

Hunter New England Human Research Ethics Committee

TERMS of REFERENCE

Version dated 28 March 2006

OBJECTIVES

1. The objectives of the Hunter New England Human Research Ethics Committee (hereafter 'the Committee') are to:
 - 1.1. protect the mental and physical welfare, rights, dignity and safety of participants of research;
 - 1.2. facilitate ethical research through efficient and effective review processes; and
 - 1.3. promote ethical standards of human research.

FUNCTIONS

2. The Committee's functions are to:
 - 2.1 review research in accordance with the *National Statement on Ethical Conduct in Research Involving Humans 1999* (the *National Statement*);
 - 2.2 provide independent, competent and timely review of research projects involving humans in respect of their ethical acceptability;
 - 2.3 provide ethical oversight, monitoring and advice for research projects involving humans; and
 - 2.4 prescribe the principles and procedures to govern research projects involving human participants, human tissue and/or personal records.

SCOPE OF RESPONSIBILITY

3. Research proposals will be reviewed by the Committee where the research involves patients, employees, data and human tissue samples from any institutions governed by the Hunter New England Area Health Service (HNEAHS).
4. Paragraph 3 does not prohibit the HNEAHS from accepting an ethical approval given by another Health Research Ethics Committee (HREC) as sufficient to allow the institution to approve the commencement of the project, provided that such other HREC is registered with the Australian Health Ethics Committee.
5. The Committee may grant ethical approval for research undertaken by external institutions/organisations and researchers.
6. Paragraph 5 shall only apply where an agreement exists between the HNEAHS and the external institution/organisation that defines the role of the Committee in providing the approval and ethical monitoring of the research and the role of the external institution/organisation in giving approval for the research to take place within its organisation.
7. The agreement referred to in Paragraph 6 shall specify which party bears legal responsibility for the liabilities that arise from the ethical review conducted by the Committee, and shall also specify that the external institution/organisation is responsible for liabilities arising from the conduct of the research.
8. Research involving humans includes research on pharmaceuticals, medical devices, medical radiation and imaging, surgical procedures, innovative therapies, biological

samples, medical records, as well as epidemiological, social, and psychological investigations.

STATUS OF THE HNEHREC WITHIN THE HEALTH SERVICE

- 9 The status of the Committee within the HNEAHS shall be as follows:
- 9.1 The Committee is a committee of the HNEAHS;
 - 9.2 The Chief Executive of the HNEAHS (hereafter the Chief Executive) or delegate is responsible for granting the HNEAHS's institutional approval for research to be conducted within its institution, giving due consideration to the advice of the Committee HNEAHS's institutions unless ethical approval has been granted by the Committee; and
 - 9.3 The Chief Executive has delegated to the Committee the authority to:
 - (a) give approval on behalf of the HNEAHS to the conduct of ethically approved research in the institutions referred to in Paragraph 3;
 - (b) approve amendments on behalf of the HNEAHS to research conducted at those institutions;
 - (c) monitor approved research in accordance with Paragraph 31;
 - (d) suspend approval on behalf of the HNEAHS for the conduct of research at those institutions; and
 - (e) withdraw approval on behalf of the HNEAHS for the conduct of research at those institutions.

ACCOUNTABILITY OF THE COMMITTEE

- 10 The Committee shall be accountable to the Chief Executive, through the Director of Population Health, Planning and Performance, in the conduct of its business.
- 11 The minutes of each Committee meeting shall be forwarded to the Chief Executive, following confirmation by the Committee.
- 12 The Committee shall provide an annual report to the Chief Executive at the end of each calendar year, which will include information on membership, the number of proposals reviewed, the status of proposals, a description of any complaints received and their outcome, and general issues raised.
- 13 The Committee may from time to time bring to the attention of the Chief Executive, or delegate, issues of significant concern.
- 14 The Committee will provide reports to:
- 14.1 the Australian Health Ethics Committee in accordance with the requirements of the National Health and Medical Research Council; and
 - 14.2 the NSW Privacy Commissioner, in accordance with the requirements of the Health Records and Information Privacy Act 2002 (NSW).
- 15 The Committee's Terms of Reference, Standard Operating Procedures and Statement of Composition will be available upon request to the general public and will be posted on the HNEAHS website.

