1. **OBJECTIVES**

The objectives of the Ethics Review Committee (HREC) are to:

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

1.2 Promote ethical standards in human research.

1.3 Review research in accordance with the *National Statement on Ethical Conduct in Human Research (March 2007, updated May 2015)* (the *National Statement*).

1.4 Facilitate ethical research through efficient and effective review processes.

2. **FUNCTIONS**

2.1 Provide independent, competent and timely review of human research projects with respect to their ethical acceptability.

2.2 Provide ethical oversight and monitoring of approved human research projects in respect of their ethical and scientific acceptability for as long as projects are active.

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

3. **SCOPE OF RESPONSIBILITY**

3.1 The HREC is responsible for:

(i) Reviewing applications for multicentre research where such research will take place at any institutions governed by NSW Public Health Organisations.

(ii) Reviewing applications for multicentre clinical trial research where such research will take place at any Public Health Organisation which is participating in the multi-state process of the National Mutual Acceptance Scheme.
(iii) Reviewing applications for single-centre or multi-centre research where such research will take place at any external institution / organisation / private practice which has entered into an External Entity Agreement with the SLHD (under Policy Directive PD2008_046).

The External Entity Agreement between the SLHD and the external institution / organisation / private practice shall define the role of the HREC in providing ethical approval and ethical monitoring of the research and the role of the external institution / organisation / private practice in giving approval for the research to take place within its organisation. The agreement shall specify which party bears legal responsibility for the liabilities that arise from the ethical review conducted by the HREC, and shall also specify that the institution / organisation / private practice (not the SLHD) is responsible for liabilities arising from the conduct of the research.

(iv) Reviewing applications for single-centre research where such research will normally take place at any institution governed by the SLHD (RPAH Zone):

- Royal Prince Alfred Hospital
- Balmain Hospital
- Canterbury Hospital
- Sydney Dental Hospital
- Division of Population Health

3.2 This term of reference does not prohibit the SLHD from accepting an ethical approval undertaken by another human research ethics committee (HREC) as a sufficient ethical approval to allow the institution to authorise the commencement of the project, provided that such other HREC is registered with the NSW Ministry of Health as a “NSW Lead HREC” or with the Australian Health Ethics Committee (AHEC) as a HREC certified under the National Approach to Single Ethical Review of Multi-centre Research (National Approach).

3.3 Human research includes research involving pharmaceuticals, medical devices, medical radiation and imaging, surgical procedures, biological samples, medical records, as well as epidemiological, social and psychological investigations.

4. STATUS OF THE HREC WITHIN THE SLHD

4.1 The HREC is a committee of the SLHD Board (reporting to the Education and Research Committee) with responsibility for:

- granting ethical approval;
- withholding ethical approval;
• suspending ethical approval; and
• withdrawing ethical approval

for research proposed to be carried out within the institutions noted in Section 3.

5. **ACCOUNTABILITY OF THE HREC**

5.1 The HREC is accountable to the Chief Executive in the conduct of its business. The minutes of each HREC meeting shall be forwarded to the Chief Executive, following confirmation.

5.2 The HREC shall provide an annual report to the Chief Executive at the end of each calendar year, which shall include information on membership, the number of research applications reviewed, status of research applications, a description of any complaints received and their outcome, and any other general issues.

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

5.4 The HREC shall provide reports to:

• the Australian Health Ethics Committee (AHEC), in accordance with the requirements of the National Health and Medical Research Council (NHMRC);
• the NSW Privacy Commissioner, in accordance with the requirements of the Health Records and Information Privacy Act 2002 (NSW);

5.5 The HREC’s Terms of Reference, Standard Operating Procedures and membership shall be available upon request to the general public and shall be posted on the SLHD website.

