



Royal Adelaide Hospital **RESEARCH ETHICS COMMITTEE**

TERMS OF REFERENCE

1. PREAMBLE:

The Research Ethics Committee is a Standing Committee of the Central Adelaide Local Health Network. The Committee is constituted and functions in accordance with the National Statement on Ethical Conduct in Human Research (2007) and is guided by the principles outlined in the Declaration of Helsinki, International Conference on Harmonisation of Good Clinical Practice and relevant National Health and Medical Research Council (NHMRC) guidelines. The Committee promotes public interest to ensure that research is conducted using systems that facilitate, encourage and support ethically informed research on humans.

2. HREC OBJECTIVES:

The committee:

- Safeguards the rights, safety and well being of all research participants and ensures that any research involving human subjects is underpinned by the basic ethical principles of respect for persons, non-maleficence and justice.
- Encourages research to the extent that it is judged to be both scientifically worthwhile and ethically satisfactory.

3. HREC FUNCTIONS:

- Ensures that the proposed research will not expose participants to unacceptable risks and practices; and that the potential participants can evaluate the expected consequences of their involvement and decide for themselves whether to participate.
- Undertakes its role with due regard to cultural and social factors which may be important to research participants.
- Continuously monitors and reviews, at least annually, the progress of research to maintain satisfaction regarding compliance with contemporary ethical standards and requirements.
- Receives and responds to adverse event and other safety reports relating to approved studies. Undertakes an educational role with research in matters relating to ethics. Seeks and maintains certification under the National Certification Scheme.
- Works under the principles of the National Approach to Single Ethical Review (the National Approach).
- Maintains registration with the National Health and Medical Research Council (NHMRC).
- Reviews and makes a determination whether to support applications made by Medical Practitioners to become Authorised Prescribers of unapproved therapeutic goods under Therapeutic Goods Administration requirements.

4. SCOPE:

The Research Ethics Committee undertakes ethical and scientific review of:

- Proposed research projects to be carried out by staff of the Royal Adelaide Hospital (RAH) and SA Pathology on human subjects;
- Proposed research projects to be carried out by researchers from the University of Adelaide, University of South Australia or Flinders University involving human subjects (patients, staff and volunteers) or human tissues on the RAH/SA Pathology campus;
- Other research projects involving the RAH or SA Pathology, and the community; and
- Research undertaken by individuals who are not affiliated with the any of the above listed institutions, in accordance with Chapter 5.3 of the National Statement and the National Approach.

The Committee shall consult with the Aboriginal Health Research Ethics Committee of South Australia or otherwise seek advice on the appropriateness of any research proposal which is specific to Aboriginal and Torres Strait Islander people.

5. ACCOUNTABILITY OF THE HREC:

The Committee is accountable to the Central Adelaide Local Health Network (CALHN) Chief Operating Officer.

The reporting obligations are to:

- Provide a ratified copy of the minutes of each meeting, signed by the Chairman, to the Chief Operating Officer of CALHN.
- Report annually, in writing, to the Chief Operating Officer of CALHN and the NHMRC on activity and procedural changes including
 - Membership / Membership Changes
 - Number of Meetings held per annum
 - Number of protocols presented, approved and rejected
 - Monitoring procedures in place and any problems encountered
 - Complaints procedures and number of complaints received

External to the institution the committee will:

- Establish and maintain communication with the National Health and Medical Research Council (NHMRC) and provides access on request (without revealing the personal details of any research participant or responder) to information in the Royal Adelaide Hospital Research Ethics Committee's Register.
- Provide information from aggregated records as requested by the NHMRC.
- Make the HRECs Terms of Reference publicly available in accordance with Section 5.1.27 of the National Statement.

6. HREC SUBCOMMITTEES:

The HREC may appoint such sub-committees as it sees fit to carry out a scientific or technical review of a research proposal, or ethical review of minimal risk, submitted to the HREC.

The Chair of such subcommittee will be elected by the members of the subcommittee.

Members of the subcommittee need not be members of the HREC.

Currently the Royal Adelaide Hospital Investigational Drugs Subcommittee (IDSC) and the Royal Adelaide Hospital Research Ethics Committee Cancer Subcommittee (CSC) provide advice to the Human Research Ethics Committee.

7. MULTI-CENTRE RESEARCH

To facilitate multi-centre research the HREC may communicate with any other HREC, and accept a scientific/technical and/or ethical assessment of the research by another HREC.

Under the National Approach, the institution will give due regard to institutional objectives and responsibility to RAH participants and researchers when considering the ethical review of another HREC.

8. MEMBERSHIP

Membership of the Committee shall comply with the requirements of sections 5.1.29 – 5.1.31 of the National Statement on Ethical Conduct in Research Involving Human Subjects (2007).

