STANDARD OPERATING PROCEDURES OF THE HUNTER NEW ENGLAND HUMAN RESEARCH ETHICS COMMITTEE

Contents

KEY DEFINITIONS

CTSC	The Clinical Trials Sub-Committee of the Hunter New England Human Research Ethics Committee which assesses the methodology and safety of all clinical trials/interventional research involving humans to determine whether or not the research is scientifically valid, and advises the HREC accordingly
HREA	Human Research Ethics Application embedded in the REGIS system
HNEHREC	Hunter New England Human Research Ethics Committee
HNELHD	Hunter New England Local Health District
HNERO	Hunter New England Local Health District - Research Office
HNEHREC Executive Officer	Within the Hunter New England Local Health District this function is performed by the Manager Research Ethics within the HNE Research Office
NMA	National Mutual Acceptance: Australian state and territory health departments have signed a Memorandum of Understanding for the mutual acceptance of ethical and scientific review of multi-centre human research projects by NHMRC certified HREC's undertaken in public health organisations.
NHMRC	National Health and Medical Research Council
National Statement	The *National Statement on Ethical Conduct in Human Research (2007)* incorporating all updates. The most recent update being 2018
REGIS	Research Ethics and Governance Information System, the IT platform for submitting all applications for review by Human Research Ethics Committees based in NSW Public Health Organisations

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 001 **Date**: June 2022

Subject: Hunter New England Human Research Ethics Committee (HNEHREC)

Purpose: To describe the objectives, function, accountability, scope of responsibility and reporting requirements of the HNEHREC

1. OBJECTIVES

The objectives of the HNEHREC are to:

1.1 Ensure all applications to conduct human research projects 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 in research.

1.3 Facilitate ethical research through efficient and effective review processes.

1.4 Promote ethical principles in human research.

2. FUNCTIONS

The functions of the Human Research Ethics Committee (HREC) 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 approved by the HNEHREC in respect of their ethical and scientific acceptability for as long as the projects are active.

2.3 Provide advice on strategies to the HNELHD Executive to promote awareness of the ethical conduct of human research.

3. SCOPE OF RESPONSIBILITY

The responsibilities of the HNEHREC are to:

3.1 Review Human Research Ethics applications where the research is involving human participants, biological samples or data that takes place at:

- Any institutions governed by Hunter New England Local Health District;
- As a NHMRC Certified HREC any Public Health Organisations within the scope of the scheme of National Mutual Acceptance (NMA) of ethical and scientific review entered into by NSW Ministry of Health;

3.2 The HNEHREC will review submissions in accordance with their risk category:

- Projects considered Greater than Low Risks 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

- 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.

3.3 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 Manager Research Ethics who, where appropriate, will provide the exemptions to the researchers.

4. ACCOUNTABILITY OF THE HUMAN RESERCH ETHICS COMMITTEE (HREC)

4.1 The HNEHREC is accountable to the Chief Executive in the conduct of its business. The minutes of each HREC meeting shall be signed by the Chairperson and made available to the Chief Executive or their delegate, following confirmation by the HNEHREC.

4.2 A copy of the minutes shall be made available to the Director, HNE Research Office

4.3 The Manager Research Ethics will compile an annual report at the end of each calendar year, which will include:

- membership/membership changes;

- number of projects reviewed, approved and rejected;
- monitoring procedures for ethical aspects of research in progress and any problems encountered by the HNEHREC in undertaking its monitoring role;
- description of any complaints received and their outcome;
- description of any research where ethical approval has been withdrawn and the reasons for withdrawal of approval; and
- general issues raised.

After endorsement at a HNEHREC meeting the report shall be forwarded to the Director Research.

4.4 The Manager Research Ethics will provide the following annual reports:

- HREC Annual Report to the National Health and Medical Research Council (NH&MRC);
- Report to the NSW Privacy Commissioner in accordance with the requirements of the Health Records and Information Privacy Act 2002 (NSW); and
- Any other reports as required.

4.5 The HNEHRECs Terms of Reference, Standard Operating Procedures will be available upon request to the general public via the Hunter New England Local Health District (HNELHD) Research Office website.

4.6 The HNEHREC will undertake its review of applications in a timely and efficient manner in line with the Research Ethics and Governance metrics program detailed in the Chief Executive Service Agreement and any other agree Key Performance Indicators.

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Reference Number: SOP 002 **Date:** June 2022

Subject: **HNEHREC** Membership composition

Purpose: To describe the membership composition of the HREC

1. The composition of the HNEHREC is in accordance with the *National Statement* section 5.1.30. 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 should be external to the HNELHD. The membership comprises representatives from the following categories:

    a) A Chairperson with suitable experience whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the *National Statement*;

    b) 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;

    c) At least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people;

    d) At least one member who performs a pastoral care role in the community, for example, an Aboriginal Elder or a Minister of Religion;

    e) At least one member who is a lawyer and, where possible, one who is not engaged to advise the institution for which the HREC is reviewing research; and

    f) At least two members with knowledge of and current experience in research that is relevant to the applications to be considered at the meetings they attend.

2. To ensure that the membership will equip the HNEHREC to address all the relevant considerations arising from the categories of research for applications that are likely to be submitted, some or all of the above categories may be represented by more than one person.

3. No member will be appointed in more than one of the membership categories.

4. In addition, in accordance with the HNELHD's commitment to local communities in Closing the Gap, at least two Aboriginal Health Workers based in the LHD or Community Members identifying as Aboriginal with familiarity with research and the requirements for conducting research with the Aboriginal communities will be included on the HREC. This will not mitigate the requirement for researchers to obtain approval from the AHMRC HREC for all research targeting Aboriginal and/or Torres Strait Islander Peoples as participants.

5. Further, where the HREC identifies specific expertise required when reviewing a type of application regularly submitted, a member will be sought with that expertise.

6 Where required, the HREC may seek advice and assistance from appropriate experts to assist with the review of an application. However, the HREC must be satisfied that such

experts have no conflicts of interest in relation to the application under consideration arising from any personal involvement or participation in the application, any financial interest in the outcome or any involvement in competing research. Such person(s) shall be required to provide an undertaking of confidentiality and shall not be entitled to vote on any matter.

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Reference Number: SOP 003 **Date:** June 2022

Subject: Clinical Trials Sub-Committee

Purpose: To describe the composition of and the role of the Clinical Trials Sub-Committee of the HREC.

1. The Clinical Trials Sub-Committee (CTSC) of the HNEHREC operates according to its own Terms of Reference.

2. The purpose of the CTSC is to advise the HNEHREC on the scientific and safety aspects of all applications involving clinical research.

3. At a minimum, the membership of the CTSC should comprise of:

    - A Clinical Pharmacologist
    - A Pharmacist with appropriate Clinical Trials experience
    - A Statistician with experience in the design of Clinical Trials
    - Staff Specialists with research experience and/or expertise relevant to the areas of research reviewed by the Committee
    - A Clinical Trials Research Nurse

4. Additional members will be invited, if the CTSC deem such expertise is required for the comprehensive review of the applications to be considered by CTSC.

5. All members of the CTSC are standing members of the HNEHREC and may, but are not required to attend meeting of the HNEHREC.

6. All member of the CTSC will be giving access to:

    - An electronic copy of the latest version of the *National Statement*
    - The REGIS IT platform for the purpose of reviewing applications
    - Any other regulatory documents as required

7. The Manager Research Ethics will determine whether an application requires review by the CTSC prior to review by the HNEHREC.