6. **MEMBERSHIP**

6.1 Composition

6.1.1 The composition of the HREC shall be in accordance with the *National Statement*. The minimum membership comprises ten members and shall include at least:

• a chairperson;
• chairperson of the Clinical Trials Sub-committee (or nominee);
• at least two members who are lay people, one man and one woman, who have no affiliation with the Health Service, and are not currently involved in medical, scientific, academic or legal work;

• at least two members 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;

• at least one member who is a minister of religion, or a person who performs a similar role in the community; and

• at least one member who is a lawyer and, where possible, one who is not engaged to advise the institution for which the HREC is reviewing research; and

• an Executive Officer (non-voting member).

6.1.2 To ensure that membership shall equip the HREC to address all the relevant considerations arising from the categories of research likely to be submitted, some or all of the above categories may be represented by more than one person. No member shall be appointed in more than one of the membership categories.

6.1.3 For the purposes of holding a meeting of the HREC, a quorum shall exist when the minimum membership as specified in paragraph 6.1.1 is present. In circumstances where such core members cannot be present, they may provide written comments in lieu of attendance. The HREC shall establish a pool of inducted members in each category, who attend meetings as needed, to meet the HREC requirements and are available to provide expertise for the research under review.

6.1.4 The HREC shall be free to consult any person(s) considered by the HREC to be qualified to provide advice and assistance in the review of any research proposal submitted to it, subject to that person(s) having no conflict of interest and providing an undertaking of confidentiality. Such person(s) shall not be entitled to vote on any matter.

6.2 Appointment

6.2.1 The Chief Executive shall appoint members of the HREC in consultation with the HREC and other senior SLHD officials, as deemed appropriate.

6.2.2 Prospective members of the HREC may be recruited by direct approach, by nomination or by advertisement.
6.2.3 A selection committee, consisting of the Chairperson, the Executive Officer and at least one other HREC member, shall interview prospective applicants, consult with the HREC members and make a recommendation to the Chief Executive.

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

6.3 Terms of appointment

6.3.1 Members shall be appointed for a period of three years and may be reappointed at the discretion of the Chief Executive.

The Chairperson, Deputy Chairperson and Chairperson of any Sub-committee shall be appointed for a period of five years and may be reappointed at the discretion of the Chief Executive.

6.3.2 Membership shall lapse if a member fails to attend three consecutive meetings of the HREC without reasonable excuse or without notifying the Chairperson, unless exceptional circumstances exist. The Chairperson shall notify the member in writing of such lapse of membership and steps shall be taken to fill the vacancy of the lapsed member.

6.3.3 A member may resign from the HREC at any time by giving notice in writing to the Chairperson. Upon receipt of such notice, steps shall be taken to fill the vacancy of the former member.

6.3.4 The Chief Executive may terminate the appointment of any member of the HREC if the Chief Executive is of the opinion that:

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

6.3.5 Members shall be provided with a letter of appointment which shall include 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 an HREC member, HREC meeting attendance responsibilities and general responsibilities as a HREC member.

6.4 Conditions of appointment

6.4.1 Members must agree to their names and professions being made publicly available, including being published on the SLHD website.
6.4.2 Members are not offered remuneration. However, members shall be reimbursed for legitimate expenses incurred in attending HREC meetings or in otherwise carrying out the business of the HREC.

6.4.3 Members shall be required to sign a statement undertaking:

- that all matters of which he/she becomes aware during the course of his/her work on the HREC shall be kept confidential;
- that any conflicts of interest which exist or may arise during his/her tenure on the HREC shall 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.

6.5 Education for HREC members

6.5.1 Newly appointed members shall be provided with adequate orientation.

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

6.6 Sub-committees

6.6.1 The HREC may appoint such sub-committees as it sees fit to carry out a scientific or technical review of a research proposal, or ethical review of research deemed to be of low or negligible risk, submitted to the HREC. The Chair of any such sub-committee shall be appointed by the Chief Executive. Members of the sub-committee need not be members of the HREC. See Appendix 1: Terms of Reference of the Clinical Trials Sub-committee.

6.6.2 The HREC may appoint such sub-committees as it sees fit to carry out ethical review of issues related to clinical practice. See Appendix 2: Terms of Reference of the Ethics of Clinical Practice Sub-committee and Appendix 3: Terms of Reference of the Clinical Ethics Advisory Panel.

