SYDNEY LOCAL HEALTH DISTRICT (SLHD)

HUMAN RESEARCH ETHICS COMMITTEE

Concord Repatriation General Hospital

HUMAN RESEARCH ETHICS COMMITTEE (HREC)

STANDARD OPERATING PROCEDURES (SOP)

Date: JUNE 2024

CONTENTS

ATTACHMENTS

Note: The Attachments are the latest versions at the time of the SOP review date. Attachments shall be revised/amended from time to time as required. The SLHD Research Office will keep a record of the latest templates approved by the Executive Research Manager.

KEY DEFINITIONS

Co-ordinating Principal Investigator – the person who takes overall responsibility for the research project and submits the project for ethical and scientific review. They are responsible for ongoing communication with the ethics committee and passing on any outcomes from this to the Principal (site) Investigators, if the research is multi-centre. For single centre research, Co-ordinating Principal Investigator and Principal Investigator are synonymous.

CRGH – Concord Repatriation General Hospital

Executive Committee – A sub-committee of the SLHD HREC which meets out of session to undertake the review and approval of business that does not require full review.

HREA – Human Research Ethics Application

HREC – Human Research Ethics Committee

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

NHMRC – National Health and Medical Research Council

Principal Investigator – the person who takes responsibility for the conduct of the research project at their site.

REGIS – Research Ethics and Governance Information System

Scientific Sub-committee (ScSC) – the sub-committee of the Sydney Local Health District HREC – CRGH which assesses clinical drug trials/interventional research and other research requiring scientific review to determine whether or not the research is scientifically valid, and advises the HREC accordingly.

REGO – Research Ethics and Governance Office

SLHD – Sydney Local Health District

TGA – Therapeutic Goods Administration

Sydney Local Health District Human Research Ethics Committee (HREC)
Concord Repatriation General Hospital (CRGH)
Standard Operating Procedures

Reference Number: SOP 001 **Date**: June 2024
Subject: Human Research Ethics Committee
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 to:

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

1.2 Facilitate ethical research through efficient and effective review processes.

1.3 Promote ethical principles in human research.

1.4 Review research in accordance with the National Health and Medical Research Council *National Statement on Ethical Conduct in Human Research*, incorporating all updates, hereafter called the *National Statement*.

2. FUNCTIONS

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

2.1 Provide independent oversight of human research projects; and

2.2 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;

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

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

3. SCOPE OF RESPONSIBILITY

3.1 The responsibilities of the HREC are to review human research applications where the research takes place at:

- Concord Repatriation General Hospital; and/or

  Any institutions governed by NSW Public Health Organisations for multi-centre studies; and/or

- External institutions/organisations and investigators external to the public health system where an agreement has been made between the organisation or individual and the Sydney Local

Health District in accordance with Policy directive Human Research Ethics Committees: Ethical Review for External Entities (PD 2008_046).

- Interstate institutions or organisations within the scope of a scheme of mutual acceptance of ethical and scientific review entered into by NSW Ministry of Health on behalf of the HREC.

3.2 The scope of responsibility described above does not prohibit the institution from accepting an ethical approval undertaken by another HREC as a sufficient ethical approval to allow the institution to authorise the commencement of the project, provided that such HREC is registered with the NSW Ministry of Health as a "NSW Lead HREC" or is certified under the National Certification Scheme for ethical review of multi-centre human research.

4. ACCOUNTABILITY

4.1 The HREC is directly accountable to the Chief Executive of the Public health Organisation under which it is constituted in the conduct of its business. The minutes of each HREC meeting shall be signed by the Chairperson and forwarded to the Chief Executive and the SLHD Board, following confirmation by the HREC.

4.2 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.

4.3 The HREC may from time to time bring to the attention of the Chief Executive issues of significant concern.

4.4 The HREC will provide the following annual reports:

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

4.5 The HREC Terms of Reference, Standard Operating Procedures and membership will be available to the general public and posted on the Research Ethics and Governance Office website.

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

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Reference Number: SOP 002 **Date: June 2024**
Subject: Membership composition
Purpose: To describe the membership composition of the HREC

1. The composition of the HREC shall be in accordance with the *National Statement*. The minimum membership shall be eight (8) members, ensuring membership is diverse (including gender diversity). At least one-third of the members should be external to the Sydney Local Health District. The membership comprises representatives from the following categories:

   - A Chairperson with suitable experience whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the *National Statement*. The Chairperson role may be shared with other persons, such as a Deputy Chair or Co-Chair;
   - A Chairperson of the Scientific Sub-Committee (or nominee);
   - At least two members who bring a broader community or consumer perspective and who have no paid affiliation with the institution and are not currently involved in medical, scientific, legal or academic work;
   - At least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people;
   - At least one member who performs a pastoral care role in the community, for example, an Aboriginal elder or a minister of religion;
   - 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
   - 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.
   - An Executive Officer (non-voting member).

2. To ensure that the membership shall equip the HREC to address all the relevant considerations arising from the categories of research likely to be submitted to it, and that a quorum is present at all meetings, 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. Where practicable, HREC committee membership shall include representatives from Divisions of Medicine, Surgery, Nursing, Allied Health and Clinical Trials Pharmacy. Additional members may be appointed to ensure the HREC has the expertise required to assess the applications submitted to it for consideration. If additional members are appointed, the composition of the HREC shall continue to reflect the diversity and balance of its members, including gender and the relative proportion of institutional and non-institutional members.

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.

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Reference Number: SOP 003 **Date: June 2024**
Subject: Appointment of Members
Purpose: To describe the procedure for the appointment of members to the HREC

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

2. Prospective members of the HREC may be recruited by direct approach, nomination or by advertisement. The minister of religion is nominated by the retiring or former member in this category, or by the Concord Repatriation General Hospital Pastoral Care service, or by other means as deemed appropriate. Prospective members shall be asked to provide a copy of their Curriculum Vitae to the selection committee. Members must agree to their name and profession being made available to the public, including being published on the SLHD Research Office website.

3. A selection committee, consisting of the Chairperson, Executive Officer and at least one other HREC member shall interview the prospective applicant, consult with the Human Research Ethics Committee members and make a recommendation to the Chief Executive. Prospective members may be invited to attend meetings of the HREC as an observer.

4. All members including the Chairperson, Deputy Chairperson and Chairperson of any sub-committee 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, the circumstances whereby membership shall be terminated and the conditions of their appointment.

6. A new member will be required to sign a confidentiality undertaking (see Attachment N) and conflict of interest declaration upon appointment, stating that all matters of which they becomes aware during the course of their work on the HREC will be kept confidential; that any conflicts of interest, which exist or may arise during their tenure on the HREC will be declared; and that they have not been subject to any criminal conviction or disciplinary action, which may prejudice their standing as a HREC member.

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

   - HREC Terms of Reference
   - HREC Standard Operating Procedures
   - Up-to-date list of members' names and roles on the Committee including that of the Executive Officer and the Executive Officer's contact details
   - Responsibilities of Members of the Sydney Local Health District Human Research Ethics Committee (Attachment O)
   - *National Statement on Ethical Conduct in Human Research*
   - *NSW Health Records and Information Privacy Act 2002*
   - Statutory Guidelines under HRIPA, specifically the "use or disclosure of health information for research purposes" and the "use or disclosure of health information for the management of health services"

- Guidelines under Section 95 of the *Privacy Act 1988* 2014
- Guidelines approved under Section 95A of the *Privacy Act 1988* 2014
- The HREC meeting dates

and any other relevant information about the HREC's processes, procedures and protocols. Members are expected to familiarise themselves with these documents.

8. Members are appointed for a period of three years, renewable at the discretion of the Chief Executive.

9. The Chairperson, Deputy Chairperson and Chairperson of any sub-committee may serve longer terms at the discretion 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. Membership will be reviewed annually. New and renewed appointments shall allow for continuity, the development of expertise within the HREC, and the regular input of fresh ideas and approaches.

12. Members are not offered remuneration. However, reimbursement for legitimate expenses incurred in attending HREC meetings, such as travelling and parking expenses, may be considered.

13. Members may seek a leave of absence from the HREC for extended periods. Steps shall be taken to fill the vacancy.

14. Membership will lapse if a member fails to attend:
    - three consecutive meetings without reasonable excuse/apology or exceptional circumstances; and
    - at least two thirds of all scheduled HREC meetings in each year, barring exceptional circumstances.

    The Chairperson will notify the member of such lapse of membership in writing. Steps shall be taken to fill the vacancy. Membership attendance conditions do not apply to the Chairperson role, as this may be a shared role with shared attendance. It should be ensured that there be at least one Chairperson attending and chairing each HREC meeting.

15. Members will be expected to participate in relevant specialised working groups as required.

16. The Chairperson is expected to be available between meetings to participate in Executive meetings where required.

17. 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.

18. 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;
    - the person has failed to carry out their duties as an HREC member.

19. Sydney 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.

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Reference Number: SOP 004 **Date: June 2024**
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.
    - Informal meeting with Chair and Executive Officer to explain their responsibilities as an HREC member, the HREC processes and procedures.
    - Orientation presentation to provide an overview of the HREC and Sub-Committee, member responsibilities, overview of the National Statement and HREC processes and procedures.
    - An opportunity to sit in on HREC meetings before their appointment takes effect.
    - 'Partnering' with another HREC member in the same category.
    - Priority given to participate in training sessions.

4. Each member shall be expected to become familiar with the *National Statement* and to consult other guidelines relevant to the review of specific research applications.

5. Each member shall be encouraged to attend continuing education or professional development activities in research ethics at least once in each period of appointment.

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Reference Number: SOP 005 **Date: June 2024**
Subject: Training and Education of HREC members
Purpose: To promote ongoing education and training opportunities for all members of the HREC.

1. All members shall be encouraged to attend education and training sessions. New members shall be expected to attend NSW Health and NHMRC education and training sessions as soon as practicable after their appointment. Reasonable costs associated with attendance at training and education sessions will be met by the SLHD.

2. Every member of the HREC should aim to attend at least one training session every three years.

3. New members will be given an orientation presentation and package, and priority to participate in training sessions. They will also be offered Introductory HREC training.

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

5. The HREC Chairperson may delegate a person with suitable expertise (e.g. Executive Officer, HREC member or internal/external persons) to provide training presentations to the HREC members.

6. The Executive Officer will keep a record of HREC training and education undertaken individual HREC members and the Committee as a whole.

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Reference Number: SOP 006 **Date: June 2024**
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 via REGIS to the Executive Officer of the HREC, 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.

2. The closing dates for applications should normally be no later than 9 days prior to each HREC meeting. The closing dates for the Scientific Sub-Committee will be no later than 9 days prior to the 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. 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 HREC is necessary.

5. A fee will be charged for HREC review of externally sponsored clinical trials, in line with NSW Ministry of Health's Policy Directive *Schedule for Research Ethics and Governance Review of Clinical Trial Research* (PD2023_015).The fee policy shall be made available to applicants prior to submission of an application to the HREC.

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Reference Number: SOP 007 **Date: June 2024**
Subject: Processing of applications for review
Purpose: To describe the procedure for the processing of new applications

1. The Executive Officer (or delegate) will provide a preliminary review of draft applications in the week prior to each agenda closing date to those applicants who request it. A list of the preliminary review cut-off dates will be made readily available to prospective applicants.

2. Applications will be checked for their completeness by the Executive Officer or their delegate prior to their acceptance onto the agenda, in line with a submission checklist (see Attachment P). Incomplete applications will be returned to the applicant with feedback. Submission cut-off dates for subsequent meetings will be provided to the applicant.