8. The CTSC meets a week before the HREC and provides advice on all Clinical Trials submitted to the HREC for approval.

9. The agenda papers will be distributed through REGIS at least five working days prior to the CTSC scheduled meeting.

10. The Agenda for the CTSC will include at least the following items:

    - Acknowledgement of Country
    - Apologies
    - Minutes of the previous meeting
    - Business arising from the previous minutes
    - Report from the Manager Research Ethics

- New applications
- Correspondence
- Other business

11. The CTSC shall usually meet on the second Wednesday of every month apart from January. Meeting dates and submission closing dates shall be publicly available on the HNE Research Office website from October the previous year. If necessary, the meeting date can change in consultation with the Chair, as long as the members receive sufficient notice. Where there are no applications to the HNEHREC requiring CTSC review the meeting will be cancelled

12. Diary appointments will be sent to all members at the end of the year for all meeting in the following year

13. Members may attend HNEHREC meetings in person, via teleconference or video conference. The meeting link will be circulated to all members prior to the meeting

14. Any member of the CTSC who has any interest, financial or otherwise, in relation to applications considered by the CTSC, should as soon as practicable declare such interest. The remaining members of CTSC will need to determine if such a declaration is a conflict of interest. Declarations of conflicts of interest by any member of the CTSC and the absence of the member concerned during the CTSC consideration of the relevant submission will be included in the minutes of the CTSC meeting.

15. All protocols will be reviewed by a member with clinical trials expertise, a statistician and, if the study involves an investigational product, a member with clinical pharmacology expertise

16. After reviewing an application, the CTSC may:
    - Recommend the HNEHREC approve the application;
    - Recommend the HNEHREC approve the application contingent on a satisfactory response to the CTSC questions or concerns; or
    - Recommend the HNEHREC not approve the application, and provide reasons for the recommendation.

17. The Minutes of the CTSC will record the advice given by the CTSC to the HNEHREC on each of the protocols listed on the Agenda. This advice will be incorporated into the Minutes of the HNEHREC meeting where the submissions are considered.

18. The draft recommendations from the CTSC will be circulated to the HNEHREC members prior to the HREC meeting.

19. Where necessary the Chair of the CTSC, or another member, will attend the HREC meeting to discuss any or all of the applications that the CTSC has provided recommendations.

Standard Operating Procedures

Reference Number: SOP 004 **Date:** June 2022

Subject: Appointment of Members to HNEHREC and CTSC

Purpose: To describe the procedure for the appointment of members to the HREC

1. Members are appointed as individuals rather than in a representative capacity.

2. Prospective members of the HREC may be recruited by direct approach, nomination or as a response to a call for Expression of Interest. Prospective members shall be asked to provide a copy of their Curriculum Vitae.

3. Prospective members will be provided with background information for consideration including the Committee's Terms of Reference, a statement of member's responsibilities, electronic access to the most recent version of the N*ational Statement* and invited to meet with the Manager Research Ethics and/or the Chair of the HNEHREC for a preliminary discussion.

4. Prospective members will be invited to meet with the HNEHREC and CTSC Chairs and/or Manager Research Ethics for an orientation discussion.

5. Prospective members will be invited to attend a meeting of the HNEHREC as observers prior to joining the committee. Prospective members will be provided with the agenda and the documentation for one or two applications prior to the meeting. Prospective members will be asked to sign an Observer Confidentiality Agreement prior to the meeting commencing.

6. All members including the Chairperson, Deputy Chairperson and Chairperson of any Sub-Committee are appointed by the Chief Executive or their delegate, and will receive a formal notice of appointment.

7. The letter of appointment will include the date of appointment, length of tenure, assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of their duties as a HREC member, and the conditions of their appointment.

8. A new member will be required to sign a confidentiality undertaking upon appointment, stating 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.

9. Upon appointment, members shall be provided access to the following:
    - The *National Statement* (only available electronically)
    - The Committee's Terms of Reference
    - The meeting dates for the current year
    - The current version of the SOPs and any other relevant information about the HREC's processes, procedures and protocols
    - The Research Ethics and Governance Information System (REGIS) IT Platform for the purpose of reviewing HREC applications

10. Members are appointed for a period of 3 years and may serve a total of 6 years (two consecutive terms), unless otherwise approved by the Chief Executive or Delegate.

11. The Chairperson, Deputy Chairperson and Chairperson of any Sub-Committee may serve longer terms with the approval of the Chief Executive or Delegate.

12. Members are advised when their term or appointment is due to expire. An invitation to extend the appointment will be issued automatically except in unusual circumstance, but may be declined. Where the invitation is accepted a new confidentiality agreement will be signed.

13. HNEHREC will review membership at least every three years. New and renewed appointments allow for continuity, development of expertise within the HREC, and the regular input of fresh ideas and approaches.

14. Members are not offered remuneration. Members will be reimbursed for legitimate expenses incurred in attending HREC meetings, such as travelling and parking expenses.

15. Membership lapses if a member fails to attend:
    - Three consecutive meetings without reasonable explanation or exceptional circumstances; and
    - At least two thirds of all scheduled HREC meetings in each year, barring exceptional circumstances.

16. Members will be invited to participate in the HNEHREC Executive Committee on a needs basis.

17. Members will be expected to participate in relevant specialist working groups as required.

18. The Chairperson is expected to be available between meetings to assist with HREC business, including review and approval of amendments [see SOP 020]. Investigations of complaints [see SOP 025] and any other decisions, except where the Chairperson has a Conflict of Interest.

19. For any item of the HREC's business, where the Chairperson has a Conflict of Interest, the Deputy Chairperson will assist with those business items.

20. In the absence of the Chairperson, the Deputy Chairperson will perform the Chairperson's functions except where the Deputy Chairperson has a Conflict of Interest.

21. Where the Chair and Deputy Chairperson have Conflict of Interests with an item/s of HREC business, another senior HREC member will be asked to assist.

22. A member may resign from the HREC at any time upon giving notice to the Chairperson. Steps shall be taken to fill the vacancy of the former member.

23. The Chief Executive may terminate the appointment of any member of the HREC 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 a HREC; or
    - the person has failed to carry out their duties as a HREC member.

24. Members of the HREC are indemnified 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.

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Reference Number: SOP 005 **Date:** June 2022

Subject: Orientation of New HNEHREC and CTSC members (after appointment)

Purpose: To describe the procedure for the orientation of new HNEHREC members

1. New CTSC or HNEHREC members must be provided with adequate orientation.

2. Orientation may involve all or some of the following:

    - Introduction to other CTSC or HNEHREC members prior to the meeting;
    - 'Partnering' with another HREC member in the same category for mentoring and coaching purposes;
    - Further meetings with the Manager Research Ethics to discuss Committee processes and members responsibilities; and
    - Priority given to participate in training opportunities.

3. New HREC members will be invited to meet with the HNEHREC/CTSC Chairs and/or Manager Research Ethics to discuss their reviews of application or any other issues early in their tenure

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Reference Number: SOP 006 **Date:** June 2022

Subject: Training and Education of HREC members

Purpose: To promote ongoing education and training opportunities for all members of the HREC

1. In accordance with the NHMRC requirements, every HNEHREC member will be offered at least one training opportunity relating to HREC activities every three years, with all cost being covered by the Hunger New England Local Health District.

2. Educational opportunities include, but are not limited to:

    - Training courses provided by NSW Ministry of Health or the NH&MRC (National Health & Medical Research Council) are examples of suitable educational forums;
    - Online and/or face-to-face training courses such as those offered through Universities or Specialist Organisations such as PRAXIS; and
    - In-house training days to address the specific issues or areas relating to Human Research Ethics identified by the Committee. These will be organised and hosted by the HNE Research Office at least every three years.

3. Where available, members should provide proof of completion of training and these should be kept on file at the HNE Research Office.

