Date of Revision:	**April 2026**
Review Date:	**December 2026**
Authorised by:	**Bayside Health Chief Executive**

ALFRED HOSPITAL HUMAN RESEARCH ETHICS COMMITTEE ("THE COMMITTEE")

Statement of Purpose:

The Committee shall carry out the functions of an institutional ethics committee consistent with those set out in the NHMRC *National Statement on Ethical Conduct in Human Research (2023)* and subsequent revisions and provide a forum for consideration of general ethical issues.

1. TERMS OF REFERENCE

The Committee shall:

- consider proposed research projects involving human participants and determine whether or not they are acceptable on ethical grounds;
- provide for surveillance of research projects until completion so that the Committee may be satisfied that they continue to conform to approved ethical standards;
- maintain a record of all research proposals received and reviewed, as stipulated by the *National Statement on Ethical Conduct in Human Research (2023)* and subsequent revisions;
- retain on file each ethics application, including any information sheets, consent forms or relevant correspondence, in the form in which they were approved;
- maintain confidentiality of all information and documents relating to the business of the Committee;
- provide an appropriate forum for the consideration of research related ethical issues
- contribute as appropriate to the National Clinical Trials Governance Framework (NCTGF)
- consider matters referred to it by the Health Service Executive.

Certain specified committees, sub-committees or consultants may assist the Committee by providing advice and recommendations.

Changes in these terms of reference shall be reviewed and approved by the Chief Executive.

2. Composition and membership

2.1 The Chief Executive shall appoint members of the Committee for renewable 12-month periods. Renewal of appointment is at the discretion of the Chief Executive.

2.2 Each year the Chief Executive shall appoint a Chair of the Committee.

2.3 The large number of projects requiring assessment has required that after consideration of general business, the Committee splits into two sections for the assessment of research proposals. One section assesses drug and intervention projects and the other has a focus on health & social science projects. In accordance with the NHMRC National Statement on Ethical Conduct in Human Research (2023), each section requires:

- A section chairperson
- At least two members who provide a broader community or consumer perspective, who have no paid affiliation with Alfred Health and are not currently involved in medical or legal work
- At least two members with current or recent human research experience, that is relevant to research considered at the meetings
- At least one member with knowledge of, and current experience in the professional care, counselling or treatment of people. Examples include a nurse or allied health professional
- At least one member who performs a pastoral care role in a community including, but not limited to, a chaplain or a minister of religion, an Aboriginal and/or Torres Strait Islander elder or community leader or other religious leader.
- At least one member who is a lawyer who is not engaged (or likely to be engaged) in medical litigation or contractual arrangements with Alfred Health
- Where possible one or more of the members should have lived experience as a research subject and/or be experienced in reflecting on and analysing ethical decision-making
- Other members chosen to provide a balance between those with research expertise and those reflecting community values

2.4 Inducted members: In accordance with the National Statement on Ethical Conduct in Human Research, additional members may be appointed (as per 2.1 above) to a pool of inducted members. Members of this pool will typically be past members who may attend meetings on an ad-hoc basis (e.g. to cover annual leave) and/or provide out-of-session review and expertise as needed.

2.5 Members with relevant expertise are also appointed as ex officio members of the Research Review Sub-committee.

In Attendance

- The Secretariat.

2.6 **Non-sitting members**

- On the recommendation of the Chair, members may be appointed in their existing membership categories as non-sitting members.
- Non-sitting members may provide assessments of individual research projects
- Non-sitting members must have served on the Committee prior to this appointment.

2.7 **Recruitment of new members**

- New members in the role of ‘community’ member and lawyer are recruited through external advertising and interview. The Chair of the Committee may use his/her discretion to waive the advertising requirement.

- New members in research-related roles may be recruited via prior membership of the Ethics sub-committees or by direct targeted approach to individuals with recognized and appropriate expertise
- Prospective members are required to undergo an interview by representatives from the Ethics Committee and Secretariat.
- New members are to serve a trial period of three months, unless the Chair deems otherwise, before being appointed as full members.

2.8. Leave of absence

Members are eligible to apply for leave of absence (LOA) after a period of two consecutive years' service. The period of leave can vary between three and twelve months.

- Leave may be granted provided the requisite membership category is filled either by existing members, new members or temporary substitute members
- In exceptional circumstances (e.g. maternity or employment related) the minimum LOA eligibility period may be waived at the discretion of the Chair of the Committee

2.9 Resignation

Members are deemed to have resigned from the Committee when:

- they no longer hold the position on which their membership is based, or
- they submit a letter of resignation, or
- they do not submit an expression of interest to be reappointed. This will also apply to those who have been granted 12 months leave of absence.

2.10. Rotation of members

Members may be rotated between the Health & Social Sciences group and the Drugs & Interventions groups at the discretion of the Chair in consultation with appropriate Deputy Chairs.

