



# Child and Adolescent Health Service Scientific Advisory Safety Committee

## Terms of Reference

### 1. Purpose

- 1.1 The Ethics Committee will appoint a Scientific Advisory and Safety Committee (SASC) to advise on research proposals presented to CAHS Human Research Ethics Committee in accordance with these Terms of Reference.
- 1.2 This Committee may (at the request of the Research Governance office) also advise on research to be conducted at CAHS, or involving CAHS patients or staff when ethical approval is provided by another Lead HREC under National Mutual Acceptance and CAHS is providing site approval and /or where CAHS is acting as the sponsor of the research.
- 1.3 This committee will assess projects prior to Ethics Committee meetings, identifying remedial problems and resolving these and by providing expert advice to the Ethics Committee.
- 1.4 Where Ethics approval is provided by an external Lead HREC, the committee will advise on specific issues as requested by the Research Governance Officer.

### 2. Functions

- 2.1 Pursuant to clause 2.5 (d) of the Ethics Committee Terms of reference, the SASC will:
  - (a) Assess the scientific validity and the methodology of the proposed research.
  - (b) Advise the Ethics Committee, in lay terms, of the scientific validity, significance and impact of the proposed research and its outcome.
  - (c) Assess the impact of the proposed research on CAHS services.
  - (d) Monitor the surveillance reports of approved research projects.
  - (e) Review and assess adverse events including serious adverse events that are reported to the 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 Ethics Committee / Health Service Executive Committee regarding surveillance and adverse event reports.
  - (g) Seek external review of proposal research if the SASC considers additional expertise is required to assess the scientific validity, significance and impact of the proposal research.



- 2.2 Each new research proposal will be assigned to two members of the SASC for presentation at the meeting. These members will summarise the research proposal for the meeting and raise any concerns the member has about the research proposal.
- 2.3 The name of a reviewer appointed by the SASC pursuant to clause 2.2 above will not be disclosed to any person who is not a member of the SASC or the Ethics Committee until the Ethics Committee has made a decision in relation to the research proposal being reviewed by that reviewer.
- 2.4 The SASC will determine whether the Coordinating Principal Investigator, Principal Investigator (or delegate) of the research proposal is required to attend the Ethics Committee meeting to discuss the research proposal.
- 2.5 The member to whom a research proposal is allocated or the Chairperson of the SASC, may contact the applicant (or supervisor) to discuss any problems identified by the SASC if required and if the reviewer is happy to do so.
- 2.6 Communication of any problems/issues identified during SASC review of the application will be provided in writing to the applicant.
- 2.7 If the SASC determines that there are significant matters of related to the research merit and integrity, justice, beneficence and respect the SASC may advise the applicant to clarify/ revise the research proposal and resubmit the proposal for re-review by the SASC prior to recommending the project to the HREC for further consideration and approval
- 2.8 The SASC may invite the applicant to attend an "Out of Session" SASC meeting to address any specific concerns identified during SASC assessment of the research application or to address concerns raised during the monitoring of approved research.
- 2.9 An applicant has the right to reject the advice of the SASC and seek to be heard by the Ethics Committee. The applicant will be required to provide in writing a request to the Chairperson of the Ethics Committee to be heard by the Ethics Committee.
- 2.10 The Chairperson of the SASC, or the nominated deputy of the Chairperson of the SASC, shall provide a written report on the research proposals submitted to the Ethics Committee and be present at the Ethics Committee meeting to speak to that report.
- 2.11 The SASC will consider the annual and final reports submitted by researchers as part of it role in monitoring of approved research.
- 2.12 In the event of a problem with a research proposal which is underway being brought to the attention of the Chairperson of the SASC :
  - (i) The Chairperson of the SASC or their delegate should seek full details from the researcher and other sources as appropriate.
  - (ii) The Chairperson of the SASC should then advise the Chairperson of the Ethics Committee (where HREC approval is provided by CAHS) and/or the EDMS (where HREC approval is provided by an external HREC) of the course of action proposed, which may include suspension of the study or suspension of site approval.
  - (iii) The Chairperson of the SASC may need to convene special meetings of the SASC or recommend convening a special meeting of the Ethics Committee or meet directly with the EDMS to deal with the problem.