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Reference Number: SOP 007 **Date:** June 2022

Subject: Mentoring program for HNE Staff at the CTSC and HNEHREC meetings

Purpose: To describe the process for mentoring HNE staff interested in pursuing research as part of their career to attend CTSC and HNEHREC meetings as part of their education in developing research protocols and conducting research.

1. The review of applications to conduct human research and attendance at CTSC and/or HNEHREC meetings where those applications are considered, provides an excellent learning opportunity for HNE Staff intending to have a research focus in their careers.

2. Participation in the Mentoring Program will be offered to Junior Medical Officers, Advanced Trainees, Registrars, Allied Health Staff, Nursing Staff, PhD students and other staff who have an intention to include research in their clinical/health careers.

3. There will be a call for Expression of Interest through appropriate networks and forums which would include the following eligibility criteria:
   - An expressed interest in pursuing clinical or health related research;
   - Possible involvement in a research project in the short term; and
   - A commitment to attend between 2-5 consecutive CTSC and HNEHREC meetings.

4. The Expressions of Interests will be considered by a panel consisting of the Chair of the HNEHREC or delegate, Chair of the CTSC or delegate, and the Manager Research Ethics.

5. Staff invited to participate in the mentoring program (hereafter known as “Mentees”) will be invited to attend CTSC and/or HNEHREC meetings, contingent on their profession and research interest, as observers and will be encouraged to participate in the discussion on the protocol they are assigned for review. Prospective mentees will be required to sign a confidentiality agreement prior to receiving any documentation and attending any meetings. This agreement must be countersigned by the mentee’s manager or supervisor.

6. Mentee’s who have expressed an interest in conducting Clinical Interventional research will be invited to attend both the CTSC and HREC meetings and will be assigned an application for review and will be given access to the documentation for that application outside of REGIS. Prior to the meetings, each mentee will be partnered with the member from the CTSC and a member from the HNEHREC who have been assigned the same application for review. Mentees will be mentored by the relevant CTSC and HREC members in the review process. Mentee’s will attend all meetings where the protocol they have been assigned is to be reviewed.

7. Mentees who have expressed an interest in conducting other types of health research will be invited to attend a HREC meeting and will be assigned an application for review and given access to the documentation for that application outside of REGIS. Prior to the meetings, each mentee will be partnered with a member from the HNEHREC who have been assigned the same application for review. Mentees will be mentored by the relevant HREC member in the review process. Mentees will attend all meetings where the protocol they have been assigned is to be reviewed.

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Reference Number: SOP 008 **Date:** June 2022

Subject: Role of HNEHREC Executive Officer

Purpose: To describe the role of the HNEHREC Executive Officer or delegate

1. The role of Executive Officer of the HREC will be one of the functions of the Manager for Research Ethics within the HNE Research Office. Other staff members within that office may be nominated as the Manager Research Ethics delegate.

2. In order to ensure the smooth operations of and timely consideration of the day to day business of the HNEHREC, the Chief Executive at the recommendation of the Hunter New England Human Research Ethics Committee has given the Manager Research Ethics the delegated authority to:

    - Determine whether a research project requires Human Research Ethics Committee approval.
    - Determine whether a submission is eligible for HREC review and the appropriate review pathway
    - Perform all tasks delegated by the HNEHREC including reviewing HREC requirements for approval and determining final approval and all post approval monitoring and review of research project under the HNEHREC approval
    - To educate and advise researchers about ethical issues relating to research involving humans and the requirements of the *National Statement*.
    - Investigate complaints concerning research approved by the HNEHREC
    - Liaise and assist Human Research Ethics Executive Officers from other Public Health Organisations in accordance with the Memorandum of Understanding for National Mutual Acceptance of Single Ethical and Scientific Review of Multicentre Human Research.
    - Complete and submit annual reports on the HNEHREC's activity as required.
    - Undertake preliminary review of audit and quality improvement activities to determine whether HREC approval is required, and either communicate the need for an ethics application to be submitted to the applicants, or grant a waiver of ethics review so the results of such activities may be published or presented.

3. All correspondence issued on behalf of the HREC will be sent via REGIS using the state wide approved email templates embedded within that system.

4. There is separate documentation describing the tasks and activity of the Manager Research Ethics

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Reference Number: SOP 009 **Date:** June 2022.

Subject: Submission procedure for new applications

Purpose: To describe the procedure for the submission of new applications

1. All applications for ethical review must be submitted in REGIS by midnight on the relevant closing date. The closing date for receipt of new applications for the next HREC agenda shall be publicly available to prospective applicants in October of the preceding year and advertised on the HNE Research Office website.

2. A list of documentation required for a submission to the HNEHREC and guidelines to assist applicants in the preparation of their submissions will be available on the HNE Research Office Website.

3. The closing dates for applications should normally be at least 7 days prior to each HREC meeting.

4. Applications must be submitted through REGIS. The HREA will be completed in REGIS and all other documentation associated with the application will be uploaded into REGIS as part of the submission. REGIS will generate unique Project IDs, Ethics IDs and Site IDs (one per each NSW PHO site) for each project. The procedures for the submission of applications to the HNEHREC shall be detailed on REGIS and the HNE Research Office websites.

5. As part of the HNELHD's commitment to Closing the Gap, for those applications for research targeting Aboriginal and Torres Strait Islander peoples, researchers are required to demonstrate their commitment to cultural sensitivity and safety for Aboriginal and Torres Strait Islander research participants.

6. Fees for HREC review will be levied in accordance with the Fee Schedule endorsed by the HNELHD Chief Executive. The approved Fee Schedule will be available on the HNE Research Office website.

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Reference Number: SOP 010 **Date:** June 2022

Subject: Processing of submissions for review

Purpose: To describe the procedure for the processing of new applications

1. All submissions through REGIS will undergo an eligibility check by the Manager Research Ethics to ensure each submission meets the requirements for review. Until a submission is deemed eligible, in accordance with the criteria endorsed by the HNEHREC, it will not progress to review.

2. An automated email from REGIS will be sent to the Co-ordinating Principle Investigator advising whether their submission is eligible for review. If a submission is ineligible, advice will be provided as to why and what is required to progress the submission. Once a submission is deemed eligible, the Co-ordinating Principle Investigator will be advised of the review pathway, and if the study is greater than low risk, the date of the HREC meeting when the application will be reviewed. [see SOP 017 for the process for submissions eligible for the low risk review pathway]

3. All eligible submissions requiring full HREC review will be included on the agenda for the next available HREC meeting, provided the submission is received by the relevant closing date. The Manager Research Ethics will also determine whether a submission requires review by the Clinical Trials Sub-Committee prior to being considered by the HNEHREC, and if so, the submission will be included on the Agenda for the next meeting of the Clinical Trials Sub-Committee.

4. If more than 15 submissions are received, some applications may need to be deferred to the following HREC meeting. If this occurs, submissions will be reviewed in order of receipt. Urgent submissions may be given priority at the discretion of the HNEHREC Chair.

5. Applicants will be made aware that their submission has been deferred to a future meeting and will be given the opportunity to withdraw it and submit to another HREC if appropriate.

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Reference Number: SOP 011 **Date:** June 2022

Subject: Preparation of HNEHREC agenda

Purpose: To describe the format and preparation of the agenda for a HNEHREC meeting

1. The Manager Research Ethics or delegate will prepare an agenda for each HNEHREC meeting.

2. All eligible submissions requiring full HREC Review will be included on the agenda for HNEHREC review at its next available meeting.

3. The agenda and associated documents will be prepared by the Manager Research Ethics or their delegate and circulated to all HNEHREC members through REGIS at least 7 days prior to the next meeting.

