Research Ethics & Ethics Committee Procedure

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 the CHCB Research Ethics and Ethics Committee (REEC) 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 the 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.

This document outlines the procedures and processes that the Committee must follow to ensure compliance with the National Statement and the Australian Code.

2 Responsibilities

Chairperson

The Chairperson, or Deputy Chairperson when required, will ensure that the Committee is compliant with its obligations and reporting requirements under the National Statement and the Australian Code and is aligned to the LCMHC philosophy and the Catholic Code.

CHCB Executive

The CHCB Executive is responsible for adequately resourcing, and maintaining, the Committee, including providing sufficient administrative support.

Will ensure that the CHCB REEC *Application Guidelines for Researchers* and CHCB research governance processes are reviewed regularly and revised as required.

Administrative Assistant

The Administration Assistant shall provide administrative support to the Chairperson and to the CHCB General Manager to ensure the effective operation of the Committee and to ensure all relevant record keeping is accurate and current.

All members

Each member will abide by the procedures contained herein in addition to their respective signed confidentiality agreements. Further, each member will comply with their obligations under the National Statement and the Australian Code.

3 Operating Procedures

3.1 Frequency of Meetings

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

3.2 Attendance at Meetings

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.

3.3 Conduct of Meetings

The Committee will function under the generally accepted and standard rules and procedures for the conduct of committee meetings.

3.4 Preparation of Agenda and Minutes

The preparation of Agendas for meetings of the Committee and Minutes of such meetings shall be undertaken by the Administration Assistant or General Manager under the supervision of the Chairperson.

3.5 Timely distribution of papers

The Agenda, Minutes and Action Log of the previous meeting and papers relevant to research applications to be discussed, considered or noted shall be circulated to Committee members a minimum of one week prior to the scheduled date of the meeting.

3.6 Research proposals

For the presentation and submission of research proposals to the Committee, there shall be relevant standard protocol forms drawn up in such a manner as to ensure compliance with the provisions of *The National Statement* and all other relevant statutory requirements. The *Research Ethics and Ethics Committee Application Guidelines for Researchers* shall:

- contain guidelines on content regarding patient information;
- contain a sample Plain Language Participant Information Sheet;
- contain a sample Consent Form;
- contain a Declaration by the Researcher(s) to observe the provisions of *The National Statement.* The *Human Research Ethics Application (HREA)* will be the accepted template for submission to the REEC;
- provide the researcher(s) with details regarding the procedure for the reporting of adverse occurrences, and of the manner in which monitoring of the research will be undertaken;
- provide the researcher(s) with details regarding fees, if any, that may be charged; and
- contain information about complaint procedures.

3.7 Timely Consideration of Research Applications

Consideration and review of research proposals submitted less than three weeks prior to the date of a scheduled meeting of the Committee may be deferred to the next following scheduled meeting of the Committee.

3.7.1 Negligible and Low Risk Research Proposals

For Negligible risk research, where there is no foreseeable risk of harm or discomfort, and any foreseeable impact is no more than inconvenience to participants; Low risk research, where the only foreseeable risk is discomfort; or quality assurance proposals, the CHCB General Manager may consider use of an Expedited Review for research proposals involving low or negligible risk to participants, for example:

- Observation of current treatment and/or practices with no therapeutic intervention

- Review of patient records
- Surveys

The CHCB General Manager will review all documentation if the proposal qualifies for Expedited Review, and if approves shall communicate the approval to the researcher(s), and shall further table the documentation and report the decision to the next meeting of the Committee, at which meeting the decision shall be ratified. In the event that approval is not granted, the CHCB General Manager shall inform the researcher(s) that expedited approval cannot be given and that the proposal shall be put to the next meeting of the Committee.

The CHCB General Manager will be advised of all decisions of the Committee. The researcher(s) and or institution(s) will be advised by the Chairperson in writing within two weeks of the decision having been made.

3.8 Methods of Deliberation and Decision Making

The Committee shall consider the documentation provided in support of each research application. At the discretion of the Chairperson researchers may be invited to present at the meeting at which their proposal is to be considered but shall leave the meeting before the Committee moves to taking a decision on the proposal.

Where possible decision making shall be by consensus however, if that is not possible, proposals may be approved by a majority vote of the Committee.

Any dissent to a decision taken should be recorded in the minutes as well as the reasons for the dissent.

If a proposal has been approved as suitable to proceed, the CHCB General Manager shall be advised.

Projects will be given a two-year approval period, save that the Committee may elect to extend the approval period for low risk longitudinal studies.

