



**Cabrini  
Institute**

Education  
and Research

# **Cabrini Human Research Ethics Committee Handbook**

**Last updated January 2012**

This document is subject to update and amendment as required by the  
Cabrini Human Research Ethics Committee.

Copies of the most recent version of the document are available:

Online: [www.cabrini.com.au](http://www.cabrini.com.au)

By email request to [hrec@cabrini.com.au](mailto:hrec@cabrini.com.au)

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## CABRINI HUMAN RESEARCH ETHICS COMMITTEE

The office of the Cabrini Human Research Ethics Committee (CHREC) is located within the Cabrini Institute on the first floor of the hospital at:

183 Wattletree Road  
Malvern, VIC 3144

Telephone: 03 9508 1375  
Facsimile: 03 9508 1368  
Email: [hrec@cabrini.com.au](mailto:hrec@cabrini.com.au)

CHREC is staffed by Anne Spence (Manager), Grace Wijnen and Stephanie Heriot. Please contact the office using the above information if you have any questions or would like to know more. Anne Spence also manages research governance.

CHREC is a committee of the Board and reports directly to the Board. CHREC approves and reviews research projects involving human participants being conducted at Cabrini Health to ensure that:

- the research affirms the mission and values of Cabrini Health and the teaching of the Catholic Church
- ethical standards are maintained in research projects to protect the interests of the research subjects, the investigator and the institution.

Research projects include clinical drug and device trials, surveys, audits, focus groups and databases. Additionally, any activity that involves sending Cabrini patient data to other institutions in the name of research should be reviewed by CHREC.

CHREC conducts its business in accordance with:

- the [National Statement on Ethical Conduct in Human Research](#), issued by the National Health and Medical Research Council (NHMRC) in March 2007
- other relevant federal and state legislation and regulations
- Catholic Health Australia's Code of Ethical Standards for Catholic Health and Aged Care Services in Australia (2001).

## INSTRUCTIONS TO APPLICANTS

### Before you get started

All intending investigators should read Cabrini Health's Mission Statement, the Annual Report and this Handbook and also familiarise themselves with:

- the [National Statement on Ethical Conduct in Human Research](#), NHMRC
- *Chapter 6: Research*, Catholic Health Australia's [Code of Ethical Standards](#) for Catholic Health and Aged Care Services in Australia
- the [Privacy Act 1988](#) (Commonwealth)
- the [Health Records Act 2001](#) (Victorian).

Other useful references include:

- NHMRC's [Making Decisions about Tests and Treatments: Principles for Better Communication between Healthcare Consumers and Healthcare Professionals \(2005\)](#)
- [International Conference on Harmonisation \(ICH\) Guidelines for Good Clinical Practice](#)
- The Joint NHMRC/ARC/UA [Australian Code for the Responsible Conduct of Research 2007](#)
- [The Australian Clinical Trial Handbook \(2006\)](#)
- Medical Journal of Australia, volume 186:12 (2007) [Clinical practice guidelines for communicating prognosis and end-of-life issues with adults in the advanced stages of a life-limiting illness, and their caregivers](#)
- [Victorian Managed Insurance Authority](#)

## Deciding which level of review you need

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

1. Full
  2. Low and negligible risk
  3. Governance
- 
1. Projects that have more than low risk and that have not been approved by another committee require full review by CHREC at a meeting.
  2. Expedited approval processes apply to quality assurance and low and negligible risk projects. CHREC review of low risk projects is commensurate with the level of risk. Final assessment of risks (see Chapter 2.1 on page 15 of the [2007 National Statement](#)) is the domain of the Manager, CHREC (and not the researcher).  
*Please see Appendix A 'Processes for Review of Human Research Applications' and Appendix B 'Level of review flow chart'.*

To determine if your project is quality assurance, complete [Attachment 3](#). If QA review applies, send this checklist, a project protocol and any patient information to Anne Spence.

CHREC has formal agreements with Deakin and Monash Universities and Alfred Hospital regarding mutual recognition. Please talk to Anne Spence if you need to use these agreements.

