

# **NORTH COAST NEW SOUTH WALES HUMAN RESEARCH ETHICS COMMITTEE**

Northern NSW Local Health District and  
Mid North Coast Local Health District

## **TERMS of REFERENCE**

**Dated 15 September 2022 (next review: September 2025)**

### **1. OBJECTIVES**

The objectives of the North Coast New South Wales Human Research Ethics Committee (the HREC) are to:

- 1.1 Protect the mental and physical welfare, rights, dignity and safety of participants of research;
- 1.2 Promote ethical principles in human research;
- 1.3 Review research in accordance with the *National Statement on Ethical Conduct in Human Research* (2007) (the National Statement); and
- 1.4 Facilitate ethical research through efficient and effective review processes.

### **2. FUNCTIONS**

The HREC functions on behalf of the Northern New South Wales (NNSW) and Mid North Coast (MNC) Local Health Districts (LHDs) to:

- 2.1 Provide independent oversight of human research projects;
- 2.2 Provide competent, timely review and monitoring of human research projects in respect of their ethical and scientific acceptability for as long as projects are active;
- 2.3 Determine the compliance of a human research project with the National Statement and grant, withhold or withdraw ethical approval; and
- 2.4 Provide advice to the NNSW and MNC LHDs on strategies to promote awareness of the ethical conduct of human research.

### **3. ACCOUNTABILITY**

- 3.1 The HREC is directly accountable to the Chief Executives of the NNSW and MNC LHDs.
- 3.2 The HREC provides an annual report to the Chief Executives or delegate of the NNSW and MNC LHDs at the end of each calendar year.
- 3.3 The HREC brings to the attention of the Chief Executives or delegate of NNSW and MNC LHDs issues of significant concern.
- 3.4 The HREC provides the following reports on behalf of the NNSW and MNC LHDs:
  - Annual Report to the National Health and Medical Research Council (NHMRC); and
  - NSW Privacy Commissioner Report in accordance with the requirements of the *Health Records and Information Privacy Act 2002* (NSW).
- 3.5 Monitoring Measures: The HREC will undertake its review in a timely and efficient manner and have mechanisms to monitor and evaluate its performance.

### **4. SCOPE OF RESPONSIBILITY**

The responsibilities of the HREC are to:

- 4.1 Review human research applications where the research takes place at:
  - Any institutions governed by NNSW and/or MNC LHDs for single-centre studies; and/or
  - By the following external institutions/organisations and researchers within the geographical boundaries of NNSW and/or MNC LHDs as approved by the HREC Chairperson/s including:
    - North Coast Primary Health Network;
    - Aboriginal Community Controlled Health Services;
    - Unaffiliated researchers, including health service providers and students wishing to conduct research involving humans.

## The HREC Executive Committee

4.2 The HREC may have an Executive Committee comprised of the following positions:

- Director of Research, NNSWLHD
- Director of Research & Knowledge Translation, MNCLHD
- Research Governance Officer, MNCLHD
- Research Ethics and Governance Officer, NNSWLHD (Executive Officer to the NCNSW HREC)
- NCNSW HREC Chairperson or Delegate.

The Executive Committee will not have a Chairperson per se but rather a meeting Facilitator.

An Executive Committee meeting can proceed where there is less than a full attendance of the minimum membership if the Facilitator is satisfied “that the views of those absent who belong to the minimum membership have been received and considered”, for instance through prior submission of written comments.

A quorum is required at each meeting for the Executive Committee to meet a final decision on any agenda item. The quorum is the Executive Officer for the HREC and the NCNSW HREC Chairperson or Delegate attending in person, by telephone or videoconference.

4.3 The HREC Executive Committee undertakes expedited review of business that does not require full HREC review, including some or all of the following:

- Low and negligible risk research applications;
- Amendments to current HREC approved research projects;
- Responses to HREC queries, as approved by the full HREC for HREC Executive Committee review and approval;
- Annual progress reports and final reports; and
- Serious adverse events and suspected unexpected serious adverse reactions reports.