4. Documentation received after the closing date will be included on the agenda and/or tabled at the meeting at the discretion of the Chairperson. Under no circumstances shall new applications for research be tabled at the meeting.

5. The Agenda will include at least the following items:

    - Acknowledgement of Country;
    - Apologies;
    - Minutes of the previous meeting;
    - Business arising from the previous minutes;
    - Research Ethics Report
    - New applications previously reviewed by the CTSC;
    - New applications requiring HREC review only;
    - Low Risk applications considered under the HNEHREC expedited review processes (see SOP 012);
    - Amendments to approved applications reviewed by the Chair, Deputy Chair another HREC Member or the Manager Research Ethics out of session (see SOP020 for the management of amendments);
    - Final Reports received since the last HREC minutes;
    - Correspondence; and
    - Other Business.

6. After the agenda is distributed, an addendum to the agenda with the same items, will record all of the ongoing business of the meeting that occurs between the distribution of the agenda papers and the meeting. This will be distributed to HNEHREC members prior to the meeting via email.

7. The agenda and all meeting documentation shall remain confidential.

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Reference Number: SOP 012 **Date:** June 2022

Subject: Conduct of HNEHREC meetings

Purpose: To describe the format of meetings of the HREC

1. The HNEHREC shall usually meet on the second Wednesday of every month apart from January. Meeting dates and submission closing dates shall be publicly available on the HNE Research Office website from October the previous year. If necessary, the meeting date can change in consultation with the Chair, as long as the members receive sufficient notice.

2. Diary appointments will be sent to all members at the end of the year for all meeting in the following year

3. Members may attend HNEHREC meetings in person, via teleconference or video conference, on the preferred NSW Health virtual meeting platform. The meeting links will be circulated to all members prior to the meeting

4. If there is less than a full attendance of the minimum membership, the meeting may still proceed if absent members have submitted their review in REGIS and the Chairperson is satisfied that the views of those absent have been received and considered.

5. If the meeting does not achieve quorum, the Chairperson shall decide it can proceed only in exceptional circumstances. In such circumstances, decisions made by the HNEHREC must be ratified by at least one representative from those membership categories not present or at the next meeting where all membership categories are represented.

6. Alternatively, the Chairperson may cancel a scheduled meeting if a quorum cannot be achieved. Should this occur, the HREC will convene within 5 working days of the cancelled meeting to ensure all agenda items, are considered.

7. Meetings will be scheduled for an allocated time. If the business has not been completed within the allocated time, then the HNEHREC may either continue the meeting until all agenda items have been considered or schedule an additional meeting. If an additional meeting is called for, then the meeting should be held within 5 working days.

8. The HNEHREC meeting will be conducted in private, to ensure confidentiality and open discussion.

9. The HNEHREC may agree to the presence of observers to a meeting. Such visitors (eg expert reviewers) and observers will be asked to sign a Confidentiality Agreement. If an observer has a conflict of interest (see SOP 13) with any item of business on the agenda, he/she must leave the meeting whilst the item of business is under discussion.

10. In addition see SOP 007 for the arrangements for HNELHD staff who have an expressed interest in research, to participate in a mentoring program by attending CTSC and HNEHREC meetings.

11. Members are required to submit their reviews through REGIS by 9am on the morning before the day of the meeting.

12. The minutes should record the submission of reviews in REGIS from members not in attendance at the meeting.

13. Any member of the HNEHREC who has any interest, financial or otherwise, in a project or other related matter(s) considered by the HREC, should declare such interest. Please see SOP 013

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Reference Number: SOP 013 **Date:** June 2022

Subject: Managing conflicts of interest

Purpose: To describe the procedure for the handling of conflicts of interest of HNEHREC members,

1. The Manager for Research Ethics will identify any conflict of interests CTSC or HNEHREC with application submitted for review as part of the initial eligibility check of all submissions for review

2. Any member of the CTSC or HNEHREC or an observer at a CTSC or HNEHREC meeting, who has a conflict of interest in a proposal or other related matter(s) considered by the HNEHREC, should as soon as practicable declare such interest. Conflicts of interest includes being an investigator on a project under review, having had a consultative role on a project under review, financial interests, familial relationship with researchers, personal, professional or institutional benefits or advantages that depend significantly on the research outcomes.

3. Declarations may be made orally at the meeting prior to the matter being considered or in writing to the Chairperson prior to the meeting. The remaining members of the HNEHREC will determine whether the level of interest results in:
    - A substantial conflict of interest which will result in that member being asked to withdraw from the meeting until the HREC's consideration of the relevant matter has been completed. The member will not participate in discussions. Being an investigator or consultant on a research project is considered to represent a substantial conflict of interest. Other substantial conflict of interest include, but are not limited to having a role in the conduct of the research under review or being in a familial/personal relationship with a member of the research team;
    - A non-substantial conflict of interest whereby the member declares the nature of the conflict may either at their discretion, choose to leave during the discussion of the matter or the Committee may request they leave; or
    - No conflict of Interest.

    If the Chairperson has a potential conflict of interest as described above, the Deputy Chairperson will take over the conduct of the meeting for the consideration of the agenda item in question.

4. Declarations of conflicts of interest by any member of the HNEHREC and the absence of the member concerned during the discussing and decision in relation to the relevant application will be included in the minutes of the HNEHREC meeting.

4. If there is another reason, for example personal circumstances whereby a Committee member believes he/she would be unable to provide an objective review of a submission, they may request for the protocol to be reassigned to another Committee member for review.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 014 **Date:** June 2022

Subject: Consideration of applications for ethical review by the HNEHREC

Purpose: To describe the process of the HNEHRECs consideration of applications for ethical assessment

1. The HNEHREC will consider a new submission at its next available meeting provided that the submission was in REGIS by the closing date, and was deemed eligible by the Manager Research Ethics or their delegate.

2. Each application will be assigned two reviewers (if the application has already been reviewed by the CTSC) or three reviewers who will provide a detailed review of each submission and submit this review in REGIS.

3. For those applications previously reviewed by the CTSC, the HNEHREC will take the CTSC advice and recommendations into account when making its decision in relation to that application.

4. The HNEHREC will deal with multi-centre research applications in accordance with SOP 015.

5. The HNEHREC will ethically assess each application in accordance with the *National Statement* and ensure that it is sufficiently informed on all aspects of a research protocol, including its scientific validity, in order to make a determination.

6. Where relevant, the HNEHREC will review research in accordance with other relevant guidelines and legislation such as the *Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes*, the *NSW Health Records and Information and Privacy Act* (2002) and the *NSW Human Tissue Act (2003)*.

7. The HNEHREC will consider the cultural resect requirements for all research where there may be Aboriginal and Torres Strait Island Peoples as participants. For those application which target Aboriginal and Torres Strait Islander People, approval by the AHMRC HREC will be a requirement for approval.

8. The HNEHREC will consider whether an advocate for any participant or group of participants should be invited to the HNEHREC meeting to ensure informed decision-making.

9. The HNEHREC, after consideration of a submission, will make one of the following determinations:
   - To approve the submission as being ethically acceptable,
   - To approve the submission as being ethically acceptable, after a satisfactory response has been received to the Committee's requirements for approval;
   - To not approve a submission and invite the Co-ordinating Principal Investigator to make a new submission for the research project. The Committee will provide comments to guide the resubmission; or

- To reject a submission because it cannot be designed to comply with the requirements of the *National Statement*.

10. The HNEHREC will endeavor to reach a decision concerning the ethical acceptability of a proposal by unanimous agreement. Members present will be allowed reasonable opportunity to express relevant views on matters on the agenda.

