Nepean Blue Mountains Local Health District (NBMLHD)

Human Research Ethics Committee (HREC)

Terms of Reference (TOR)

TERMS of REFERENCE
Version 3 dated September 2022.

1. OBJECTIVES

1.1 The objectives of the NBMLHD HREC are to:

1.2 Protect the mental and physical welfare, rights, dignity and safety of participants of research.

1.3 Promote ethical principles in human research.

1.4 Review research in accordance with the *National Statement on Ethical Conduct in Human Research* (2007) updated 2018 [*National Statement*].

1.5 Facilitate ethical research through efficient and effective review processes.

1.6 Protect the privacy and confidentiality of participants and / or their personal health information in compliance with the Health Records and Information Privacy Act (2002).

2. FUNCTIONS

The NBMLHD HREC functions, on behalf of the Public Health Organisation, are to:

2.1 Provide independent oversight of human research projects in accordance with NSW Health system of single ethical and scientific review and in line with the National Statement requirement to minimise duplication of ethical review.

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.

2.4 Provide advice to the Public Health Organisation on strategies to promote awareness of the ethical conduct in human research.

3. ACCOUNTABILITY

3.1 The NBMLHD HREC is directly accountable to the Chief Executive (CE) of the Public Health Organisation under which it is constituted. The NBMLHD HREC brings to the attention of the Chief Executive or delegate issues that may be of significant concern.

3.2 The minutes of each meeting are confirmed and ratified at the following HREC meeting.

3.3 A CE Report is prepared each meeting and ratified at the following meeting.

3.4 In quarter 3 of each year, an Annual Report will be prepared for the CE summarising the previous 4 quarters of HREC activity.

3.5 The NBMLHD HREC provides the following reports on behalf of the Public Health Organisation:

- Annual Report to the National Health and Medical Research Council (NHMRC).
- Continuous Certification Monitoring requests to the National Health and Medical Research Council (NHMRC), and any other reports as required.
- NSW Privacy Commissioner Report in accordance with the requirements of the *Health Records and Information Privacy Act 2002 (NSW)*.

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 NBMLHD HREC is accredited by the NSW Ministry of Health as a lead HREC.

4.1 The responsibilities of the HREC are to conduct the scientific and ethical review of human research on behalf of the NSW public health system in the categories of:

- Clinical Trials Phases II, III & IV
- Clinical Trials drugs, devices and surgery
- Clinical Trials other
- Clinical Interventional research other than clinical trials
- Population health and / or public health
- Qualitative Research
- Mental Health
- Paediatric and adolescent medicine research
- Retrospective / prospective and audit type research

- Other Health and Medical Research Including – Laboratory research on human specimens, pregnant women and human foetus research, survey research; retrospective / prospective

4.2 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 Nepean Blue Mountains Local Health District for single-centre studies; and/or
- External institutions/organisations and investigators seeking research ethics approval from the NBMLHD HREC where there is no other appropriate HREC to provide such review, and it is impractical for the external entity to constitute such a HREC.
- The HREC may review applications from interstate institutions or organisations within the scope of a scheme of National Mutual Acceptance (NMA) of ethical and scientific review entered into by the NSW Ministry of Health on behalf of the NBMLHD HREC.

4.3 Monitor Safety as per the NHMRC Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods November 2016, the NSW Ministry of Health Policy Directive – Safety Monitoring and Reporting for Clinical Trials Conducted in NSW Public Health Organisations (PD2017_039).

4.4 The HREC may provide scientific assessment of new and innovative therapies if required by the Interventional Procedures Assessment Committee (NIPAC) within NBMLHD or the NBMLHD Executive.

5. NBMLHD HREC Subcommittees:

5.1 HREC subcommittees are appointed to advise the NBMLHD HREC on the ethical and scientific aspects of research applications. Members of the subcommittees need not be members of the HREC and are appointed by the Subcommittee Chairperson. The Chairs of the Subcommittees must be a member of the NBMLHD HREC.

