

HUMAN RESEARCH ETHICS COMMITTEE TERMS OF REFERENCE

1. OBJECTIVES

The objectives of the Justice Health and Forensic Mental Health Network Human Research Ethics Committee, which is to be known as the Justice Health HREC, are to:

- 1.1. protect the rights, dignity and safety of participants of research within the jurisdiction of the Justice Health and Forensic Mental Health Network (the Network)
- 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 Research – Ethical and Scientific Review of Human Research in NSW Public Health Organisations (PD2010_05)
- 1.4. facilitate ethical research through efficient and effective review processes.

2. SCOPE OF RESPONSIBILITY

The responsibilities of the Justice Health HREC are to review human research applications where the proposed research involves the health and wellbeing of people in custody in NSW, and/or patients of Network, and/ or involves Network staff, programs, services or specific populations, and/or is carried out by Network staff and affiliates. The responsibilities of the Justice Health HREC do not extend to privately operated prisons.

3. FUNCTIONS

The Justice Health HREC's functions on behalf of the Network are to:

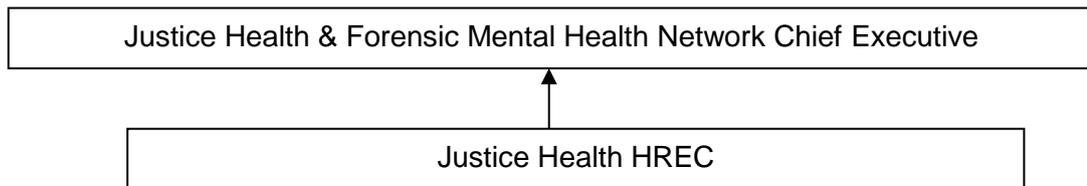
- 3.1. provide an informative and functional process for application for research approval to be made to the Network in accordance with the policies of the NSW Office of Health and Medical Research
- 3.2. determine the compliance of a research project with the *National Statement* and grant, withhold or withdraw ethical approval
- 3.3. provide oversight of relevant research projects, as long as they are active, including oversight of:
 - amendments to current HREC approved research projects
 - annual progress reports and final reports
 - serious adverse events and suspected unexpected serious adverse reactions reports
- 3.4. respond to complaints about research conducted in the Justice Health HREC scope
- 3.5. provide advice to the Network on strategies to promote awareness of the ethical conduct of research
- 3.6. provide information and guidance on the distinction between research, quality improvement, quality assurance, program evaluation and research translation.

4. ACCOUNTABILITY

The Justice Health HREC:

- 4.1. is directly accountable to the Chief Executive of the Network, and the minutes of each HREC meeting are provided to the Chief Executive or delegate following confirmation
- 4.2. provides an annual report to the Chief Executive or delegate at the end of each calendar year
- 4.3. brings to the attention of the Chief Executive or delegate issues of significant concern
- 4.4. provides the following reports on behalf of the Network:
 - an annual report to the National Health and Medical Research Council (NHMRC)
 - a report to the NSW Privacy Commissioner in accordance with the requirements of the *Health Records and Information Privacy Act 2002* (NSW)
- 4.5. undertakes reviews in a timely and efficient manner and has mechanisms to monitor and evaluate its performance, in accordance with responsibilities set out by the Office of Health and Medical Research.

5. ORGANISATIONAL CONTEXT



6. COMMITTEE COMPOSITION

- 6.1. The composition of the Justice Health HREC is in accordance with the *National Statement*. There is a minimum of eight members. As far as possible, gender diversity is to be achieved. At least one-third of the members are to be external to the Network. The membership comprises representatives from the following categories:
- a Chairperson with suitable experience whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the *National Statement*;
 - at least two members who are lay people with no affiliation with the Network 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 and/or Torres Strait Islander 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 Justice Health HREC is reviewing research; and
 - at least two members with knowledge and experience of current research that is relevant to the applications to be considered at the meetings they attend.