Should you contemplate any audits and staff surveys or any type of study that requires access to medical records, you must seek approval. This is mostly a very simple process and it ensures that we have a central register of such activities going on within the hospital. Please also read the Cabrini Hospital inpatient registration form and the Cabrini privacy statement 'What happens to information about you?' These documents give clear guidance about how patient information may be used. If you propose using the information in any other way or for any other purpose, you must inform CHREC.

3. CHREC will recognise the ethical approval of other human research ethics committees properly constituted under the National Statement on Ethical Conduct in Human Research and accredited under the HoMER or SERP schemes. CHREC is accredited under both of these.

This does not mean that all studies approved by any other human research ethics committee will be deemed suitable for Cabrini. All studies undertaken here will need to fit within Cabrini's research agenda, the Catholic Health Australia code and all special Victorian requirements.

Wherever resources are required from Cabrini staff or facilities, please be sure to fill in the Cabrini Project Resourcing and Costing Form (available at [www.cabrini.com.au](http://www.cabrini.com.au)).

## Applying

CHREC accepts applications using all forms currently utilised by the Victorian Government and available on <http://www.health.vic.gov.au/cchre>, including the [Victorian Specific Module](#) (VSM), applications using the Cabrini specific form ([attachment 1](#)) and applications using the [National Ethics Application Form](#) (NEAF). If using the NEAF or VSM, you will need to complete the Cabrini supplement ([attachment 2](#)). This applies for both full and governance review. The procedures for copies, attachments and wording are outlined below and apply no matter which form/s you use.

As Victorian and Commonwealth Government requirements vary, if you use the NEAF, you must ensure you consider Victorian specific issues of the Health Records Act, Ionising Radiation and Guardianship.

### For full review

The Cabrini application form ([attachment 1](#)) is available from the Cabrini Health website. It is designed to be completed electronically then printed and submitted in hard copy. Applicants should use as much space as necessary to give a full and complete answer to each question.

If a section is not relevant to your research, please answer 'not applicable' at the start of the section, delete the rest of the section and remove the page break so that the next section begins immediately.

The application is divided into 10 sections as follows:

### Section 1 Administrative information

Complete in full and attach copies of supporting documents to this section, including:

- letters of approval from other human research ethics committees
- letters of support from clinicians expected to recruit patients
- project resourcing and costing template—relevant sections.

Where one or more of the researchers is not connected with Cabrini Health and/or the research is being carried out in conjunction with agencies outside of Cabrini Health, the connection to Cabrini of all researchers must be listed, as must the names of all agencies participating in the project.

Please note that where Cabrini staff are involved, there is a cost to Cabrini associated with the project or use of Cabrini facilities is proposed, permission to proceed must be obtained prior to submission of the proposal, using the project resourcing and costing template.

## **Section 2 Project summary**

The project summary should be written in simple language suitable for lay people, aimed at the reading comprehension of a 14-year-old. It should include the rationale, background from the literature, aims, methodology and method of analysis and should be no longer than one A4 page.

## **Section 3 Resource information**

This section should contain sufficient information to assure the Committee that the resources necessary to carry out the project to completion will be made available in line with paragraph 3.3.5 of the 2007 [National Statement](#).

## **Section 4 Project information**

Please ensure that all questions are answered, either on the form or as part of an attachment. Please ensure all attachments have appropriate footers.

You must also outline the potential risks arising from the project (paragraphs 3.3.7 to 3.3.10 of the 2007 [National Statement](#) apply), the potential consequences of those risks and the measures to be taken to deal with those consequences. Explain the monitoring, reporting and other procedures to be put in place to manage serious adverse and other unforeseen events. This includes adverse events of a physical or emotional nature, as well as adverse events relating to project information, such as de-identified information becoming identified.

## **Section 5 Drugs and therapeutic devices**

Please read chapter 3.3 of the 2007 [National Statement](#) and complete this section only if the project involves trials of drugs or therapeutic devices. If this section is not relevant to your research, please answer 'not applicable' at the start of the section and remove the page break so that the next section begins immediately.

