

Terms of Reference: Human Research Ethics Committee



In accordance with **NSW Health GL2013_009** *Human Research Ethics Committee: Standard Operating Procedures for NSW Public Health Organisations*

Approved February 2021

1. OBJECTIVES

The objectives of 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) incorporating all updates [National Statement]*; and
- 1.4 Facilitate ethical research through efficient and effective review processes.

2. FUNCTIONS

The HREC functions on behalf of the Public Health Organisation are 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 Public Health Organisation on strategies to promote awareness of the ethical conduct of human research.

3. ACCOUNTABILITY

- 3.1 The HREC is directly accountable to the Chief Executive of the Public Health Organisation under which it is constituted.
- 3.2 The HREC provides an annual report to the Chief Executive or delegate at the end of each calendar year.
- 3.3 The HREC brings to the attention of the Chief Executive or delegate issues of significant concern.
- 3.4 The HREC provides the following reports on behalf of the Public Health Organisation:
 - Annual Report to the National Health and Medical Research Council (NHMRC);
 - NSW Privacy Commissioner Report in accordance with the requirements of the *Health Records and Information Privacy Act 2002 (NSW)*;
 - Certified Institution Annual Report to the National Health and Medical Research Council (NHMRC), and any other reports as required.
- 3.5 Monitoring Measures: The HREC will have mechanisms to monitor and evaluate its performance. This performance will be reported as appropriate to the

Members, the Research Directorate, and the Chief Executive, no less than once per calendar year.

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 NSW Public Health Organisations for multi-centre studies; and/or
- Any institutions governed by South Eastern Sydney Local Health District for single-centre studies and/or
- External institutions/organisations and investigators as approved by the Chief Executive in accordance with Policy directive PD 2008_046.
- The HREC may review applications from interstate institutions or organisations within the scope of a scheme of mutual acceptance of ethical and scientific review entered into by NSW Ministry of Health on behalf of the HREC.

HREC Executive Committee

4.2 The HREC has an Executive Committee comprising at least the HREC Chairperson or their delegate and a member of the Research Support Office.

4.3 The HREC Executive Committee undertakes 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;
- Annual progress reports and final reports; and
- Serious adverse events and suspected unexpected serious adverse reactions reports.

4.4 The feedback issued by the HREC Executive Committee is available to any HREC member to review. Upon their request, the Executive Officer will forward the member them the relevant document from the study file.

Low/Negligible Risk HREC Sub-Committee (LNR Committee)

4.5 The HREC has a LNR Committee comprising a Chairperson, at least 1 representative from the HREC, at least 1 representative from SESLHD and the HREC Executive Officer (or delegate).

4.6 The LNR committee undertakes expedited review of research applications involving no greater than low and/or negligible risk (i.e. the greatest foreseeable risk is discomfort and/or inconvenience) and for which review and approval by the HREC is not required in accordance with section 'Research involving no more

than' in the **National Statement on Ethical Conduct in Human Research 2007** (NHMRC).

- 4.7 The feedback issued by the HREC Executive Committee is available to any HREC member to review. Upon their request, the Executive Officer will forward the member them the relevant document from the study file.

HREC subcommittee

- 4.8 HREC subcommittees may be appointed 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

Please refer to Appendix 1 which outlines the reporting lines of the Research Office within the South Eastern Sydney Local Health District.

6. MEMBERSHIP

6.1 Composition

- 6.1.1. The composition of the HREC is in accordance with the *National Statement*. 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 for which the HREC is reviewing research. Minimum membership comprises eight members 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 institution or organisation 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 institution for which the HREC is reviewing research; 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. Individuals who do not meet the requirements of the membership categories but who are capable of assisting with review and decision making may be appointed as non-categorised members.
- 6.1.4. No member is appointed in more than one of the membership categories. Public Health Organisations are encouraged to 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.
- 6.1.5. The HREC 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.

