



CHILD AND ADOLESCENT HEALTH SERVICE

TERMS OF REFERENCE

Princess Margaret Hospital for Children Human Research Ethics Committee

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 (**Ethics Committee**) is 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.
- 1.5 Variations to these Terms of Reference may be made by the Health Service Executive Committee (**HSEC**) and must be consistent with the National Health and Medical Research Councils (**NHMRC**) Guidelines and the Guidelines of the Australian Health Ethics Committee (**AHEC**).

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 Institute of Child Health Research; and

the scientific content and clinical implications of which have been considered by the Scientific Advisory Subcommittee (**SASC**), and to determine whether or not they are acceptable on ethical grounds;

- (b) Provide for expeditious review of the Research Projects 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)
 - (i) Maintain a register of all proposed research projects, so that the following items of information are 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
 - (ii) The research proposal protocols shall be preserved in the form in which they are approved for a period of seven (7) years from the approval or extension of the approval:
- (e) Discuss and advise on specific issues the Ethics Committee considers of importance;
- (f) Monitor the total impact of approved research projects on patients, families and hospital services;
- (g) Establish and maintain communication with the NHMRC Australian Health Ethics Committee and provide access, 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 HSEC as described in paragraph 3 below.

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

- (a) Conform with the NHMRC *National Statement on Ethical Conduct in Human Research* (**the National Statement**) in particular fields that may be published from time to time;
- (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 proposals 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) Set up working parties and/or sub-committees 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 an advisory committee of CAHS with responsibility for recommending:
- (a) ethical approval; or
 - (b) that ethical approval be withheld; or
 - (c) the withdrawal of ethical approval
- for Research Projects .
- 3.2 The Executive Director Medical Services of CAHS (**Executive Director Medical 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 Executive Director Medical Services requires the Ethics Committee to provide advice on whether to:
- (a) give or withhold approval on behalf of CAHS to the conduct of Research Projects ;
 - (b) approve amendments of Research Projects on behalf of CAHS;
 - (c) suspend approval of Research Projects on behalf of CAHS ;or
 - (d) withdraw approval of Research Projects on behalf of CAHS.
- 3.4 The Executive Director Medical Services shall sponsor the Ethics Committee in CAHS business.

4. ACCOUNTABILITY OF THE ETHICS COMMITTEE

- 4.1 The Ethics Committee is accountable to the Executive Director Medical Services in the conduct of its business.
- 4.2 The Minutes of each Ethics Committee meeting shall be forwarded to the Executive Director Medical Services following confirmation.
- 4.3 The Ethics Committee may from time to time bring to the attention of the Executive Director Medical Services issues of concern to the Ethics Committee.
- 4.4 The Ethics Committee will provide a report to the **AHEC** in accordance with the requirements of the NHMRC, 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 Ethics Committee will provide a copy of the annual report to NHMRC.
- 4.6 The Terms of Reference shall be available upon written request and shall be posted upon the Child and Adolescent Health Service (CAHS) website.

5. COMPOSITION OF THE ETHICS COMMITTEE

5.1 The Ethics Committee shall consist of:

(a)	Chairman	1
(b)	female community representative not associated with PMH	1
(c)	male community representative not associated with PMH	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 HSEC	1
(i)	member with nursing and research experience	1
(j)	member with pharmaceutical knowledge	1
	Total	<u>13</u>

- 5.2 Up to 6 additional members may be co-opted by the Ethics Committee with the approval of the HSEC.
- 5.3 Each member may have a delegate appointed by the HSEC to replace the member at any meeting of the Ethics Committee the member does not attend;
- 5.4 Any delegate replacing a member at a meeting of the Ethics Committee pursuant to subparagraph 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.

