HUNTER NEW ENGLAND
HUMAN RESEARCH ETHICS COMMITTEE
STANDARD OPERATING PROCEDURES

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KEY DEFINITIONS

APREG – Australian Paediatric Research Ethics and Governance Network

CTSC — The Sub-Committee of the Hunter New England Human Research Ethics Committee which assesses clinical drug trials/interventional research involving humans to determine whether or not the research is scientifically valid, and advises the HREC accordingly.

HREC – Human Research Ethics Committee

HNELHD – Hunter New England Local Health District

NHMRC – National Health and Medical Research Council

NEAF - National Ethics Application Form

National Statement – the *National Statement on Ethical Conduct in Human Research (2007)* incorporating all updates.

RIAC – Research Innovation and Advisory Council **-** Purpose: To provide leadership, integration and direction for Research and innovative activities across Hunter New England Health.

RSDO – Research Support and Development Office

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 001 **Date**: December 2015

Subject: Human Research Ethics Committee (HREC)

Purpose: To describe the objectives, function, accountability and scope of responsibility of the HREC

1. OBJECTIVES

The objectives of the Human Research Ethics Committee (HREC) are:

1.1 To protect the mental and physical welfare, rights, dignity and safety of participants in research.

1.2 To facilitate ethical research through efficient and effective review processes.

1.3 To promote ethical principles in human research.

1.4 To review research in accordance with the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (2007), incorporating all updates.

2. FUNCTIONS

The functions of the Human Research Ethics Committee (HREC) are:

2.1 To provide independent oversight of human research projects; and

2.2 To provide competent, timely review and monitoring of human research projects in respect of their ethical and scientific acceptability for as long as the projects are active; and

2.3 To determine the compliance of a human research project with the National Statement and grant, withhold or withdraw ethical approval; and

2.4 To provide advice on strategies to promote awareness of the ethical conduct of human research.

3. SCOPE OF RESPONSIBILITY

The responsibilities of the Human Research Ethics Committee (HREC) are to:

3.1 Review human research applications where the research is undertaken:

- Within Hunter New England Local Health District facilities;
- By HNE Employees; and/or
- By 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 on behalf of the HREC.

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

4.1 The HREC 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, following confirmation by the HREC.

4.2 A copy of the minutes shall be made available to the Director Research, Innovation and Partnerships

4.3 The HREC shall provide an annual report to the Chief Executive at the end of each calendar year, which will include information on membership and the number of proposals reviewed. A copy of this report shall also be forwarded to the Director Research Innovation and Partnerships

4.4 The HREC may from time to time bring to the attention of the Chief Executive issues of significant concern. Where appropriate, such issues will be first discussed at the HNE Research & Innovation Advisory Council.

4.5 The HREC will provide the following annual reports:

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

4.6 The HREC Terms of Reference, Standard Operating Procedures and membership will be available upon request to the general public and will be posted on the Hunter New England Local Health District Research Support and Development Office website.

4.7 Monitoring Measures: The HREC will undertake its review in a timely and efficient manner and have mechanisms to monitor and evaluate its own performance.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 002 **Date:** December 2015

Subject: Membership composition

Purpose: To describe the membership composition of the HREC

1. The composition of the HREC is in accordance with the National Statement on Ethical Conduct in Human Research (2007) 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 Hunter New England Local Health District. 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 HREC to address all the relevant considerations arising from the categories of research 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, an Aboriginal Health Worker based in the LHD or Community Member 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 Aboriginal Research targeting Aboriginal and Torres Strait Islander Peoples

5. Where required, the HREC may seek advice and assistance from appropriate experts to assist with the review of a project. However, the HREC must be satisfied that such experts have no conflicts of interest in relation to the project under consideration arising from any personal involvement or participation in the project, 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.

Hunter New England Human Research Ethics Committee
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Reference Number: SOP 003 **Date:** December 2015

Subject: Appointment of Members

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 by advertisement. Prospective members shall be asked to provide a copy of their Curriculum Vitae.

3. A prospective member will be provided with background information for consideration including the Committee's Terms of Reference, a statement of members responsibilities, a copy of the National Statement on Ethical Conduct in Human Research (2007) and invited to meet with the Executive Officer and/or the Chair for a preliminary discussion and then be invited to attend a meeting of the HREC as an observer.

4. All members including the Chairperson, Deputy Chairperson and Chairperson of any subcommittee are appointed by the Chief Executive and will receive a formal notice of appointment.

5. 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.

6. A new member will be required to sign a confidentiality undertaking (see Attachment A) 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.

7. Upon appointment, members shall be provided with the following:

    - A list of the members' names and their roles on the committee
    - Responsibilities of Members of the Hunter New England Human Research Ethics Committee
    - Health Records and Information Privacy Act 2002
    - Human Research Ethics Committees and the Therapeutic Goods Legislation
    - A copy of the NHMRC National Statement on Ethical Conduct in Human Research
    - The Committee's Terms of Reference
    - The meeting dates any other relevant information about the HREC's processes, procedures and protocols

8. 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.

9. The Chairperson, Deputy Chairperson and Chairperson of any subcommittee may serve longer terms with the approval of the Chief Executive or Delegate.

10. 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.

11. Hunter New England Local Health District 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.

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

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

14. Members will be expected to participate in relevant specialised working groups as required. The Chairperson will be expected to be available between meetings to participate in Executive Meetings where required.

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

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

17. 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 an HREC; or
    - the person has failed to carry out their duties as an HREC member.

18. Hunter New England Local Health District 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.

Hunter New England Human Research Ethics Committee
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Reference Number: SOP 004 **Date:** December 2015

Subject: Orientation of new members

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

1. New HREC members must be provided with adequate orientation.

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

    - Introduction to other HREC members prior to the HREC meeting
    - 'Partnering' with another HREC member in the same category for mentoring and coaching purposes
    - Further meetings with the Executive Officer to discuss HREC processes and members responsibilities
    - Priority given to participate in training sessions

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 005 **Date:** December 2015

Subject: Training and Education of HREC members

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

Every member of the HREC should aim to attend at least one training session relation to HREC activities every three years, with all cost being covered by the Hunger New England Local Health District.