MEMBERSHIP

16 Composition

- 16.1 The composition of the Committee shall be in accordance with the *National Statement* and shall include at least:
- (a) a chairperson;
 - (b) at least two members who are lay people, one man and one woman, who have no affiliation with the HNEAHS, and are not currently involved in medical, scientific, or legal work;
 - (c) a member with knowledge of, and current experience in, the areas of research that are regularly considered by the Committee;
 - (d) a member with knowledge of, and current experience in, the professional care, counselling or treatment of people;
 - (e) at least one member who is a minister of religion, or a person who performs a similar role in the community;
 - (f) at least one member who is a lawyer; and
 - (g) at least two members of Aboriginal communities.
- 16.2 The membership of the Committee will be drawn from the broad range of the communities covered by the HNEAHS;
- 16.3 To ensure the membership will equip the Committee to address all the relevant considerations arising from the categories of research likely to be submitted, some or all of the above categories may be represented by more than one person;
- 16.4 For the purposes of holding a meeting of the Committee, a quorum shall be present when a representative of each of the categories designated in the *National Statement* as specified in Sub-paragraph 16.1 is present;
- 16.5 Where any core members cannot be present, he/she may provide written comments in lieu of attendance;
- 16.6 Sub-paragraph 16.5 only applies in those circumstances where at least seven (7) members are physically present to achieve a Quorum, including one of each of the following categories:
- (a) Chair/Deputy Chair;
 - (b) lay person;
 - (c) researcher familiar with the types of proposals that are normally reviewed by the Committee; and
 - (d) a member of any Subcommittee, pursuant to Sub-paragraph 24.4;
- 16.7 The Committee shall be free to consult any person considered by the Committee to be qualified to provide advice and assistance in the review of any research proposal submitted to it, subject to that person having no conflict of interest and providing an undertaking of confidentiality; and
- 16.8 Any person consulted pursuant to Sub-paragraph 16.7 shall not be entitled to vote on any matter before the Committee.

17 Appointment

- 17.1 The Chief Executive shall appoint members of the Committee, in consultation with the Committee and other senior Hunter New England Area Health Service officials, as deemed appropriate;
- 17.2 Prospective members of the Committee may be recruited by direct approach, nomination or by advertisement;
- 17.3 A selection committee, consisting of the Chairperson, the Executive Officer and at least one other Committee member shall interview prospective

applicants, consult with the Committee members and make a recommendation to the Chief Executive;

- 17.4 Appointments will allow for continuity, the development of expertise within the Committee, and the regular input of fresh ideas and approaches; and
- 17.5 Where there is a vacancy on the Committee, for whatever reasons, that vacancy shall be filled in accordance with this Paragraph.

18 Appointment of Chairperson

- 18.1 The Chief Executive shall appoint the Chairperson of the Committee, in consultation with the Director of Population Health, Planning and Performance and other senior Hunter New England Area Health Service officials, as deemed appropriate;
- 18.2 The Chairperson shall be appointed for three years with the possibility of renewal.

19 Appointment of Deputy Chairperson

- 19.1 The Deputy Chairperson shall be elected by the Committee from amongst its members;
- 19.2 The Deputy Chairperson shall be appointed for three years with the possibility of renewal.
- 19.3 Where the Chairperson does not have medical expertise then the Deputy Chairperson should be a member of the Committee who has such expertise.
- 19.4 The Chief Executive shall be advised of the election of the Deputy Chairperson
- 19.5 In the Chairperson's absence the Deputy Chairperson shall act as Chairperson
- 19.6 The Deputy Chairperson shall assist with the Committee Business between meetings as required.

20 Terms of appointment

- 20.1 Members are appointed for a period of three years and may serve two consecutive terms only, unless otherwise approved by the Chief Executive;
- 20.2 Reappointment is by application to the Chairperson of the Committee who will then make a recommendation to the Chief Executive, through the Director of Population Health, Planning and Performance;
- 20.3 Membership will lapse, unless exceptional circumstances exist, if a member fails to attend three consecutive meetings of the Committee -
 - (a) without reasonable excuse, and/or
 - (b) without notifying the Chairperson.
- 20.4 The Chairperson shall, in writing, notify any member who becomes subject to the provision of Sub-paragraph 20.3;
- 20.5 A member may resign from the Committee at any time upon giving notice in writing to the Chairperson;
- 20.6 The Chief Executive may terminate the appointment of any member of the Committee if the Chief Executive is of the opinion that:
 - (a) it is necessary for the proper and effective functioning of the Committee;
 - (b) the person is not a fit and proper person to serve on an Committee; and

- (c) the person has failed to carry out his/her duties as an Committee member.
- 20.7 Members shall be provided with a letter of appointment which will include date of appointment, length of tenure, assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of their duties as a Committee member, Committee meeting attendance responsibilities and general responsibilities as a Committee member.

