Government of **Western Australia**
Child and Adolescent Health Service

Human Research Ethics Committee

TERMS OF REFERENCE

1. ESTABLISHMENT OF THE ETHICS COMMITTEE

1.1 The King Edward Memorial and Princess Margaret Hospitals Ethics Committee was originally formed in July 1995 by combining the existing Princess Margaret Hospital for Children Ethics Committee and the King Edward Memorial Hospital for Women Institutional Ethics Committee.

1.2 With a change in hospital management structure, this Committee of King Edward Memorial and Princess Margaret Hospitals was ratified by the WA Women's and Children's Health Authority ("**WAWCHA"**) Board at its meeting on 12 February 2001.

1.3 Due to the increasing number of applications to be reviewed, the King Edward Memorial and Princess Margaret Hospitals Ethics Committee was split into two separate committees for a trial period of 1 year with effect from March 2003. The Princess Margaret Hospital Ethics Committee for Children ("**Ethics Committee"**) was one of those committees. This change was endorsed by the Women's & Children's Health Service.

1.4 On the completion of the trial period (March 2004) it was agreed that separate committees were required and the Ethics Committee would continue in its current form. It was renamed the Child and Adolescent Health Service Human Research Ethics Committee prior to the re-location to Perth Children's Hospital to better reflect the scope of projects under review.

1.5 Variations to these Terms of Reference may be made by the CAHS Executive and must be consistent with the National Health and Medical Research Councils ("**NHMRC"**) National Statement on Ethical Conduct in Human Research 2007 ("National Statement") and all updates.

2. FUNCTIONS OF THE ETHICS COMMITTEE

2.1 The functions and authority of the Ethics Committee shall be to;

(a) Consider the ethical implications of all proposed research projects involving humans submitted to the Ethics Committee for approval ("**Research Projects**");

(i) involving the staff, patients or resources of the Child and Adolescent Health Service ("**CAHS"**);

(ii) involving the staff, patients or resources of the Telethon Kids Institute ("**TKI"**); or

(iii) multi-centre research proposals, which are conducted in line with Section 5.3 of the National Statement on Ethical Conduct in Human Research 2007 and submitted from external organisations or researchers and may be accepted for review at the discretion of the Ethics Committee and CAHS;

where the scientific content and clinical implications of such proposed research projects have previously been considered by the Scientific Advisory Subcommittee ("**SASC"**);

(b) Provide for expeditious review of the Research Projects referred to in clauses 2.1(a) in extraordinary circumstances from any other research organisation the Ethics Committee in its discretion decides to consider;

(c) Provide for surveillance of research projects until completion so that the Ethics Committee may be satisfied that they continue to conform with approved ethical standards;

(d) Retain and archive records in accordance with the Department of Health Record Keeping Plan Retention and Disposal Schedule, as follows:

(i) Maintain a register of all Research Projects, so that the following items of information are recorded and readily available;

- name of responsible institution
- project identification number
- principal investigator(s)
- short title of project
- ethical approval or non-approval with date
- date(s) designated for review
- research proposal protocols; and

(ii) The Research Projects proposals shall not be destroyed and shall be preserved in the form in which they are approved in accordance with the State Records Act 2000 (WA);

(e) Discuss and advise on specific issues the Ethics Committee considers of importance;

(f) Monitor the total impact of the Research Projects on patients, families and hospital services;

(g) Establish and maintain communication with the NHMRC and provide access to the NHMRC, upon request, to information in the Ethics Committee's records;

(h) Consider any recommendations made by the Medical Advisory Committee ("**MAC"**);

(i) Make recommendations to representatives of the CAHS Executive as described in clause 3 below.

2.2 In carrying out the functions referred to in clause 2.1 above, the Ethics Committee shall:

(a) Comply with the National Statement on Ethical Conduct in Human Research 2007 and any updates;

(b) Take account of local cultural and social attitudes;

(c) Ensure that procedures relating to obtaining informed consent are observed;

(d) Ensure that no members of the Committee adjudicate on Research Projects in which they may be personally involved;

(e) Ensure that, while accepting that health care professionals have a duty to advance knowledge by research, the rights of individual patients, or subjects of research, take precedence over the expected benefits to human knowledge or to the community; and

(f) Appoint sub-committees or person/s to investigate and report on issues of relevance to the Ethics Committee and Princess Margaret Hospital as the need arises.

