

# Concord Repatriation General Hospital



## SYDNEY SOUTH WEST AREA HEALTH SERVICE HUMAN RESEARCH ETHICS COMMITTEE (HREC) - Concord Repatriation General Hospital Zone

### Terms of Reference

#### OBJECTIVES

1. The Human Research Ethics Committee's objectives are:
  - 1.1 To protect the mental and physical welfare, rights, dignity and safety of participants in research.
  - 1.2 To facilitate ethical research through efficient and effective review processes.
  - 1.3 To promote ethical standards of human research.
  - 1.4 To review research in accordance with the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (2007) and appropriate state and federal legislation .

**A copy of the NHMRC Statement can be found at:  
<http://www.nhmrc.au/>**

#### FUNCTIONS

2. The Human Research Ethics Committee functions are:
  - 2.1 To provide independent, competent and timely review of human research projects.
  - 2.2 To provide ethical and scientific oversight and advice for human research projects.
  - 2.3 To monitor approved research projects to ensure compliance with the conditions of approval. This includes requests for annual, final and safety reports and deviations from the approved protocol. The HREC may also

adopt any other appropriate mechanism for monitoring eg. Audits of research sites, data or consent documentation. In very high risk research, the HREC may, in its letter of approval, request on-site monitoring at recommended intervals or randomly throughout the research project.

- 2.4 To determine the compliance of a human research project with the National Statement and grant, withhold or withdraw ethical approval.
- 2.5 To provide advice on strategies to promote awareness of the ethical conduct of human research.
- 2.6 To receive complaints about any aspect of a research study from researchers or participants in research.
- 2.7 To ensure that HREC members comply with the terms of their appointment.
- 2.8 To monitor requests (by researchers and staff members) for access to health data and medical records held within the organisation, for the purposes of audit, quality assurance and research.
- 2.9 To co-ordinate submissions to the *Ethics of Clinical Practice Sub-Committee* of the Royal Prince Alfred Hospital Ethics Committee in relation to clinical innovations, clinical practice ethics and other matters.
- 2.10 To provide ethical advice regarding any other relevant activities referred to it by the Chief Executive or delegate, the General Manager of CRGH, clinical, research and/or teaching staff of the hospital.

## **SCOPE OF RESPONSIBILITY**

3. In its role as a Lead Human Research Ethics Committee, the HREC is authorized to provide a single ethical and scientific review of human research\* proposals involving participants from:
  - 3.1 Concord Repatriation General Hospital
  - 3.2 Any institution governed by NSW Public Health Organisations
  - 3.3 Organisations and individuals external to the public health system where an agreement has been made between the organisation or individual and the SSWAHS. This form of agreement is to be found in the NSW Health Proforma Agreement to Undertake Ethical Review for an External Entity (NSW Health Policy Directive PD2008\_046)
4. The HREC shall establish mechanisms to ensure the appropriate scientific review of research applications by, for example, convening a scientific review sub-committee or by the establishment of a pool of expert reviewers.

\* Human research includes research involving pharmaceuticals, medical devices, medical radiation and imaging, surgical procedures, biological samples, medical records as well as epidemiological, social and psychological investigations.

## **STATUS OF THE HREC WITHIN THE AREA HEALTH SERVICE**

- 6.1 The Human Research Ethics Committee is delegated by the Chief Executive of the SSWAHS to grant ethical approval, withhold ethical approval and withdraw ethical approval.
- 6.2 Once HREC approval is given, The Chief Executive of the SSWAHS or their delegate is responsible for granting the Area Health Service's approval for research to be conducted within its institutions giving due consideration to the advice of the HREC.

## **ACCOUNTABILITY OF THE HREC**

7. The HREC is accountable to the Chief Executive in the conduct of its business. The minutes of each HREC meeting shall be signed by the Chairperson and forwarded to the Chief Executive, following confirmation.
8. A copy of the minutes shall be forwarded to the General Manager, Concord Hospital.
9. The HREC shall provide an annual report to the Chief Executive at the end of each financial year, which will include information on membership and the number of proposals reviewed. A copy of this report shall also be forwarded to the General Manager, Concord Hospital.
10. The HREC may from time to time bring to the attention of the Chief Executive issues of significant concern.
11. The HREC will provide reports:
  - to the Australian Health Ethics Committee (AHEC) in accordance with the requirements of the National Health and Medical Research Council (NH&MRC)
  - to the NSW Privacy Commissioner in accordance with the requirements of the Health Records and Information Privacy Act 2002 (NSW).
12. The HREC Terms of Reference, Standard Operating Procedures and membership will be available upon request to the general public and will be posted on the Concord Hospital Research Office website.

## **MEMBERSHIP & MEETINGS**

### **13. Composition**

- 13.1 The composition of the HREC shall be in accordance with the National Statement and shall include at least:
  - Chairperson
  - At least two lay people, one man and one woman, who are not currently involved in medical, scientific, legal or academic work

and who have no affiliation with the hospital.