The HREC will have a minimum membership of eight (8) members. As far as possible:

- there should be equal numbers of men and women; and
- at least one third of the members should be from outside the institution

The minimum membership is:

- (a) a chairperson, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under this National Statement;
- (b) at least two lay people, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work;
- (c) at least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional;
- (d) at least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion;
- (e) at least one lawyer, where possible one who is not engaged to advise the institution; and
- (f) at least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend. These two members may be selected, according to need, from an established pool of inducted members with relevant expertise.

Appointment of members (including proxy members)

- CALHN shall appoint members in a fair and transparent manner via the Office of the Chief Operating Officer of CALHN.
- Members shall receive a formal notice of appointment and an assurance that CALHN will provide legal protection for their activity as members of the committee.
- Members shall be required to sign a confidentiality agreement and conflict of interest statement annually.
- Members of the committee not employed by SA Health may receive an honorarium as gazetted in the Department of Health Policy, "Sitting Fees/Reimbursement of External Individuals for Department of Health Internal Committees and Workgroups Policy".

Appointment of Chair and Deputy Chair

- On advice from the retiring Chairperson, and with due consultation, the new Chairperson, from within the Committee Membership, will be appointed by the Chief Operating Officer of CALHN.
- On advice from the current Chair, and with due consultation, one or more Deputy Chairpersons, from within the Committee membership, will be appointed by the Chief Operating Officer of CALHN.

Attendance at Meetings

- Members shall make an attempt to attend all scheduled meetings. Where a member is absent for a meeting they shall give an apology to the Executive Officer at least 2 weeks in advance of the meeting.
- Where necessary a proxy member will attend the meeting to ensure quorum requirements are met in accordance with National Statement 5.2.28. Should a proxy member not be available, the absent member should expect to receive all the relevant meeting papers and take the opportunity to contribute their views so that these can be recorded and considered (National Statement 5.2.30).

Tenure

- The tenure of members is for three years and members may be reappointed for additional terms with the agreement of the Chief Operating Officer of CALHN.

- One third of members will be appointed or reappointed at the beginning of each calendar year.
- The tenure of the Chair is for three years and the Chair may be reappointed for additional terms with the agreement of the committee and the Chief Operating Officer of CALHN.
- In accordance with the National Statement 5.1.35 members are not appointed as representatives of any organisation, group or opinion.
- Appointments and tenure should take into consideration the need to maintain a high level of relevant skills and expertise within the committee.

Function of the Chair

- To lead Group and provide vision to meet stated objectives
- Direct discussions to effectively use the time available to review research protocols.
- Ensure minutes / action plan accurately reflect discussions / decisions / issues
- Ensure group has the necessary information to undertake required actions
- Maintain liaison with CALHN Executive Committee on activity.

Member responsibilities

In addition to the requirements outlined above for attendance at meetings, members are required to:

- Where relevant, ensure any objections to consensus decisions are formally documented.
- Treat all deliberations of the committee in the strictest of confidence.

9. MEETINGS

- The HREC agenda, accompanied by all the required documentation for review of research proposals will be distributed not later than 5 working days prior to the HREC meeting.
- A formal record of a meeting will be maintained and clearly identify date/time of meeting, name of chair and minute taker, list of attendees and apologies received. Minutes will identify decisions that are made at the meeting, and incorporate key discussion points that contextualise the decision making and be formally accepted as correct at the following meeting.
- A record of activity shall be maintained which allows tracking of progress relating to approval of studies.
- Decisions should be made upon consensus.
- In instances where full agreement is not reached, outstanding issues will be resolved with the investigator(s).
- The Committee will decide whether to delegate authority to the Chair to adjudicate on investigator responses.
- The Committee may request the advice of an expert to assist in assessing an application.
- The Committee must ratify the review of decisions which have been delegated to the Chairman for consideration.
- Observers may be present by invitation and agreement of the members present providing that they have signed a confidentiality and conflict of interest declaration.
- Researchers may be invited to attend the meeting to support their application for ethical approval.

10. STANDING ORDERS:

Meeting Frequency:	Monthly Meetings (except for January)
Quorum to Meet:	<i>In accordance with N.S. 5.2.28, quorum shall be at least one member from each category of the minimum membership. Where there is less than full attendance of the minimum membership at a meeting, the Chairperson should be satisfied, before a decision is reached, that the views of those absent who belong to the minimum membership have been received and considered (N.S. 5.2.30)</i>
Chairman:	Dr Andrew Thornton
Notification of Apologies:	Heather O'Dea, Executive Officer, Ex 24139
Contact details	Rah.ethics@health.sa.gov.au

ENDORSED: (Operations / CIT / Core / Standing Committee)

DATE:

DISTRIBUTION: All Clinical / Nursing Directors, FSU
Working Party Members