

HREC Lodgement Information for Research Applications

HREC Meeting dates 2020	Application cut-off date
February 19	January 29
April 15	March 25
June 24	June 3
October 21	September 30
December 16	November 25

The purpose of the Calvary Public Hospital Human Research and Ethics Committee (HREC) is to ensure the principles of ethically good human research is practiced when research is being conducted in this hospital.

CPHB HREC ensure that consistently high ethical standards are maintained and that research undertaken within the hospital protects the interests of research participants, investigators and the institution. In carrying out these functions, Calvary HREC at all times adheres to the ethical guidelines detailed in the NHMRC National Statement while also respecting our local cultural and social attitudes.

When is HREC approval necessary?

Ethics approval should be considered for any study which will involve patients, staff, volunteers, personal information, historical information and records access. Such studies may take many forms and be of either a quantitative or a qualitative nature. Contact the HREC (ethics@calvary-act.com.au) for details if your research is in this category.

Applying for HREC approval

To apply for Calvary HREC approval you need complete an Application Form, links are below. CPHB HREC accepts

- HREA forms with an accompanying letter.
- ACT Health applications with changes to addressee and site specific changes

*CPHB HREC will accept REGIS applications **once REGIS comes online for CPHB HREC**. Information for lodging applications will be updated on this website when REGIS is available to this site.*

When lodging an application you need to include a covering letter addressed to:

Delivered:

Professor Frank Bowden
Chairman
CPHB HREC
Cnr Haydon Dr and Belconnen Way
Bruce ACT 2614

Postal Address:

Professor Frank Bowden
Chairman
CPHB HREC
P.O. Box 254,
Jamison Centre ACT 2614

In plain English (without jargon) the letter should include the following information:

- Name of the project
- An outline of the project
- name of the head P.I
- the risk level
- the anticipated length of time the study will take

The letter should also include details of the documents sent and name the hospital you wish to apply to: Calvary Public Hospital Bruce HREC, Calvary Hospital Private Bruce HREC, Calvary John James Hospital or Calvary Retirement Community. Please make sure you include contact details.

Prior to submitting an application for Calvary John James or Calvary Retirement Community, approval to conduct studies at these campus' needs to be obtained.

Include all documents that are relevant. They must be in PDF format and numbered according to the sequence they need to be represented for submission to the HREC e.g.

- 1. Sampledoc.pdf,
- 2. Sampledoc.pdf
- 3. Sampledoc.pdf.

Please ensure that all pages (including the attachments) are numbered sequentially.

Anticipated start dates need to be following HREC meeting approval date. Applications with start dates prior to HREC approval cannot be tabled. CPHB HREC are unable to provide retrospective approval for applications and incorrectly dated applications may delay your approval until the next HREC meeting. For consideration of your application, you need to submit an electronic copy of your completed application to ethics@calvary-act.com.au prior to the **closing date** for the next HREC.

HREC coverage

Calvary has two HREC's – one for the Public Hospital and one for the Private Hospitals. They are constituted in accordance with the NHMRC guidelines and HREC practice ensures compliance. Both HRECs meet on the same date and work concurrently.

Clinical Audit undertaken by Students

In some defined areas CPHB HREC has established a review process for students undertaking a retrospective medical records audit for which there is a separate application process. Please contact the HREC ethics@calvary-act.com.au if you feel that your research is in this category.

How long does it take?

The HREC meets 6 times a year, generally every 2 months. The closing date for proposals is 3 weeks prior to each meeting. Dates of meetings and closing dates for applications are available above. Late applications won't be presented for ethical review and will be held over until the next HREC meeting. Following HREC approval, applications are forwarded to the Executive Management Group for operational and resource approval. Following Executive Management Group approval you will receive a formal letter by post or email informing you of the outcome of your application. The approval letter sets out your obligations to the CPHB HREC. Failure to uphold your obligations could result in your HREC approval being withdrawn.

What are the charges?

Proposals submitted to the HREC for approval are subject to a Research Protocol Levy.

Type of project	Levy
Calvary Health Care ACT staff Low-risk and research applications without funding	\$0 If funded \$125 levy
Student low-risk projects unfunded	\$0
Student low-risk studies funded	\$110
Research projects funded/unfunded	\$220
Clinical trials	\$4,500
Clinical Trial sub-studies or extensions	\$2,000
Amendments to approved projects (Clinical)	\$660
Administrative changes and updated Investigator's Brochure	\$165

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

All clinical trials require an additional approval process by the Calvary insurers. Following favourable consideration by the HREC, the trial proposal will be sent to the hospital's insurers for further consideration and approval prior to formal approval from the Calvary Executive Management Group. Researchers should note that they should, therefore, allow extra time for approval of clinical trials.

Use of Calvary Staff and/or Equipment

Applications need to be accompanied by a completed [Estimate of Costs Form](#), which can be downloaded from this website. This form is required for approval from the Calvary Executive Management Group. Failure to complete and submit this form may result in your application being delayed or rejected.

Length of Time of Research

Please be aware that all research is approved for a maximum 3 year period. If your research extends beyond this time period, you need to reapply to continue your study. It is up to the researcher to ensure that their research continues and that their reapplication/s arrives by the due date. Failure to comply may result in your ethics approval being cancelled.

[Annual and Progress Reports](#)

Researchers are required to provide annual progress reports and final reports. The submission dates for these reports should be noted in your calendar. CPHB HREC needs to be notified of any changes that occur to your research or researchers, such as, change of address or contact details. Staff changes including CVs need to be supplied as 'Amendments' to CPHB HREC for noting. Failure to provide this information may result in cancellation of your ethics approval at Calvary Health Care ACT.

[Forms links here](#)

[Student HREC low risk application form](#)

[Non-Student Low Risk application form](#)

[Estimate of Costs Form](#)

[Interim or Final Report Form](#)

[Request for extension form](#)

HREC Terms of Reference 2019.

[Complaints form](#)

CHECK LIST

Essential Documentation	YES	NO
Covering letter		
Your fully completed application form		
Participant Information Sheet		
Participant Consent Form		
Liability Insurance Certificate of Currency		
Indemnity Cover between the sponsor and investigators		
Indemnity Cover between the sponsor and CHCACT		
Medicines Australia Form of Indemnity for clinical trials standard		
Questionnaire, Surveys, etc		
Study Protocol		
Protocol Amendment		
Subject Diary		
Advertisement		
Poster		
Visit Schedule		
Visit Reminder Card		
Physician Referral Card		
Notification of intent to supply unapproved therapeutic goods under the clinical trial notification (CTN) Scheme		
Copy of PI an Co-I Medical Registration Certificate and personal medical insurance cover		
Evidence of Registration of the trial in a publicly accessible register		
Other HREC approvals		
Investigator		
pdf Format		
Sequential numbering of files		