- At least one person who performs a pastoral care role in the community
  - At least one lawyer who is not engaged to advise the institution
  - At least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend
  - At least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people (eg. medical practitioner, clinical psychologist, nurse)
- 13.2 To ensure the membership will equip the HREC to address all 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.
- 13.3 No member will be appointed in more than one of the membership categories.
- 13.4 A quorum shall exist when a representative of each of the categories listed in 13.1 is present. Members may make prior submissions of written comments so that where there is less than a full attendance of the minimum membership the meeting may still proceed if the Chairperson is satisfied that “the views of those absent who belong to the minimum membership have been received and considered.”
- 13.5 The HREC shall be free to consult any person(s) considered 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. Such person(s) shall not be entitled to vote on any matter.

## **APPOINTMENT**

- 14.1 The Chief Executive shall appoint members to the HREC in consultation with the HREC and other senior institutional officers, as appropriate.
- 14.2 Prospective members may be recruited by direct approach, nomination or by advertisement. The minister of religion may be nominated by the retiring or former member in this category or by the Concord Hospital Pastoral Care service or by other means as deemed appropriate.
- 14.3 A selection committee, consisting of the Chairperson, the Executive Officer and any other interested HREC member shall interview prospective applicants, consult with the HREC members and make a recommendation to the Chief Executive.
- 14.4 Appointments will allow for continuity and the development of expertise within the HREC.

## **TERMS OF APPOINTMENT**

- 15.1 Membership is reviewed every third calendar year, regardless of the fraction of the term already served by each member.
- 15.2 Reappointment is by application to the Chairperson of the HREC who will then make a recommendation to the Chief Executive.
- 15.3 Unless there are exceptional circumstances, membership will lapse if a member fails without reasonable excuse or without notifying the Chairperson to attend three consecutive meetings of the HREC. The Chairperson will notify the member in writing of such lapse of membership. Steps shall then be taken to fill the vacancy of the lapsed member.
- 15.4 A member may resign from the HREC at any time upon giving notice in writing to the Chairperson. Steps shall be taken to fill the vacancy of the former member.
- 15.5 The Chief Executive may terminate the appointment of any member of the HREC if the Chief Executive is of the opinion that:
  - it is necessary for the proper and effective functioning of the HREC;
  - the person is not a fit and proper person to serve on an HREC;
  - the person has failed to carry out their duties as an HREC member.
- 15.6 Members will 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 HREC member, HREC meeting attendance responsibilities and general responsibilities as a HREC member.

## **CONDITIONS OF APPOINTMENT**

- 16.1 Members must agree to their name and profession being made available to the public, including being published on the Concord Hospital Research Office website.
- 16.2 Members are not offered remuneration. However, reimbursement for legitimate transport expenses incurred in attending HREC meetings (eg taxi vouchers) will be considered after discussion with the Chairman.
- 16.3 Members will be required to sign a statement undertaking:
  - that all matters of which he/she becomes aware during the course of his/her work on the HREC will be kept confidential;
  - that any conflicts of interest, which exist or may arise during his/her tenure on the HREC will be declared; and
  - that he/she has not been subject to any criminal conviction or disciplinary action which may prejudice his/her standing as a HREC member.

## **EDUCATION FOR HREC MEMBERS**

- 17.1 Potential new members will be given the opportunity to attend HREC meetings as observers.
- 17.2 Newly appointed members shall be provided with adequate orientation.
- 17.3 Throughout their tenure, members shall be given the opportunity to attend conferences and workshops relevant to the work and responsibilities of the HREC, at the expense of the Health Service, where possible.

## **SUB-COMMITTEES**

- 18.1 The HREC 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 minimal risk research submitted to the HREC. The Chair of any such sub-committee will be appointed by the Chief Executive. Members of the sub-committee need not be members of the HREC. Minutes of the Scientific Sub-Committee and the Expedited Ethics Review Panel shall be tabled for comment at the next HREC meeting.

## **LIABILITY COVERAGE**

- 19.1 The Health Service provides indemnity for members of the HREC for any liabilities that arise as a result of the member exercising his or her duties as a member in good faith. Details of the indemnity are provided in the member's letter of appointment. Such indemnity is provided through the NSW Treasury Managed Fund.

