RESEARCH ETHICS & ETHICS COMMITTEE
APPLICATION GUIDELINES FOR RESEARCHERS May 2023

The Research Ethics and Ethics Committee (REEC) at Calvary Health Care Bethlehem (CHCB) is properly constituted in accordance with the National Health and Medical Research Council (NHMRC) guidelines, relevant Commonwealth and State legislation and regulations and Catholic Health Australia's Code of Ethical Standards for Catholic Health and Aged Care Services in Australia.

The aim of the REEC is to ensure that high ethical standards are maintained in research projects conducted at CHCB, to protect the interests of research subjects, investigators and the institution. In carrying out these functions, the REEC, at all times, takes into consideration guidelines issued by the NHMRC together with the teaching of the Catholic Church and local cultural and social attitudes.

CHCB encourages collaborative research with university partners and other institutions. CHCB REEC will recognise the ethical approval of other Human Research Ethics Committees (HREC) that are properly constituted under the National Statement on Ethical Conduct in Human Research and accredited under the HoMER or SERP schemes.

In Victoria, the Consultative Council for Human Research Ethics is responsible for accreditation of HRECs within public hospitals. It is preferred that any drug or device trial is approved by a recognized lead HREC committee with CHCB REEC responsible for Site Specific Assessment (SSA) authorization.

Any research undertaken at CHCB must comply with:
The Australian Code for the Responsible Conduct of Research (2018)
VMIA toolkit (relevant sections)
The National Statement on Ethical Conduct in Human Research (2007) incorporating all updates
Catholic Health Australia Code of Ethical Standards (2001)
Health Records Act 2001 (Vic) – Health Privacy Principles
Sections 95 and 95A of the Privacy Act 1988
CHCB Mission and Values
CHCB policies
Medicines Australia guidelines
Australian Clinical Trials Registry

When is REEC approval necessary?

Ethics approval should be considered for any study, which involves humans (patients/families, staff or volunteers) or personal information. Such studies may take many forms and be of either a quantitative or a qualitative nature. Research projects include clinical drug and device trials, surveys, audits, focus groups and databases.

Not all projects require full review by CHCB REEC; three distinct types are offered:

1. Low or Negligible risk
2. Full ethical approval
3. Research Governance approval

NOTE: Submissions of applications to Research and Ethic Committee Meetings **must be received 3 weeks prior** to each meeting date**.**

How to apply to the REEC

1. Low or Negligible Risk

Expedited approval processes apply to low and negligible risk projects.

To determine if your project requires ethical review, please refer to **Attachment 2.**

If ethical review is required, submit:

- Cover letter
- CHCB Supplementary Form (**Attachment 1)**
- Complete either:
    - The CHCB Single Site Low or Negligible Risk form **(Attachment 3)** or;
    - The low risk HREA form with study protocol and relevant documents including the Victoria Health Specific module. Please visit the website at **www.hrea.gov.au**
- CHCB REEC Initial Application Fee form (**Attachment 9**)

Note: if using the CHCB Negligible or Low risk form you **are not required** to complete the Vic Health Victoria Specific module.

Submit **One hard copy and one electronic copy** to the GM via the Executive Assistant for expedited approval. 1 Hard copy to be sent to Executive Assistant, CHCB, 152 Como Parade West, Parkdale 3195 and one electronic copy emailed to BET-REEC@calvarycare.org.au.

Please note: this process can take up to 3 weeks.

2. Full approval

Projects that are more than low risk and that have not been approved by an accredited HREC committee for multisite research require full review by CHCB REEC.

Complete the HREA form. Please visit the website at **www.hrea.gov.au** and use the online application form. Complete the online application form, print, add all the attachments and documents listed and make sure that all pages (including the attachments) are numbered sequentially.

Relevant sections of the CHCB Supplementary form **(Attachment 1)** and the Clinical Trials Checklist (if relevant) for Principal Investigators **(Attachment 7)** must both be completed and included with your submission.