3.8 Amendments

Requests for minor amendments to approvals granted during the undertaking of research projects will be considered by the CHCB General Manager and action taken will be ratified at the next Committee meeting.

3.9 Disclosure of Interests and Management of conflicts of Interest

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.

3.10 Appropriate Confidentiality of the Content of applications and the Deliberations of the REEC

The content of a research protocol submitted to the Committee shall be regarded by the Committee as confidential, even if the protocol is not approved by the Committee.

Committee members shall regard the deliberations of the Committee on proposals as confidential.

3.11 Prompt notification of Decisions to Researchers

The researcher(s) or institution(s) will be advised in writing by the Chairperson within two weeks of any decision having been made.

3.11 Record Keeping

The Administration Assistant and CHCB General Manager shall maintain a record of all proposed research projects so that the following items of information are readily available:

- Name of responsible institution/lead agency
- Project identification number
- Principal investigators
- Approval or non-approval by Research Ethics and Ethics Committee
- Date designated for review
- Progress reports

- Final reports
- Record of location of stored documentation

3.12 Monitoring

The Administration Assistant and CHCB General Manager shall monitor approved research projects until completion consistent with CHCB Safety Reporting and Monitoring of Clinical Trials involving Therapeutic Goods Procedure so that the Committee is satisfied that researchers continue to conform to approved ethical standards and research methodology. The Committee also has the right to withdraw ethical approval for good reason.

3.13 Reporting and Handling Adverse Events

Ethics and Governance approval is conditional on researchers:

- Reporting safety information as required;
- Reporting progress and monitoring outcomes;
- Submitting amendments where needed to eliminate immediate risks or address increased risks; and
- Informing the REEC as soon as possible of new safety information that may affect the ethical acceptability of the research.

The Committee requires an annual progress report and a report on completion from researchers.

The CHCB General Manager is responsible for annual reporting to the NHMRC and the LCMHC Board Mission and Ethics Committee.

The Administration Assistant and CHCB General Manager shall ensure that a summary of projects approved and those where consent was waived are reported in the CHCB Annual Report.

3.14 Receiving and Handling of Complaints

Complaints or concerns about the conduct of an approved research project should be directed to the CHCB Director of Clinical Services on (03 9834 900), prior to consideration by the Committee.

Complaints from researchers about the consideration of their research proposal by the Committee should be directed to the CHCB General Manager on (03 9834 9000).

In the event that the Chairperson or the Committee is unable to resolve the complaint(s), the matter shall be referred to the CHCB Executive Committee in the first instance.

3.15 Advising of Decisions to Suspend or Withdraw Ethics and Governance Approval of a Research Project

In the event of the Committee taking a decision to suspend or withdraw ethics approval of a research project, the Chairperson shall advise the Principal Investigator of the project in writing of the decision taken, and the reasons for the decision, at the earliest possible opportunity.

3.16 Attendance of People other than Members at Meetingsrence

The Chairperson may invite observers to attend meetings of the Committee. Any invited observers should not be involved in deliberations or decision making but are still bound by the same confidentiality and disclosure of interests requirements as Committee members.

4 Related Calvary Documents

- Calvary Feedback and Complaints Management Policy
- Calvary Feedback and Complaint Management Guideline
- CHCB Principal Investigator Role & Responsibility Procedure
- CHCB Research Ethics and Ethics Committee Terms of Reference Policy
- CHCB Research Ethics and Ethics Committee Procedure
- CHCB General Consent Patients and Relatives Policy
- CHCB Information Privacy Policy
- Calvary Speak Out Procedure
- CHCB Safety Reporting & Monitoring of Clinical Trials Involving Therapeutic Goods
- CHCB Reporting and Managing Breaches of the Protocol for Trials using Therapeutic Goods
- CHCB Consent for Research in Those Lacking Decision Making Capacity Procedure
- CHCB Consent to Sharing Research Information with Treating Clinicians Policy
- CHCB Sharing Research Information with Treating Clinicians Procedure
- CHCB Research – Informed Consent Policy
- CHCB Research – Informed Consent Procedure

5 Definitions

Not applicable.

6 References

- National Health and Medical Research Council (NHMRC), Australian Research Council (ARC) & Universities Australia 2023, National Statement on Ethical Conduct in Human Research (2023), Chapter 5
- Australian Code for the Responsible Conduct of Research 2018 and its Supplementary Guides
- CHA Code of Ethical Standards for Catholic Health and Aged Care Services in Australia
- Privacy Act 1988 (Cth)