Training courses provided by NSW Ministry of Health or the NH&MRC (National Health & Medical Research Council) are examples of suitable educational forums.

Online Training courses such as those offered through Universities or Specialist Organisations such as PRAXIS would also fulfill this requirement.

Hunter New England Human Research Ethics Committee
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Reference Number: SOP 006 **Date:** December 2015

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 to the RSDO, by close of business on the relevant closing date. The closing date for receipt of new applications for the next HREC agenda shall be readily available to prospective applicants at least six months in advance.

2. The closing dates for applications should normally be at least 14 days prior to each HREC meeting.

3. Applications must be submitted in the appropriate format as determined by the HREC, and shall include all documentation as required by the HREC. The procedures for application to the HREC and the application format shall be readily available to applicants.

4. As part of the Hunter New England Local Health District's commitment to Closing the Gap, for those applications for research targeting Aboriginal and Torres Strait Islander people, a separate document is required demonstrating the researchers commitment to cultural sensitivity and safety for Aboriginal and Torres Strait Islander research participants.

5. Guidelines shall be issued by the HREC to assist applicants in the preparation of their applications, including guidance on how to determine whether application to the Human Research Ethics Committee is necessary.

6. A fee will be charged for HREC review of commercially-sponsored clinical trials, in line with NSW Health Document Number PD2008_030 *"HREC and Research Governance: Fee Policy for Review of Commercially Sponsored Research"*. The fee policy shall be made available to applicants prior to submission of an application to the HREC.

Hunter New England Human Research Ethics Committee
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Reference Number: SOP 007 **Date:** December 2015

Subject: Processing of applications for review

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

1. Applications will be checked for their completeness by the Executive Officer or their delegate prior to their acceptance onto the agenda. Incomplete applications will be returned to the applicant.

2. The Executive Officer or their delegate will determine whether or not the application requires review by the Clinical Trials Sub-Committee prior to being considered by the HREC.

3. Once a completed application has been accepted for ethical review, a unique HREC reference number to the project and a file will be established in the electronic filing system and all documents associated with the application filed accordingly. The project will be added to the HREC's register of received and reviewed applications and also to any and all IT Platforms as required under the National Mutual Acceptance scheme for multicenter ethics and scientific review or subsequent co-operative interstate arrangements.

4. The Ethics Administration Officer will acknowledge acceptance of the application for ethical review by issuing an acknowledgement letter to the principal investigator within 7 days of receipt of the application. The acknowledgement letter shall include the date of the meeting at which the application will be reviewed, as well as the unique project identification number given by the HREC to the project.

5. The application will be included on the agenda for the next available HREC meeting provided it is received by the relevant closing date and is complete. If necessary the protocol will also be included on the Agenda of the next meeting of the Clinical Trials Sub-Committee.

6. If a substantial number of applications are received, some applications may need to be deferred to the following HREC meeting. If this occurs, applications will be reviewed in order of receipt. Urgent applications may be given priority at the discretion of the Chairperson.

7. Applicants will be made aware that there study has been deferred and will be given the opportunity to withdraw it and submit to another HREC if appropriate.

Hunter New England Human Research Ethics Committee
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Reference Number: SOP 008 **Date:** December 2015

Subject: Preparation of agenda

Purpose: To describe the process and format of agenda for an HREC meeting

1. The Executive Officer or their delegate will prepare an agenda for each HREC meeting.

2. All completed applications and relevant documents received by the Executive Officer will be included on the agenda for HREC consideration at its next available meeting.

3. The meeting agenda and associated documents will be prepared by the Executive Officer or their delegate and circulated to all HREC members 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. Agenda items will include at least the following items:

    i) Apologies;
    ii) Minutes of the previous meeting;
    iii) Business arising from the previous minutes;
    iv) Research Ethics Report;
    v) New applications previously reviewed by the CTSC ;
    vi) New applications requiring HREC review only;
    vii) LNR applications reviewed under expedited review processes (see SOP 012);
    viii) Renewal applications reviewed and approved by the Chair, Deputy Chair or another HREC Member out of session;
    ix) Variations to approved applications by the Chair, Deputy Chair or another HREC Member out of session;
    x) SAE and other Safety reporting reviewed by a CTSC or HREC member out of session
    xi) Final reports received since the last HREC minutes
    xii) Correspondence; and
    xiii) Other business.

6. The agenda and all documentation shall remain confidential.

Hunter New England Human Research Ethics Committee
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Reference Number: SOP 009 **Date:** December 2015

Subject: Conduct of meetings

Purpose: To describe the format of meetings of the HREC

1. The HREC shall meet on a regular basis, which will normally be at monthly intervals. Meeting dates and agenda closing dates shall be publicly available.

2. Members may attend HREC meetings in person or via tele or video conference link.

3. The Chairperson may cancel a scheduled meeting if a quorum cannot be achieved (refer to Point 7). Should this occur, the HREC will convene within 5 working days of the cancelled meeting to ensure all agenda items are considered. Alternatively, if the Chairperson decides the meeting should proceed, all decisions will be interim and endorsed at the next quorate meeting.

4. 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 HREC must be ratified by at least one representative from those membership categories not present.

5. Meetings will be scheduled for an allocated time. If the business has not been completed within the allocated time, then the HREC 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.

6. The HREC meeting will be conducted in private, to ensure confidentiality and open discussion. Members will be advised of the meeting room details in the meeting agenda.

7. Notwithstanding paragraph 5, the HREC may agree to the presence of visitors or observers to a meeting. Such visitors (eg expert reviewers) and observers will be asked to sign a Confidentiality Agreement, unless they are a named researcher on the proposal under consideration.

8. There will be no direct communication between the HREC and the sponsor of a research proposal. Such communication shall be via the researcher. However, communication between a sponsor and the Executive Officer in relation to regulatory requirements and other procedural matters is permitted, in order to facilitate the timely review of research.

9. Members may make prior submissions of written comments so that where there is less than a full attendance of the minimum membership the meeting may still proceed if the Chairperson is satisfied that the views of those absent who belong to the minimum membership have been received and considered.

