Terms of Reference

Metro South Human Research Ethics Committee (EC00167)

These terms of reference set out the authorisation, purpose, functions, guiding principles, membership and reporting arrangements of the Metro South Health Human Research Ethics Committee (MSHREC). These terms of reference should be read in conjunction with the overarching Metro South Health (MS) Common Arrangements for Tier 3 to 7 Committees document.

1. AUTHORISATION

The MSHREC (the Committee) functions under the authority and delegations of the Executive Director, Metro South Research, to whom it reports.

In accordance with the *Hospital and Health Boards Act 2011* (Qld) and as authorised by the Metro South Hospital and Health Service Board and the Health Service Chief Executive (HSCE) all decisions made within MS must be made by a person with the delegated authority to do so. Registers of human resource, financial, contract and other delegations are published on QHEPS.

The role of the Committee is to "approve, request amendment of, or reject a research proposal on ethical grounds" (National Statement on Ethical Conduct in Human Research 2023 5.2.7, p 94).

The HSCE or delegate, upon recommendation of the Committee, may grant ethical approval for research proposals. The Committee has been certified by the National Health and Medical Research Council (NHMRC) (Code EC00167), to conduct reviews of research conducted within MS and jurisdictions participating in the National Mutual Acceptance (NMA) model and participates in the Queensland Health single ethical review process.

2. PURPOSE

The MSHREC is constituted and functions in accordance and compliance with the:

- National Statement on Ethical Conduct in Human Research 2023 ('National Statement')
- Australian Code for the Responsible Conduct of Research
- Queensland Health: Research Ethics and Governance Health Service Directive
- Metro South Research Policy Framework
- National Safety and Quality Health Service Standards
- Human Rights Act 2019

The MSHREC acts to protect research participants to ensure that all clinical, research and management practices are conducted in an ethical and scientifically robust manner.

Key objectives of the Committee are to:

- safeguard the mental and physical welfare, rights, dignity and safety of participants involved in human research;
- facilitate and promote high calibre ethical research through efficient and effective review processes; and
- ensure that all clinical and health research is conducted responsibly and in the interests of the wider community.

V3.0 Effective: October 2023 Review: January 2027















FUNCTIONS AND RESPONSIBILITIES

The MSHREC is appointed by the Metro South Hospital and Health Service. The Committee considers submitted research protocols involving humans across MS and other jurisdictions participating in the NMA.

The functions of the Committee set out below are a non-exhaustive description of how the Committee will give effect to its purpose:

- Provide balanced, independent, and timely review of research protocols eliciting expert opinion where necessary, involving human participants with respect to their ethical acceptability and scientific merit.
- Review and where appropriate recommend approval of research.
- Oversee approved research protocols during the course of the research until completion to ensure that they comply with approved ethical standards, legislation, codes of practice, and policies.
- Specific monitoring of the conduct of research will be conducted via the Metro South Research Governance
 Office (RGO) and in the case of multi-centre research, the Co-ordinating Principal Investigator at the respective
 Institution.

Decisions by the Committee as to whether the research protocol meets the requirements of the National Statement must be informed by the exchange of opinions from each of the members that constitute the minimum membership of the MSHREC.

GUIDING PRINCIPLES

In performing its functions, the Committee must recognise and adhere to the principles set out in Section 13 of the *Hospital and Health Boards Act 2011* (Qld), Section 25 of the *Public Service Act 2008* (Qld), and Section 61 of the *Financial Accountability Act 2009* (Qld).

Members of, and attendees at the committee, and the Committee must conduct themselves in accordance with the MSH I CARE² Values:

- Integrity
- Compassion
- Accountability
- Respect
- Engagement
- Excellence

RISK MANAGEMENT

The Committee pro-actively identifies and manages risks within its scope. The role of this Committee in relation to risk management is to:

- identify risks within its scope including for all recommendations;
- · develop and review controls and treatments where appropriate; and
- take such action as is appropriate to receive assurance that risk is being managed if relevant.

REPORTING

This Committee is a Tier 5 Operational Committee which supports the Executive Director, Metro South Research in meeting their accountabilities.

This Committee, established by MSH will:

- Report to the Executive Director, Metro South Research; and
- Oversee the monitoring of approved research until completion and the provision of final reports to ensure that the
 research has complied with approved ethical standards along with relevant legislation, regulations, codes of practice,
 policies, and procedures.

Formal mechanisms of standard reporting include the HREC Annual Compliance Report to the NHMRC, minutes for all MSHREC meetings are signed off by the Chair and reporting to relevant MS committees as required.

7.

MEMBERSHIP

The membership of the MSHREC is constituted according to the National Statement: -

- "5.1.30 The minimum membership of an HREC is eight and must include the following categories
- (a) a chairperson with suitable experience, including previous membership of an HREC, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement;
- (b) two people who bring a broader community or consumer perspective and who have no paid affiliation with the institution;
- (c) a person with knowledge of, and current experience in, the professional care or treatment of people; for example, a nurse, counsellor or allied health professional;
- (d) a person who performs a pastoral care role in a community including, but not limited to, an Aboriginal and/or Torres Strait Islander elder or community leader, a chaplain or a minister of religion or other religious leader;
- (e) a qualified lawyer, who may or may not be currently practicing and, where possible, is not engaged to advise the institution on research-related or any other matters; and
- (f) two people with current research experience that is relevant to research proposals to be considered at the meetings they attend."