21 Conditions of appointment

- 21.1 Members shall be required to sign a statement undertaking:
- (a) that all matters of which he/she becomes aware during the course of his/her work on the Committee will be kept confidential;
 - (b) that any conflicts of interest, which exist or may arise during his/her tenure on the Committee will be declared; and
 - (c) that he/she has not been subject to any criminal conviction or disciplinary action, which may prejudice his/her standing as a Committee member
- 21.2 Members are not offered remuneration; and
- 21.3 Notwithstanding the provisions of Sub-paragraph 21.2, members shall be reimbursed for legitimate expenses incurred in attending Committee meetings or in any otherwise carrying out the business of the Committee.

22 Education for Committee members

- 22.1 All members shall be provided with adequate orientation.
- 22.2 All members shall be given the opportunity to attend conferences and workshops relevant to the work and responsibilities of the Committee, at the expense of the HNEAHS.

23 Liability coverage

- 23.1 The HNEAHS shall provide indemnity for members of the Committee for any liabilities that arise as a result of the member exercising his or her duties as a member in good faith.

CONDUCT OF BUSINESS

24 Procedures

- 24.1 The Committee will perform its functions according to written standard operating procedures;
- 24.2 All written standard operating procedures shall be reviewed at least every two years and amended and updated where necessary; and
- 24.3 All Committee members shall have access to and/or be provided with copies of the procedures and shall be consulted with regard to changes thereto.

25 Submissions, notifications and approvals

- 25.1 All applications for ethical approval must be submitted to the Executive Officer of the Committee, by the relevant closing date, in writing in format approved

- from time to time by the Committee and shall include such documentation as the Committee may specify;
- 25.2 Guidelines shall be issued from time to time to assist applicants in their preparation of applications;
 - 25.3 The Committee may request an applicant to supply any further information in relation to an application and/or request the applicant to attend a meeting of the Committee at which the application will be considered for the purpose of providing information to and answering questions from the Committee members;
 - 25.4 The Committee or its subcommittees will consider every correctly completed application which it receives at its next available meeting following receipt, provided that the application is received by the relevant closing date;
 - 25.5 The Executive Officer shall circulate the completed application and associated documents received with a meeting agenda to all members of the Committee at least seven days prior to the next meeting;
 - 25.6 The Committee may delegate consideration of certain scientific/technical matters to a Committee member or sub-committee members;
 - 25.7 The Committee may also obtain expert scientific/technical advice, subject to Sub-paragraph 16.7;
 - 25.8 The Committee may take into account the views or opinions of another HREC in relation to a research protocol; and
 - 25.9 The Committee will notify the applicant promptly, in writing, advising whether the application, which it has considered, has received ethical approval and any conditions of that approval and that the research may commence.

26 Sub-committees

- 26.1 The Committee may appoint such sub-committees as it sees fit to carry out a scientific or technical review of a research proposal, or ethical review of a minimal risk research, submitted to the Committee;
- 26.2 The Chief Executive shall appoint the Chair of each sub-committee;
- 26.3 Members of the sub-committee need not be members of the Committee;
- 26.4 At least one member of each sub-committee will usually be in attendance each meeting of the Committee; and
- 26.5 A report from the sub-committees for each application reviewed by that sub-committee will be circulated with agenda papers for the Committee

27 Authority Delegated

- 27.1 The Committee may recommend to the Chief Executive Officer that the Executive Officer be delegated the authority to facilitate the day to day working of the committee.
- 27.2 The delegated authority to the Executive Officer may include:
- to determine whether an application meets the requirements to be considered by the Committee and reject any application that does not;
 - to complete a preliminary review of audit and quality improvement activities to determine whether HREC approval is required, and if so, communicate the need for an ethics application to the appropriate person;
 - to approve amendments/variation to approved protocols within the areas of the Executive Officer's expertise and experience; and
 - grant extensions of approval for protocols whose period of approval has expired under specific conditions
- 27.3 The authority delegated to the Executive Officer should be reviewed annually or when the staff member in that position changes.