5.2 NBMLHD HREC Subcommittees may be appointed on an ad hoc basis to carry out a review of specified matter / applications (s). Members of such an ad hoc committee need not be members of the HREC and are appointed by the Subcommittee Chairperson.

5.3 The NBMLHD HREC endorses the Terms of Reference of its subcommittees which are embedded in the following sections.

5.4 The NBMLHD HREC has an Executive Committee comprising of at least the HREC Chairperson, the HREC Deputy Chair or their delegate and a member of the Research Development Governance Unit (RDGU).

5.5 The NBMLHD HREC has a Low and Negligible Risk (LNR) Subcommittee comprising of the NBMLHD HREC Chair, HREC Deputy Chair, a member of the RDGU and other members as deemed appropriate by the HREC Chair.

5.6 The NBMLHD HREC has a Quality Improvement / Quality Assurance Committee call The Apollo Subcommittee comprising of The Manager of the Clinical Governance Unit (CGU) and other members from the CGU as appointed by the Chair. At least two members and the Chair will review applications.

5.7 The minutes and decision of the NBMLHD HREC Subcommittees are noted and ratified at the next HREC meeting.

6. NBMLHD HREC Executive Committee:

6.1 The HREC Executive Committee is delegated to undertake expedited review and approval of business that does not require full HREC review, Including some or all the following:

- Amendments to current HREC approved research projects.
- Protocol deviations and violations.
- Clinical Case Reports / Series.
- Responses to HREC queries, as approved by the full HREC for HREC Executive Committee review and approval.
- Annual progress reports and final reports.
- Requests for extensions of approvals (or annual renewals) without significant change to the project.
- Significant Safety Issues and Urgent Safety Measures.
- Noting of correspondence including – Annual Safety Reports, Data Safety Monitoring Board Reports, Safety Update Reports and Data Safety Monitoring Reports.
- To review and approve applications under the Special Access Scheme (SAS) and Authorised Prescriber Scheme for use of unapproved therapeutic goods via the Therapeutic Goods Administration (TGA) [under sections 19(5) and 41HC of the TGA Act 1989].
- Any other matters deemed necessary for review by the HREC Executive Sub-Committee.
- The Executive Committee may review urgent HREC business and (as appropriate) grant covering or final approval for the item. The Executive Committee may seek advice from appropriate sources before reaching a decision.
    - The Executive Committee may refer or escalate matters to the full HREC Committee for review.
    - The Executive Committee will be considered quorum where the HREC Chair or Deputy Chair and RDGU member are present.

5. Low and Negligible Risk (LNR) Subcommittee:

5.1 The National Statement permits institutions to establish levels of ethical review that are proportionate to the degree of risk involved The LNR Subcommittee is delegated to undertake ethical review of Low and Negligible Risk Research as defined in the National Statement.

5.2 In addition, it functions as per the NSW Office of Health and Medical Research Guidelines for Low and Negligible (LNR) Research review processes or Exemption form Ethics Review Version 1.1 dated 31 May 2018.

5.3 The LNR Subcommittee aims to expedite the review of LNR research applications.

6. Apollo Subcommittee:

6.1 The Apollo Subcommittee (AS) is a subcommittee of the NBMLHD HREC. Its purpose is to review and approve quality assurance and quality improvement initiatives and projects for ratification by the NBMLHD HREC in accordance with the.

- NSW Health Guideline (GL2007-020) – HRECs – QI & Ethical Review: A Practice Guide for NSW.
- The NHMRC Ethical Considerations in Quality Assurance, Evaluation Activities (March 2014), and
- The National Statement on Ethical Conduct in Human Research 2007 (updated 2018).

6.2 It is responsible for the review and oversight of the ethical aspects of Quality Improvement Projects in accordance with the National Statement on Ethical Conduct in Human Research (2007 updated in 2018).

6.3 Quality Assurance and Quality Improvement includes but is not limited to clinical audits, quality improvement initiatives and projects of various methodologies including redesign, practice development, improvement science and accelerated implementation methodology.

