



Child and Adolescent Health Service Clinical Trials Subcommittee

Terms of Reference

1. Purpose

The Child and Adolescent Health Service Human Research Ethics Committee (**CAHS HREC**) will appoint a Clinical Trials Subcommittee (**CTS**) to advise on clinical trial proposals presented to CAHS HREC in accordance with these Terms of Reference.

This committee will assess the scientific merit and integrity of the clinical trial as per the NHMRC National Statement on Ethical Conduct in Human Research and provide expert advice to the CAHS HREC for consideration.

2. Functions

2.1. Pursuant to the CAHS HREC Terms of reference, the CTS will:

- a) Assess the scientific validity and the methodology of the proposed research.
- b) Assess the risk benefit ratio of the study in particular the novel therapies under investigation.
- c) Advise the CAHS HREC, in lay terms, of the scientific validity, significance and impact of the proposed research and its outcome.
- d) Monitor the surveillance reports of approved research projects.
- e) Review and assess adverse events including serious adverse events that are reported to the CAHS HREC (in accordance with NHMRC requirements) or to CAHS as the approving institution and/or sponsor of the research.
- f) Provide a report and comments to the CAHS HREC and/or CAHS Executive Committee regarding surveillance and adverse event reports.
- g) Seek external review of proposed research if the CTS considers additional expertise is required to assess the scientific validity, significance, and impact of the proposal research.

2.2. Confidentiality of individual member opinions will be upheld outside the CAHS HREC & CTS.

- 2.3. The CTS may invite the applicant to attend a CTS meeting to address any specific concerns identified during CTS assessment of the research application or to address concerns raised during the monitoring of approved research.
- 2.4. The CTS may recommend whether the Coordinating Principal Investigator, Principal Investigator (or delegate) of the research proposal should attend the CAHS HREC meeting to discuss the research proposal.
- 2.5. Members to whom a research proposal is allocated or the Chair of the CTS, may contact the applicant (or supervisor) to discuss any problems identified by the CTS if required at their discretion.
- 2.6. Communication of any issues or concerns identified during CTS review of the application will be provided in writing to the CAHS HREC, to be considered and then relayed to the applicant as per the CAHS HREC queries.
- 2.7. However, if the CTS determines that there are significant matters related to research merit or integrity then the committee may recommend the applicant to clarify/ revise the research proposal and a) resubmit for review by the CAHS HREC or b) return to the CTS for further review prior to recommending the project to the CAHS HREC for consideration and approval.
- 2.8. In these cases an applicant has the right to reject the advice of the CTS and seek to be heard by the CAHS HREC. The applicant will be required to provide in writing a request to the CAHS HREC Chair.
- 2.9. The CTS Chair will be a member of the CAHS HREC and shall be present at the CAHS HREC meeting to speak to the CTS minutes or recommendations.

3. Authority

- 4.1 The CTS is a committee functioning under the authority of the CAHS HREC and reporting to the CAHS HREC.
- 4.2 The CTS may bring to the attention of the CAHS HREC (via the CTS Minutes which will be tabled at HREC, or via the CTS Chair) issues of concern.
- 4.3 These Terms of Reference shall be available upon written request and shall be posted upon the CAHS website.

4. Membership

- 4.1. The CTS shall consist of a minimum of 8 members including a Chair, who will also have membership on the HREC, and several members from varied and experienced scientific and clinical backgrounds.
- 4.2. Members will be drawn from a list of nominations from all departments/clinical areas of Child and Adolescent Health Service that wish to nominate a member of the CTS. Nominations will also be open to colleagues at collaborating institutions such as Telethon



Kids Institute and academic institutions. If no nomination is received from a particular area which is seen to be important to the functioning of the CTS then the Chair will endeavour to obtain a suitable nomination.

- 4.3. Members of the CTS shall be approved and appointed (or re-appointed) by the Director of Research upon the recommendation of the CTS Chair following endorsement by Research Ethics Manager.
- 4.4. The term of appointment of each member of the CTS shall be three years from the date of that member's appointment. Members of the CTS may be reappointed for up to three terms (nine years).
- 4.5. The Chair of CTS will ensure that sufficient expertise is available to adequately assess the protocols submitted and will co-opt additional ad hoc members as required.
- 4.6. The CTS may seek external review of a research proposal following initial consideration by the CTS if the CTS decides that additional expertise is required to assess the scientific validity, significance and impact of the proposed research and its outcome.
- 4.7. Each member of the CTS may appoint a delegate to replace themselves at any meeting the member cannot attend. Any delegate replacing a member at a meeting of the CTS pursuant to clause 4.3 shall have the power to vote at that meeting.
- 4.8. Where reference is made to a member of the CTS in these Terms of Reference, that reference includes reference to the delegate(s) of that member.
- 4.9. All new members to the CTS are oriented to their role and receive copies of Terms of Reference, Conflict of Interest declaration documents and meeting schedule. This is the responsibility of the Chair.

