South Eastern Sydney Local Health District
Human Research Ethics Committee

Standard Operating Procedures

SOP 001: **HREC function**
Purpose: To describe the function of the HREC
Date: February 2021

OVERALL FUNCTION

1. The primary objective of the HREC is to protect the mental and physical welfare, rights, dignity and safety of participants of research, to facilitate ethical research through efficient and effective review processes, to promote ethical standards of human research and to review research in accordance with the National Health and Medical Research Council (NHMRC) *National Statement on Ethical Conduct in Human Research* March 2007 *(National Statement)*.

Scope of Responsibilities

1. The functions of the HREC are:

i. To provide independent, competent and timely review of research projects involving humans in respect of their ethical acceptability.
ii. To provide ethical oversight, monitoring and advice for research projects involving humans.
iii. To prescribe the principles and procedures to govern research projects involving human subjects, human tissue and/or personal records.

2. Research projects involving humans will be reviewed by the HREC where the research involves patients of any institutions governed by South Eastern Sydney Local Health District.

This operating procedure does not prohibit the institution from accepting an ethical approval undertaken by another HREC as a sufficient ethical approval to allow the institution to approve the commencement of the project, provided that such other HREC is registered and certified with the National Health and Medical Research Council.

This operating procedure also does not prohibit the HREC from reviewing a research project for an external entity per point 6 below.

3. Research projects may include, but are not limited to, research involving pharmaceuticals, medical devices, medical radiation and imaging, surgical procedures, biological samples, access to health information, as well as epidemiological, social, and psychological investigations.

4. The HREC will assess projects submitted to it for review in accordance with the *National Statement* (and any other legal requirements) in order to determine their ethical acceptability.

5. The HREC may review projects involving quality assurance when required. In determining whether or not quality assurance proposals require review, the HREC will refer to the NHMRC document '*When does quality assurance in health care require independent ethical review*?', the NSW Health Guideline *'Quality improvement and ethics review: a practice guide for NSW'* and the '*Health Records and Information Privacy Act 2002: Statutory Guidelines on Management of Health Services'*.

6. The HREC will review human research proposals for external institutions/organisations as specified in the Terms of Reference. In such circumstances, an agreement shall exist between SESLHD and the external institution/organisation that defines the role of the HREC in providing ethical approval and ethical monitoring of the research and the role of the external institution/organisation in giving approval for the research to take place within its organisation. The agreement shall specify which party bears legal responsibility for the liabilities that arise from the ethical review conducted by the HREC, and shall also specify that the institution/organisation (not SESLHD) is responsible for liabilities arising from the conduct of the research.

SOP 002: **Membership composition**
Purpose: To describe the membership composition of the HREC
Date: February 2021

1. The composition of the HREC shall be in accordance with the *National Statement*. Minimum membership shall comprise of seven members, being men and women, comprising:

- a Chairperson
- at least two members who are lay people, one man and one woman, who have no affiliation with the institution or organisation, and who are not currently involved in medical, scientific, or legal work
- at least one member with knowledge of, and current experience in, the areas of research that are regularly considered by the HREC
- at least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people
- at least one member who is a minister of religion, or a person who performs a similar role in the community
- at least one member who is a lawyer.

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

3. 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.

4. 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.

SOP 003: Appointment of members
Purpose: To describe the procedure for the appointment of members to the HREC
Date: February 2021

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

2. Prospective members of the HREC may be recruited by direct approach, nomination or by advertisement. Prospective members shall be asked to provide a copy of their Curriculum Vitae to the selection committee. Members must agree to their name and profession being made available to the public, including being published on the SESLHD Research Directorate website.

3. A selection committee, consisting of the Chairperson, Executive Officer and at least one other HREC member shall review the nomination(s). An interview with the prospective applicant and discussion with at least one referee will be undertaken if deemed necessary. The selection committee will consult with the HREC members and make a recommendation to the Chief Executive. Prospective members may be invited to attend a meeting of the HREC as an observer.

4. Members are appointed by the Chief Executive in consultation with the HREC and will receive a formal notice of appointment.

5. The Chairperson and Deputy Chairperson will be appointed by the Chief Executive. In the absence of the Chairperson, the Deputy Chairperson will perform the role and duties of the Chairperson.

6. The letter of appointment shall 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 may be terminated and the conditions of their appointment.

7. Members will be required to sign a confidentiality undertaking upon appointment, stating that all matters of which he/she becomes aware during the course of his/her work on the HREC will be kept confidential; that any conflicts of interest, which exist or may arise during his/her tenure on the HREC will be declared; and that he/she has not been subject to any criminal conviction or disciplinary action, which may prejudice his/her standing as a HREC member.

8. 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 contact information including that of the Executive Officer
- NHMRC National Statement on Ethical Conduct in Research Involving Humans
- Any previous reports on the HREC's activities
- SESLHD HREC New Member Induction Pack & Training G
- Any other relevant information about the HREC's processes, procedures and protocols.

9. Members are appointed for a period of up to three years and may serve two consecutive terms only unless otherwise approved by the Chief Executive. The Chair, Deputy Chair and Chair of any subcommittee may serve longer terms with the approval of the Chief Executive. Members will be advised when his/her term has expired. Reappointment is by application to the Chairperson of the HREC who will then make a recommendation to the Chief Executive.

10. Appointments shall allow for continuity, the development of expertise within the HREC, and the regular input of fresh ideas and approaches.

11. New members are expected to attend NSW Health and NHMRC education and training sessions as soon as practicable after their appointment. All members are expected to attend education and training sessions. Reasonable costs associated with attendance at training and education sessions will be met by SESLHD, where possible.

12. Members shall not be remunerated. Members may be reimbursed for legitimate expenses incurred in attending HREC meetings, such as travelling and parking expenses.

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 of the HREC without reasonable excuse/apology, unless exceptional circumstances exist. The Chairperson will notify the member of such lapse of membership in writing. Steps shall be taken to fill the vacancy, which may arise.

15. Membership will lapse if a member fails to attend in full at least two thirds of all scheduled HREC meetings in each year, barring exceptional circumstances.

16. Members will be expected to participate in relevant specialised working groups as required. The Chairperson, or nominee, will be 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.

SOP 004: **Orientation of new members**
Purpose: To describe the procedure for the orientation of new members
Date: February 2021

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.
- 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.

3. New HREC members will be provided with the following written information:
- A list of the members' names and their roles on the HREC.
- A copy of the NHMRC National Statement on Ethical Conduct in Human Research.
- The HRECs Terms of Reference.
- SESLHD New Member Induction Pack & Training Guide. This guide will be updated as needed by the HREC members and the SESLHD Research Directorate to reflect current best practice and the in-force legislative requirements relating to the Committee's activities.
- Calendar of meeting dates.

SOP 005: Submission procedure for new applications
Purpose: To describe the procedure for the submission of new applications
Date: February 2021

1. All applications for ethical review must be submitted to the Executive Officer of the HREC, by close of business on the relevant closing date. The closing date for receipt of new applications onto the next HREC agenda will be available on the Research Directorate website.

2. The closing dates for applications are normally 4 weeks prior to the HREC meeting. This ensures adequate time for review.
3. In accordance with NSW Health Policy Directive PD2010_055 "Research - Ethical & Scientific Review of Human Research in NSW Public Health Organisations", applications to the HREC must be submitted using the Human Research Ethics Application (HREA) and shall include all documentation as required by the HREC. The procedures for application to the HREC via REGIS shall be readily available to applicants on the Research Directorate and REGIS websites.

4. Applications deemed as "quality improvement", "quality assurance" and "low ethical risk" research activities may be submitted to the HREC via REGIS and will be considered by the HREC Executive or other Sub-Committee for expedited review (refer to SOP 011).

5. Guidelines shall be issued by the HREC to assist applicants in the preparation of their applications, including guidance on how to determine whether application to the HREC is necessary. Such guidelines will be published on the Research Directorate Website.

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

SOP 006: Processing of applications for review
Purpose: To describe the procedure for the processing of new applications
Date: February 2021

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

2. The Executive Officer will determine whether or not the application has been reviewed for scientific merit and will only forward reviewed applications to the HREC for ethical review.

3. Applications which cannot be accepted for lead ethical review by this HREC include:
- All research projects involving persons in custody, which require review by the HREC of NSW Justice Health
- Research projects coming within section 6.4 of the NSW Aboriginal Health Information Guidelines should be considered for review by the HREC of the Aboriginal Health and Medical Research Council
- Research projects requiring access to statewide data collections owned by NSW Health[1], which require review by the NSW Population & Health Services Research Ethics Committee.

4. The application will be included on the agenda for the next available HREC meeting, provided the following:
i. The application is received by the relevant closing date
ii. The application is complete
iii. Peer review and/or the Scientific Review Committee confirms that the application is of adequate scientific merit to proceed to HREC.

5. If a substantial number of applications are received, a number of applications may need to be deferred to the following HREC meeting. If this occurs, priority will be given to those applications that were received first and/or urgent applications at the discretion of the Chairperson.

1 This includes the following: NSW Central Cancer Registry; NSW Pap Test Register; NSW Inpatient Statistics Collection; NSW Emergency Department Data Collection; NSW Midwives Data Collection; etc.

SOP 007: Preparation of agenda
Purpose: To describe the process and format of agenda for an HREC meeting
Date: February 2021

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

2. In accordance with SOP 006, only those applications which have been approved for scientific merit shall be forwarded to the HREC for ethical review.

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

4. The meeting agenda and associated documents will be prepared by the Executive Officer and circulated to all HREC members at least 7 days prior to the next meeting. In practice HREC members will have access to meeting documents 14 days prior to the next meeting.

5. Committee members will forward their written comments on the Agenda items to the Executive Officer by Close of Business the day prior to the meeting for tabulation in the provisional Minutes.

6. 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.

7. Agenda items will include at least the following items:

i. apologies
ii. minutes of the previous meetings of: the HREC; the HREC Executive Committee; and the Scientific Review Committees
iii. business arising from the previous meeting
iv. conflicts of interest
v. new applications
vi. amendments to approved protocols
vii. correspondence
viii. other business
ix. close and next meeting

8. The agenda and all documentation shall remain confidential.

SOP 008: **Conduct of meetings**
Purpose: To describe the format of meetings of the HREC
Date: February 2021

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

2. Members may attend HREC meetings in person or via teleconference or video link (if available).

3. The Chairperson may cancel a scheduled meeting if a quorum cannot be achieved (refer to Point 8). Should this occur, the HREC will convene within 5 working days of the cancelled meeting to ensure all agenda items are considered.

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

5. 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. The meeting may be electronically recorded by the Research Office to aid in the preparation of meeting minutes as required; any such recording will be destroyed upon completion of the minutes.

6. Notwithstanding paragraph 5, the HREC may agree to the presence of visitors or observers to a meeting; or in order to facilitate consideration of an application, the HREC may invite the applicant to be present at the relevant meeting for its discussion and to answer questions (refer to SOP 009).

7. Members who are unable to attend a meeting should contribute prior to the meeting through written submissions to the Executive Officer or Chairperson. These should normally be received at least 3 working days prior to the meeting so that copies may be made available in advance to members. The minutes should record the submission of written comments.

8. A quorum must be present in order for the HREC to reach a final decision on any agenda item. A quorum shall exist when a representative of each of the following categories is present:

- a Chairperson
- at least two members who are lay people, one man and one woman, who have no affiliation with the institution or organisation, and who are not currently involved in medical, scientific, or legal work
- at least one member with knowledge of, and current experience in, the areas of research that are regularly considered by the HREC
- at least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people
- at least one member who is a minister of religion, or a person who performs a similar role in the community
- at least one member who is a lawyer.

In circumstances where such core members cannot be present, they may provide written comments in lieu of attendance. However, in those circumstances, there must be at least 5 members physically present to achieve quorum, including one of each of the following categories: Chairperson/Deputy Chairperson, lay person, researcher familiar with the types of proposals that are normally reviewed by the HREC.

9. 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.

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, should declare such interest. This will be dealt with in accordance with SOP 023.

SOP 009: Consideration of applications for ethical review

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

Date: February 2021

1. The HREC will consider a new application at its next available meeting provided that the application is received by the relevant closing date and all documents are in order.

2. In accordance with SOP 006, only those applications which have been approved for scientific merit shall be forwarded to the HREC for ethical review.

3. The application will be reviewed by all members of the HREC present at the meeting or providing written comments in lieu of attendance. At least two member of the HREC will present a detailed review of a given application to the rest of the Committee. All Committee members are expected to be familiar with the content of each application

4. The HREC will deal with multi-centre research applications in accordance with SOP 019.

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

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

7. Where research involves the targeted recruitment of persons unfamiliar with the English language, the HREC will ensure that the researcher has put in place arrangements for an interpreter to be present during the discussion on the project, unless alternative arrangements are available (and approved by the HREC).

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

- It will approve the project as being ethically acceptable, with or without conditions.
- It will defer making a decision on the project until the clarification of information or the provision of further information to the HREC.
- It will request modification of the project.
- It will reject the project.

9. The HREC will endeavour to reach a decision concerning the ethical acceptability of a project by unanimous agreement. Where a unanimous decision is not reached, the decision will be considered to be carried by a majority of two-thirds of members who examined the project, provided that the majority includes at least one layperson. Any significant minority view shall be noted in the minutes.

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

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

- Chairperson alone; or
- Chairperson, in oral or written consultation with one or more named members that were present at the meeting or who submitted written comments on the application; or
- A sub-committee of the HREC such as the Executive Committee; or

- The Executive Officer. In such circumstances, the HREC shall be informed at the next available meeting, of the final decision taken on its behalf, including the applicant's response and the reason for the decision taken.

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

13. The HREC may conduct expedited review of projects in accordance with SOP 011.

SOP 010: Preparation of minutes
Purpose: To describe the process and format for minutes of a meeting of the HREC
Date: February 2021

1. The Executive Officer will prepare and maintain minutes of all meetings of the HREC.

2. The format of the minutes will include at least the following items:

i. apologies
ii. attendance
iii. minutes of the previous meeting
iv. business arising from the previous minutes
v. conflicts of interest
vi. new applications
vii. amendments to approved projects
viii. correspondence
ix. other business
x. close and next meeting.

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

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

5. In recording a decision made by the HREC, any significant minority view (i.e. 2 or more members) will be noted in the minutes. Discussion will also be noted where it relates to the broader approach of the Committee in reviewing applications.

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

7. Declarations of conflicts of interest by any member of the HREC and the absence of the member concerned during the HREC consideration of the relevant application will be minuted (refer to SOP 023 regarding a members declaration of a conflict of interest).

8. The minutes will be produced as soon as practicable following the relevant meeting and shall be emailed to the Chairperson for approval. The Chairperson and/or the Deputy Chairperson will provide comment and/or approval within 1 working day of circulation.

9. The minutes will be circulated to all members of the HREC as an agenda item for the next meeting. 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 shall not be forwarded to the Chief Executive. Rather, the HREC will provide an annual summary report of the activities of the HREC to the Chief Executive, SESLHD (refer to SOP 024).

SOP 011: Expedited review
Purpose: To describe the procedure for the expedited review of research by the HREC
Date: February 2021

1. The HREC will establish an Executive to provide expedited review of human research. Membership of the Executive Committee shall be at the discretion of the Chairperson. It is expected that all members of the HREC will serve on the Executive Committee in a given calendar year, on a rotational basis.

2. The HREC Executive membership will consist of at least:
- Chairperson (ie the HREC Chairperson or Deputy Chairperson) or his/her nominee
- Two members of the HREC
- HREC Executive Officer

Any one member may fill more than one category.

3. A quorum will consist of 2 members. The Executive Committee may conduct meetings via exchange of correspondence rather than set meetings, at its discretion.

4. The Executive may undertake expedited review of business that is considered minimal risk, including the following:
- Amendments to current HREC approved projects
- Responses to HREC queries, as approved by the HREC for review and approval
- Adverse Events
- Quality Assurance and low ethical risk research activity proposals
- Medical records research
- Authorised Prescriber applications
- Advertisements
- Annual reports
- Minimal risk research, such as questionnaires on non-controversial, non-personal issues; research which is being conducted primarily at another institution/Health Service and has been approved by another HREC, but which involves a minimal risk component at this Health Service.

5. Expedited review of research projects may be undertaken between scheduled meetings at the discretion of the Chairperson and/or Executive Officer. The Executive may seek advice from other HREC members or suitably qualified experts, as appropriate, before reaching a decision.

6. The Executive Officer may undertake review of HREC business that is considered administrative or extremely low risk, such as:
- Amendments to Patient Information Sheets and Consents Forms that adhere to changes requested by the HREC and that require little interpretation of the ethical impact of the amendments. Changes may include e.g. standard statements re: insurance/indemnity, contact details, version control and dates.
- Amendments to other study documents that are administrative in nature or of low ethical risk.
- Case Report forms and study diaries
- Changes to study personnel (in collaboration with the Research Governance Officer)
- Other issues as delegated by the Executive Committee of the HREC, on a case by case basis.

The Executive Officer will seek advice from the Chairperson, HREC or other HREC Executive Committee members about a matter if he/she is unsure about the ethical risk posed and appropriateness of his/her authority to approve.

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

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

9. If not generated by the meeting itself, feedback for researchers will be produced as soon as practicable following the relevant meeting. The Chairperson and/or the Deputy Chairperson will provide comment and/or approval within 1 working day of circulation. Once finalised by the Executive Committee, its comments or approval will be sent to applications by the Research Office within one working day.

SOP 012: Notification of decisions of the HREC for new applications
Purpose: To describe the procedure for the notification of decisions of the HREC
Date: February 2021

1. The HREC will report in writing to the principal investigator, advising whether the application has received ethical approval (including any conditions of approval), within 5 working days of the meeting, unless otherwise notified.

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

3. A standard response will be issued via REGIS for proposals requiring additional information for consideration by the HREC before approval may be given.

4. If the requested information is not received from the applicant within 3 months or 2 meetings (whichever occurs sooner), the project will be withdrawn and the applicant will be required to re-submit the project at a later date, unless otherwise negotiated with, and confirmed in writing from, the HREC Executive Officer.

5. The HREC shall endeavour to openly communicate with applicants to resolve outstanding requests for further information, clarification or modification of projects relating to ethical issues. The HREC may nominate one of its members to communicate directly with the applicant or by inviting the applicant to attend the relevant HREC meeting (refer to SOP 009).

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

- title of project
- name of the principal investigator(s)
- unique HREC project identification number
- the version number and date of all documentation reviewed and approved by the HREC including Clinical Protocols, Patient Information Sheets, Consent Forms, advertisements, questionnaires, etc
- date of HREC meeting at which the project was first considered
- date of HREC approval
- duration of HREC approval
- conditions of HREC approval, if any.

A standard response will be issued via REGIS.

7. If the HREC determines that a project is ethically unacceptable, the notification of the HREC's decision will include the grounds for rejecting the project with reference to the *National Statement* or other relevant pieces of legislation. A standard response will be issued via REGIS.

8. The status of the project shall be updated in REGIS.

SOP 013: Submission of amendments, extensions, revised Investigator Brochures to approved projects

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

Date: February 2021

1. Proposed changes to approved research projects and/or Investigator Brochures, changes to the conduct of the research, or requests for extensions to the length of HREC approval, are required to be reported by the 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 change/request, and an assessment of any ethical implications arising from the request on the conduct of the research. All amended documents must be submitted with the changes tracked, and a clean version (with the changes accepted), and contain revised version numbers, dates and page numbers on every page (eg page 19 of 48).

3. Requests for amendments, updates and extensions will be undertaken by the HREC Executive between scheduled meetings of the full HREC in accordance with SOP 011. Where an urgent protocol amendment is required for safety reasons, the Chairperson may review and approve the request. In such circumstances, the HREC Executive will review the decision at its next available meeting.

4. The HREC will report in writing to the principal investigator, advising of the ethical approval of the proposed amendment and/or request for extension, within 10 working days of the HREC Executive meeting at which the request was considered. The HREC may inform the applicant in writing that the amended research may commence.

5. A standard response will be issued via REGIS for approvals.

6. 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 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.

7. A standard response will be issued via REGIS for a request for additional information.

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

SOP 014: Handling of adverse events
Purpose: To describe the procedure for the reporting and handling of adverse events
Date: February 2021

1. The HREC shall require that, as a condition of approval of each project, researchers report significant safety issues and an annual safety report to the HREC in accordance with the guidelines in force with NHMRC (currently *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (NHMRC 2016)).

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

3. In the first instance the HREC Executive Officer will review adverse events reports submitted by investigators to determine whether or not they have been reported in accordance with the current guidelines.

4. Adverse events which are reported in accordance with the guidelines and do require HREC consideration will be reviewed by the HREC Executive Committee, which shall determine the appropriate course of action. This may include:
- notation on file of the occurrence
- increased monitoring of the project
- request for an amendment to the protocol and/or Patient Information Sheet/Consent Form
- suspension of ethical approval
- termination of ethical approval.

5. Adverse events shall be reported to the full HREC at the discretion of the HREC Executive Committee.

6. The Chairperson may take the appropriate course of action for those adverse events deemed serious and requiring immediate attention. This may include:
- Referral to the Scientific Review Committee
- Referral to an independent expert with expertise in the area
- Immediate request for additional information
- Immediate suspension of ethical approval
- Immediate termination of ethical approval.

7. The HREC shall provide notice to the investigator that it has received notification of the adverse events, and the course of action it has deemed necessary to take.

SOP 015: Monitoring of approved research projects

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

Date: February 2021

1. The HREC will monitor approved projects to ensure compliance with its ethical approval. 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 completion of the study. Continuing approval of the research will be subject to the principal investigator submitting an annual report.

2. The HREC shall require the following information in the annual report:
- progress to date or outcome in the case of completed research
- maintenance and security of records
- compliance with the approved protocol
- compliance with any conditions of approval.

3. The HREC may adopt any additional appropriate mechanism/s for monitoring, as deemed necessary, such as:
- random inspections of research sites, data and signed consent forms;
- interview, with their prior consent, of research participants.

4. 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 protocol, including:
- proposed changes in the protocol
- any unforeseen events that might affect continued ethical acceptability of the project
- new information from other published or unpublished studies which may have an impact on the continued ethical acceptability of the trial, or which may indicate the need for amendments to the trial protocol.

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 project, the HREC may withdraw approval. In such circumstances, the HREC shall inform the principal investigator and the institution of such withdrawal of approval in writing, and recommend to the institution that the research project be discontinued, suspended, or that other necessary steps be taken.

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.

SOP 016: Complaints about the conduct of a research project
Purpose: To describe the mechanism for receiving, handling and responding to complaints concerning the conduct of a project approved by the HREC
Date: February 2021

1. The HREC shall nominate a person to whom complaints from research participants, researchers, or other interested persons about the conduct of approved research projects, may be made in the first instance. The name and/or position and contact details of the person nominated by the HREC to receive complaints must be included in the Patient Information Sheet and Consent Form for each project.

2. Any concern or complaint received about the conduct of a research project approved by the HREC should be directed to the attention of the HREC Executive Officer, who shall notify the HREC Chairperson as soon as possible after a complaint is received.

3. The Chairperson will send a letter of acknowledgement to the complainant and a letter of notification to the principal investigator, outlining the complaint and the mechanisms for investigating the complaint, as set out below.

4. The Chairperson will instigate an investigation of the complaint and its validity, and make a determination as to the appropriate course of action. The investigation will be conducted in accordance with the *Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research 2018* (NHMRC). The investigation shall take no longer than 4 weeks from the time of notification of the complaint or concern, unless exceptional circumstances exist. If the complaint is substantiated, action may include:

- the requirement for amendments to the project, including increased monitoring by the HREC
- suspension of the project
- termination of the project
- other action to resolve the complaint.

The complainant shall be informed of the outcome of the Chairperson's investigation. The Chief Executive will also be informed of the outcome of the Chairperson's investigation,

5. 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 Policy Directive PD2018_032 "Managing Complaints and Concerns about Clinicians".

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

7. The HREC Chairperson will provide the Chief Executive or his/her nominee with all relevant information about the complaint/concern, including:

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

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

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

10. The panel will include, at least, the following members:
- the Chief Executive or his/her nominee as convenor of the panel
- two nominees of the Chief Executive (not members of the HREC)
- the HREC Executive Officer.

11. The panel will afford the HREC and 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 and the Chairperson of the outcome of the investigation, and the investigator if an allegation against them has been found to be proven, or dismissed.

SOP 017: 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

Date: February 2021

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

2. The Chairperson may at his/her discretion inform the Chief Executive as soon as possible of any complaints received by him/her. The Chief Executive will inform the Chairperson as soon as possible of any complaints received by him/her.

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

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

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

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

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

7. If the Chief Executive determines there is to be a further investigation, then he/she will establish a 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.

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

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

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

10. The panel may access any documents relating to the project. The panel may interview other parties, including internal and external expert advice. In conducting its review, the panel shall be concerned with ascertaining whether the HREC acted in accordance with the NHMRC *National Statement on Research Ethical Conduct in Human Research*, its Terms of Reference, Standard Operating Procedures, or otherwise acted in an unfair or biased manner.

11. 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.

12. The panel may also make recommendations about the operation of the HREC including such actions as:

- Review Terms of Reference and Standard Operating Procedures
- Review Committee membership
- Take other such action as appropriate.

SOP 018: Complaints concerning the HREC's rejection of an application
Purpose: To describe the procedure for receiving and handling complaints from investigators about the HREC's rejection of an application
Date: February 2021

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 HREC Chairperson. Complaints may also be made to the Chief Executive.

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

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

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

5. The Chairperson of the HREC will provide the Chief Executive with all relevant information about the complaint, including:
- the complaint
- material reviewed in the Chairperson's investigation
- the results of the Chairperson's investigation
- any other relevant documentation.

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

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

8. The panel will include, at least, the following members:
- The Chief Executive or his/her nominee as convenor of the panel
- Two nominees of the Chief Executive (not members of the HREC)
- Expert(s) in the discipline of research of the project under consideration.

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

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

11. 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.

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

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

SOP 019: Handling of multi-centre research

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

Date: February 2021

1. The HREC will abide by the NSW Health Policy Directive PD2010_055 "*Research - Ethical & Scientific Review of Human Research in NSW Public Health Organisations"* under which every human research project is ethically and scientifically reviewed once only by a NSW Health accredited lead HREC.

2. The HREC accepts the ethical and scientific review of multi-centre research undertaken by a suitable lead HREC as a sufficient review for the purposes of the project being conducted at institutions under the control of SESLHD, and does not require the project to be reviewed by this or any other HREC.

3. To facilitate the review of multi-centre research the HREC may:

- communicate with any other HREC, especially a lead HREC
- accept a scientific/technical and/or ethical assessment of the research by another HREC, especially a lead HREC
- share its scientific/technical and/or ethical assessment of the research with another HREC on request by that HREC.

SOP 020: Record keeping

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

Date: February 2021

1. The Executive Officer will prepare and maintain written records of the HREC's activities, including agendas and minutes of all meetings of the HREC. These will be stored in REGIS.

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

- unique project identification number
- the principal investigator(s)
- the name of the responsible institution or organisation
- title of the project
- ethical approval or non-approval with date
- approval or non-approval of any changes to the project
- the terms and conditions, if any, of approval of the project
- whether approval was by expedited review
- action taken by the HREC to monitor the conduct of the research.

The file shall contain the application, all approved documents and other material used to inform potential research participants, and any correspondence including that between the applicant and the HREC and its Sub- Committee(s).

3. All records of the HREC, including applications, membership, training and compliance records, minutes and correspondence, will be kept as confidential files in accordance with the requirements of the Health Records and Information Privacy Act 2002 (HRIPA) 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.

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

6. A register of all the applications received and reviewed shall be maintained in accordance with the NHMRC *National Statement on Ethical Conduct in Human Research*. The register shall include metrics for HREC performance as required from time to time by the NSW Ministry of Health.

SOP 021: Authorised Prescriber applications

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

Date: February 2021

1. The HREC Executive Committee will consider Authorised Prescriber applications. The HREC may also seek advice from its Scientific Review Committee and/or expert reviewers within SESLHD when considering the issues outlined in Point 3.

2. All decisions made by the Executive shall be minuted and provided for information at the next HREC meeting.

3. When considering a proposal by a medical practitioner to become an Authorised Prescriber, the HREC Executive Committee shall undertake an assessment of the following, in accordance with the *Therapeutic Goods Act 1989* and associated regulations[2]:

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

4. If endorsed, the HREC shall provide a letter of endorsement to the applicant, in the format set out in Appendix A suggested by the Therapeutic Goods Administration. The HREC may impose any conditions on the endorsement such as:

a. 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

b. Requirements for reporting of any adverse events.

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

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

6. The HREC may withdraw its endorsement of the Authorised Prescriber if it is satisfied 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.

2 Refer to the *Therapeutic Goods Administration Access to Unapproved Therapeutic Goods – Authorised Prescribers, October 2004*

SOP 022: Handling of conflicts of interest

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

Date: February 2021

1. A HREC member shall, as soon as practicable during the HREC meeting, inform the Chairperson if he/she has a potential conflict of interest, financial or otherwise, in a project or other related matter(s) considered by the HREC.

2. The HREC will determine if this results in a conflict of interest for the member and if so, the member will withdraw (leave the room) from the meeting until the HREC's consideration of the relevant matter has been completed. The member shall not be permitted to adjudicate on the research.

3. All declarations of conflict of interest and the absence of the member concerned will be minuted.

SOP 023: **HREC reporting requirements**
Purpose: To describe the reporting requirements of the HREC
Date: February 2021

1. The HREC shall provide an annual report to the Chief Executive at the end of each calendar year on its progress, including:
- membership/membership changes;
- number of meetings;
- number of projects reviewed, approved and rejected;
- monitoring procedures for ethical aspects of research in progress and any problems encountered by the HREC in undertaking its monitoring role;
- description of any complaints received and their outcome;
- description of any research where ethical approval has been withdrawn and the reasons for withdrawal of approval; and
- general issues raised.

2. The HREC will provide reports to the NHMRC in accordance with their requirements.

3. The HREC will provide reports to the NSW Privacy Commissioner in accordance with the requirements of the Health Records and Information Privacy Act 2002 (NSW).

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

SOP 024: 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
Date: February 2021

1. The Standard Operating Procedures and Terms of Reference shall be reviewed at least every three years and amended as necessary.

2. The Standard Operating Procedures and Terms of Reference may be amended by following the procedure 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 his or her 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.

3. HREC Standard Operating Procedures, Terms of Reference and membership will be included on the Research Directorate website and reviewed for currency every 12 months.

Appendices

Appendix A: Standard letter for Authorised Prescriber to submit to TGA

HUMAN RESEARCH ETHICS COMMITTEE – Northern Hospital Network

Room G71, East Wing
Edmund Blacket Bldg
Prince of Wales Hospital
Cnr High & Avoca Streets
RANDWICK NSW 2031
Tel: (02) 9382 3587
Fax: (02) 9382 2813

DATE

NAME, ADDRESS
Via email

Dear

Re: **Ethics committee endorsement for the purpose of becoming an Authorised Prescriber of an unapproved product under subsection 19(5) of the Therapeutic Goods Act**

The Human Research Ethics Committee hereby endorses you for the purpose of becoming an Authorised Prescriber under subsection 19(5) of the Therapeutic Goods Act.

This endorsement is restricted to the following circumstances:

Unapproved product: <<drug/ device: trade and generic names if available>>

Indication for use: <<illness/condition/class of patient>>

Site(s) covered by the endorsement: <<hospital/rooms>>

Conditions imposed by the HREC (if applicable):
<<provision of usage reports to HREC>>
<<reporting of adverse events to HREC>>

Please present a copy of this endorsement letter to the TGA as part of your application to become an Authorised Prescriber.

Yours sincerely

Executive Officer
SESLHD Human Research Ethics Committee