6.4 In making recommendations to the HREC regarding the approval of projects submitted to the Committee for review, the following considerations will be taken into account:

- Privacy and Confidentiality – consent; data collection, usage and storage processes; reporting results.
- Risks and Burdens - beyond those expected to be experienced as a part of routine care or employment.
- Appropriateness of qualifications, expertise and/or supervision of personnel proposing to undertake the proposed project.

- To promote, train, mentor and support the conduct of Practice Improvement in the NBMLHD.

6.5 The Apollo Subcommittee shall have delegated authority from the HREC Chair to conduct the review of applications and grant approval for ratification by the HREC.

6.6 The Apollo Subcommittee Chair is required to be a member of the NBMLHD HREC. The Chair or a member from the Committee should attend the NBMLHD HREC meeting on a rotating basis.

6.7 The Apollo Subcommittee shall provide a quarterly report to the NBMLHD HREC for its activity in the previous months of that quarter for ratification and reporting to the CE.

7. NBMLHD HREC MEMBERSHIP

7.1 Composition

7.1.1 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 the institution for which the HREC is reviewing research. 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 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 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.

7.1.2 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.

7.1.3 No member is appointed in more than one of the membership categories. NBMLHD HREC may establish a pool of inducted members

in each category, who attend meetings as needed, to meet the HREC requirements and are available to provide expertise for the research under review.

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

7.2 Appointments:

7.2.1 HREC members are recruited by direct approach, nomination or by advertisement through an open and transparent process.

7.2.2 Prospective members may be invited to observe a meeting of the HREC.

7.2.3 Prospective members are asked to provide a copy of their curriculum vitae to a selection committee comprising the Chairperson, Research Development Governance 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.

7.2.4 Members are appointed as individuals for their knowledge, qualities and experience and not as representatives of any organisation, group or opinion.

7.2.5 Membership of the HREC is made publicly available.

7.2.6 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.

7.2.7 Members are not offered remuneration. However, members will be reimbursed for legitimate expenses incurred in attending HREC meetings or in otherwise carrying out the business of the HREC. AND

7.2.8 Eligible members (such as lay members or non-affiliated members) of the HREC will be offered an honorarium for attending each committee meeting. The value of the honorarium will be determined by institutional policy.

7.2.9 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.

7.2.10 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.

7.2.11 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 is due to expire. Reappointment will be by application to the Chairperson of the HREC who then makes a recommendation to the Chief Executive or delegate.

7.2.12 The Public Health Organisation 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.

7.2.13 All members sign a conflict-of-interest declaration, which will be maintained on the members' personal file.

7.2.14 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.

7.2.15 The Chairperson notifies the member of a lapse of membership in writing. Steps are taken to fill the vacancy.

7.2.16 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.

7.2.17 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.

7.2.18 Members are expected to participate in relevant specialised working groups as required.

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

7.2.20 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.

8. Orientation and training for HREC members:

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

8.2 Orientation involves some or all of the following:

- Introduction to other HREC members prior to the HREC meeting.
- Provision of an 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 sessions.

8.3 Each member is:

- expected to become familiar with the *National Statement* and consult other guidelines relevant to the review of specific research applications; and
- is 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

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

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

9.2 Meetings

9.2.1 The HREC meets on a regular basis every four weeks. The HREC holds at least 11 scheduled meetings in each year for the purpose of reviewing new applications.

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

9.2.3 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 category (*National Statement* 5.2.28) attending in person or via telephone.

9.2.4 A meeting of the 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* 5.2.30).

9.3 Declaration of interest

9.3.1 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. Refer to the National Statement on Ethical Conduct in Human Research Chapter 5.4.

9.3.2 A substantial conflict of interest is defined in the NBMLHD SOP section 011

9.3.3 A less than substantial conflict of interest is defined in the NBMLHD SOP section 011

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

9.4 Confidentiality:

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

9.5 Decision making

9.5.1 The HREC endeavours to reach a decision concerning the ethical and scientific acceptability of an application by unanimous agreement and in accordance with the National Statement.

