Sydney Children's Hospitals Network
Human Research Ethics Committee
TERMS of REFERENCE
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
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

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 HREC functions on behalf of the Sydney Children's Hospitals Network are to:

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 in respect of 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. Accountability

3.1. 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.

3.2. The SCHN HREC is to also provide annual 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.

3.3. The SCHN HREC shall bring to the attention of the CE or delegate any ethical issues that may be of significant concern.

3.4. 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.

3.5. 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.

4. Scope of Responsibility

The SCHN HREC is accredited by the NSW Ministry of Health as a lead HREC. The responsibilities of the SCHN HREC are to:

4.1. Conduct ethical and scientific review of human research on behalf of the NSW public health system in the categories of (a) clinical trials / interventional clinical research; and / or (b) general research; with a specific area of interest and expertise in paediatrics.

4.2. Review applications for human research where that research takes place at:

- Any institution/s governed by NSW Public Health Organisations for multicentre studies; and/or
- Any institutions governed by the SCHN for single-centre studies; and/or
- 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.

HREC sub-Committees

4.3. Subcommittees are delegated by the HREC to carry out scientific, technical or expedited reviews of applications. Members of the subcommittees need not be members of the HREC, and are appointed by the subcommittee Chair.

Scientific Advisory Committee (SAC)

4.4. The Scientific Advisory Committee (SAC) provides advice on scientific, technical and clinical aspects of human research protocols and clinical trials, and on compliance with regulatory requirements.

4.5. All clinical trials (both single-centre and multi-centre, including drug trials, and trials of devices and other clinical interventions) are required to have:

- A scientific assessment completed in accordance with the Assessment Checklist
- A Certificate of Scientific Review

4.6. The SAC operates in accordance with its own Terms of Reference (TOR).

HREC Executive Committee (Executive Committee)

4.7. The HREC has an Executive Committee (Executive Committee) comprising, at a minimum, the HRES Chair or their delegate and a member of the research office. The Executive operates within defined Terms of Reference (TOR) which are embedded within this section.

4.8. The Executive Committee is delegated to undertake expedited review and final approval of business that does not require full HREC review, including some of 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 Data Safety Monitoring Reports
- Applications for HREC endorsement of Authorised Prescriber Status for unapproved products (under sections 19(5) and 41HC of the Therapeutic Goods Act 1989)

4.9. The minutes and decision of the Executive Committee are noted and ratified at the next HREC meeting.

4.10. The Executive Committee may review urgent HREC business and (as appropriate) grant covering or final approval for the item.

4.11. The Executive Committee may seek advice from HREC or SAC members as appropriate before reaching a decision.

4.12. The Executive Committee may refer or escalate matters to a full SAC or HREC Committee meeting for review.

4.13. The Executive Committee will minute all meetings and make finalised minutes available for review at request by the HREC or an authorised auditor.

4.14. 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.

4.15. The Executive Committee will be considered a quorum when the HREC Chair (or their delegate) and Executive Officer (or Research Ethics Officer as delegate) are in attendance. The wider membership will comprise of one member of the SAC and one member of the HREC.

4.16. The Executive Committee will endeavour to meet every two weeks.

5. Organisational Context

5.1. The HREC is a committee of SCHN and reports to the Chief Executive who is responsible for granting the SCHN's institutional approval for research to be conducted, giving due consideration to the advice of the SCHN HREC and RGO. The CE may not give approval for research to be conducted within the SCHN's

institutions unless ethical approval has been granted by the SCHN HREC or another NSW Lead HREC.

6. Membership

6.1. Composition

6.1.1. 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 Chair, 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 do 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.

6.1.2. 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.

6.1.3. No member is appointed in more than one of the membership categories listed at 6.1.1.

6.1.4. 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.

6.1.5. 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 Network 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.

6.1.6. 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.

6.1.7. In attendance:

- HREC Executive Officer
- Research Ethics Officer as Secretariat

6.1.8. 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.

6.2. Appointment

6.2.1. HREC members are recruited by direct approach, nomination or by advertisement through an open and transparent process.

6.2.2. Prospective members may be invited to observe a meeting of the HREC.

6.2.3. Prospective members are asked to provide a copy of their curriculum vitae to a selection committee comprising the Chair, Executive Officer and at least one other HREC member. The selection committee interviews prospective members, consults with HREC members and makes a recommendation on new appointments to the Chief Executive or delegate.