3. STATUS OF THE ETHICS COMMITTEE WITHIN THE HEALTH SERVICE

3.1 The Ethics Committee is a committee of CAHS with responsibility for:

(a) Providing ethical approval;

(b) Withholding ethical approval

(c) Withdrawal of existing ethical

approval for Research Projects.

3.2 The Director Clinical Services of CAHS (**"Director Clinical Services"**) 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 Ethics Committee.

3.3 The Ethics Committee delegates to the Director Clinical Services the authority to sign correspondence on behalf of the committee. Such correspondence may include:

(a) Giving or withholding approval of Research Projects ;

(b) Approval of amendments to Research Projects;

(c) Suspension of approval of Research Projects ;or

(d) Withdrawal of approval of Research Projects.

3.4 The Director Clinical Services shall sponsor the Ethics Committee in CAHS business.

4. ACCOUNTABILITY OF THE ETHICS COMMITTEE

4.1 The Ethics Committee is accountable to the Director Clinical Services in the conduct of its business.

4.2 The Minutes of each Ethics Committee meeting shall be forwarded to the Director Clinical Services following confirmation.

4.3 The Ethics Committee may from time to time bring to the attention of the Director Clinical Services issues of concern to the Ethics Committee.

4.4 The Ethics Committee 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 or proposals reviewed, status of proposals, a description of any complaints received and their outcome and general issues raised.

4.5 The Terms of Reference shall be available upon written request and shall be posted upon the CAHS website.

5. COMPOSITION OF THE ETHICS COMMITTEE

5.1 The Ethics Committee shall consist of:

(a)	Chairperson	1
(b)	female community representative not associated with PMH, TKI	1
(c)	male community representative not associated with PMH, TKI	1
(d)	minister of religion, or equivalent	1
(e)	lawyer	1
(f)	members with knowledge of, and current experience in, the areas of research that are regularly considered by the Ethics Committee	2
(g)	members with knowledge of, and current experience in, the professional care, counselling or treatment of people	3
(h)	member of CAHS Executive or delegate	1
(i)	member with nursing and research experience	1
(j)	member with pharmaceutical knowledge	1
	Total	**13**

5.2 Up to 6 additional members may be co-opted by the Ethics Committee with the approval of the CAHS Executive or delegate.

5.3 Each member may have a delegate appointed by the CAHS Executive to replace the member at any meeting of the Ethics Committee the member does not attend and such delegate will be a member of the Ethics Committee for the purpose of that meeting.

5.4 Any delegate replacing a member at a meeting of the Ethics Committee pursuant to clause 5.3 shall have the power to vote at that meeting.

5.5 Where reference is made to a member of the Ethics Committee in these Terms of Reference, that reference includes reference to the delegate of that member.

5.6 Member of CAHS Executive or delegate is an ex officio observer member and does not vote.

5.7 Membership of men and women shall as far as possible be equal in number.

6. METHOD AND TERMS OF APPOINTMENT FOR MEMBERS

6.1 The members of the Ethics Committee shall be appointed (or re-appointed) by the CAHS Executive.

6.2 The term of appointment of each member of the Ethics Committee shall be three years from the date of that member's appointment. Members of the Ethics Committee may be reappointed for one or more terms.

6.3 Members will be reimbursed for legitimate expenses incurred in attending meetings, such as travelling and parking expenses by application to the office of the Ethics Committee.

6.4 A member may resign from the Ethics Committee upon giving notice in writing to the Chairperson.

6.5 The members of the Ethics Committee shall be aware of the:

(a) National Statement;

(b) Australian Code for Responsible Conduct in Research; and

(c) Ethics Committee Terms of Reference.

7. LIABILITY COVERAGE

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

8. CHAIRPERSON

8.1 The Chairperson of the Ethics Committee ("**Chairperson"**) will be appointed by the CAHS Executive or their delegate from nominations given by the Director of Clinical Research and Education of PMH ("**Director of Clinical Research and Education**") or the Ethics Committee.

8.2 The term of appointment of the Chairperson shall be three years from the date of the Chairperson's appointment. The Chairperson may be reappointed for one or more terms.

8.3 The Chairperson will appoint one of the members of the Ethics Committee as Deputy Chairperson who will be responsible for signing correspondence on behalf of the Ethics Committee and the review of Ethics Committee requested changes to applications, administrative amendments, annual reports and Serious Adverse Events / Suspected Unexpected Serious Adverse Reactions reports. The Deputy Chairperson shall hold office at the Chairperson's discretion.

