

SOUTHERN ADELAIDE CLINICAL HUMAN RESEARCH ETHICS COMMITTEE

TERMS OF REFERENCE

1. NAME

The Committee will be known as the **Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC)**.

2. PURPOSE

The SAC HREC will assist the CEO, Southern Adelaide Local Health Network (SALHN) and the Deputy Vice-Chancellor (Research), Flinders University (the University), to provide ethics review and monitor any clinical human research which these organisations conduct or for which they are responsible, in accordance with the *National Statement on Ethical Conduct in Human Research* (2007) or its successor.

3. SCOPE

The SAC HREC will assist the CEO, SALHN and the Deputy Vice-Chancellor (Research), the University, to discharge responsibility to exercise due care, diligence and skill in relation to:

- 3.1 Providing scientific and ethics review of clinical research proposals to be conducted at SALHN or University sites, and on other sites where clinical research is to be performed by SALHN or University staff. Research may not commence without ethics approval.
- 3.2 Providing scientific and ethics review of clinical research involving patients or staff of SALHN, or staff and/or students of the University.
- 3.3 Providing scientific and ethics review of clinical research from organisations that have requested the SAC HREC review application(s) on their behalf.
- 3.4 Improving ethics systems and processes at SALHN and the University.
- 3.5 Compliance with applicable standards, laws and regulations. The SAC HREC shall ensure that any other relevant requirements of the following instruments (and their successors) and such other statutes that have relevance to ethics considerations, are not offended by the research practices and policies of SALHN and the University.

The instruments are:

- *National Statement on Ethical Conduct in Human Research* (2007, updated 2018) (the *National Statement*).
- *NH&MRC Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders* (2018).
- *Australian Code for the Responsible Conduct of Research* (2018) (the *Code*).
- *National Health and Medical Research Council Act 1992* (Commonwealth).
- *Therapeutic Goods Act 1989* (Commonwealth).
- Section 95 (Medical Research Guidelines) of *Privacy Act 1988* (Commonwealth).
- *Guardianship and Administration Act 1993* (SA).
- *Consent to Medical Treatment and Palliative Care Act 1995* (SA).

- 3.6 Compliance with the policies and procedures of SALHN and the University, as appropriate.

4. EXPECTED OUTCOMES

4.1 SALHN and the University are responsible for ensuring that:

- members have relevant experience/expertise, and undertake induction and continuing education;
- review of research proposals is thorough, and review processes and procedures are expeditious;
- decisions are transparent, consistent, and promptly communicated;
- actual and potential conflicts of interest that may affect research and its review are identified and managed;
- good communication is promoted between SALHN, the University and the SAC HREC; and
- the workload of the SAC HREC does not compromise the quality and timeliness of ethics review.

4.2 The SAC HREC will:

- Review and either approve or reject protocols that detail proposed clinical investigation on human participants by researchers of SALHN, the University and related institutions, or by researchers of other institutions, who request participation of, or access to information concerning, patients or staff attending SALHN, staff and/or students of the University.
- Review and make a determination whether to support applications made by medical practitioners to become Authorised Prescribers of unapproved therapeutic goods under *Therapeutic Goods Administration* requirements.
- Establish and promulgate guidelines for research practice within SALHN and the University, with approval from the CEO, SALHN and the Deputy Vice-Chancellor (Research), the University, that are consistent with the *National Statement* where applicable, and take into account local cultural and social attitudes and established policies of the institutions.
- Receive progress reports and other documentation (including proposed amendments) relating to approved research applications. The SAC HREC shall review such reports and either continue to approve the research or request further information, temporarily suspend the research, or permanently terminate the research, as determined by the opinion of the SAC HREC.
- Assure institutions using the SAC HREC that the SAC HREC is operating in accordance with the *National Statement*.
- Establish, implement and document working procedures necessary to promote good ethics review.

5. MEMBERSHIP

5.1 The SAC HREC shall have a minimum membership of eight people, comprised as far as possible of:

- equal numbers of men and women;
- a Chair with suitable experience, whose other responsibilities will not impair the SAC 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 institutions 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, or a minister of religion;
- at least one lawyer, where possible one who is not engaged to advise the institutions; and

- 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.

No member may be appointed in more than one of the categories above.