10. The minutes should record the submission of written comments from absent members.

11. Any member of the HREC who has any interest, financial or otherwise, in a project or other related matter(s) considered by the HREC, should declare such interest. This will be dealt with in accordance with SOP 027.

Hunter New England Human Research Ethics Committee
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Reference Number: SOP 010 **Date:** December 2015

Subject: Consideration of applications for ethical review by the HREC

Purpose: To describe the process of the HREC's consideration of applications for ethical assessment

1. The HREC will consider a new application at its next available meeting provided that the application is received by the relevant closing date.

2. The application will be reviewed by all members of the HREC present at the meeting or providing written comments in lieu of attendance.

3. Each application will be assigned two reviewers (if the application has already been reviewed by the Clinical Trials Subcommittee) or three reviewers who will provide a detailed review of each submission.

4. The HREC will deal with multi-centre research applications in accordance with SOP 023.

5. The HREC will ethically assess each application in accordance with the NHMRC *National Statement on Ethical Conduct in Human Research 2007* The HREC must ensure that it is sufficiently informed on all aspects of a research protocol, including its scientific validity, in order to make an ethical assessment.

6. Where relevent, the HREC 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 HREC will consider whether an advocate for any participant or group of participants should be invited to the HREC meeting to ensure informed decision-making.

8. The HREC, after consideration of an application at a meeting, will make one of the following decisions:

    - It will approve the project as being ethically acceptable, with or without conditions; or
    - It will defer making a decision on the project until the clarification of information or the provision of further information to the HREC; or
    - It will request the project be resubmitted and provide comments to guide the resubmission; or
    - It will reject the project.

9. The HREC will endeavour 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.

10. 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.

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

12. 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.

13. For projects where the HREC has requested clarification, the provision of further information, or modification of the project, the HREC may choose to delegate the authority to review that information and approve the project between meetings to one of the following:

    - The Executive Officer alone
    - The Executive Officer in consultations with the Reviewers
    - The Executive Officers in consultation with the Reviewers, Chair and/or Deputy Chair

14. Exceptionally, the HREC may decide that the information should be considered at a further meeting of the HREC.

Hunter New England Human Research Ethics Committee
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Reference Number: SOP 011 **Date:** December 2015

Subject: Preparation of minutes

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

1. The HREC Executive Officer 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:

    i) Apologies
    ii) Attendance
    iii) Minutes of the previous meeting
    iv) Research Ethics Report
    v) New applications previously reviewed by the CTSC
    vi) New applications requiring HREC review only
    vii) LNR application reviewed under expedited review processes (see SOP 012)
    viii) Renewal application reviewed and approved by the Chair, Deputy Chair or another HREC Member out of session for ratification
    ix) Variations to approved applications by the Chair, Deputy Chair or another HREC Member out of session for ratification
    x) SAE and other Safety reporting reviewed by a CTSC or HREC member out of session for noting
    xi) Final reports received since the last HREC meeting for noting
    xii) Correspondence
    xiii) Other business
    xiv) Close and Next Meeting

3. The minutes should include the recording of decisions taken by the HREC as well as a summary of relevant discussion. This includes reference to views expressed by absent members.

4. In relation to the review of new applications or amendments, the minutes shall record a summary of the main ethical issues considered, including any requests for additional information, clarification or modification of the project.

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

6. To encourage free and open discussion and to emphasize the collegiate character of the HREC, 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.

7. 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 minuted (refer to SOP027 regarding a member's declaration of a conflict of interest).

8. 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.

9. The original copy of each meeting's minutes will be retained in an electronic confidential 'Minutes' file.

10. The minutes of each Committee meeting will be available to the Director, Research Innovation and Partnerships and the Chief Executive, HNELHD

Hunter New England Human Research Ethics Committee
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Reference Number: SOP 012 **Date:** December 2015

Subject: Expedited Review of Low and Negligible Risk Research

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

1. The Executive Officer determines the level of review required and applicants must contact the Executive Officer to confirm that their application is eligible for review as Low and Negligible Risk Research in accordance with section 5.1.18 - 5.1.21 of the National Statement on Ethical Conduct in Human Research (2007)

2. Applications are reviewed by the Manager Research Ethics and Governance Executive Officer

3. The application will then be emailed to two members of the Committee with the relevant expertise or experience in reviewing that type of application.

4. The nominated reviewers will email comments back to the Executive Officer for collation:
    a. If the comments are substantive then a teleconference may be convened to discuss the issues
    b. The Chair, nominated reviewer and Manager Research Ethics and Governance may decide the application requires a submission be made to for full HREC review.

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

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

7. Once the requirements for approval are met the approval letter will be issued and the protocol listed on the agenda for the next HREC meeting for ratification.

Hunter New England Human Research Ethics Committee
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Reference Number: SOP 013 **Date:** December 2015

Subject: Scientific Sub-Committee

Purpose: To describe the role of the Clinical Trials Sub-Committee in providing expert reviews for the HREC.

1. The HREC has a Clinical Trials Sub-Committee (CTSC) which operates according to its own Terms of Reference and Standard Operating Procedures.

2. All members of the CTSC are standing members of the HREC

3. The Executive Officer will determine whether an application requires review by the CTSC prior to review by the HNEHREC.

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

5. The CTSC may defer an application if additional information is required prior to providing advice to the HREC

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

    I. Apologies
    II. Minutes of the previous meeting
    III. Business arising from the previous minutes
    IV. Research Ethics Report
    V. New applications
    VI. Correspondence
    VII. Other business

7. The Minutes of the CTSC will record the advice given by the CTSC to the HREC on each of the protocols listed on the Agenda

8. The draft Minutes from the CTSC will be circulated to the HREC members via email at least three days before the HREC meeting

9. Where necessary the Chair of the CTSC, or another member, will attend the HREC meeting to discuss any or all, of the project the CTSC has provided advice on.

