



Child and Adolescent Health Service Human Research Ethics Committee

Terms of Reference

1. Purpose

The purpose of the Child and Adolescent Health Service Human Research Ethics Committee (**CAHS HREC**) is:

- a) To assess the conduct of proposed human research against ethical principles as outlined in the National Health and Medical Research Council's (**NHMRC**) National Statement on Ethical Conduct in Human Research (2007) (and subsequent updates) (**National Statement**) and advise on the ethical suitability of its commencement;
- b) To protect the welfare and rights of participants in research being mindful of the safety of individuals conducting the research;
- c) To facilitate research that is or will be of benefit to the wider community; and
- d) To promote ethical, equitable and inclusive research projects with the aim of providing benefit to participants, researchers and consumers.

2. Scope

- a) The CAHS HREC shall consider the ethical implications of human research projects in the following categories:
 - i. involving the staff, patients or resources of the Child and Adolescent Health Service (**CAHS**);
 - ii. involving the staff, participants, or resources of the Telethon Kids Institute (**TKI**);
or
 - iii. multi-centre research proposals submitted from external organizations or researchers, in line with the National Mutual Acceptance (**NMA**) program for which CAHS is accredited by the NHMRC; and
 - iv. research proposals referred from another health service where paediatric expertise is required.
- b) The CAHS HREC will provide for monitoring and surveillance of research projects until completion so that they may be satisfied that they continue to conform with approved ethical standards.

- c) The CAHS HREC will advise on specific ethical issues of importance as requested by CAHS Executive Committee.
- d) The CAHS HREC will not review Quality Improvement projects, those projects are the scope of the CAHS GEKO Triage Committee.

3. Functions

3.1 Procedures

- a) The CAHS HREC will perform their functions by adopting the requirements laid out in the National Statement and according to CAHS HREC standard operating procedures **(SOPs)** and relevant CAHS policies (as agreed by the CAHS Executive). These procedures will be reviewed periodically and amended and updated as necessary.
- b) All Ethics committee members and researchers will have access to these policies and procedures.
- c) In carrying out its functions the CAHS HREC shall:
 - i. ensure their enquiries of the researcher will be made in a spirit of courtesy and support, to develop mutual respect and a sense of partnership in the development of sound ethical practice.
 - ii. provide the decisions of the CAHS HREC in writing and within a reasonable timeframe to the persons nominated in the submission.
 - iii. determine the method of monitoring appropriate to each project. Projects that have received ethical approval will be monitored and may be audited to ensure that they conform to the protocol approved. The CAHS HREC shall request that any amendments to approved protocols be presented to it for approval.

3.2 Establishment of HREC Subcommittees & Expert Reviewers

- a) The CAHS HREC delegates consideration of scientific and safety matters for clinical trials to the CAHS Clinical Trials Subcommittee **(CTS)**.
- b) The CAHS HREC may seek external review and or advice to assist with consideration of a Research Project if the CAHS HREC decides that additional expertise is required to assess ethical matters related to the Research Project.
- c) The CAHS HREC will consider whether an advocate for any participant or group of participants should be invited to the CAHS HREC meeting to ensure informed decision- making.
- d) Where a Research Project involves the participation of persons unfamiliar with the English language, the CAHS HREC will ensure that the participant information sheet is translated into the participant's language and that an interpreter is present during the discussion on the project.

3.3 Delegations

- a) The CAHS HREC may delegate any or all its decision-making power to the Chair to



enable expedited review and decision making through:

- i. specifying the situation where this occurs on a case-by-case basis (e.g., final approval following provisional approval by the CAHS HREC) or
 - ii. in relation to a category of types of decisions (e.g., amendments).
- b) When enacting the delegation, the Chair must act in a way consistent with the principle that HREC decision making encompasses the diversity of perspectives provided by the composition of the CAHS HREC and in accordance with the guidance of the National Statement.
 - c) The delegation may include signing relevant documentation on behalf of the CAHS HREC.
 - d) Decisions made by the Chair under delegated authority are ratified by the CAHS HREC at the subsequent meeting.
 - e) The Chair may authorise the Director, Research Operations, or, with the agreement of the Director, another member of the Research Ethics and Governance team, to carry out administrative tasks and make decisions on behalf of the CAHS HREC providing the granting of such an authority is registered in a permanent record. Any limitations or conditions of the authority must be noted.

3.4 Expedited Review

- a) The review of research proposals defined as Low or Negligible risk to participants (as defined by the National Statement and through the HREC standard operating procedures), may be through an expedited review process between scheduled meetings at the discretion of the Chair.
- b) The Chair may seek advice from other HREC members, as appropriate, before reaching a decision. If approval is granted, such approval shall be considered for ratification at the subsequent HREC meeting.
- c) The review of modifications and renewals of approved research protocols may be through an expedited review process between scheduled meetings at the discretion of the Chair or delegate. The Chair or delegate may seek advice from other CAHS HREC members or a person with relevant expertise, as appropriate, before reaching a decision. If approval is granted, such approval shall be considered for ratification at the next meeting.

