

WOMEN'S AND CHILDREN'S HEALTH NETWORK (WCHN)

HUMAN RESEARCH ETHICS COMMITTEE (HREC)

TERMS OF REFERENCE

Role

The role of the WCHN Human Research Ethics Committee is to:

- provide ethical review and where appropriate grant approval to research (single or multi site) or audit projects involving patients, patients' families, patient tissue (including stored tissue), patient information and/or staff;
- authorise multi-centre and multi-jurisdictional review of research; and
- foster research which is of benefit to the community (*National Statement on Ethical Conduct in Human Research 2007 - p7*).

The Committee will only approve a research project or allow a project to continue if the following five conditions are satisfied:

- the project, as set out in the protocol, is acceptable on ethical grounds as defined in the *National Statement*;
- the project complies with legal obligations;
- the rights and welfare of human participants are respected and safeguarded;
- in the case of children, participation in research is not contrary to their best interests (*National Statement 4.2.13*); and
- the project continues to conform to the approved protocol and any approved amendments.

The WCHN Human Research Ethics Committee is certified for the ethical review of multi-centre human research via the Harmonisation of Multi-centre Ethical Review (HoMER) in the following areas:

- clinical trials Phase I-IV;
- clinical interventional research other than clinical trials;
- population health;
- qualitative health research;
- mental health;
- paediatric;
- women's health;
- genetic studies;
- oncology; and
- tissue banking.

From 2012, the WCHN Human Research Ethics Committee will act in accordance with the SA Health model for single ethical review as described within the *SA Health Research Ethics Operational Policy and Research Governance Policy*. In addition, the WCHN Human Research Ethics Committee will accept the ethical review of other appropriately constituted and certified healthcare institutions (or affiliated) Human Research Ethics Committee. However, the WCHN Human Research Ethics Committee may perform its own review for research conducted at the WCHN or with WCHN patients/clients as deemed appropriate in relation to research governance.

Desired outcomes

The WCHN Human Research Ethics Committee will comply with the principles set out in the following documents:

- National Health and Medical Research Council (NHMRC) *National Statement on Ethical Conduct in Human Research 2007* and other NHMRC Guidelines as issued,
- *Australian Code for the Responsible Conduct of Research 2007*; and
- all relevant State and Australian Government legislation.

The Committee will ensure that all research projects involving therapeutic substances are additionally considered by the Drug and Therapeutics Committee Clinical Trials Group.

In the case of audits, the Committee will ensure that the process as outlined in the *WCHN Guidelines for the Preparation of Audit Submissions* is followed.

Membership

The Patient Ethicist or other suitable person shall hold the position of Chair.

The Human Research Ethics Committee (HREC) will call for nominations and interview suitable candidates. It will then recommend appointment of the most suitable candidate, via the Executive Director, Acute Services to the WCHN Chief Executive Officer.

The period of tenure may be for three years, with renewal for an additional three years. The maximum term may be six years. No more than 40% of the membership should change in any one calendar year.

Membership shall meet the minimum NHMRC requirements of:

- a Chair;
- a laywoman not associated with the WCHN;
- a layman not associated with the WCHN;
- a pastoral care member;
- a lawyer;
- a person with knowledge of, and current experience in, the care, counselling or treatment of people; and
- a person with knowledge of, and current experience in, research.

Additional members may be appointed, with the agreement of the Executive Director, Acute Services, to facilitate the work of the Human Research Ethics Committee.

Meeting processes

The Human Research Ethics Committee will meet once a month with the exception of January.

A quorum will be a simple majority of members.

In the absence of the Chair of the Human Research Ethics Committee, the Chair will appoint an acting Chairperson from the membership.

There is no provision for proxies should members be unable to attend the meeting.

Minutes of the meeting will be recorded (with reference to the *National Statement* for the decisions made) and endorsed by members at the following meeting of the Committee.

Reporting

The following reports are to be provided by the Chair of the WCHN HREC:

- an annual Australian Health Ethics Committee (AHEC) report of the previous calendar year to the WCHN Chief Executive Officer via the Executive Director, Acute Services; and
- an annual report of the previous financial year to the WCHN Safety and Quality Committee.

Review of Terms of Reference

The terms of reference and membership of the WCHN HREC will be reviewed by the Chair annually and, in the event of significant change, notified to the Executive Director, Acute Services.

Decision making process

The HREC aims to make all decisions by consensus and referenced to the relevant part/s of the *National Statement*.

Any concerns that members of the HREC have regarding applications should be expressed during meetings.

If concerns cannot be satisfactorily answered by those present and agreement reached, the applicant(s) may be invited to the meeting to speak to their proposal and answer questions with a view to modifying the relevant aspect(s) of the project such that consensus may be achieved.

If after this process there is still no consensus about the issue, the Committee may explore conditions which, if placed on the application, may result in a consensus. If these are agreed, then the application may be approved subject to those conditions.

Grievance/complaints process

If a member of the HREC or a researcher has any grievance about the operation (but not the decisions) of the Committee, they should discuss this, in confidence, with the Chairperson of the HREC who will, if necessary, liaise with the Executive Director, Acute Services. If the grievance cannot be resolved, the matter will be referred to the WCHN Executive.

Concerns about the decision/s of the committee should be addressed in writing to WCHN HREC.

SA Health has developed an HREC Appeals Process to enable researchers submitting protocols to any of the SA Health Ethics Committees to appeal a decision by that HREC.

In addition, if the WCHN HREC receives complaints about researchers or the conduct of research, the complaint/s will be handled promptly and sensitively in accordance with:

- the *National Statement 5.6*;
- the *Australian Code for the Responsible Conduct of Research*; and
- the *WCHN Code of Conduct for Research*.

Further information about complaints/concerns by participants or by researchers can be found on the WCHN website.

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