Hunter New England Human Research Ethics Committee
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Reference Number: SOP 014 **Date:** December 2015

Subject: Role of Executive Officer and RSDO Staff

Purpose: To describe the role of the Executive Officer of the HREC and the RSDO Staff

1. The role of Executive Officer of the HREC will be one of the functions of the Manager for Research Support and Development. Either the Ethics and Governance Support Officer and the Ethics Administration Officer may be the Executive Officer's delegate.

2. In order to ensure the smooth operations of and timely consideration of the day to day business of the HNE Health Research Ethics Committee, the Chief Executive at the recommendation of the Hunter New England Human Research Ethics Committee has given the Executive Officer the delegated authority to:
    a. Determine whether a project needs Human Research Ethics Committee approval
    b. Determine whether an application meets the requirements to be considered by the Committee and reject any application that does not
    c. Undertake a 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 or grant a waiver of ethics review
    d. Grant extensions of approval under specific conditions
    e. Review amendments and variations to approved protocols and make recommendations to the Chair of the Hunter New England Human Research Ethics Committee
    f. To educate and advise researchers about ethical issues relating to research involving humans and the requirements of the National Statement on Ethical Conduct in Human Research (2007)
    g. Provide ethical advice and assistance to applicants and potential applicants to the Hunter New England Human Research Ethics Committee
    h. Investigate complaints to research approved by the Hunter New England Human Research Ethics Committee
    i. 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

    2. All correspondence issued on behalf of the HREC will be signed by the Executive Officer or the Executive Officer's delegate:
        a. Approval letter will be signed over the Chairperson's name
        b. Request for amendments will be signed over the Executive Officers names
        c. Notification of deferrals, request for resubmissions will be signed over the Chairperson's name

d. Advice that a project will not be approved or approval will be withdrawn will be signed by the Chairperson or Deputy Chairperson. If both are unavailable then the Executive Officer will sign over the Chairperson's name.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 015 **Date:** December 2015

Subject: Notification of decisions of the HREC for new applications

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

1. The HREC will report in writing to the Co-ordinating Principal Investigator, advising whether the application has received ethical approval (including any conditions of approval), within 10 working days of the meeting, unless otherwise notified.

2. If the HREC determines that further information, clarification or modification is required for the consideration of a project, 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 NHMRC *National Statement on Ethical Conduct in Human Research 2007* or relevant pieces of legislation.

3. The HREC shall endeavour to openly communicate with applicants to resolve outstanding requests for further information, clarification or modification of projects relating to ethical issues. The HREC may nominate one of its members to communicate directly with the applicant or by inviting the applicant to attend the relevant HREC meeting.
In addition, the Chair of the HREC, the Chair of the Scientific Sub-Committee, the Executive Officer, and other institutional members of the HREC are available to speak with researchers about applications and matters arising from review of research proposals. This is arranged via consultation with the Executive Officer.

4. If the requested information is not received from the applicant within 3 months, the project will be dismissed and the applicant will be required to re-submit the project at a later date. The applicant may request an extension of time to respond to the HRECs requirements for approval.

5. The HREC will notify the applicant of the ethical approval of a project only when all outstanding requests for further information, clarification or modification have been satisfactorily resolved. Notification of ethical approval will be in writing, and will contain the following information:

    - Title of project
    - Name of the principal investigator(s)
    - Unique HREC project identification number
    - The version number and date of all documentation reviewed and approved by the HREC including Clinical Protocols, Participant Information Sheets, Consent Forms, Advertisements, Questionnaires etc.
    - Date of HREC meeting at which the project was first considered
    - Date of HREC approval
    - Duration of HREC approval
    - Conditions of HREC approval, if any

    A standard response will be issued, in the format set out in Attachment B.

6. If the HREC 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 or other relevant pieces of legislation. A standard response will be issued, in the format set out in Attachment C.

7. The status of the project shall be updated on the HREC's register of received and reviewed applications and on all IT Platforms as required.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 016 **Date:** December 2015

Subject: Review of amendments to approved projects

Purpose: To describe the procedure for the HREC 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 to the HREC for review.

2. 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. The request for amendment must be presented on the HRECs *Application for Variation* Form which is available on the HREC's website. All amended documents must include a summary of the proposed changes, and contain revised version numbers and dates.

3. Amendments to approved research projects will generally be reviewed by the Chair with advice from the Executive Officer. Where necessary another HREC member or member of the CTSC may review an amendment as an alternative to, or in conjunction with the Chair.

4. An exception to 3 above is revised safety documentation such as Investigator's Brochures which are reviewed by a member of the CTSC, where possible the member who originally reviewed that protocol or a protocol involving that drug.

5. The HREC will report in writing to the Co-ordinating Principal Investigator, advising of the ethical approval of the proposed amendment and/or request for extension, within 10 working days of the meeting at which the request was considered.

6. A standard response will be issued, in the format set out in Attachment D.

   If the HREC determines that further information, clarification or modification is required for the consideration of the request for amendment or extension, 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.

7. All reviewed and approved requests for amendments and extensions to a protocol shall be recorded, and the status of the project shall be updated on the HREC's register of received and reviewed applications.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 017 **Date:** December 2015

Subject: Renewal of Approval from the HREC

Purpose: To describe the procedure for the renewing ethics approval for projects approval by the HREC

1. The HREC gives approval for three or five years, contingent on the proposed duration of the project set out in the original ethics application.

2. The Principle Investigator, or in case of multi-centre research, the Co-ordinating Principal Investigator, will be notified that their ethics approval is due to expire as part of the process for reminding applications that their annual reports are due (see SOP 019)

3. For those project that have not been complete, the Principle Investigator or Co-ordinating Principal Investigator will be required to complete and submit a HREC *Application for Renewal* form.

4. The Application for Renewal will be reviewed and approved by the Chair, with advice form the Executive Officer, and then included on the agenda for the next HREC agenda for ratification.

5. If a research project is to completed within 11 months and there will be no more contact with research participants or anticipated amendments other than those relating to analysis of study results, then the Executive Officer has the delegated authority from the HREC to grant an extension of approval for up to 11 months.