4. Authority

- a) The CAHS HREC is a committee functioning under the authority of the CAHS Executive Director of Medical Services (**EDMS**) and reporting to CAHS Executive Committee (**CEC**).
- b) The EDMS or his or her delegate is responsible for granting the CAHS institutional approval for Research Projects to be conducted within its institutions giving due



- consideration to the advice of the approving Ethics Committee.
- c) The CAHS HREC may from time to time bring to the attention of the EDMS issues of concern to the CAHS HREC.
 - d) The CAHS HREC will provide an annual report to the NHMRC in accordance with the requirements of the NHMRC and the National Statement, including information on membership, the number of proposals reviewed, status of proposals, a description of any complaints received, and their outcome and general issues raised. A copy of this report will be tabled at CEC.
 - e) The Terms of Reference shall be available upon written request and shall be posted upon the CAHS website.
 - f) These Terms of Reference shall be altered on the recommendation and approval of the CEC. The EDMS, Director of Research Operations or HREC Chair shall be responsible for initiating this process. The HREC members will be consulted in the amendment of the Terms of Reference, which are ratified by CEC.

5. Membership

5.1 Committee Composition

- a) The CAHS HREC will have a minimum of eight members. The core membership of the CAHS HREC will be in accordance with NHMRC National Statement as follows:
 - i. a Chair with suitable experience;
 - ii. at least 2 laypeople, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work;
 - iii. at least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people;
 - iv. at least one person who performs a pastoral care role in a community;
 - v. at least one lawyer, where possible one who is not engaged to advise the institution; and
 - vi. at least 2 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 experience.
- b) The committee will operate with a broadly diverse range of people and ensure the avoidance of bias of views from any particular group.
- c) Additional members may be co-opted by the CAHS HREC with the approval of the CAHS Executive.
- d) Each member may have a delegate appointed by the CAHS Executive to replace the member in the relevant category at any meeting of the CAHS HREC. Any delegate



replacing a member at a meeting of the Ethics Committee shall have the power to vote at that meeting.

- e) Where reference is made to a member of the Ethics Committee in these Terms of Reference, that reference includes reference to the delegate(s) of that member.
- f) Membership will include a representative of CAHS Executive (or delegate) who is an ex officio observer member of the HREC and does not vote.
- g) Membership of men and women shall as far as possible be equal in number.

5.2 Method and terms of appointment for members

- a) The members of the CAHS HREC shall be appointed (or re-appointed) by the CAHS Executive.
- b) The term of appointment of each member of the CAHS HREC shall be three years from the date of that member's appointment. Members of the CAHS HREC may be reappointed for up to three terms.
- c) Members will be reimbursed for legitimate expenses incurred in attending meetings, such as travelling and parking expenses by application to the office of the CAHS HREC.
- d) A member may resign from the CAHS HREC upon giving notice in writing to the Chair.
- e) The members of the CAHS HREC shall be aware of the: National Statement; Australian Code for Responsible Conduct in Research; and CAHS HREC Terms of Reference as well as CAHS HREC SOPs
- f) All new members to the CAHS HREC are oriented to their role and receive copies of Terms of Reference, CAHS HREC SOPs, Conflict of Interest and Confidentiality declaration documents, and meeting schedule. This is the responsibility of the Chair and the administrative office.

5.3 Liability Coverage

CAHS shall indemnify members of the CAHS HREC for any liabilities that arise as a result of the member exercising his or her duties as a member in good faith.

5.4 Chair

- a) The Chair of the CAHS HREC (Chair) will be appointed by the CAHS Executive.
- b) The term of appointment of the Chair shall be three years from the date of the Chair's appointment. The Chair may be reappointed for up to 3 terms.
- c) The Chair will appoint one of the members of the CAHS HREC as Deputy Chair (Chair CTS). The Deputy Chair shall hold office at the Chair's discretion.
- d) The Deputy Chair will preside over any meeting of the CAHS HREC the Chair does not attend and may act in the place of the Chair in any other capacity of the Chair when requested to do so by the Chair.
- e) Where both the Chair and the Deputy Chair are unable to attend a meeting of the Ethics Committee the Chair will appoint one of the members present at that meeting to preside over that meeting as Chair.