Submit:

- Cover letter
- Clinical Trials Checklist with documents attached **(Attachment 7)**
- HREA form
- CHCB Supplementary form
- CHCB REEC Initial Application Fee form (**Attachment 10**)

Submit **One hard copy and one electronic copy** of the complete final proposal along with all attachments and supporting information to the GM via the Executive Assistant for approval. 1 Hard copy to be sent to Executive Assistant, CHCB, 152 Como Parade West, Parkdale 3195 and one electronic copy emailed to BET-REEC@calvarycare.org.au.

If your application is not correctly completed this will delay your approval by the committee.

3. Governance approval

CHCB REEC will recognise the ethical approval of other HREC committees that are properly constituted under the National Statement on Ethical Conduct in Human Research and accredited under the HoMER or SERP schemes. This usually applies to sponsored clinical trials involving therapeutic goods or devices.

This does not mean that all studies approved by another HREC committee will be always deemed suitable to proceed at CHCB. All studies undertaken at CHCB need to undergo a governance review to ensure they fit within CHCB's research agenda, the Catholic Health Australia Code of Ethical Standards and all special Victorian requirements.
Please note: no documents will be signed by CHCB until after review and approval by the CHCB REEC.

Investigators are to use forms as per the Vic Health website
https://www2.health.vic.gov.au/about/clinical-trials-and-research/health-and-medical-research/site-specific-assessment-and-research-governance

Complete the online Site Specific Assessment (SSA) application form, print, add all the attachments and documents listed and make sure that all pages (including the attachments) are numbered sequentially.

Relevant sections of the CHCB Supplementary form **(Attachment 1)** must be completed and included with your submission.

Submit:

- Research Governance Cover letter and checklist, available to download as a word document from: https://www2.health.vic.gov.au/about/publications/formsandtemplates/research-governance-cover-letter-and-checklist (or use **Attachment 9)**
- Relevant forms
- CHCB Supplementary form
- CHCB REEC Initial Application Fee form (**Attachment 10**)

Submit **one electronic copy** of the complete final proposal along with all attachments and supporting information to the GM via the Executive Assistant for approval by emailing it to BET-REEC@calvarycare.org.au.

If your application is not correctly completed this will delay your approval by the committee.

General Information

1. Approvals

Research proposals are usually approved for a maximum 2- year period and must commence within 12 months of approval, otherwise the researcher will need to resubmit the project for approval. If your research goes beyond this timeframe, you will need to reapply in order to continue your study. This is the responsibility of the researcher and failure to comply will result in cancellation of your ethics approval. Note: The Committee may elect to extend the approval period for low risk, longitudinal studies.

Separate to the ethical approval process, CHCB undertakes an operational approval process. The research application will be forwarded to the relevant Department heads with final approval to proceed with the research project given by the General Manager or as confirmed by signing of a contract for Clinical trials involving therapeutic goods. You will receive a written letter informing you of the outcome in relation to ethical and operational approval, once it has been considered by the Executive- generally decisions are communicated to researchers within two weeks of a meeting. If you have gained approval, the letter will also outline your obligations to CHCB REEC. Failure to comply with these obligations will result in your ethical approval being withdrawn.

2. Committee meetings

The REEC meets bi – monthly. **The closing date for proposals is 3 weeks prior to each meeting**. Any late applications for full or governance approval will be held over until the next meeting.

Meeting dates are listed on the 'Research' Page of the CHCB website at: **http://www.bethlehem.org.au/research.html**.

You may be required to attend the REEC meetings to talk to your proposal and will be contacted by the REEC Research & Ethics Administration Assistant to advise.

3. Complaints

Complaints from researchers about the consideration of their research proposal by the REEC should be directed to the CHCB General Manager on 9595 3290 which will be dealt with as per CHCB Complaints Policy and procedure.

4. Documents requiring review by the REEC

The REEC requires, as a condition of approval, that researchers immediately report anything which might warrant review of ethical approval of the protocol, including:

- serious or unexpected adverse effects on participants
- proposed changes in the protocol or serious breaches of the protocol
- unforeseen events that might affect continued ethical acceptability of the project.

