

Hunter New England Human Research Ethics Committee

TERMS of REFERENCE

1. OBJECTIVES

The objectives of the Hunter New England Human Research Ethics Committee (HNEHREC) are to:

- 1.1 Ensure all applications to conduct human research project submitted for review meet the requirements of the latest version of the *National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)* and associated guidance;
- 1.2 Protect the mental and physical welfare, rights, dignity and safety of participants of research;
- 1.3 Promote ethical principles in human research; and
- 1.4 Facilitate ethical research through efficient and effective review processes.

2. FUNCTIONS

The HNEHREC functions on behalf of the Hunter New England Local Health District (HNELHD) are to:

- 2.1 Review applications to conduct human research to ensure compliance with the National Statement, and grant, withhold or withdraw ethical approval;
- 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 Provide advice to the HNELHD Executive on strategies to promote awareness of the ethical conduct of human research;
- 2.4 HNEHREC Executive Committee
 - 2.4.1 The HNEHREC has an Executive Committee comprising at least the HREC Chairperson, or their delegate, and a member of the research office, usually the HREC Executive Officer.
 - 2.4.2 Any member of the HNEHREC or CTSC may be invited to participate in a meeting of the Executive Committee.

- 2.4.3 The HNEHREC Executive Committee is delegated to undertake expedited review and approval of business that does not require full HREC review, including some or all of the following:
- Amendments to current HREC approved research projects;
 - Responses to HREC queries, as approved by the full HREC for HREC Executive Committee review and approval;
 - Review of Annual progress reports and final reports; and
 - Other Business of the HNEHREC.
- 2.4.4 The HREC or the HREC Chair may delegate any of these tasks to the Executive Officer.
- 2.4.5 All decisions of the HREC Executive Committee are recorded in the Agenda for the next HNEHREC meeting and are ratified when the minutes of that meeting are endorsed at a future meeting of the HNEHREC.

2.5 HNEHREC Clinical Trials Sub-Committee

- 2.5.1 The Clinical Trials Sub-Committee (CTSC) is appointed to advise the HNEHREC about the scientific validity and safety issues of submissions for clinical research.
- 2.5.2 The CTSC has its own Terms of Reference.
- 2.5.3 Members of the CTSC are standing members of the HNEHREC and may but are not required to attend meetings of the HNEHREC.

3. ACCOUNTABILITY

- 3.1 The HNEHREC is directly accountable to the Chief Executive of the HNELHD through the Executive Director of Partnerships, Innovation and Research in the conduct of its business.
- 3.2 The HNEHREC provides an annual report to the Chief Executive or delegate at the end of each calendar year.
- 3.3 The HNEHREC brings to the attention of the Chief Executive or delegate issues of significant concern.
- 3.4 HNEHREC provides the following reports on behalf of the HNELHD:
- 3.4.1 Annual Report to the National Health and Medical Research Council (NHMRC); and
- 3.4.2 NSW Privacy Commissioner Report in accordance with the requirements of the *Health Records and Information Privacy Act 2002 (NSW)*.

- 3.5 The HNEHREC will undertake its review of applications in a timely and efficient manner in line with the metrics program detailed in the NSW Health Chief Executive's Service Agreement and any other agreed Key Performance Indicators.

4. SCOPE OF RESPONSIBILITY

The responsibilities of the HNEHREC are to:

- 4.1 Review human research applications where the research involving human participants, biological samples or data that takes place at:
 - 4.1.1 Any institutions governed by Hunter New England Local Health District;
 - 4.1.2 Applications from any Public Health Organisations in New South Wales, ACT, Victoria, Queensland, South Australia and Western Australia within the scope of a scheme of mutual acceptance of ethical and scientific review entered into by NSW Ministry of Health; and/or
 - 4.1.3 External institutions/organisations and investigators as approved by the Chief Executive, in accordance with NSW Health Policy directive PD 2008_046.
- 4.2 The HNEHREC will review submissions in accordance with their risk category:
 - 4.2.1 Projects considered Greater than Low Risk in accordance with sections 5.1.24 and 5.1.25 of the National Statement, and will be reviewed at a full meeting of the HNEHREC; and
 - 4.2.2 Projects considered Low Risk in accordance with section 5.1.18 - 5.1.21 of the National Statement, and will be reviewed under the expedited review process. An exception will be projects with a waiver of consent is sought in accordance with section 2.3.10 of the *National Statement*, where full HREC review is required.
- 4.3 Those projects deemed to be negligible risk projects are exempt from HREC review, in accordance with section 5.1.22 and the 5.1.23 of the *National Statement*. The HNEHREC delegate review of these projects to the HREC Executive Officer, who will provide the exemptions to the researchers.

5. MEMBERSHIP

- 5.1 The composition of the HNEHREC is in accordance with section 5.1.30 of 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 the institution.