## **Section 6 Human tissues**

Please read chapter 3.4 of the 2007 [National Statement](#) and complete this section only if the project involves use of human tissue, such as blood. If this section is not relevant to your research, please answer 'not applicable' at the start of the section and remove the page break so that the next section begins immediately.

## **Section 7 Human genetic research**

Please read section 3.5 of the 2007 [National Statement](#) and complete this section only if the project involves genetic analysis of human tissue. If this section is not relevant to your research, please answer 'not applicable' at the start of the section and remove the page break so that the next section begins immediately.

## **Section 8 Ionising radiation**

Complete this section only if the project involves ionising radiation. If this section is not relevant to your research, please answer 'not applicable' at the start of the section and remove the page break so that the next section begins immediately. Otherwise, please use the [Radiation Safety form \(attachment 5\)](#), noting that Cabrini's radiation safety officer is Dr Graeme Hall, contactable at Cabrini Medical Imaging on 03 9508 1444.

Please note that the project will require the approval of the Victorian Radiation Advisory Committee if it involves radiation that is not part of normal treatment. For further information please consult the [Department of Human Services website](#) and complete module 4 of the Victorian Common Application Form.

## **Section 9 Human research ethics committee issues**

Please ensure that you note sections f, h and j of this document.

## **Section 10 Declaration**

The application requires original signatures of all members of the research team.

### **For low and negligible risk review**

Please complete the Cabrini application form as detailed above, deleting all irrelevant sections.

### **For governance review**

Please submit the application form as used for the initial application and complete the Cabrini supplement form.

## **Attachments**

### **For full and low and negligible risk review**

Please attach to each of the 16 application forms the following documents (where applicable) in this order:

- a flow chart of the study processes
- a full project protocol outlining all procedures and details of data collection, storage and analysis
- participant information summarising the project for participants, written in plain language (grade 8 reading level)—see chapter 2.2 and paragraph 3.3.13 of the 2007 [National Statement](#). Cabrini requires that certain clauses and wording are included in this information, see items b, c, d, e, i, j and k.

- a consent form/s
- a letter of support from any involved external hospital departments or personnel
- for student projects—see 'a' below
- project budget
- CVs for any member of the research team who has not previously submitted a proposal
- advertisements
- all relevant tools and questionnaires.

*Please note that attachments must include a footer indicating the name of the document, version number, date, page number and number of pages.*

In addition, please provide two (2) copies of the investigator's brochure.

And one copy of:

- insurance details
- indemnity
- contracts/agreements
- CTN form/s
- Cabrini project resource and costing template (where applicable).

### **For governance reviews**

Please submit the application with all attachments as included in the submission to the committee providing ethical review, including the Master participant information and consent form. This must also be revised to be specific to Cabrini, listing Anne Spence as the complaints person, including Cabrini's mandated wording regarding prevention of conception (see item **Z**) and including a Cabrini logo. The logo can be obtained by contacting the CHREC office. Please also provide a copy of the letter of approval from the reviewing committee.

## **Submission**

### **For full review**

The original documents **compiled** into a single set and sixteen (16) **compiled** copies (including the attachments listed above) must be submitted to CHREC.

Font should be no smaller than 12 point, each section should be stapled if possible and each copy bound with a rubber band. Please do not use paper clips or other forms of binding.