Paragraph 5.2.23 of the 2007 National Statement advises that 'All documents and other material used in recruiting potential research participants, including advertisements, letters of invitation, information sheets and consent forms, should be approved by the review body.

The REEC does not require submission of extra documents with no ethical content, such as patient diaries and patient cards.

If there are administrative amendments, protocol deviations, or documents that require review, complete either the Vic Health Amendment Request Form for all clinically sponsored trials or CHCB **Attachment 5** for negligible or low risk studies outlining the summary of the change and impact on the study. In addition, to **Attachment 11** CHCB REEC Amendment Fee Form.

The General Manager will grant governance approval for those with minimal clinical or ethical impact and it will be noted at the next meeting of the REEC. In the case of complex protocol amendments, the GM may refer the request to the REEC.

5. Fees

CHCB Research Ethics & Ethics Committee Fee Structure 2023

Type of Research	**CHCB REEC Fees (Not including GST) $**
Staff or student initiated research projects within CHCB application (ie: in-house)	Nil
Co-operative/collaborative group research project, external sponsored, non-commercial application	600
Unsponsored external investigator initiated research project application: • For profit organization • Not for profit organization	 400 300
Commercially sponsored research project and trials application	3,500
Any collaborative-type study with commercial sponsorship application	3,500
Clinical Trials sub-studies	1,800
Ethics approval: Protocol Amendments to clinical trials	660
Governance approval: Protocol amendments to clinical trials	200
Approval for amendments to investigator brochure	200
Approval for Administrative changes for sponsored trials – includes updates to patient-facing docs, CTRA amendments, single word changes, update of investigator	200
Amendments to CHCB internal study, collaborative unsponsored project	Nil

If you have been granted permission by CHCB REEC to access records, which are not ordinarily available to the public (medical records and computer data), a fee of $3.50 per record may apply.
Archiving Costs
$0.52 per month per box for storage $3.25 per box for the initial lodgement with $32.45 for transport $3.75 per box for any retrieval plus $32.45 for transport

In all cases CHCB reserves the right to negotiate fees. Negotiations must be entered into before submission. You may incur an additional fee if your document requires re-submission by the committee.

Submission fees are required at the time your application is submitted. Please complete either **Attachment 10** CHCB REEC Initial Application Fee Form or **Attachment 11** CHCB REEC Amendment Fee Form.

A complying tax invoice will be issued on receipt of the fee. Our ABN is 81 105 303

6. Guidelines for informing participants about the outcome of research

In line with paragraph 3.3.4 of the 2007 National Statement, REEC believes that participants should have the opportunity, where possible and appropriate, to hear about the outcome of a study in which they have participated preferably within 6 months of completion of the study and encourages researchers to consider this in their study design.

7. If your application involves a clinical trial of a drug or device:

It should be noted that all clinical trials may require an additional approval process by the Calvary insurers. Following favourable consideration by the REEC, the trial proposal may be sent to the hospital's insurers for further consideration and approval prior to formal approval from the CHCB Executive. Researchers should note that they should therefore allow extra time for approval of such clinical trials.

8. Patient Information Sheets for Research Subjects:

The CHCB REEC requires a *Patient Information Sheet* to be given to potential research subjects to assist them in their decision about potential participation. The *Patient Information Sheet* must accompany each *Consent Form*. In order to assist researchers in preparing *Patient Information Sheet* the following guidelines on content and use have been prepared:

a. The *Patient Information Sheet* is one aspect of providing information so that people may come to informed decisions about their involvement in research. It must not replace personal communication between the investigator and the potential subject.

b. The investigator should ensure that the potential subject has the mental capacity and English comprehension necessary and is given sufficient time to consider the verbal and written information provided, and to discuss it with other people, before being asked to give consent to involvement.

c. The *Patient Information Sheet* is to remain the property of the subject and a copy of the signed Consent Form should also be provided on request.