8.4 The Deputy Chairperson will preside over any meeting of the Ethics Committee the Chairperson does not attend and may act in the place of the Chairperson in any other capacity of the Chairperson when requested to do so by the Chairperson.

8.5 Where the Deputy Chairperson is unable to attend a meeting of the Ethics Committee the Ethics Committee will appoint one of the members present at that meeting to preside over that meeting and that person shall be deemed to be chairperson for the meeting.

9. QUORUM

9.1 A quorum of the Ethics Committee (subject to clauses 8.3, 8.5, 9.2, 9.3 and 9.4) shall consist of all those in the category referred to in clauses 5.1 (a), (b), (c), (d) and (e), one member of clause 5.1 (g) and two members of clause 5.1(f) ("**Required Members"**).

9.2 At a meeting of the Ethics Committee where there is not a quorum of members as referred to in clause 9.1 present, a quorum will be deemed to be present if the Chairperson is satisfied at the commencement of the meeting that any Required Member who is absent from that meeting has received the agenda and papers relevant to the meeting and has had an opportunity to comment and to have those comments recorded and considered by the members present at the meeting.

9.3 In the absence of a delegate, a member who is unable to attend a meeting of the Committee shall review the agenda and papers relevant to the meeting and shall provide the secretary of the Ethics Committee referred to in clause 10 below with any comments the member wants the Ethics Committee to consider at the meeting, or advise the secretary of the Ethics Committee that the member has no comments the member wishes to make, prior to the meeting.

9.4 If, during any meeting of the Ethics Committee a Required Member absents himself or herself from the meeting for any reason and, consequently, there is not a quorum of members as referred to in clause 9.1 present, a quorum will be deemed to be present if the Chairperson is satisfied that the views of the Required Member on any undecided business before the Ethics Committee at that meeting have been received and considered.

10. SECRETARY TO THE COMMITTEE

10.1 The **Director of Clinical Research and Education** will be responsible for the appointment of the administrative support the Ethics Committee ("Administrative Officer**"**) and the provision of facilities and staff sufficient to support the functions of the Ethics Committee ("**Ethics Office"**).

10.2 The 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 Ethics Committee;

(c) prepare the minutes of meetings of the Ethics Committee;

(d) convey the decisions of the Ethics Committee as directed by the Ethics Committee to applicants for the Ethics Committee approval of research projects; and

(e) update the Ethics internet website to ensure all applicants can view current requirements for applications to the Ethics Committee

10.3 The Administrative Officer shall maintain a database of all Research Projects in accordance with clause 2.1(d) above and ensure all reporting required by the Ethics Committee is complied with.

10.4 The Administrative Officer may delegate any of the Administrative Officer functions to an employee of the Ethics Office or CAHS with the consent of the Chairperson.

11. SCIENTIFIC ADVISORY SUBCOMMITTEE

11.1 The Ethics Committee will appoint a scientific advisory sub-committee ("**SASC"**) in accordance with the SASC Terms of Reference attached.

11.2 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 outcomes;

(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;

(f) provide a report and comments to the Ethics Committee regarding surveillance and adverse event reports; and

(g) seek external review of proposed research if SASC considers additional expertise is required to assess the scientific validity, significance and impact of the proposed research.

12. CONDUCT OF BUSINESS

12.1 Procedures

The Ethics Committee will perform its functions by adopting the requirements laid out in the National Statement on Ethical Conduct in Human Research (2007) inclusive of all updates.

12.2 Submissions, notifications and approvals

(a) All applications for ethical approval must be submitted to the Ethics Office in writing in the format approved by the Ethics Committee and shall include such documentation as the Ethics Committee may specify.

(b) The Ethics Committee will issue guidelines to assist applicants in their preparation of applications for Ethical Approval of Research Projects.

(c) The Ethics Committee may request an applicant to supply any further information in relation to an application and request the applicant to attend a meeting of the Ethics Committee at which the application will be considered for the purpose of providing information to and answering questions from the Ethics Committee members.

(d) The Ethics Committee will consider every correctly completed application ("**Application"**) that it receives at its next available meeting following receipt, provided that the Application is received by the relevant closing date for that meeting. The Ethics Office shall circulate the Application and associated documents received with a meeting agenda to all members of the Ethics Committee at least 7 days prior to the next meeting.

(e) The Ethics Committee delegates consideration of scientific and technical matters to the SASC.