All completed paperwork is to be sent to:

Anne Spence  
 Cabrini Human Research Ethics Committee  
 Cabrini Institute  
 183 Wattletree Road  
 MALVERN VIC 3144

**E-mail submissions cannot be accepted.**

**Only fully compiled applications received by the submission deadline in the complete form and with the correct number of copies will be processed for the relevant CHREC meeting.**

<b>MEETING</b>	<b>SUBMISSION DEADLINES</b>
Monday, 30 January 2012	Thursday, 12 January 2012
Monday, 5 March 2012	Thursday, 16 February 2012
Monday, 23 April 2012	Thursday, 5 April 2012
Monday, 21 May 2012	Thursday, 3 May 2012
Monday, 25 June 2012	Thursday, 7 June 2012
Monday, 6 August 2012	Thursday, 19 July 2012
Monday, 10 September 2012	Thursday, 23 August 2012
Monday, 22 October 2012	Thursday, 4 October 2012
Monday, 3 December 2012	Thursday, 15 November 2012

<http://www.cabrini.com.au/cabriniinstitute/meetingdates.asp>

All documents—applications, progress reports, SAEs and so forth—are due by the submission deadline.

For any enquiries regarding ethics applications please contact the office.

**For low and negligible risk and governance review**

Applications may be submitted whenever completed. Meeting dates do not apply to these reviews. Approval will be ratified at the next meeting.

**Submission fees**

**Fees for submission of your application are as follows:**

	<b>Effective 1 July 2009</b>
Commercially Sponsored Initial Proposal	\$5,500 +gst
Governance Review	\$4,000 +gst
Commercially Sponsored Protocol Amendments	\$650 +gst
Un-sponsored Initial Proposal	\$300 +gst
Document Administration Fee	\$100 +gst

In all cases the Manager of CHREC reserves the right to negotiate the submission fee.

Submission fees are required at the time your application is submitted. Fees may be paid by:

- cheque made payable to Cabrini Health Limited – Cabrini Institute; **or**
- direct deposit to Cabrini Health Limited – Cabrini Institute  
 BSB number: 033 059  
 Account number: 12 2820

A complying tax invoice will be issued on receipt of the fee. Our ABN is 33 370 684 005.

## GENERAL INFORMATION

### a Review of the science for students

Are you a student? Does this project form part of your tertiary study? If so, you must ask your university supervisor and the head of the relevant Cabrini Department (that might be two different people or it could be the same person) to write a letter of endorsement to accompany the application stating that he/she has reviewed the scientific methodology of the study and that methodology is appropriate.

### b Advice for research participants

Trials involving medical therapies require a standard clause in the participant information (plain language statements) on the page with the contact details for the study personnel saying:

*We encourage you to discuss study participation with your family, friends and medical advisers. We recommend that you ask your medical advisers to contact the study investigator.*

### c Statement of CHREC review

Participant information (plain language statements) may also include a statement that:

*The ethical aspects of this study have been reviewed by the Cabrini Human Research Ethics Committee and the study complies with the NHMRC's National Statement on Ethical Conduct in Human Research.*

### d Complaints

Please read Chapter 5.6 of the 2007 [National Statement](#) regarding handling complaints. All participant information (plain language statements) should include Anne Spence (telephone 03 9508 1376) as the contact in the instance of a complaint relating to the ethical conduct of the project.

*See Governance Handbook*

## e Requirements for research in humans of reproductive age

CHREC 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, Cabrini 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 participant information (plain language statements) **MUST** include the following statement:

*If you are a sexually active woman who is potentially fertile, you will be excluded from taking part in this study unless you are using a medically reliable method of preventing conception for the duration of the study. Should you become pregnant during the study you should notify your family doctor and the study doctor as soon as possible.*

Equally, the male partner of a sexually active woman who is potentially fertile will be excluded from taking part in the study unless using a medically reliable method of preventing conception for the duration of the study.

The participant information (plain language statements) **MUST** include the following statement.

*If you are the partner of a sexually active woman who is potentially fertile, you will be excluded from taking part in this study unless you are using a medically reliable method of preventing conception for the duration of the study.*

## f Guidelines for informing participants about the outcome of research

CHREC notes that:

- the results of a study may not be available for many years and their relevance to participants may become remote
- the results may not be in the public domain, that is, they may remain the property of the sponsoring agency
- it may be that the release of results is not in the best interests of participants
- confidentiality could be seen to be questionable if participants are contacted after studies are completed
- researchers seldom have editorial control of publications

- the ability to deliver results in a secure and confidential manner is dependant on many factors, including the ability of a researcher to maintain an accurate participant database.