6. METHOD AND TERMS OF APPOINTMENT FOR MEMBERS

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

- 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 The members of the Ethics Committee will be fully aware of the:
- (a) NHMRC 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. CHAIRMAN

- 8.1 The Chairman of the Ethics Committee (Chairman) will be appointed by the HSEC from nominations given by the Director of Clinical Research and Education of PMH (DCRE) or the Ethics Committee.
- 8.2 The term of appointment of the Chairman shall be three years from the date of the Chairman's appointment. The Chairman may be reappointed for one or more terms.
- 8.3 The Chairman will appoint one of the members of the Ethics Committee as Deputy Chairman. The Deputy Chairman shall hold office at the Chairman's discretion.
- 8.4 The Deputy Chairman will preside over any meeting of the Ethics Committee the Chairman does not attend and may act in the place of the Chairman in any other capacity of the Chairman when requested to do so by the Chairman.
- 8.5 Where the Deputy Chairman 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 chairman 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 a simple majority of members of the Ethics Committee including all those in the category referred to in subparagraph 5.1 (a), (b), (c), (d) and (e) and one member from each of the categories referred to in subparagraph 5.1(f) and (g) (**Required Members**)).
- 9.2 At a meeting of the Ethics Committee where there is not a quorum of members as referred to in subparagraph 9.1 present, a quorum will be deemed to be present if the Chairman is satisfied at the commencement of the meeting that the Required Members have received the agenda and papers relevant to the meeting and have had an opportunity to comment and 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 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 member necessary for the quorum absents himself or herself from the meeting for any reason the Ethics Committee will be deemed to continue to have a quorum at that meeting.

10. SECRETARY TO THE COMMITTEE

10.1 The DCRE will be responsible for the appointment of the secretary to the Ethics Committee (**the Secretary**) and the provision of facilities and staff sufficient to support the functions of the Ethics Committee (**Ethics Office**).

10.2 The Secretary shall:

- (a) receive all correspondence and applications addressed to the Committee or the Chairman;
- (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 Secretary shall keep a register of all approved research projects in accordance with subparagraph 2.1(d) above and ensure all reporting required by the Ethics Committee is complied with.

10.4 The Secretary may delegate any of the Secretary's functions to an employee of the Ethics Office or CAHS with the consent of the Chairman.

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;
- (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.

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 (**the 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 Proposal protocol.
- (g) The Ethics Committee may seek external review and or advice to assist with consideration of a Research Proposal 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 proposal.
- (h) The Ethics Committee will promptly notify the applicant in writing or email, advising whether the Application, which it has considered, 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 applications submitted for assessment by the Ethics Committee (refer to Schedule of Fees).

12.5 Records

- (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).
- (d) Records shall be held for sufficient time to allow for future reference. The minimum period for retention is at least 7 years from the date of completion of a project but for specific types of research, such as clinical research, 15 years shall apply.
- (e) The Ethics Office will maintain a register of all the applications received and reviewed in accordance with the National Statement.

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.

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 Chairman, detailing it in writing;
- (b) Upon receiving a complaint referred to in 14.1(a) above:
 - (i) The Chairman 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 Chairman's investigation, then the Complainant can refer the Complaint to the Executive Director Medical Services, or his or her nominee, or request the Chairman to do so;
 - (iii) The Chairman will provide to the Executive Director Medical Services all relevant information about the Complaint. The Executive Director Medical Services will determine whether there is to be a further investigation of the Complaint;
 - (iv) If the Executive Director Medical Services decides that there is to be a further investigation, then the Executive Director Medical 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 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 Executive Director Medical Services.
- (b) The Executive Director of Medical Services shall write to the complainant acknowledging the complaint and advising that further investigation is pending.
- (c) The Executive Director Medical Services shall inform the Secretary and Chairman of the SASC within three working days of receipt of a complaint referred to in subparagraph 14.2(a) by the office of the Executive Director

Medical Services and provide copies of sufficient information to enable identification of the Research Project referred to in the complaint.

- (d) The Chairman of the SASC will meet at the earliest opportunity after receiving notice of a complaint with Executive Director of Medical 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 Chairman of Ethics Committee of the complaint and the Chairman of the SASC will confer with Chairman of the Ethics Committee about the complaint.
- (f) Chairman 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);
 - (iv) investigate the circumstances and confirm details surrounding the complaint; and
 - (v) prepare a report for the Ethics Committee and the Executive Director of Medical 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 Chairman of the SASC the Ethics Committee will forward their recommendations regarding the Research Project and complaint to Executive Director of Medical 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 Chairman 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, including the Chairman, shall have one vote.
- (b) The Chairman shall not have a casting vote; and

- (c) A decision of the Ethics Committee will be made by a three quarter majority of the quorum at the meeting of the 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 HSEG 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 paragraph 20 below) of the Ethics Committee for certification by the Chairman 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 Committee, save as referred to in paragraph 11(e) above, unless such disclosure is authorised by the Ethics Committee or required by law.

