SYDNEY LOCAL HEALTH DISTRICT

ETHICS OF CLINICAL PRACTICE SUB-COMMITTEE

OF THE ETHICS REVIEW COMMITTEE (RPAH ZONE)

TERMS OF REFERENCE

1. Purpose

To consider ethical issues pertaining to:

- clinical practice
- clinical innovations
- teaching, training and accreditation
- resource allocation
- any other issues referred to it

undertaken within the following designated institutions of the Sydney Local Health District (SLHD):

- Royal Prince Alfred Hospital
- Concord Repatriation General Hospital
- Balmain Hospital
- Canterbury Hospital
- Concord Centre for Mental Health
- Sydney Dental Hospital
- SLHD Division of Population Health
- Department of Forensic Medicine
- Institute of Rheumatology & Orthopaedics

or by any other individual or organisation requesting ethical consideration provided this has been approved by the SLHD Chief Executive.

2. Scope of Activities

2.1 To review ethical aspects of clinical care taking account of guidelines issued by NHMRC, Royal Colleges, Commonwealth and NSW Departments of Health, the SLHD Chief Executive, and other relevant bodies.

2.2 To review innovative therapy in accordance with:

- *National Statement on Ethical Conduct in Human Research 2007 (updated May 2018)* (Chapter 3.3: Interventions and therapies, including clinical and non-clinical trials, and innovations)

- *NHMRC Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (June 2017)*

- SLHD Policy Directive SLHD_PD2015_022*: The Safe Introduction of New Interventional Procedures and Clinical Innovations into Clinical Practice.*

2.3 To review ethical aspects of undergraduate and postgraduate teaching, procedural training and recertification activities undertaken within the SLHD taking account of guidelines issued by the Royal Colleges, Commonwealth and NSW Departments of Health, the SLHD Chief Executive, the Australian Health Practitioner Registration Agency and other relevant bodies.

2.4 To provide ethical advice regarding any other relevant activities, including policy development, referred to it by:

- SLHD Chief Executive

- administrative officers, clinical, research and/or teaching staff of the institutions listed in point 1 above.

Policy development by the Sub-committee will be confined to SLHD issues and to the application of NSW Ministry of Health policy within the SLHD.

2.5 Individual case consultations will be referred to a properly constituted Clinical Ethics Advisory Panel (see paragraph 12 below).

3. Status of the Committee within the Organisation

The Ethics of Clinical Practice Sub-committee is a sub-committee of the SLHD Ethics Review Committee (RPAH Zone) which is in turn a committee of the SLHD with delegated authority:

- to make recommendations concerning the ethical acceptability of clinical practices and other issues that may arise from time-to-time
- to approve the ethical aspects of innovative therapy proposals
- to approve the ethical aspects of the safe introduction of innovative procedures, including information/consent documents.

4. Reporting to the SLHD Ethics Review Committee (RPAH Zone) and the SLHD Chief Executive

4.1 The minutes of the Sub-committee's meetings shall be forwarded to the SLHD Ethics Review Committee (RPAH Zone) for information.

4.2 The Sub-committee may from time to time:

- bring to the attention of the SLHD Ethics Review Committee (RPAH Zone) and the SLHD Chief Executive issues of significant concern
- refer any matter of concern requiring legal opinion to the SLHD Chief Executive
- seek rulings from the SLHD Executive and/or Chief Executive on policy issues
- refer any issues affecting or requiring statewide policy to the SLHD Executive and /or Chief Executive for referral on to the NSW Ministry of Health
- make recommendations to the SLHD Chief Executive concerning any other matters which it considers relevant.

5. Composition of the Committee

5.1 The composition of the Sub-committee shall include:

- Chairperson
- Chairperson, SLHD Ethics Review Committee (RPAH Zone)
- Chairperson, SLHD Human Research Ethics Committee (CRGH)
- SLHD Director of Clinical Governance
- Executive Officer (non-voting member)

and may include:

- a lay man and a lay woman
- an allied health professional
- a minister of religion
- clinician(s) with relevant expertise
- a non-clinician with training in bioethics
- a non-clinician with relevant expertise in legal matters
- any other members of the two SLHD human research ethics committees who wish to attend.