(f) The Ethics Committee may take into account the views or opinions of another Human Research Ethics Committee in relation to a Research Project's protocol.

(g) The Ethics Committee may seek external review and or advice to assist with consideration of a Research Project following initial consideration by the SASC and the Ethics Committee if the Ethics Committee decides that additional expertise is required to assess ethical matters related to the Research Project.

(h) After consideration of the Application, the Ethics Committee will promptly notify the applicant in writing or email, advising whether the Research Project has been recommended for ethical approval and any conditions of that recommendation.

12.3 **Advocates and interpreters**

(a) The Ethics Committee will consider whether an advocate for any participant or group of participants should be invited to the Ethics Committee meeting to ensure informed decision-making.

(b) Where a Research Project involves the participation of persons unfamiliar with the English language, the Ethics Committee 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.

12.4 **Fees**

The Ethics Committee may charge a fee for review of each Application (refer to Schedule of Fees).

12.5 **Records**

In addition to the records referred to in clause 2.1(d) above:

(a) The Ethics Office will prepare and maintain written records of the Ethics Committee's activities, including agendas and minutes of all meetings of the Ethics Committee.

(b) The Ethics Office will prepare and maintain a file for each application received including a copy of the application, and any relevant correspondence including that between the applicant and the Ethics Committee.

(c) Files shall be kept securely and confidentially in accordance with the requirements of the Health Services (Conciliation and Review) Act 1995 (WA), The State Records Act 2000 (WA) and the Privacy Act-Cwth (1988).

13. POST APPROVAL RESPONSIBILITIES

13.1 The Ethics Committee will, as a condition of approval of each Research Project, require that investigators immediately report anything which might warrant review of ethical approval of the Research Project, including:

(a) proposed changes in the Research Project protocol or conduct;

(b) unforeseen events that might affect continued ethical acceptability of the project e.g. serious or unexpected adverse events that independent review by the investigator, TGA or sponsor, if any, has determined materially affect the safety of the study and require a change to the Protocol or the consent documentation;

(c) if the project is abandoned for any reason;

(d) if a project has not commenced within 12 months of approval date; and

(e) requests for extensions of approved interval for research projects to be undertaken.

13.2 The Ethics Committee will, as a condition of approval of each Research Project, require that investigators provide:

(a) An annual report of the progress of the Research Project;

(b) A final report upon completion or cessation of the Research Project;

(c) Upon request study documentation for monitoring of approved Research Projects to verify that the conduct of the research conforms to the approved proposal.

13.3 The Ethics Committee will review a Research Project upon receiving a report referred to in clause 13.1 above and may review a Research Project at any time should the Ethics Committee consider such review is warranted.

13.4 After a review referred to in clause 13.3 above, the Ethics Committee may recommend that ethical approval for the Research Project being reviewed be:

(a) suspended pending further consideration by the Ethics Committee;

(b) withdrawn; or

(c) continue subject to conditions.

14. COMPLAINTS AND REVIEW

14.1 Complaints concerning the Ethics Committee review process

(a) Any concern or complaint about the Ethics Committee's review process should be directed to the attention of the Chairperson, detailing it in writing;

(b) Upon receiving a complaint referred to in 14.1(a) above:

(i) The Chairperson will investigate the Complaint and its validity, and make a recommendation to the Ethics Committee on the appropriate course of action;

(ii) If the complainant is not satisfied with the outcome of the Chairperson's investigation, then the Complainant can refer the

Complaint to the Director Clinical Services, or his or her nominee, or request the Chairperson to do so;

(iii) The Chairperson will provide to the Director Clinical Services all relevant information about the Complaint. The Director Clinical Services will determine whether there is to be a further investigation of the Complaint;

(iv) If the Director Clinical Services decides that there is to be a further investigation, then the Director Clinical Services will convene a suitable panel to review the Complaint (**Panel**), ensuring that both the Complainant and the Ethics Committee are afforded the opportunity to make submissions;

(v) In conducting its review, the Panel shall determine whether the Ethics Committee acted in accordance with the National Statement on Ethical conduct in Human Research and its Terms of Reference and whether the Ethics Committee acted in a fair or unbiased manner.

14.2 **Complaints Procedure in relation to approved Research Projects**

(a) All complaints in relation to Research Projects approved by the Ethics Committee are to be forwarded immediately by the Ethics Office to the Director Clinical Services.

(b) The Director Clinical Services shall write to the complainant acknowledging the complaint and advising that further investigation is pending.