(National Statement on Ethical Conduct in Human Research, 2023, 5.1.30, p 90).

Members are required to declare Conflicts of Interest annually and ad hoc during their tenure and these will be reviewed by the Chair and centrally recorded.

Committee Members provide their services and expertise on a voluntary basis. Consumer remuneration is available for MSHREC Members 'Category B', who are not employees, contractors or a consultant of MS, in accordance with the MS Remuneration and Reimbursement of Consumer Partners Procedure (PR2021-285).

The Principal Investigator or a representative for the Investigator may be invited to attend the relevant meeting to discuss a proposal but would be required to leave the meeting before any decision is taken.

8. FREQUENCY

- Committee meetings will be held monthly, except for January when there will be no scheduled meeting. However, in
 months involving significantly higher submission numbers a second meeting may be held following adequate period
 of notice to members (minimum two weeks).
- An annual calendar of meeting dates will be published and made available on the MS Research website.
- Cancellation and re-scheduling of meetings will be at the discretion of the Chair.
- Notice of meetings will be given to members for the current year and at least two (2) weeks prior to a meeting.
- A copy of the agenda, previous minutes, along with any other papers relevant to the meeting, will be forwarded to all members at least one (1) week prior to the meeting.
- Reviews of the Low-Risk studies are undertaken by the Deputy Chair and MSHREC administration team and if
 required by members of the MSHREC, throughout the year via the Ethical Review Manager (ERM) Portal.

Where there is less than full attendance of the minimum membership at a meeting (quorum is one representative from each category as per NS 5.1.30), the Chair must be satisfied, before a decision is reached, that those members unable to attend the meeting have received all papers and have had an opportunity to contribute their views and that the views of all members have been recorded and considered. Members who are unable to attend a rostered meeting are asked to contribute and advise their opinion via ERM Portal submission to the MSHREC administration team prior to the meeting.

9. SECRETARIAT

MS Research will provide secretariat support to the Committee, including the preparation of meeting papers and administrative support.

The Secretariat will prepare and maintain a corporate file of the Committee's records.

10. TERMS OF REFERENCE REVISION HISTORY

Version	Date	Comment	Author	Reviewed by
1.0	24/09/2020	Endorsed	Metro South Research	A/Prof Scott Campbell, Chair MSHREC
2.0	15/09/2022	Endorsed	Metro South Research	Dr Mary Boyde, Chair MSHREC
3.0	7/11/2023	Endorsed	Metro South Research	Dr Mary Boyde, Chair MSHREC

The Terms of Reference will be reviewed by the Committee every three (3) years.

11. APPROVAL

These terms of reference should be read in conjunction with the overarching MS Common Arrangements for Tier 3 to 7 Committees document ('the common arrangements') which set out the common administrative arrangements of all MS committees which are subordinate to the Tier 2 Executive Leadership Team Committees.

These terms of reference have been endorsed by the Committee and are approved by the Chair.

Signature Mayde

Date 7/11/2023

Dr Mary Boyde

Chair, Metro South Human Research Ethics Committee

Any amendments to these terms of reference require the endorsement of the Committee and approval of the Chair. Terms of reference may be amended from time to time by following the procedure below:

• The proposal must be in writing and circulated to all MSHREC Members for their consideration to allow for the views of Members to be discussed at the next scheduled meeting of the MSHREC for ratification.

12.

References

Australian Code for the Responsible Conduct of Research (2018) National Health and Medical Research Council, Australian Research Council and Universities Australia. Commonwealth of Australia, Canberra, Australia. https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018 (Accessed 19 October 2023)

Australian Commission on Safety and Quality in Health Care (2021) National Safety and Quality Health Service Standards. 2nd ed; V2. Australian Commission on Safety and Quality in Health Care. Sydney, Australia. https://www.safetyandguality.gov.au/sites/default/files/2021-

05/national_safety_and_quality_health_service_nsqhs_standards_second_edition_-_updated_may_2021.pdf (Accessed 19 October 2023)

Hospital and Health Boards Act 2011 available at https://www.legislation.qld.gov.au/view/pdf/inforce/current/act-2011-032 (Accessed 19 October 2023)

Human Rights Act 2019 Act no 5 of 2019 available at https://www.legislation.qld.gov.au/view/pdf/asmade/act-2019-005 (Accessed 19 October 2023)

Metro South Health Procedure Remuneration and Reimbursement of Consumer Partners (2021) PR 2021/285 V1.1 https://docs.sth.health.qld.gov.au/documents/metro-south-health/pr2021-285 (Accessed 19 October 2023)

Metro South Health Research Policy (2023) PL2023 -92 V1.0

https://metrosouth.health.qld.gov.au/sites/default/files/content/pl2023-92.pdf (accessed 19 October 2023)

National Statement on Ethical Conduct in Human Research 2023. National Health and Medical Research Council and Universities Australia., Canberra, National Health and Medical Research Council Australia https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023 (Accessed 19 October 2023)

Queensland Health: Research, Ethics and Governance Health Service Directive (2023) (QH-HSD-035) V 4.0 Office of Precision Medicine and Research. Brisbane, Queensland.

https://www.health.qld.gov.au/system-governance/policies-standards/health-service-directives/research,-ethics-and-governance (Accessed 19 October 2023)