5.5 Decision Making

- a) Decisions of the CAHS HREC will only be made after members from each of the member categories has had an opportunity to contribute their views during or prior to the decision-making process. Members unable to attend the meeting will be asked to forward comments to the Secretariat prior to the meeting.
- b) The CAHS HREC will endeavour to reach a decision concerning the ethical acceptability of a proposal by general agreement. The decision need not be unanimous. Decisions of the CAHS HREC will be made wherever possible by consensus:
 - i. Each appointed member of the CAHS HREC except the member of CAHS executive or their delegate, including the Chair, shall have one vote.
 - ii. The Chair shall not have a casting vote; and
 - iii. Where consensus cannot be reached decision will be made by a majority vote of the required members at the meeting of the CAHS HREC.
- c) Minutes of the CAHS HREC meeting are ratified as a true record of proceedings and decisions taken (or amended) by the CAHS HREC at its subsequent meeting. The HREC Chair will consider and authorise actions arising from a draft record of a meeting in advance of this ratification to enable timely communication with researchers.

5.6 Suspension or withdrawal of ethical approval

- a) The CAHS HREC may suspend or withdraw ethical approval if a project is not being, or cannot be, conducted in accordance with the approved protocol.
- b) The CAHS HREC will inform the investigator(s) and the relevant institution(s) or organisation(s) of such a withdrawal and recommend to the institution(s) or organisation(s) that the project be discontinued, suspended, or that other necessary steps be taken.

5.7 Records

- a) The Director of Research Operations will be responsible for the appointment of the administrative support for the Ethics Committee ("Administrative Officer") and the provision of facilities and staff sufficient to support the functions of the CAHS HREC ("Ethics Office").
- b) The Administrative Officer shall prepare and maintain records of the CAHS HREC's activities including agendas and minutes of all meetings of the CAHS HREC in line with the CAHS HREC SOPs.

6. Frequency of Meetings

- a) The CAHS HREC will meet monthly (except January).
- b) Special "out of session" meetings may be organised as required.
- c) Notice of Meetings: the agenda and supporting papers shall be sent to all members of the Committee at least 7 days before a meeting.



7. Quorum

- a) A quorum shall consist of the eight (8) members required to fulfil the minimum membership requirements as outlined in the National Statement (as outlined in 4.1 above).
- b) If the eight core members are not present the Chair must be satisfied that these members have received all the relevant papers and have had the opportunity to contribute their views and that these have been received and considered before a final decision is made (as per Section 5.2.30 of the National Statement).

8. Confidentiality

- a) Members of the CAHS HREC will treat as, and keep confidential, all information and documents which relate to the business considered by the CAHS HREC. CAHS HREC members who are not CAHS employees will complete a declaration of confidentiality upon their appointment and at such frequency as required under CAHS policy.
- b) The discussions and decisions of any Ethics Committee meeting shall not be disclosed to any person, who is not a member of the Ethics Committee or the SASC, save for the Administrative Officer and staff of the Ethics Office, unless such disclosure is authorised by the Ethics Committee or required by law.

9. Conflict of Interest

- a) Committee members are required to comply with [Department of Health policy on Conflict of Interest](#).
- b) Any member of the CAHS HREC who has an interest, financial or otherwise, in a proposal or other related matter considered by the CAHS HREC, should as soon as practicable declare such an interest.
- c) No members of the CAHS HREC may adjudicate on Research Projects in which they may be personally involved.
- d) All declarations of interest and the absence of the member concerned must be minuted.

10. Key Performance Indicators

The HREC expected outcomes for the next twelve (12) months are evaluation of committee administrative processes against the following administrative KPIs:

1.	Rate of meetings held according to annual planner	100%
2.	Rate of meetings with quorum achieved	100%
3.	Rate of reviews completed within NHMRC timeframe	100%

The HREC shall be evaluated annually against its expected outcomes and KPIs. This evaluation shall be tabled and presented annually to the Health Service Executive Committee.



11. Approval

These Terms of Reference shall be altered on the recommendation and approval of the CAHS Executive Committee This should be annually in response to evaluation of committee. The Chair shall be responsible for initiating this process. The members are responsible for the development, amendment and adoption of the Terms of Reference as ratified by CAHS Executive Committee.



Signature of Chairperson on behalf of Committee

Simon Erickson

Name of Chairperson on behalf of Committee

12th June 2023

Date

Document History

Version	Date	Changed by	Nature of amendment
1	10 July 2019	Helen Hughes	ToR for HREC and SASC split to better reflect changes required under National Mutual Acceptance and the functioning of the SASC on behalf of CAHS as a sponsor of research
2	16 Oct 2019	Helen Hughes	HSEC provided feedback following review of ToR for HREC and SASC, some changes were incorporated after review of the feedback received
3	20 March 2023	Alexandra Robertson	Removal of duplication between HREC SOP and Terms of Reference. Updated to reflect 2018 update to National Statement including expedited review for low-risk research. Accountability clarified, as well as independence of HREC.

Previous version should be recorded and available for audit.



ADOPTION AND AMENDMENT OF TERMS OF REFERENCE:	
First formulated:	July 1995
Revised:	May 1998
Revised:	February 2001
Revised:	June 2003
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