Reference Number: SOP 018 **Date:** December 2015

Subject: Review of adverse events

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

1. The HREC shall require, as a condition of approval of each project, that researchers report serious or unexpected adverse events to the HREC in a timely manner. This includes serious or unexpected adverse events that have occurred at other institutions for which the HREC has provided approval under a model of single ethical review of multi-centre research.

2. Adverse event reporting for clinical trials will be in line with the NHMRC Australian Health Ethics Committee (AHEC) Position Statement (May 2009): *Monitoring and reporting of safety for clinical trials involving therapeutic products.*

3. Notifications of adverse events must be submitted in the appropriate format as determined by the HREC. This documentation shall include as a minimum:

    - Advice from the principal investigator as to whether, in his/her opinion, the adverse event was related to the protocol or in the case of a drug/device trial, whether the adverse event was related to the study drug/device, if adequate information is available to make this assessment.
    - Advice from the principal investigator as to whether, in his/her opinion, the adverse event necessitates an amendment to the project and/or the Participant Information Sheet/Consent Form.
    - Advice as to whether the event has been notified to the Independent Safety and Data Monitoring Board (if one exists).

4. The procedures and format for notification of adverse events to the HREC shall be readily available to investigators.

5. Adverse events will be reviewed by a member of the CTSC which shall determine the appropriate course of action. This may include:

    - notation on file of the occurrence;
    - increased monitoring of the project;
    - request for an amendment to the protocol and/or Participant Information Sheet/Consent Form;
    - a recommendation to the HREC to suspend ethical approval; or
    - a recommendation to the HREC to terminate ethical approval.

6. The Chairperson of the HREC, in consultation with the Chair of the CTSC, may take the appropriate course of action for those adverse events deemed serious and requiring immediate attention. This may include:

    - Immediate request for additional information;
    - Immediate suspension of ethical approval;
    - Immediate termination of ethical approval.

7. The HREC shall provide notice to the Co-ordinating Principal Investigator that it has received notification of the serious or unexpected adverse event, and the course of action it has deemed necessary to take.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 019 **Date:** December 2015

Subject: Monitoring of approved research projects

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

1. The HREC 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 HREC 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 HREC includes review of annual progress reports. The HREC shall require the following information in the annual report:

    - progress to date or outcome in the case of completed research;
    - maintenance and security of records;
    - compliance with the approved protocol; and
    - compliance with any conditions of approval.

    The Principle Investigator will receive a reminder email with the *HREC Annual Report* form attached four weeks before the report is due. If a response is not received within two months, then a reminder email is sent. If a response is not received within a month of the reminder email, the Principle Investigator is advised that ethics approval is suspended for that project and the matter is referred to the Chair.

4. The Principle Investigator must provide a final report upon completion of the project. A reminder email with the *HREC Final Report* form attached four weeks before ethics approval expires. The Principle Investigator will be advised of the process for renewing ethics approval (SOP 017) at that time.

5. The HREC 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;
    - Request and review reports from independent agencies such as Data & Safety Monitoring Boards.

6. Where the HREC is satisfied that circumstances have arisen such that a research project is not being or cannot be conducted in accordance with the approved project, 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 HREC will give consideration to the degree of risk to participants in the research project.

8. 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.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 020 **Date:** December 2015

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 Executive Officer reviews the documents and determines whether further information is required.

2. If further information is required the Executive Officer will email the applicant or whoever submitted the document requesting the information

3. If no further information is required, the email with the document attached will be forwarded to either the Executive Officer's delegate with advice that no further action is required and to acknowledge the document on behalf of the Executive Officer.

4. Where necessary the information has implications for the continuation of an approved protocol, the document will be listed on the protocol for the next HREC meeting.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 021 **Date:** December 2015

Subject: HREC requirements for research projects involving Investigational Devices.

Purpose: To describe the requirements of the HREC 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:
        (i) the clinical trial's protocol number and title
        (ii) the individual tracking numbers
        (iii) the trial identity of the participant into whom each device is implanted, ie the participant's study number
        (iv) the date of device implantation
        (v) 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 022 **Date:** December 2015

Subject: Complaints about the conduct of an approved research 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 HREC Executive Officer, or their delegate, who will notify the Chairperson as soon as possible.

2. The Executive Officer of the HREC will instigate an investigation of the complaint and make a recommendation on the appropriate course of action. The investigation will take no longer than 2 weeks from the time of notification of the complaint or concern, unless exceptional circumstance exists. The Executive Officer 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 HREC advising of the outcome of the Executive Officer's investigation. A report will also be provided at the next HREC 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 convenor of the panel;
    - Two nominees of the Chief Executive (not members of the HREC); and
    - The HREC Executive Officer.

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 against them. The outcomes may include:

    - The complaint/concern is dismissed
    - 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 023 **Date:** December 2015

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 HREC's review process should be directed to the attention of the Chairperson of the HREC, detailing in writing the grounds of the concern or complaint. Complaints may also be made to the Chief Executive.

2. The Chairperson will inform the Chief Executive 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 HREC 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 HREC 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 HREC 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 Convenor of the panel.
    - 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 HREC acted in accordance with the NHMRC *National Statement on Research Ethical Conduct in Human Research 2007*, its Terms of Reference, Standard Operating Procedures, or otherwise acted in an unfair or unbiased manner.

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

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
    - Take other action as appropriate

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 024 **Date:** December 2015

Subject: Complaints concerning the HREC's rejection of 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 HREC's rejection of their application 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 HREC 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 HREC 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 HREC 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 convenor of the panel
    - Two nominees of the Chief Executive (not members of the HREC)
    - 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
    - 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 HREC be requested to review its decision, then the outcome of this review by the HREC 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 025 **Date:** December 2015

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

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

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 should be lodged with the Chairperson in the first instance.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 026 **Date:** December 2015

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.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 027 **Date:** December 2015

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 research in NSW: The HREC will comply with the requirements of PD 2010_055 (Research - Ethical & Scientific Review of Human Research in NSW) ie a project will be ethically and scientifically reviewed once only, irrespective of the number of NSW Health sites involved in the project.

2. Multi-centre research in NSW is research that is conducted at more than one site within the NSW Public Health System, where those sites are within the jurisdiction of more than one NSW Health HREC.