6.7 Liability coverage

6.7.1 The SLHD shall provide indemnity for members of the HREC for any liabilities that arise as a result of the member exercising his/her duties as a member in good faith. Such indemnity is provided through the NSW Treasury Managed Fund.
7. CONDUCT OF BUSINESS

7.1 Procedures

7.1.1 The HREC shall perform its functions according to written Standard Operating Procedures. These procedures shall be reviewed at least every two years and amended and updated as necessary. All HREC members shall have access to and/or be provided with copies of the procedures and shall be consulted with regard to any proposed changes.

7.2 Submissions, notifications and approvals

7.2.1 All applications for ethical approval must be submitted to the Executive Officer of the HREC, by the relevant closing date, in writing in the format approved from time to time by the HREC and shall include such documentation as the HREC may specify.

7.2.2 Guidelines shall be issued to assist applicants in the preparation of their applications.

7.2.3 The HREC may request the applicant to supply further information in relation to an application and/or request the applicant to attend a meeting of the HREC at which the application shall be considered for the purpose of providing information to and answering questions from the HREC members.

7.2.4 The HREC shall consider every correctly completed application which it receives at its next available meeting following receipt, provided that the application is received by the relevant closing date. The Executive Office shall circulate the completed application and associated documents received with a meeting agenda to all members of the HREC at least seven (7) days prior to the next meeting.

7.2.5 The HREC may delegate consideration of certain scientific/technical matters to an HREC member or sub-committee of members. The HREC may also obtain expert scientific/technical advice, subject to paragraph 6.1.4.

7.2.6 The HREC may take into account the opinions or decisions of another human research ethics committee (HREC) in relation to a research protocol.

7.2.7 Following its review, the HREC shall clearly and promptly notify its decision to the applicant:

(a) Where an application is approved, communication will be in writing and will include an explicit statement that the application meets the requirements of the National Statement.
(b) Where amendments are required, communication will be either written or, where appropriate, informal. Reasons will be given for the requested amendments.

(c) Where an application is rejected, communication of the rejection will be in writing and will include reasons linked to the National Statement.

Notification of HREC decisions shall normally be sent within five (5) working days. The Executive Officer has delegated authority from the HREC to sign its correspondence, including letters of ethics approval.

7.3 Expedited review

7.3.1 The HREC shall establish an Executive, consisting of at least the Chairperson (or nominee) or Chairman of the Clinical Trials Subcommittee (or nominee) and Executive Officer. In accordance with the Standard Operating Procedures, the Executive shall undertake expedited review of research deemed to be of low or negligible risk between scheduled meetings. Expedited review of other categories of research will be at the discretion of the Chairperson. The Executive may seek advice from other HREC members, as appropriate, before reaching a decision. If approval is granted, such approval shall be considered for ratification at the next HREC meeting.

7.3.2 The Executive may consider other items of business that are considered to be of minimal risk to participants such as expected adverse events, protocol reports, minor amendments and the like. The minutes of any such meetings shall be tabled for ratification at the next HREC meeting.

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

7.4 Multi-centre research

7.4.1 The HREC shall comply with Policy Directive PD2010_055 "Research - Ethical & Scientific Review of Human Research in NSW Public Health Organisations".

7.4.2 The HREC shall participate in the National Mutual Acceptance Scheme and shall seek and maintain certification by the NHMRC under the National Approach to Single Ethical Review of Multi-centre Research (National Approach).
7.4.3 To facilitate multi-centre research the HREC may also:

- communicate with any other HREC;
- accept a scientific/technical and/or ethical assessment of a research proposal by another HREC.
- share its scientific/technical and/or ethical assessment of the research with another HREC.

7.5 Advocates and interpreters

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

7.5.2 Where research involves the participation of persons unfamiliar with the English language, the HREC shall ensure that the participant information sheet is translated into the participant’s language and/or that an interpreter is present during the discussion on the project.