18. COMMUNICATION WITH RESEARCHERS

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

19. QUALITY ASSURANCE

- 19.1 Medical record reviews, audits and quality assurance projects conforming to clauses 5.1.18 to 5.1.23 of the National Statement, will be submitted to the relevant Hospital Quality Improvement Committee for consideration and approved by the Executive Director Medical Services.
- 19.2 The Ethics Committee can request that quality assurance proposals are reviewed by the SASC if the Ethics Committee believes such review is necessary.

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 Chairman of the Ethics Committee, or the Chairman 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 Committee Secretary by a specified time;
 - (c) 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

21.1 These Terms of Reference may be amended by following the procedure below:

- (a) 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 Chairman shall send the amendment to the Executive Director for review and approval if appropriate.
- (b) For those proposals made by the Executive Director the Executive Director will send the proposal to the Ethics Committee and seek the views of any relevant person.

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 Chairman, appointed by the Ethics Committee and being a member of the Ethics Committee, and a number of members.
- (b) The Chairman of the SASC will be appointed from nominations drawn from a list given by the Director of Clinical Research and Education of Princess Margaret Hospital (**DCRE**), the Ethics Committee and the SASC.
- (c) The members will be recommended for appointment by the Chairman of SASC and will be drawn from a list of nominations from all departments/clinical areas of Princess Margaret Hospital 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 Chairman will endeavour to obtain a suitable nomination.
- (e) All members of the SASC will be approved and appointed by the Ethics Committee. These members need not be members of the Ethics Committee. The Chairman 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 Ethics Committee upon the recommendation of the Chairman 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 will be fully aware of the:
 - (i) NHMRC National Statement
 - (ii) Australian Code for Responsible Conduct in Research
 - (iii) Ethics Committee Terms of Reference

2. Duties

As outlined in the Ethics Committee Terms of reference, the duties of the SASC is to:

- (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.
- (f) provide a report and comments to the Ethics Committee regarding surveillance and adverse event reports
- (g) as per 11.2 (g).

3. Committee Secretary

- (a) The DCRE will be responsible for the appointment of the secretary to the SASC (**the Secretary**).
- (b) The Secretary shall:
 - (i) receive all correspondence and applications addressed to the Committee or the Chairman;
 - (ii) compile the agenda and papers for meetings of the SASC Committee;
 - (iii) prepare the minutes of meetings of the SASC Committee; and
 - (iv) convey the decisions of the SASC Committee as directed by the SASC Committee 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 shall consist of half the members (or recognised) proxies. 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 Chairman of the SASC, will contact the applicant (or supervisor) to discuss any problems identified by the sub-committee.
- (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) 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 Chair of the Ethics Committee to be heard by the Ethics Committee.
- (j) The Chairman of the SASC, or the nominated deputy of the Chairman 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.
- (k) To fulfil its monitoring role, the SASC will consider the annual and final reports submitted by researchers.
- (l) In the event of a problem with a research proposal which is underway being brought to the attention of the Chairman of the SASC:
 - (i) The Chairman of the SASC should seek full details from the researcher and other sources as appropriate;
 - (ii) The Chairman of the SASC should then advise the Chairman of the Ethics Committee of the course of action proposed, which may include the suspension of the study.
 - (iii) The Chairman 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.
- (m) 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.
- (n) The name of a reviewer appointed by the SASC pursuant to sub paragraph (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 Committee meeting shall not be disclosed to any person, who is not a member of the SASC Committee or the Ethics Committee, save as referred to in paragraph 4 (m, n) above, 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:

- (i) Each appointed member of SASC, including the Chairman of the SASC, shall have one vote.
- (ii) The Chairman of the SASC shall not have a casting vote.
- (iii) A decision of the SASC 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
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