Government of South Australia | Health Women's and Children's Health Network

COMMITTEE CHARTER & TERMS OF REFERENCE

Drug and Therapeutics Clinical Trials Group
Tier 3 Committee
of the Women's and Children's Health Network

Date: 20 August 2020	**Review Date:** 20 August 2021	**Version:** 1.2

1. Authority

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

The Drug and Therapeutics Committee - Clinical Trials Group ("the Committee") is a sub-committee of the Drug and Therapeutics Committee.

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

The Committee has no executive powers and is directly responsible and accountable to the Drug and Therapeutics 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 Committee is an advisory and recommending group to Human Research Ethics Committee (HREC) and is a sub-committee of the Drug and Therapeutics Committee (DTC).

The Committee has the designated role to:

a) Provide scientific review of trials and any amendments involving a drug or therapeutic substance.

For the purpose of this Committee a therapeutic substance includes diagnostic agents, complementary or alternative medicines or nutritional products.

b) Recommend to the Human Research Ethics Committee on study design/methodology.

c) Ensure trials are designed so that they safeguard the safety and wellbeing of all research participants.

d) Assist the HREC in monitoring approved trials involving a drug or therapeutic substance by reviewing reports of adverse and serious adverse events, and reports from independent committees (e.g. a Data Safety Monitoring Board).

If the Chair determines that there is insufficient expertise available to the Committee to ensure adequate scientific review; or the Committee is not able to provide review in a timely manner then expertise from outside the WCHN may be sought.

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.

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 of the delivery of objectives as outlined in the NSQHS Standards and through analysis of the system, incidents, consumer and staff feedback and clinical performance results.

5. Membership

The Committee shall be comprised of:

	Name		Type of Appointment	Term of Office
1	Sean Turner	A representative of the DTC as Chairperson	Member	Ongoing
2	Maria Kirby	Expert with relevant pharmacological, scientific and clinical expertise	Member	Ongoing
3	David Foster	Expert with relevant pharmacological, scientific and clinical expertise	Member	Ongoing
4	Alka Garg	Expert with relevant pharmacological, scientific and clinical expertise	Member	Ongoing
5	Sharelle Campbell	Expert with relevant pharmacological, scientific and clinical expertise	Member	Ongoing
6	Laura Burgoyne	Expert with relevant pharmacological, scientific and clinical expertise	Member	Ongoing
7	Currently vacant	Expert with relevant pharmacological, scientific and clinical expertise	Member	Ongoing
8	Mary Thorne	Executive Officer, WCHN Research Secretariat	Executive Officer	Ongoing

a) The Chair of the Committee will recommend appointment of a suitable candidate to the Executive Director, Corporate Services.

b) In keeping with 5.1.33 of the *National Statement on Ethical Conduct in Human Research*, the Committee will ensure that members are appointed so as to ensure the committee has sufficient expertise in order to provide scientific review of research it is likely to consider.

c) The Executive Officer will be provided by the WCHN Research Secretariat.

d) Members will **not** be remunerated.

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

Chairperson
The Chairperson of the Committee shall be a representative of the DTC and be nominated by the DTC.

The Chairperson will nominate a Deputy Chairperson for any meetings where the Chairperson is unable to attend. Duties include:

a) Approve committee membership.

b) Preside over the monthly meeting in accordance with the Terms of Reference.

c) Ensure that reports generated from the committee that have recommendations included are presented to the relevant internal and external recipients.

5. Quorum

A quorum will be half the members plus one.

6. Frequency and Length of Meeting

- The meetings will be planned to be held a minimum of 11 times per calendar year – however if there are no new trials to review, the meeting may be cancelled.
- Meetings will be set at the beginning of each calendar year and circulated to members.
- Meetings will be approximately 1 ½ hours in length.

7. 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 Executive Officer to the Committee and circulated one week prior to the meeting date.

Agenda items must be forwarded to the Executive 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 two weeks' time following the meeting date.

Ratified Minutes will be forwarded to the DTC for tabling at that meeting.

In accordance with WCHN Clinical Governance Framework, reports and other relevant documents will be circulated widely throughout WCHN.

Documents endorsed by committees should be stored electronically in PDF format.

8. Conflict of Interest

a) 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.

b) 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.

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

9. Reporting Lines

The Minutes of the Committee will be forwarded to the Drug and Therapeutics Committee for tabling at that meeting.

10. Evaluation/Key Performance Indicators

The Chair of the Committee provides an annual report to the Drug and Therapeutics Committee.

11. Review

The terms of reference will be reviewed annually and endorsed by the WCHN Drug and Therapeutics Committee.