Notwithstanding the above and in line with paragraph 3.3.4 of the 2007 [National Statement](#), CHREC believes that participants should have the opportunity, where possible and appropriate, to hear about the outcome of a study in which they have participated and encourages researchers to consider this in their study design.

#### **g Guidelines for privacy and confidentiality**

All participant information (plain language statements) must contain a paragraph on privacy and confidentiality. All privacy information must comply with the *Health Records Act 2001 (Vic)*, the *Privacy Act 1988*, NHMRC Guidelines under Section 95 of the *Privacy Act 1988* and all other NHMRC privacy guidelines and regulations.

Information regarding privacy and confidentiality should be simple and concise, not bold and no more than one page. For a sample privacy statement, please contact the CHREC office.

#### **h Payment of participants in research projects**

CHREC considers it appropriate to offer participants reimbursement for 'direct out of pocket' expenses (such as travel expenses). CHREC 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.

#### **i Compensation for injury attributable to the study**

If your study is sponsored, your participant information (plain language statements) should include this paragraph:

*'In the event that you suffer any injury attributable to the administration of a medicinal product within the study or any clinical intervention or procedure required under the study that would not have occurred but for your inclusion in the study, you will be compensated in accordance with the Medicines Australia Guidelines for compensation for injury resulting from participating in a company-sponsored research project. A copy of the Medicines Australia Guidelines is available to you from the research staff on request.'*

If your study is not sponsored, please substitute an appropriate paragraph.

## **j Disclosure regarding potential rewards for researchers**

Researchers are asked to describe the arrangements, costs and potential rewards and benefits of the study. This includes but is not limited to the following:

- study budget, grants, sources of funding and additional study costs and payments incurred by investigators
- organisational structure of the study, any beneficial interests, duality and/or conflict of interest for the investigators
- intellectual property, impact on career and reputation, requirements for course work or higher education, travel grants and publications.

The participant information and consent should include what is basically a statement advising who is paying for the study, who gets something out of it and what the financial and organisational arrangements underpinning the study are. While we do not wish to be prescriptive, the following paragraphs may provide researchers with ideas as to appropriate wording:

1. *<funding organisation> will pay Cabrini a standard per person payment for doing this study. This will compensate for the cost of staff, resources and facilities used in conducting the study. The researcher has a beneficial interest in the company contracted to perform the study.*
2. *A grant of \$x has been received from <supporting organisation> to cover part of the cost of the study. Cabrini Health has agreed to contribute additional staff, resources and facilities to assist in completion of the study.*
3. *The study is being undertaken to answer an important medical research question. It will also fulfil the research requirements of a Ph.D. degree and is being jointly funded by <university> and Cabrini Health.*
4. *The investigators will receive payments of up to \$x from <funding company> for each research participant who is recruited and who completes the study. The payment has been calculated to cover the costs of the investigators, providing the trial drug and undertaking the associated tests and reporting over the life of the study. The investigators do not expect to benefit financially from these payments.*
5. *Funding for this research is being provided by <sponsor>. This includes payments to <researchers> and to <institution>. This funding seems sufficient to conduct and complete the trial without compromising the design, conduct, findings or publication of the research. The researcher has a beneficial interest in the company contracted to perform the study.*
6. *This study is being conducted by <researcher>, a <position>/role> of <organisation>, which is a research centre providing the infrastructure necessary to enable clinicians to be involved in clinical research. This infrastructure includes <list of facilities and services>.*

7. *The investigators involved in this study are reimbursed on a fee for service basis for study consultations and time spent in study-related meetings. The costs of providing this infrastructure are covered by <sponsor> as part of the study budget.*

## **k Genetics and pharmacogenetics studies**

The Australian Law Reform Commission and the NHMRC's Human Genetics Advisory Committee are currently reviewing the ethic of pharmacogenetics. Guidelines appear in the 2007 [National Statement](#). Other useful references, particularly regarding the insurance and employment implications for participants, include:

- ['ACCC re-authorises life insurance bar on genetic testing'](#) press release by Graeme Samuels on website of the Australian Competition and Consumer Commission
- Life insurance products and genetic testing in Australia ([Fact sheet 23A](#)) from The Australasian Genetics Resource Book of 2007
- ['Genetic information and life insurance products in Australia'](#) of May 2003 produced by The Centre for Genetics Education;
- ['Essentially Yours: The Protection of Human Genetic Information in Australia \(ALRC 96\)'](#) of May 2003 a joint enquiry by the Australian Law Reform Commission & the Australian Health Ethics Committee
- ['Insurance and genetic privacy'](#) section 25 of the Australian Law Reform Commission's review of privacy
- ["Cancer in the family" and genetic testing: implications for life insurance'](#) by Lynch, Elly et al in eMJA 2003; 179(9): 480-483.

Participants in genetics studies need to be informed that any genetic testing information received needs to be declared in applications for life insurance. This may influence their decision to take part in genetic testing studies or sub-studies or on their decision to receive the information.

Studies where genetic samples are not re-identifiable (except via the 'genetic footprint') would permit application for life insurance with honest declarations that testing has been done as part of a research study but that no results are obtainable to the participant or their treating doctors.

Where results are available to participants, please include the following paragraph:

*'If you have chosen to be informed about genetic information AND the study has informed you that we have found genetic information relevant to you and your family, your **insurance** and **employment** may be affected'.*

Please ensure the words '*insurance*' and '*employment*' are in bold.

## **I Advertising**

It is acknowledged that advertising on noticeboards within the hospital environment and the media generally is an important aspect of recruitment for clinical trials. All advertising requires the approval of a Human Research Ethics Committee.

The advertisement may include a statement that this study complies with the NHMRC's [National Statement](#) on Ethical Conduct in Human Research but need not state that this study was approved by the Cabrini Human Research Ethics Committee.

## **m Risk management—insurance and indemnity**

Where Cabrini projects fall within *usual clinical care*, they will be covered by the hospital's insurance policy.

Any treatment by professionals (doctors or therapists) which exposes them to litigation will not be covered by the hospital's insurance and must be the responsibility of the professional involved. All professionals involved in treatment should provide details of their professional indemnity cover and a record will be kept of this information. This is a requirement for all accredited medical practitioners at Cabrini and will be on record with the hospital.

Any queries regarding indemnification of the medical professionals involved should be addressed to the practitioner's medical defence/insurance organisation.

Any trial involving a new device, medication or biological agent must be fully indemnified by the sponsor and evidence of that indemnification will be kept on file. This indemnification needs to cover all aspects of the treatment and any potential future complications. Such cover must include the hospital and all trial personnel.

Cabrini Institute cannot allow any trials not fully indemnified to proceed.

Trials of currently approved drugs for a new indication (not currently listed) require decisions on a case-by-case basis. If a reasonable body of opinion exists among medical practitioners that this was a reasonable use of the medication, it would probably fit within *usual clinical care*.

Where the placebo arm of a controlled trial involves an invasive procedure that is not part of *usual clinical care*, a separate insurance policy would need to be in place to cover potential litigation. The 'up front excess' requirements of hospital policies in Australia (up to \$500,000 per claim) would mean that it would not be financially viable to carry out such trials at Cabrini.

Trials where an invasive placebo arm leads on to active treatment at a later stage may be possible. Proposed studies would need to be carefully scrutinised by the Manager of the CHREC with the Executive Director of Cabrini Institute (and, in turn, Cabrini's insurers).

## n Monitoring

Under section 5.5 of the [National Statement](#), CHREC is responsible for monitoring your research. Such monitoring includes:

- audits/site visits/interviews to ensure compliance with conditions of approval
- completion of satisfactory annual progress ([attachment 4](#)) and final reports
- submission of serious adverse event reports (see 'w').

## o Documents requiring review by the CHREC

CHREC 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
- 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.'

