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Authorised by:	Alfred Health Chief Executive

ALFRED HEALTH 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 to 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
- 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 they attend
 - 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, 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 member who is a lawyer who is not engaged in medical litigation or contractual arrangements with Alfred Health
 - Where possible one or more of the members should 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 must have served on the Committee prior to this appointment.

2.7 Recruitment of new members

- New members in the role of lay member and lawyer are typically to be recruited through external advertising and interview. The Chair of the Committee may use his/her discretion to waive the advertising requirement.
- New members in other roles may be recruited through 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 is granted by the Chair of the Committee, who may use his/her discretion about the timing and duration of the leave
- 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
- If 12 months' leave is granted from the start of any one year, members will be required to submit an expression of interest to be considered for appointment the following year.

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 intervals of six months or more 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 conduct of its business.

5.2 Performance is reviewed at least annually.

- 5.3 Shall provide reports to the Alfred Health Chief Executive annually and the Alfred Health Board as required.
- 5.4 Shall provide data annually to the Alfred Research Alliance (ARA+, formerly AMREP).
- 5.5 May from time to time bring to the attention of the Chief Executive issues of significant concern.
- 5.6 Will provide external reports annually:
 - to the Australian Health Ethics Committee (AHEC) in accordance with the requirements of the National Health and Medical Research Council
 - to 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 all agenda items until the agenda items for consideration of the projects assigned to the Health & Social Sciences Group and the Drugs & Intervention Group. At this point in the agenda, the two groups meet separately.
- 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 those members who comprise the minimum membership, whether in full attendance or through the receipt and consideration of comments from some of those members 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 endeavors to reach decisions by general agreement or consensus, which need not necessarily involve unanimity. Accordingly, 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. On occasion, the Chair may decide to call for 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

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 (& comment if necessary).

Matters approved for delegation include:

- Single-site Low Risk applications
- Amendments to previously approved projects
- Determination of whether a research project may be exempt from review
- Case Study Report applications
- Expedited reviews
- TGA Authorised Prescriber applications

Individuals or groups to whom limited delegation may be made include

- Members of the Research Review Committee
- 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.

8. Relationship to non-affiliated researchers

- 8.1 Non-affiliated researchers conducting research at Alfred Health must include at least one senior Alfred Health member of staff from the appropriate discipline on the research team. This person shall assume responsibility for the conduct of the research at Alfred 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.