- 5.2 The membership comprises representatives from the following categories:
 - 5.2.1 A Chairperson with suitable experience whose other responsibilities will not impair the HREC capacity to carry out its obligations under the *National Statement*;
 - 5.2.2 At least two lay people, one man and one woman, with no affiliation with the institution or organisation and not currently involved in medical, scientific, legal or academic work;
 - 5.2.3 At least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people;
 - 5.2.4 At least one member who performs a pastoral care role in the community, for example, an Aboriginal elder or a minister of religion;
 - 5.2.5 At least one member who is a lawyer, where possible, one who is not engaged to advise the institution for which the HREC is reviewing research; and
 - 5.2.6 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.
- 5.3 In addition, in accordance with the HNELHD's commitment to local communities in Closing the Gap, an Aboriginal Health Worker based in the LHD or Community Member with familiarity with research and the requirements for conducting research with the Aboriginal communities will be included amongst the membership of the HNEHREC. This will not mitigate the requirement for researchers to obtain approval from the Aboriginal Health and Medical Research Council's Human Research Ethics Committee for all research targeting Aboriginal and/or Torres Strait Islander Peoples as participants.
- 5.4 To ensure the HNEHREC 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.
- 5.5 No member is appointed in more than one of the membership categories.

- 5.6 The HNEHREC is free to consult person(s) considered by the HREC to be qualified to advise and assist in reviewing applications provided that there is no conflict of interest and an undertaking of confidentiality is given. Such person(s) are not entitled to vote on any matter.
- 5.7 Appointment of New Members
- 5.7.1 HREC members are recruited by direct approach, nomination or by advertisement calling for Expressions of Interest through an open and transparent process.
- 5.7.2 Prospective members will meet with the Executive Officer for Orientation.
- 5.7.3 Prospective members will be required to attend a meeting of the HNEREC as an observer, and after doing so, confirm their willingness to join the HNEHREC.
- 5.7.4 Prospective members are asked to provide a copy of their curriculum vitae which will accompany a recommendation for appointment from the HNEHREC to the Chief Executive or their delegate.
- 5.7.5 All members including the Chairperson, Deputy Chairperson and Chairperson of any subcommittees of the HNEHREC are appointed by the Chief Executive or their delegate. The letter of appointment includes the date of appointment, length of tenure, indemnity and termination.
- 5.7.6 Upon appointment, members are asked 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.
- 5.7.7 Members are appointed for a period of up to 3 years and may serve a total of 6 years (two consecutive terms), unless otherwise approved by the Chief Executive or delegate. The Chief Executive or delegate, in consultation with the Chairperson, may implement a probationary period.
- 5.7.8 The Chairperson, Deputy Chairperson and Chairperson of any subcommittee may serve longer terms with the approval of the Chief Executive or delegate.

- 5.7.9 Members are advised when their term is due to expire and may be invited to consider reappointment. A recommendation will be made to the Chief Executive or delegate for those members who wish to be reappointed.
- 5.7.10 Members are appointed as individuals for their knowledge, qualities and experience and not as representatives of any organisation, group or opinion.
- 5.8 Membership of the HREC is made publicly available on the HNELHD Research Ethics and Governance website
- 5.9 Members are not offered remuneration. However, members will be reimbursed for legitimate expenses incurred in attending HNEHREC meetings or in otherwise carrying out the business of the HNEHREC.
- 5.10 The HNEHREC 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.
- 5.11 Membership lapses if a member fails to attend:
- Three consecutive meetings without reasonable excuse/apology or exceptional circumstances; or
 - At least two thirds of all scheduled HREC meetings in each year, barring exceptional circumstances.
- 5.12 Chairperson notifies the member of a lapse of membership in writing. Steps are taken to fill the vacancy.
- 5.13 Members seeking to resign or take a leave of absence for an extended period from the HNEHREC are asked to give notice to the Chairperson. Steps are taken to fill the vacancy.
- 5.14 The appointment of any member of the HNEHREC may be terminated if the Chief Executive is of the opinion that:
- It is necessary for the proper and effective functioning of the HNEHREC;
 - The person is not a fit and proper person to serve on the HNEHREC; or
 - The person has failed to carry out their duties as a HNEHREC member.
- 5.15 Members are required to review the submissions allocated to review, to submit their review in the Research Ethics and Governance Information System (REGIS) and attend the meetings to discuss those submissions. If it is not possible for a member to attend a meeting, he/she is expected to submit their review in REGIS.

- 5.16 Members are required to review low and negligible risk applications as per the HNEHREC's agreed process for expedited review, and participate in relevant specialised working groups as required outside of the scheduled HNEHREC meetings.
- 5.17 The Chairperson or their delegate, is expected to be available between meetings to participate in HREC Executive Committee meetings where required.
- 5.18 The HNELHD 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.
- 5.19 Orientation and training for HREC members
- 5.19.1 New HNEHREC members are provided with orientation/training as determined to be appropriate by the HNELHD.
- 5.19.2 Orientation involves some or all of the following:
- Provision of an Electronic orientation package;
 - Informal meeting with the Chairperson and Executive Officer to explain their responsibilities as an HREC member, the HREC processes and procedures;
 - 'Partnering' with another HREC member in the same category; and
 - Priority given to participate in training opportunities.
- 5.20 Each member is:
- Expected to become familiar with the *National Statement* and consult other guidelines relevant to the review of specific research applications; and
 - Is encouraged to participate in online or face-to-face continuing education or professional development activities in research ethics once in each period of appointment.

