



CALVARY HEALTH CARE BETHLEHEM RESEARCH ETHICS & ETHICS COMMITTEE

APPLICATION GUIDELINES FOR RESEARCHERS

The Research Ethics and Ethics Committee (RE&EC) at Calvary Health Care Bethlehem (CHCB) is properly constituted in accordance with the National Health and Medical Research Council (NHMRC) guidelines.

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

Applicants should read the NHMRC National Statement on Ethical Conduct in Research Involving Humans (2007) and the guidelines for the Protection of Privacy in the Conduct of Medical Research before completing this application. Refer to link below

When is RE&EC approval necessary?

Ethics approval should be considered for any study, which involves humans (clients/patients, staff or volunteers) or personal information. Such studies may take many forms and be of either a quantitative or a qualitative nature. There are some exemptions for research involving laboratory samples.

Quality Assurance/Audit and Ethical Review

Under the *National Statement on Ethical Conduct in Research Involving Humans*, any research project involving humans must be submitted to an HREC for ethical review – refer to link below

The **NHMRC** publication "*When does quality assurance in health care require independent ethical review?*", has served as the basis for a checklist (refer to link below)

<http://www.nhmrc.gov.au/publications/synopses/e46syn.htm>

How to apply to the RE&EC

The CHCB RE&EC is trialling the use of the new National Ethics Application Form (NEAF). Please visit the website at www.neaf.gov.au and use the online application form. It will be necessary to log in as a 'New User' in order to be able to download and print the required documents for submission. NEAF is a dynamic, interactive, web-based tool for researchers of all disciplines to complete research ethics proposals for submission to Human Research Ethics Committees (HRECs, at CHCB the RE&EC). Follow the instructions on the website to complete a research proposal.

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.

The chief investigator will need to submit a covering letter addressed to the CEO of CHCB, together with 10 hard copies of the complete final protocol/proposal. This MUST include ALL attachments and supporting information before it can be considered.

Send to: CHCB Research Ethics & Ethics Committee, C/- CEO's PA, CHCB, 476 Kooyong Road, Caulfield 3162. The RE&EC meets bi – monthly. The closing date for proposals is 3 weeks prior to each meeting. [Click here for dates](#) You may be required to attend the RE & EC meetings to talk to your proposal. RE&EC decisions are generally communicated to researchers within one week of a meeting.

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

It should be noted that all clinical trials require an additional approval process by the Calvary insurers. Following favourable consideration by the RE&EC, the trial proposal will 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.

Complaints

Complaints from researchers about the consideration of their research proposal by the RE & EC should be directed to the CEO on 9595 3290 which will be dealt with by the CHCB Executive Committee as per CHCB Complaints Policy.

Fees

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 will apply.

Guidelines for Payment of Volunteers

In the ordinary course of clinical research no monetary payments (other than for bona fide expenses) should be made to the subjects participating in a research study. However, there are circumstances in which the participants are acting as normal volunteers in a project which is of no possible advantage to themselves and may involve inconvenience, loss of time and possible discomfort. In these circumstances, the payment of an honorarium may be justified subject to the following restrictions:

1. No financial inducements of the kind should be made to individuals who at the relevant time are patients.
2. The payment must in no circumstance be offset against the possible risk of the procedure involved. It is only to be regarded as compensation for loss of time, inconvenience and possible discomfort.
3. Great care must be exercised to ensure that the volunteers to whom payment is made are of an age and maturity to be able to make an independent decision.
4. Payment for services of this kind in no way absolves medical staff concerned of their responsibility should the procedure have any untoward consequence.

Patient Information Sheets for Research Subjects:

Guidelines on Content and Use

The HREC 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.

General

1. 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.
2. 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.
3. 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.

4. Use simple plain English language with minimal technical terminology or jargon.
5. The sheet must be translated if non-English speaking subjects are to be recruited.
6. The following items will usually be included:-
 - I. Purpose of the study
 - II. Accurate information and declaration of all risks, burdens and benefits from the study to the subject and/or the community
 - III. All procedures that involve the subject, including the use of drugs or radioisotopes.
 - IV. Alternative procedures or treatments for patients, if they elect not to enter the study.
7. The following must be included:
 - (i) *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 any way.* (Include this at or near the beginning of the information sheet).
 - (ii) Investigators names, institution affiliations and contact details.
 - (iii) *"If you have a complaint or concerns about the conduct of the project you should contact the Director of Mission on 95953211 prior to consideration by the RE & EC.*

In protocols involving significant drug therapy and or clinical interventions, the following information should be included:-

- a. Name of medicine(s) – generic preferred, trade names if necessary to study design
- b. Conditions in which the medicine should not be taken – e.g. pregnancy
- c. Whether the drug is meant to treat the disease or to relieve symptoms and therefore how important it is to take the medicine
- d. How to tell if the medicine is working and what to do if it appears not to be working
- e. When, how and how long to take the medicine, before or after meals etc
- f. What to do if a dose is missed and the implications of ceasing the medicine for any length of time
- g. Important side-effects and what to do about them, including effects on driving, work etc.
- h. Interactions with alcohol and other drugs (generic and trade names)
- i. Storage and disposal of medicines.
- j. 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
- k. A comparison of the likelihood and probability of adverse effects from other procedures (or drugs) used for the same purpose.
- l. An explanation that randomization and/or placebos may be used (where relevant).

- m. 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)
- n. Assurances of confidentiality and data protection and storage (may be on Consent Form)
- o. Measures that will be taken in case of an adverse event
- p. The name and telephone numbers (work and after hours) of all members of the research group who can be contacted if any problems arise.
- q. Contact details of the Director of Mission, who is available to discuss general aspects of participation in a research project (telephone 9596 2853).

Researchers should be aware of the possibility of exploiting subjects who are in a dependent relationship of any sort. These would include patients, fellow employees, students. Care must be taken to ensure that no subtle coercion is applied to encourage research participation. ([link to Consent Form](#))