

Central Adelaide Local Health Network Human Research Ethics Committee

Terms of Reference

1. Title

Central Adelaide Local Health Network Human Research Ethics Committee

2. Purpose

Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC) is responsible for the approval and monitoring of ethical aspects of research involving humans. In so doing 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. Scope

The CALHN HREC undertakes ethical and scientific review of:

- Proposals for human research to be undertaken at or under the auspices of Central Adelaide Local Health Network (CALHN) and Northern Adelaide Local Health Network (NALHN), including research conducted by investigators not affiliated with CALHN, NALHN or other SA Health entities
- Proposals for human research received by the CALHN HREC in the exercise of its function as an accredited HREC within the SA Health Single Ethical Review Model.
- Proposals for human research received by the CALHN HREC in the exercise of review processes accepted, accredited or certified for the purposes of any other system designed to eliminate unnecessary duplication of ethical review of human research in accordance with Chapter 5.3 of the NHMRC National Statement on Ethical Conduct in Human Research (2007) (herein the “National Statement”), including the National Mutual Acceptance program operating in Australia.

The CALHN HREC 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.

4. Responsibilities

The CALHN HREC:

- 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.

The CALHN HREC's reporting obligations are to:

- Provide a ratified copy of the minutes of each meeting to the Executive Director Medical Services of CALHN upon request.
- Report annually, in writing, to the Executive Director Medical Services 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 CALHN HREC will:

- Establish and maintain communication with the National Health and Medical Research Council (NHMRC) and provide access on request (without revealing the personal details of any research participant or responder) to information held by the CALHN HREC.
- Provide information from aggregated records as requested by the NHMRC.
- Report annually, in writing to the Executive Director Medical Services of CALHN on the reviewing activity of the CALHN HREC for human research conducted at or under the auspices of CALHN.
- Make the CALHN HREC Terms of Reference publicly available in accordance with Section 5.1.27 of the NHMRC National Statement.

5. Subcommittees

a. CALHN Investigational Drug Sub Committee (IDSC)

The IDSC is a subcommittee of technical experts in pharmacology and pharmacy who are able to provide a detailed expert review of the pharmacology associated with research involving the administration of drugs, in particular early phase trials. The IDSC objectives and operations are detailed in the IDSC Terms of Reference. The Whilst the primary responsibility of IDSC is to review pharmacological issues it may make recommendations on any other ethical or safety issues associated with the research.

The IDSC may recommend that CALHN HREC not approve a protocol if it considers the proposal involves unacceptable risk in terms of the safety of participants. Whilst the opinion of IDSC is critical in the review process the approval of the research is the responsibility of HREC.

The CALHN HREC considers that IDSC need not comply with the requirements of the NHMRC statement in relation to composition because:

- All IDSC decisions are subject to further review by the CALHN HREC
- The specialist technical expertise expected of members of IDSC would make it impossible to comply with clauses 5.1.29-5.1.33.
- The Chair of the CALHN HREC observes at the meetings of IDSC.

b. CALHN Expedited Review Panel (ERP)

The ERP is a joint research ethics and governance panel responsible for reviewing studies low/negligible risk research proposals that are eligible for review by processes other than a full HREC, as determined by the National Statement.

The ERP is comprised of the CALHN HREC Chair, Research Services Manager and CALHN Research Governance Officer. Where applications involve South Australian sites outside of CALHN, the local Research Governance Officer may attend an ERP meeting to provide local governance review.

All decisions of the ERP are ratified by the full CALHN HREC via recording on CALHN HREC meeting agendas. The CALHN HREC may request copies of approved applications and if required may conduct its own review of applications.

6. Membership

Membership of the CALHN HREC shall comply with the requirements of sections 5.1.29 – 5.1.36 of the National Statement.

The CALHN 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

a. Minimum Membership

As a minimum the CALHN HREC membership will comprise:

- a Chair, with suitable experience, whose other responsibilities will not impair the CALHN HREC's capacity to carry out its obligations under the National Statement;
- 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;
- 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;
- at least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion;
- at least one lawyer, where possible one who is not engaged to advise the institution;
- 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.

b. Appointment of members (including proxy members)

CALHN shall appoint members in a fair and transparent manner via the Office of the Executive Director Medical Services 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 CALHN HREC not employed by SA Health may receive an honorarium as gazetted in the SA Health Policy Directive, "Sitting Fees and Reimbursement for External Individuals".

c. Appointment of Chair and Deputy Chair

On advice from the retiring Chair, and following a competitive recruitment process, the new Chair will be appointed by the Executive Director Medical Services of CALHN.

On advice from the current Chair, and with due consultation, one or more Deputy Chairs, from within the CALHN HREC membership, will be appointed by the Executive Director Medical Services of CALHN.

d. 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 one (1) week 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).

Where required meetings may be held remotely via teleconference/videoconference/web conference systems.

If required members may attend any meeting via teleconference/videoconference/web conference systems.

e. Tenure

The tenure of members is for three years and members may be reappointed for additional terms with the agreement of the Executive Director Medical Services 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 Executive Director Medical Services 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 CALHN HREC.

f. Function of the Chair

To lead CALHN HREC 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 CALHN HREC has the necessary information to undertake required actions

Maintain liaison with CALHN Executive on activity.

g. 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.

7. Ways of Working

The CALHN 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 CALHN HREC meeting.

The CALHN HREC Chair may assign research proposals for review by CALHN HREC members with specific expertise prior to the review at the CALHN 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 CALHN HREC will decide whether to delegate authority to the Chair or a sub- committee of CALHN HREC members with specific expertise to adjudicate on investigator responses.

The CALHN HREC may request the advice of an expert to assist in assessing an application.

The CALHN HREC must ratify the review of decisions which have been delegated to the Chair 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.

Investigators may be invited to attend the meeting to support their application for ethical approval.

From time to time CALHN HREC may be required to convene for extraordinary meetings either in person or out of session. Where such a meeting is required for urgent review the CALHN HREC agenda, accompanied by all the required documentation for review of research proposals will be distributed not later than 3 working days.

CALHN HREC members' behaviour is to be based on the principles of the South Australian Public Sector Code of Conduct and the relevant SA Health policies which include the following:

- Respectful Behaviors
- Organisational Development
- Communication
- Employee Relations
- Supportive Working Environments
- Occupational Health, Safety & Welfare.

8. Quorum

In accordance with National Statement Section 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 Chair 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 (National Statement Section 5.2.30).

9. Executive Sponsor

CALHN Executive Director, Medical Services.

10. Administrative Support

Administrative support for the CALHN HREC and CALHN HREC Chairs is provided by CALHN Research Services.

11. Frequency of Meetings

Twice monthly (except January).

12. Business Papers

The Chair shall approve the agenda prior to the meeting. Minutes and agenda will be distributed by the CALHN HREC Support Officer one week before the next meeting.

Members of the CALHN HREC can add items for discussion to the Agenda by submitting items and attachments via email 10 days prior to the next meeting.

All meetings will be minuted. Where no alterations to meeting minutes are required, a motion to approve the minutes of the previous meeting will be made and seconded at each CALHN HREC meeting.

13. Reporting Committees

Investigational Drug Subcommittee

Expedited Review Panel

14. Version Control

Version	1.0
Reviewed by	Executive Director, Medical Services
Last reviewed	August 2018
Next Review date	December 2019

Version	1.1
Reviewed by	CALHN HREC
Last reviewed	April 2021
Next Review date	April 2022