SYDNEY LOCAL HEALTH DISTRICT

HUMAN RESEARCH ETHICS COMMITTEE (HREC) (RPAH ZONE)

TERMS of REFERENCE: June 2024

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 in research.

1.2 Facilitate ethical research through efficient and effective review processes.

1.3 Promote ethical principles in human research.

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

1.5 Monitor approved research to ensure compliance with the conditions of approval.

1.6 Provide education and training opportunities for HREC members and researchers to maintain currency of expertise.

2. FUNCTIONS

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

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

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

3. SCOPE OF RESPONSIBILITY

3.1 The HREC is responsible for:

- Reviewing applications for multi-centre human research where such research will take place at institutions governed by NSW Public Health Organisations.
- Reviewing applications for multi-centre human research where the research will take place at any institution or organisation which is participating in the multi-state process of the National Mutual Acceptance Scheme of single ethical and scientific review.
- Reviewing applications for single- or multi-centre research for organisations external to the public health system where an agreement has been made between the organisation and the Sydney Local Health District (SLHD).
- Reviewing applications for single-centre research where such research will normally take place at any institution governed by the SLHD:

3.2 This term of reference does not prohibit the SLHD from accepting an ethical approval undertaken by another HREC as a sufficient ethical approval to allow the institution to authorise the commencement of the project, provided that such HREC is registered with the NSW Ministry of Health as a "NSW Lead HREC" or is certified under the National Certification Scheme for Ethical Review of Multi-centre Research (National Approach).

Expedited Executive Review

3.3 The HREC may delegate out-of-committee or expedited review to the Chairperson, Chairperson of the Sub-Committee and/or the Executive Officer, or their delegate, hereafter referred to as the Executive.

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

3.5 The Executive delegated to undertake expedited review and approval of business that does not require full HREC review, including but not limited to:

- Research applications which meet the definitions of low risk research given in the *National Statement*;
- Amendments to current HREC approved research projects; and

- Responses to HREC queries, as approved by the full HREC for Chair review and approval.

3.6 The Executive review the above submissions on an ad hoc basis. The Executive may seek advice from other HREC members, as appropriate, before reaching a decision.

3.7 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.

3.8 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.

3.9 The decisions of the Executive are ratified at the next HREC meeting.

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 signed by the Chairperson and 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 will provide the following reports:

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

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 Research Office website.

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

6. MEMBERSHIP

6.1 Composition of the HREC

6.1.1 The composition of the HREC shall be in accordance with the *National Statement.* The minimum membership comprises eight (8) members and shall include at least:

- a Chairperson with suitable experience whose other responsibilities will not impair the HREC capacity to carry out its obligations under the *National Statement*;
- Chairperson of the Clinical Trials Sub-committee (or nominee);

- at least two members who bring a broader community or consumer perspective, who have no paid affiliation with the institution, and are not currently involved in medical, scientific, academic or legal work;

- at least two members with knowledge of and current research experience that is relevant to the applications to be considered at the meetings they attend;

- a member with knowledge of, and current experience in, the professional care, counselling or treatment of people;

- at least one member who performs a pastoral care role in a community including, but not limited to, an Aboriginal and/or Torres Strait Islander elder or community leader, a chaplain or a minister of religion or other religious leader;

- 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 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 to the HREC

6.2.1 All members including the Chairperson, Deputy Chairperson(s) and Chairperson of any sub-committee are appointed by the Chief Executive.

6.2.2 Prospective members may be recruited by direct approach, by nomination or by advertisement. The minister of religion may be nominated by the retiring or

former member in this category or by the SLHD Pastoral Care service or by other means as deemed appropriate

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 Prospective members may be invited to observe meetings of the HREC.

6.2.5 Prospective members are asked to provide a copy of their curriculum vitae to a selection committee comprising the Chairperson, Executive Officer and at least one other HREC member.

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

6.2.7 Membership will be reviewed annually. New and renewed appointments allow for continuity, development of expertise within the HREC, and regular 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 re-appointed at the discretion of the Chief Executive or their delegate.

The Chairperson, Deputy Chairperson and Chairperson of any Sub-committee shall be appointed for a period of five years and may be re-appointed 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/apology or exceptional circumstances; or

- at least two thirds of all scheduled HREC meetings in each year, without notifying the Chairperson, unless exceptional circumstances exist.

6.3.3 The Chairperson shall notify the member of a lapse of membership in writing. Steps will be taken to fill the vacancy of the former member.

6.3.4 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.

6.3.5 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 their duties as an HREC member.

6.3.6 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.

6.3.7 Members are advised when their term is due to expire. Reappointment will be by application to the Chairperson of the HREC who then makes a recommendation to the Chief Executive or delegate.