5.1 Chairperson

The Chair of the CTS will hold a salaried role in the Research Department to perform this function. The Chair is also responsible for the review of Serious and suspected breaches, adverse events and other reports. The Chair will provide approval for amendments to approved protocols out of session, to be ratified at the meeting.

5.2 Voting

Decisions by the CTS will be made by consensus whenever possible and opinions of all reviewers will be heard and considered. If a consensus cannot be reached, decision will be made by a majority of the members attending a meeting. Each appointed member of CTS, including the Chair of the CTS, shall have one vote. The Chair of the CTS shall not have a casting vote.

5.3 Liability Coverage

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



6. Frequency of Meetings

- 6.1 Meetings will be held 11 times per year (monthly - except January) and a schedule of meetings will be agreed in advance.
- 6.2 The CTS will meet between the closing date for submission of applications and the CAHS HREC Meeting (allowing time for the committee's report to be circulated to the CAHS HREC).

7. Quorum

A quorum for a scheduled CTS meeting shall consist of half the members. Written comments received from members will count towards a quorum.

8. Apologies

Members who will be absent from a meeting are required to submit an apology to the Secretary and/or Chairperson.

Members must nominate a suitable proxy to attend in their absence. The proxy may be another member of the Committee. The proxy will have full voting rights

9. Conduct of meetings

The decision of the Chairperson is final in all matters of procedure.

All meetings shall be conducted in accordance with the CAHS values (Compassion, Collaboration, Equity, Respect, Excellence, and Accountability).

10. Reporting

The CTS provides ratified minutes and action list from the meeting to the HREC and Health Services Executive Committee for tabling.

11. Confidentiality

The discussions and decisions of the meeting shall not be conveyed to unauthorised persons.

12. Secretary to the Committee

- 12.1 The CTS will be supported by the Research Department will be responsible for the appointment of the Administrative Officer to the CTS ("CTS Administrative Officer").
- 12.2 The CTS Administrative Officer shall:
 - a) receive all correspondence and applications addressed to the Committee or the Chairperson;
 - b) compile the agenda and papers for meetings of the CTS;
 - c) prepare the minutes of meetings of the CTS; and
 - d) convey the decisions of the CTS to the HREC.



13. Conflict of Interest

- 13.1 Committee members are required to comply with Department of Health policy on [Conflict of Interest](#).
- 13.2 No members of the Committee may adjudicate on Research Projects in which they may be personally involved.

14. Key Performance Indicators

The CTS expected outcomes for the next twelve (12) months are listed below.

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 30 working day KPI	100%

The CTS shall be evaluated annually against its expected outcomes and KPIs. This evaluation shall be tabled and presented annually to the CAHS HREC.

11. Approval

These Terms of Reference may be altered on the recommendation of the Director of Research Operations, HREC Chair or CTS Chair. Amended Terms of Reference shall be brought by the Director of Research Operations to the CAHS Executive Committee for approval.

The CTS members are responsible for the adoption of the Terms of Reference as ratified by CAHS Executive Committee.



Signature of Chairperson on behalf of Committee

Dr Laurence Cheung

Name of Chairperson on behalf of Committee

11th July 2023

Date



Document History

Version	Date	Changed by	Nature of amendment
Updated Template Version 1	10.07.19	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.
Updated Template Version 2	16.10.19	Helen Hughes	HSEC provided feedback following review of ToR for HREC and SASC, some changes were incorporated after review of the feedback received.
Updated March 2023	9.03.23	Alexandra Robertson	Committee name changed to Clinical Trials Subcommittee (CTS, previously SASC) and scope defined for clinical trials including safety, research merit and integrity. Clarified role as ethical review; governance is the responsibility of CAHS Executive.

Previous version should be recorded and available for audit.

ADOPTION AND AMENDMENT OF TERMS OF REFERENCE:	
First formulated:	July 1995
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