- 6.2. Some or all of the above membership categories may be represented by more than one person.
- 6.3. No member is appointed in more than one of the membership categories.
- 6.4. The Network is encouraged to establish a pool of inducted members in each category, who attend meetings as needed, to meet the Justice Health HREC requirements and to be available to provide expertise for the research under review.
- 6.5. The Justice Health HREC is free to consult any 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.

7. APPOINTMENT OF MEMBERS

- 7.1. Justice Health HREC members are recruited by direct approach, nomination or by advertisement through an open and transparent process.
- 7.2. Prospective members may be invited to observe a meeting of the Justice Health HREC. As observers, they will not be provided with access to documents pertaining to that meeting.
- 7.3. Prospective members are asked to provide a copy of their curriculum vitae to a selection committee comprising the Chairperson and Research Governance and Ethics Officer (RGEO). The selection committee interviews prospective members and makes a recommendation on new appointments to the Chief Executive.
- 7.4. Members are appointed as individuals for their knowledge, qualities and experience and not as representatives of any organisation, group or opinion.
- 7.5. Membership of the Justice Health HREC is made publicly available.
- 7.6. 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 date of termination.
- 7.7. With the prior approval of the Chief Executive, members may be reimbursed for legitimate expenses incurred in attending Justice Health HREC meetings or in otherwise carrying out the business of the Justice Health HREC.
- 7.8. Upon appointment, members are provided with an orientation package and asked to sign a statement undertaking:
 - that all matters of which they become aware during the course of their work on the Justice Health HREC will be kept confidential;
 - that any conflicts of interest that exist or may arise during their tenure on the Justice Health HREC will be declared; and
 - that they have not been subject to any criminal conviction or disciplinary action, which may prejudice their standing as a Justice Health HREC member.
- 7.9. Members are appointed for a period of up to three years and may serve a total of six years (two consecutive terms), unless otherwise approved by the Chief Executive. The Chief Executive, in consultation with the Chairperson, may implement a probationary period.
- 7.10. The Chairperson, Deputy Chairperson and Chairperson of any subcommittee may serve longer terms with the approval of the Chief Executive. Members are advised when their term is due to expire. Reappointment will be by application to the Chairperson of the Justice Health HREC, who then makes a recommendation to the Chief Executive.

- 7.11. The Network will review membership at least every three years. New and renewed appointments allow for continuity, development of expertise within the Justice Health HREC, and regular input of fresh ideas and approaches.
- 7.12. All members sign a conflict of interest declaration, which will be maintained on the member's personnel file.
- 7.13. 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 Justice Health HREC meetings in each year, barring exceptional circumstances.
- 7.14. The Chairperson notifies the member of a lapse of membership in writing. Steps are taken to fill the vacancy.
- 7.15. Members wishing 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.
- 7.16. The appointment of any member of the Justice Health HREC may be terminated if the Chief Executive is of the opinion that:
 - it is necessary for the proper and effective functioning of the Justice Health HREC; or
 - the person is not a fit and proper person to serve on a Justice Health HREC; or
 - the person has failed to carry out their duties as a Justice Health HREC member.
- 7.17. Members are expected to participate in relevant specialised working groups as required.
- 7.18. The Chairperson is expected to be available between meetings to participate in Justice Health HREC reviews and decision-making where required.
- 7.19. The Network provides indemnity for members of the Justice Health HREC for liabilities that arise as a result of the member discharging their duties in good faith. Such indemnity is provided through the NSW Treasury Managed Fund.

8. ORIENTATION AND TRAINING FOR JUSTICE HEALTH HREC MEMBERS

- 8.1. Justice Health HREC members are provided with orientation and training as determined to be appropriate by the Network.
- 8.2. Orientation involves some or all of the following:
 - an introduction to other Justice Health HREC members prior to the Justice Health HREC meeting;
 - provision of an orientation package;
 - an informal meeting with the Chairperson and the RGEO to explain responsibilities as a HREC member, the HREC processes and procedures;
 - mentoring by another HREC member; and
 - priority given to participate in training sessions.
- 8.3. Each member is:
 - expected to become familiar with the National Statement and Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018), and to consult other guidelines relevant to the review of specific research applications; and

- encouraged to attend continuing education or professional development activities in research ethics once in each period of appointment.