## **MEETINGS**

- 20.1 The HREC shall meet at monthly intervals although no meeting will be held in January.
- 20.2 Meeting dates and agenda closing dates will be published on the Research Office website:  
<http://www.sswahs.nsw.gov.au/concord/Ethics/default.htm>
- 20.3 Minutes of the meeting shall be taken by the Executive Officer. A copy of the minutes is to be distributed to all committee members prior to the next meeting. A clean copy of the minutes is to be signed by the chairperson and filed as a true record of that meeting. A copy of the minutes shall be forwarded to the Chief Executive, Sydney South West Area Health Service and the General Manager, Concord Hospital.
- 20.4 Any member of the HREC who has any interest, financial or otherwise, in a proposal or other related matter(s) considered by the HREC, should as soon as practicable declare such interest. If the member is present at a meeting at which the project is the subject of consideration, the member will be asked to withdraw from the meeting until the HREC's consideration of the

relevant matter has been completed. The member will not participate in discussions. If the Chairperson has a potential conflict of interest as described above, the Deputy Chairperson will take over the conduct of the meeting for the proposal in question. All declarations of interest will be minuted.

- 20.5 The HREC will endeavour to reach a decision concerning the ethical acceptability of a proposal by unanimous agreement. Members present will be allowed reasonable opportunity to express relevant views on matters on the agenda. Where a unanimous decision cannot be reached the decision will be considered to have been carried by a majority of two-thirds of members provided that the majority includes at least one lay member. Any significant minority view will be noted in the minutes.
- 20.6 To encourage free and open discussion and to emphasise the collegiate character of the HREC particular views will not be attributed to particular individuals in the minutes except where a member wishes to have their opinion or objection recorded.

## **CONDUCT OF BUSINESS**

### **21. Procedures**

- 21.1 The HREC will perform its functions according to written standard operating procedures. These procedures shall be reviewed at least every two years and amended and updated as necessary. All HREC members shall have access to and/or be provided with copies of the procedures and shall be consulted with regard to any proposed changes.

### **22. Submissions, notifications and approvals**

- 22.1 All applications for ethical approval must be submitted to the Executive Officer of the HREC, by the relevant closing date, in writing in the format approved by the HREC and shall include such documentation as the HREC may specify.
- 22.2 Guidelines are available to assist applicants in their preparation of applications at <http://www.sswahs.nsw.gov.au/concord/Ethics/default.htm>
- 22.3 The HREC may request the applicant to supply any further information in relation to an application and/or request the applicant to attend a meeting of the HREC at which the application will be considered for the purpose of providing information to and answering questions from the HREC members.
- 22.4 The HREC 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. The Executive Officer shall circulate the completed application and associated documents received with a meeting agenda to all members of the HREC at least 7 days prior to the next meeting.

- 22.5 The HREC may delegate consideration of certain scientific/technical matters to an HREC member or sub-committee of members. The HREC may also obtain expert scientific/technical advice, subject to paragraph 13.5.
- 22.6 The HREC will take into account the views or opinions of another HREC in relation to a research protocol.
- 22.7 The HREC will promptly notify the applicant in writing, advising whether the application, which it has considered, requires amendment or clarification or has received ethical approval and any conditions of that approval.

## **EXPEDITED REVIEW**

- 23.1 The HREC may establish and convene an Expedited Ethical Review Panel which will meet as required to review:
- Minimal risk proposals
  - Other matters referred by the Chairman of the HREC.
- 23.2 The proceedings of the Expedited Ethical Review Panel (EERP) will be tabled at the next full HREC meeting.
- 23.3 Membership of the EERP shall be open to anyone on the HREC who wishes to attend. The minimum membership shall comprise the Chairperson or Deputy Chairperson of the Ethics Committee, at least one clinician and the Executive Officer of the HREC or their delegate.

## **MULTI-CENTRE RESEARCH**

- 24.1 To facilitate multi-centre research the HREC may:
- communicate with any other HREC;
  - accept a scientific/technical and/or ethical assessment of the research by another Human Research Ethics Committee.
- 24.2 The HREC will comply with the NSW Model for Single Ethical and Scientific Review of Multi-Centre Research (PD2007\_072)

## **ADVOCATES AND INTERPRETERS**

- 25.1 The HREC will consider whether an advocate for any participant or group of participants should be invited to the HREC meeting to ensure informed decision-making.
- 25.2 Where research involves the participation of persons unfamiliar with the English language, the HREC will ensure that the researcher has put in place arrangements for an interpreter to be present during the discussion on the project, unless alternative arrangements are available (and approved by the HREC).

## **FEES**

- 26.1 A fee will be charged for applications submitted for assessment by the HREC in the case of commercially-sponsored research. These fees will comply with the NSW Health Fee Policy for Review of Commercially Sponsored Research (PD2008\_030)

## **RECORDS**

- 27.1 The Executive Officer, or delegate, will prepare and maintain written records of the HREC's activities including agendas and minutes of all meetings of the Human Research Ethics Committee and the Expedited Ethical Review Panel.
- 27.2 The Executive Officer, or delegate, 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 HREC.
- 27.3 Files shall be kept securely and confidentially in accordance with the requirements of Health Records and Information Privacy Act 2002.
- 27.4 Records shall be held for sufficient time to allow for future reference. Retention periods will comply with NSW State Records Act 1998 as outlined in the State Records New South Wales General Retention and Disposal Authority – Public Health Services: Administrative Records (GDA21). The minimum period for retention is at least 5 years from the date of completion of a project or of the last publication but for specific types of research, such as clinical research, 15 years shall apply.
- 27.5 The HREC will maintain a register of all the applications received and reviewed in accordance with the National Statement.