11. Where a unanimous decision cannot be reached, the Chair will need to 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.

12. Any significant minority view will be noted in the minutes.

13. In order to facilitate consideration of an application, the HREC may invite the applicant to be present at the relevant meeting for its discussion and to answer questions.

14. For submissions where the HNEHREC has requested clarification, the provision of further information, or minor modification of the project prior to approval, the HNEHREC may choose to delegate the authority to review that information and approve the project between meetings to one of the following:
    - The Manager Research Ethics alone;
    - The Manager Research Ethics in consultations with the Reviewers; or
    - The Manager Research Ethics in consultation with the Reviewers, Chair and/or Deputy Chair.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 015 **Date:** June 2022

Subject: Review of multi-centre research

Purpose: To describe the procedure for the reviewing by the HREC of multi-centre research.

1. With regards to multi-centre applications submitted under NMA: the HNEHREC may review applications from interstate institutions or organisations within the scope of a scheme of National Mutual Acceptance of Ethical and Scientific Review entered into by NSW Ministry of Health.

2. All amendments, safety and annual reporting and any other communications will be from the Co-ordinating Principal Investigator at the lead site to the HREC. Where necessary, for example, a cumulative report of all relevant information from each site, for example annual reporting, will be provided by the Co-ordinating Principal Investigator.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 016 **Date:** June 2022

Subject: Preparation of HNEHREC minutes

Purpose: To describe the process and format for minutes of a meeting of the HREC.

1. The Manager Research Ethics or their delegate will prepare and maintain minutes of all meetings of the HREC.

2. The format of the minutes will include at least the following items:
    - Acknowledgment of Country
    - Attendance;
    - Apologies;
    - General Business
        - Minutes of the previous meeting;
        - Business arising from the previous minutes;
        - Research Ethics Report;
    - New applications previously reviewed by the CTSC;
    - New applications requiring HREC review only;
    - LNR applications reviewed under expedited review processes (see SOP 012);
    - Amendments to approved applications reviewed by the Chair, Deputy Chair, another HREC Member or the Manager Research Ethics out of session (see SOP020 for the management of amendments);
    - Final reports received since the last HREC minutes;
    - Correspondence (including safety reporting see SOP 021); and
    - Other business.

3. The minutes should record the decisions made by the HNEHREC in relation to new submissions or amendments for the minutes shall record a summary of the main ethical issues considered, requests for additional information, clarification or modification of the project and requests for amendments/modifications to any documentation submitted with the application prior to approval, any additional conditions of approval, and specify the process for reviewing the response as delegated by the Committee which could be: one of the following:
    - The Manager Research Ethics alone;
    - The Manager Research Ethics in consultations with the Reviewers; or
    - The Manager Research Ethics in consultation with the Reviewers, Chair and/or Deputy Chair.

4. Where absent members provided reviews or comment on any agenda items, this should be noted against that agenda item.

5. Where the HREC's decision in relation to a new submission is that the Co-ordinating Principal Investigator be invited to make a new submission for that research project, a list of specific issues and concerns and how they relate to the requirements of *the National Statement* must be recorded.

6. In recording a decision made by the HREC, any significant minority view will be noted.

7. To encourage free and open discussion and to emphasize the collegial character of the HNEHREC, particular views should not be attributed to individuals in the minutes, except in circumstances where a member seeks to have his/her opinions or objections recorded.

8 Declarations of conflicts of interest by any member of the HREC and the absence of the member concerned during the HREC consideration of the relevant application, will be minutes (refer to SOP013] regarding management of a member's declaration of a conflict of interest).

9. The final approval of an application, approval of amendments outside of the meetings in accordance with SOP020 and safety reviews SOP 021, will be recorded for ratification by the full HNEHREC membership.

10. 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.

11. If for some reason, a HNEHREC meeting is not quorate, ratification of the minutes of a previous HNEHREC minutes will be held over to a meeting which is quorate as per SOP017.

11. The original copy of each meeting's minutes will be retained in an electronic confidential 'Minutes' file on the HNE Research Office password protected file share and in REGIS in the Meeting where the Minutes are ratified.

14. The minutes of each Committee meeting will be available on request to the Director of Research and the Chief Executive, HNELHD.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 017 **Date:** June 2022

Subject: Expedited Review of Low Risk Research

Purpose: To describe the procedure for the Expedited Review of Low Risk Research

1. The Manager Research Ethics or delegate determines the level of review required when undertaking the Eligibility Check in REGIS in accordance with section 5.1.18 - 5.1.21 of the National Statement and guidance from the NSW Ministry of Health's Office of Health and Medical Research.

2. Applications are reviewed by the two members of the HNEHREC with the relevant expertise or experience in reviewing that type of application and the Manager Research Ethics.

3. The nominated reviewers will submit their reviews in REGIS and the Manager Research Ethics will consolidate these comments.
    - If the comments are substantive then a teleconference may be convened to discuss the issues.
    - The Manager Research Ethics may seek clarification from reviewers/s regarding their comments.
    - The Chair, nominated reviewer(s) and/or the Manager Research Ethics and Governance may decide the submission requires review by the full HNEHREC at a meeting.

4. Once collated, any comments or requirements for approval will be sent to the applicant through REGIS for a response.

5. The applicant will submit their response to the requirements for approval through REGIS.

6. The response will be reviewed by the Manager Research Ethics in consultation with the reviewers if necessary.

7. Once the requirements for approval are met, the approval email will be issued via REGIS and approval of the project listed on the agenda for the next HNEHREC meeting for ratification.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 018 **Date:** June 2022

Subject: Notification of decisions of the HNEHREC for new submissions

Purpose: To describe the procedure for the notification of decisions of the HNEHREC concerning the review of new applications.

1. The Co-ordinating Principal Investigator will be advised via REGIS of the outcome of the HNEHREC review of their submission within 7 working days of the meetin. Any delays will be advised via email.

2. If the HNEHREC determines that further information, clarification or modification is required for the consideration of a submission, the correspondence to the Co-ordinating Principal Investigator should clearly articulate the reasons for this determination, and clearly set out the information that is required. Where possible, requests for additional information/clarification/modification will refer to the *National Statement* or relevant legislation. This correspondence will be sent via REGIS.

3. The HNEHREC shall whenever possible to openly communicate with researchers to resolve outstanding requests for further information, clarification or modification of their submissions, relating to ethical issues. The HNEHREC may nominate the Manager Research Ethics or one of its members to communicate directly with the researchers, or inviting the researchers to attend the relevant HNEHREC meeting. In addition, the Chair of the HNE HREC, the Chair of the CTSC, the Manager Research Ethics, and other institutional members of the CTSC or HNEHREC are available to speak with researchers about applications and matters arising from review of research proposals. This is arranged via consultation with the Manager Research Ethics.

4. There will be no direct communication between the HNEHREC and the sponsor of a research proposal. Such communication shall be via the researcher. However, communication between a sponsor and the Manager Research Ethics in relation to regulatory requirements and other procedural matters is permitted, in order to facilitate the timely review of research.

5. An application will be approved by the HNEHREC once all outstanding requests for further information, clarification or modification have been satisfactorily resolved. Notification of ethical approval will be through REGIS and will contain the following information:

    - Title of project;
    - Name of the Co-ordinating Principal Investigator;
    - The version number and date of all documentation reviewed and approved by the HREC including but not limited to Clinical Protocols, Participant Information Sheets, Consent Forms, Advertisements, Questionnaires;
    - Date of HNEHREC meeting at which the project was first considered;
    - Date of HREC approval;
    - Duration of HREC approval; and
    - Annual and Safety reporting requirements;

- Any additional conditions of approval as specified by the HNEHREC at the time of review.