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

6.2.5. Membership of the HREC is made publicly available.

6.2.6. All members including the Chair, Deputy Chair and Chair of any subcommittee are appointed by the CE or delegate. The letter of appointment includes the date of appointment, length of tenure, indemnity and termination.

6.2.7. Upon appointment, members are provided with an orientation package and asked to sign a statement undertaking:

- 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.

6.3. Terms and Conditions of Appointment

6.3.1. 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.

6.3.2. The Chair, Deputy Chair and Chair of any subcommittee may serve longer terms with the approval of the Chief Executive or delegate. 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.

6.3.3. New and renewed appointments allow for continuity, development of expertise within the HREC, and regular input of fresh ideas and approaches.

6.3.4. 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.

6.3.5. The Chair notifies the member of a lapse of membership in writing. Steps are taken to fill the vacancy.

6.3.6. 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.

6.3.7. The appointment of any member of the HREC may be terminated if the Chief Executive is of the opinion that:

- It is necessary for the proper and effective functioning of the HREC;
- The person is not a fit and proper person to serve on an HREC;
- The person has failed to carry out their duties as an HREC member.

6.3.8. Members are expected to participate in relevant education activities and specialist working groups as required.

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

6.3.10. 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.

6.3.11. Members must agree to their name and position being made publicly available in annual reports, on the SCHN website and in other routine processes.

6.3.12. Internal SCHN HREC members are not offered remuneration. However, members will be reimbursed for legitimate expenses incurred in attending HREC meetings or in otherwise carrying out the business of the HREC. For External SCHN members this will be paid as an annual stipend.

6.3.13. 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.

6.4. Orientation and Training for HREC Members

6.4.1. New SCHN HREC members are to be provided orientation/ training as determined to be appropriate by the SCHN.

6.4.2. 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.

6.4.3. 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 once in each period of appointment.

6.4.4. Throughout their tenure, members shall be given the opportunity to attend conferences and workshops relevant to the work and responsibilities of the HREC.

7. Conduct of Business

7.1. Procedures

7.1.1. The SCHN HREC conducts its business in accordance with the Terms of Reference, and Standard Operating Procedures.

7.1.2. The SCHN HREC Standard Operating Procedures are made publicly available.

7.1.3. These procedures shall be reviewed at least every two years and amended and updated as necessary. All SCHN HREC members shall be consulted with regard to changes thereto.

7.2. Meeting Protocol

7.2.1. The SCHN HREC meets on a regular basis at least every four (4) weeks with at least ten (10) scheduled meetings in each calendar year for the purposes of reviewing new applications. Additional meetings can be scheduled as required.

7.2.2. Meeting dates and application closing dates are made publicly available on the SCHN Research Ethics website.

7.2.3. A quorum is required at each meeting for the SCHN HREC to reach a final decision on any agenda item. The quorum for meetings is at least one member from each of the core categories and the Chair/Deputy Chair as specified in the National Statement attending in person or via telephone or videoconference.

7.2.4. Where there is less than full attendance of the minimum membership at a meeting, the Chair would be satisfied, before a decision is reached, that the views of those absent who belong to the minimum membership have been received and considered, for instance through prior submission of written comments.

7.3. Declaration of Interest

7.3.1. An SCHN HREC member declares to the SCHN 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 includes financial interests, personal, professional or institutional benefits or advantages that depend significantly on the research outcomes.

7.3.2. 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.

7.3.3. 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.

7.3.4. The member may remain in the room if the SCHN HREC requires their expertise and/or requires them to answer queries regarding the project from an investigator perspective.

7.3.5. The member shall not participate in the discussions as an SCHN HREC member and shall not be entitled to vote in the decision with respect to the proposal.

7.3.6. A non-substantial conflict of interest: the member has the discretion to leave during the discussion of the matter.

7.3.7. If the Chair declares a conflict of interest, the duties of the Chair will fall to the Deputy Chair while the relevant proposal is under discussion.

7.3.8. 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.

7.3.9. The declaration of interest and absence/presence of the member concerned shall be minuted.

7.4. Confidentiality

7.4.1. SCHN HREC meetings are held in private. The agenda and minutes of meetings, applications, supporting documentation and correspondences are all treated confidentially.

7.5. Decision Making

7.5.1. The HREC endeavours to reach a decision concerning the ethical and scientific acceptability of an application by unanimous agreement.

7.5.2. Where a unanimous agreement is not reached, the matter is determined by a majority of two-thirds of members present at the meeting, provided that the majority includes at least one layperson.