7.6 Meetings

7.6.1 The HREC shall meet on a regular basis, which shall normally be at monthly intervals.

7.6.2 Meeting dates and agenda closing dates shall be published at the beginning of each calendar year.

7.6.3 Any member of the HREC who has any interest, financial or otherwise, in a proposal or other related matter(s) considered by the HREC shall declare such interest prior to its consideration. If the member is present at a meeting at which the matter is considered, the member shall withdraw from the meeting until the HREC’s consideration of the relevant matter has been completed. The member shall not participate in the discussions and shall not be entitled to vote in the decision with respect to the matter. The declaration of interest and absence of the member concerned shall be minuted.

7.6.4 The HREC shall endeavour to reach a decision concerning the ethical acceptability of a proposal by consensus. Any significant dissenting view or concern shall be recorded in the minutes. Where a unanimous decision is not reached, the decision shall be considered to be carried by a majority of two-thirds of members who examined the proposal, provided that the majority includes at least one layperson.
7.7 Fees

7.7.1 A fee shall be charged for clinical trial applications and amendments submitted for assessment by the HREC in accordance with the NSW Health Department’s Policy Directive PD2008_030 – *HREC and Research Governance: Fee Policy for Review of Commercially Sponsored Research*.

7.7.2 A fee shall not be charged for non-clinical trial applications submitted for assessment by the HREC.

7.8 Records

7.8.1 The Executive Officer shall prepare and maintain written records of the HREC’s activities, including agendas and minutes of all meetings of the HREC.

7.8.2 The Executive Officer shall prepare and maintain a file for each application received including a copy of the application, and any relevant correspondence including that between the applicant and the HREC.

7.8.3 Files shall be kept securely and confidentially in accordance with the requirements of *Health Records and Information Privacy Act 2002*.

7.8.4 Records shall be held for sufficient time to allow for future reference. The minimum period for retention is at least five years from the date of completion of a project but for specific types of research, such as clinical research, 15 years shall apply\(^1\)\(^2\). Files which are no longer required for retention shall be electronically archived.

7.8.5 The HREC shall maintain a register of all the applications received and reviewed in accordance with the *National Statement*.

8. POST-APPROVAL RESPONSIBILITIES

8.1 The HREC shall monitor approved projects for compliance with the HREC’s ethical approval. In doing so, the HREC may request and discuss information on any relevant aspects of the project with the investigators at any time. In particular, the HREC shall require investigators to provide a report at least annually, and at completion of the study.

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\(^1\) NSW Health General Retention and Disposal Authority – Public Health Services: Patient/Client Records (GDA 17) and General Retention & Disposal Authority - Public Health Services: Administrative Records (GDA 21)

\(^2\) Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)
8.2 The HREC shall, as a condition of approval of each project, require that investigators immediately report anything which might warrant review of the ethical approval of the project, including:

- proposed changes in the research protocol or conduct;
- unforeseen events that might affect continued ethical acceptability of the project;
- suspected unexpected serious adverse reactions (SUSARs) occurring in participants at sites monitored by the HREC, other adverse event reports / line listings as decided by the HREC and data and safety monitoring board (DSMB) reports, in accordance with NHMRC and other relevant guidelines; and
- if the project is abandoned for any reason.

8.3 The HREC may adopt any additional appropriate mechanism(s) for monitoring as deemed necessary.

9. COMPLAINTS AND REVIEW

9.1 Complaints from a participant concerning the conduct of a project

9.1.1 Any concern or complaint about the conduct of a project should be directed to the attention of the person nominated by the HREC. The person nominated by the HREC to receive complaints shall notify the Chairperson as soon as possible after a complaint is received. The Chairperson of the HREC shall investigate the complaint and make a recommendation on the appropriate course of action. If the complainant is not satisfied with the outcome of the Chairperson’s investigation, then he/she can refer the complaint to the Chief Executive or his/her nominee, or request the Chairperson to do so.