4.4 The minutes of the HREC Executive Committee are noted at the next HREC meeting.

## The HREC subcommittee/s

4.5 The HREC may establish subcommittees to carry out a scientific or technical review of applications. Members of the subcommittee need not be members of the HREC, and are appointed by the subcommittee Chairperson.

## 5. ORGANISATIONAL CONTEXT

### Reporting lines within the NNSW and MNC LHDs

5.1 The HREC provides an annual report to the Chief Executives or delegates of NNSW and MNC LHDs at the end of each calendar year.

- 5.2 The HREC brings to the attention of the Chief Executives or delegates of NNSW and MNC LHDs issues of significant concern.
- 5.3 The HREC provides annual reports on behalf of the NNSW and MNC LHDs to the Australian Health Ethics Committee (AHEC), in accordance with the requirements of the National Health and Medical Research Council (NHMRC);

## 6. MEMBERSHIP

### 6.1 Composition

6.1.1 The composition of the HREC is in accordance with the National Statement. Minimum membership comprises eight members. As far as possible, men and women are represented in equal numbers and at least one third of the members are external to NNSW and MNC LHDs. The membership comprises representatives from the following categories:

- A Chairperson with suitable experience whose other responsibilities will not impair the HREC capacity to carry out its obligations under the National Statement;
- At least two members who are lay people, one man and one woman, with no affiliation with the NNSW or MNC LHDs and not currently involved in medical, scientific, legal or academic work;
- At least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people;
- At least one member who performs a pastoral care role in the community, for example, an Aboriginal elder or a minister of religion;
- At least one member who is a lawyer, where possible one who is not engaged to advise the NNSW or MNC LHDs; and
- At least two members with knowledge of and current research experience that is relevant to the applications to be considered at the meetings they attend.

6.1.2 To ensure the HREC is equipped to address all of the relevant considerations arising from the categories of research, some or all of the above membership categories may be represented by more than one person.

6.1.3 No member is appointed in more than one of the membership categories. The HREC may establish a pool of inducted members in each membership class who attend meetings as needed to meet the HREC requirements and are available to provide expertise for the research under review.

6.1.4 The HREC is free to consult person(s) considered by the HREC to be qualified to advise and assist in reviewing applications provided there is no conflict of interest and an undertaking of confidentiality is given. Such person(s) are not entitled to vote

on any matter.

## 6.2 Appointment

- 6.2.1 HREC members are recruited by direct approach, nomination or by advertisement through an open and transparent process.
- 6.2.2 Prospective members may be invited to observe a meeting of the HREC.
- 6.2.3 Prospective members are asked to provide a copy of their curriculum vitae to the Chairperson, Executive Officer and at least one other HREC member (the Selection Panel). The Selection Panel may consult prospective members and existing HREC members as deemed appropriate, before making a recommendation on new appointments to the Chief Executive NNSW LHD or delegate.
- 6.2.4 Members are appointed as individuals for their knowledge, qualities and experience and not as representatives of any organisation, group or opinion.
- 6.2.5 Membership of the HREC is made publicly available.
- 6.2.6 All members including the Chairperson, Deputy Chairperson and Chairperson of any subcommittee are appointed by the Chief Executive NNSW LHD or delegate. The letter of appointment includes the date of appointment, length of tenure, indemnity and termination.
- 6.2.7 Members are not offered remuneration. However, members will be reimbursed for legitimate expenses incurred in attending the HREC meetings or in otherwise carrying out the business of the HREC;  
OR  
Eligible members (such as lay members or non-affiliated members) of the HREC may be offered an honorarium for attending each meeting. The value of the honorarium will be determined by the institutional policy.
- 6.2.8 Upon appointment, members are provided with an orientation package and asked to sign an undertaking that:
- all matters considered or discussed during the course of their membership will be kept confidential;
  - any conflicts of interest, which exist or that may arise during their membership will be declared; and
  - they have not been subject to any criminal conviction or disciplinary action, which may prejudice their standing as a member.