6 CONDUCT OF BUSINESS

6.1 Procedures

6.1.1 The HNEHREC conducts its business in accordance with the Terms of Reference and Standard Operating Procedures.

6.1.2 The HNEHREC Terms of Reference and Operations Manual and/or Standard Operating Procedures are made publicly available on the HNELHD Research Ethics and Governance Website.

6.2 Meetings

- 6.2.1 The HNEHREC holds 11 scheduled meetings in each year for the purpose of reviewing new applications. The HNEHREC meets on a regular basis at least every 4 weeks, with the exception of January
- 6.2.2 Meeting dates and application closing dates are made publicly available on the HNELHD Research Ethics and Governance Website from October the previous year.
- 6.2.3 A quorum is required at each meeting for the HNEHREC to reach a final decision on any agenda item. The quorum for meetings is at least one member from each category (*National Statement 5.2.28*) attending in person or via telephone or videoconference.
- 6.2.4 A meeting of the HNEHREC can proceed where there is less than a full attendance of the minimum membership at a meeting but only 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 (*National Statement 5.2.30*).
- 6.2.5 If a meeting is inquorate, that is one of the core members as defined in section 5.1.30 of the National Statement is not available then the meeting will proceed but the minutes from that meeting will not be endorsed until that a person from that membership category is available at a future meeting

6.3 Declaration of Conflict of Interest

- 6.3.1 An HNEHREC member is required to declare any conflicts of interest they have in relation to an application for ethical and scientific review or any other matter for consideration at the meeting. Conflict of interest includes familial relationship with researchers submitting to the HNEHREC financial interests, personal, professional or institutional benefits or advantages that depend significantly on the research outcomes.
- 6.3.2 The minutes record declaration of conflict of interest, the decision of the HNEHREC on the procedures to be followed and, where relevant that the procedures were followed.

6.4 Confidentiality

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

6.5 Decision making

6.5.1 The HNEHREC shall make a decision about all the submissions listed for review on the agenda. If for some reason, one or more submissions are not discussed, an arrangement must be made for that application to be reviewed within a week of the meeting.

6.5.2 The HNEHREC endeavours to reach a decision concerning the ethical and scientific acceptability of an application by a unanimous agreement.

6.5.3 Where a unanimous decision is not reached, the Chair will need to facilitate the expression of opinion from all members, identify points of agreement and of disagreements and judge when a sufficient degree of general agreement has been reached.

6.5.4 Any significant minority view (i.e. 2 or more members) is noted in the minutes.

6.6 Records

6.6.1 Written records of all meetings of the HNEHREC are maintained (including agendas and minutes).

6.6.2 Electronic Files are kept securely and confidentially in accordance with the requirements of the State Records Act 1998.

6.6.3 The HNEHREC maintains a register of all the applications received and reviewed in accordance with the *National Statement* 5.2.24.

6.7 Monitoring research projects

6.7.1 The HNEHREC monitors approved research projects to ensure compliance with the conditions of approval and to protect the rights, safety and welfare of participants. This includes:

- Approval of any amendments to the approved protocol and other documentation prior to the implementation of that amendment;
- Review of annual progress reports and final reports;
- Safety reports and reports of protocol violations; and
- Review reports from independent agencies such as a Data and Safety Monitoring Board.

6.7.2 The HNEHREC 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; and
- Interview with research participants or other forms of feedback from them.

6.7.3 The HNEHREC also has the discretion to recommend in the letter of approval that the site co-ordinates onsite or remote monitoring at recommended intervals or randomly throughout the project.

7 APPEALS AND COMPLAINTS

7.1 Appeals regarding HNEHREC rejection

7.1.1 Where the HNEHREC has rejected an application, the investigator has the discretion to:

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

7.2 Appeals regarding HNEHREC approval

7.2.1 Where the HNEHREC 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.

7.3 Appeals to the Chief Executive

7.3.1 If the appellant considers that the HREC has failed to follow due process after making an appeal in line with 7.1 and 7.2, and remains unsatisfied with the outcome, they have the discretion to lodge an appeal with the HNELHD Chief Executive or their delegate or request that the Chairperson do so.

7.4 Complaints about the conduct of HREC members

7.4.1 Complaints about the conduct of a HREC member are managed by the Chief Executive or delegate who informs the Chairperson of the complaint.

7.5 Complaints about the conduct of an approved research project.

7.5.1 Complaints about the conduct of an authorised research project, including allegations of research misconduct, are managed in accordance with the Public Health Organisation's local complaint handling procedures.

8 REVIEW/AMENDMENTS OF THE HNEHREC TERMS OF REFERENCE

8.1 These Terms of Reference will be reviewed every three years and may be amended in consultation with the HREC.

9 TERMINATION OF HNEHREC RESPONSIBILITY

9.1 Where the HNEHREC is to be merged, closed or has ceased to function, the HNELHD notifies the NHMRC and determines the appropriate course of action, such as the status of its registration and/or status as a certified institution with the NHMRC and the monitoring of previously approved research. The HNELHD is also required to notify the NSW Ministry of Health.