(c) The Director Clinical Services shall inform the Administrative Officer and Chairperson of the SASC within three working days of receipt of a complaint referred to in clause 14.2(a) by the office of the Director Clinical Services and provide copies of sufficient information to enable identification of the Research Project referred to in the complaint.

(d) The Chairperson of the SASC will meet at the earliest opportunity after receiving notice of a complaint with Director of Clinical Services.

(i) to discuss the complaint;

(ii) to determine if immediate sanctions or suspension of the Research Project is warranted

(e) Upon receiving notice of the complaint the Secretary will inform the Chairperson of Ethics Committee of the complaint and the Chairperson of the SASC will confer with Chairperson of the Ethics Committee about the complaint.

(f) Chairperson of the SASC or delegate will within 3 working days of receiving notification of the complaint:

(i) contact the investigator of the Research Project and supervisor to notify the investigator and supervisor of the complaint, discuss the complaint and to request further details of the complaint (where necessary);

(ii) investigate the circumstances and confirm details surrounding the complaint; and

(iii) prepare a report for the Ethics Committee and the Director of Clinical Services.

(g) The complaint will be tabled at the next Ethics Committee meeting after the Secretary has received notification of the complaint for notice and consideration.

(h) Following receipt of a report from the Chairperson of the SASC the Ethics Committee will forward their recommendations regarding the Research Project and complaint to Director Clinical Services who will correspond with the complainant.

15. MEETING PROCEDURES

15.1 Frequency

(a) The Ethics Committee will meet monthly (except January).

(b) Special meetings may be organised as required.

(c) A special meeting of the Ethics Committee may be held by telephone conference where the Chairperson considers such a meeting is necessary.

15.2 Notice of Meetings

Notices of meetings, the agenda and supporting papers shall be sent to all members of the Committee at least 7 days before a meeting.

15.3 Voting

While the Ethics Committee generally works on consensus:

(a) Each appointed member of the Ethics Committee except the member of CAHS executive or their delegate, including the Chairperson, shall have one vote.

(b) The Chairperson shall not have a casting vote; and

(c) A decision of the Ethics Committee will be made wherever possible by consensus. Where consensus cannot be reached decision will be made by ¾ majority vote of the Required Members at the meeting of the Ethics Committee.

16. MINUTES

16.1 Minutes of each meeting shall be prepared by the Secretary and distributed to each member of the Ethics Committee.

16.2 The Minutes of each meeting of the Ethics Committee shall be submitted to the CAHS Executive for its information or for decision upon matters specifically referred by the Ethics Committee.

16.3 The Minutes of each meeting of the Ethics Committee shall be submitted to the next meeting (other than a meeting referred to in clause 20 below) of the Ethics Committee for certification by the Chairperson as a correct record of the proceedings.

16.4 Minutes of each meeting of the Ethics Committee will be sent to the MAC for its information.

17. CONFIDENTIALITY

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 Secretary and staff of the Ethics Office, unless such disclosure is authorised by the Ethics Committee or required by law.

18. COMMUNICATION WITH RESEARCHERS

Following ratification by the Director Clinical Services or delegate, the Secretary will forward letters of approval for research promptly to researchers.

19. QUALITY ASSURANCE

19.1 Medical record reviews, audits and quality assurance projects conforming to clause 5.1.18 to 5.1.21 of the National Statement will be submitted to the relevant Hospital Quality Improvement Committee for consideration and approved by the Director Clinical Services.

19.2 The Ethics Committee will not review Quality Improvement projects that do not meet the requirements of a research proposal as determined by the Quality Improvement Committee.

19.3

The Quality Improvement Committee can refer projects that it feels meet the definition of research to the ethics office for guidance regarding the application and review process for consideration by the ethics committee of a research project.

20. EXPEDITIOUS REVIEW

20.1 In extraordinary circumstances a research proposal may receive expeditious review and approval outside an ordinary meeting. If, in the opinion of the Chairperson of the Ethics Committee, or the Chairperson of the SASC, a research proposal warrants expeditious review the procedure outlined below will be followed:

(a) The research proposal will be sent (couriered, faxed, emailed or hand delivered) to all Ethics Committee members;

(b) The Ethics Committee members will be requested to provide written or verbal comments in relation to the research proposal to the Administrative Officer by a specified time;

(c) The Chairperson is satisfied that Required Members have exchanged opinions.

(d) Once clauses 20.1(a), (b) and (c) are complied with the Chairperson may make a decision concerning the research proposal.