## **POST APPROVAL RESPONSIBILITIES**

28. The HREC will monitor approved projects in terms of compliance with the HREC's ethical approval. In doing so, the HREC may request and discuss information on any relevant aspects of the project with the investigators at any time. In particular, the HREC will require applicants to provide an annual report and a final report at completion of the study.
29. The HREC will, as a condition of approval of each project, require that investigators immediately report anything which might warrant review of ethical approval of the project including:
- proposed changes in the research protocol or conduct;
  - unforeseen events that might affect continued ethical acceptability of the project;
  - serious or unexpected adverse events; and
  - if the project is abandoned for any reason.

30. The HREC may adopt any additional appropriate mechanism for monitoring, as deemed necessary.

## **COMPLAINTS AND REVIEW**

### **31. Complaints concerning the conduct of a project**

- 31.1 Any concern or complaint about the conduct of a project should be directed to the attention of the HREC Executive Officer, who shall notify the Chairperson as soon as possible. The Chairperson of the HREC will instigate an investigation of the complaint and make a recommendation on the appropriate course of action. The complainant will receive a written response, if appropriate, from the HREC. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the Chief Executive or his/her nominee, or request the Chairperson to do so.

### **32. Complaints concerning the HREC's review process**

- 32.1 Any concern or complaint about the HREC's review process should be directed to the attention of the Chairperson of the HREC, detailing it in writing. Complaints may also be made to the Chief Executive. The Chairperson may at his/her discretion notify the Chief Executive of any complaints received by him/her. The Chief Executive will inform the Chairperson of any complaints received by him/her as soon as possible.

The Chairperson will instigate an investigation of the complaint and its validity and make a recommendation to the HREC on the appropriate course of action. The complainant will receive a written response, if appropriate, from the HREC. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the Chief Executive or his/her nominee or request the Chairperson to do so. The Chairperson will provide to the Chief Executive all relevant information about the complaint/concern. The Chief Executive will determine whether there is to be a further investigation of the complaint. If it is decided there is to be a further investigation, then the Chief Executive will convene a suitable panel to review the complaint and ensure that both the complainant and the HREC are afforded the opportunity to make submissions.

- 32.2 In conducting its review, the panel shall be concerned with ascertaining whether the HREC acted in accordance with the National Statement, its Terms of Reference and its Standard Operating Procedures.

### **33. Appeals against unfavourable decisions**

- 33.1 A person with a complaint about the HREC's rejection of their application should bring the complaint to the attention of the Chairperson of the HREC detailing the grounds of the complaint. Complaints may also be made to the Chief Executive. The Chairperson may at his/her discretion notify the Chief Executive of the complaint. The Chief Executive will notify the Chairperson of any complaints received by him/her as soon as possible.

The Chairperson will instigate an investigation of the complaint and its validity and make a recommendation to the HREC on the appropriate course of action. The complainant will receive a written response, if appropriate, from the HREC. If the complainant is not satisfied with the action taken by the HREC, then he/she can refer the complaint to the Chief Executive or his/her nominee or request the Chairperson to do so. The Chairperson will provide to the Chief Executive all relevant information about the complaint. The Chief Executive will determine whether there is to be a further investigation of the complaint. If it is decided that there is a case to be investigated, then the Chief Executive will convene a suitable panel to review the complaint and ensure that both the complainant and the HREC are afforded the opportunity to make submissions.

The outcomes of this process may include:

- The complaint/concern is dismissed.
- The complaint/concern is referred back to the HREC for consideration, bearing in mind the findings of the panel.

Should the HREC be requested to review its decision, then the outcome of this review by the HREC will be final. In accordance with point 6.2, the panel or Chief Executive cannot substitute its approval for the approval of the HREC.

## **AMENDMENT TO THE TERMS OF REFERENCE**

34. These Terms of Reference will be reviewed every three years and may be amended by following the procedure below:

For proposed amendments to the Terms of Reference made by a HREC member:

- The proposal must be in writing and circulated to all HREC members for their consideration.
- The views of the members should be discussed at the next scheduled meeting of the HREC, and a vote taken at that meeting. Any member unable to attend such a meeting may register his or her views in writing.
- The proposal shall be ratified if two thirds of the members agree to the amendment.
- The Chairperson shall send the amendment to the Chief Executive for review and approval if appropriate.

For proposed amendments to the Terms of Reference made by the Chief Executive:

- The Chief Executive will send the proposal to the HREC and seek the views of any relevant person.