3. With regards to interstate multi-centre research: The HREC 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.

4. For Multi-centre Paediatric Applications reviewed under the National Mutual Acceptance Scheme, all other sites will be notified that the application will be considered at the next HREC meeting and that they can expect a governance application in due course.

5. All amendments, safety and annual reporting and any other communications will be from the Co-ordinating 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 Investigator to the HREC.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 028 **Date:** December 2015

Subject: Record keeping

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

1. The Executive Officer or their delegate will prepare and maintain written records of the HREC's activities, including agendas and minutes of all meetings of the HREC.

2. The Executive Officer or their delegate will prepare and maintain a confidential electronic record for each application received and reviewed and shall record the following information:

    I. unique project identification number;
    II. the Co-ordinating Principal Investigator;
    III. the name of the responsible Institution or Organisation;
    IV. title of the project;
    V. ethical approval or non-approval with date;
    VI. approval or non-approval of any changes to the project;
    VII. the terms and conditions, if any, of approval of the project;
    VIII. whether approval was by expedited review; and
    IX. action taken by the HREC to monitor the conduct of the research.

    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.

3. 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.*

4. To ensure confidentiality, all documents provided to HREC members, which are no longer required, are to be disposed of in a secure manner, such as shredding or placed in confidential bins. Members who do not have access to secure disposal should leave their documents with the Executive Officer for disposal.

4. 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)'.*

6. 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*.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 029 **Date:** December 2015

Subject: Special Access Scheme applications

Purpose: To describe the procedure for the review and approval of access to unapproved therapeutic goods via the Special Access Scheme

HREC responsibilities in relation to the Special Access Scheme (SAS)* are primarily concerned with the granting of approvals under section 19(1)(a) of the Therapeutic Goods Act by 'external delegates'. In accordance with Regulation 47A(6)(b) of the Act, all special access scheme applications approved by an external delegate must be approved by an HREC.

*Refer to the Therapeutic Goods Administration *Access to Unapproved Therapeutic Goods via the Special Access Scheme, November 2009* http://www.tga.gov.au/pdf/access-sas-guidelines.pdf

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 030 **Date:** December 2015

Subject: Authorised Prescriber applications

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

1. Applications under s19(5) of the Therapeutic Goods for HNELHD clinicians to become authorized prescribers will be considered by the Chairpersons, who will consult with the Chair of the CTSC where necessary.

2. All decisions made by the Chairperson shall be tabled for ratification at the next HREC meeting.

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

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

4. If endorsed, the HREC 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:

    iv. 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;
    v. requirements for reporting of any adverse events.

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

    vi. inappropriate use of the product by the Authorised Prescriber;
    vii. a concern about the safety of the product;
    viii. failure of the Authorised Prescriber to comply with conditions imposed by the HREC; or
    ix. failure of the Authorised Prescriber to comply with State/Territory legislation

6. 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.

    * Refer to the Therapeutic Goods Administration *Access to Unapproved Therapeutic Goods – Authorised Prescribers, November 2009.*

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 031 **Date:** December 2015

Subject: Managing conflicts of interest

Purpose: To describe the procedure for the handling of conflicts of interest of HREC members, Scientific Sub-Committee members and expert reviewers.

Potential conflicts of interest for HREC members

1. Any member of the HREC who has a conflict of interest in a proposal or other related matter(s) considered by the HREC, should as soon as practicable declare such interest. Conflict of interest includes financial interests, personal, professional or institutional benefits or advantages that depend significantly on the research outcomes.

2. Declarations are made orally at the meeting prior to the matter being considered or in writing to the Chairperson prior to the meeting. The HREC determines whether the level of interest results in:
    a) A substantial conflict of interest: the member will be 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 on a research project is considered to represent a substantial conflict of interest.
    b) A non-substantial conflict of interest: the member has the discretion to leave during the discussion of the matter.

    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 proposal in question.

3. All declarations of conflict of interest and the decision of the HREC on the procedures to be followed will be minuted.

Potential conflicts of interest for Clinical Trials Sub-Committee (CTSC) members

4. Any member of the CTSC who has any interest, financial or otherwise, in research considered by the CTSC, should as soon as practicable declare such interest. The CTSC will need to determine if such a declaration is a conflict of interest.

5. 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 application will be included in the minutes of the CTSC.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 032 **Date:** December 2015

Subject: HREC reporting requirements

Purpose: To describe the reporting requirements of the HREC.

1. The minutes of each HREC meeting will be available to the Director, Research, Innovation and Partnership and the Chief Executive, following confirmation.

2. The HREC shall provide an annual report to the Chief Executive at the end of each calendar year on its progress, including:

    - membership/membership changes;
    - number of meetings;
    - number of projects reviewed, approved and rejected;
    - monitoring procedures for ethical aspects of research in progress and any problems encountered by the HREC 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.

3. The HREC will provide the following annual reports:
    - Report to the NSW Privacy Commissioner in accordance with the requirements of the Health Records and Information Privacy Act 2002 (NSW);
    - HREC Annual Report to the National Health and Medical Research Council (NH&MRC);
    - Certified Institution Annual Report to the National Health and Medical Research Council (NHMRC); and
    - Any other reports as required.

4. The HREC Terms of Reference, Standard Operating Procedures and membership will be available upon request to the general public, and will be posted on the CRGH Research Office website.

Hunter New England Human Research Ethics Committee
Standard Operating Procedures

Reference Number: SOP 033 **Date:** December 2015

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 every three years and amended as necessary in consultation with the HREC.

2. Revised Standard Operating Procedures and Terms of Reference will be sent to the Chief Executive and the Hunter New England Local Health District Board for approval.

Attachment A

Responsibilities of Members of the Hunter New England Human Research Ethics Committee (HREC)

The following policy is consistent with the *National Statement on Ethical Conduct in Human Research 2007*. It is important that all members of the HREC are familiar with the requirements of this document.

