



# GREATER WESTERN

## HUMAN RESEARCH ETHICS COMMITTEE

### Terms of Reference

#### 1 Objectives

The Human Research Ethics Committee (HREC) objectives are to:

- Protect the mental and physical welfare, rights, dignity and safety of participants of research;
- Promote ethical principles in human research;
- Review research in accordance with the *National Statement on Ethical Conduct in Human Research (2023)* [*National Statement*] and legislation; and
- Facilitate ethical research through efficient and effective review processes.

#### 2 Functions

The HREC functions on behalf of the Western NSW and Far West Local Health Districts to:

- Provide independent oversight of human research projects;
- 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;
- Determine the compliance of a human research project with the *National Statement* and grant, withhold or withdraw ethical approval; and
- Provide advice to the Western NSW & Far West Local Health Districts on strategies to promote awareness of the ethical conduct of human research.

#### 3 Accountability of the HREC

- The HREC is directly accountable to the Chief Executives of Western NSW & Far West Local Health Districts under which it is constituted. The minutes of each HREC meeting will be forwarded to the Chief Executives following confirmation.
- The HREC provides an annual report to the Chief Executives at the end of each calendar year.
- The HREC will bring to the attention of the Chief Executives issues of significant concern.

- The HREC will provide the following reports on behalf of the Western NSW & Far West Local Health Districts:
  - Australian Health Ethics Committee (AHEC) report in accordance with the requirements of 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)*.

## 4 Scope of responsibility

The responsibilities of the HREC are to:

- 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 Western NSW & Far West Local Health Districts for single-centre studies; and/or
  - Any institutions governed by Murrumbidgee, Illawarra Shoalhaven & Southern NSW Local Health Districts as per current service level agreements; and/or
  - Appropriate external institutions/organisations.
- The HREC has an Executive Committee comprising at least the HREC Chairperson or delegate and a member of the research office.
- The HREC Executive Committee may undertake 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 Officer review and approval;
  - Annual progress reports and final reports.
- The minutes of the HREC Executive Committee will be noted at the next HREC meeting.
- 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 Membership and composition

- The composition of the HREC will be in accordance with the *National Statement*. Minimum membership will comprise eight members. As far as possible, men and women will be represented in equal numbers and at least one third of the members will be external to the institution for which the HREC is reviewing research. The membership comprises representatives from the following category:
  - 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 bring a broader community or consumer perspective and who have no paid affiliation with the institution;
  - 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, 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 research applications to be considered at the meetings they attend.
- To ensure the HREC is equipped to address all 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.
  - No member will be 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 will be available to provide expertise for the research under review.
  - The HREC is free to consult person(s) considered by the HREC to be qualified to advise and assist in reviewing research 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 HREC appointment**

- HREC members are recruited by direct approach, nomination or by advertisement through an open and transparent process.
- Prospective members may be invited to observe a meeting of the HREC.
- Prospective members are asked to provide a copy of their curriculum vitae to the 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.
- Members are appointed as individuals for their knowledge, qualities and experience and not as representatives of any organisation, group or opinion.
- Membership of the HREC is made publicly available.
- 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.
- 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.
- Members are appointed for a period of up to 3 years, and members may be reappointed by the Chief Executive. The Chief Executive, in consultation with the Chair, may implement a probationary period.
- The Chairperson, Deputy Chairperson and Chairperson of any subcommittee may serve longer terms with the approval of the Chief Executive or delegate. Members

will be advised when their term has expired. Reappointment is by application to the Chairperson of the HREC who will then make a recommendation to the Chief Executive or delegate.

- New and renewed appointments will allow for continuity, the development of expertise within the HREC, and the regular input of fresh ideas and approaches.
- Membership will lapse 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.
- The Chairperson will notify the member of a lapse of membership in writing. Steps shall be taken to fill the vacancy.
- 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 shall be taken by the HREC to fill the temporary vacancy.
- The appointment of any member of the HREC may be terminated if the Chief Executive or their 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.
- Members are expected to participate in relevant specialised working groups as required.
- The Chairperson will be expected to be available between meetings to participate in HREC Executive Committee meetings where required.
- The Western NSW & Far West Local Health Districts 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.

## **7 Orientation and training for HREC members**

- New HREC members will be provided with orientation/training as determined by Western NSW & Far West Local Health Districts.
- Orientation will involve some or all of the following:
  - Introduction to other HREC members prior to the HREC meeting;
  - Provision of an orientation package;
  - Informal meeting with Chairperson and Executive Officer to explain their responsibilities as an HREC member, the HREC processes and procedures;
  - An opportunity to attend HREC meetings before their appointment takes effect;
  - 'Partnering' with another HREC member in the same category; and
  - Priority given to participate in training sessions.
- Each member will:
  - Become familiar with the *National Statement* and consult other guidelines relevant to the review of specific research applications; and
  - Attend continuing education or training programs in research ethics once in

each period of appointment.

## **8 Conduct of business**

### **8.1 Procedures**

- The HREC will conduct its business in accordance with the Terms of Reference and Standard Operating Procedures incorporated in the GW HREC Operations Manual.
- The GW HREC Operations Manual will be publicly available. Each HREC member will have access to the Operations Manual.