6. An application may be “Approved with Conditions”, with those conditions being specified in the approval email sent form REGIS. Whilst the relevant conditions will be project specific, examples include:
    - The project not commencing until approval has also been obtained from the NSW Aboriginal Health and Medical Research Council’s Human Research Ethics Committee;
    - Additional Monitoring requirements

7. If the HNEHREC determines that a project is ethically unacceptable, the notification of the HREC’s decision will include the grounds for rejecting the project with reference to the *National Statement* and any relevant legislation.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 019 **Date:** June 2022

Subject: Monitoring of approved research projects

Purpose: To describe the procedure for monitoring research projects approved by the HNEHREC to ensure compliance with ethical approval.

1. In accordance with chapter 5.5 of the *National Statement,* the HNEHREC will monitor approved projects to ensure compliance with the conditions of approval and to protect the rights, safety and welfare of participants. In doing so, it may request and discuss information on any relevant aspects of the project with the investigators at any time.

2. The HNEHREC will, as a condition of approval of each project, require that investigators immediately report anything which might warrant review of ethical approval of the project including:

    - proposed changes in the research protocol or conduct;
    - unforeseen events that might affect continued ethical acceptability of the project;
    - serious or unexpected adverse events; and
    - if the project is abandoned for any reason.

3. Monitoring by the HNEHREC includes review of annual progress reports. The HNEHREC shall require the following information in the annual report:

    - progress to date or outcome in the case of completed research;
    - intended progress for the next 12 month reporting period;
    - maintenance and security of records;
    - ongoing compliance with the approved protocol; and
    - compliance with any conditions of approval.

    The Co-ordinating Principle Investigator will be advised through their list of milestones in REGIS when the annual report for a project is due. The report must be submitted through REGIS.

4. The Co-ordinating Principle Investigator must provide a final report upon completion of the project. This report should include a summary of the results and a plan for the dissemination of the results. The report should be submitted as a Milestone through REGIS

5. The HNEHREC may adopt any additional appropriate mechanisms for monitoring, as deemed necessary, depending on the complexity, design and risk perceived. These include:

    - Discussion of relevant aspects of the project with the investigators at any time;
    - Random inspection of research sites, data or consent documentation;
    - Interview research participants or other forms of feedback from them; and
    - Request and review reports from independent agencies such as Data & Safety Monitoring Boards.

6. Where the HNEHREC is satisfied that circumstances have arisen such that a research project is not being or cannot be conducted in accordance with the approved protocol, the HREC may withdraw approval. In such circumstances, the HREC shall inform the Co-ordinating Principal Investigator of such withdrawal of approval in writing.

7. In determining the frequency and type of monitoring required for approved projects, the HNEHREC will give consideration to the degree of risk to participants in the research project.

8. The HNEHREC 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.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 020 **Date:** June 2022

Subject: Submission and Review of amendments to projects approved by the HNEHREC

Purpose: To describe the procedure for the submission and HNEHREC review of requests for amendments and extensions to approved protocols.

1. Proposed changes to approved research projects, changes to the conduct of the research, or requests for extensions to the length of HREC approval, are required to be submitted by the Co-ordinating Principal Investigator through REGIS and be approved prior to implementation.

2. Contingent on the proposed amendment, it should be submitted using one of the following forms in REGIS:

    - General Amendment
    - Addition of a New Site
    - Change of CPI/PI
    - Extension of Approval

3. Requests shall outline the nature of the proposed changes and/or request for extension, reason/s for the request, and an assessment of any ethical implications arising from the request on the conduct of the research. Cleaned and tracked versions of any revised documents with updated version numbers and dates, must be uploaded into REGIS as part of the amendment submission.

4. The review and approval process for subsequent amendments to projects approved by the HNEHREC is contingent of the type and complexity of the amendment.

Review Process	Type of Variation
Review by Manager Research Ethics	• New Research Personnel • Additional sites • Addition of standardised survey instruments in line with aims of study • Minor administrative changes to protocols, or recruitment documentation • The addition/removal of approved Standardised assessment tools • Requests for Extension of Approval
Review by the HREC Chair with advice from the Manager Research Ethics (Note: the HREC Chair can refer an amendment to another HREC member, the CTSC Chair, a CTSC member or the full HREC Committee)	• New Participant Cohorts (including the addition of controls) • Protocol Amendments • Significant adjustments to recruitment and/or consent processes • Addition of non-standardised assessment tools
HREC Chair and Legal member	• Amendments involving requests for a waiver of consent
Review by Deputy Chair	• Any amendment where the HREC Chair has a conflict of interest • Any amendment where the HREC Chair seeks a second opinion
CTSC Chair/Members	• Complex Amendments to the Protocol as referred by the HREC Chair • Investigational Brochures and any accompanying documents (ie. revised protocols or recruitment documentation)
Full HREC Review	• Complex Sub-Studies • Addition of New Cohorts • Significant revision to the intervention • Any amendment referred by the Chair

5. If it is determined that further information, clarification or modification is required for the consideration of the request for amendment or extension of approval, the Co-ordinating Principal Investigator will be advised of these requirements and how to progress this application via REGIS.

6. The Co-ordinating Principal Investigator will be advised via REGIS of the approval of the proposed amendment and/or request for extension, within 10 working days of receipt of the application.

7. All reviewed and approved requests for amendments and extensions to a protocol shall be recorded on the Agenda for the next meeting of the HNEHREC and ratified by the Committee at the next meeting.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 021 **Date:** June 2022

Subject: Safety reporting

Purpose: To describe the procedure for the reporting and review of adverse events.

1. The HNEHREC shall require, as a condition of approval of each project, that researchers undertake safety and other adverse reporting (including protocol deviations and violations).

2. Safety reporting for clinical trials will be in line with the NHMRC Australian Health Ethics Committee (AHEC) Position Statement (May 2009): *Safety and Monitoring Clinical trials involving therapeutic products* and the NSW Health Policy Directive (PD2017_039) *Safety Monitoring and Reporting for Clinical Trials Conducted in NSW public health organisations* (released October 2017).

3. All safety reporting required under the NHMRC Guidelines and Policy at point 2 must be submitted through REGIS.

4. Protocol Deviations and Violations may be reported via an email or letter, and only need to be reported if the deviation/violation will impact on the safety of the participants or continuation of the project. These will be reviewed and acknowledged by the Manager Research Ethics.

5. Reports from Data Safety Monitoring Boards or the equivalent must be submitted throughout the life of the approved project.

6. For non-clinical trials, all safety issues must be reported within 24 hours by email to the Manager Research Ethics. The report should include:

    - A description of the event;
    - The consequences for the research participant;
    - What action was taken by the researchers;
    - Whether there are any long term circumstances; and
    - Whether a protocol amendment is required.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 022 **Date:** June 2022

Subject: Acknowledgment of documents submitted to the HREC for information

Purpose: To describe the procedure for acknowledgment of documents sent to the HREC for information.

1. The Manager Research Ethics reviews the documents and determines whether further information is required.

2. If further information is required the Manager Research Ethics will request that information via email.

3. The Manager Research Ethics will consult with the Chair as required

4, If no further information is required, the email with the document attached will be forwarded to the Co-ordinating Principal Investigator or their delegate acknowledging receipt of the document and that no further action is required.

5. The document and the acknowledgment will be uploaded into REGIS against the project.

6. Where the information has implications for the continuation of an approved project, it will be listed on the agenda for the next HREC meeting as “Correspondence” or “Other Business”.

Reference Number: SOP 023 **Date:** June 2022

Subject: HNEHREC requirements for research projects involving Investigational Devices.

Purpose: To describe the requirements of the HNEHREC for research involving Investigational Devices.