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 Research Office website.

6.4.2 Members are not offered remuneration. However, reimbursement for legitimate expenses incurred in attending HREC meetings or in otherwise carrying out the business of the HREC shall be considered.

6.4.3 Members shall be required to sign a statement undertaking:

- that all matters of which they become aware during the course of their work on the HREC shall be kept confidential;
- that any conflicts of interest which exist or may arise during their tenure on the HREC shall be declared; and
- that they have not been subject to any criminal conviction or disciplinary action which may prejudice their standing as a HREC member.

6.5 Education for HREC members

6.5.1 Newly appointed members shall be provided with adequate orientation:

- Provision of an orientation presentation and package;

- Informal meeting with the Chairperson and Executive Officer to explain their responsibilities as an HREC member, the HREC processes and procedures; and

- Priority given to participate in training sessions.

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, where possible.

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 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 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 Terms of Reference of the Ethics of Clinical Practice Sub-committee and 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 their duties as a member in good faith. Details of the indemnity are provided in the member's letter of appointment. 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 Terms of Reference and Standard Operating Procedures. The HREC Terms of Reference and Standard Operating Procedures shall be reviewed at least every three 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.

7.1.2 The HREC Terms of Reference and Standard Operating Procedures are made publicly available.

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 Expert Reviewers

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

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 by the beginning of each calendar year.

7.6.3 A quorum is required at each meeting for the HREC to reach a final decision on any agenda item. A quorum exists when a representative of each of the categories listed in 6.1 is in attendance, whether in person or via videoconference.

7.6.4 There is an expectation that members will have read the meeting papers and will, therefore, be in a position to contribute to the discussion of each agenda item. Members are expected to remain for a substantial proportion of each meeting they attend. Where members who have received the meeting papers are unable to attend in person

7.6.5 Where members who have received the meeting papers are unable to attend in person, they may make prior submissions of written comments so that where there is less than a full attendance of the minimum membership the meeting may still proceed if the Chairperson is satisfied that the views of those absent who belong to the minimum membership have been received and considered.

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

7.6.7 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 community representative/consumer member.

7.7 Conflicts of Interest

7.7.1 Any member of the HREC who has any conflicts of interest related to a proposal or other related matter(s) considered by the HREC shall declare such interest prior to its consideration. Conflict of interest includes financial interests, personal, professional or institutional benefits or advantages that depend significantly on the research outcomes.

7.7.2 If the member is present at a meeting at which the proposal 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.

7.7.3 If the Chairperson has a potential conflict of interest as described above, the Deputy Chairperson will take over the conduct of the meeting for the proposal in question.

7.7.4 The minutes will record all declarations of interest and the procedures to be followed.

7.8 Decision Making

7.8.1 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; or
- It will defer making a decision on the project until the clarification of information or the provision of further information to the HREC; or
- It will request modification of the project; or
- It will reject the project.

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

7.8.3 Where a unanimous decision cannot be reached, the Chairperson will need to facilitate the expression of opinion from all members, identify points of agreement and of disagreement and judge when a sufficient degree of general agreement has been reached.

7.8.4 Any significant minority view will be noted in the minutes.

7.9 Minutes

7.9.1 To encourage free and open discussion and to emphasise the collegiate character of the HREC, particular views will not be attributed to particular individuals in the minutes except where a member wishes to have their opinion or objection recorded.

7.9.2 Minutes of the meeting shall be taken by the Executive Officer, or their delegate. A copy of the minutes is to be distributed to all committee members prior to the next meeting. A clean copy of the minutes is to be signed by the Chairperson and filed as a true record of that meeting. A copy of the minutes shall be forwarded to the Chief Executive, SLHD and the SLHD Board (reporting to the Education and Research Committee).

7.10 Records

7.10.1 The Executive Officer, or delegate, shall prepare and maintain written records of the HREC's activities, including agendas and minutes of all meetings of the HREC and any expedited reviews.

7.10.2 The Executive Officer, or delegate, 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.

7.10.3 Files shall be kept securely and confidentially in accordance with the requirements of the *Health Records and Information Privacy Act 2002* and *State Records Act 1998*.

7.10.4 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, pending the SLHD Chief Executive's approval.

7.10.5 Files that are to be kept indefinitely as part of State archives include:

- Projects involving misconduct allegations and found to be legitimate after a formal inquiry (Misconduct allegations which are unsubstantiated and do not lead to formal inquiry should be kept for 7 years)
- Contracts and agreements for use of the final product/research outcomes – eg. Contracts regarding Intellectual Property, patents or commercialisation arrangements
- HREC records, including agendas, minutes, details of appointments (membership), terms of reference and standard operating procedures. (See GDA21 Section 5.3.0)
- Project Final Reports

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

7.11 Fees

[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)

7.11.1 A fee shall be charged for clinical trial applications and amendments submitted for assessment by the HREC in accordance with the NSW Health Policy Directive *Fee Schedule for Research Ethics and Governance Review of Clinical Trial Research* (PD2023_015).

