 - Minutes that record decisions and other aspects of the HREC's operation.
 - Records of inspections conducted by the HREC that include the names of attendees, observations, any identified problems, recommended actions, ongoing or outstanding issues, and outcomes.
- f. Files will be kept securely and confidentially in accordance with the Commonwealth and State privacy legislation and the Public Records Act 1973 (Vic).
- g. The DIU will close and archive the file in accordance with the Public Records Act 1973 (Vic).
- h. Records will be held for sufficient time to allow for future reference. The minimum period of retention will be in accordance with [the Code](#) and [the Public Records Act 1973](#) (Vic).

6.6 Voting

- a. The HREC will endeavour to reach a unanimous consensus decision concerning the ethical acceptability of a research protocol. Where a unanimous decision is not reached, the HREC should explore with the applicant(s) ways of modifying the project that may lead to consensus. If necessary, the investigators should be invited to attend the next meeting.
- b. If consensus is still not achieved, the HREC should only proceed to a majority decision after members have been allowed a period of time to review their positions, followed by further discussion. In this instance the decision will be carried by a majority vote of two-thirds of members who examined the proposal, providing the majority includes at least one layperson. Minority views will be recorded in the minutes.
- c. Any person elected or appointed as a member of the Committee is entitled to one vote and in the event of an equality of votes the Chair shall have the casting vote. Any invited attendee does not have voting rights.

6.7 Complaints or appeals

- a. All complaints will be managed in accordance with Austin Health's complaints policy and procedure.
- b. All complaints, concerns or enquiries will be treated confidentially and sympathetically. Complaints must be submitted to feedback@austin.org.au.
- c. If a member of a HREC or a researcher has any grievance about the operation of that committee, they should discuss this, in confidence, with the DIU.
- d. If the grievance cannot be resolved, they should then take their concerns to the Research Steering Committee, CMO or CEO.
- e. Conscientious objection - If a staff member or student wishes to conscientiously object to participation in an activity occurring under Austin Health, then this should be first addressed with the Principal Investigator. If a resolution is not achieved, the objection can be provided in writing to DIU who will refer it to the appropriate person/s.

7. EVALUATION

The Committee will conduct an evaluation and review its Terms of Reference in response to changes in legislation, policies or upon the request of the HREC, or on an annual basis, whichever occurs first and submit a copy to the OPPIC system.

8. ENDORSEMENT:

Research Steering Committee