

COMMITTEE CHARTER & TERMS OF REFERENCE

Human Research Ethics Committee Tier 2 Committee of the Women's and Children's Health Network (WCHN)

Date: August 2020	Review Date: August 2021	Version: 1.5
--------------------------	---------------------------------	---------------------

1. Authority

The Women's and Children's Health Network Governing Board has the responsibility for the overall governance of the Women's and Children's Health Network.

The Human Research Ethics Committee (HREC) is a committee of the Women's and Children's Health Network (WCHN).

The Executive Sponsor of the Human Research Ethics Committee ("Committee") is the Executive Director, Corporate Services.

This Charter defines the purpose, scope, functions and authority of the Committee.

The Committee has no executive powers and is directly responsible and accountable to the WCHN Corporate Services Governance Committee in carrying out its responsibilities, the Committee must at all times recognise that the primary responsibility for management of WCHN rests with the Chief Executive Officer.

2. Purpose

The purpose of the Committee is to review and approve research protocols and audit applications on behalf of the Women's and Children's Health Network and other institutions as requested.

The Committee has the designated role to provide ethical review in accordance with the values and principles set out in the *National Statement on Ethical Conduct in Human Research 2007 (updated 2018) (National Statement)*, other National Health and Medical Research Council (NHMRC) guidelines pertaining to research and ethical review, the *Australian Code for Responsible Conduct to Research (2018)*, and all relevant State and Commonwealth legislation.

The Committee has key responsibilities to 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.

3. Terms of Reference

The Committee will:

- Consider the safety and quality impact of all decisions and ensure the allocation of resources supports the achievement of safety and quality goals.
- 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 committee is the lead or sole reviewer of a research project.
- Ensure that all research projects that are directly related to the health and well-being of Aboriginal people are reviewed by the Aboriginal Health Research Ethics Committee (AHREC).
- 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 committee approval* is followed.
- The Committee acts in accordance with the *SA Health Research Ethics Operational Policy (2020)* and *SA Health Research Governance Policy (2020)* which recognise two streamlined approaches based upon the mutual acceptance of ethical review by other appropriate committees as defined by these 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 committee 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 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.
- The Committee undertakes ethical review of research proposals by non-affiliated researchers unless; i) the Chair determines that there is insufficient expertise available to the Committee to ensure adequate scientific and ethical review; or ii) the Committee is not able to provide review in a timely manner.

4. Organisational Risks addressed by this Committee

The primary organisational risks addressed by the Committee are risks captured on the WCHN Risk Register that have an impact on the delivery of objectives as outlined in the NSQHS Standards, the Australian Commission on Safety & Quality in Health Care, National Clinical Trials Governance Framework and through analysis of the effectiveness of the system, incidents, consumer and staff feedback and clinical performance results.

5. Membership

Membership will meet the minimum requirements as specified by 5.1.30 of the *National Statement*.

Name	Type of Appointment	Term of Office
Patient Ethicist WCHN (Chair) <ul style="list-style-type: none"> • Dr Tamara Zutlevics 	Member	Ongoing
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 <ul style="list-style-type: none"> • Ms Heather Karmel • Mr Geoff Vass 	Member	3 years with renewal for additional 3 years
At least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people. <ul style="list-style-type: none"> • Ms Breda Macdonald • Dr Rachel Earl • Dr David Thomas • Dr Leigh Mackey 	Member	3 years with renewal for additional 3 years
At least one person who performs a pastoral care role in a community <ul style="list-style-type: none"> • Rev Carl Aiken 	Member	3 years with renewal for additional 3 years
At least one lawyer, where possible who is not engaged to advise the institution <ul style="list-style-type: none"> • Ms Assunta Fuda 	Member	3 years with renewal for additional 3 years
Researchers <ul style="list-style-type: none"> • Ms Andrea Deussen • A/Prof Michael Stark • Prof Peter Andersen • Dr Clemence Due 	Member	3 years with renewal for additional 3 years
Research Information Officer WCHN <ul style="list-style-type: none"> • Mr Luke Fraser 	Executive Officer	Ongoing

In keeping with 5.1.33 of the *National Statement*, the Committee 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.

The Committee may co-opt other members or attendees as required.

Chairperson

The Chairperson of the Committee shall be the Patient Ethicist, WCHN.

Duties of the Chairperson include:

- Approve committee membership.
- Preside over the monthly meeting in accordance with the Terms of Reference.
- Ensure that reports generated from the committee that have recommendations included are presented to the relevant internal and external recipients.

In the absence of the nominated Chair, the Chairperson will nominate a Deputy Chairperson.

Remuneration

Members will **not** be remunerated.

6. Quorum

A quorum will be half the members plus one.

7. Frequency and Length of Meeting

- The meetings will be held a minimum of 11 times per calendar year.
- Meetings will be set at the beginning of each calendar year and circulated to members.
- Meetings will be up to three hours in length.

8. Agenda Preparation and Minutes Circulation

The Agenda will include as its opening item, acknowledgement to the traditional owners of the land.

The Agenda will include as its closing item, the matter titled "Communication". At this point of the meeting the Committee is to decide which of the items covered during the meeting, if any, must remain confidential.

Papers for the Committee will be prepared by the Research Information Officer as the Executive Officer to the Committee and circulated one week prior to the meeting date.

Agenda items must be forwarded to Research Information Officer at least one week prior to circulation of the agenda i.e., two weeks prior to next meeting.

Draft minutes will be distributed to members within three weeks following the meeting date as attached to the next scheduled meeting agenda.

Documents endorsed by the committee are stored electronically in pdf format.

9. Conflict of Interest

Members are required to declare interests that could constitute a real, potential or apparent conflict of interest with respect to participation on the Committee.

The declaration must be made on appointment to the Committee and be updated as necessary when interests change.

In relation to specific agenda items of Committee meetings, real, potential or apparent conflicts of interest are to be advised at the beginning of each Committee meeting for recording in the minutes.

A register of conflicts of interest of members will be maintained by the Secretariat.

10. Reporting Lines

Monthly meetings are scheduled with the HREC Chair and the Executive Director, Corporate Services (who is also the Chair of the WCHN Corporate Services Governance Committee) to update the WCHN Executive on any issues of relevance to the HREC.

The HREC Chair submits the HREC annual report to the NHMRC via the Executive Director Corporate Services for consideration and endorsement.

The annual report informs an assessment of whether the HREC has met the requirements of the *National Statement*. Information collected from this annual report is also provided to the Australian Health Ethics Committee and to the Office of the Australian Information Commissioner.

11. Evaluation/Key Performance Indicators

The Chair of the Committee will establish a mechanism to review and report on the performance of the Committee at least annually.

Annual evaluation of the performance of the Committee will be through individual member evaluation of committee performance and outcomes.

12. Review

The Terms of Reference will be reviewed annually at the beginning of the year and will coincide with committee member evaluation of performance and outcomes.