9. CONDUCT OF BUSINESS

9.1. Procedures

- The Justice Health HREC conducts its business in accordance with the Terms of Reference.
- The Justice Health HREC Terms of Reference is made publicly available.

9.2. Meetings

- The Justice Health HREC meets on a regular basis approximately every eight weeks. The HREC holds at least six scheduled meetings in each year for the purpose of reviewing new applications.
- Meeting dates and application closing dates are made publicly available.
- A quorum is required at each meeting for the Justice Health HREC to reach a final decision on any agenda item. The quorum for meetings is at least one member from each category (*National Statement NS 5.2.28*) attending in person or via telephone or videoconference.
- A meeting of the Justice Health HREC 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 NS 5.2.30*).
- The Justice Health HREC may convene meetings out-of-session for the purpose of reviewing submissions and discussing urgent matters. This meeting may be held face-to-face or by telephone or videoconference or by exchange of emails, as appropriate. Decisions of the Justice Health HREC made out of session are noted in the minutes relating to the next meeting.

9.3. Declaration of interest

- A Justice Health HREC member declares to the Justice Health HREC any conflicts of interest they have in relation to an application for ethical review or any other matter for consideration at the meeting. Conflict of interest includes financial interests and personal, professional or institutional benefits or advantages that depend significantly on the research outcomes.
- The minutes record the declaration of conflict of interest and the decision of the HREC on the procedures to be followed.

9.4. Confidentiality

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

9.5. Decision-making

- The Justice Health HREC endeavours to reach a decision concerning the ethical acceptability of an application by unanimous agreement.

- Where a unanimous decision is not reached, the Chair will facilitate the expression of opinion from all members, identify points of agreement and of disagreement and judge when a sufficient degree of general agreement has been reached.
- Any significant minority view (i.e. two or more members) is noted in the minutes.

9.6. Records

- The RGEO prepares and maintains written records of the HREC's activities, including agendas and minutes of all meetings.
- The RGEO maintains a register of all the applications received and reviewed in accordance with the *National Statement (NS 5.2.24)*, including copies of the relevant correspondence between the applicant and the HREC.
- Files will be kept securely and confidentially in accordance with the requirements of *State Records Act 1998* and the *Privacy and Personal Information Protection Act 1998* NSW.

9.7. Monitoring research projects

- The Justice Health 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.
- The Justice Health 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 of 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.

- 9.8. The Justice Health 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.

10. APPEALS AND COMPLAINTS

- 10.1. Where the Justice Health HREC has rejected an application, the investigator has the opportunity to:

- be provided with sufficient information to understand the rationale for rejection;
- submit a new application to the HREC, taking into account the Justice Health HREC's concerns; or
- lodge an appeal with the HREC Chairperson specifying the grounds of the appeal in writing.

- 10.2. Where the Justice Health HREC has approved an application and an ethical issue is subsequently identified or it becomes apparent that the decision was based on an inconsistent application of policy and guidelines, then a written appeal is to be lodged with the Chairperson.

- 10.3. If the appellant considers that the Justice Health HREC has failed to follow due process after lodging an appeal in line with 10.1 and 10.2 and remains dissatisfied with the outcome, the appellant has the discretion to lodge an appeal with the Chief Executive of the Network.
- 10.4. Complaints about the conduct of a Justice Health HREC member are managed by the Chief Executive, who informs the Chairperson of the complaint.
- 10.5. Complaints about the conduct of an authorised research project, including allegations of research misconduct, are managed in accordance with the Network's local complaint handling procedures.

11. REVIEW / AMENDMENTS OF THE TERMS OF REFERENCE

- 11.1. These Terms of Reference will be reviewed every three years and may be amended in consultation with the Justice Health HREC.

12. TERMINATION OF HREC RESPONSIBILITY

- 12.1. Where the Justice Health HREC is to be merged, closed or has ceased to function, the Network will notify the NHMRC and determine 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 Network will also notify the NSW Ministry of Health.