1. Where there is a possible risk to the safety of the researcher and/or the participant, the HREC may require certification of an investigational device by the relevant biomedical authority.

2. In the case of an implantable medical device, the sponsor, on behalf of the manufacturer of the investigational device is responsible for the following:

    - Ensuring that each investigational device is individually identified with a tracking number;
    - Ensuring that each device is supplied to the trial site with a registration card which includes the device's individual tracking number for completion by the clinician, with details of the trial participant into which it is implanted;
    - Collecting the completed card from the clinician following implantation of the investigational device;
    - Maintaining a register of the investigational device, including:
        - the clinical trial protocol number and title;
        - the individual tracking numbers;
        - the trial identity of the participant into whom each device is implanted, ie the participant's study number;
        - the date of device implantation;
        - details of any suspected unexpected serious adverse events experienced by the participant;
    - Reporting all serious adverse events to the Therapeutic Goods Administration (TGA).

3. In the case of an implantable medical device, the Principal Investigator at each study site is responsible for maintaining a register of the devices implanted at his/her site and recording details of the device into each study participant’s medical record.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 024 **Date:** June 2022

Subject: Early Phase Clinical Trials

Purpose: To describe the reasons why the HNEHREC will not review Early Phase Clinical Trials

1. In accordance with the NSW Health Early Phase Clinical Trials Framework, the HNEHREC will not accept submissions for ethics review of Early Phase Clinical Trials, defined as all clinical trial phases up to but not including Phase II, including studies with any Phase I component.

2. Applications of such trials will be referred to Bellberry Limited where the trial involves adult participants and Sydney Children's Hospital Network where the trial involves paediatric patients.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 025 **Date:** June 2022

Subject: Complaints about the conduct of an approved project

Purpose: To describe the mechanism for receiving, handling and responding to complaints concerning the conduct of a project approved by the HREC.

1. Any concern or complaint from a participant or any other person about the conduct of a project should be directed to the attention of the Manager Research Ethics or their delegate, who will notify the Chairperson as soon as possible.

2. The Manager Research Ethics will instigate an investigation of the complaint and make a recommendation on the appropriate course of action. The investigation will take no longer than two weeks from the time of notification of the complaint or concern, unless exceptional circumstance exists. The Manager Research Ethics will keep the Chairperson informed about the progress and outcome of the investigation. If the complaint is substantiated, action may include the requirement for amendments to the project, including increased monitoring by the HREC, suspension of the project, termination of the project, or other action to resolve the complaint.

3. The complainant will receive a written response, if appropriate, from the Manager Research Ethics advising of the outcome of the investigation. The details of the complaint and the outcome of the investigation will be included in the Research Ethics report at the next HNEHREC meeting.

4. If the complainant is not satisfied with the outcome of the investigation, then he/she can refer the complaint to the Chief Executive or his/her nominee, or request the Chairperson to do so.

5. The Chairperson of the HREC will provide the Chief Executive or his/her nominee with all relevant information about the complaint/concern, including:
   - the complaint;
   - material reviewed in the investigation;
   - the results of the investigation; and
   - any other relevant documentation.

6. The Chief Executive will determine whether there is to be a further investigation of the complaint. Where there is no further investigation, the Chief Executive will inform the complainant and the Chairperson of this.

7. If the Chief Executive determines there is to be a further investigation, then he/she will convene a suitable panel to consider the complaint.

8. The panel will include, at least, the following members:
   - The Chief Executive or his/her nominee as convener of the panel;
   - Two nominees of the Chief Executive (not members of the HREC); and
   - The Manager Research Ethics.

9. The panel will afford the HREC and complainant the opportunity to make submissions.

10. The panel may access any documents relating to the project. The panel may interview other parties, and seek internal and external expert advice as it sees fit.

11. The Chief Executive will notify the complainant and the Chairperson of the outcome of the investigation, and the investigator if an allegation is against them. The outcomes may include:
    - The complaint/concern is dismissed; or
    - The Chief Executive directs appropriate action to be taken to resolve the complaint.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 026 **Date:** June 2022

Subject: Complaints concerning the HREC's review process

Purpose: To describe the procedure for receiving and handling concerns or complaints from investigators about the HREC's review process.

1. Any concern or complaint about the HNEHREC's review process should be directed to the attention of the Chairperson, detailing in writing the grounds of the concern or complaint. Complaints may also be made to the Chief Executive or their delegate.

2. The Chairperson will inform the Chief Executive or their delegate as soon as possible of any complaints received by him/her. The Chief Executive will inform the Chairperson as soon as possible of any complaints received by him/her.

3. The Chairperson will instigate an investigation of the complaint and its validity, and make a recommendation to the HNEHREC on the appropriate course of action. This investigation shall take no longer than 2 weeks from the time of notification of the complaint or concern, unless exceptional circumstances exist.

4. The complainant will receive a written response, if appropriate, from the HNEHREC advising of the outcome of the Chairperson's investigation.

5. 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.

6. The Chairperson of the HNEHREC will provide the Chief Executive with all relevant information about the complaint/concern, including:
   - The complaint;
   - Material reviewed in the Chairperson's investigation;
   - The results of the Chairperson's investigation; and
   - Any other relevant documentation.

7. The Chief Executive will determine whether there is to be a further investigation of the complaint.

8. If the Chief Executive determines there is to be a further investigation, then he/she will convene a suitable panel to consider the complaint/concern. Where there is to be no further investigation, the Chief Executive will inform the complainant and the Chairperson of this.

9. The panel will include, at least, the following members:

   - The Chief Executive or his/her nominee as convener of the panel; and
   - Two nominees of the Chief Executive (not members of the HREC).

10. The panel will afford the HREC and the complainant the opportunity to make submissions.

11. The panel may access any documents relating to the project. The panel may interview other parties, including internal and external expert advisors. In conducting its review, the panel shall be concerned with ascertaining whether the HNEHREC acted in accordance with the *National Statement*, its Terms of Reference, Standard Operating Procedures, or otherwise acted in an unfair or unbiased manner.

12. The Chief Executive or their delegate will notify the complainant and the HREC of the outcome of the investigation. The outcomes of this process may include:
    - The complaint/concern is dismissed; or
    - The complaint/concern is referred back to the HREC for consideration, bearing in mind the findings of the panel.

13. The panel may also make recommendations about the operation of the HREC including such actions as:
    - Review Terms of Reference and Standard Operating Procedures;
    - Review committee membership; and
    - Take other action as appropriate.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 027 **Date:** June 2022

Subject: Complaints concerning the HNEHREC's decision in relation to an application

Purpose: To describe the procedure for receiving and handling complaints about the HREC's rejection of an application.

1. A person with a concern or complaint about the HNEHREC's rejection of their submission should detail the grounds of the concern or complaint in writing and bring it to the attention of the Chairperson of the HREC. Complaints may also be made to the Chief Executive.

2. The Chairperson will bring to the attention of the Chief Executive as soon as possible any complaints received by him/her. The Chief Executive will inform the Chairperson as soon as possible of any complaints received by him/her.

3. The Chairperson will instigate an investigation of the complaint and its validity, and make a recommendation to the HNEHREC on the appropriate course of action. This investigation shall take no longer than 2 weeks from the time of notification of the complaint or concern, unless exceptional circumstances exist.

4. The complainant will receive a written response, if appropriate, from the HNEHREC advising of the outcome of the Chairperson's investigation.

5. 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.

6. The Chairperson of the HNEHREC will provide the Chief Executive with all relevant information about the complaint, including:

    - the complaint;
    - material reviewed in the Chairperson's investigation;
    - the results of the Chairperson's investigation; and
    - any other relevant documentation.

