# Human Research Ethics Committee

*(Calvary Health Care ACT Public Division)*

**Sub group Clinical Ethics Committee**

## Terms of Reference

| DATE: | 1 | April 2009, reviewed November 2012 |
| ROLE: | 2 | The primary role of any Human Research Ethics Committee (HREC) is to protect the welfare and the rights of participants in research. The primary responsibility of each member is to decide, independently, whether, in his or her opinion, the conduct of each research proposal submitted to the HREC will so protect participants (NHMRC 2007). The role of the HREC is to advise the Executive Management Group on research and ethical aspects of any proposal to carry out human research in Calvary Health Care ACT, Public Hospital. |
| REPORTS TO: | 3 | The Committee reports to the Chief Executive Officer via the Patient Safety Committee. No research project may proceed without prior consideration and recommendation from the Committee and approval from the Executive Management Group or the National Board. |
| FUNCTIONS: | 4 | The functions of the HREC are to:  
4.1 consider research merit and ethical implications of all proposed research projects and to determine whether or not they are acceptable;  
4.2 provide for surveillance of research projects until completion so that the Committee may be satisfied that they continue to conform with approved standards;  
4.3 maintain a register of all proposed and approved research projects, so that the following items of information are readily available:  
  - name of responsible institution;  
  - project identification number;  
  - principal investigator(s);  
  - approval or non-approval with date;  
  - whether the application was approved by an expedited or out of... |
session review
- whether the project was approved under Section 95A of the Privacy Act
- in the case of applications approved under Section 95A of the Privacy Act what matters were taken into consideration in weighing the public interest; and
- date(s) designated for review.

4.4 The protocols of research proposals shall be preserved in the form in which they are approved;

4.5 Establish and maintain communication with the Australian Health Ethics Committee and provide access, upon request, to appropriate HREC information;

4.6 Consider any other matters referred to it by the Hospital Executive Management Group or the National Board;

4.7 In carrying out these functions the HREC shall:
- conform with the:
  o National Health and Medical Research Council (NH&MRC) National Statement on Ethical Conduct in Research Involving Humans (2007);
  o Catholic Health and Aged Care Services in Australia Code of Ethical Standards (2001); and
  o teaching of the Magisterium of the Catholic Church on the subject under consideration;
- take account of local cultural and social attitudes in making decisions;
- ensure that procedures relating to obtaining consent are observed;
- ensure that no members of the committee adjudicate on proposals in which they may be personally involved,
- ensure that while accepting that clinicians have a duty to advance knowledge by research, the rights of individual patients, or subjects of research, take precedence over the expected benefits to human knowledge or to the community,
- Submit an annual report to the NHMRC
- Submit an annual report to the Little Company of Mary Health Care
- Ensure all accreditation standards & criterion are met as outlined in ACHS EQuIP 5

MEMBERSHIP:

5 Members of the Committee shall be appointed by the Executive Management Group or the National Board and include eight people from the following categories. (A layperson, in this context, is one who has no affiliation with the institution, is not attached involved in medical, scientific or legal work.)

- Chief Executive Officer
- Chief Financial Officer
- Director of Mission
- Catholic Priest
- Director of Medical Services (Chairperson)
- Director of Operations (Private Division)
- Director of Clinical Operations (Public Division)
- Clinical Operations Manager (Registered Nurse)
- Director, Calvary Centre for Palliative Care Research
- Lawyer
- Medical Graduate with research experience
- Nursing Graduate with research experience
- Representative from Calvary John James Hospital
- 2 Researchers
- Lay person (1 male and 1 female)

The Executive Management Group or the National Board may appoint other persons outside the above categories as it sees fit.

The Committee shall have the power to co-opt.

**REPORTING RESPONSIBILITIES**

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| 6 | Minutes for each meeting to be submitted to Executive Management Group and to Patient Safety Committee  
Annual reports to Little Company of Mary Health Care and the NH&MRC |

**AUTHORISATION & SUB COMMITTEE**

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| 7 | Decision Making within delegations  
Sub Committee – Clinical Ethics Advisory Committee |

**QUORUM:**

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| 8 | Eight members  
Where there is less than full attendance at a meeting, the Chairperson must be satisfied, before a decision is reached, that a minimum of seven members from the categories specified by the NH&MRC have received all papers and have had an opportunity to contribute their views and that these have been recorded and considered. |

**AGENDA:**

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<td>The Agenda of each meeting together with reports and documents which relate to it is to be forwarded to members in sufficient time to enable them to consider it prior to the meeting.</td>
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**PROCEEDINGS:**

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| 10 | The Committee meets every 2 months for the consideration of research proposals and other aspects of medical ethics, and in any case at least six times per year.  
Applications which conform to the ‘Expedited Review Protocol’ (Appendix 1) or Student Application (Appendix 2) stipulations may be dealt with by circulation of papers without formal meeting. Outcomes of expedited reviews must be tabled at the next formal meeting.  
The Committee shall keep a record of all meetings. |

**KEY PERFORMANCE INDICATORS**

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| 11 | 1. To meet the reporting requirements of LCMHC and the NH&MRC  
2. To maintain a minimum Moderate Achievement (MA) in the Australian Council on Healthcare Standards (ACHS) EQuIP5 against: |
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<th>Standard 2.5 The organisation encourages and adequately governs the conduct of health and medical research to improve the safety and quality of health care.</th>
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| CHAIRPERSON: | 12 | As elected  
All research projects decisions shall be notified to the Executive Management Group which shall also consider any other aspects of clinical ethics on which the Committee may from time to time make recommendations. |
| SECRETARY: | 13 | There shall be a Minutes Secretary. |
When does quality assurance in health care require independent ethical review (2003)  
Guidelines under section 95A of the Privacy Act 1988  
Committee on Publication Ethics (COPE) http://publicationethics.org/  
Vancouver Protocol  
Calvary Health Care ACT (Public Hospital) Intellectual Policy to be endorsed  
Calvary Health Care ACT Guidelines for Research Practice  
Calvary Health Care ACT QI or Research checklist  
Calvary Health Care ACT Publications, abstracts and presentations policy  
Calvary Health Care ACT Research & Education Grant application Policy to be endorsed  
Calvary Health Care ACT Research & Education Grant application Flowchart to be endorsed  
Little Company of Mary Health Care National Policy No 5.2.1 Ethics Research and Reporting Requirements |
Appendix 1 Expedited Review Protocol

Applications are only eligible for expedited/ out of session review if they meet the following criteria:

1. do not require patient/participant consent
2. are considered to be minimal risk by the Chair or delegate

Applications for expedited review are to be provided electronically to the HREC Chair or delegate.

The application will be distributed electronically by the HREC Chair or delegate to all HREC members.

A minimum of 8 HREC members are required to provide written comment and/or approval to the Chair within 10 days.

If any concerns are raised then the application will be held over for consideration at the next full HREC meeting.

All applications submitted for expedited review will be tabled and outcomes minuted at the next full HREC meeting.