

Research Ethics & Ethics Committee - Terms of Reference

1 Purpose

Consistent with its values of hospitality, healing, stewardship and respect, Calvary Health Care Bethlehem (CHCB) is committed to respecting the welfare, dignity and privacy of all individuals and requires that all research conducted at CHCB is to be conducted responsibly, ethically and with integrity.

The role of CHCB Research Ethics & Ethics Committee (the Committee) is to:

- Review research applications which relate to research to be conducted at CHCB in accordance with the NHMRC National Statement on Ethical Conduct in Human Research (the National Statement) and the Australian Code for Responsible Conduct of Research and its supplementary guides (the Australian Code);
- In reviewing research applications ensure that proposed research is aligned with the Little Company of Mary Health Care (LCMHC) philosophy and the Code of Ethical Standards for Catholic Health and Aged Care Services in Australia (the Catholic Code); and
- Review and make recommendations with respect to ethical issues, both actual and possible, at CHCB which are referred to it for consideration.

2 Membership

The Committee will comprise a minimum of eight people with, as far as possible, diversity, including gender diversity and at least one third of the members external to the CHCB.

The Committee must include:

- A Chairperson with suitable experience;
- Two people who bring a broader community or consumer perspective and who have no paid affiliation with CHCB;
- 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 the community;
- A qualified lawyer who may or may not be currently practicing; and
- Two people with current research experience that is relevant to research proposals to be considered.

One or more of the above members should be experienced in reflecting on and analysing ethical decision making.

CHCB may appoint members who are additional to the eight minimum members. These members may also represent minimum membership categories or have experience or expertise relevant to the work of the Committee. There shall be no remuneration paid to Committee members for undertaking their responsibilities.

The following shall be permitted to attend meetings as ex officio observers:

- The CHCB General Manager;
- A Calvary Mission representative; and
- An Administration Assistant.

3 Term of Membership

All appointments shall be for three years with incumbents being eligible for reappointment.

4 Roles and Responsibilities of Committee Members

4.1 General

The Committee's research governance responsibility includes providing and promoting a research culture that reflects its core values of research integrity, collaboration and collegiality and facilitating an environment where the design and planning of research is supported and valued.

4.2 Chairperson

The Chairperson will conduct meetings in such a way as to ensure that the Committee is compliant with its obligations and reporting requirements under the National Statement and the Australian Code and is aligned with the LCMHC philosophy and the Catholic Code.

4.3 All Members

Each member will independently decide whether each research proposal submitted to the Committee should be granted ethics and/or governance approval by giving consideration to whether the research is ethically sound and will reasonably protect participants. Further, each member will comply with their obligations under the National Statement and the Australian Code.

Each member will commit to attending a majority of meetings each year and, if unable to attend a meeting, will make every effort to submit their views on research proposals to the Chairperson prior to such meeting.

Each member will undertake appropriate induction, which can include mentoring by an experienced Committee member.

Each member will undertake continuing education.

4.4 Ex Officio Observers

Ex officio observers shall, at the discretion of the Chairperson, be permitted to attend and participate in meetings.

5 Appointment of Chair and Committee Members

The Chairperson, who shall be from outside CHCB, shall be a nominee of the CHCB General Manager.

The appointment of other committee members shall be as nominated by the CHCB General Manager save for a medical representative with research experience as nominated by the CHCB Medical Staff Group.

6 Reporting

This committee reports to the Calvary Kooyong Executive Governance Committee.

6.1 Frequency of Reporting

The Committee shall report following each meeting.

6.2 Method of Reporting

The Committee's decisions in relation to research projects are communicated to the CHCB General Manager for adoption by CHCB.

The Committee shall provide an annual report to the NHMRC and to LCMHC Board Mission and Ethics Committee.

7 Meetings

The Committee shall meet six times per year or as deemed appropriate by the CHCB General Manager in consultation with the Chairperson. Meetings are generally held at CHCB.

8 Quorum

Where there is less than full attendance of members from the minimum membership categories at a meeting the Chairperson shall use their best endeavours to obtain the views of the members who are not present in order that those views are considered by all members of the Committee participating in the meeting before a decision is made. Otherwise half the members shall constitute a quorum.

9 Decision-making Process

The Committee shall:

- Satisfy itself that the human research for which it is responsible meets both the relevant ethical standards and scholarly or scientific standards.
- Satisfy itself that the human research for which it is responsible takes account of consumer and community perspectives.
- Satisfy itself that any human research for which it is responsible is designed, reviewed, approved, authorised, conducted and monitored in accordance with the National Statement and the Australian Code.
- Review research proposals to ensure methodology, approach and the aims of the research are consistent with good research practice and the aims of CHCB.
- Consider ethical implications of all proposed research to ensure best practice in accordance with the LCMHC philosophy and the relevant research guidelines outlined in the Catholic Code.
- In determining whether a research proposal meets all requirements of the National Statement, and there is less than full attendance of Committee members, the Chairperson should be satisfied that the opinions of those absent have been considered.
- Advise the CHCB General Manager if a project has been approved as suitable to proceed, with such projects being given a two year approval period. Note – The Committee may elect to extend the approval period for low risk longitudinal studies.
- Monitor approved research projects until completion to satisfy itself that the research projects conform

to approved ethical standards and research methodology as well as protecting the safety of research participants.

- Have the right to withdraw approval for good reason.
- Maintain a record of all proposed and approved research projects.
- Ensure that CHCB has a process in place to manage complaints related to research, or potential breaches of the National Statement and the Australian Code.
- Have a process to manage any potential conflict of interest. Note – If a member of the Committee is the Principal Investigator for a proposal being considered by the Committee that person shall not vote on the proposal.
- Ensure that CHCB has identified at least three senior staff members to provide an ethical consultative service in relation to ethical issues for staff, patients and families.
- Consider the ethical implications of clinical or corporate practice as referred to the Committee by the CHCB General Manager to ensure that it is acceptable on ethical grounds and consistent with the philosophy of LCMHC.
- Report annually to NHMRC and LCMHC Board Mission and Ethics Committee on proposals, ethical matters and Committee composition.
- Ensure that CHCB undertakes appropriate continuing education to ensure that staff and Committee members understand the ethical and philosophical views of the organisation and their relationship to research conducted at CHCB.

10 Changes to the Terms of Reference

These Terms of Reference will be reviewed by the Committee at least once every two years. The Terms of Reference may also be reviewed at the request of any Committee member.

Where possible, changes to the Terms of Reference shall be by consensus. If not possible, changes can be approved by a majority vote of Committee members.