28 Multi-centre research

- 28.1 To facilitate multi-centre research the Committee may:
- (a) communicate with any other HREC; and
 - (b) accept a scientific/technical and/or ethical assessment of the research by another HREC; and
- 28.2 The Committee shall participate in the NSW Health Shared Scientific Assessment Scheme by requiring eligible protocols to be submitted to that Scheme, or other such arrangements introduced by NSW Health.

29 Advocates and interpreters

- 29.1 The Committee shall consider whether an advocate for any participant or group of participants should be invited to the Committee meeting to ensure informed decision-making; and
- 29.2 Where research involves the participation of persons unfamiliar with the English language, the Committee shall ensure that the participant information sheet is translated into the participant's language and that an interpreter is present during the discussion of the project.

30 Meetings

- 30.1 The Committee shall meet on a regular basis, the fourth week of the month, with the exception of January;
- 30.2 Meeting dates and agenda closing dates will be published;
- 30.3 The Committee shall endeavour to reach a decision concerning the ethical acceptability of a proposal by unanimous agreement;
- 30.4 Where a unanimous decision is not reached, the decision shall be carried by a majority of two-thirds of members who examined the proposal, provided that the majority includes at least one lay person; and
- 30.5 Any significant minority view of two or more members may be recorded in the minutes.

31 Declaration of Interest

- 31.1 Any member of the Committee who has any interest, financial or otherwise, in a proposal or other related matter considered by the Committee, shall declare such interest as soon as practicable;
- 31.2 Where any member is present at a meeting at which a proposal in which he or she has a declared interest is the subject of consideration, that member shall withdraw from the meeting until the Committee's consideration of the relevant matter has been completed;
- 31.3 Any member who declares an interest shall not participate in the discussions and shall not be entitled to vote in the decision with respect to the proposal; and
- 31.4 All declarations of interest and absence of the member concerned shall be recorded in the minutes.

32 Fees

- 32.1 A fee may be charged to an application submitted for assessment by the Committee in accordance with the Committee fee schedule; and
- 32.2 The Chief Executive or delegate will review the fees annually.

33 Records

- 33.1 The Executive Officer shall prepare and maintain written record of the Committee's activities, including agenda and minutes of all meetings of the Committee;
- 33.2 The Executive Officer 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 Committee;
- 33.3 Files shall be kept securely and confidentially in accordance with the requirements of Health Records and Information Privacy Act 2002;
- 33.4 Records shall be held for sufficient time to allow for future reference. The minimum period for retention is at least five years from the date of completion of a project but for specific types of research, such as clinical research, 15 years shall apply;
- 33.5 The Committee shall maintain a register of all the applications received and reviewed in accordance with the *National Statement*; and
- 33.6 Members of the Committee shall have access to the official minutes and records of the Committee for the time period they are members.

34 POST APPROVAL RESPONSIBILITIES

- 34.1 The Committee shall monitor approved projects in terms of compliance with the Committee's ethical approval;
- 34.2 The Committee may request and discuss information on any relevant aspects of the project with the investigators at any time;
- 34.3 The Committee shall require all successful applicants to provide an annual report and a report at completion of study;
- 34.4 The Committee shall, as a condition of approval of each proposal, require that investigators immediately report in writing anything which might warrant review of ethical approval of the project, including:
 - (a) proposed changes in the research protocol or conduct;
 - (b) unforeseen events that might affect continued ethical acceptability of the project;

- (c) serious or unexpected adverse events; or
 - (d) where the project is being abandoned for any reason; and
- 34.5 The Committee may adopt any additional mechanism for monitoring, as deemed necessary.