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

Where documents require review, CHREC's process is for the Manager to review all documents and to request review by an expert and Executive committee member where appropriate. Document amendments do not go to a full committee meeting but approval is ratified at meetings.

The following forms are for use when submitting any documents relating to your project. They can be found on the website. **Please note that the use of these forms negates the need for a cover letter.**

When completing these forms, please ensure you include:

- CHREC project number and title
- a brief summary of what has changed since the previous edition
- comments from the Principal Investigator about how this may impact on the study.

Please submit a single original document with relevant form attached. In the case of some complex protocol amendments, further copies may be requested. If in doubt, please telephone the CHREC office.

- Documents to be presented ([attachment 7](#)): Please use this form for all document submissions, including IBs, protocols, PICFs, letters, memos etc.
- Events to be noted ([attachment 8](#)): Please use this form for all events excluding SAEs (see 'q'), notably protocol deviations and violations.
- Administrative Amendments ([attachment 9](#)): Please use this form for changes to research project team, dates, contact details, logistics and other issues which raise no ethical concerns.

**p 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 CHREC is completely satisfied with the resolution, ethical approval will be withdrawn.

**q Serious Adverse Events**

<b>Serious Adverse Event Reporting – What to submit the CHREC</b>	
<p><b>Phase 1 &amp; 2 Trials</b></p> <ul style="list-style-type: none"> <li>• Original signed coversheet (<a href="#">attachment 10</a>) plus SAE reports;</li> <li>• In addition, six collated copies of coversheet and SAE reports for ALL adverse events.</li> </ul>	<p><b>Phase 3 &amp; 4 Trials</b></p> <ul style="list-style-type: none"> <li>• Original signed coversheet (<a href="#">attachment 10</a>) plus SAE reports;</li> <li>• In addition, six collated copies with:               <ul style="list-style-type: none"> <li>• Any reports involving a death;</li> <li>• Any Cabrini related deaths;</li> <li>• If no deaths, or relation to Cabrini, please provide 6 copies of coversheet only.</li> </ul> </li> </ul>
<p><b>All SAE submissions</b></p> <ul style="list-style-type: none"> <li>• An email/phone call to notify the CHREC of the SAE when it happens is encouraged.</li> <li>• Please ensure coversheets and reports correspond.</li> <li>• If there are multiple follow-up reports relating to the same participant, please include the most recent follow-up only.</li> </ul>	

A serious adverse effect 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.

Issue 15 of the NHMRC's *HREC Bulletin* reported that the handling of adverse event reporting by HRECs has been a vexed issue for a number of years. It has its

origins in the changes wrought when the CTN/CTX options for conducting clinical trials were established more than a decade ago. The Australian Health Ethics Committee (AHEC) convened a meeting on this issue in November 2002 but an effective and efficient solution is yet to be found.

A key issue appears to be that an individual trial site does not have access to the entire context of adverse event reporting from other sites and therefore lacks access to accumulated data and cannot be briefed by the relevant researchers at other sites. This means a HREC is unable to evaluate the importance or potential significance of the multiple reports that are forwarded to it.

For all trials undertaken solely at the local level (those approved by CHREC), the HREC monitoring role is critical and investigators need to notify CHREC promptly of any and all adverse events. All incidents which occur within the Cabrini study population and all deaths that occur on the trial anywhere must be reported. This applies to all trials whether clinical or non-clinical. Incidents occurring within the Cabrini study population need to be notified to the Manager, CHREC, as soon as possible, ideally at the time you are notifying any sponsor.

The form for reporting serious adverse events is [attachment 10](#). Please complete this form with an original signature and send it to CHREC with a full report. The report is what you provided to your sponsor, or what was provided by the hospital/treating clinician, detailing the event and relevant medical intervention that the hospital or treating doctor should have completed and sent to you.

If there are no deaths or events relating to your patient population then please only supply six copies of the cover sheet.

Should any events include a death or a member of your patient population we require an additional six copies of the full report of these events (one copy attached to each cover sheet copy).