5.2 The Sub-committee may from time to time co-opt individuals with expertise relevant to specific areas of activity.

5.3 The Chief Executive shall appoint the Executive Officer of the Sub-committee.

6. Appointment of Members

6.1 The Chairperson shall be appointed by the SLHD Chief Executive following consultation with the Chairpersons of the SLHD human research ethics committees and with other senior institutional officers, as deemed appropriate.

6.2 Upon appointment, each member 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 Sub-committee will be kept confidential

- that any conflicts of interest which exist or may arise during his/her tenure on the Sub-committee will be declared

- that he/she has not been subject to any criminal conviction or disciplinary action which may prejudice his/her standing as a Sub-committee member.

7. Terms of Appointment

7.1 The term of appointment for Sub-committee members shall normally be three years.

7.2 The term of appointment for the Chairperson shall normally be four years.

7.3 Appointments may be renewed. Recommendations for renewal of appointment shall be made to the SLHD Chief Executive by the Chairperson.

7.4 In considering recommendations for appointments and renewals of appointments, the SLHD Chief Executive shall take the following into consideration:

- gender balance
- age balance
- expertise
- duration of service on the Sub-Committee.

8. Meetings

8.1 Sub-committee face-to-face or video-teleconferencing meetings shall be held approximately ten (10) times per year at monthly intervals from February to November.

8.2 If there is insufficient business to warrant a face-to-face or video-teleconferencing meeting, agenda items will be circulated electronically for online discussion.

8.3 Meeting dates and agenda closing dates shall be published appropriately.

9. Procedures

9.1 In order to be considered at a scheduled meeting, items for discussion and other correspondence shall normally be received at the RPAH Research Ethics and Governance Office at least eight (8) calendar days before the advertised meeting date.

9.2 Other issues may be tabled and considered at a scheduled meeting with the approval of the Chairman (or delegate).

9.3 The Sub-committee may resolve to invite a correspondent to attend a Sub-committee meeting to discuss his/her proposal.

9.4 A Sub-committee member involved in an issue under consideration shall absent him/herself from the meeting during the discussion.

9.5 The Sub-committee shall reach decisions by consensus after all members have been given the opportunity to express their views. In the event that a consensus cannot be reached, a decision may be taken by voting (show of hands). A two-thirds majority shall normally be required for a decision to be made. Dissenting views shall be recorded in the minutes.

9.6 The Sub-committee may make recommendations and/or prepare discussion papers/reports for consideration by the Sub-committee, the SLHD Chief Executive, the NSW Ministry of Health, or any other person or organisation considered appropriate by the Sub-committee.

10. Responsibilities of the Executive Officer

10.1 The Executive Officer shall be responsible for the preparation of the meeting agendas, which shall normally be circulated one week prior to the meeting.

10.2 The Executive Officer shall be responsible for the preparation of the minutes of meetings, and of correspondence arising from the minutes.

10.3 The Executive Officer shall endeavour to notify correspondents of the Sub-committee's decisions within one week, and no more than ten days, after each meeting.

10.4 The Executive Officer shall undertake such other tasks as are requested by the Chairman and/or the Sub-committee.

11. Assisted Reproductive Technology (ART)

11.1 The Ethics Review Committees shall oversee ART research activities within SLHD in accordance with the *NHMRC Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (2017)*.

11.2 Applications for research studies involving ART shall normally be considered at scheduled meetings of the SLHD human research ethics committees.

11.3 The Sub-committee shall undertake review of ART clinical activities, clinical protocols, operations manuals and patient information documents conducted/used within SLHD. This should be undertaken once every five years, or more frequently if the need arises.

11.4 The Sub-committee shall undertake ethical review of proposed altruistic surrogacy arrangements.

11.5 If all issues are addressed to its satisfaction, the Sub-committee may indicate that it has no ethical objection to the surrogacy arrangement taking place.

11.6 The Sub-committee shall not consider or support commercial surrogacy arrangements.

12. Clinical Ethics Advisory Panel

12.1 The Sub-committee may from time to time convene a Clinical Ethics Advisory Panel (CEAP) meeting when confronted with an ethical issue pertaining to a particular clinical case that requires rapid resolution.

12.2 The minutes of the CEAP will be included on the Sub-committee's agenda.