3. The Executive Officer or their delegate will determine whether the application requires review by the Scientific Sub-Committee.

4. Once a completed application has been accepted for ethical review, the Executive Officer shall assign a unique project identification number to the project. The project will be added to the HREC's register of received and reviewed applications.

5. The Executive Officer or their delegate will acknowledge acceptance of the application for ethical review by issuing an acknowledgement letter/email to the principal investigator within five (5) working days of receipt of the application, or at the discretion of the Chairperson. The acknowledgement letter/email 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.

6. The application will be included on the agenda for the next available HREC meeting and/or Scientific Sub-Committee meeting (as appropriate), provided it is received by the relevant closing date and is complete.

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Reference Number: SOP 008 **Date: June 2024**
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 complete 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 seven (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) opening and introduction;
    iii) declarations of interests, conflicts of interest or disclosures;
    iv) minutes of the previous meeting;
    v) business arising from the previous minutes;
    vi) resubmissions;
    vii) new applications;
    viii) minutes of the sub-committees for ratification;
    ix) low risk applications and amendments reviewed and approved out-of-committee for ratification;
    x) correspondence;
    xi) education or training;
    xii) other business;
    xiii) close and next meeting.
    xiv) annual reports & amendments approved executively (as appendix)

6. The agenda and all documentation shall remain confidential.

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Reference Number: SOP 009 **Date: June 2024**
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, except for January. Meeting dates and agenda closing dates shall be publicly available.

2. Members may attend HREC meetings in person or via teleconference or video link. Members who are unable to attend a meeting 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. The minutes should record the submission of written comments.

3. A quorum is required at each meeting for the HREC to reach a final decision on any agenda item. A quorum exists when a representative of each of the categories listed in SOP 002 (Item 1) is in attendance, whether in person or via videoconference.

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. The Chairperson may cancel a scheduled meeting if a quorum cannot be achieved (refer to paragraphs 2 and 3). Should this occur, the HREC will convene within ten (10) working days of the cancelled meeting or at the discretion of the Chairperson, to ensure all agenda items are considered.

6. Meetings will not be scheduled for an allocated time. Meetings will continue until all agenda items have been considered. If the business has not been completed at the meeting, then the HREC may defer the matter to the next available meeting.

7. 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.

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

9. There will be no direct communication between the HREC and the sponsor of a research proposal. Such communication shall be via the investigator. 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.

10. Any member of the HREC who has any interest, financial or otherwise, in a project or other related matter(s) considered by the HREC, must declare such interest before the item is discussed. This will be dealt with in accordance with SOP 029.

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Reference Number: SOP 010 **Date: June 2024**
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 complete 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, in accordance with SOP 009.

3. The HREC will review multi-centre research applications in accordance with SOP 025.

4. The HREC will ethically assess each application in accordance with the *National Statement*. 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.

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

6. Where research involves the targeted recruitment of persons unfamiliar with the English language, the HREC will ensure that the participant information sheet is translated into the participant's language and/or that an interpreter is present during the discussion of the project, in accordance with NSW Health Policy Directive *Interpreters – Standard Procedures for Working with Health Care Interpreters (*PD2017_044).

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

    - It may approve the project as being ethically acceptable, with or without conditions/minor amendments; or
    - It may defer making a decision on the project until an issue(s) is clarified or further information is provided to the HREC, or the project is modified; or
    - It may reject the project.

8. The HREC will endeavour to reach a decision concerning the ethical acceptability of a proposal by consensus. Members present will be allowed reasonable opportunity to express relevant views on matters on the agenda.

9. Where a unanimous decision cannot be reached by a majority of members who examined the project, the Chairperson will need to facilitate the expression of opinion from all members (including at least one consumer/community member), identify points of agreement and of disagreement and judge when a sufficient degree of general agreement by the majority of members (i.e. two-thirds) has been reached. Any significant dissenting view or concern will be noted in the minutes.

    In order to facilitate consideration of an application, the HREC may invite the applicant to attend the relevant meeting to discuss the application and to answer questions. The applicant will be asked to leave the meeting prior to HREC deliberation and decision-making concerning the application.

10.

11. For projects which the HREC considers ethically acceptable with conditions / amendments, the HREC may choose to delegate the authority to review the applicant's response and give final approval for the project to proceed to one of the following:

    - chairperson alone; or
    - chairperson, in oral or written consultation with one or more named members who were present at the meeting or who submitted written comments on the application; or
    - the Executive Committee of the HREC;
    - a sub-committee of the HREC; or
    - the Executive Research Manager; or
    - the Executive Officer.

    In such circumstances, the HREC shall be informed at the next meeting of the final decision taken on its behalf.

12. For projects on which the HREC has deferred making a decision until an issue is clarified or further information is provided or the project is modified, the HREC may decide that the project and the investigator' response will be considered at a subsequent meeting of the HREC.

13. The HREC may conduct expedited review of projects in accordance with SOP 012.

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Reference Number: SOP 011 **Date: June 2024**
Subject: Preparation of minutes
Purpose: To describe the process and format for minutes of a meeting of the HREC.

1. The Executive Officer and/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) attendance;
   ii) apologies;
   iii) declaration of any interests, conflicts of interest or disclosures;
   iv) minutes of the previous meeting;
   v) business arising from the previous minutes;
   vi) resubmissions;
   vii) new applications;
   viii) minutes of the sub-committees for ratification;
   ix) correspondence;
   x) low risk applications and amendments reviewed and approved out-of-committee for ratification;
   xi) education or training;
   xii) other business;
   xiii) close and next meeting;
   xiv) annual reports and amendments approved executively (as an appendix).

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, the HREC's decision and any requests for additional information, clarification or modification of the project.

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

6. To encourage free and open discussion and to emphasise the collegiate character of HREC deliberations, particular views shall not be attributed to particular individuals in the minutes, except in circumstances where a member seeks to have their opinions or objections recorded.

7. Declarations of interests or 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 SOP 029 regarding a member's declaration of a conflict of interest).

8. The minutes will be produced as soon as practicable following the relevant meeting and, where appropriate, should be checked by either the Chairperson and/or the Deputy Chairperson, for accuracy.

9. 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.

10. The original copy of each meeting's minutes will be retained in a confidential 'Minutes' file.

11. The minutes of each Committee meeting will be forwarded to the SLHD Chief Executive and the SLHD Board (reporting to the SLHD Education and Research Committee).

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Reference Number: SOP 012 **Date: June 2024**
Subject: Expedited review
Purpose: To describe the procedure for the executive review of research by the HREC.

1. The HREC will establish an Executive Committee consisting of least the Chairperson (or nominee), or the Chairperson of the Scientific Sub-Committee (or nominee) and the Executive Officer. The Executive may undertake expedited review of research projects in the following circumstances:

    - Research applications which meet the definitions of low risk research given in the *National Statement*;
    - Amendments to current HREC approved research projects;
    - projects which the HREC has previously approved as being ethically acceptable, with conditions / minor amendments;
    - Responses to HREC queries, as approved by the full HREC for review and approval;

    Expedited review of research projects may be undertaken between scheduled meetings, at the discretion of the Chairperson, by either the Chairperson or Executive. Either may seek advice from other HREC members or suitably qualified experts, as appropriate, before reaching a decision. The decision of this review must be tabled for ratification at the next HREC meeting.

    The Executive may consider other items of business that are considered to be of minimal risk to participants such as expected adverse events, project reports, minor amendments and the like.

2. The HREC will empower the Executive Officer to respond to minor issues, such as reports on studies that have not yet commenced, uncontroversial reports from Data and Safety Monitoring Boards, and inclusion of additional study sites, which require noting only. In addition, the HREC will empower the Executive Officer to review responses from investigators that involve clerical checking of requested corrections / amendments to documents and may issue appropriate correspondence.

3. Research involving a commercial entity, for example as a sponsor or as the recipient of personal or health information about staff and/or patients/clients of a public or private health organisation, will generally not be considered for expedited review.

4. Research with the potential for physical or psychological harm will generally not be considered for expedited review. This includes clinical trials, research involving invasive physical procedures and research exploring sensitive personal or cultural issues.

5. Where the Chairperson considers that a research project may involve a departure from the ethical principles of integrity, respect for persons, beneficence and justice, the protocol must be considered by the full HREC and cannot be dealt with by expedited review.

6. A summary of the matters dealt with at Executive meetings and by the Executive Officer will be included in the agenda for the next HREC meeting.

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Reference Number: SOP 013 **Date: June 2024**
Subject: Scientific Sub-Committee
Purpose: To describe the role of the Scientific Sub-Committee in providing expert reviews for the HREC.

1. The HREC has a Scientific Sub-committee (ScSC) which operates according to its own Terms of Reference and Standard Operating Procedures.

2. ScSC assesses clinical trials/interventional research or other research requiring scientific review involving humans to determine whether or not the research is scientifically valid and advises the HREC accordingly.

Expert Reviewers

3. The ScSC will seek a review from at least one expert with the appropriate skills and expertise relevant to each research proposal being considered by the ScSC.

4. Expert reviewers may be sought from within or outside Sydney Local Health District.

5. As part of the invitation to provide an expert review, the reviewer is provided with the name of the study, the investigators and the study sponsor. The reviewer therefore has the opportunity to declare any potential conflicts of interest prior to agreeing to undertake the review.

6. Expert reviewers will be required to provide a scientific review which will aid the ScSC in its overall review of the research. Expert reviewers will, where possible, use the template provided by NSW Health for Scientific Assessment. The expert reviewer will be required to sign the conflict of interest declaration and the confidentiality undertaking on the form.

7. The Research Ethics and Governance Office (REGO) maintains a register of all expert reviewers which includes information about their relevant expertise and training. This register is not made publicly available to preserve the confidentiality of the review process.

8. The REGO maintains copies of formal correspondence with expert reviewers on each project file.

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Reference Number: SOP 014 **Date: June 2024**
Subject: Role of the Executive Officer and Administrative Officer
Purpose: To describe the role of the Executive Officer of the HREC and the Administrative Officer

1. All correspondence issued on behalf of the HREC will be signed by the Chairperson or by the Executive Officer or the Executive Officer's delegate. The Administrative Officer and Research Ethics & Governance Support Officer are the Executive Officer's delegates.

2. In addition, the Executive Officer, or their delegate, may respond to minor issues, such as reports on studies that have not yet commenced, uncontroversial reports from Data and Safety Monitoring Boards, inclusion of additional study sites and changes in named investigators.

3. The Executive Officer or their delegate may review responses from investigators that involve clerical checking of requested corrections / amendments to documents, and may issue appropriate correspondence.

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Reference Number: SOP 015 **Date: June 2024**
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 Coordinating Principal Investigator on the outcome of the ethical review within 10 working days of the meeting or at the discretion of the Chairperson or delegate, 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 Coordinating Principal Investigator should clearly articulate the reasons for this determination (see Attachment C), and clearly set out the information that is required. Where possible, requests for additional information/clarification/modification should refer to the *National Statement* or relevant legislation(s).

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 (Attachment C). The HREC may nominate one of its members to communicate directly with the applicant or invite the applicant to attend the relevant HREC meeting. This is arranged via consultation with the Executive Officer.

4. If the requested information is not received from the applicant within 30 days (20 days for clinical trials), the applicant will be advised in the HREC correspondence that the project will be withdrawn and the applicant will be required to re-submit the project at a later date (Attachment C).

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 the project and unique ethics/project identification numbers;
    - unique HREC project identification number;
    - name of the Coordinating Principal Investigator(s);
    - the version number and date of all documentation reviewed and approved by the HREC including Protocol, 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; and
    - conditions of HREC approval, if any.

