1. PURPOSE AND SCOPE

This document describes the terms of reference, membership and functions of the Ethics Committee.

2. KEYWORDS

Ethics, Terms, Reference

3. BODY OF POLICY

3.1. Background

3.1.1. The Committee shall be known as the Ethics Committee of the Royal Australasian College of Surgeons.

3.1.2. The Committee is established as and shall function as a Human Research Ethics Committee within the *National Statement on Ethical Conduct in Human Research* issued by the *National Health and Medical Research Council* (NHMRC), and as such the Committee shall guide itself by the *National Statement* as in force from time to time and protocols there under issued by the NHMRC.

3.1.3. The Committee is further established to give independent advice and assistance to Professional Development and Standards Board (PDSB) on ethical and research matters as set out herein, or as referred to the Committee by PDSB from time to time.

3.2. Purpose

3.2.1. The primary role of the Human Research and Ethics Committee is to promote ethical human research.

3.2.2. To be and operate as a Human Research Ethics Committee under the *National Statement* in relation to research applications, involving humans, which have a proper connection with RACS and which the Committee considers it appropriate to be dealt with by itself rather than by the Human Ethics Committee of some other institution.

3.2.3. To certify as requested by PDSB whether RACS-related research activities involving humans have been approved by an appropriate and properly constituted Human Research Ethics Committee.

3.2.4. To provide policy advice and comment as requested by PDSB in relation to ethical issues generally and in particular to research and training.

3.2.5. To analyse and clarify ethical issues relating to the contemporary practice of surgery and the proper practice of health care.

3.2.6. To assist PDSB in relation to the formulation of guidelines relating to clinical trials.
3.2.7. To draw to the attention of PDSB any ethical issue or problem which comes to its attention and which is seems to be proper to be referred to PDSB.

3.3. Composition of the Committee

3.3.1. Members of the Committee shall be chosen and appointed by PDSB for such a term as PDSB shall decide, usually for a three (3) year term, with the ability to serve two (2) further periods of three years.

3.3.2. The minimum membership of an HREC is eight. As far as possible:

   a. There should be equal numbers of men and women; and
   b. At least one third of the members should be from outside the institution for which the HREC is reviewing research.

3.3.3. The composition of the Committee shall be consistent with the National Statement and the Code and shall be made up of the following Institutional members:

   a. Chair (refer Clause 3.3.4.a)
   b. Five (5) Fellows (refer Clause 3.3.4.f)
   c. One (1) Younger Fellow (refer Clause 3.3.4.f)
   d. The Executive Director for Surgical Affairs (Australia) of RACS (Ex-Officio) (refer Clause 3.3.4.c)
   e. Eight (8) Non-Institutional members (refer Clause 3.3.4.b,d,e,f)

3.3.4. The members shall include:

   a. Chairperson (Institutional member)
      A Chairperson, a Fellow of RACS appointed by PDSB with suitable experience, whose other responsibilities will not impair the HREC’s capacity to carry out its obligations under this National Statement.

   b. Layman/Laywoman (Non-Institutional members)
      At least two lay people, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work.

   c. Professional Care/Counselling (Institutional member)
      At least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional.

   d. Pastoral Care Role (ie Minister/Elder) (Non-Institutional member)
      At least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion.
e. Lawyer (Non-Institutional member)
   At least one lawyer, where possible one who is not engaged to advise
   the institution.

f. Research (Non-Institutional and Institutional members)
   Non-Institutional members will be:
   At least two people with current research experience that is relevant
   to research proposals to be considered at the meetings they attend.
   These two members may be selected, according to need, from an
   established pool of inducted members with relevant expertise.
   Institutional members will be:
   Five (5) Fellows of RACS
   One (1) Younger Fellow of RACS

3.3.5. No member may be appointed in more than one of the categories listed in
paragraph 3.3.4.

3.3.6. Members shall be chosen for their personal qualifications and experience,
and not in a representative capacity, and shall have responsibility to
decide any matter before the Committee on the basis of their own
independent judgement.

3.3.7. Subject to the presence of a quorum within Clause 3.4.4. the Committee
may meet and act notwithstanding that its composition is less than as
described above.

3.4. Proceedings

3.4.1. The Committee shall meet at least twice per year.

3.4.2. The Committee may meet face to face, by teleconference or by both.

3.4.3. As far as practicable, each meeting shall be so arranged as to give all
members the opportunity to attend and to be fully informed by prior timely
distribution of all relevant papers.

3.4.4. A quorum shall constitute eight (8) members as follows:
   a. at least three (3) Fellows of RACS including Younger Fellow (refer
      Clause 3.3.4.f)
   b. at least three (3) Non-Institutional members (refer Clause
      3.3.4.b,d,e,f)

3.4.5. The Chair may allow non members to be present during all or part of
the meeting as it sees fit.

3.4.6. As with normal RACS procedure, conflicts of interest will be declared to
the Committee at the commencement of the meeting or at a time during
the meeting when such a matter is brought to the member’s notice.
The member(s) shall not vote on the matter and, subject to the discretion of the Chair, shall not be present during deliberations on the matter. The declaration and abstention from voting shall be recorded in the Minutes of the meeting.

3.4.7. Each member shall be entitled to one vote. In the event of a tied vote, the Chair shall have a further casting vote.

3.4.8. The proceedings of the Committee shall be recorded in the Minutes.

3.4.9. A member who opposes the decision of the Committee shall be entitled to have that dissent recorded in the Minutes and, if he or she requests, notified to PDSB.

3.4.10. RACS accepts legal responsibility for decisions of and advice received from the Committee and agrees to indemnify the members of the Committee against all claims made against them in respect thereof, and all costs and expenses incurred in defending any such claim.

3.5. Reporting

3.5.1. The Committee shall participate in and provide a brief report (for noting only) to the Fellowship Services Committee.

In relation to all matters involving ethical considerations and all matters to do with its functioning as a Human Research Ethics Committee, the Committee shall address its communication to the PDSB, providing a regular report to PDSB.

3.5.2. In relation to other administrative matters, the Committee shall communicate with the PDSB provided that in the event of dispute the Committee shall have power to take the dispute direct to PDSB.

3.5.3. The Committee shall make such reports to the PDSB as are required to enable RACS to lodge all reports required by RACS with the NHMRC.

4. ASSOCIATED DOCUMENTS

Approval to Conduct Surveys Policy
Designing, Conducting and Coordinating Surveys Procedure
Conducting Surveys Manual
NHMRC National Statement on Conduct in Human Research (2007 Update 2009)
NHMRC Guidelines on ethical considerations in quality assurance Ethical Considerations in Quality Assurance and Evaluation Activities.