9.2 Complaints from an investigator concerning the HREC’s review process

9.2.1 Any concern or complaint about the HREC’s review process should be directed to the attention of the Chairperson of the HREC, detailing it in writing. Complaints may also be made to the Chief Executive. The Chairperson shall notify the Chief Executive of any complaints received by him/her, as soon as possible. The Chief Executive shall inform the Chairperson of any complaints received by him/her as soon as possible.
The Chairperson shall investigate the complaint and its validity, and make a recommendation to the HREC on the appropriate course of action. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the Chief Executive, or his/her nominee, or request the Chairperson to do so. The Chairperson shall provide to the Chief Executive all relevant information about the complaint/concern. The Chief Executive shall determine whether there is to be a further investigation of the complaint. If it is decided that there is to be a further investigation, then the Chief Executive shall convene a suitable panel to review the complaint, ensuring that both the complainant and the HREC are afforded the opportunity to make submissions.

9.2.2 In conducting its review, the panel shall be concerned with ascertaining whether the HREC acted in accordance with the National Statement, its Terms of Reference, its Standard Operating Procedures, or otherwise acted in an unfair or biased manner.

9.3 Complaints from an investigator concerning the HREC’s rejection of an application

9.3.1 A person with a complaint about the HREC’s rejection of his/her application should bring the complaint to the attention of the Chairperson of the HREC, detailing the grounds of the complaint. Complaints may also be made to the Chief Executive. The Chairperson shall notify the Chief Executive of the complaint as soon as possible. The Chief Executive shall notify the Chairperson of any complaints received by him/her as soon as possible.

The Chairperson shall investigate the complaint and its validity, and make a recommendation to the HREC on the appropriate course of action at its next meeting. At the Chairperson’s discretion, the complainant may be invited to attend the next HREC meeting, or the complainant may request the opportunity to attend.

The complainant shall be informed of the HREC’s response in writing, normally within seven (7) working days of the HREC meeting. If the complainant is not satisfied with the action taken by the HREC, then he/she can refer the complaint to the Chief Executive, or his/her nominee, or request the Chairperson to do so. The Chairperson shall provide to the Chief Executive all relevant information about the complaint. The Chief Executive shall determine whether there is to be a further investigation of the complaint. If it is decided that there is a case to be investigated, then the Chief Executive shall convene a suitable panel to review the complaint, ensuring that both the complainant and the HREC are afforded the opportunity to make submissions.
The outcomes of this process may include:

- The complaint/concern is dismissed.
- The complaint/concern is referred back to the HREC for consideration, bearing in mind the findings of the panel.
- The application may be referred for external review by an independent HREC if the Chief Executive concludes that due process has not been followed by the HREC in reaching its decision.

Should the HREC be requested to review its decision, then the outcome of this review by the HREC shall be final. The panel or Chief Executive cannot substitute its approval for the approval of the HREC.

10. ASSISTED REPRODUCTIVE TECHNOLOGY (ART)

10.1 ART research activities in SLHD

10.1.1 The HREC shall oversee ART clinical and research activities within SLHD in accordance with the *NHMRC Ethical guidelines on the use of assisted reproductive technology in clinical practice and research (July 2007)*.

10.1.2 Applications for research studies involving ART shall normally be considered at scheduled HREC meetings.

10.2 ART clinical activities in SLHD

10.2.1 Matters concerning ART clinical activities within SLHD shall be considered at scheduled meetings of the Ethics of Clinical Practice Subcommittee. Review of clinical protocols, operations manuals and patient information documents will be undertaken at least annually or more frequently if the need arises.

11. REVIEW / AMENDMENT OF TERMS OF REFERENCE

11.1 The Executive Committee of the HREC shall review these Terms of Reference and those of its Sub-committees at least every three years and propose changes to the Chief Executive for approval if appropriate.

11.2 Members of the HREC may from time to time propose changes to the Terms of Reference for review by the HREC. If considered acceptable, such changes shall be forwarded to the Chief Executive for approval if appropriate.