

Approved by the Council:

1.0 INTRODUCTION

- 1.1 The Human Research Ethics Committee (HREC) was established by the Academic Senate (resolution 142/90) at its 11/90 meeting, as a successor to the Research Ethics Committee.
- 1.2 The HREC was re-established by the Council (resolution C213/96) at its 4/96 meeting as a Committee of the Council.
- 1.3 The Council resolved:
 - (i) *that the Human Research Ethics Committee be re-established as a Committee of the Council, directly responsible to the Vice-Chancellor; and*
 - (ii) *that the Deputy Vice-Chancellor (Research) be the Vice-Chancellor's delegate as the officer of the University responsible for ensuring compliance by the Human Research Ethics Committee with statutory requirements and University policies and procedures; and to whom the Human Research Ethics Committee will report on a routine basis.*
- 1.4 The Deputy Vice-Chancellor (Research & Innovation) will act as the University officer responsible for the approval of policies, procedures and guidelines concerning the conduct of human research that are endorsed by the Human Research Ethics Committee (Council resolution C13:078). The Deputy Vice-Chancellor (Research & Innovation) will actively participate in the development of such documents through input and debate.

2.0 TERMS OF REFERENCE

- 2.1 As a recipient of Australian Government research funding, the University must ensure that any human research conducted under its auspices is:
 - (a) designed and conducted in accordance with the *Australian Code for the Responsible Conduct of Research*; and
 - (b) ethically reviewed and monitored in accordance with the *National Statement on Ethical Conduct in Human Research*.
- 2.2 The HREC is responsible for the review of applications for ethics approval for human research to be conducted at, or under the auspices of, the University and for the provision of advice to the University on related matters.
- 2.3 The HREC performs its responsibilities within the terms of reference as set out in the *National Statement*, issued jointly by the National Health and Medical Research Council (NHMRC), the Australian Research Council (ARC) and Universities Australia, and relevant state and commonwealth legislation, policies and codes. The HREC is required to:

- 2.3.1 consider the ethical implications of all proposed human research as defined by the *National Statement* and determine whether or not it is ethically acceptable;
 - 2.3.2 provide for the monitoring of research projects until completion so that the HREC may be satisfied that they continue to conform to the approved protocol;
 - 2.3.3 provide for a confidential mechanism for receiving complaints or reports on the conduct of research projects;
 - 2.3.4 ensure the maintenance of records of all proposed human research projects;
 - 2.3.5 establish and maintain communication with the Australian Health Ethics Committee (AHEC), a principal Committee of the NHMRC, provide access, upon request, to information in the HREC's records to the AHEC and/or NHMRC, and provide information to the University to enable it to report annually to the NHMRC on compliance with the *National Statement*.
- 2.4 Researchers not affiliated with the University, but who propose to conduct research specifically in the University, are required to obtain ethics approval from the HREC prior to commencing the research. In all other cases, ordinarily the HREC will not be available to non-affiliated researchers who do not have access to an institution or organisation with a human research ethics committee constituted in accordance with the *National Statement*. However, they may make application to the Deputy Vice-Chancellor (Research & Innovation) to have their research examined by the HREC.

3.0 MEMBERSHIP

- 3.1 The Human Research Ethics Committee shall comprise:
- 3.1.1 At least eight (8) members as required by the *National Statement*, being men and women, selected in consultation with the HREC, comprising:
 - 3.1.1.1 a chair, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the *National Statement*;
 - 3.1.1.2 at least two (2) lay people, one man and one woman, who have no affiliation with the University and not currently engaged in medical, scientific, legal or academic work;
 - 3.1.1.3 at least one (1) person with knowledge of, and current experience in, the professional care, counselling or treatment of people;
 - 3.1.1.4 at least one (1) person who performs a pastoral care role in a community;