As far as possible, each SAC HREC meeting will be arranged to enable at least one member in each category to attend.

Additional members in each category may be appointed on the advice of the Chair, while maintaining the membership balance required by the *National Statement*.

Wherever possible, one or more of the members listed above should be experienced in reflecting on and analysing ethical decision-making.

Membership of the SAC HREC is made public and is available to researchers submitting research proposals to the SAC HREC.

5.2 Additional Members

- A Radiation Safety Officer as necessary.
- A Bioethicist as necessary.
- Staff from SALHN and the University as invited by the Chair.
- Aboriginal and Torres Strait Islander peoples

Further members may be appointed. There is no maximum number of members.

5.3 In Attendance

The following parties may also be in attendance:

- Manager, Research Governance and Ethics, Office for Research, SALHN.
- Executive Officer and other staff of the Office for Research, SALHN.
- Observers who have signed a confidentiality agreement.

The SAC HREC may seek advice or assistance from other persons with relevant expertise related to a particular research application.

5.4 Appointment of Members

- SALHN shall appoint members in a fair and transparent manner via the Office of the Chief Executive Officer, SALHN. The University may appoint two members via the Deputy Vice-Chancellor (Research), the University. The process of appointment will be managed by the Office for Research, SALHN.
- Members shall receive a formal notice of appointment and will be indemnified by SALHN or the University as appropriate, for their activities as members.
- In line with the National Statement, members are not appointed in a representative capacity.
- Members are requested to give at least 2 weeks notice prior to non-attendance at a meeting. Should this not be possible, members 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.
- Members are to submit their resignation in writing to the Chair unless the member is disqualified for non-attendance.
- The SAC HREC remunerates the following HREC Members as detailed below:
Chair (if not a SA Health employee) - Honorarium of \$15,000 p.a.

Deputy Chair(s) (if not a SA Health employee) - Honorarium of \$5,000 p.a.
Lay Members – reimbursed for 3 hours at a rate as per the SA Health Schedule of Sitting Fees and Reimbursement for External Individuals
Other members who provide a unique and valuable viewpoint as determined by the Chair - reimbursed for 3 hours at a rate as per the SA Health Schedule of Sitting Fees and Reimbursement for External Individuals

5.5 Chair and Deputy Chair Appointment

- The Chair will be jointly appointed by the CEO, SALHN, and the Deputy Vice-Chancellor (Research), the University.
- A Deputy Chair(s) will be appointed from the Committee membership by the CEO, SALHN and the Deputy Vice-Chancellor (Research) in collaboration with the Chair, SAC HREC.
- The Chair and the Deputy Chair(s) are appointed for an initial 3 year period. They may be reappointed for additional periods of up to 3 years.
- A Chair or Deputy Chair's appointment will automatically terminate if not renewed prior to expiration of term.

5.6 Tenure

- Members are appointed for an initial period of 3 years. They may be reappointed for additional periods of up to 3 years.
- A member's appointment will automatically terminate if not renewed prior to expiration of term.

5.7 Proxy

At the time of appointment, each Member may also have a named proxy (appointed HREC Members) appointed via the same process as detailed in 5.4 and 5.5.

5.8 Absence

Apologies are required prior to the meeting. The Chair has the discretion to propose the replacement of any member who, when required to attend, fails to attend three consecutive meetings without providing apologies.

5.9 Appointment of Sub-Committees

To assist the SAC HREC in its work, subcommittees may be established to provide advice, recommendations and/or decisions. The Secretariat shall establish procedures for the workings of these sub-committees.

6. OPERATING PROCEDURES

6.1 Quorum

The quorum shall be eight members and HREC decisions will be informed by an exchange of opinions from each of those who constitute the minimum membership, during a meeting ideally with all those members present.

Where there is less than full attendance of the minimum membership at a meeting, the Chairperson must be satisfied, before a decision is reached, that the views of those absent who belong to the minimum membership, have been received and considered.

6.2 Meetings

Meetings may be scheduled every month and will not be held on public holidays. Extra meetings and special meetings may be convened as required. Any meeting may be cancelled if there is insufficient business to consider.