d. Use simple plain English language with minimal technical terminology or jargon.

e. The sheet must be translated if non-English speaking subjects are to be recruited.

f. The following items will usually be included:
   - Purpose of the study
   - Participant description
   - Accurate information and declaration of all risks, burdens and benefits from the study to the subject and/or the community
   - All procedures that involve the subject, including the use of drugs or radioisotopes.
   - Alternative procedures or treatments for patients, if they elect not to enter the study.
   - Participant rights and responsibilities
   - Privacy and confidentiality including handling of information
   - Financial issues
   - Results
   - Cessation of study

g. The following **must** be included:
   - *This is a research project and you do not have to be involved. If you do not wish to participate, your medical care will not be affected in anyway.* (Include this at or near the beginning of the information sheet).
   - Investigators names, institution affiliations and contact details.
   - *If you have a complaint or concerns about the conduct of the project you should contact the General Manager, CHCB on 9595 3290 prior to consideration by the REEC.*

h. For protocols involving significant drug therapy and or clinical interventions, the following information should be included: -
   - Name of medicine(s) – generic preferred, trade names if necessary to study design

- Conditions in which the medicine should not be taken – e.g. pregnancy
- Whether the drug is meant to treat the disease or to relieve symptoms and therefore how important it is to take the medicine
- How to tell if the medicine is working and what to do if it appears not to be working
- When, how and how long to take the medicine, before or after meals etc
- What to do if a dose is missed and the implications of ceasing the medicine for any length of time
- Important side-effects and what to do about them, including effects on driving, work etc.
- Interactions with alcohol and other drugs (generic and trade names)
- Storage and disposal of medicines.
- All foreseeable risks, side effects, discomforts, inconveniences and restrictions, both immediate and late (especially after leaving hospital) that will be involved eg: travel, absence from work
- A comparison of the likelihood and probability of adverse effects from other procedures (or drugs) used for the same purpose.
- An explanation that randomization and/or placebos may be used (where relevant).
- A statement that the subject may withdraw from the trial at any time without prejudice to his/her future treatment (may be on Consent Form)
- Assurances of confidentiality and data protection and storage (may be on Consent Form)
- Measures that will be taken in case of an adverse event
- The name and telephone numbers (work and after hours) of all members of the research group who can be contacted if any problems arise.
- Contact details of the CEO, who is available to discuss general aspects of participation in a research project (telephone 9596 2853).

9. Payment of participants in research projects

CHCB REEC considers it appropriate to offer participants reimbursement for 'direct out of pocket' expenses (such as travel expenses) or considering the inconvenience, loss of time and possible discomfort. The REEC encourages researchers to consider such reimbursement when planning clinical studies though reimbursement should be structured so as not to be considered an inducement to participants. It is also important that lack of reimbursement does not exclude patients from participation in a research study.

10. Progress/Final reports

Researchers are required to provide annual progress reports by 30 May each year and a final report on conclusion of the study. Clinically sponsored trials are to complete the Vic Health progress or final report template, all other studies are to complete **Attachment 4**. The dates for these reports should be noted in your calendar. Note: When completing your annual project report, clinical trials must complete the Organisational Self-Assessment Reporting Tool template at the same time. CHCB REEC should also be notified of any changes that occur to your research project, including change of researchers. Failure to provide this information will result in cancellation of your ethics approval. All reports and correspondence is to be submitted to BET-REEC@calvarycare.org.au

11. Registration of clinical trials

In accordance with paragraph 3.3.12 of the 2007 National Statement, all clinical trials must be registered. The Australian Clinical Trials website is at www.actr.org.au. Please advise registration number and date. If your trial has been registered on another registry, please advise.

12. Requirements for research in humans of reproductive age

CHCB has concerns about any research study involving drugs with potential side effects on the unborn child. All women participating in studies involving drugs with an unknown effect on the unborn child are required to have a pregnancy test prior to entering the study and to be informed that they could potentially be excluded from the study.