7.5.3. Any significant minority view (i.e. 2 or more members) is to be noted in the minutes.

7.6. Authority Delegated

7.6.1. The Executive Officer is delegated the authority to facilitate the day to day working of the committee.

7.6.2. The delegated authority to the Executive Officer includes:

- To determine whether an application meets the requirements to be considered by the HREC and reject any application that does not;
- To complete a preliminary review of audit and quality improvement activities to determine whether HREC approval is required, and if so, communicate the need for an ethics application to the appropriate person:
- 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.
- Grant extensions of approval for protocols whose period of approval has expired under specific conditions
- Sign/endorse Clinical Trial Notifications (CTN) on behalf of the HREC.
- To 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.

7.6.3. The EO may refer/escalate any submissions for review to the HREC Chair, Executive Committee, SAC or HREC.

7.6.4. The EO will minute all delegated reviews using the established Executive meeting minute template.

7.6.5. The minutes and decision of the EO are noted and ratified at the next HREC meeting.

7.6.6. The authority delegated to the Executive Officer should be reviewed annually or when the staff member in that position changes.

7.7. Records/Data Management

7.7.1. Written records of all meetings of the HREC are maintained (including agendas and minutes).

7.7.2. Files are kept securely and confidentially in accordance with the requirements of Health Records and Information Privacy Act (2002) and the State Records Act 1998.

7.7.3. The HREC maintains a register of all the applications received and reviewed in accordance with the National Statement (NS 5.2.24).

7.7.4. Members of the HREC shall have access to the official minutes and records of the HREC for the time period they are members plus 7 years.

7.8. Monitoring Research Projects

7.8.1. The HREC monitors approved research projects to ensure compliance with the conditions of approval and to protect the rights, safety and welfare of participants. This includes review of annual progress reports and final reports, safety reports and reports of protocol violations.

7.8.2. The HREC has the discretion to adopt other appropriate mechanisms for monitoring depending on the complexity, design and risk perceived, including:

- 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 reports from independent agencies such as a Data and Safety Monitoring Board.

7.8.3. The HREC also has the discretion to recommend in the letter of approval that the site co-ordinates onsite monitoring at recommended intervals or randomly throughout the project.

7.8.4. The HREC may adopt any additional appropriate mechanism for monitoring as deemed necessary.

8. Appeals and Complaints

8.1. Appeals regarding HREC rejection

8.1.1. Where the HREC has rejected an application, the investigator has the discretion to:

- Submit a new application to the same HREC, taking due account of the HREC‟s concerns; or
- Lodge an appeal with the HREC Chair specifying the grounds of the appeal in writing.

8.2. Appeals regarding HREC approval

8.2.1. 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 may be lodged with the Chair in the first instance.

8.3. Appeals to the Chief Executive or Delegate

8.3.1. If the appellant considers that the HREC has failed to follow due process after making an appeal in line with 8.1 and 8.2, and remains unsatisfied with the outcome, they have the discretion to lodge an appeal with the Chief Executive or delegate of the Public Health Organisation or request that the Chair do so.

8.4. Complaints about the conduct of HREC members

8.4.1. Complaints about the conduct of an HREC member are managed by the Chief Executive or delegate who informs the Chair of the complaint.

8.5. Complaints about the conduct of an approved research project

8.5.1. Complaints about the conduct of an authorised research project, including allegations of research misconduct, are managed in accordance with the Sydney Children’s Hospitals Network local complaint handling procedures.

9. Amendments/review to the Terms of Reference

9.1. These Terms of Reference will be reviewed every two (2) years and may be amended following the procedure at 9.2 below.

9.2. Proposed amendments to the Terms of Reference should be presented at the next scheduled meeting of the HREC, and a vote taken at that meeting. Any member unable to attend such a meeting may register their views in writing.

10. Termination of HREC responsibility

10.1. Where the SCHN HREC is to be merged, closed or has ceased to function, the SCHN notifies the NHMRC and determines the appropriate course of action, such as the status of its registration and / or status as a certified institution with the NHMRC and the monitoring of previously approved research. The SCHN also notifies the NSW Ministry of Health.

Document History

Version Date	Brief Description
February 2014	-
February 2014 (v1.2)	Updated Definitions to include "Research Ethics Support Officer" Addition of Document History table at end of document 4.3.12.2 and 7.6.2 – Update to the delegations of the EO to delegate the review of further information received to the REO or RESO 7.6.2 – Update to the delegations of the EO to sign Clinical Trial Notifications on behalf of the HREC
April 2017	Summary of changes have been saved on TRIM (record number: TRIM E17/3285) and can be accessed on the G: Drive via this link.