- 6.2.9 Members are appointed for a period of 3 years and may serve a total of 6 years (two consecutive terms), unless otherwise approved by the Chief Executive, NNSW LHD or delegate. The Chief Executive, NNSW LHD or delegate, in consultation with the Chairperson, may implement a probationary period.
- 6.2.10 The Chairperson, Deputy Chairperson and Chairperson of any subcommittee may serve longer terms with the approval of the Chief Executive, NNSW LHD or delegate. The Executive Officer for the HREC will advise members when their term has expired. Reappointment will be by application to the Chairperson who then makes a recommendation to the Chief Executive, NNSW LHD or delegate.
- 6.2.11 The NNSW and MNC LHDs will review membership at least every three years. New and renewed appointments allow for continuity, development of expertise within the HREC, and regular input of fresh ideas and approaches.
- 6.2.12 All members sign a conflict of interest declaration, which will be retained by the Executive Officer for the HREC.
- 6.2.13 Membership lapses if a member fails to attend:
- Three consecutive meetings without reasonable excuse/apology or exceptional circumstances; and
  - At least two thirds of all scheduled HREC meetings in each year, barring exceptional circumstances.
- 6.2.14 The Chairperson notifies the member of a lapse of membership in writing. Steps are taken to fill the vacancy.
- 6.2.15 Members seeking to resign or take a leave of absence for an extended period from the HREC are asked to give notice to the Chairperson. Steps are taken to fill the vacancy.
- 6.2.16 The appointment of any member of the HREC may be terminated if the Chief Executive, NNSW LHD or delegate 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; or
  - The person has failed to carry out their duties as an HREC member.
- 6.2.17 Members are expected to participate in relevant specialised

working groups as required.

6.2.18 The Chairperson is expected to be available between meetings to participate in HREC Executive Committee meetings where required.

6.2.19 The NNSW and MNC LHDs provide indemnity for members of the HREC for liabilities that arise as a result of the member exercising their duties in good faith. Such indemnity is provided through the NSW Treasury Managed Fund.

### 6.3 Orientation and training for the HREC members

6.3.1 New members are provided with orientation/training as determined to be appropriate by the NNSW and MNC LHDs.

6.3.2 Orientation may involve the following:

- Introduction to other members prior to the HREC meeting;
- Provision of an orientation package;
- Informal meeting with the Chairperson and Executive Officer for the HREC to explain member responsibilities, the HREC processes and procedures;
- Partnering with another HREC member in the same category; and
- Priority to participate in training sessions.

6.3.3 Each member is:

- Expected to become familiar with the National Statement and consult other guidelines relevant to the review of specific research applications; and
- Encouraged to attend continuing education or professional development activities in research ethics at least once in each period of appointment.

## 7. CONDUCT OF BUSINESS

### 7.1 Procedures

7.1.1 The HREC conducts its business in accordance with the Terms of Reference, Operations Manual and/or Standard Operating Procedures.

7.1.2 The HREC Terms of Reference and Operations Manual and/or Standard Operating Procedures are made publicly available.

### 7.2 Meetings

7.2.1 The HREC or Executive Committee meets on a regular basis at least every 6 weeks. The HREC holds at least 8 scheduled meetings in each year for the purposes of reviewing new applications.

7.2.2 Meeting dates and application closing dates are made publicly available.

7.2.3 A quorum is required at each meeting for the HREC to reach a final decision on any agenda item. The quorum is at least one member from each category (see: the National Statement NS.5.2.28) attending in person, by telephone or videoconference.

7.2.4 A meeting of the HREC can proceed where there is less than a full attendance of the minimum membership if the Chairperson is satisfied “that the views of those absent who belong to the minimum membership have been received and considered”, for instance through prior submission of written comments (see: the National Statement NS 5.2.30).

### 7.3 Declaration of interest

7.3.1 An HREC member declares to the HREC any actual or perceived conflicts of interest they have in relation to an application for ethical and scientific review or any other matter for consideration at the meeting. Conflicts of interest may include those pertaining to financial interests, personal, professional or institutional benefits or advantages that depend significantly on the research outcomes.