(e) The Chairperson's decision upon the research proposal will be put before the Ethics Committee at its next meeting for ratification of the decision made.

20.2 In some instances it may not be possible, due to the comments received from the Ethics Committee members, for the proposal to be approved outside a scheduled meeting. In such cases the proposal will form part of the agenda at the next scheduled meeting of the Ethics Committee.

21. AMENDMENT TO THE TERMS OF REFERENCE

(a) These Terms of Reference may be amended by following the procedure below: For those proposals made by a 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 Ethics Committee and seek the views of any relevant person.

21.2 SCIENTIFIC ADVISORY SUB-COMMITTEE

TERMS OF REFERENCE

The Ethics Committee will appoint a scientific advisory sub-committee (SASC) to advise on research to be conducted at Princess Margaret Hospital, or involving Princess Margaret Hospital patients or staff. This sub-committee has been formed to ease the burden on the Ethics Committee by assessing projects prior to Ethics Committee meetings, identifying remedial problems and resolving these and by providing expert advice to the Ethics Committee.

1. Composition

(a) The SASC will consist of a Chairperson, appointed by the Ethics Committee and being a member of the Ethics Committee, and a number of members.

(b) The Chairperson of the SASC will be appointed from nominations drawn from a list given by the Director of Clinical Research and Education, the Ethics Committee and the SASC.

(c) The members will be recommended for appointment by the Chairperson of SASC 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 for the SASC.

(d) 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.

(e) All members of the SASC will be approved and appointed by the Director Clinical Services. These members need not be members of the Ethics Committee. 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.

(f) The members of the SASC shall be appointed (or re-appointed) by the Director Clinical Services after consultation with the Ethics Committee upon the recommendation of the Chairperson of SASC.

(g) 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.

(h) **Members of SASC shall be aware of the:**

(i) National Statement

(ii) Australian Code for Responsible Conduct in Research

(iii) Ethics Committee Terms of Reference

(iv) SASC Terms of Reference

2. Duties

Pursuant to clause 11.2 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.

(f) provide a report and comments to the Ethics 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.

3. Committee Secretary

(a) The **Director of Clinical Research and Education** 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.

4. Procedures

To discharge the duties of the SASC, the following procedures will be adopted:

(a) The SASC will meet between the closing date for submission of applications and the Ethics Committee meeting (allowing time for the sub-committee's report to be circulated to members of the Ethics Committee).

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

(c) 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.

(d) The SASC will assess research proposals for scientific validity and impact on services and resources of Princess Margaret Hospital.

(e) The SASC will determine whether the applicant or supervisor of the research proposal is required to attend the Ethics Committee meeting to discuss the research proposal.

(f) The member to whom a research proposal is allocated or the Chairperson of the SASC, will contact the applicant (or supervisor) to discuss any problems identified by the SASC.

(g) If the problems can be easily corrected, the applicant will be given the opportunity to submit any modified or additional documentation prior to the Ethics Committee meeting.

(h) If the SASC considers that significant matters of scientific integrity, methodology or logistics exist, the SASC may advise the applicant to review /revise the research proposal and resubmit once those problems are remedied.

(i) The SASC may invite the applicant to attend an "Out of Session" SASC meeting to address any specific concerns noted during the initial application process or to address concerns raised during the monitoring of approved research.

(j) 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.

(k) 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.

(l) 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.

(m) To fulfil its monitoring role, the SASC will consider the annual and final reports submitted by researchers.

(n) 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 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 of the course of action proposed, which may include the suspension of the study.

(iii) The Chairperson of SASC may need to convene special meetings of the SASC or recommend the convening of a special meeting of the Ethics Committee to deal with the problem.

(o) 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.

(p) The name of a reviewer appointed by the SASC pursuant to clause (m) 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.

5. Confidentiality

The discussions and decisions of any SASC meeting shall not be disclosed to any person, who is not a member of the SASC or the Ethics Committee, save for the

SASC Secretary, the Secretary and the staff of the Ethics Office, unless such disclosure is authorised by the SASC and/or Ethics Committee or required by law.

5.1 **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.

ADOPTION 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
Revised:	March 2013
Ratified:	18 April 2013
Ratified:	19 June 2014
Revised:	24 July 2014
Revised:	17 September 2014
Ratified:	18 September 2014
Revised:	16 June 2016
Ratified:	16 June 2016
Revised:	07September2016
Ratified:	07September 2016