### 3. Authority

- 3.1 The Scientific Advisory Safety Committee (SASC) is a committee functioning under the authority of the Child and Adolescent Health Service Human Research Ethics Committee (CAHS HREC), and reporting to the CAHS HREC where CAHS is providing ethical approval and reporting to Health Services Executive Committee.
- 3.2 The Scientific Advisory Safety Committee (SASC) is also a committee functioning under the authority of the Child and Adolescent Health Service and reporting to Health Service Executive Committee ], where CAHS is providing site approval for the research to be conducted and where CAHS is acting as the sponsor of research.
- 3.3 The SASC may from time to time bring to the attention of the EDMS issues of concern to the SASC
- 3.4 The Terms of Reference shall be available upon written request and shall be posted upon the CAHS website.

### 4. Membership

#### 4.1 The SASC Committee shall consist of the following members:

- (a) A Chairperson, appointed by the Ethics Committee and being a member of the Ethics Committee, and a number of members from varied and experienced scientific and clinical backgrounds.
- (b) The members will be recommended for appointment by the EDMS following endorsement by SASC members and 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 SASC. Nominations will also be open to colleagues at collaborating institutions such as Telethon Kids Institute and academic institutions.
- (c) If no nomination is received from a particular area which is seen to be important to the functioning of the SASC then the Chairperson will endeavor to obtain a suitable nomination
- (d) Members of the SASC shall be approved and appointed (or re-appointed) by the EDMS upon the recommendation of the Chairperson of SASC following endorsement by SASC members.
- (e) The term of appointment of each member of the SASC shall be three years from the date of that member's appointment. Members of the SASC may be reappointed for one or more terms.
- (f) The Chairperson of SASC will ensure that sufficient expertise is available to adequately assess the protocols submitted and will co-opt additional ad hoc members as required.
- (g) The SASC may seek external review of a research proposal following initial consideration by the SASC if the SASC decides that additional expertise is required to assess the scientific validity, significance and impact of the proposed research and its outcome.
- (h) Each member of the SASC may have a single delegate appointed by the CAHS Executive to replace the member at any meeting of the SASC the member does not attend and such delegate will be a member of the SASC for the purpose of that meeting.

- (i) Any delegate replacing a member at a meeting of the SASC pursuant to clause 4.3 shall have the power to vote at that meeting.
- (j) Where reference is made to a member of the SASC in these Terms of Reference, that reference includes reference to the delegate(s) of that member.
- (k) All new members to the SASC are oriented to their role and receive copies of Terms of Reference, Committee Guidelines, Conflict of Interest declaration documents and meeting schedule. This is the responsibility of the Chair.

#### **4.2 Chairperson**

The Chairperson of the SASC will be appointed from nominations drawn from a list given by the Director Child Health Research Department, the Ethics Committee and the SASC.

#### **4.3 Voting**

While the SASC generally operates on consensus:

- (a) Each appointed member of SASC, including the Chairperson of the SASC, shall have one vote.
- (b) The Chairperson of the SASC shall not have a casting vote. A decision of the SASC will be made by consensus whenever possible. If a consensus cannot be reached, decision will be made by a three quarter majority of the members attending a meeting of the SASC.
- (c) Where a safety report is under review the opinions of all reviewers will be considered and consensus reached

#### **4.4 Liability Coverage**

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

## **5. Frequency of meetings**

- 5.1 Meetings will be held 11 times per year (monthly - except January) and a schedule of meetings will be agreed in advance.
- 5.2 The SASC will meet between the closing date for submission of applications and the Ethics Committee Meeting (allowing time for the committee's report to be circulated to members of the Ethics committee).
- 5.3 In addition, the Chair may call additional meetings as necessary to address any matters referred to the committee or in respect of matters the committee wishes to pursue within its terms of reference.