- 3.1.1.5 at least one (1) lawyer, where possible one who is not engaged to advise the University; and
 - 3.1.1.6 at least two (2) people with current research experience that is relevant to research proposals considered at the meetings they attend.
 - 3.1.2 A Deputy Chair or Deputy Chairs, elected by the Committee from its members who shall:
 - 3.1.2.1 chair meetings of the HREC in the absence of the Chair;
 - 3.1.2.2 provide assistance to the Chair in the completion of the HREC's business;
 - 3.1.2.3 take a leading role in reviewing and approving applications eligible for expedited review.
 - 3.1.3 Eight (8) members, selected in consultation with the Chair of the Committee, with experience in the research areas of:
 - 3.1.3.1 Arts and the social sciences(1 member);
 - 3.1.3.2 Business and Law (1 member);
 - 3.1.3.3 Education (1 member);
 - 3.1.3.4 Engineering and Built Environment (1 member);
 - 3.1.3.5 Health and Medicine (2 members);
 - 3.1.3.6 Psychology (1 member);
 - 3.1.3.7 Science and Information Technology (1 member).
 - 3.1.4 Additional co-opted members may be appointed upon the request of the Committee.
- 3.2 The Chair is appointed by the Vice-Chancellor, on the recommendation of the Deputy Vice-Chancellor (Research & Innovation).
- 3.3 New members of the HREC, other than the Chair, are appointed by the Vice-Chancellor or the Deputy Vice-Chancellor (Research & Innovation) as the Vice-Chancellor's nominee. The University Council will be advised of changes in the HREC membership.
- 3.4 In making appointments to the Committee consideration shall be given to the broad knowledge of and commitment to excellence in ethical decision-making demonstrated by candidates for appointment and, in the case of members in category 3.1.3 their expertise and experience in relevant research areas.
- 3.5 Members appointed to category 3.1.1.3 or 3.1.1.6 may hold positions concurrently in category 3.1.3 subject to satisfying the specific requirements.
- 3.6 Additional members may be appointed to all categories with the exception of 3.1.1.1, to ensure the HREC remains compliant with the

National Statement and has sufficient expertise available for the research under review.

- 3.7 Members are appointed as individuals for their knowledge, qualities and experience, and not as representatives of any organisation, group or opinion.
- 3.8 As far as possible there should be:
 - 3.8.1 equal numbers of men and women; and
 - 3.8.2 at least one third of members who are from outside the University.
- 3.9 Members are indemnified by the University in the course of *bona fide* conduct of their duties as members of the HREC.
- 3.10 Members not affiliated with the University shall be reimbursed travel, parking and extraneous costs associated with attending meetings and other business associated with performing their duties as members. There is otherwise no remuneration to members.

4.0 OFFICERS IN ATTENDANCE

- 4.1 The Senior Human Research Ethics Officer shall attend meetings of the Committee as an officer in attendance and shall have rights of audience and debate.
- 4.2 The Manager, Research Integrity Unit may attend meetings of the Committee as an officer in attendance and shall have the rights of audience and debate.

5.0 TERMS OF OFFICE

- 5.1 The term of office shall be for two (2) years.
- 5.2 The term of office of the Chair and Deputy Chair shall be coincident with the appointee's term on the HREC itself.
- 5.3 Members may, if qualified, be considered for re-appointment for subsequent terms of office. Members would not usually serve for more than four years continuously, however it is acknowledged that a member may serve for longer periods in exceptional circumstances.

6.0 SUB-COMMITTEES

- 6.1 The HREC may establish and maintain such sub-committees as it deems necessary to respond effectively to its responsibilities.
- 6.2 Chairs of sub-committees shall be appointed from members of the HREC.

- 6.3 A sub-committee shall exercise such functions as the HREC delegates and shall report at least annually to the HREC.

7.0 DELEGATION

- 7.1 The HREC may delegate authority to act on its behalf and may delegate functions to the Chair, Deputy Chair or human ethics administrators.
- 7.2 Each matter dealt with on behalf of the HREC will be reported to the Committee.

8.0 MODE OF OPERATION

- 8.1 The HREC shall meet as frequently as necessary but at least eight times a year.
- 8.2 The HREC may invite applicants or other persons to attend for particular items of business at its meetings, or for such complete meetings, as the HREC may believe appropriate.
- 8.3 As required by the *National Statement*, where there is less than full attendance at a meeting of the HREC, the Chair must be satisfied, before a decision is reached, that the minimum membership listed in 3.1.1 have received all papers and have had an opportunity to contribute their views and that these have been recorded and considered.
- 8.4 The quorum for meetings of the HREC shall be a majority of the number of members in category 3.1.1.
- 8.5 The HREC shall endeavour to reach decisions by general agreement.
- 8.6 The HREC shall suspend and/or withdraw approval for any project which no longer complies with the approved research protocol or where the research ceases to be ethically acceptable.

9.0 REPORTING

- 9.1 The HREC shall report to the Council through the Vice-Chancellor at least annually.

10.0 SERVICING OF COMMITTEE

- 9.1 The Deputy Vice-Chancellor (Research & Innovation) shall appoint an administrative officer to the Committee, who shall have the rights of audience and debate.

Related Documentation:

- *HREC Procedures*
- *Australian Code for the Responsible Conduct of Research*
- *National Statement on Ethical Conduct in Human Research*
- *The University of Newcastle Policy Library*

Approval History:

Vice-Chancellor: 17 September 1996 (noted by Council 25 October 1996)

Council: 29 October 1999 (Resolution C99:246)

Amended by Vice-Chancellor 15 June 2002 (noted by Council 7 March 2003).

Council: 30 November 2007

Council: 24 May 2013 (Resolution C13:078)

Council: 9 October 2015 (Resolution C15:153)