As a Catholic health care service, CHCB is committed to reflecting the Church's teaching regarding respect for the personal dignity of human life in all stages. It is therefore imperative that there is certainty of causing no harm to the life or integrity of a human embryo or foetus. As such, we require that the following **unedited** statements be included in the information for participants in medical research:

'The effects of [Name of investigational product] on the unborn child and on the newborn baby are not known. Because of this, it is important that research project participants are not pregnant or breast-feeding and do not become pregnant during the course of the research project. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding. If you are female and child-bearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the research project. If you are male, you should not father a child or donate sperm for at least [number] months after the last dose of study medication.

Both male and female participants must avoid pregnancy during the course of the research and for a period of [number] months after the last dose of study medication. You should discuss effective methods of avoiding pregnancy with your study doctor.

[For female participants] If you do become pregnant whilst participating in the research project, you should advise your study doctor immediately. Your study doctor will withdraw you from the research project and advise on further medical attention should this be necessary. You must not continue in the research if you become pregnant.

[For male participants] You should advise your study doctor if you father a child while participating in the research project. Your study doctor will advise on medical attention for your partner should this be necessary.'

13. Serious Adverse Events

A serious adverse event is defined in the Glossary to the National Statement as any untoward medical occurrence that results in death, is life threatening, leads to in-patient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity or a congenital anomaly/birth defect or is a medically important event or reaction.
Investigators need to notify the REEC promptly of all serious adverse events that occur at CHCB as per Safety Reporting and Monitoring of Clinical Trials Involving Therapeutic Goods Procedure. Sponsored Clinical trials are to complete the Vic Health AE/SAE or SUSAR/USADE Site Report form, all other studies to complete **Attachment 6** and submit to the REEC.

14. Template Consent Form (attachment 8)

This template articulates the obligations of both investigators and participants and is attached to the back of this document if you should wish to use it.

15. Withdrawal of ethical approval

Where researchers fail to comply with approved protocol or conditions of approval, researchers will be invited to explain and rectify the issue. Unless the REEC is completely satisfied with the resolution, ethical approval will be withdrawn.

Attachments

1. **Attachment 1 CHCB Supplementary form**. Only relevant sections need be completed.

2. **Attachment 2 Checklist for identifying low or negligible risk projects.** This checklist is designed to aid researchers in determining the level of risk of their projects. Applicable to low-risk, negligible risk and quality assurance projects.

3. **Attachment 3 CHCB Single Site Low or Negligible Risk form.**

4. **Attachment 4 Progress/Final Report** - As per terms of approval of projects, all researchers are required to submit periodic progress reports annually. This is the responsibility of the Researcher.
   Clinically sponsored trials:
   https://www2.health.vic.gov.au/Api/downloadmedia/%7B932C758D-B433-40D3-9A25-2A09874C1C8A%7D
   https://www2.health.vic.gov.au/Api/downloadmedia/%7B01A644E3-860F-49A6-A2D6-50DF25F1002D%7D

5. **Attachment 5 Request for amendments & extensions** - To be used for amendments to protocol, protocol deviations, administrative changes, requests for extensions to the study & other issues.

Clinically sponsored trials: https://www2.health.vic.gov.au/Api/downloadmedia/%7B47FA4436-9363-43CC-B341-7F0CCCFDA0F3%7D

6. **Attachment 6 Adverse Events/Serious Adverse Events (AE/SAE) Form**
   Clinically sponsored trials: https://www2.health.vic.gov.au/Api/downloadmedia/%7BA3A1EFD5-CED1-4BC2-B33E-E26FF88D3B77%7D
7. **Attachment 7 Clinical Trial Checklist- Full Approval**
8. **Attachment 8 Template Participation consent form**
9. **Attachment 9 Cover Letter for Research Governance Approval**
10. **Attachment 10 CHCB REEC Initial Application Fee Form**
11. **Attachment 11 CHCB REEC Amendment Fee Form**
    Note: Sponsored Clinical Trials are expected to use forms available on Vic health website

    https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting