

Sydney Children's Hospitals Network
Human Research Ethics Committee
STANDARD OPERATING PROCEDURES
April 2017

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Definitions

Certified HREC	A HREC that is hosted by an institution that has been certified by the National Health and Medical Research Council to participate in the national approach to single ethical review
Chair	Chairperson of the SCHN HREC
Chief Executive/CE	Chief Executive of the Sydney Children's Hospitals Network or his/her delegate
Executive Committee	HREC Executive Committee
Executive Officer/EO	Executive Officer, Research Ethics
HREC	Human Research Ethics Committee
Lead HREC	A HREC accredited by the NSW Ministry of Health to conduct a single ethical and scientific review of multi-centre research projects within NSW
Local HREC	A HREC established by a NSW Public Health Organisation to provide ethical and scientific review of human research to be conducted at sites under its control
Multi-Centre	Research that is conducted at more than one site, where those sites are within the jurisdiction of more than one HREC
National Statement	National Statement on Ethical Conduct in Human Research (2007)
NHMRC	National Health and Medical Research Council
NSW Health	New South Wales Ministry of Health
REAA	Research Ethics Administrative Assistant
REO	Research Ethics Officer
RESO	Research Ethics Support Officer
RGO	Research Governance Officer
SAC	Scientific Advisory Committee
SAS	Special Access Scheme
SCHN	The Sydney Children's Hospitals Network
SCHN HREC	The Sydney Children's Hospitals Network Human Research Ethics Committee
Single Centre	Research that is conducted at no more than one site within the NSW Public Health System or at two or more sites under the jurisdiction of a single NSW Health HREC
Site	A facility, location or service where the research is being conducted
TGA	Therapeutic Goods Administration

SOP 001 – HREC Function

Sydney Children's Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 001	Date: April 2017
Subject: Human Research Ethics Committee (HREC)	
Purpose: To describe the objectives, function and scope of responsibilities of the HREC.	

1. Objectives

The objectives of the SCHN HREC are to:

- 1.1. Facilitate ethical research through efficient and effective review processes that are in accordance with the National Statement on Ethical Conduct in Human Research (2007) [National Statement]. The SCHN also subscribes to the ethical standards outlined in the Declaration of Helsinki, the Royal Australian College of Physicians Guidelines: Paediatric Policy on the Ethics of Research in Children, and CPMP/ICH Note for Guidance on Good Clinical Practice.
- 1.2. Protect the mental and physical welfare, rights, dignity and safety of participants of research.
- 1.3. Promote ethical principles in human research.
- 1.4. Protect the privacy and confidentiality of participants and/or their personal health information in compliance with the Health Records and Information Privacy Act (2002).

2. Functions

The functions of the HREC are:

- 2.1. Provide independent oversight of human research projects in accordance with the NSW Health system of single ethical and scientific review, and in line with the National Statement requirement to minimise duplication of ethical review;
- 2.2. Provide competent, timely review and monitoring of human research projects with respect to their ethical and scientific acceptability for as long as projects are active;
- 2.3. Determine the compliance of a human research project with the National Statement and grant, withhold or withdraw ethical approval; and
- 2.4. Provide advice to the SCHN Executive on issues relating to the ethical conduct of research and the ethical acceptability of research proposals submitted for approval or on any other issue as requested by the Chief Executive; and on strategies to promote awareness of the ethical conduct of human research.

3. Scope of Responsibility

The responsibilities of the SCHN HREC are to:

- 3.1. Review human research applications where the research is undertaken:
 - Any institution/s governed by NSW Public Health Organisations for multicentre studies;
 - Any institutions governed by the SCHN for single-centre studies;
 - External institutions/organisations and investigators as approved by the Chief Executive or delegate via 'External Entity Agreement' as per NSW Health policy directive PD2008_046 (or any subsequent update).
 - The HREC may review applications from 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.

4. Accountability

- 4.1. The SCHN HREC is directly accountable to the Chief Executive (CE) of the SCHN. The minutes of each SCHN HREC meeting shall be forwarded to the CE or delegate following their confirmation.
- 4.2. The SCHN HREC shall also provide monthly reports to the CE via the Research Director which includes information on membership, the number of proposals reviewed, status of proposals, a description of any complaints received and their outcome, and any general issues raised.
- 4.3. The SCHN HREC shall bring to the attention of the CE or delegate any ethical issues that may be of significant concern.
- 4.4. The SCHN HREC shall provide the following reports on behalf of the SCHN Executive:
 - Annual Report to the National Health and Medical Research Council (NHMRC);
 - The NSW Privacy Commissioner report in accordance with the requirements of the Health Records and Information Privacy Act (2002).
 - Certified Institution Annual Report to the NHMRC; and
 - Any other reports as required.
- 4.5. Monitoring Measures: The HREC will undertake its review in a timely and efficient manner and have mechanisms to monitor and evaluate its performance. The HREC is to conduct an annual review of its performance as per the organisation's Committees policy.

SOP 002 – Membership Composition

Sydney Children’s Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 002	Date: April 2017
Subject: Membership composition	
Purpose: To describe the membership composition of the HREC	

1.1. The SCHN HREC is constituted in accordance with the National Statement. Minimum membership comprises eight members. As far as possible, men and women are represented in equal numbers and at least one third of the members are external to the institution for which the SCHN HREC is reviewing research. The membership comprises representatives from the following categories:

- A Chairperson, with suitable experience, whose other responsibilities will not impair the HREC capacity to carry out its obligations under the National Statement;
- At least two lay people, one man and one woman, with no affiliation with the institution and who are not currently involved in medical, scientific, legal or academic work;
- At least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional;
- At least one person who performs a pastoral care role in the community, for example an Aboriginal elder, a minister of religion;
- At least one lawyer, where possible one who is not engaged to advise the institution; and
- At least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend. These two members may be selected, according to need, from an established pool of inducted members with relevant expertise.

1.2. To ensure the SCHN HREC is equipped to address all of the relevant considerations arising from the categories of research, some or all of the above membership categories may be represented by more than one person.

- 1.3. No member is appointed in more than one of the membership categories listed at 1.1.
- 1.4. The SCHN HREC may establish a pool of inducted members in each membership class who attend meetings as needed to meet the HREC requirements and are available to provide expertise for the research under review.
- 1.5. Additional to the minimum requirements of the National Statement, and to ensure that the HREC membership is sufficient to address all categories of research likely to be submitted, HREC members shall also include:
 - At least one member of the Hospital Executive who has clinical experience
 - Research members with experience and knowledge in the following areas:
 - Medical research; and/or
 - Surgical/anaesthetic research; and/or
 - Nursing or allied research; and/or
 - General research; and/or
 - Basic laboratory research.
- 1.6. 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.
- 1.7. The HREC is free to consult person(s) considered by the HREC to be qualified to advise and assist in reviewing applications provided that there is no conflict of interest and an undertaking of confidentiality is entered into. Such person(s) are not entitled to vote on any matter.
- 1.8. In attendance:
 - HREC Executive Officer
 - Research Ethics Officer as Minutes Secretary
- 1.9. The Executive Officer to the HREC shall attend the meetings in an ex-officio capacity with rights of audience and debate, but shall have no voting rights.

SOP 003 - Appointment of Members

Sydney Children's Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 003	Date: April 2017
Subject: Appointment of members	
Purpose: To describe the procedure for the appointment of members to the HREC	

- 1.1. Members are appointed as individuals rather than in a representative capacity.
- 1.2. 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.
- 1.3. A selection committee, consisting of the Chair, HREC Executive Officer and at least one other HREC member shall interview the prospective applicant and make a recommendation to the Chief Executive or delegate. Prospective members may be invited to attend a meeting of the HREC as an observer.
- 1.4. Members are reference checked, police checked and appointed by the Chief Executive or delegate in consultation with the HREC and will receive a formal notice of appointment.
- 1.5. The Chair and Deputy Chair will be appointed by the Chief Executive. In the absence of the Chair, the Deputy Chair will perform the role and duties of the Chair.
- 1.6. 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.
- 1.7. 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.
- 1.8. 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 their role on the Committee, including that of the Executive Officer;

- NHMRC National Statement on Ethical Conduct in Human Research;
 - SCHN Code of Conduct
 - SCHN Conflict of Interest and Gifts and Benefits Policy
 - Declaration of Helsinki
 - NSW Privacy Guidelines for Research
 - SCHN HREC Reviewer template
 - The meeting dates and any other relevant information about the HREC's processes, procedures and protocols.
- 1.9. Members are appointed for a period of up to 3 years and may serve only 6 years unless otherwise approved by the Chief Executive or delegate. The Chief Executive or delegate, in consultation with the Chair, may implement a probationary period.
- 1.10. The Chair, Deputy Chair and Chair of any subcommittee may serve longer terms with the approval of the Chief Executive or delegate.
- 1.11. Members are advised when their term has expired. Reappointment will be by application to the Chair of the HREC who then makes a recommendation to the Chief Executive or delegate.
- 1.12. New and renewed appointments allow for continuity, development of expertise within the HREC, and regular input of fresh ideas and approaches.
- 1.13. The HREC and SAC Chairs hold a position within SCHN and are reimbursed accordingly.
- 1.14. Members shall not be remunerated. Members will be reimbursed for legitimate expenses incurred in attending HREC meetings, such as travelling and parking expenses. For external SCHN members this will be provided in an annual payment and provision of parking vouchers following each meeting.
- 1.15. Members should prepare for and attend scheduled meetings of the HREC or, if unavailable, provide opinions on the ethical acceptability of research proposals before meetings wherever possible.
- 1.16. Membership lapses if a member fails to attend:
- Three consecutive meetings without reasonable excuse/apology or exceptional circumstances; and
 - At least two thirds of all scheduled HREC meetings in each year, barring exceptional circumstances.
- 1.17. The Chair notifies the member of a lapse of membership in writing. Steps are taken to fill the vacancy.

- 1.18. Members seeking to resign or take a leave of absence for an extended period from the HREC are asked to give notice to the Chair. Steps are taken to fill the vacancy.
- 1.19. A member may resign from the HREC at any time upon giving notice in writing to the Chair. Steps shall be taken to fill the vacancy of the former member.
- 1.20. Members are expected to participate in relevant specialist working groups as required.
- 1.21. The Chair is expected to be available between meetings to participate in HREC Executive Committee meetings where required.
- 1.22. The SCHN provides indemnity for members of the HREC for liabilities that may arise as a result of the member exercising their duties in good faith. Such indemnity is provided through the NSW Treasury Managed Fund.
- 1.23. Members must agree to their name and position being made publicly available in annual reports, on the SCHN website and in other routine processes.

SOP 004 – Orientation of new members

Sydney Children’s Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 004	Date: April 2017
Subject: Orientation of new members	
Purpose: To describe the procedure for the orientation of new members.	

1. New members must be provided with adequate orientation.
2. Orientation involves the provision of an orientation package, and may involve a combination, or all of the following:
 - Introduction to other SCHN HREC members prior to the SCHN HREC meeting;
 - Informal meeting with the Chair and Executive Officer to explain their responsibilities as an HREC member, as well as processes and procedures;
 - “Partnering” with another HREC member in the same category; and
 - Priority given to participate in training sessions offered both internal and external to the Network.

SOP 005 – Training and Education of HREC members

Sydney Children's Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 005	Date: April 2017
Subject: Training and Education of HREC members	
Purpose: To describe the procedure for the training and education of HREC members.	

1. Each member is:
 - expected to become familiar with the National Statement and consult other guidelines relevant to the review of specific research applications; and
 - encouraged to attend continuing education or professional development activities in research ethics during their appointment.
2. Every member of the HREC should aim to attend at least one training session relating to HREC activities every three (3) years, with cost being covered by the SCHN.

SOP 006 - Submission procedure for new applications

Sydney Children's Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 006	Date: April 2017
Subject: Submission procedure for new applications	
Purpose: To describe the procedure for the submission of new applications	

1. All applications for ethical review must be submitted to the Research Ethics Office by the relevant closing date and time.
2. The closing date for receipt of new applications for the next HREC agenda shall be readily available to prospective applicants.
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 applications submitted for assessment by the HREC in the circumstances outlined in the HREC's Fee Policy (available on the SCHN internet site) and in the Terms of Reference. Fees will be charged in line with NSW Health Document Number PD2008_030 "HREC and Research Governance: Fee Policy for Review of Commercially Sponsored Research".

SOP 007 – Processing of applications for review

Sydney Children's Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 007	Date: April 2017
Subject: Processing of applications for review	
Purpose: To describe the procedure for the processing of new applications	

1. Applications will be checked for their completeness by the Research Ethics Office prior to their acceptance onto the agenda. Incomplete applications will be returned to the applicant with instructions on how to resubmit a complete application.
2. The Executive Officer or their delegate will determine whether or not the application requires review by the Scientific Advisory Committee (SAC) in accordance with the SAC Terms of Reference.
3. Once a completed application has been accepted for ethical review, a unique project identification number shall be assigned to the project. A project file will also be created in the relevant electronic filing systems in which the application's documentation will be filed. The project will be added to the HREC's register of received and reviewed applications, kept on the IT platform as required by the NSW Health.
4. The Research Ethics Office will acknowledge acceptance of the application for Scientific and Ethical review by email to the Investigator or nominated contact within 5 working days of receipt of the completed application. The acknowledgement 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.
5. The application will be included on the agenda for the next available HREC meeting, provided it is received by the relevant closing date and is complete. If necessary, the application will also be included on the agenda for the next SAC meeting.

SOP 008 – Preparation of Agenda

Sydney Children’s Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 008	Date: April 2017
Subject: Preparation of agenda	
Purpose: To describe the process and format of agenda for an HREC meeting.	

1. The HREC Secretariat will prepare an agenda for each HREC meeting.
2. All completed applications and relevant documents received by the Research Ethics Office 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 Secretariat and circulated to all HREC members at least 7 days prior to the next meeting.
4. Copies of the reviewer reports, if available, will be provided to the Committee 48 hours prior to the meeting.
5. Documentation received after the closing date will be included on the agenda and/or tabled at the meeting at the discretion of the Chair. Under no circumstances shall new applications for research be tabled at the meeting.
6. Agenda items will include at least the following items:
 - Apologies;
 - Minutes of the previous meeting;
 - Sub-committee meeting minutes;
 - Business arising from the previous minutes;
 - Conflicts of interest;
 - New applications;
 - Amendments to approved protocols;
 - Correspondence;
 - Other business;
 - Close and next meeting.
7. The agenda and all documentation shall remain confidential.

SOP 009 - Conduct of meetings

Sydney Children's Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 009	Date: April 2017
Subject: Conduct of meetings	
Purpose: To describe the format of meetings of the HREC.	

1. The HREC shall meet on a regular basis, which will normally be at monthly intervals. Meeting dates and agenda closing dates shall be publicly available.
2. Members may attend the HREC meeting in person or via tele or video conference.
3. 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.
4. 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.
5. Notwithstanding point 4, the HREC may agree to the presence of visitors or observers to a meeting. Such visitors and observers will be asked to sign a Confidentiality Agreement, unless they are a named researcher on the proposal under consideration.
6. Members who are unable to attend a meeting should contribute prior to the meeting through written submissions to the Secretary/Executive Officer or Chair. These should normally be received prior to the meeting. The minutes should record the submission of written comments.
7. A quorum must be present in order for the HREC to reach a final decision on any agenda item. A quorum shall exist when one representative of each of the following categories is present:
 - A chairperson;
 - Lay people, who have no affiliation with the institution or organisation, and who are not currently involved in medical, scientific, or legal work;
 - A member with knowledge of, and current experience in, the areas of research that are regularly considered by the HREC;
 - A member with knowledge of, and current experience in, the professional care, counselling or treatment of people;
 - A member who is a minister of religion, or a person who performs a similar role in the community;
 - A lawyer.

8. The Chair may cancel a scheduled meeting if a quorum cannot be achieved. Should this occur, the HREC will convene within 5 working days of the cancelled meeting to ensure all agenda items are considered.
9. If the meeting does not achieve quorum, the Chair shall decide it can proceed only in exceptional circumstances. The meeting may still proceed if the Chair is satisfied that the views of those absent who belong to the minimum membership have been received and considered.
10. If the Chair decides that the meeting should proceed, all decisions will be provisional and endorsed by at least one representative from those membership categories not present at the next quorate meeting.
11. Any member of the HREC who has any interest, financial or otherwise, in a project or other related matter(s) considered by the HREC, should declare such interest as soon as possible. This will be dealt with in accordance with [SOP 027](#).

SOP 010 - Consideration of applications for ethical review

Sydney Children's Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 010	Date: April 2017
Subject: Consideration of applications for ethical review by the HREC	
Purpose: To describe the process of the HREC's consideration of applications for ethical assessment	

1. The HREC will consider a new application at its next available meeting provided that the application is received by the relevant closing date.
2. The application will be reviewed by all members of the HREC present at the meeting or providing written comments in lieu of attendance.
3. Each application will be assigned to two HREC reviewers who will provide a detailed review of each submission. If the application requires review by the SAC, two SAC reviewers will also be assigned to review the application.
4. The HREC will ethically assess each application in accordance with the most recent version of 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.
5. Where relevant, the HREC will review research in accordance with other relevant guidelines and legislation such as the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes, the NSW Health Records and Information and Privacy Act (2002) and the NSW Human Tissue Act (2003).
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. 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.
8. 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.

9. 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.
10. 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:
 - Chair/Executive Officer alone; or
 - Chair/Executive Officer, 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
 - The Reviewers; or
 - A sub-committee of the HREC.
11. Exceptionally, the HREC may decide that the information should be considered at a further meeting of the HREC.
12. The HREC may conduct expedited review of projects in accordance with SOP012.

SOP 011 – Preparation of Minutes

Sydney Children's Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 011	Date: April 2017
Subject: Preparation of minutes	
Purpose: To describe the process and format for minutes of a meeting of the HREC.	

1. The HREC Secretariat will prepare and maintain minutes of all meetings of the HREC.
2. The format of the minutes will include at least the following items:
 - Apologies;
 - Attendance;
 - Minutes of the previous meeting;
 - Business arising from the previous minutes;
 - Conflicts of interest;
 - New applications;
 - Amendments to approved projects
 - Correspondence;
 - Other business;
 - Close and next meeting.
3. The minutes should include the recording of decisions taken by the HREC as well as a summary of relevant discussion. This includes reference to views expressed by absent members.
4. In relation to the review of new applications or amendments, the minutes shall record a summary of the main ethical issues considered, including any requests for additional information, clarification or modification of the project.
5. In recording a decision made by the HREC, any significant minority view will be noted in the minutes.
6. To encourage free and open discussion and to 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 [SOP027](#) regarding a member's declaration of a conflict of interest).
8. The minutes will be finalised within 5 working days following the relevant meeting and should be reviewed by either the Chair and/or the Deputy Chair, for accuracy.

9. The minutes will be circulated to all members of the HREC and Sub-committees as appropriate 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 an electronic confidential 'Minutes' file.
11. The minutes of each Committee meeting shall be forwarded to the Chief Executive or delegate.

SOP 012 - Expedited review

Sydney Children's Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 012	Date: April 2017
Subject: Expedited review	
Purpose: To describe the procedure for the expedited review of research (including low and negligible risk applications) by the HREC.	

1. The HREC has an Executive Committee (Executive Committee) comprising of at least the HRE Chair or their delegate and a member of the research office.
2. The Executive Committee is delegated to undertake expedited review and final approval of business that does not require full HREC review, including some or all of the following:
 - Low and Negligible Risk (LNR) research applications;
 - Quality Improvement (QI) projects
 - Clinical Case Reports (CCR)
 - Amendments to current HREC approved research projects;
 - Requests for extensions of approvals (or annual renewals) without significant change to the project
 - Responses to HREC queries, as approved by the full HREC for HREC Executive Committee review and approval;
 - Annual progress reports and final reports;
 - Serious adverse events and suspected unexpected serious adverse reactions reports;
 - Noting of Correspondence including:
 - Safety reports and Data Safety Monitoring Board (DSMB) reports.
 - Non-serious protocol deviations, safety update reports; and
 - Applications for HREC endorsement of Authorised Prescriber Status for unapproved products (under sections 19(5) and 41HC of the Therapeutic Goods Act 1989)
3. Expedited review of other research projects not listed above (i.e. point 2) may be undertaken between scheduled meetings at the discretion of the Chair. The Executive Committee 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.
4. The minutes and decision of the Executive Committee are noted and ratified at the next HREC meeting.
5. The Executive Committee may review urgent HREC business and (as appropriate) grant covering or final approval for the item.

6. The Executive Committee may seek advice from HREC or SAC members as appropriate before reaching a decision.
7. The Executive Committee may refer or escalate matters to a full SAC or HREC Committee meeting for review.
8. The Executive Committee will minute all meetings and make finalised minutes available for review at request by the HREC or an authorised auditor.
9. At the 11 May 2012 HREC meeting the Committee agreed that:
 - The HREC will not review submissions made to the Executive Committee unless explicitly referred/escalated by the SCHN Executive for HREC review.
 - The HREC will review and acknowledge the Executive Committee minutes at each HREC meeting.
 - The HREC will provide ratification of HREC Executive approvals.
 - For the purpose of quality assurance and monitoring, every six months (HREC agenda availability permitting) the HREC Chair and Executive Officer (EO) will present to the full HREC Committee two or three examples of reviews conducted and approvals granted by the Executive Committee.
10. The Executive Committee will meet every two weeks.
11. The Executive Officer is delegated the authority to conduct initial review of all negligible risk submissions (LNR, Clinical Case Reports, amendments and correspondence). A submission is considered negligible risk when the activities proposed in the submission do not include contact with participants or affect the treatment participants currently receive; and there is no change to the risk, safety, scientific or ethical profile of the project.
12. The Executive Officer may grant extensions of approval for protocols whose period of approval has expired under specific conditions.
13. The Executive Officer may delegate the review of further information received following initial review of a low risk and negligible risk submission at the Executive Committee level, or reviewed initially by the Executive Officer, to the Research Ethics Officer, the Research Ethics Support Officer or the Research Ethics Administrative Assistant.
14. The Executive Officer may refer/escalate any submissions for review to the HREC Chair, Executive Committee, SAC or HREC.
15. The Executive Officer will minute all delegated reviews using the established Executive meeting minute template.
16. The minutes and decision of the EO are noted and ratified at the next HREC meeting.

SOP 014 – Notification of decisions of the HREC for new applications

Sydney Children’s Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 013	Date: April 2017
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 Secretariat will report in writing to the principal investigator within 5 working days of the meeting at which the request was considered, advising whether the application has received ethical approval (including any conditions of approval).
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 most recent version of the NHMRC *National Statement on Ethical Conduct in Human Research* or other relevant pieces of legislation.
3. If the requested information is not received from the applicant within 3 months, the project will be dismissed and the applicant will be required to re-submit the project. The applicant may request an extension of time to respond to the HREC’s queries.
4. 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.
5. The HREC will notify the applicant of the ethical approval of a project only when all outstanding requests for further information, clarification or modification have been satisfactorily resolved. Notification of ethical approval will be in writing , and will contain the following information:
 - Title of project;
 - Name of the principal investigator(s);
 - Unique HREC project identification number;
 - The version number and date of all documentation reviewed and approved by the HREC including Clinical Protocols, 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; and
 - Conditions of HREC approval, if any.
6. If the HREC determines that a project is ethically unacceptable, the notification of the HREC’s decision will include the grounds for rejecting the project with reference to the *National Statement* or other relevant pieces of legislation.

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

SOP 014 – Amendments to Approved Projects

Sydney Children's Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 014	Date: April 2017
Subject: Submission of amendments to approved projects	
Purpose: To describe the procedure for the submission and HREC review of requests for amendments to approved protocols.	

1. Proposed changes to approved research projects, 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 request, and an assessment of any ethical implications arising from the request on the conduct of the research.
3. The request for amendment must be presented on the HREC's Amendment Application Form which is available on the Research Ethics website. All amended documents must have the changes highlighted and contain revised version numbers and dates. All written communication with the HREC regarding an existing project should contain the project name and unique project number.
4. Amendments to approved research projects will generally be reviewed by the Executive Committee / Executive Officer in accordance with [SOP 012](#).
5. 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 5 working days of the meeting at which the request was considered.
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. 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 on all IT Platforms as required.

SOP 015 – Renewal of Approval from the HREC

Sydney Children’s Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 015	Date: April 2017
Subject: Renewal of Approval from the HREC	
Purpose: To describe the procedure for the renewal of ethics approval by the HREC.	

1. The HREC approval timeframes are as per the following:
 - Medical Records Review: One (1) year
 - Other Low and Negligible Risk (LNR) applications: three (3) years
 - Non-LNR applications: five (5) years
2. For those projects not completed within this timeframe, and requiring more than 12 months of extension, the Principal Investigator will be required to complete and submit a *HREC Application for Renewal* form.
3. The application for renewal will be initially reviewed by the Executive Committee in accordance with [SOP 012](#).
4. The Executive Committee may refer or escalate the renewal application to SAC or HREC for review if required.
5. If a research project is to be completed within 12 months, an amendment application requesting an extension for up to 12 months can be submitted for consideration by the Executive Committee/Executive Officer in accordance with [SOP 012](#).

SOP 016 – Review of Adverse Events

Sydney Children’s Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 016	Date: April 2017
Subject: Review of Adverse Events	
Purpose: To describe the procedure for the reporting and handling of adverse events	

1. The HREC shall require, as a condition of approval of each project, that researchers report serious or unexpected adverse events to the HREC in a timely manner. This includes serious or unexpected adverse events that have occurred at other institutions for which the HREC has provided approval under a model of single ethical review of multi-centre research.
2. Notifications of adverse events must be submitted in the appropriate format as determined by the HREC, and shall include all documentation as required by the HREC. This documentation shall include as a minimum:
 - Advice from the principal investigator as to whether, in his/her opinion, the adverse event was related to the protocol or in the case of a drug/device trial, whether the adverse event was related to the study drug/device.
 - Advice from the principal investigator as to whether, in his/her opinion, the adverse event necessitates an amendment to the project and/or the Participant Information Sheet/Consent Form.
 - Advice from the principal investigator regarding the frequency of the event in relation to the total number of participants, for the trial in which the event occurred.
 - Advice from the principal investigator as to whether the event has been notified to the Independent Data and Safety Monitoring Board (if one exists).
3. The procedures and format for notification of adverse events to the HREC shall be readily available to investigators via the SCHN website.
4. The Adverse Event notifications will be reviewed by the Executive Committee in accordance with [SOP 012](#), which shall determine the appropriate course of action. This may include:
 - Notation on file of the occurrence;
 - Increased monitoring of the project;
 - Request for an amendment to the protocol and/or Participant Information Sheet/Consent Form;
 - A recommendation to the HREC to suspend ethical approval; or
 - A recommendation to the HREC to terminate ethical approval.
5. The Chair may take the appropriate course of action for those adverse events deemed serious and requiring immediate attention. This may include:
 - Referral to the Scientific Advisory subcommittee;

- Immediate request for additional information;
 - Immediate suspension of ethical approval;
 - Immediate termination of ethical approval.
6. The HREC shall provide notice to the Principal Investigator that it has received notification of the serious or unexpected adverse event, and the course of action it has deemed necessary to take.

SOP 017 - Monitoring of approved research projects

Sydney Children's Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 017	Date: April 2017
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 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.
2. The HREC will, as a condition of approval of each project, require that investigators immediately report anything which might warrant review of ethical approval of the project including:
 - All proposed changes to the research protocol or conduct;
 - Addition/removal of study sites or Principal Investigators;
 - Unforeseen events that might affect continued ethical acceptability of the project;
 - For multi-centre projects, if the project is discontinued at a site before the expected date of completion;
 - Serious or unexpected adverse events; and
 - If the project is abandoned for any reason.
3. The Principal Investigator (or delegate) will provide an annual report to the HREC on the anniversary of approval and a final report on completion.
4. Annual and final reports are reviewed by the Executive Committee in accordance with [SOP 012](#).
5. The HREC shall require the following information in the annual/final report:
 - Progress to date or outcome in the case of completed research;
 - Maintenance and security of records;
 - Compliance with the approved protocol; and
 - Compliance with any conditions of approval.
6. The HREC may adopt any additional appropriate mechanism/s for monitoring, as deemed necessary, such as:
 - Discussion of relevant aspects of the project with investigators, at any time;
 - Random inspection of research sites, data, or consent documentation;
 - Interview with research participants or other forms of feedback from them; and
 - Request and review of reports from independent agencies such as a Data and Safety Monitoring Board.

7. The HREC also has the discretion to recommend in the letter of approval that the site coordinates onsite monitoring at recommended intervals or randomly throughout the project.
8. The HREC may adopt any additional appropriate mechanism for monitoring as deemed necessary.
9. 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.
10. 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 018 - Complaints about the conduct of a research project

Sydney Children's Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 018	Date: April 2017
Subject: 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	

1. Any concern or complaint from a participant or any other person about the conduct of a project approved by the HREC should be directed to the attention of the HREC Executive Officer, or their delegate, who will notify the Chair as soon as possible. The contact details of the Executive Officer must be included in the Participant Information Sheet and/or Consent Form for each project.
2. The Executive Officer will send a letter of acknowledgement to the complainant and a letter of notification to the Principal Investigator, outlining the complaint and the mechanism for investigating the complaint as prescribed below.
3. The Chair 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. If the complaint is substantiated, actions may include:
 - The requirement for amendments to the project, including increased monitoring by the HREC;
 - Suspension of the project;
 - Termination of the project; or
 - Other action to resolve the complaint.
4. If the Chair declares a substantial conflict of interest, the duties of the Chair will fall to the Deputy Chair in investigating the complaint.
5. The complainant will receive a written response, if appropriate, from the HREC advising of the outcome of the Chair's investigation. A report will also be provided at the next HREC meeting.
6. If the complainant is not satisfied with the outcome of the Chair's investigation, he/she can refer the complaint to the Chief Executive or delegate (i.e. the Director of Research), or request that the Chair to do so.
7. The Chair of the HREC will provide the Chief Executive or delegate with all relevant information about the complaint/concern, including:
 - The Complaint;
 - Material reviewed during the Executive Officer's investigation;
 - The results of the Executive Officer's investigation; and
 - Any other relevant documentation.

8. The Chief Executive or delegate will determine whether there is to be a further investigation of the complaint.
9. If no further investigation is required, the Chief Executive or delegate will inform the complainant and the Chair of this.
10. If the Chief Executive or delegate determines that further investigation is required, then he/she will establish a panel to consider the complaint.
11. The panel will include, at least, the following members:
 - The Chief Executive or delegate as convenor of the panel;
 - Two nominees of the Chief Executive (not members of the HREC); and
 - The HREC Executive Officer
12. 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.
13. 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.
14. The Chief Executive or delegate will notify the complainant and the Chair of the outcome of the investigation, and the investigator if an allegation was raised against them. The outcome may include:
 - The complaint/concern is dismissed
 - The Chief Executive directs appropriate action to be taken to resolve the complaint

SOP 019 - Complaints concerning HREC's review process

Sydney Children's Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 019	Date: April 2017
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 Chair of the HREC, detailing in writing the grounds of the concern or complaint. Complaints may also be made to the Chief Executive or delegate (i.e. Director of Research).
2. The Chair will inform the Chief Executive or delegate as soon as possible of any complaints received by him/her. The Chief Executive or delegate will also inform the Chair as soon as possible of any complaints received by him/her.
3. The Chair 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 Chair declares a substantial conflict of interest, the duties of the Chair will fall to the Deputy Chair in investigating the complaint.
5. If the complainant is not satisfied with the outcome of the Chair's investigation, then he/she can refer the complaint to the Chief Executive or delegate, or request the Chair to do so.
6. The Chair of the HREC will provide the Chief Executive with all relevant information about the complaint/concern, including:
 - The complaint;
 - Material reviewed in the Chair's investigation;
 - The results of the Chair's investigation; and
 - Any other relevant documentation.
6. The Chief Executive will determine whether there is to be a further investigation of the complaint.
7. If no further investigation is required, the Chief Executive or delegate will inform the complainant and the Chair of this.
8. If the Chief Executive determines there is to be a further investigation, then he/she will establish a panel to consider the complaint/concern.
9. The panel will include, at least, the following members:
 - The Chief Executive or delegate as Convenor of the panel.

- Two nominees of the Chief Executive (not members of the HREC).
10. The panel will afford the HREC and the complainant the opportunity to make submissions.
 11. The panel may access any documents relating to the project. The panel may interview other parties, including internal and external experts. In conducting its review, the panel shall be concerned with ascertaining whether the HREC acted in accordance with the most recent version of the NHMRC National Statement on Ethical Conduct in Human Research, its Terms of Reference, Standard Operating Procedures, or otherwise acted in an unfair or biased manner.
 12. The Chief Executive or delegate will notify the complainant and the HREC of the outcome of the investigation. The outcomes of this process may include:
 - The complaint/concern is dismissed.
 - The complaint/concern is referred back to the HREC for further review, taking into consideration the findings of the panel.
 13. The panel may also make recommendations about the operation of the HREC including such actions as:
 - Review its Terms of Reference and Standard Operating Procedures;
 - Review committee membership;
 - Take other such action as appropriate.

SOP 020 – Complaints concerning HREC’s rejection of an application

Sydney Children’s Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 020	Date: April 2017
Subject: 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	

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 Chair of the HREC. Complaints may also be made to the Chief Executive or delegate.
2. The Chair will bring to the attention of the Chief Executive or delegate as soon as possible any complaints received by him/her. The Chief Executive or delegate will also inform the Chair as soon as possible of any complaints received by him/her.
3. The Chair 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 Chair declares a substantial conflict of interest, the duties of the Chair will fall to the Deputy Chair in investigating the complaint.
5. If the complainant is not satisfied with the outcome of the Chair’s investigation, then he/she can refer the complaint to the Chief Executive or delegate, or request the Chair to do so.
6. The Chair of the HREC will provide the Chief Executive with all relevant information about the complaint, including:
 - The complaint;
 - Material reviewed in the Chair’s investigation;
 - The results of the Chair’s investigation; and
 - Any other relevant documentation.
7. The Chief Executive will determine whether there is to be a further investigation of the complaint.
8. If no further investigation is required, the Chief Executive or delegate will inform the complainant and the Chair of this.
9. If the Chief Executive determines there is a case to be investigated, 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 delegate as convener of the panel

- Two nominees of the Chief Executive (not members of the HREC)
 - An expert/s in the discipline of research of the project under consideration
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 further review, taking into consideration the findings of the panel.
 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.

SOP 021 - Complaints about the HREC's approval of an application

Sydney Children's Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 021	Date: April 2017
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 Chair of the HREC. Complaints may also be made to the Chief Executive or delegate.
2. The Chair will bring to the attention of the Chief Executive or delegate as soon as possible any complaints received by him/her. The Chief Executive or delegate will also inform the Chair as soon as possible of any complaints received by him/her.
3. The Chair 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 Chair declares a substantial conflict of interest, the duties of the Chair will fall to the Deputy Chair in investigating the complaint.
5. If the complainant is not satisfied with the outcome of the Chair's investigation, then he/she can refer the complaint to the Chief Executive or delegate, or request the Chair to do so.
6. The Chair of the HREC will provide the Chief Executive with all relevant information about the complaint, including:
 - The complaint;
 - Material reviewed in the Chair's investigation;
 - The results of the Chair's investigation; and
 - Any other relevant documentation.
7. The Chief Executive will determine whether there is to be a further investigation of the complaint.
8. If no further investigation is required, the Chief Executive or delegate will inform the complainant and the Chair of this.
9. If the Chief Executive determines there is a case to be investigated, 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 delegate as convenor of the panel
 - Two nominees of the Chief Executive (not members of the HREC)
 - An expert/s in the discipline of research of the project under consideration
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 further review, taking into consideration the findings of the panel.
14. Should the HREC be requested to review its decision, then the outcome of this review by the HREC will be final.

SOP 022 – Complaints about the conduct of HREC members

Sydney Children's Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 022	Date: April 2017
Subject: Complaints about the conduct of HREC members	
Purpose: To describe the procedure for managing complaints about the conduct of HREC members.	

1. Complaints about the conduct of an HREC member are investigated and managed by the Chair in the first instance.
2. If the Chair declares a substantial conflict of interest, the duties of the Chair will fall to the Deputy Chair in investigating the complaint.
3. If the complainant is not satisfied with the outcome of the Chair's investigation, then he/she can refer the complaint to the Chief Executive or delegate, or request the Chair to do so.
4. The Chair of the HREC will provide the Chief Executive with all relevant information about the complaint, including:
 - The complaint;
 - Material reviewed in the Chair's investigation;
 - The results of the Chair's investigation; and
 - Any other relevant documentation.
5. The Chief Executive will then consider the complaint in accordance with [SOP 019](#).

SOP 023 – Review of Multi-Centre Research

Sydney Children's Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 023	Date: April 2017
Subject: Review of Multi-Centre Research	
Purpose: To describe the procedure for the reviewing by the HREC of multi-centre research.	

1. Multi-Centre Research in NSW

- 1.1. Multi-centre research in NSW is research that is conducted at more than one site within the NSW Public Health System, where those sites are within the jurisdiction of more than one NSW Health HREC.
- 1.2. In reviewing multi-centre research conducted in NSW, the HREC will comply with the requirements of [PD 2010_055](#) (Research - Ethical & Scientific Review of Human Research in NSW Public Health Organisations). According to this policy directive, a human research project will be ethically and scientifically reviewed once only, irrespective of the number of NSW Health sites involved in the project.
- 1.3. The SCHN HREC is a lead HREC which means that it can provide ethical and scientific review of paediatric multi-centre research applications on behalf of the NSW public health system.

2. Interstate Multi-Centre Research

- 2.1. The HREC may review applications from 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. Please refer to this [link](#) for more information.

SOP 024 – Record keeping

Sydney Children’s Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 024	Date: April 2017
Subject: Record keeping	
Purpose: To describe the procedure for the preparation and maintenance of records of the HREC’s activities.	

1. The Research Ethics Office will prepare and maintain written records of the HREC’s activities, including agendas and minutes of all meetings.
2. The Research Ethics Office 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;
 - Health Service approval for commencement of research 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; and
 - Action taken by the HREC to monitor the conduct of the research.
3. All relevant records of the HREC, including applications, membership, minutes and correspondence, will be kept as confidential files in accordance with the requirements of the State Records Act 1998.
4. To ensure confidentiality, all documents provided to HREC members, which are no longer, required, are to be disposed of in a secure manner, such as shredding or placed in confidential bins. Members who do not have access to secure disposal should leave their documents with the Secretary/Executive Officer for disposal.
5. The following table outlines the minimum retention requirements for different types of documentation held by the Research Ethics Office:

Type of document	State Record’s retention requirements
Project folders of approved projects	Clinical Research: Retain minimum of 15 years after research concluded, then destroy
	Non-clinical Research: Retain minimum of 5 years after research concluded, then destroy
Project folder of projects not-approved	Retain minimum of 3 years after last action, then destroy

<p>Records relating to the establishment and meetings of ethics/research committees such as Human Research Ethics Committees, Ethics Policy Committees, Animal Experimentation Ethics Committees, Bioethics Committees etc. Includes records relating to terms of reference, appointments to, terms and conditions of membership, policies and working procedures, and master sets of minutes, agendas, resolutions, reports, research protocol decisions, terms and conditions of approvals and associated background and working papers etc of the committee.</p>	<p>Required as State archives</p>
<p>Records relating to misconduct allegations against researchers that are deemed to be legitimate are sustained and result in a formal inquiry. This includes records relating to appeals.</p>	<p>Required as State archives</p>
<p>Records relating to allegations that are unsubstantiated or not sustained and do not lead to a formal inquiry</p>	<p>Retain minimum of 7 years after action completed, then destroy</p>

SOP 025 – Special Access Scheme applications

Sydney Children’s Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 025	Date: April 2017
Subject: Special Access Scheme applications	
Purpose: To describe the procedure for the review and approval of access to unapproved therapeutic goods (the product) via the Special Access Scheme	

1. The Special Access Scheme refers to the arrangements which provide for the import and/or supply of an unapproved therapeutic good on a single patient, case-by-case basis under the Therapeutic Goods Act 1989, Therapeutic Goods Regulations 1990 and Therapeutic Goods (Medical Devices) Regulations 2002. Full details of SAS are available from the Therapeutic Goods Administration (TGA) at:
<https://www.tga.gov.au/form/special-access-scheme>
2. For the purposes of SAS, patients are categorised as follows:
 - a) Category A patients: “persons who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment”. Medical practitioners can import and/or supply the unapproved therapeutic goods to this category of patient, having obtained the informed consent of the patient or the patient’s legal representative, without the approval of the TGA but the TGA must be notified using the Special Access Scheme Category A Form.
 - b) Category B: “all other patients”. Medical practitioners must obtain approval from a delegated medical officer within the TGA or a delegate outside the TGA (external delegate) to import and/or supply the unapproved therapeutic good.
3. The choice of categorisation lies with the prescriber.

‘External Delegates’

4. When seeking approval to supply unapproved therapeutic goods to a single patient, if appropriate, medical practitioners may apply to a nominated ‘external delegate’. An ‘external delegate’ is a person external to the TGA, given the delegation to approve the supply of unapproved therapeutic goods.
5. HREC responsibilities in relation to SAS are primarily concerned with granting approvals under section 19(1)(a) of the Therapeutic Goods Act 1989. In accordance with Therapeutic Goods Regulation 1990 47A (6)(b) and Therapeutic Goods (Medical Devices) Regulations 2002 10.6(6)(b), all SAS applications approved by an ‘external delegate’ must be approved by an HREC. In practice, external delegations are rare and thus HRECs are not asked to deliberate on such issues as a routine matter.

6. Before agreeing to an approval by an 'external delegate', the HREC should be provided with the following information:
 - 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 sought;
 - An assessment of the seriousness of the condition treated;
 - The intended mode of use/treatment 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.
7. Further details on the role of HREC in agreeing to an approval by an 'external delegate' are provided in the TGA Human Research Ethics Committees and the Therapeutic Goods Legislation, June 2001.
8. Special Access Scheme applications will be reviewed by the Executive Committee in accordance with [SOP 012](#).
9. Decisions by the HREC Executive Committee are tabled for ratification at the next HREC meeting.

Institutional Approval

10. Final responsibility for the use of an unapproved product within an institution always rests with that institution. Medical practitioners working in a NSW Public Health Organisation should discuss the use of the product and the approval process with the institution before applying for authorisation.

SOP 026 – Authorised Prescriber Applications

Sydney Children's Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 026	Date: April 2017
Subject: Authorised Prescriber applications	
Purpose: To describe the procedure for the review and approval of access to unapproved therapeutic goods via Authorised Prescribers.	

1. In accordance with the Therapeutic Goods Act 1989, Therapeutic Goods Regulations 1990 and Therapeutic Goods (Medical Devices) Regulations 2002, the Therapeutic Goods Administration (TGA) is able to grant to a medical practitioner authority to prescribe a specified unapproved therapeutic good or class of unapproved therapeutic goods to specified recipients or classes of recipients (identified by their medical condition). An Authorised Prescriber can then prescribe that product for that condition (also known as the 'indication') and no approval from the TGA is required for each individual patient. Full details of Authorised Prescribers are available from the TGA at: <https://www.tga.gov.au/form/authorised-prescribers>
2. The legislation requires that the medical practitioner obtains endorsement from the ethics committee at the institution at which they practice (except where the practitioner can demonstrate that he/she does not have access to an appropriate HREC, in which case endorsement from a specialist college is acceptable). The HREC is responsible for providing a letter of endorsement to be submitted by the medical practitioner to the TGA as part of the practitioner's application. Full details of the HREC responsibilities are provided in the TGA Human Research Ethics Committee and the Therapeutic Goods Legislation, June 2001 and Access to Unapproved Therapeutic Goods – Authorised Prescribers October 2004.
3. Applications for HREC endorsement of Authorised Prescriber Status for unapproved products (under sections 19(5) and 41HC of the Therapeutic Goods Act 1989) are reviewed by the Executive Committee in accordance with [SOP 012](#).
4. Decisions by the HREC Executive Committee will be ratified at the next HREC meeting.
5. When reviewing applications to become an Authorised Prescriber, the HREC needs to assess not only the safety of the product in relation to its proposed use, but also the suitability of the medical practitioner. The HREC considers:
 - The indication for which the product will be prescribed;
 - Efficacy and safety of the product in relation to its proposed use;
 - For medicines, the route of administration and dosage form;
 - Clinical justification for use of the product;
 - Suitability of the medical practitioner; and
 - Patient information about the product and the informed consent form.

6. If endorsed, the HREC provides a letter to the applicant in the format suggested by the TGA. The HREC imposes conditions on the endorsement, if required, such as:
 - Regular reports to the HREC comprising information such as the number of patients prescribed the unapproved product; and
 - Reporting of any adverse events.
7. The HREC will review its endorsement of the Authorised Prescriber if it is aware of:
 - Inappropriate use of the product by the Authorised Prescriber;
 - Safety concerns about the product;
 - Failure of the Authorised Prescriber to comply with conditions imposed by the HREC; or
 - Failure of the Authorised Prescriber to comply with the legislation.
8. Where the HREC becomes aware that the welfare and/or rights of patients are not being or will not be protected, it will:
 - Advise the medical practitioner and the Chief Executive or delegate of its concerns;
 - Withdraw its approval of the Authorised Prescriber; and
 - Report to the TGA (Chief Executive or delegate and Chair to determine)

Institutional Approval

9. Final responsibility for the use of an unapproved product within an institution always rests with that institution. Medical practitioners working in a NSW Public Health Organisation should discuss the use of the unapproved therapeutic product and identify the approval process with the institution before applying for authorisation.

SOP 027 – Managing Conflicts of Interest

Sydney Children’s Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 027	Date: April 2017
Subject: Managing conflicts of interest	
Purpose: To describe the procedure for managing conflicts of interest of HREC members	

1. An SCHN HREC member declares to the HREC any conflicts of interest they have in relation to an application for ethical and scientific review or any other matter for consideration at the meeting. Conflict of interest 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 Chair and/or Executive Officer prior to the meeting.
3. A substantial conflict of interest: a member is excluded from the meeting where there is a substantial conflict of interest until the HREC has concluded consideration of the matter. Being an investigator on a research project is considered to represent a substantial conflict of interest.
4. The member may remain in the room if the HREC requires their expertise and/or requires them to answer queries regarding the project from an investigator perspective.
5. The member shall not participate in the discussions as an HREC member and shall not be entitled to vote in the decision with respect to the proposal.
6. A non-substantial conflict of interest: the member has the discretion to leave during the discussion of the matter.
7. If the Chair declares a substantial conflict of interest, the duties of the Chair will fall to the Deputy Chair while the relevant proposal is under discussion.
8. If the Chair, Executive Officer or any member of the SCHN HREC is aware of an undeclared interest of another member present, such a member will raise the conflict of interest with the Chair during the meeting. All proceedings will be minuted.
9. The declaration of interest and absence/presence of the member concerned shall be minuted.

SOP 028 – HREC Reporting Requirements

Sydney Children's Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 028	Date: April 2017
Subject: HREC reporting requirements	
Purpose: To describe the reporting requirements of the HREC	

1. The minutes of each HREC meeting shall be forwarded to the Chief Executive or delegate following confirmation. A monthly report on the activities of the HREC shall also accompany the minutes.
2. The Executive Officer and Chair will also meet with the Director of Research on a bi-monthly basis to provide an update on the activities of the HREC.
3. The HREC shall provide an annual report to the Chief Executive at the end of each 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.
4. The SCHN HREC shall bring to the attention of the CE or delegate any ethical issues that may be of significant concern.
5. The SCHN HREC shall provide the following reports on behalf of the SCHN Executive:
 - Annual Report to the National Health and Medical Research Council (NHMRC);
 - The NSW Privacy Commissioner report in accordance with the requirements of the Health Records and Information Privacy Act (2002).
 - Certified Institution Annual Report to the NHMRC; and
 - Any other reports as required.
6. The HREC Terms of Reference, Standard Operating Procedures and membership will be available upon request to the general public, and will be posted on the SCHN Research Ethics website.

SOP 029 - Review of Standard Operating Procedures and Terms of Reference

Sydney Children's Hospitals Network Human Research Ethics Committee Standard Operating Procedures	
Reference Number: SOP 029	Date: April 2017
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 two years and amended as necessary.
2. The Standard Operating Procedures and Terms of Reference may be amended by following the procedure below:
 - 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 Executive Officer or Chair shall send the amendment to the Director of Research and the Chief Executive for review and approval if appropriate.