Confidentiality
Members of the HREC have a responsibility to:-

- treat the matters discussed at meetings confidentially;
- exercise care with the storage and disposal of meeting papers, both in paper and electronic form; and
- return paper copies of the agenda papers to the Executive Officer of the HREC at the end of a meeting.

Conflict of Interest
If, at any time, a HREC member finds that he or she has a potential conflict of interest, the member should make the Chair aware of this. In general, a person who is involved in research that is to be discussed by the HREC will be asked to leave the room.

If any member is unsure whether they have a conflict of interest or not, he or she should bring it to the attention of the Chair. If the Chair is unsure, it will be brought to the attention of the HREC for its consideration and decision.

If, at any time, the Chair finds he or she has a potential conflict of interest, the Chair should make the Committee aware of this, vacate the chair in favour of the Deputy Chair during the discussion and leave the room**.**

Preparation for Meeting
Members of the HREC are requested to:-

- Prepare for the meeting appropriately, and, if asked to review a research project, be prepared to comment on all aspects of the research and give the HREC an opinion as to whether it should be approved and under what conditions.
- Submit any agenda items or reports in reasonable time for inclusion in the pre-circulated meeting papers;
- Inform the Secretariat if they are unable to attend, or will be arriving late; and
- If asked to give an opinion for the meeting but are unable to attend, pass on that opinion before the meeting or within a reasonable time period after the meeting.

During the Meeting
Members of the HREC should:-

- Address all matters through the Chair;
- Treat each other with respect and be respectful of the opinion of others
- Leave the room when taking telephone calls; and
- Endeavour to stay until the end of the meeting, unless special arrangements have been made with the Chair.

HREC processes, policies and procedures
Members of the HREC must undertake to read and understand the relevant documents, policies and procedures supplied to them regarding the role, function, responsibilities and operation of the HREC and its members.

Declaration
I understand my responsibilities as a member of the HREC.

I declare that I have not been subject to any criminal conviction or disciplinary action, which may prejudice my standing as a HREC member.

I will keep confidential all matters discussed at HREC meetings.

I will inform the Chair of any conflicts of interest.

Signed: …….. Date: ……..2014

Name: …….

Attachment B

Standard Letter for HREC Approval of New Application

[Enter Today's Date]

[Recipient's Name]
[Recipient's Address]
[SUBURB STATE Postcode]

Dear [name]

Re: (insert full protocol title and HNEREC Number)

HNEHREC Reference No:
NSW HREC Reference No:
NSW SSA Reference No:

Thank you for submitting the above protocol for single ethical review for a multi-centre study. This project was first considered by the Hunter New England Human Research Ethics Committee at its meeting held on [insert date]. This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research (2007) (National Statement) and the CPMP/ICH Note for Guidance on Good Clinical Practice. Further, this Committee has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review. The Committee's Terms of Reference are available from the Hunter New England Local Health District website.

As part of the procedure for ethical approval of research involving humans in Hunter New England Health the above protocol has reviewed by the Clinical Trials Subcommittee, an advisory group of the Hunter New England Human Research Ethics Committee.

I am pleased to advise, the Hunter New England Human Research Ethics Committee has determined that the above protocol meets the requirements of the National Statement on Ethical Conduct in Human Research and following acceptance of the requested clarifications and revised ********** by Dr Nicole Gerrand Manager, Research Support & Development under delegated authority from the Committee, grants ethical approval of the above project.

The following documentation has been reviewed and approved by the Hunter New England Human Research Ethics Committee:

- [Insert documents approved]

For the protocol: [Insert protocol]

Approval has been granted for this study to take place at the following sites:

- [insert sites]

Approval from the Hunter New England Human Research Ethics Committee for the above protocol is given for a maximum of [insert number of years for approval] years from the date of this letter, after which a renewal application will be required if the protocol has not been completed.

The National Statement on Ethical Conduct in Human Research (2007), which the Committee is obliged to adhere to, include the requirement that the committee monitors the research protocols it has approved. In order for the Committee to fulfil this function, it requires:

- A report of the progress of the above protocol be submitted at 12 monthly intervals. Your review date is [insert date]. A proforma for the annual report will be sent two weeks prior to the due date.

- A final report must be submitted at the completion of the above protocol, that is, after data analysis has been completed and a final report compiled. A proforma for the final report will be sent two weeks prior to the due date.

- All variations or amendments to this protocol, including amendments to the Information Sheet and Consent Form, must be forwarded to and approved by the Hunter New England Human Research Ethics Committee prior to their implementation.

- The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:

    -any serious or unexpected adverse events

- Adverse events, however minor, must be recorded as observed by the Investigator or as volunteered by a participant in this protocol. Full details will be documented, whether or not the Investigator or his deputies considers the event to be related to the trial substance or procedure. These do not need to be reported to the Hunter New England Human Research Ethics Committee

- Serious adverse events that occur during the study or within six months of completion of the trial at your site should be reported to the Manager, Research Support & Development Office, of the Hunter New England Human Research Ethics Committee as soon as possible and at the latest within 72 hours.

- All other safety reporting should be in accordance with the NHMRC's Safety Monitoring Position Statement – May 2009 available at http://www.nhmrc.gov.au/health_ethics/hrecs/reference/_files/090609_nhmrc_position_statement.pdf

- Serious adverse events are defined as:

    - Causing death, life threatening or serious disability.
    - Cause or prolong hospitalisation.
    - Overdoses, cancers, congenital abnormalities whether judged to be caused by the investigational agent or new procedure or not.
    - Unforeseen events that might affect continued ethical acceptability of the project.

- If for some reason the above protocol does not commence (for example it does not receive funding); is suspended or discontinued, please inform Dr Nicole Gerrand as soon as possible.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of your site has been obtained.

A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Please quote [insert reference no.] in all correspondence.