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

8. POST-APPROVAL RESPONSIBILITIES / MONITORING RESEARCH PROJECTS

8.1 The HREC shall monitor approved projects for compliance with the conditions of the HREC's ethical approval and to protect the rights, safety and welfare of participants. 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.

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, for example Significant Safety Issues (SSIs), serious breaches, security breaches, participant complaints, or privacy breaches;
- For clinical trials: SSIs that are implemented or not implemented as Urgent Safety Measures (USMs), or as a temporary halt/early termination of a clinical trial;
- 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, these include:

- Discussion of relevant aspects of the project with the investigators at any time;
- Random inspection of research sites, data or consent documentation;
- Interview with research participants or other forms of feedback from them; and
- Request and review reports from independent agencies such as Data & Safety Monitoring Boards.

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

9. COMPLAINTS AND REVIEW

9.1 Complaints concerning the conduct of a research project

9.1.1 Any concern or complaint from a participant or any other person about the conduct of a project should be directed to the attention of the Executive Research Manager via HREC Executive Officer, or their delegate, who will notify the Chairperson as soon as possible. The Executive Research Manager will assess the concern or complaint in accordance with the Policy Compliance Procedure *Research: Managing and Investigating Complaints about Research Integrity* (SLHD_PCP2022_036) and determine whether the matter requires further investigation. The Executive Research Manager make a recommendation on the appropriate course of action. The complainant will receive a written response, if appropriate, from the HREC. If the complainant is not satisfied with the outcome of the Chairperson's review, then they can refer the complaint to the Chief Executive or their nominee, or request the Chairperson to do so.

9.1.2 A concern or complaint about the conduct of a research project which involves allegations of research misconduct, is managed in accordance with the SLHD local procedures (Research: Managing and Investigating Complaints about Research Integrity SLHD_PCP2022_036).

9.2 Complaints 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 via the Executive Research Manager shall notify the Chief Executive of any complaints received by them, as soon as possible. The matter should be referred to the

Executive Research Manager for further advice. The Chief Executive shall inform the Chairperson of any complaints received by them as soon as possible.

9.2.2 The Chairperson and the Executive Research Manager shall review the complaint and its validity in accordance with Policy Compliance Procedure Research: Managing and Investigating Complaints about Research Integrity (SLHD_PCP2022_036). A recommendation shall be made to the HREC on the appropriate course of action. The complainant will receive a written response, if appropriate, from the HREC. If the complainant is not satisfied with the outcome of the Chairperson's review, then they can refer the complaint to the Chief Executive, or their nominee or request the Chairperson to do so. The Chairperson via the Executive Research Manager 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.

9.2.3 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.

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

9.3 Complaints concerning the HREC's rejection of an application

9.3.1 A person with a complaint about the HREC's rejection of their application should bring the complaint to the attention of the Chairperson of the HREC, detailing the grounds of the complaint. The matter should be referred to the Executive Research Manager for further advice. Complaints may also be made to the Chief Executive. The Chairperson via the Executive Research Manager shall notify the Chief Executive of the complaint as soon as possible. The Chief Executive shall notify the Chairperson of any complaints received by them as soon as possible.

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

appropriate course of action. 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.

9.3.3 The complainant will receive a written response, if appropriate, from HREC advising of the Chairperson's review. If the complainant is not satisfied with the action taken by the HREC, then they can refer the complaint to the Chief Executive, or their 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.

9.4 Complaints about the HREC's approval of an application

9.4.1 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 is lodged with the Chairperson in the first instance. The matter should be referred to the Executive Research Manager for further advice.

9.5 Complaints about the conduct of HREC members

9.5.1 Complaints about the conduct of an HREC member are managed by the Chief Executive, or their delegate who informs the Chairperson of the complaint. The matter should be referred to the Executive Research Manager for further advice.

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 These Terms of Reference and those of its Sub-committees shall be reviewed at least every three years and amended in consultation with the HREC. Proposed changes will be sent to the Chief Executive and the SLHD Board 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.

12. TERMINATION OF HREC RESPONSIBILITY

12.1 Where the HREC is to be merged, closed or has ceased to function, Sydney Local Health District will notify the National Health & Medical Research Council (NHMRC) and will determine 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. Sydney Local Health District will also notify the NSW Ministry of Health.