COMPLAINTS AND REVIEW

35 Complaints concerning the conduct of a project

- 35.1 The Committee shall nominate a person to receive complaints about the conduct of a project;
- 35.2 Any concern or complaint about the conduct of a project shall be directed to the attention of the person nominated pursuant to Sub-paragraph 35.1;
- 35.3 The person nominated to receive complaints shall notify the Chairperson as soon as possible after a complaint is received;
- 35.4 The Chairperson or his/her delegate, will investigate the complaint and make a recommendation on the appropriate course of action; and
- 35.5 Where the complainant is not satisfied with the outcome of the investigation, then he/she can refer the complaint to the Chief Executive, through the Director of Population Health, Planning and Performance, or request the Chairperson to do so.

36 Complaints concerning the Committee's review process

- 36.1 Any concern or complaint about the Committee's review process shall be dealt with either by being:
 - (a) directed to the Chairperson and dealt with through the Committee process; or
 - (b) directed to the Chief Executive and dealt with through the organisation's complaints procedure.
- 36.2 The Chairperson shall investigate the complaint and its validity, and make a recommendation to the Committee on the appropriate course of action;
- 36.3 Where the complainant is not satisfied with the outcome of the Chairperson's investigation and any subsequent action, then he/she can refer the complaint to the Chief Executive, or his/her nominee, or request the Chairperson to do so, who shall provide to the Chief Executive all relevant information about the complaint;
- 36.4 The Chief Executive shall carry out an initial assessment of a complaint or determine whether there is to be a further investigation of a complaint referred by the Chairperson using the organisation's complaints procedure;
- 36.5 Where it is decided there is to be a further investigation, then the Chief Executive may convene a suitable panel to review the complaint, ensuring that both the complainant and the Committee are afforded the opportunity to make submissions; and
- 36.6 In conducting its review, the panel shall be concerned with ascertaining whether the committee acted in accordance with the *National Statement*, its Terms of Reference, the written standard operating procedures, and in a fair and unbiased manner.

37 Complaints concerning the HNEHREC's rejection of an application

- 37.1 A person with a complaint about the Committee's rejection of their application shall refer the complaint to the attention of the Chairperson detailing the grounds of the complaint;
- 37.2 Complaints may also be made to the Chief Executive;
- 37.3 The Chairperson shall notify the Chief Executive in writing of any complaints received by him/her as soon as possible;
- 37.4 The Chief Executive shall notify the Chairperson in writing of any complaints received by him/her as soon as possible;
- 37.5 The Chairperson shall investigate the complaint and its validity, and make a recommendation to the Committee on the appropriate course of action;
- 37.6 Where the complaint is not satisfied with the action taken by the Committee, he/she can refer the complaint to the Chief Executive, through the Director of Population Health, Planning and Performance, or request the Chairperson to do so;
- 37.7 The Chief Executive shall determine whether there is to be a further investigation of the complaint;
- 37.8 Where it is decided that there is a case to be investigated, then the Chief Executive will convene a suitable panel to review the complaint, ensuring that both the complainant and the Committee are afforded the opportunity to make submissions;
- 37.9 Where the Committee is requested to review its decision, then the outcome of that review by the Committee will be final; and
- 37.10 Pursuant to Sub-paragraph 9.3, the panel or Chief Executive cannot substitute its approval for the approval of the Committee.

38 AMENDMENTS TO THE TERMS OF REFERENCE

- 38.1 These Terms of Reference may only be amended by the Committee with the agreement of the Chief Executive or by the Chief Executive with the agreement of the Committee;
- 38.2 The Committee shall only consider a proposal to amend these Terms of Reference where that amendment has been submitted by a member in writing and circulated to all Committee members for their consideration;
- 38.3 The amendment shall be discussed at the next scheduled meeting of the Committee, and a vote taken at that meeting;
- 38.4 Any member unable to attend such a meeting may register his or her views in writing;
- 38.5 The amendment shall only pass if two thirds of the members entitled to voted agree to the amendment;
- 38.6 The Chairperson shall forward the amendment to the Chief Executive for agreement;
- 38.7 The Chief Executive shall forward any amendment he/she proposes to these Terms of Reference to the Committee for its agreement;
- 38.8 The Chief Executive may seek the views of any relevant person in relation to the proposed amendment;
- 38.9 Any amendment proposed by the Chief Executive shall only be adopted by the Committee if two thirds of the members entitled to vote agree to the amendment;
- 38.10 The Chairperson shall inform the Chief Executive of the Committee's decision; and
- 38.11 The Committee shall review these Terms of Reference annually or whenever the *National Statement* is revised.