3. Meetings

3.1 The Committee will meet at least 12 times each year.

3.2 By invitation of the Chair, non-members may attend for all or part of one or more meetings of the Committee as a resource, in an advisory capacity, or as an observer (by prior arrangement). A confidentiality declaration is required from each person.

3.3 A majority of Committee members representing all of the minimum membership categories either present at a meeting or having the opportunity to review and comment prior to the meeting shall constitute a quorum

4. Remuneration

4.1 A sitting fee will be paid for eligible members

5. Accountability of the Committee

The Committee:

5.1 Via the Chair, is accountable to the Chief Executive in the effective conduct of its business.

5.2 Shall report annually to the Bayside Health Chief Executive and additionally to the Bayside Health Board as requested

5.4 Shall report annually to the Alfred Research Alliance (ARA+).

5.5 May from time to time bring to the attention of the Chief Executive ethical issues of significant concern.

5.6 Will provide annual reports to:

- the Australian Health Ethics Committee (AHEC) in accordance with the requirements of the National Health and Medical Research Council
- the National Health and Medical Research Council in accordance with the requirements as a certified institution under the National Certification Scheme.

6. Committee Procedures

6.1 An agenda that includes appropriate documentation to inform the Committee and support decision making will be circulated before each meeting to ensure that members have time to consider the contents and raise questions they may have before the meeting date.

6.2 The Committee meets as a whole to discuss key agenda items and then split to consider the projects assigned to the Health & Social Sciences Group and the Drugs & Intervention Group.

6.3 A complete record of proceedings of each meeting of the Committee will be retained. The minutes of each meeting will be confirmed or amended and confirmed at the next ordinary meeting of the Committee.

6.4 The absence of a quorum shall not invalidate the proceedings of a meeting. However, decisions made at a meeting without a quorum must be ratified at the next meeting with a quorum unless an alternative out-of-session ratification process has been agreed to by the Committee in advance.

6.6 Decisions are informed by an exchange of views from members, whether in full attendance or through the receipt and consideration of comments from those who cannot be present.

Achieving such decisions requires that the Chair:

- actively engages all members;
- elicits their views; and
- communicates their responses to other members.

The Committee endeavours to reach decisions by general agreement or consensus, which need not necessarily require unanimity. Accordingly, the Chair is responsible for facilitating views from all members, identify points of agreement and of disagreement and judge when a sufficient degree of agreement has been reached. On occasion, the Chair may decide to request a vote in order to reach a decision.

7. Relationship to other processes of research review

To assist the Committee in its work, the following committees and delegates of the Committee may provide advice, recommendations and/or decisions:

Committees:

- Research Review Committee
- Clinical Innovations Committee
- Research Ethical Issues Sub-committee
- Ad hoc committees established by the EC to consider a project in depth. One or more of the members may be asked to attend the EC to discuss specific projects.
- Genetically Modified Organism (GMO) Advisory Committee
- AI Governance (Artificial Intelligence review panel)

Certain decisions of the Ethics committee are delegated to individuals as described below. A summary of these decisions is provided to the EC at each meeting for ratification (and comment if necessary).

Matters which may be delegated for consideration outside of the full ethics Committee meetings may include:

- Single-site Low Risk applications
- Single site low risk applications which include a request for a consent waiver*
- Amendments to previously approved projects
- Determination of whether a research project may be exempt from review
- Case Study Report applications
- Approved expedited reviews**
- TGA Authorised Prescriber applications

*These projects are subsequently presented for discussion and/or endorsement to the full Ethics Committee by the Low Risk Chair (or delegate).

** These projects are subsequently presented for discussion and/or endorsement to the relevant Group of the Ethics Committee by the Chair (or delegate).

Individuals or groups to whom limited delegation may be made include

- Ethics Officers and the Manager, Office of Ethics & Research Governance
- Research Governance Officers
- Reviewers of Expedited Review and Cross Approval applications
- Independent expert reviewers
- Non-sitting members performing tasks as requested by The Committee

The Committee shall establish procedures for the workings of delegates and for communicating with the committees.

Limits of authority: the scope of authority of the Committee is limited to ensuring the safety and welfare of adult research participants and the protection of the reputation of involved institutions. The authority and expertise of the Committee is limited with respect to the approval of projects involving children and will commonly seek external advice and/or referral to a committee with appropriate expertise.

Similar approaches may include research involving Aboriginal & Torres Strait Islander people as participants and/or their data and projects involving overseas participants or institutions.

8. Relationship to non-affiliated researchers

8.1 Non-affiliated researchers conducting research at Alfred Health must include at least one senior Bayside Health member of staff from the appropriate discipline on the research team. This person shall will be required to take responsibility for the conduct of the research at Bayside Health sites.

8.2 The review of research to be conducted elsewhere under streamlined review programs, or other institutions' single-site application, is to conform to memoranda of understanding between the relevant institutions.