In total, we require one set of originals with signed coversheet, and six copies with coversheets, which will be tabled at the CHREC executive meeting.

The matter of overseas serious adverse event reporting for phases 3 and 4 trials was considered at the Cabrini Human Research Ethics Committee Executive meeting on 30 May 2005.

The Therapeutic Goods Administration's '[Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting. \(CPMP/ICH/377/95\) Annotated with TGA comments](#)' was reviewed. Particular note was taken of the TGA comment on page 7, '*TGA does not require sponsors to submit individual overseas reports of suspected adverse drug reactions. The TGA expects sponsors to continually monitor the safety of its clinical development program and advise the TGA within 72 hours of any significant issue that has arisen from its analysis of overseas reports or action which has been taken by another country's regulatory agency and the TGA comment on page 11, 'Sponsors should inform any Australian investigator(s) and, through the*

*investigator, the HREC(s) of any information that may be new and have an impact on the continued ethical acceptability of the trial, or that may indicate the need for amendments to the trial protocol, including altered monitoring of safety.'*

Having considered this guidance, the CHREC Executive decided that, as long as the sponsors continually update the investigator with ongoing safety reports for the product under study, the investigator need only report to the CHREC should any information derived from the safety reports have an impact on the *continued ethical acceptability of the trial or that may indicate the need for amendments to the trial protocol, including altered monitoring of safety.*

Investigators may make a single report of any drug-related incident where the drug is involved in more than one trial. Please list all the relevant studies at the top of the form. If study monitors require that original signed documents be filed in each study, the CHREC will agree to that request.

Pharmaceutical studies of phases earlier than three are typically studies where less is known about the safety and efficacy of the compound/study drug/device being trialled. This being the case, it is our current interpretation of the NHMRC National Statement and the ICH Guidelines for Good Clinical Practice that ALL serious adverse events for studies in phases earlier than three be reported to and reviewed by CHREC Executive.

## **Further information**

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](http://www.actr.org.au). Please advise registration number and date. If your trial has been registered on another registry, please advise.

If a project approved by the Committee does not commence within twelve months of being approved, such approval will lapse and the researcher will need to re-submit the project for approval. Equally, if progress reports ([attachment 4](#)) are not received as requested, approval will lapse (see 'p').

For further information about any aspect of your application please contact the CHREC office, details listed on page 3.

Cabrini Institute offers a range of services that may interest you. These include: assistance with development of your research proposal, occasional lectures and regular seminars, an annual research day and small grants and scholarships. We endeavour to keep researchers informed of current events by advertising on the intranet and website and by circulating flyers to researchers on our database.



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## CABRINI HUMAN RESEARCH ETHICS COMMITTEE

### MEMBERSHIP

<b>Name</b>	<b>NHMRC Category *</b>	<b>Gender</b>
Dr Melissa Barber	Additional	F
Mr Cameron Barnes	Additional	M
Mrs Beatrice Bastomsky	Lay Person - Female	F
Dr Michael Ben-Meir	Medical Graduate with Research Experience	M
Ms Frances Brockhus	Nurse Administration	F
Prof Tracey Bucknall	Nursing Graduate with Research Experience	F
Mr David Curtain, QC	Lawyer	M
A/Prof Henry Debinski	Medical Graduate with Research Experience	M
Revd Kevin McGovern	Minister of Religion	M
A/Prof Marilyn Poole	Sociologist	F
Prof Miles Prince	Medical Graduate with Research Experience	M
Mr John Robertson	Lay Person – Male	M
Dr Margaret Staples	Chairman	F
Dr Sharon Woolf	Medical Graduate with Caring Experience	F
Ms Anne Spence	Secretary (by invitation)	F

The Cabrini Human Research Ethics Committee is constituted under the 2007 *National Statement on Ethical Conduct in Human Research* sections 5.1.26 – 5.1.37.

All members (whether present at any meeting or not) receive the papers and have opportunity to comment on the projects.