6.3 Correspondence

Standing items will include minutes of the last meeting, conflicts of interest, and applications for review. Agendas and papers will be distributed at least two weeks prior to the meeting. Minutes of meetings will be circulated to all members.

6.4 Conflict of Interest

Any member of the SAC HREC who has any actual or potential personal, financial, professional or institutional interest in a proposal or other related matter considered by the SAC HREC shall, as soon as possible, declare such interest in accordance with Chapter 5.4 of the *National Statement*, and relevant policies of SALHN and the University. Note that the University's Conflict of Interest Policy requires that such interests be disclosed in writing.

Conflicts of Interest are a standing item at all SAC HREC meetings and the Committee will make a determination regarding the nature of the conflict at the beginning of each meeting and will advise the member of the role that he/she may play in the review of the proposal.

In cases where the conflict of interest is considered to be significant, the member will be asked to leave the room while the protocol is being discussed, but may be invited to stay briefly to clarify any issues surrounding the protocol. Upon completion of discussions, the member is to return to the meeting. All declarations of interest shall be recorded in the minutes.

6.5 Confidentiality

Members of the SAC HREC will treat and keep confidential all information and documents which relate to business considered by the SAC HREC.

Members are required to sign a confidentiality deed. All new members will receive a copy of this confidentiality deed prior to their appointment to the SAC HREC.

6.6 Specific Actions

- Request the advice of an expert, where necessary, to assist in assessing an application.
- Consult on the appropriateness of any research proposal which involves or impacts upon indigenous people, with the Aboriginal Health Research Ethics Committee of South Australia. Alternatively, the SAC HREC will seek advice from other people who have networks with or knowledge of research with Aboriginal and Torres Strait Islander people, or people who are familiar with the cultural practices of the Aboriginal and Torres Strait Islander people with whom participation in the research will be discussed.
- Delegate review of low risk research to the Chair or to a designated member or members.
- Refer research matters dealing with social and behavioural issues which do not involve the conduct of clinical research within SALHN, the University, and related institutions to the Flinders University Human Research Ethics Committee at the University.
- Provide guidance to researchers about the ethical aspects of their proposed research.

7. REPORTING RESPONSIBILITY

- 7.1 The SAC HREC will provide a report annually to the CEO, SALHN, and the Deputy Vice-Chancellor (Research), the University, on the activities and ethical review of research, or at other times on request.
- 7.2 The SAC HREC will report as required to the NHMRC, Health Services personnel or other duly appointed authorities on its activities, or at other times on request.

8. COMPLAINTS

Where a complaint raises the possibility of 'research misconduct' as described in the *Code*, the complaint will be handled in accordance with 'research misconduct' processes specified in the *Code*.

Where a complaint about researchers alleges serious or other misconduct that falls outside the range of 'research misconduct' as described in the *Code*, the complaint will be referred to the respective institutional processes.

Where a complaint is received regarding the conduct of review bodies in reviewing research proposals as described in the *Code*, the complaint will be referred to the respective institutional processes for receiving, handling and seeking to resolve such complaints.

9. RESEARCH GOVERNANCE

Where the activities of the SAC HREC lead it to believe a researcher is performing work that does not or might not comply with the *National Statement*, it may investigate the matter and request further information from the researcher as required.

If a matter cannot be resolved within a reasonable timeframe, the SAC HREC can refer the matter through the Research Governance pathway of SA Health.

10. REVIEW OF TERMS OF REFERENCE

The Terms of Reference for the SAC HREC will be reviewed biennially and endorsed by the Chair, SAC HREC, the CEO, SALHN and the Deputy Vice-Chancellor (Research), the University. The Terms of Reference will become operative on the date that the final endorsement is completed.


.....
PROFESSOR BILL HEDDLE


CHAIR,

SOUTHERN ADELAIDE CLINICAL HUMAN RESEARCH ETHICS COMMITTEE

29 November 2021
.....
DATE


.....
PROFESSOR ROBERT SAINT
DEPUTY VICE-CHANCELLOR (RESEARCH),
FLINDERS UNIVERSITY

30th November 2021
.....
DATE


.....
MR WAYNE GADD
INTERIM CHIEF EXECUTIVE OFFICER,
SOUTHERN ADELAIDE LOCAL HEALTH NETWORK

7 December 2021
.....
DATE