7. The Chief Executive will determine whether there is to be a further investigation of the complaint.

8. If the Chief Executive determines there is a case to be investigated, then he/she will convene a suitable panel to consider the complaint.

9. The panel will include, at least, the following members:
    - The Chief Executive or his/her nominee as convener of the panel;
    - Two nominees of the Chief Executive (not members of the HREC); and
    - An expert/s in the discipline of research of the project under consideration.

10. The panel will afford the HREC and the complainant the opportunity to make submissions.

11. The panel may access any documents relating to the project. The panel may interview other parties, and seek any other internal and/or external expert advice.

12. The Chief Executive will notify the complainant and the HREC of the outcome of the investigation. The outcomes of this process may include:

    - The complaint/concern is dismissed; The complaint/concern is referred back to the HREC for consideration, bearing in mind the findings of the panel; or
    - The application may be referred for external review by an independent HREC if the Chief Executive concludes that due process has not been followed. The independent HREC will make a recommendation to the Chief Executive.

13. Should the HNEHREC be requested to review its decision, then the outcome of this review by the HNEHREC will be final.

14. The panel or Chief Executive cannot substitute its approval for the approval of the HREC.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 028 **Date:** June 2022

Subject: Complaints about the HNEHREC's approval of an application

Purpose: To describe the procedure for receiving and handling complaints about the HNEHREC's approval of an application.

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 should be lodged with the Chairperson in the first instance.

2. The Manager Research Ethics will review the information in relation to the protocol and prepare a summary including the details of the concerns raised in relation to the HRECs approval of the research. Where necessary, discussions will be held with the relevant stakeholders and may include the HREC Chair

3. The complaint will be discussed at the next meeting of the HNEHREC and the complainant advised of the outcome.

4. If the HNEHREC's review of the decision indicates that amendments are required to the approved protocol, the Co-ordinating Principal Investigator of that project will be advised of the necessary amendments, the timeline for submitting the amendment and whether the research needs to be suspended until the amendments are approved.

5. The stakeholder raising the issue will be advised of the outcome and if they are not satisfied may raise their concerns with the Director of Research

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 029 **Date:** June 2022

Subject: Complaints about the conduct of HREC members

Purpose: To describe the procedure for managing complaints about the conduct of HREC members

Complaints about the conduct of an HREC member are managed by the Chief Executive, or their Delegate who will inform the Chairperson of the complaint in accordance with the HNELHD standard procedures.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 030 **Date:** June 2022

Subject: Record keeping

Purpose: To describe the procedure for the preparation and maintenance of records of the HREC's activities.

1. A register of all the applications received and reviewed shall be maintained in accordance with the NHMRC *National Statement on Ethical Conduct in Human Research 2007*.(updated 2018) This is done within the REGIS IT platform The records and which at a minimum will contain the following information:

    - unique project identification number;
    - the Co-ordinating Principal Investigator;
    - the name of the responsible Institution or Organisation;
    - title of the project;
    - ethical approval or non-approval with date;
    - approval or non-approval of any changes to the project;
    - the terms and conditions, if any, of approval of the project;
    - whether approval was by expedited review;
    - action taken by the HREC to monitor the conduct of the research;
    - the sites where the study will be conducted;
    - any amendments and the associated documentation to the original submission with the corresponding approval;
    - any safety reporting; and
    - annual and final reports.

    The electronic file shall contain a copy of the application, including signatures, and any relevant correspondence including that between the applicant and the HREC, all approved documents and other material used to inform potential research participants.

2. All relevant records of the HREC, including applications, membership, minutes and correspondence, will be kept as confidential files in accordance with the requirements of the *State Records Act 1998.*

3. Data pertaining to research projects shall be held for sufficient time to allow for future reference. The minimum period for retention for non-clinical research is at least 5 years after the date of publication or completion of the research, or termination of the study. For clinical research, 15 years shall apply. Retention periods shall comply with NSW Health *'Information Bulletin 2004/20 General Retention and Disposal Authority – Public Health Services: Patient/Client Records (GDA 17)'.*

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Reference Number: SOP 031 **Date:** June 2022

Subject: Authorised Prescriber applications

Purpose: To describe the procedure for the review and approval of access to unapproved therapeutic goods via Authorised Prescribers.

1. The Authorised Prescriber Scheme allows authorised **medical practitioners** to supply therapeutic goods (such as medicines, medical devices or biologicals) that are not included in the Australian Register of Therapeutic Goods (ARTG) to a class of patients with a particular medical condition.

2. There are 2 pathways to apply to become an Authorised Prescriber, depending on the product to be prescribed. There are the Established History of Use Pathway and the Standard pathway. Approval from a HREC is only required for the Standard Pathway

3. The 'Standard pathway' requires a 2-step application process for products that are not included in sub regulation 12B(1B) and 12B(1C) of the *Therapeutic Goods Regulations 1990*.

4. Approval from a human research ethics committee (HREC) or endorsement by specialist college **must be obtained** before applying to the TGA.

5. Applications under s19(5) of the Therapeutic Goods Act for HNELHD clinicians to become authorised prescribers will be considered by the Chairperson or Deputy Chair of the CTSC where necessary.

6. When considering a proposal by a medical practitioner to become an Authorised Prescriber, the CTSC Chairperson shall undertake an assessment of the following, in accordance with the *Therapeutic Goods Act 1989* and associated regulations*:

    - the safety of the product in relation to its proposed use;
    - the suitability of the medical practitioner; and
    - information to be given to the patient about the product and the informed consent form.

7. If endorsed, the Manager Research Ethics shall provide a letter of endorsement to the applicant in the format suggested by the Therapeutic Goods Administration [Note: Refer to Access to Unapproved Therapeutic Goods – Authorised Prescribers, November 2009]. The HREC may impose any conditions on the endorsement such as:

    - a requirement that regular reports be provided to the HREC containing such information as, the number of patients for whom the unapproved product has been prescribed; and
    - requirements for reporting of any adverse events.

8. The HREC shall review its endorsement of the Authorised Prescriber if it becomes aware of:

    - inappropriate use of the product by the Authorised Prescriber;

- a concern about the safety of the product;
- failure of the Authorised Prescriber to comply with conditions imposed by the HREC; or
- failure of the Authorised Prescriber to comply with State/Territory legislation.

9. The HREC may withdraw its endorsement of the Authorised Prescriber if it is concerned that the welfare and/or rights of patients are not or will not be protected. The HREC shall advise the medical practitioner and the Chief Executive of its concerns in the first instance. The Chief Executive and the Chairperson of the HREC, shall jointly determine whether to contact the Therapeutic Goods Administration.

Detailed information on the application process is found in Authorised Prescriber Scheme - Guidance for medical practitioners, Human Research Ethics Committees, specialist colleges and sponsors and Guidance for the Authorised Prescriber Online System

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 033 **Date:** June 2022

Subject: Review of Standard Operating Procedures and Terms of Reference

Purpose: To describe the procedure for the approval of amendments to the HREC Standard Operating Procedures and Terms of Reference.

1. The Standard Operating Procedures and Terms of Reference shall be reviewed at least every five years and amended as necessary in consultation with the HNEHREC.

2. The revised Standard Operating Procedure shall be circulated for comment at the CTSC and the HNEHREC meetings.

3. Where minor updates are required prior to the next review date these can be approved by the HRECHREC Chair, who may refer the changes to the full Committee

4. Once all comments have been incorporated into the revised Standard Operating Procedures, they will be listed on the HNEHREC agenda for endorsement by the Committee.

5. The Revised Standard Operating Procedures and Terms of Reference will be uploaded to the HNE Research office website.