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 one or more meetings of the HREC.
- 6.2.3. Prospective members are asked to provide a copy of their curriculum vitae to a selection committee comprising the Chairperson, Executive Officer and at least one other HREC member. The selection committee interviews prospective members, consults with HREC members and makes a recommendation on new appointments to the Chief Executive.
- 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. The letter of appointment includes the date of appointment, length of tenure, indemnity and termination.
- 6.2.7. Upon appointment, members are provided with an orientation package and 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.
- 6.2.8. Members are appointed for a period of up to 3 years; subsequent appointments of up to 3 years may be approved by the Chief Executive or delegate. The Chief Executive or delegate, in consultation with the Chairperson, may implement a probationary period.
- 6.2.9. The Chairperson, Deputy Chairperson and Chairperson of any subcommittee may serve longer terms with the approval of the Chief Executive or delegate. Members are advised when their term has expired. Reappointment will be by application to the Chairperson of the HREC who then makes a recommendation to the Chief Executive or delegate.
- 6.2.10. New and renewed appointments allow for continuity, development of expertise within the HREC, and regular input of fresh ideas and approaches.
- 6.2.11. Membership lapses if a member fails to attend:
- Three consecutive meetings without reasonable excuse/apology or exceptional circumstances; and either of:
 - At least two thirds of all scheduled HREC meetings in each year, barring exceptional circumstances, or
 - At least the number of meetings agreed to by prior arrangement and in consultation with the chair, where the member has from the outset declared a limited capacity to attend meetings.
- 6.2.12. The Chairperson notifies the member of a lapse of membership in writing. Steps are taken to fill the vacancy.
- 6.2.13. 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.
- 6.2.14. The appointment of any member of the HREC may be terminated 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; or
 - The person has failed to carry out their duties as an HREC member.
- 6.2.15. Members are expected to participate in relevant specialised working groups as required.
- 6.2.16. The Chairperson, Deputy Chairperson, and all Committee members are expected to be available between meetings to participate in HREC Executive Committee meetings where required.

6.2.17. The Public Health Organisation provides 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 HREC members

6.3.1. New HREC members are provided with orientation/training as determined to be appropriate by the Public Health Organisation.

6.3.2. Orientation involves some or all of the following:

- Introduction to other HREC members prior to the HREC meeting;
- Provision of a training and induction 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 to provide new member support; and
- Priority given 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
- expected to maintain a record of their completed ethics-related training activities over the course of each calendar year appropriate to their work on the Committee.

7. CONDUCT OF BUSINESS

7.1 Procedures

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

7.1.2. The HREC Standard Operating Procedures are made publicly available.

7.2 Meetings

7.2.1. The HREC 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 for meetings is at least one member from each of the core categories and the Chairperson/Deputy Chairperson as specified in the *National Statement* attending in person or via telephone or videoconference.

7.2.4. A quorum can be reached where there is less than a full attendance of the minimum membership at a meeting 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.

7.2.5. Where less than a full attendance of the minimum core membership is anticipated a quorum can be ensured by inviting members from other NHMRC accredited HRECs to attend and represent the membership category they fulfil on the other committee.

7.3 Declaration of interest

7.3.1. An HREC member declares to the HREC 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 financial interests, personal, professional or institutional benefits or advantages that depend significantly on the research outcomes and/or the decision of the HREC.

7.3.2. The minutes record declaration of interest and the decision of the HREC on the procedures to be followed.

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 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.

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 requirements of the *State Records Act 1998*.

7.6.3. The HREC maintains a register of all the applications received and reviewed in accordance with the *National Statement*.

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 of the Public Health Organisation 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 or delegate or the Research Support Office 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 Public Health Organisation's local complaint handling procedures and/or by the Research Support Office.

9. TERMINATION OF HREC RESPONSIBILITY

9.1 Where the HREC is to be merged, closed or has ceased to function, the Public Health Organisation notifies the NSW Department of Health and NHMRC and determines the appropriate course of action, such as the status of its registration and/or status as a certified institution.

10. TERMINATION OF HREC RESPONSIBILITY

10.1 Where the HREC has ceased to function, the Public Health Organisation notifies the NSW Department of Health and NHMRC and determines the appropriate course of action.

Appendix One