7.3.2 The minutes record the declaration of interest and the responsive action taken to appropriately manage the actual or perceived conflict.

### 7.4 Confidentiality

7.4.1 HREC meetings are held in private. The agenda and minutes of meetings, applications, supporting documentation and correspondences are all treated confidentially.



7.5 Decision making

- 7.5.1 The HREC endeavours to reach a decision concerning the ethical and scientific acceptability of an application by unanimous agreement.
- 7.5.2 Where a unanimous decision is not reached, the Chairperson will facilitate the expression of opinion from all members, identify points of agreement and of disagreement to determine when a sufficient degree of general agreement has been reached.
- 7.5.3 Any significant minority view (i.e. 2 or more members) is noted in the minutes.

7.6 Records

- 7.6.1 Written records of all meetings of the HREC are maintained (including agendas and minutes).
- 7.6.2 Files are kept securely and confidentially in accordance with the *State Records Act 1998* (NSW).
- 7.6.3 The HREC maintains a register of all research applications received and reviewed in accordance with the National Statement (see: NS 5.2.24).

7.7 Monitoring research projects

- 7.7.1 The HREC monitors approved research projects to ensure compliance with the conditions of approval and to protect the rights, safety and welfare of participants. This includes review of annual progress reports and final reports, safety reports and reports of protocol violations.
- 7.7.2 The HREC has the discretion to adopt other appropriate mechanisms for monitoring depending on the complexity, design and risk perceived, including:
  - Discussion of relevant aspects of the project with investigators, at any time;
  - Random inspection of research sites, data, or consent documentation;
  - Interview with research participants or other forms of feedback from them; and
  - Request and review reports from independent agencies such as a Data and Safety Monitoring Board.
- 7.7.3 The HREC also has the discretion to recommend in the letter of approval that the site co-ordinates onsite monitoring at recommended intervals or randomly throughout the project.

## 8. APPEALS AND COMPLAINTS

### 8.1 Appeals regarding HREC rejection

8.1.1 Where the HREC has rejected an application, the investigator has the discretion to:

- Submit a new application to the same HREC, taking due account of the HREC's concerns; or
- Lodge an appeal with the HREC Chairperson specifying the grounds of the appeal in writing.

### 8.2 Appeals regarding HREC approval

8.2.1 Where the HREC has given a favourable decision on an application and

- An ethical or scientific issue is subsequently identified by any party; or
- It has become apparent that the decision was based on inconsistent application of policy and guidelines,

a written appeal is lodged with the Chairperson in the first instance.

### 8.3 Appeals to the Chief Executive

8.3.1 If the appellant considers that the HREC has failed to follow due process after making an appeal in line with 8.1 and 8.2 and remains unsatisfied with the outcome, they have the discretion to lodge an appeal with the Chief Executive or delegate of the relevant NSW or MNC LHD or request that the Chairperson do so.

### 8.4 Complaints about the conduct of HREC members

8.4.1 Complaints about the conduct of an HREC member are managed by the Chief Executive, NSW LHD or delegate who informs the Chairperson of the complaint.

### 8.5 Complaints about the conduct of an approved research project.

8.5.1 Complaints about the conduct of an authorised research project, including allegations of research misconduct, are managed in accordance with the NSW or MNC LHD complaint handling procedures.

**9. REVIEW / AMENDMENTS OF THE TERMS OF REFERENCE**

- 9.1 The HREC Terms of Reference will be reviewed every three years and may be amended in consultation with the HREC.

**10. TERMINATION OF HREC RESPONSIBILITY**

- 10.1 Where the HREC is to be merged, closed or has ceased to function, the NNSW and MNC LHDs notify the NHMRC. The NHMRC determines the appropriate course of action, such as the status of the HREC registration with the NHMRC, and the monitoring of the previously approved research. The NNSW and MNC LHDs also notify the NSW Ministry of Health.