    A standard ethics approval letter will be issued, in the format set out in Attachment A. The Executive Officer has delegated authority from the HREC to sign its correspondence.

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 legislation(s). 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.

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Reference Number: SOP 016 **Date: June 2024**
Subject: Review of amendments and extensions to approved projects
Purpose: To describe the procedure for the submission and 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. All amended documents must be provided with changes tracked, include a summary of the proposed changes and contain revised version numbers and dates.

3. Expedited review of requests for minor amendments and extensions may be undertaken by the HREC Executive between scheduled meetings at the discretion of the Chairperson and in accordance with SOP 012, on the condition that it is ratified at the next HREC meeting. In addition, protocol amendments to research projects which were originally reviewed by the Scientific Sub-Committee and which are substantial Protocol and/or Investigator Brochure changes will be reviewed by the Scientific Sub-Committee.

4. Where an urgent protocol amendment is required for safety reasons, the Chairperson may review and approve the request. In such circumstances, the HREC will review the decision at the next available meetings.

5. All other requests for amendments shall be reviewed by the HREC at its next meeting, provided the request has been received by the Executive Officer by the agenda closing date.

6. The HREC will send correspondence to the Co-ordinating Principal Investigator, advising of the ethical approval of the proposed amendment and/or request for extension, within ten (10) working days of the meeting at which the request was considered (this may be the full HREC meeting or the Executive meeting) or at the discretion of the Chairperson.

7. A standard response will be issued, in the format set out in Attachment C. The Executive Officer has delegated authority from the HREC to sign its correspondence.

8. 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. Where possible, requests for additional information/clarification/modification should refer to the *National Statement* or relevant pieces of legislation.

9. All reviewed and approved requests for amendments and extensions shall be recorded in the relevant project file and where appropriate, in the HREC's register of received and reviewed applications.

Reference Number: SOP 017 **Date: June 2024**
Subject: Review of safety reports and adverse events
Purpose: To describe the procedure for the review of safety reports and adverse events

1. The HREC shall require, as a condition of approval of each project, that investigators report to the HREC in a timely manner any safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability of the research. This includes safety issues 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. Safety reporting for clinical trials and other research where applicable will be in line with NSW Health Policy PD_2017_039: *Safety Monitoring and Reporting for Clinical Trials Conducted in NSW Public Health Organisations*. For clinical trials of therapeutic goods, this policy requires sponsors and investigators to conduct safety monitoring and reporting in line with the requirements set out in the NHMRC Guidance: *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods 2016*. For clinical trials involving interventions other than therapeutic goods (e.g. surgery, radiotherapy, psychotherapy), this policy requires safety monitoring and reporting activities to be aligned, as far as possible, with the requirements for therapeutic goods trials.

3. The NHMRC Guidance defines the following:
   - **Suspected Unexpected Serious Adverse Reaction (SUSAR):** An adverse reaction that is both serious and unexpected.
   - **Unanticipated Serious Adverse Device Effects (USADEs):** A serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report (and/or Investigator's Brochure/Instructions for Use).
   - **Urgent Safety Measure (USM):** A measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety.
   - **Significant Safety Issue (SSI):** A safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.
   - **Unexpected & Related SAEs (URSAE):** An adverse event that is:
     - **Serious –** meets the definition of a serious adverse event
     - **Related –** resulted from administration of the trial intervention
     - **Unexpected –** the event is not described in the protocol as an expected occurrence.

4. Notifications must be submitted in the appropriate format (see Attachment F).

5. The procedures and format for safety reporting to the HREC shall be readily available to investigators on the SLHD Research Office website.

6. Safety reports will be reviewed by an Executive or Sub-Committee of the HREC which shall determine the appropriate course of action. This may include:

   - notation on project file of the report;
   - increased monitoring of the project;

- a 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.

Any such adverse events shall be reported to the HREC at the next available meeting.

7. The Chairperson may take the appropriate course of action for those safety reports deemed serious and requiring immediate attention. This may include:

    - Referral to the Scientific Sub-Committee;
    - Immediate request for additional information;
    - Immediate suspension of ethical approval;
    - Immediate termination of ethical approval.

    See Attachment K

8. The HREC shall provide notice to the Co-ordinating Principal Investigator that it has received notification of the safety report, and the course of action it has deemed necessary to take (see Attachment F).

9. The Chairperson or delegate via the Executive Research Manager shall immediately notify the Chief Executive (or delegate) if a project is suspended or terminated because of a serious adverse event.

10. The HREC may reinstate ethical approval following suspension or termination of a project if it has determined that their concerns regarding the safety event have been adequately addressed. This may require modification of protocol or any relevant project-related documents.

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Reference Number: SOP 018 **Date: June 2024**
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. In particular, the HREC will require applicants to provide a report at least annually, and at the completion of the study. Continuing approval of the research will be subject to the Co-ordinating Principal Investigator's submission of an annual report.

2. The HREC shall require, as a condition of approval of each project, 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 (for example, but not limited to, conflicts of interest, serious breaches, participant complaints, privacy breaches, etc.);
    - for clinical trials: Significant Safety Issues (SSIs) reported as Urgent Safety Measures (USMs), as amendments or as a temporary halt/early termination of a clinical trial;
    - new information from other published or unpublished studies which may have an impact on the continued ethical acceptability of the project, or which may indicate the need for amendments to the project protocol; and
    - if the project is abandoned for any reason.

3. Monitoring by the HREC includes review of annual progress reports. The HREC will require applicants to provide a report at least annually, and at the completion of the study. Continuing approval of the research will be subject to the Co-ordinating Principal Investigator's submission of an annual report. The HREC shall require the following information in the annual report:

    - progress to date at all sites under the responsibility of the HREC 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.

4. The HREC may adopt any additional appropriate mechanisms for monitoring, as deemed necessary. 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, with prior consent, research participants or obtain other forms of feedback from them;
    - Establishment of an independent Data Safety Monitoring Board or request and review reports from independent agencies such as Data & Safety Monitoring Boards.

5. The HREC shall require, as a condition of approval of each project, that investigators inform the HREC, giving reasons, if the research project is discontinued before the expected date of completion.

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 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. In such circumstances, the HREC shall inform the Co-ordinating Principal Investigator of such withdrawal of approval in writing, with copies to the Research Governance Officers at participating institutions.

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.

9. The HREC will actively seek annual / quarterly progress reports (submitted as milestones) on approved studies (see Attachments I & J). The process will be as follows:

    - A report request letter will be routinely sent out. This will be accompanied by a link to the Annual Progress Report Milestone Form or Quarterly Progress Milestone Report Form, as appropriate.

    - Non-responders will be sent a reminder letter. This will be highlighted with an “OVERDUE” notice.

    - Annual / quarterly progress reports that are greater than six months overdue will automatically be changed to a ‘Not Achieved’ status.

    In the case of persistent non-responders, the HREC has the further options of:

    - Withholding ethics approval of new applications in which the non-responder is an investigator until the outstanding annual reports are provided.

    - Ethics projects with overdue milestones and an expiry date is greater than 12 months expired will have the study status automatically changed to “Suspended”. This means that the ethics approval will be suspended.

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Reference Number:	SOP 019	**Date: June 2024**
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 investigator 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's protocol number and title
     - The individual tracking numbers
     - The trial identity of the participant into whom each device is implanted (i.e. the participant's study number)
     - The date of device implantation
     - Detailed records of all adverse events and device deficiencies.
   - Undertaking safety reporting to the HREC and the Therapeutic Goods Administration (TGA) in line with the NHMRC Guidance: *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* 2016.

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 their site and recording details of the device into each study participant's medical record.

Reference Number: SOP 020 **Date: June 2024**
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 Executive Research Manager via the HREC Executive Officer or their delegate, who will notify the Chairperson as soon as possible. The Executive Officer's contact details must be included in the participant information sheet and/or consent form or other participant-facing documents (e.g. advertisements) for each project. Wherever possible, the Executive Officer is responsible for obtaining in writing the grounds of the concern or complaint. If this is not possible, the Executive Officer will take detailed notes of the concern or complaint and write a File Note.

2. The Executive Research Manager will assess the concern or complaint in accordance with the Policy Compliance Procedure *Research: Managing and Investigating Complaints about Research Integrity* (SLHD_PCP2022_036) and determine whether the matter requires further investigation. The Executive Research Manager will make a recommendation to the Chairperson on the appropriate course of action. If the complaint is substantiated, action may include:

    - the requirement for amendments to the project;
    - increased monitoring by the HREC;
    - an investigation being conducted;
    - suspension of the project;
    - termination of the project; or
    - other action to resolve the complaint.

3. The Chairperson or Executive Officer will send a letter of acknowledgement to the complainant (if an address or email address has been provided) and a letter of notification to the Co-ordinating Principal Investigator, outlining the complaint and the course of action. The identity of the complainant will be kept confidential.

4. If the complainant is not satisfied with the outcome or course of action, then they can refer the complaint to the Chief Executive, or their nominee, or request the Chairperson/Executive Research Manager to do so.

5. The complainant may seek independent advice from one or more of the Advisors in Research Integrity appointed by the SLHD or request the Chairperson to do so. The Advisors' details are publicly available on the SLHD Research Office websites. The Advisors' role does not extend to formal investigation or assessment of an allegation of research misconduct, nor are they permitted to make contact with a person who is the subject of the complaint.

6. The Chairperson of the HREC or Executive Research Manager will provide the Chief Executive or their nominee with all relevant information about the complaint/concern, including:

    - details of the complaint;
    - material reviewed by the Chairperson and the Executive Research Manager;

- the course of action (if applicable); and
- any other relevant documentation.

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

8. Where the complaint concerns a serious matter within the jurisdiction of the Health Care Complaints Commission, the Chief Executive shall consider referral of the complaint to that body in accordance with NSW Health's Policy Directive PD2018_032 "*Complaint or Concern about a Clinician".*

9. If the Chief Executive determines there is to be an investigation, then they will convene a suitable panel to consider the complaint.

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

    - the Chief Executive or their nominee as convener of the panel;
    - two nominees of the Chief Executive (not members of the HREC); and
    - the Executive Research Manager or the HREC Executive Officer.

11. The panel will afford the HREC and the complainant the opportunity to make submissions. Where the complaint concerns the conduct of an investigator or any staff member, the panel shall also provide that person with an opportunity to make submissions.

12. 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.

13. The Chief Executive will notify the complainant, the Chairperson, and the investigator (if an allegation has been made against them) of the outcome of the investigation. The outcomes may include:

    - The complaint/concern is dismissed.
    - The Chief Executive directs appropriate action to be taken to resolve the complaint.

14. A concern or complaint about the conduct of a research project which involves allegations of research misconduct is managed in accordance with the Sydney Local Health District local procedures (*Research: Managing and Investigating Complaints about Research Integrity* SLHD_PCP2022_036).

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Reference Number: SOP 021 **Date: June 2024**
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. The matter should be referred to the Executive Research Manager for further advice. Complaints may also be made to the Chief Executive.

2. The Chairperson via the Executive Research Manager will inform the Chief Executive as soon as possible of any complaints received by them. The Chief Executive will inform the Chairperson and Executive Research Manager as soon as possible of any complaints received by them. The Chief Executive will send a letter of acknowledgement to the complainant, outlining the course of action.

3. The Chairperson and Executive Research Manager will review the complaint and its validity in accordance with the Policy Compliance Procedure *Research: Managing and Investigating Complaints about Research Integrity* (SLHD_PCP2022_036). A recommendation will be made to the HREC on the appropriate course of action.

4. The complainant will receive a written response, if appropriate, from the HREC advising of the outcome of the course of action.

5. If the complainant is not satisfied with the outcome of the Chairperson's review, then they can refer the complaint to the Chief Executive, or their nominee, or request the Chairperson to do so.

6. The complainant may seek independent advice from one or more of the Advisors in Research Integrity appointed by the SLHD or request the Chairperson to do so. The Advisors' details are publicly available on the SLHD Research Office websites. The Advisors' role does not extend to formal investigation or assessment of an allegation of research misconduct, nor are they permitted to make contact with a person who is the subject of the complaint.

7. The Chairperson of the HREC or Executive Research Manager will provide the Chief Executive with all relevant information about the complaint/concern, including:

    - details of the complaint;
    - material reviewed by the Chairperson and Executive Research Manager;
    - the course of action taken (if applicable); and
    - any other relevant documentation.

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

9. If the Chief Executive determines there is to be a further investigation, then they 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.

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

    - The Chief Executive or their nominee as Convener of the panel.
    - Two nominees of the Chief Executive (not members of the HREC).

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

12. 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 *National Statement*, the HREC's Terms of Reference, Standard Operating Procedures, or otherwise acted in an unfair or unbiased manner.

13. 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.

14. 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;
    - Other such action, as appropriate.

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Reference Number: SOP 022 **Date: June 2024**
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, detailing the grounds of the complaint. The matter should be referred to the Executive Research Manager for further advice. Complaints may also be made to the Chief Executive.

2. The Chairperson via the Executive Research Manager will bring to the attention of the Chief Executive as soon as possible any complaints received by them. The Chief Executive will inform the Chairperson and Executive Research Manager as soon as possible of any complaints received by them. The Chief Executive will send a letter of acknowledgement to the complainant, outlining the course of action.

3. The Chairperson and Executive Research Manager will review the complaint and its validity in accordance with the Policy Compliance Procedure *Research: Managing and Investigating Complaints about Research Integrity* (SLHD_PCP2022_036). A recommendation will be made to the HREC on the appropriate course of action.

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

5. If the complainant is not satisfied with the outcome of the Chairperson's review, then they can refer the complaint to the Chief Executive or their nominee, or request the Chairperson to do so.

6. The complainant may seek independent advice from one or more of the Advisors in Research Integrity appointed by the SLHD or request the Chairperson to do so. The Advisors' details are publicly available on the SLHD Research Office websites. The Advisors' role does not extend to formal investigation or assessment of an allegation of research misconduct, nor are they permitted to make contact with a person who is the subject of the complaint.

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

    - details of the complaint;
    - material reviewed by the Chairperson and Executive Research Manager;
    - the course of action taken (if applicable); and
    - any other relevant documentation.

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

9. If the Chief Executive determines there is a case to be investigated, then they will convene a suitable panel to consider the complaint.

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

    - The Chief Executive or their nominee as convener of the panel
    - Two nominees of the Chief Executive (not members of the HREC)
    - An expert or experts in the discipline of research of the project under consideration

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

12. 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.

13. 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.

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

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

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Reference Number: SOP 023 **Date: June 2024**
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.

1. 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. The matter should be referred to the Executive Research Manager for further advice.

2. The steps in SOP 021 should be followed.

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Reference Number: SOP 024 **Date: June 2024**
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 informs the Chairperson of the complaint. The matter should be referred to the Executive Research Manager for further advice.

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Reference Number: SOP 025 **Date: June 2024**
Subject: Review of multi-centre research
Purpose: To describe the review procedure of multi-centre research by the HREC.

1. The HREC shall comply with Policy Directive PD 2010_055 "*Research - Ethical & Scientific Review of Human Research in NSW*" and the NSW Office for Health and Medical Research National Mutual Acceptance Guidelines. A project will be ethically and scientifically reviewed once only, irrespective of the number of NSW Health sites involved in the project.

2. The HREC shall participate in the National Mutual Acceptance of Ethical and Scientific Review Scheme and the National Approach to Single Ethical Review of Multi-centre Research (National Approach). The HREC may review applications from interstate institutions or organisations participating in the National Mutual Acceptance Scheme of single ethical and scientific review.

3. To facilitate the review of multi-centre research the HREC may also:
   - communicate with any other HREC;
   - accept a scientific/technical and/or ethical assessment of the research by another HREC;
   - share its scientific/technical and/or ethical assessment of the research with another HREC.

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Reference Number: SOP 026 **Date: June 2024**
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 and/or paper record for each application received and reviewed and shall record the following information:

    - the unique project identification number;
    - the Co-ordinating and Principal Investigator(s);
    - the name of the responsible institution or organisation;
    - the contact person for the project;
    - the name of the sponsor, in the case of clinical trials;
    - the title of the project;
    - the ethical approval or non-approval with date;
    - the 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; and
    - action taken by the HREC to monitor the conduct of the research.

    The file shall contain the ethics 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 *Health Records and Information Privacy Act (HRIPA) 2002* and 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 permanent deletion, shredding or via confidential disposal bins. Members who do not have access to secure disposal should leave their documents with the Executive Officer for disposal.

5. To ensure confidentiality, all electronic documents provided to HREC members will be via a secure password-protected manner (i.e. use of SLHD's approved electronic storage programs).

6. 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 five (5) years after the date of publication or completion of the research or termination of the study. For clinical research, fifteen (15) years shall apply. For paediatric research, records shall be maintained for a minimum of fifteen (15) years after the last attendance or official contact or access by or on behalf of the participant, or until the participant attains or

would have attained the age of 25 years, whichever is longer. Files which are no longer required for retention shall be archived. Retention periods shall comply with NSW Health *'Information Bulletin 2004/20 General Retention and Disposal Authority – Public Health Services: Patient/Client Records (GDA 17)', 'General Retention & Disposal Authority - Public Health Services: Administrative Records (GDA 21)'* and *Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95).*

7. A register of all the applications received and reviewed shall be maintained in accordance with the *National Statement*.

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Reference Number: SOP 027 **Date: June 2024**
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

1. 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*

2. The HREC may establish an Executive of members, consisting of the Chairperson, the Executive Officer and one other member to consider 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.

3. All decisions made by the Executive shall be tabled for ratification at the next HREC meeting.

4. When considering the granting of approvals by external delegates, the HREC and the Concord Hospital Drug Committee shall be provided with the following information, in accordance with the *Therapeutic Goods Act 1989* and associated regulations (refer to the *Therapeutic Goods Administration Access to Unapproved Therapeutic Goods via the Special Access Scheme, November 2009*):

   - the product for which approval is sought;
   - whether that unapproved product is included on the list of products which can be approved by the practitioner;
   - details about the product to be prescribed, including an assessment of the efficacy and safety of the product;
   - the medical condition for which approval is being sought;
   - an assessment of the seriousness of the condition being treated;
   - the intended mode of use/treatment regimen and whether this conforms to the treatment protocol; and
   - the clinical justification for use of the unapproved product, including the nature and availability of alternative treatments.

5. For HREC purposes, the procedure outlined in paragraph 4 (above) for reviewing access to unapproved therapeutic goods via the Special Access Scheme is the same for Category A and Category B patients.

Sydney Local Health District Human Research Ethics Committee (HREC)
Concord Repatriation General Hospital (CRGH)
Standard Operating Procedures

Reference Number: SOP 028 **Date: June 2024**
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 HREC may establish an Executive of members, consisting of the Chairperson, the Executive Officer and one other member to consider authorised prescriber applications. The HREC may also seek advice from its sub-committee(s), when considering the issues outlined in Point 3.

2. All decisions made by the Executive 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 the Therapeutic Goods Administration *Authorised Prescriber Scheme - Guidance for Medical Practitioners, Human Research Ethics Committees, Specialist Colleges and Sponsors, Version 5.2, December 2022*:
    - the safety of the product in relation to its proposed use and indication for which the product will be used;
    - the clinical justification for its use. The HREC shall consider the following:
        - the seriousness of the condition,
        - expected benefits of the proposed treatment versus the potential risks,
        - approved treatments for the condition (including whether they have been attempted, why they are considered inappropriate, whether they will be attempted prior to the prescribing of the unapproved product, and why the proposed unapproved product is considered a more appropriate treatment),
        - how the risks associated with the use of the unapproved product will be managed,
        - the monitoring that will be undertaken,
        - the process of investigating and reporting adverse events
    - the suitability of the medical practitioner to be an authorised prescriber of the unapproved product; and
    - information to be given to the patient about the product and the informed consent form to be signed by the patient.

4. If the Authorised Prescriber proposal is approved, the HREC shall provide a letter of approval, signed by the HREC Chairperson or delegate, to the applicant in the format suggested by the Therapeutic Goods Administration (refer to *Authorised Prescriber Scheme - Guidance for Medical Practitioners, Human Research Ethics Committees, Specialist Colleges and Sponsors*). The letter of approval should contain:
    - a clear statement that the approval or endorsement is being given for the purpose of the medical practitioner becoming an authorised prescriber;
    - the name of the medical practitioner being endorsed;
    - the medicine, biological or medical device and indication/use for which endorsement has been given;
    - the site(s) covered by the endorsement; and
    - any conditions the HREC has imposed on the endorsement.

5. The HREC may impose any conditions on the endorsement such as:
    - a restriction on the class of patients in whom the drug may be used;

- 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;
- requirements for reporting of any adverse events.

6. The HREC shall review its approve 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.

7. The HREC may withdraw its approval 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.

Sydney Local Health District Human Research Ethics Committee (HREC)
Concord Repatriation General Hospital (CRGH)
Standard Operating Procedures

Reference Number: SOP 029 **Date: June 2024**
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.

1. Any HREC or Sub-Committee member shall, as soon as practicable during the HREC meeting, inform the Chairperson if they have a conflict of interest in a project or other related matter(s) to be considered by the HREC. Conflicts of interest should be declared in accordance with the *National Statement* and the NHMRC Guidance: *Disclosure of interests and management of conflicts of interest*. Conflicts of interest include 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 (e.g. withdrawal of the member concerned from the meeting) will be minuted.

<u>Potential conflicts of interest for expert reviewers</u>

4. A person invited to provide an expert review is asked to identify any potential conflicts of interest at the time of invitation.

5. Any conflicts of interest declared by an expert reviewer will be discussed by the Chairperson and recorded in the minutes of the Sub-committee and/or the minutes of the HREC meeting at which the proposal is reviewed. The Chairperson will determine the level of interest per section 2 above and whether the interest may affect their ability to provide an impartial review. An alternate expert reviewer may be sought if the Chairperson feels that the expert reviewer has a substantial conflict of interest.

Sydney Local Health District Human Research Ethics Committee (HREC)
Concord Repatriation General Hospital (CRGH)
Standard Operating Procedures

Reference Number: SOP 030 **Date: June 2024**
Subject: HREC reporting requirements
Purpose: To describe the reporting requirements of the HREC.

1. The minutes of each HREC meeting will be forwarded to the Chief Executive and SLHD Board (reporting to the SLHD Education and Research Committee), following confirmation from the Chairperson who chaired the meeting. The Chairperson should sign and date the minutes following their review.

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 held;
    - 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
    - any other general issues raised.

3. The HREC will provide the following reports:
    - Report to the NSW Privacy Commissioner in accordance with the requirements of the *Health Records and Information Privacy Act 2002 (HRIPA)* (NSW);
    - HREC Annual Report to the National Health and Medical Research Council (NHMRC);
    - 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 to the general public and posted on the SLHD Research Office website.

Sydney Local Health District Human Research Ethics Committee (HREC)
Concord Repatriation General Hospital (CRGH)
Standard Operating Procedures

Reference Number: SOP 031 **Date: June 2024**
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 three years and amended as necessary in consultation with the HREC.

2. The Standard Operating Procedures and Terms of Reference may be amended by following the procedures below:

   For those proposals made by a HREC member:

   - The proposal must be in writing and circulated to all HREC members for their consideration.
   - The views of the members should be discussed at the next scheduled meeting of the HREC, and a vote taken at that meeting. Any member unable to attend such a meeting may register their views in writing.
   - The proposal shall be ratified if two-thirds of the members agree to the amendment.
   - The Chairperson shall send the amendment to the Chief Executive for review and approval, if appropriate.

   For those proposals made by the Chief Executive:

   - The Chief Executive will send the proposal to the HREC and seek the views of any relevant person.

SLHD Human Research Ethics Committee – Concord Repatriation General Hospital Membership

(Membership as of June 2024, membership is regularly updated on the SLHD Research Office website as required)

Member	Category
A/Professor Anne Wand	A
Dr Janani Thillainadesan	A
Dr Will Becerril	C
Dr Claire Blizard	C
A/Professor Lil Vrklevski	C
Dr Alice Cottee	C
Ms Saba Ahmad Larijani	C
Dr Henry Cheung	C
Dr Sharon Nahm	C
Professor Mark Cooper	F
Ms Lucy Nigro	F
Dr Deonna Ackermann	F
Professor Deborah Cockrell	F
A/Professor Yuen Yee Cheng	F
Dr Gabriel Moore	F
Ms Amanda Idan	F
Ms Samantha Hand	F
A/Professor Muh Geot Wong	F
Mr Matthew Halpin	F
Dr Rob Neurath	B
Mr David Luttrell	B
Ms Caren Beer	B
Ms Alison Pollard	B
Reverend Janine Steele	D
Reverend Minh Phuong Towner	D
Mr Steven Canton	E
Mr Steven Kouris	E
Ms Kate Flinders	Executive Officer

Attachment A

Standard Letter for HREC Approval of a New Application

This should include at least the following pieces of information:

- title of project and any project number;
- name of the Co-ordinating Principal Investigator;
- 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; and
- if the research is being conducted by an external organisation (if it is in the HREC's TOR to provide ethical review for that external organisation), a statement that approval of this project does not have the effect of conferring any insurance or indemnity coverage on the external organisation by the Local Health District in relation to the project, and responsibility for any liabilities arising from the conduct of the project remains entirely with the external organisation.

LETTER 1 – Ethics Approval Letter

Contact: Sydney Local Health District Human Research Ethics Committee – CRGH
Concord Repatriation General Hospital (CRGH)
Concord NSW 2139
Telephone: *(02) 9767 5622*
Email: SLHD-ConcordEthics@health.nsw.gov.au
Local Ref: *CH62/6/202x-xxx*

CONCORD
REPATRIATION GENERAL
HOSPITAL

This letter constitutes ethical approval only. You must NOT commence this research project at ANY site until you have submitted a Site Specific Assessment Form to the Research Governance Officer and received separate authorisation from the Chief Executive or delegate of that site.

Date 20xx

Dear [insert title and full name],

Re: **Local reference number:** CH62/6/202x-xxx
REGIS ethics reference number: xxx
Project title: xxx

Thank you for submitting the above research proposal for single ethical and scientific review. This project was first considered by the Scientific Sub-Committee at its meeting of xxx and by the [if applicable - Executive of the] Sydney Local Health District Human Research Ethics Committee (HREC) – CRGH Zone at its meeting held on xx 202x.

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research*, the *CPMP/ICH Note for Guidance on Good Clinical Practice* and the *National Clinical Trials Governance Framework.*

I am pleased to advise that final ethical approval has been granted based on the following:

- The research project meets the requirements of the *National Statement on Ethical Conduct in Human Research 2023*.

- *[if applicable - **HRIPA: Studies for which a waiver of consent was granted**:]:* The HREC granted a waiver of the usual requirement for the consent of the individual for the use of their health information in a research project, in accordance with the *Health Records and Information Privacy Act 2002* (NSW) and the NSW Privacy Commissioner's Statutory guidelines on research.

- *[if applicable – **Section 95A: Studies for which a waiver of consent was granted**:]:* The HREC granted a waiver of the usual requirement for the consent of the individual for the use of their health information in a research project, in accordance with the Guidelines approved under Section 95A of the *Privacy Act 1988*. You are therefore required to keep detailed records of the following: the name(s) of the private sector organisation(s) from which health information was collected, the data fields collected

and the number of records accessed for this research project. This information will be reported annually to the Commonwealth Privacy Commissioner via the Australian Health Ethics Committee.

- *[if applicable – **Section 95: Studies for which a waiver of consent was granted**:]:* The HREC granted a waiver of the usual requirement for the consent of the individual for the use of their health information in a research project, in accordance with the Guidelines approved under Section 95 of the *Privacy Act 1988*. You are therefore required to keep detailed records of the following: the name(s) of the Commonwealth agency/ies from which personal data are collected; the data fields sought from the records of such organisation(s) and the number of records accessed at each organisation(s) for this research project. This information will be reported annually to the Commonwealth Privacy Commissioner via the Australian Health Ethics Committee.

- *[if applicable – **Other non-NSW sites: Studies for which a waiver of consent was granted**:]:* The HREC granted a waiver of the usual requirement for the consent of the individual for use of their health information in a research project, in accordance with the *National Statement on Ethical Conduct in Human Research (2007) – updated 2018 - Chapter 2.3: Qualifying or waiving conditions for consent.*

The documents reviewed and approved include:

DOCUMENT	VERSION	DATE
Human Research Ethics Application (HREA)		
Protocol		
Investigator's Brochure		
Master Participant Information Sheet & Consent Form		
Master Code Sheet		
Data Collection Form		
Other (e.g. Advertisement)		
Privacy Compliance Form		
Research Data Management Plan		

The HREC has provided ethical and scientific approval for the following sites:

1. Concord Repatriation General Hospital, NSW
2. Xxxx
3. Xxxx

For sites outside of NSW/ACT REGIS, a copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

(If applicable) Special conditions:
[This section only for any conditions that are specific to the study being approved]

Please note the following conditions of approval. The conditions listed in this approval letter should be comprehensively reviewed and understood by all members of the research team:

1. HREC approval is valid for five (5) years subject to the supply of annual progress reports. The first report should be sent to the HREC by **xx/xx/2025.** You must also provide an annual report to the HREC

upon completion of the study. This will be through a submission of a milestone in REGIS, see REGIS Quick Reference Guide (QRG): **Submitting Annual Progress or Final Report (Milestone)**.

Important notes:

- **Ethics expiry:** An ethics extension amendment should be submitted prior to the ethics approval expiry date if the study is continuing beyond that date. This will be through a notification of an ethics amendment via REGIS, see REGIS QRG: **Ethics Amendment - Completing and Submitting**. Projects that are 12 months past the ethics expiry without submitting an ethics extension amendment will automatically be **suspended**.
- **Milestones:** The status of any pending annual progress report that is six or more months past the due date will automatically be changed to 'Not Achieved'. The Research Office should be contacted to create a replacement milestone for the calendar year covered by the 'Not Achieved' milestone. The Committee relies on these reports to verify that the conduct of research complies with the approved protocol and remains ethically acceptable. Failure to submit regular or ongoing reports may result in your **ethics approval being withdrawn.**

2. In accordance with the National Statement, chapter 4.7; you must seek ethical approval from the HREC of the Aboriginal Health and Medical Research Council (AHMRC) if you intend to use Aboriginal and /or Torres Strait Islander status in any presentation or publication. See Research Office website for more information.

3. The study procedures as listed in the protocol must be followed at all times. See *The Australian Code for the Responsible Conduct of Research.*

4. All study personnel must be trained in the study protocol and aware of their role and responsibilities with respect to the research. All new personnel must be appropriately onboarded.

5. **Amendments:** Any proposed changes to the research protocol should be submitted to the HREC before those changes are implemented, such as changes to:
    - The general conduct of the research, including new aims or sub-studies
    - Any study procedures or data collection/management
    - CPI, site PI, adding students or other study personnel
    - An extension to HREC approval
    - The addition of sites

    Updated study documents should be submitted as a tracked and clean copy with new version number and date. This will be through a notification of an ethics amendment via REGIS, see REGIS QRG: **Ethics Amendment - Completing and Submitting**. See the Research Office website for more information on who can submit an amendment.

6. If the project is discontinued at a site before the expected date of completion, you must notify the HREC with reasons provided. It is also important to ensure study closure and completion processes are carried out in accordance with the Research Data Management Plan, Good Clinical Practice and local governance procedures. This will be through a notification of an ethics amendment via REGIS, see REGIS QRG: **Ethics Amendment - Completing and Submitting**. The site Research Governance Officer should also be notified following ethics acknowledgment, see REGIS QRG: **Governance Amendment - Completing and Submitting**.

7. You must immediately report anything which might warrant review of ethics approval, including unforeseen events that might affect continued ethical acceptability of the project. Examples include, significant safety issues, serious breaches, participant complaints, privacy breaches. This will be

through a notification via REGIS, see REGIS QRG: **Clinical Trial Safety Reporting** (for clinical trials) or **Ethics Amendment - Completing and Submitting**.

8. **Serious breaches:** Serious breaches and complaints should be reported in accordance with NHMRC Guidance document: Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods 2018. **All complaints should immediately be reported to the HREC within 24 hours of being notified.** This will be through a notification via REGIS, see REGIS QRG: **Clinical Trial Safety Reporting** (for clinical trials) or **Ethics Amendment - Completing and Submitting**.

9. **Conflicts of interest:** Any changes to financial, business or other non-financial conflicts of interests related to this research should be declared to the HREC in accordance with the *National Statement Chapter 5.4: Conflicts of interest.* See also NHMRC guidance document Disclosure of interests and management of conflicts of interest. This will be through a notification via REGIS, see REGIS QRG: **Ethics Amendment - Completing and Submitting**.

10. ***(If applicable) For student projects:*** **Student projects:** HREC approval is granted on the assumption that all students and early career researchers are adequately supervised by the Coordinating Principal Investigator and senior investigators on a project. This supervision would ensure that all privacy concerns are met (including the completion of confidentiality agreements by participating students) and that students are supported in the conduct of the study in line with the approved research protocol.

11. ***(If applicable) Access Request/SSA requirements for survey studies, if applicable:*** The researchers are advised to discuss the study with the Research Governance Officer for each site or local health district where the surveys will be administered to ascertain whether an Access Request is sufficient or a full site-specific assessment application is required.

[If applicable] **Clinical Trial Conditions:**

12. ***(If applicable) For drug or device trials (CTN): This study requires notification to the Therapeutic Goods Administration (TGA) under the Clinical Trials Notification (CTN) Scheme.***
The clinical trial should not commence until the CTN has been submitted to the Therapeutic Goods Administration (TGA) using the online form. This HREC approval letter fulfils the documentation required to indicate the approval of the Human Research Ethics Committee responsible for monitoring the trial. A copy of the TGA acknowledgment of receipt of a CTN must be submitted to the Research Governance Office as soon as it is available.

13. **Partnering with Consumers:** As per Standard 2 of The National Clinical Trials Governance Framework, you are asked to provide an update with your annual progress report (milestone) on the ongoing involvement of consumers in the planning, design, delivery, measurement and evaluation of the trial. See the Research Office website for more information.

14. **Good Clinical Practice (GCP):** When adding additional sites, it is a condition of approval that the GCP Certificate of Completion be submitted for the principal investigators responsible for the new sites. Links to online GCP courses are available here.

15. ***(If applicable) For trials of implantable devices:*** This study involves the implantation of an investigational device. It is a requirement of ethics approval that all participants are included in a device tracking register and that arrangements are made for monitoring all participants for the lifetime of the device. Any device incidents must be reported to the Therapeutic Goods Administration (TGA) and to the Ethics Committee.

16. ***(If applicable) For clinical trials (if this information not already provided):*** It is a requirement of ethics approval that before its commencement this clinical trial is registered on a publicly accessible register, such as the Australian New Zealand Clinical Trials Registry or another appropriate international register. You are asked to provide details of the Register in which the study has been included and its registration number. This will be through a notification via REGIS.

17. ***(If applicable) Multi-site Investigator-initiated clinical trials, If applicable:*** ***It is a condition of approval that the study sites listed in this approval letter, and any subsequent additional sites added in future through the amendment process, will be sponsored by their own local health district or institution and will take on all sponsor-related liabilities, including submitting their own CTN to the TGA.***

    (If applicable) Investigator-initiated clinical trials: Add the following statement when the SLHD is the sponsor and we are approving an external site: The individual sites' RGOs are responsible for submitting their CTN to the TGA – SLHD is not acting as their Sponsor.

18. ***(If applicable)*** *For trials involving people with impaired capacity to consent* ***(trial involving NSW sites only):*** The study is not approved for the inclusion of persons with decision making disabilities, who are therefore unable to provide consent. Under Part 5 of the NSW Guardianship Act 1987, this trial will require separate review and approval by the NSW Civil & Administrative Tribunal (Guardianship Division) for those persons with decision making disabilities. Furthermore, the Tribunal will determine whether consent to participation can be delegated to the Persons Responsible or will be given by the Tribunal itself.

19. ***(If applicable)*** *For trials involving people with impaired capacity to consent (****sites in NSW and other states):*** The inclusion of persons with decision making disabilities, who are therefore unable to provide consent, must comply with legislative frameworks in each jurisdiction in which the trial is conducted. In NSW, the trial is not approved for the inclusion of persons with decision making disabilities. Under Part 5 of the NSW Guardianship Act 1987, this trial will require separate review and approval by the NSW Civil & Administrative Tribunal (Guardianship Division) for those persons with decision making disabilities. Furthermore, the Tribunal will determine whether consent to participation can be delegated to the Persons Responsible or will be given by the Tribunal itself.

(If applicable) For commercial clinical trials: Also enclosed is a copy of the HREC Review Only Indemnity Form for this study, signed by the Chief Executive of the Sydney Local Health District.

For your information at the end of this letter is a general checklist to assist you with following all the necessary steps to support the study's compliance throughout its full duration.

Should you have any queries about the HREC's consideration of your project please contact the Executive Officer - (02) 9767-5622. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the website: https://www.slhd.nsw.gov.au/concord/Ethics/Ethics.html

The HREC welcomes feedback from researchers on how the ethics review process can be improved or how researchers can be better supported. If you would like to provide feedback, please email the Research Office.

Researchers are encouraged to:

- Develop standard operating procedures for consenting in line with the National Standard Operating Procedures (if applicable).
- Regularly visit REGIS for system updates and for notifications about their project.
- Regularly review the Research Office website for up-to-date information on ethics requirements, training opportunities and drop-in clinics: https://www.slhd.nsw.gov.au/concord/ethics/default.html

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

Yours sincerely,

Executive Officer
Sydney Local Health District Human Research Ethics Committee – CRGH Zone

[if applicable] Cc: Clinical Trials Pharmacist (for drug trials)

Research Study Compliance Checklist

	Completed
Study approvals	
1. Ethics Approval	
2. Site Specific Authorisation at all sites	
Study commencement	
3. Study personnel training and on-boarding at all sites	
4. Develop Consent SOP	
5. Data Management processes established per approved RDMP	
Study conduct	
6. Check in REGIS for milestones' due dates & other updates (annual report milestones are due to be submitted each year on the ethics approval anniversary date; include an annual update on the consumer engagement plan if requested by the HREC)	
7. All ethics amendments are notified to the HREC/RGO	
8. All complaints/breaches reported to HREC	
9. At end of 5 years, request ethics extension (if the study is ongoing)	
Study closure	
10. Notify HREC/ RGO –final milestone (Closed post-analysis)	
11. Ensure study documentation archived as per the approved Protocol	
12. Ensure data is managed as per the approved Protocol	
13. Report results to participants	

Attachment B

Standard Letters for HREC Approval of an Amendment

This should include at least the following pieces of information:

- title of project and any project number;
- name of the co-ordinating investigator;
- 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 (or Sub-Committee, or Executive Meeting) at which the amendment and/or request for extension was first considered;
- date of HREC approval; and
- conditions of HREC approval, if any.

LETTER 1 – From HREC / Sub-Committee

LETTER 2 – From Executive

LETTER 1
Note: the following is sent via email on REGIS

[insert date]
«Risk review pathway»

«Salutation» «Title» «Name»,

Thank you for submitting an Amendment for the following study;
Re: «Reference_No» - "«Protocol_Title»"

The Amendment has been reviewed by the (**delete whichever not applicable)** Sydney Local Health District Concord Repatriation General Hospital Human Research Ethics Committee **or** Scientific Sub-Committee at its meeting held on xxx who have determined the Amendment has been approved.

Notification of an amendment to a research study - General Amendment with form ID xxx

The following documentation is included in this approval:

- [insert details of amendment]
- [insert details of other approved documents] OR gave its approval, subject to the following:
- [insert details of provisions]

(*Delete if not applicable*) In order for your response to be presented at the next HREC Committee meeting, this information should be forwarded to the Research Ethics and Governance Office as soon as practicable.

In accordance with the National Statement, chapter 4.7; you must seek ethical approval from the HREC of the Aboriginal Health and Medical Research Council (AHMRC) if you intend to use ATSI status in any presentation or publication.

It is noted that the Sydney Local Health District Concord Repatriation General Hospital Human Research Ethics Committee is constituted in accordance with the National Statement on Ethical Conduct in Human Research, 2023 (NHMRC).

This email constitutes ethical and scientific approval only.

For NSW authorised sites (listed in REGIS): A Site General Amendment form will need to be submitted to each affected site. You are not required to upload this form or the ethics approved documents into the site form but you will need to identify this approved amendment form ID xxx

Please contact us if you would like to discuss any aspects of this process further, as per the contact details below.

Yours sincerely,

Name of Executive Officer or delegate
Executive Officer (Or delegate)
Sydney Local Health District Human Research Ethics Committee – Concord Repatriation General Hospital

LETTER 2
Note: the following is sent via email on REGIS

[insert date]
«Risk review pathway»

«Salutation» «Title» «Name»,

Thank you for submitting an Amendment for the following study;
Re: «Reference_No» - "«Protocol_Title»"
The Amendment has been reviewed on xxx, by the Executive Officer as delegated by the HREC Chair and has been approved.

Notification of an amendment to a research study - General Amendment with form ID xxx

The following documentation is included in this approval:

- [insert details of amendment]
- [insert details of other approved documents] OR gave its approval, subject to the following:
- [insert details of provisos]

(*Delete if not applicable*) In order for your response to be presented at the next HREC meeting, this information should be forwarded to the Research Ethics and Governance Office as soon as practicable.

In accordance with the National Statement, chapter 4.7; you must seek ethical approval from the HREC of the Aboriginal Health and Medical Research Council (AHMRC) if you intend to use ATSI status in any presentation or publication.

It is noted that the Sydney Local Health District Concord Repatriation General Hospital Human Research Ethics Committee is constituted in accordance with the National Statement on Ethical Conduct in Human Research, 2023 (NHMRC).

This email constitutes ethical and scientific approval only.

For NSW authorised sites (listed in REGIS): A Site General Amendment form will need to be submitted to each affected site. You are not required to upload this form or the ethics approved documents into the site form but you will need to identify this approved amendment form ID (xxx).

Please contact us if you would like to discuss any aspects of this process further, as per the contact details below.

Yours sincerely,

Name of Executive Officer or delegate
Executive Officer (Or delegate)
Sydney Local Health District Human Research Ethics Committee – Concord Repatriation General Hospital

Attachment C

Standard Response Letter for HREC Request for Further Information

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LETTER 1 – Request for Further Information Letter for non-Clinical Trials

LETTER 2 – Request for Further Information Letter for Clinical Trials

LETTER 1

Contact: Sydney Local Health District
Human Research Ethics Committee
Concord Repatriation General Hospital
Building 20, Hospital Road
Concord NSW 2139
Telephone: (02) 9767 5622
Email: SLHD-ConcordEthics@health.nsw.gov.au

Our Ref: Item 5.x of xx.xx.202x

CONCORD
REPATRIATION GENERAL
HOSPITAL

xx xx 202x

Dear X,

Re: REGIS ethics application number:
Local reference number:
Project title:

This is a Request for Further Information letter.

PLEASE NOTE: You will need to respond via REGIS within 40 DAYS of the date of this letter.

If you require an extension to reply to the Committee's queries, you will need to write to the Executive Officer via email by Day 30 to request an extension.

If you have not responded within 40 days and have not asked for an extension, your application will be WITHDRAWN.

Thank you for submitting the above research proposal which was reviewed by the by the Sydney Local Health District Human Research Ethics Committee (HREC) – CRGH at its meeting of xx xx 202x.

The Committee requested the following information/clarification:

Please respond to the above matters in the attached researcher's response to ethics document. Please upload this response to REGIS with one clean and one tracked copy of any revised documents, with a new version number and date for ease of document management. This information should be submitted via REGIS **within 40 days of the date of this letter.**

Please contact the Concord Research Office on SLHD-ConcordEthics@health.nsw.gov.au if you require assistance addressing these matters.

Your responses will be referred to the Chair to make a final decision on the ethical acceptability of the study.

If you have not responded within 40 days and have not asked for an extension, your application will be WITHDRAWN and you will be required to submit a new application.

How to respond to a request for information in REGIS:
Please refer to the quick reference guide for 'Responding to a request for information'.

Yours sincerely,

Executive Officer
Sydney Local Health District Human Research Ethics Committee -
Concord Repatriation General Hospital

LETTER 2

Contact: Sydney Local Health District
Human Research Ethics Committee
Concord Repatriation General Hospital
Building 20, Hospital Road
Concord NSW 2139
Telephone: (02) 9767 5622
Email: SLHD-ConcordEthics@health.nsw.gov.au

CONCORD
REPATRIATION GENERAL
HOSPITAL

Our Ref: Item 5.x of xx.xx.202x

xx xx 202x

Dear X,

Re: REGIS ethics application number:
Local reference number:
Project title:

This is a Request for Further Information letter.

PLEASE NOTE: You will need to respond via REGIS within 30 DAYS of the date of this letter.

If you require an extension to reply to the Committee's queries, you will need to write to the Executive Officer via email by Day 20 to request an extension.

If you have not responded within 30 days and have not asked for an extension, your application will be WITHDRAWN.

You are invited to attend the Clinical Trials Drop-in Clinic to seek further advice or assistance with your response to this letter. Please contact the Executive Officer to organise an appointment.

Thank you for submitting the above research proposal which was reviewed by the Scientific Sub-Committee at its meeting of xx xx 202X and by the Sydney Local Health District Human Research Ethics Committee (HREC) – CRGH at its meeting of xx xx 202x.

The Committee requested the following information/clarification:

Please respond to the above matters in the attached researcher's response to ethics document. Please upload this response to REGIS with one clean and one tracked copy of any revised documents, with a new version number and date for ease of document management. This information should be submitted via REGIS **within 30 days of the date of this letter.**

Please contact the Concord Research Office on SLHD-ConcordEthics@health.nsw.gov.au if you require assistance addressing these matters.

Your responses will be referred to the Chair to make a final decision on the ethical acceptability of the study.

If you have not responded within 30 days and have not asked for an extension, your application will be WITHDRAWN and you will be required to submit a new application.

How to respond to a request for information in REGIS:
Please refer to the quick reference guide for 'Responding to a request for information'.

Yours sincerely,

Executive Officer
Sydney Local Health District Human Research Ethics Committee -
Concord Repatriation General Hospital

Attachment D

Standard Response Letter for HREC / Sub-Committee Deferral of Approval of a New Application

Contact: Sydney Local Health District Human Research Ethics Committee – CRGH
Concord Repatriation General Hospital (CRGH)
Concord NSW 2139
Telephone: *(02) 9767 5622*
Email: SLHD-ConcordEthics@health.nsw.gov.au
Local Ref: *CH62/6/2024-xxx*

CONCORD
REPATRIATION GENERAL
HOSPITAL

date

Dear X

Re: REGIS ethics application number:
Local reference number:
Project title:

Thank you for submitting the above new research proposal which was considered by the Scientific Sub-committee at its meeting of xx 202x and by the Sydney Local Health District Human Research Ethics Committee – CRGH at its meeting of xx 202x.

On the basis of the documentation presented, the Committee resolved to **defer approval at this time**, and to seek from you the following additional information:

1. [List each query separately, referring to the relevant paragraph/s of the *National Statement*, relevant legislation or other applicable guidelines, if applicable].

Please quote one of the above reference numbers in all correspondence.

Yours sincerely,

xx
Executive Officer
SLHD Human Research Ethics Committee – CRGH

Attachment E

Standard Response Letter for HREC Rejection of a New Application

Contact: Sydney Local Health District Human Research Ethics Committee – CRGH
Concord Repatriation General Hospital (CRGH)
Concord NSW 2139
Telephone: *(02) 9767 5622*
Email: SLHD-ConcordEthics@health.nsw.gov.au
Local Ref: *CH62/6/2024-xxx*

CONCORD
REPATRIATION GENERAL
HOSPITAL

date

Dear X

Re: REGIS ethics application number:
Local reference number:
Project title:

Thank you for submitting the above new research proposal which was considered by the Scientific Sub-committee at its meeting of xx 202x and by the Sydney Local Health District Human Research Ethics Committee – Concord Repatriation General Hospital (CRGH) at its meeting of xx 202x.

The Human Research Ethics Committee (HREC) was of the opinion that although this is an important and worthwhile study, the study could not be approved in its current form. The Committee were unable to conduct a detailed review of the application as there were insufficient details provided in regards to [insert reasons e.g. the proposed study design, methodology, and analysis]. The application needs to be re-written to meet the requirements of the *National Statement on Ethical Conduct in Human Research 2023* in order to receive ethics approval.

The investigators are invited to discuss the research project with the Chair of the SLHD HREC - CRGH, xxxx, <insert email> and resubmit a new application at a future time. The following comments should be taken into account with the re-submission:

1. [List each query separately, referring to the relevant paragraph/s of the *National Statement*, relevant legislation or other applicable guidelines, if applicable].

Please quote one of the above reference numbers in all correspondence.

Yours sincerely,

xx
Executive Officer
SLHD Human Research Ethics Committee – CRGH

Attachment F

Standard Requirements for Safety Reporting

FORM 1 – Significant Safety Issue (SSI) Notification Form

LETTER 1 – SSI Acknowledgment Letter

FORM 1

Project reference 202x/ETH00xxx

SIGNIFICANT SAFETY ISSUE NOTIFICATION FORM

PROJECT DETAILS	
HREC Reference No.	EC00118
Project Title	
Lead HREC	Sydney Local Health District Human Research Ethics Committee – Concord Repatriation General Hospital
Coordinating Principal Investigator	

Date significant safety issue occurred	
Report Type	Initial Report : ☐ Follow up report : ☐
Form type	☐ Urgent safety measure ☐ Temporary halt of a trial for safety reasons ☐ Early termination of a trial for safety reasons
NOTIFICATION OF AN URGENT SAFETY MEASURE	
Please describe the following • The reason for implementing the urgent safety measure • The measures taken (e.g. drug/intervention stopped) • Any further actions planed	
Reason for Urgent Safety Measure:	
The measures taken (e.g. drug/intervention stopped):	
Any further actions planned:	
Does this USM require the submission of an amendment to the HREC	☐
Would you like to submit the Final Progress Report with this notification?	

DOCUMENTS			
Document name	**Version**	**Date**	**Document type**

DECLARATION	
I declare that: The information provided above is true and accurate	
Name	
Date	

FORM 2
Note: the following is sent via email on REGIS

Date of Notification Reported to HREC: DD MMM YYYY

Dear «Title» «Name»,

Re: Protocol No «Protocol_No» - "«Protocol_Title»"

Thank you for submitting a Significant Safety Issue to the Human Research Ethics Committee; this email acknowledged the receipt of the notification to the HREC.

To help you comply with the NHMRC guidance on Safety monitoring and reporting in clinical trials this notification has been sent to each NSW Principal Investigator (site/s listed in REGIS). Please forward this acknowledgement to any other site PI's outside of NSW.

Once reviewed by the Sydney Local Health District Human Research Ethics Committee – Concord Repatriation General Hospital you will receive an email notification that the review has been completed. Each NSW Research Office will be forwarded the report and the HREC notification. You are not required to submit this separately to any NSW sites (listed in REGIS). Sites will not individually acknowledge this report.

If this SSI has resulted in safety-related changes to trial documentation these amendments should be submitted to the HREC without undue delay.

See REGIS quick reference guide: Ethics Amendment – Completing and Submitting

Please do not hesitate to contact us on the details below if you have any questions.

Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods.
Part 1C1i IMP trials & Part 2C1k IMD trials – It is the Sponsors responsibility…..
to notify the TGA, HREC and investigators of all ***significant safety issues*** *that adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.*
Significant safety issues that meet the definition of an ***urgent safety measure should be notified within 72 hours****, and* ***all other significant safety issues should be notified within 15 calendar days*** *of the sponsor instigating or being made aware of the issue.*
https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods

Regards,

Research Ethics and Governance Information System (REGIS)

Attachment G

Standard Requirements for Reporting of Serious Breaches

FORM 1 – Serious Breach Notification Form

LETTER 1 – Serious Breach Acknowledgment Letter

FORM 1

Application Reference **20xx/ETHxxxxx**

Project details

Project title

CTX/CTN Reference number

Coordinating Principal Investigator

Breach details

Sponsor

Sponsor contact

Is this an initial or follow up report?

Details of the organisation committing the breach

Indicate the impact of the breach (actual or potential) on any of the following

Provide an explanation of where, how, and when the breach occurred, and how it was identified. Provide any other relevant information (e.g. study status) if necessary.

Details of any action taken to date

Include

1. Any investigations you/ others are conducting
2. The outcome of those investigations if completed (or details of when they will be available/submitted)
3. How the breach will be reported in the final report/publication
4. Any corrective & preventative action implemented to ensure the breach does not occur again

*If the investigation or the corrective or preventative action is ongoing at the time of this report, please indicate your plans with projects timelines for completion and provide the information in a follow-up report.

Application Reference **20xx/ETHxxxxx**

Document Upload

Type	Descriptor	File name

Declaration

Your name:

Your organisation

Your role

Your contact

Date

LETTER 1

Date of Notification Noted by HREC: DD MMM YYY

Dear «Title» «Name»,

Re: Protocol No «Protocol_No» - "«Protocol_Title»"

Thank you for submitting a Serious Breach Notification with form ID XXXXX.

The Sydney Local Health District Human Research Ethics Committee – Concord Repatriation General Hospital have completed their review of the Serious Breach Notification and no further information is required at this time.

To help you comply with the NHMRC guidance on safety monitoring and reporting in clinical trials this notification has been shared with the affected NSW site and Principal Investigator listed in REGIS. If the affected site is outside of REGIS/NSW, please forward this acknowledgement to the site PI.

You are not required to submit this separately to the affected NSW site (listed in REGIS). The Site will not individually acknowledge this report.

If this Serious Breach has resulted in safety-related changes to trial documentation these amendments should be submitted to the HREC without undue delay.

See REGIS quick reference guide: Ethics Amendment – Completing and Submitting
Please do not hesitate to contact us on the details below if you have any questions.

Guidance: Reporting of Serious Breaches of Good Clinical Practice (GDP) or the Protocol for Trials Involving therapeutic Goods
Sponsors have primary responsibility for determining whether any suspected breach meets the definition of a serious breach.

Sponsors should:

- *Report serious breaches to the reviewing HREC **within 7 calendar days of confirming a serious breach has occurred** and provide follow-up reports when required.*
- *For serious breaches occurring at a trial site, notify the site's principal investigator **within 7 calendar days of confirming a serious breach has occurred.***
- *Where the sponsor determines a third party report,7 provided to it by the HREC, meets the definition of a serious breach, report the serious breach to the reviewing HREC **within 7 calendar days of this decision.***

*It is recommended that sponsors also ensure that agreements with trial sites and other vendors include a reference to a reporting timeline of **72 hours for notifying the sponsor of any suspected breach.***
https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods

Regards,
Executive Officer

Attachment H

Standard Report Form for Making a Medical Device Incident Report to the TGA, i.e. Users Medical Device Incident Report

See:

- Report a medical device adverse event (medical device consumer)- external site
- Report a medical device adverse event (medical device health professional)- external site
- Report a medical device adverse event (sponsor/manufacturer)

Attachment I

Standard Letter for Requesting an Annual or Quarterly Report for an Approved Project

Note: the following is sent via email on REGIS

Dear «Title» «Name»,

«Protocol_No»: "«Protocol_Title»"
MILESTONE OVERDUE PLEASE SUBMIT URGENTLY

Our records indicate a **Progress Report** was due on **xx/xx/202x**.
The submission of this milestone a is a condition of HREC approval. Failure to submit overdue milestones may stop you from being able to submit other post approval forms e.g. amendments and may also cause ethics approval to be halted.

All Progress Report are to be submitted in REGIS.

How to submit a Progress Report in REGIS:
Please refer to the quick reference guide for submitting a Progress Report to NSW/ACT HREC.

Access the **Progress Report** form directly by clicking this link or «link auto-populated».

If you have submitted this milestone, please contact the research office managing this study to discuss.

Details of research office managing this application:
Name: Sydney Local Health District Human Research Ethics Committee – Concord Repatriation General Hospital

Thank you,

Executive Officer
Sydney Local Health District Human Research Ethics Committee – Concord Repatriation General Hospital

Attachment J

Standard Acknowledgment Letter for an Annual or Quarterly Report for an Approved Project

Note: the following is sent via email on REGIS

Date of Decision Notification: **DD-MM-YYYY**

Dear «Title» «Name»,

Thank you for submitting a Progress Report for;
«Protocol_No»: "«Protocol_Title»"

The Human Research Ethics Committee, at its meeting of xxx 202x, considered your annual progress report on the above study, and it was noted with thanks. The milestone is Achieved.

Each authorised site in REGIS has been notified and will only contact you if they require more information. Please accept this notification on behalf of the HREC and NSW sites listed in the form.

Please contact us if you would like to discuss any aspects of this process further, as per the contact details below

Executive Officer
Sydney Local Health District Human Research Ethics Committee – Concord Repatriation General Hospital

Attachment K

Standard Letter for Notifying Withdrawal of Ethical Approval

Contact: Sydney Local Health District Human Research Ethics Committee – CRGH
Concord Repatriation General Hospital (CRGH)
Concord NSW 2139
Telephone: *(02) 9767 5622*
Email: SLHD-ConcordEthics@health.nsw.gov.au
Local Ref: *CH62/6/2024-xxx*

CONCORD
REPATRIATION GENERAL
HOSPITAL

[insert date]

Dear «Title» «Name»,

Re: REGIS ethics application number:
Local reference number:
Project title:

I refer to the above research study which was granted ethics approval by the Sydney Local Health District Human Research Ethics Committee – Concord Repatriation General Hospital in [year].

The Committee has been advised that [insert details of ethical concerns].

In the light of this/these, the Committee has significant concerns about [insert nature of concerns, eg the safety and the welfare of the participants] and has therefore resolved to withdraw the ethics approval for the study and to suspend the study, effective immediately.

As Co-ordinating Investigator, you are responsible for immediately notifying this change in the study's status to the study sponsor, and to the Principal Investigators at all the sites at which the study is being conducted.

The Principal Investigator at each site is then responsible for notifying:

- The Research Governance Officer at their site of the study's changed status, and
- The study participants in their care.

You are welcome to review the protocol and the information/consent documents [or other study materials, as appropriate] in the light of the Committee's concerns and submit amended documents for further review.

In order for your response to be presented at the next Ethics Review Committee meeting, this information should be forwarded to the Research Ethics and Governance Office by Wednesday, [insert next agenda closing date].

Yours sincerely,

Name of Executive Officer
Executive Officer
Sydney Local Health District Human Research Ethics Committee – Concord Repatriation General Hospital

Attachment L

Standard Letter for Approving a Modified Research Proposal after Ethical Approval was Withdrawn

Contact: Sydney Local Health District Human Research Ethics Committee – CRGH
Concord Repatriation General Hospital (CRGH)
Concord NSW 2139
Telephone: *(02) 9767 5622*
Email: SLHD-ConcordEthics@health.nsw.gov.au
Local Ref: *CH62/6/2024-xxx*

CONCORD
REPATRIATION GENERAL
HOSPITAL

[insert date]

Dear «Title» «Name»,

Re: REGIS ethics application number:
Local reference number:
Project title:

I refer to my correspondence of [insert date of letter] informing you of the withdrawal of ethics approval for the above study and your response dated [insert date of letter].

Thank you for submitting modified documentation for the study, which was considered by the Sydney Local Health District Human Research Ethics Committee – Concord Repatriation General Hospital at its meeting on [insert meeting date].

The Committee considered that the modifications address its concerns about [insert nature of concerns, eg the safety and the welfare of the participants], and its ethics approval of the study is now re-instated.

The following documents are approved:

-
-

As Co-ordinating Investigator, you are responsible for notifying the study sponsor and the site Principal Investigators of the re-instatement of ethics approval for the study.

The Principal Investigator at each site should then notify their Research Governance Officer and the study participants in their care of the study's reinstated ethics approval.

Yours sincerely,

Name of Executive Officer
Executive Officer
Sydney Local Health District Human Research Ethics Committee – Concord Repatriation General Hospital

Attachment M

Standard Letter for Appointment of new HREC Members

Dear xx

Re: **Appointment to the Sydney Local Health District Human Research Ethics Committee (CRGH)**

It gives me great pleasure to offer you a position on the SLHD Human Research Ethics Committee (CRGH). You have been appointed as a member in Category xx – xx.

The terms of your appointment to the Human Research Ethics Committee are as follows:

Date of appointment: xx

Review of appointment: xx

Length of tenure: 3 years renewable

As a member of the Committee, you are indemnified in respect of liabilities that may arise in the course of the bona fide conduct of your duties.

Confidentiality must be maintained at all times.

If you become aware that you have a conflict of interest with respect to any issue before the Committee, you are required to declare it to the meeting.

Please find below links to information which may be helpful during your orientation to the HREC:

- A list of the members' names and their roles on the committee.
  http://www.slhd.nsw.gov.au/concord/Ethics/membership.html
- Responsibilities of Members of the Sydney Local Health District Human Research Ethics Committee (enclosed with appointment letter)
- Statutory Guidelines on Research NSW Health Records and Information Privacy Act 2002
  http://www.ipc.nsw.gov.au/sites/default/files/file_manager/privacy_statutory_guidelines_research.pdf
- Human Research Ethics Committees and the Therapeutic Goods Legislation
  https://www.tga.gov.au/publication/human-research-ethics-committees-and-therapeutic-goods-legislation
- NHMRC National Statement on Ethical Conduct in Human Research.
  https://www.nhmrc.gov.au/guidelines-publications/e72
- The Committee's Terms of Reference
  http://www.slhd.nsw.gov.au/concord/Ethics/TOR.html
- The HREC meeting dates
  http://www.slhd.nsw.gov.au/concord/Ethics/meetings.html

The Committee meets every month, except January. Meetings are generally (but not always) on the last Thursday of the month and commence at 3.00 pm via videoconferencing. Meetings usually last about 2 to 3 hours. Your reading material will be distributed electronically via the Research Ethics Governance Information System (REGIS) at least a week before the meeting.

Please refer to Items 6.3.4, 6.3.5, 6.3.6 and 6.3.7 of the Human Research Ethics Committee's Terms of Reference, which give information about resignation from the Committee, and circumstances whereby membership may be terminated.

The Committee depends greatly on its members for their contribution to decision-making and the Sydney Local Health District is grateful to you for your willingness to help. Please do not hesitate to contact the Research Office on 9767 5622 or SLHD-ConcordEthics@health.nsw.gov.au should you have any queries.

Yours sincerely,

Chief Executive
Sydney Local Health District

Dated:

Attachment N

Confidentiality Agreement for HREC Members or Observers

CONFIDENTIALITY AGREEMENT

I understand that I will have access to confidential information as a result of my attendance as an observer at the Sydney Local Health District Human Research Ethics Committee – Concord Repatriation General Hospital meetings.

I undertake to preserve the confidentiality of all information, and the contents of the discussions to which I was a party.

I will ensure that, so far as is within my control, such information, whether in the form of paper documents, computerised data or in any other form, cannot be viewed by unauthorised persons, and that the information is stored in a secure and orderly manner which prevents unauthorised access.

I further undertake to inform the Research Ethics and Governance Office at Concord Repatriation General Hospital immediately if I become aware of any breach of privacy or security relating to the information which I access in the course of my duties.

SIGNED:……

NAME:……

POSITION: ……..……

DATE:……

CRGH Research Ethics and Governance Office:

Name:

Position: Executive Officer

Date:

Attachment O

Responsibilities of new HREC Members

Responsibilities of
Members of the Human Research Ethics Committee (HREC)
Concord Repatriation General Hospital

The following policy is consistent with the *National Statement on Ethical Conduct in Human Research 2023*. 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; and
- if paper copies are accessed, return 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. He or she may respond to any questions posed by the HREC upon returning to 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 Executive Officer 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;
- remember that all members should be able to hear any discussion;
- leave the room when taking telephone calls;
- 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

I declare that I have not been subject to 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: ……..……

Name: ……

Attachment P

Researcher Submission Checklist for Non-Clinical Trials (Greater than low risk & Low risk studies)

ETHICS CHECKLIST

Greater than Low Risk & Low Risk Studies (Non-Clinical Trials)

NSW GOVERNMENT Health Sydney Local Health District

Documentation checklist for Non-Clinical Trial submissions (Greater than low risk & Low risk studies). For the Clinical Trials Checklist, refer to the Research Office website.

IMPORTANT INFORMATION

- **Greater than low risk applications** need to be submitted for review at a Human Research Ethics Committee (HREC) meeting. Please see the dates of future HREC meetings: https://www.slhd.nsw.gov.au/concord/ethics/meetings.html
- **Lower risk applications** may be submitted via an expedited review pathway for review by the HREC Chair (or their delegate). There are no closing dates.
- Please contact the Research Office if you are unsure which risk category your application comes under. Further guidance is also on our website: https://www.slhd.nsw.gov.au/concord/ethics/lowrisk.html
- **All applications** are submitted through the Research Ethics and Governance Information System (REGIS): https://regis.health.nsw.gov.au/
- **How to Apply** to the HREC: https://www.slhd.nsw.gov.au/concord/ethics/ethicshowto.html
- Please ensure Version Numbers and Dates are on **all documentation.**
- Refer to the SLHD website for preferred template https://www.slhd.nsw.gov.au/concord/ethics/forms.html
- Researchers are also encouraged to attend the **monthly drop in clinics** prior to submitting their application. For clinic dates, visit: https://www.slhd.nsw.gov.au/concord/ethics/dropinclinics.html
- **After the HREC meeting:** You may be sent a request for further information letter via REGIS. **You must respond within 40 days of the date of this letter or request an extension from the Executive Officer. If you have not responded within 40 days and have not asked for an extension, your application will be WITHDRAWN and you will need to submit a new application in REGIS.**

***Note: The documents flagged with an asterisk are the minimum mandatory documents required for review.**

		Submitted	N/A
1.	Ethics Application Submission Cover letter (All documents submitted must be listed, along with version no. and date and sites under RPAH Ethics Approval)*	☐	
2.	HREA (Human Research Ethics Application) Completed via REGIS*	☐	
3.	Study Protocol*	☐	
4.	Consumer Engagement Plan (CEP) if not detailed in the Protocol	☐	☐
5.	Participant Information Sheet/s (if applicable)*	☐	☐
6.	Consent Form/s or eConsent (if applicable)*	☐	☐
7.	Opt-out Consent form (if applicable)	☐	☐

8.	Surveys / questionnaires / focus group scripts / guides / telephone scripts*	☐	☐
9.	Master Code Sheet*	☐	☐
10.	Data Collection Form / Data Dictionary*	☐	☐
11.	Advertisements and Social Media Plan (if applicable)	☐	☐
12.	RDMP (Research Data Management Plan)*	☐	☐
13.	SLHD Privacy Compliance form (if applicable for retrospective data)*	☐	☐
14.	If sites are located in VIC or WA supply VSM / WASM	☐	☐
15.	Conflicts of Interest Declaration*	Yes ☐	No ☐

Do any members of the research team (including persons not listed in this application), have any financial, business or other non-financial interests related to this research?

If you answered **Yes**, please ensure these are detailed in Conflicts of Interest Section of the SLHD Protocol template. If not using the SLHD Protocol template, please download the 'Conflicts of interest and management plan' template from the REGO website and upload with your submission in REGIS: https://www.slhd.nsw.gov.au/concord/ethics/forms.html

16.	Site Specific Assessment (SSA) application	☐	☐

For SLHD-sponsored studies where SLHD (RPA, Concord, Canterbury, Balmain Hospitals) is a participating site: Once the Ethics application has been submitted, the SSA should be submitted via REGIS immediately for parallel review with the Ethics application.

- Please see the Governance section of the Research Office website: https://www.slhd.nsw.gov.au/concord/ethics/Governance.html
- Please see the REGIS quick reference guide on how to submit the SSA: Site Application - Completing, Requesting Support and Submitting