9.5.2 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.

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

9.6 Records

9.6.1 Written and or electronic records of all meetings of the HREC are maintained (including agendas and minutes). Records shall be kept as per General Retention & Disposal Authority – Public Health Services: Administrative Records (GDA 21), sections 5.3.3 & 15.3.1 . For records

https://www.records.nsw.gov.au/sites/default/files/Recordkeeping/GDA21%20%28public%20health%20administration%20records%29%20July%202021_0.pdf

9.6.2 The Research Development and Governance Officer will prepare and maintain a file for each application received including a copy of the application, and any relevant correspondence including that between the applicant and the HREC. The system is use is The Research Ethics and Governance Management System (REGIS) https://regis.health.nsw.gov.au/

9.6.3 Files are kept securely and confidentially in accordance with the requirements of the Health Records and Information Privacy Act 2002.

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

9.6.5 Records shall be held for 5 years from the date of completion of a research project not involving drugs/devices and for clinical research which involve the use of drugs and/or devices for a period of 15 years after completion of the research as per the General Disposal Authority 17 (GDA 17), Public Health Services: Patient / Client Records, sections 1.15.0 & 8.0.0 (Issued May 2004) Records for research involving children shall be kept indefinitely.
https://arp.nsw.gov.au/sites/default/files/GDA%2017%20Public%20health%20patient%20records.pdf

9.7 Monitoring research projects

9.7.1 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.

9.7.2 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.

9.7.3 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.

9.8 Authority Delegated

9.1.1 The RGDU Officer is delegated the authority to facilitate the day to day working of the Committee. The RDGU Officer can further delegate this authority to other RGDU staff in their absence.

10. APPEALS AND COMPLAINTS:

10.1 Appeals regarding HREC rejection

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.

10.2 Appeals regarding HREC approval:

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.

10.3 Appeals to the Chief Executive

If the applicant considers that the HREC has failed to follow due process after making an appeal in line with 10.1 and 10.2 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.

10.4 Complaints about the conduct of HREC members:

Complaints about the conduct of an HREC member are managed by the HREC Chairperson in the first instance and escalated to the Chief Executive/delegate if required.

10.5 Complaints about the conduct of an approved research project.

10.5.1 Complaints concerning the conduct of a project:

Any concern or complaint about the conduct of a project should be directed to the attention of the person nominated by the HREC. The person nominated by the HREC to receive complaints shall notify the Chairperson as soon as possible after a complaint is received. The Chairperson of the HREC will investigate the complaint and make a recommendation on the appropriate course of action. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the Chief Executive or his/her nominee or request the Chairperson to do so.

10.5.2 Complaints concerning the HREC's review process

Any concern or complaint about the HREC's review process should be directed to the attention of the Chairperson of the HREC, detailing it in writing. Complaints may also be made to the Chief Executive. The Chairperson will notify the Chief Executive of any complaints received by him/her, as soon as possible. The Chief Executive will inform the Chairperson of any complaints received by him/her as soon as possible.

The Chairperson will investigate the complaint and its validity and make a recommendation to the HREC on the appropriate course of action. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the Chief Executive, or his/her nominee, or request the Chairperson to do so. The Chairperson will provide to the Chief Executive all relevant information about the complaint/concern. The Chief Executive will determine whether there is to be a further investigation of the complaint. If it is decided there is to be a further investigation, then the Chief Executive will convene a suitable panel to review the complaint, ensuring that both the complainant and the HREC are afforded the opportunity to make submissions.

In conducting its review, the panel shall be concerned with ascertaining whether the HREC acted in accordance with the National Statement, its Terms of Reference, the Standard Operating Procedures, or otherwise acted in an unfair or unbiased manner.

11. REVIEW/ AMENDMENTS OF THE TERMS OF REFERENCE

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

12. TERMINATION OF HREC RESPONSIBILITY

Where the HREC is to be merged, closed or has ceased to function, the Public Health Organisation 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 Public Health Organisation also notifies the NSW Ministry of Health.