## 6. Quorum

- 6.1 A quorum for a scheduled SASC meeting shall consist of half the members. Written comments received from members will count towards a quorum.
- 6.2 An “Out of Session” SASC meeting shall include at least 2 members of the SASC and the Chairperson of the SASC or their nominated deputy.

## 7. Reporting

- 7.1 The SASC provides ratified minutes and action list from the meeting to the Human Research Ethics Committee and Health Services Executive Committee for tabling.

## 8. Confidentiality

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

## 9. Secretary to the committee

- (a) The Executive Director Medical Services will be responsible for the appointment of the Administrative Officer to the SASC (“SASC Administrative Officer”).
- (b) The SASC Administrative Officer shall:
  - (i) receive all correspondence and applications addressed to the Committee or the Chairperson;
  - (ii) compile the agenda and papers for meetings of the SASC;
  - (iii) prepare the minutes of meetings of the SASC; and
  - (iv) convey the decisions of the SASC as directed by the SASC to applicants for the Ethics Committee approval of research projects.

## 10. Conflict of interest

Committee members are required to comply with Department of Health policy on Conflict of Interest WA Health Mandatory Policy [MP0113/19 Managing Conflicts of Interest Policy](#).

No members of the Committee may adjudicate on Research Projects in which they may be personally involved.

## 11. Key Performance Indicators

The SASC expected outcomes for the next twelve (12) months are listed below:

Evaluation of committee administrative processes against the following administrative KPIs:

KPI Number	KPI	Target
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 SASC shall be evaluated annually against its expected outcomes and KPIs. This evaluation shall be tabled and presented annually to the Health Services executive Committee.

## 12. Approval

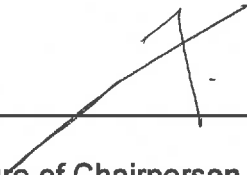
These Terms of Reference shall be altered on the recommendation and approval of the Health Services Executive Committee as outlined below. The Chair shall be responsible for initiating this process. The members are responsible for the development, amendment and adoption of the Terms of Reference as ratified by Health Services Executive Committee.

### 12.1 **AMENDMENT TO THE TERMS OF REFERENCE**

- (a) These Terms of Reference may be amended by following the procedure below: For those Proposals made by an Ethics Committee member:
- (i) The proposal must be in writing and circulated to all Ethics Committee Members for their Consideration;
  - (ii) The views of the members should be discussed at the next scheduled meeting of the Ethics Committee, and a vote taken at that meeting.
  - (iii) Any member unable to attend such a meeting may register his or her views in writing;
  - (iv) The proposal shall be ratified if three quarters of the members agree to the amendment, and
  - (v) The Chairperson shall send the amendment to the Chief executive for review and approval if appropriate
- (b) For those proposals made by the Chief Executive, the Chief Executive will send the proposal to the Scientific Advisory Safety Committee and seek the views of any relevant person.



Signed copy sent to HSEC, all members of SASC, HREC and CAHS Committee Data Steward (Organisational Development) and Secretary of SASC

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Signature of Chairperson on behalf of Committee

Lawrence Cheung  
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Name of Chairperson on behalf of Committee

Deputy Chair Person - SASC  
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Date 15 Sept 2020  
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## Document History

Version	Date	Changed by	Nature of amendment
Updated Template Version 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
Updated Template Version 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

*Previous version should be recorded and available for audit.*

## ADDOPTION AND AMENDMENT OF TERMS OF REFERENCE

First formulated:	July 1995
Revised:	May 1998
Revised:	February 2001
Revised:	June 2003
Revised:	May 2004
Revised:	June 2005
Revised:	March 2009
Ratified:	6 March 2009
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Revised:	16 June 2016
Ratified:	16 June 2016
Revised:	07 September 2016
Ratified:	18 November 2016
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