### **8.2 Submissions, notifications and approvals**

- The GW HREC will only accept research applications using REGIS.
- Applications must include additional documentation as required by the HREC. The procedures for application to the HREC and the application format will be readily available to applicants.
- The HREC will notify the applicant promptly in writing of the outcome of their ethically review application and any conditions of approval.

### **8.3 Meetings**

- The HREC will normally hold 11 scheduled meetings in each year for the purposes of reviewing new research applications. Meetings are held from 3.00 to 5.00 pm (AEST) (2.30 to 4.30 CST) on the first Wednesday of each month, except in January.
- Meetings are held by videoconference and/or teleconference at multiple sites. There will be one face-to-face meeting annually, to be held at a site within Western NSW & Far West Local Health Districts.
- Meeting dates and agenda closing dates will be made publicly available.
- The agenda for HREC meetings will be prepared by the Executive and be available to committee members seven days prior to the meeting.
- The agenda will include at least the following items:
- Agenda items will include at least the following items:
  - Apologies
  - Conflicts of interest
  - Minutes of the previous HREC and Sub-committee meeting
  - Amendments to approved protocols
  - Previously considered applications requiring a decision
  - New applications
  - Previously considered applications now approved
  - Annual/Final reports
  - Sub-committee 'Waiver of Consent' for noting
  - Other business
  - Confirmation of next sub-committee meeting
  - Close and next HREC meeting.

- The Executive Officer will prepare and maintain minutes of all meetings of the HREC. The minutes will be circulated to all members of the HREC as an agenda item for the next meeting. All members will be given the opportunity to seek amendments to the minutes prior to their ratification. The minutes will be formally ratified at the next HREC meeting.

#### **8.4 Minimum Membership**

- Where there is less than full attendance at a meeting, the Chair must be satisfied, before a decision is reached, that the minimum membership as specified by NH&MRC have received all papers and have had an opportunity to contribute their views and that these have been recorded and considered.
- The minimum membership of the Committee shall consist of least one member from each of the core categories participating by attending via videoconference / teleconference or by prior submission of written comments i.e.:
  - A Chairperson,
  - Two people who provide a broader community or consumer perspective
  - One person with knowledge of, and current experience in, the professional care, counselling or treatment of people;
  - One person who performs a pastoral care role in a community;
  - Lawyer; and
  - Two people with current research experience.

#### **8.5 Declaration of interest**

- An HREC member will declare to the HREC conflicts of interest they have in relation to a research application for ethical and scientific review or any other matter for consideration at that meeting. Conflict of interest includes financial interests, personal, professional or institutional benefits or advantages that depend significantly on the research outcomes.
- The minutes will record declarations of interest and the decision of the HREC on the procedure to be followed.

#### **8.6 Decision making**

- The HREC will endeavour to reach a decision concerning the ethical and scientific acceptability of a research application by unanimous agreement.
- Where a unanimous decision is not reached, the matter will be determined by a majority of two-thirds of members present at the meeting, provided that the majority includes at least one community representative. Both community representatives must be present or have had input into the decision.
- Any significant minority view (i.e. 2 or more members) is noted in the minutes.

#### **8.7 Records**

- Written records of all meetings of the HREC are maintained (including agendas and minutes).
- The HREC Executive Officer prepares and maintains a file for each research

application received including relevant documentation. Files will be kept securely and confidentially in accordance with the requirements of State Records Act 1998.

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

## **8.8 Monitoring research projects**

- 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 report of protocol violations.
- 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.
- The HREC also has the discretion to recommend in the letter of approval that the site coordinates onsite monitoring at recommended intervals or randomly throughout the project.
- The HREC requires that investigators immediately report any matter which might warrant review of ethical approval of the project, including:
  - Proposed changes in the research project;
  - Unforeseen events that might affect continued ethical acceptability of the research project;
  - Serious or unexpected adverse events; and
  - If the project is discontinued for any reason.

## **8.9 Confidentiality**

HREC meetings are held in private. The agenda and minutes of meetings, applications, supporting documentation and correspondences are all treated confidentially. Matters discussed at a HREC meeting will be of a confidential nature and must be treated as such by Committee members.

# **9 Appeals and Complaints**

## **9.1 Appeals regarding HREC rejection**

Where the HREC has rejected a research application, the investigator has the discretion to:

- Submit a new application to the same HREC, taking due account of the HREC's concerns. This will be processed and reviewed in the same way as any other new application; or
- Lodge an appeal with the HREC Chairperson specifying the grounds of the appeal in writing.

## **9.2 Appeals regarding HREC approval**

Where the HREC has given a favourable decision on a research 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.

## **9.3 Appeals to the Chief Executive**

If the appellant considers that the HREC has failed to follow due process after making an appeal and remains unsatisfied with the outcome, they have the discretion to lodge an appeal with the Chief Executive of Western NSW & Far West Local Health Districts or request that the Chairperson do so.

## **9.4 Complaints about the conduct of HREC members**

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

## **9.5 Complaints about the conduct of an approved research project**

Complaints about the conduct of an authorised research project, including allegations of research misconduct, will be managed in accordance with Western NSW & Far West Local Health Districts' local complaint handling procedures.

## **10 Termination of HREC Responsibility**

In the exceptional circumstances where the HREC has ceased to function, it is the responsibility of Western NSW & Far West Local Health Districts to notify the NSW Ministry of Health and NHMRC and determine the appropriate course of action.

## **11 Review Date**

The Terms of Reference must be reviewed annually by the HREC.