

WOMEN'S AND CHILDREN'S HEALTH NETWORK

HUMAN RESEARCH ETHICS COMMITTEE

TERMS OF REFERENCE

Role and responsibilities of the Committee

The Women's and Children's Health Network (WCHN) Human Research Ethics Committee (HREC) reviews research protocols and audit applications on behalf of the Women's and Children's Health Network and other institutions as requested.

The WCHN HREC provides ethical review in accordance with the values and principles set out in the *National Statement on Ethical Conduct in Human Research (National Statement)*, other National Health and Medical Research Council (NHMRC) guidelines pertaining to research and ethical review, *Australian Code for Responsible Conduct to Research*, and all relevant State and Commonwealth legislation.

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

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

In addition to providing ethical review of research projects, the WCHN HREC will:

- Ensure that all research projects involving therapeutic substances are additionally reviewed and monitored by the WCHN Drug and Therapeutics Committee Clinical Trials Group (DTC CTG) when the WCHN HREC is the lead or sole reviewer of a research project.
- Receive and review adverse events reports.
- Monitor and review, at least annually, the progress of research in keeping with the requirements of the *National Statement*.
- Maintain a register of all research and audit projects.
- Ensure, in the case of audits, that the process as outlined in the WCHN procedure, *Audits requiring WCHN HREC approval* is followed.

The WCHN HREC acts in accordance with the *SA Health Research Ethics Operational Policy* and *SA Health Research Governance Policy* which recognize two streamlined approaches based upon the mutual acceptance of ethical review by other appropriate HRECs as defined by these SA Health policies.

The two approaches are complementary and provide two pathways for researchers conducting research within the South Australian public health system:

- i. The SA Health Single Ethical Review Model—for all multi-centre research taking place within the South Australian Public Health system only.
- ii. The National Mutual Acceptance (NMA) of Ethical and Scientific Review - for multi-centre human research projects taking place across Australian jurisdictions within public health organizations.

Under the NHMRC National Certification Scheme criteria for multi-centre ethical review processes, the certified ethical review processes for the WCHN HREC apply to the following categories of research:

- Clinical trial—Phases I, II, III, & IV
- Clinical interventional research other than clinical trials
- Population health
- Qualitative health research
- Mental health
- Paediatric
- Women's health
- Genetic studies
- Oncology
- Tissue banking

The WCHN HREC may perform its own review for research conducted at the WCHN or with WCHN patients/clients as deemed appropriate in relation to research governance.

Relationship to non-affiliated researchers

The WCHN HREC undertakes ethical review of research proposals by non-affiliated researchers unless i) the Chair determines that there is insufficient expertise available to the HREC to ensure adequate scientific and ethical review; or ii) the HREC is not able to provide review in a timely manner.

Membership

Membership shall at least meet the minimum requirements as specified by 5.1.30 of the *National Statement*:

- A chairperson, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the *National Statement*;
- At least two lay people, one man and one woman, who have no affiliation with the institution and do not currently engage 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;
- At least one person who performs a pastoral care role in a community;
- At least one lawyer, where possible who is not engaged to advise the institution;
- At least two people with current research experience that is relevant to research proposals considered by the WCHN HREC.

Additional members may be appointed, with the agreement of the Executive Director, Corporate Services, to facilitate the work of the WCHN HREC.

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

In keeping with 5.1.33 of the *National Statement*, the WCHN HREC will ensure that members are appointed so as to ensure the committee has sufficient expertise to address the ethical issues arising from the categories of research it is likely to consider.

In keeping with 5.1.34 of the *National Statement* the appointment process will be transparent whereby WCHN HREC will call for nominations via advertisement and then interview suitable candidates. The Chair will then submit a list of nominations, in priority order, to the Executive Director, Corporate Services.

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

Members will not be remunerated, however, community members will be provided with vouchers or equivalent to utilise for the purpose of attending and returning from scheduled meetings.

Meeting processes

The WCHN HREC will meet once a month with the exception of January.

A quorum will be a simple majority of members. To enable decisions to be acted on, if a quorum of members is not present at a meeting, comments will be obtained from a sufficient number of members who reviewed the protocol/study, but who were not present at the meeting, to make the meeting quorate.

In the absence of the Chair of the WCHN HREC, the Chair will appoint an acting Chairperson from the membership.

There is provision for proxies should members be unable to attend the meeting. Minutes of the meeting will be recorded and endorsed by members at the following meeting of the Committee.

Reporting

The WCHN HREC is accountable, via its Chair to:

- The WCHN Chief Executive Officer, via the Executive Director, Corporate Services, for the provision and submission of an annual report to the NHMRC's *Australian Health Ethics Committee*;
- The Executive Director, Corporate Services, to update the WCHN Executive on any issues of relevance relating to human research ethics.

Decision making process

The WCHN HREC will make all decisions in accordance with the *National Statement* and other NHMRC guidelines pertaining to research and ethical review (including NHMRC referenced guidelines such as the Declaration of Helsinki), and all relevant State and Commonwealth legislation.

Any concerns that members of the WCHN HREC have regarding applications should be expressed during meetings or provided in writing if a member is unable to attend a meeting.

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 any questions with a view to providing clarification or modifying the relevant aspect(s) of the project such that a consensus may be achieved.

Grievance/complaints process

In keeping with 5.1(4) of the *National Statement*, the WCHN HREC takes complaints and concerns by participants, researchers or others very seriously and uses them as an opportunity to facilitate general improvements in the conduct of research and ethical review.

The complaints/grievance process is documented in the WCHN *Human Research Ethics and Research Governance Standard Operating Procedures* document.

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, Corporate Services.