Should you have any concerns or questions about your research, please contact Dr Gerrand as per the details at the bottom of the page. The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Yours faithfully

For: Name of Chair
Chair
Hunter New England Human Research Ethics Committee

Attachment C

Standard Response Letter for HREC Rejection of New Application

February 2015

[Recipient's Name]
[Recipient's Address]
[SUBURB STATE Postcode]

Dear [name]

Re: (insert full protocol title and HAREC Number)

HNEHREC Reference No:
NSW HREC Reference No:
SSA Reference No:

Thank you for submitting the above protocol for single ethical review. This project was first considered by the Hunter New England Human Research Ethics Committee at its meeting held on **18 February 2015.** This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* (National Statement) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Further, this Committee has been accredited by the NSW Ministry of Health as a lead HREC under the model for single ethical and scientific review. The Committee's Terms of Reference are available from the Hunter New England Local Health District website: http://www.hnehealth.nsw.gov.au/research_ethics_and_governance_unit

As part of the procedure for ethical approval of research involving humans in the Hunter New England Local Health District the above protocol has reviewed by the Clinical Trials Sub-Committee, an advisory group of the Hunter New England Human Research Ethics Committee.

The Hunter New England Human Research Ethics Committee has resolved that the above protocol will be approved subject to the following conditions being met:

- Clarification being given in relation to the following:

- Satisfactory clarification being provided in relation to some aspects of your research. Each of the following concerns should be responded to in a letter - **DO NOT amend the National Ethics Application form (NEAF), or any part thereof.**

- In addition, in accordance with Section 3.3.12 of the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* prior to commencing the study, it should be registered in a publicly accessible register. The Committee recommends the Australian New Zealand Clinical Trials Registry (ANZCTR) at www.anzctr.org.au/default.aspx

- in accordance with the requirements of s. 2.2.6 of the *National Statement on Ethical Conduct in Human Research (2007)* relating to informed consent the following changes should be made to the Participant Information Statement:

- The following changes being made to the consent form:

- The following changes being made to the questionnaires/surveys/interview schedules:

Please do not forget to put a new version number and/or date on your revised documentation.
For ease of review please track the requested changes to the revised documentation.

If this application is for multicentre research please submit both Master and Site Specific recruitment documentation. The version numbers and dates should be sequential for each type of documents. Please note that the Site specific documentation will usually be version 1 regardless of the version number of the Master documentation.

Please note that all responses should be from the Chief Investigator or where the research involves a postgraduate student, the students Principal Supervisor

In order to facilitate the further review of your application, please provide the requested information as soon as possible. Your response should be emailed to the Manager, Research Ethics & Governance: HNELHD-HREC@hnehealth.nsw.gov.au **Please note only an electronic copy is required do NOT sent a hard copy.**

Please note that if a response to this letter is not received within 3 months or two meetings (whichever occurs sooner), the project will be dismissed and you will be required to re-submit the project at a later date. You may request additional time to respond.

Please quote **(HNEHRC Ref No.)** in all electronic correspondence.

You are reminded that it is a condition of the *National Statement on Ethical Conduct in Human Research (2007)* that your Research may not commence until you have received an approval letter.

Yours Sincerely,

Dr Nicole Gerrand
Manager, Research Ethics & Governance
Hunter New England Local Health District

Attachment D

Standard Letter for HREC Approval of Amendment

(date)

(name & address)

Dear

Re: (study title)

HNEHREC Reference No:
NSW HREC Reference No:
NSW SSA Reference No:

Thank you for submitting a request for an amendment to the above project. This amendment was reviewed by the Hunter New England Human Research Ethics Committee. This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research (2007) (National Statement) and the CPMP/ICH Note for Guidance on Good Clinical Practice. Further, this Committee has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review.

I am pleased to advise that the Hunter New England Human Research Ethics Committee has determine the variation meets the requirements of the National Statement on Ethical Conduct in Human Research and has granted ethical approval for the following amendment requests:

-

For the protocol: (Protocol title)

Approval from the Hunter New England Human Research Ethics Committee for the above protocol is given for a maximum of (3 or 5) years from the date of the approval letter of your initial application, after which a renewal application will be required if the protocol has not been completed. The above protocol is approved until month & year.

Approval has been granted for this study to take place at the following sites:

-

The National Statement on Ethical Conduct in Human Research (2007) which the Committee is obliged to adhere to, include the requirement that the committee monitors the research protocols it has approved. In order for the Committee to fulfil this function, it requires:

- A report of the progress of the above protocol be submitted at 12 monthly intervals. Your review date is month & year. A proforma for the annual report will be sent two weeks prior to the due date.

- A final report must be submitted at the completion of the above protocol, that is, after data analysis has been completed and a final report compiled. A proforma for the final report will be sent two weeks prior to the due date.

- All variations or amendments to this protocol, including amendments to the Information Sheet and Consent Form, must be forwarded to and approved by the Hunter New England Human Research Ethics Committee prior to their implementation.

- The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:

    - any serious or unexpected adverse events

- Adverse events, however minor, must be recorded as observed by the Investigator or as volunteered by a participant in this protocol. Full details will be documented, whether or not the Investigator or his deputies considers the event to be related to the trial substance or procedure.

- Serious adverse events that occur during the study or within six months of completion of the trial at your site should be reported to the Ethics Officer of the Hunter New England Human Research Ethics Committee as soon as possible and at the latest within 72 hours.

- Copies of serious adverse event reports from other sites should be sent to the Hunter New England Human Research Ethics Committee for review as soon as possible after being received.

- Serious adverse events are defined as:

    - Causing death, life threatening or serious disability.
    - Cause or prolong hospitalisation.
    - Overdoses, cancers, congenital abnormalities whether judged to be caused by the investigational agent or new procedure or not.

    - Unforeseen events that might affect continued ethical acceptability of the project.

- If for some reason the above protocol does not commence (for example it does not receive funding); is suspended or discontinued, please inform Dr Nicole Gerrand, the Manager, Research Support & Development Office as soon as possible.

The Hunter New England Human Research Ethics Committee also has delegated authority to approve the commencement of this research on behalf of the Hunter New England Local Health District. This research may therefore commence.

Should you have any queries about your project please contact Dr Nicole Gerrand as per the contact details at the bottom of the page. The Hunter New England Human Research Ethics Committee Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Hunter New England Local Health District website.

Please quote study no in all correspondence.

The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Yours faithfully

For: Name of Chair
Chair
Hunter New England Human Research Ethics Committee