

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 (MS) Human Research Ethics Committee (HREC). These terms of reference should be read in conjunction with the overarching MSH Common Arrangements for Tier 3 to 7 Committees document.

1. AUTHORISATION

The MS HREC (the Committee) functions under the authority and delegations of the Health Service Chief Executive (HSCE), to whom it reports, providing advice and recommendations.

In accordance with the Hospital and Health Boards Act 2011 and as authorised by the Metro South Hospital and Health Service Board and the HSCE all decisions made within MSH 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 2007 (Updated 2018) 5.2.23, p 91).

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) – EC00167, to conduct reviews of research conducted within jurisdictions participating in the National Mutual Acceptance (NMA) model and participates in the Queensland Health single ethical review process.

2. PURPOSE

The MS HREC, is constituted and functions in accordance and compliance with the:

- National Statement on Ethical Conduct in Human Research 2007 (Updated 2018),
- Australian Code for the Responsible Conduct of Research,
- Queensland Health: Research Ethics and Governance Health Service Directive,
- Metro South Research Management Policy and associated procedures,
- National Safety and Quality Health Service Standards, and
- Human Rights Act 2019.

The MS HREC 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.

3. FUNCTIONS AND RESPONSIBILITIES

The MS HREC is appointed by the Metro South Hospital and Health Service. The Committee considers submitted research protocols involving humans across the Metro South Hospital and Health Service 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 in 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 Health 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 MSH HREC.

4. 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, must conduct themselves in accordance with the MSH I CARE² Values:

- Integrity,
- Compassion,
- Accountability,
- Respect,
- Engagement, and
- Excellence.

5. RISK MANAGEMENT

The Committee is to pro-actively identify and manage 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.

6. REPORTING

This Committee, established by MSHHS will:

- Report to the HSCE via the Chief People, Engagement and Research Officer,

- 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 MS HREC meetings signed off by the Chair, and ad hoc reporting to MSHHS relevant committees.

7. MEMBERSHIP

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

“ 5.1.29 The minimum membership of an HREC is eight. As far as possible:

(a) there should be equal numbers of men and women; and

(b) at least one third of the members should be from outside the institution for which the HREC is reviewing research.

5.1.30 This minimum membership is:

(a) a chairperson, with suitable experience, whose other responsibilities will not impair the HREC’s capacity to carry out its obligations under this National Statement;

(b) 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;

(c) at least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional;

(d) at least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion;

(e) at least one lawyer, where possible one who is not engaged to advise the institution; and

(f) at least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend. These two members may be selected, according to need, from an established pool of inducted members with relevant expertise.”

(National Statement on Ethical Conduct in Human Research, 2007 (Updated 2018) 5.1.29-30, p 87).

“5.1.33 The institution should ensure that the HREC has access to the expertise necessary to enable it to address the ethical issues arising from the categories of research it is likely to consider. This may necessitate going outside the HREC membership.”

(National Statement on Ethical Conduct in Human Research, 2007 (Updated 2018) 5.1.33, p 87).

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 HREC Members ‘Category B Lay Membership’, who are not employees, contractors or a consultant of MSH, in accordance with the Metro South Health Procedure Remuneration and Reimbursement of Consumer Partners (2021).

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 Metro South 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 and Negligible Risk (LNR) studies are undertaken by the Deputy Chair and HREC administration team and if required by members of the HREC, throughout the year via the 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 HREC administration team prior to the meeting.

9. SECRETARIAT

Metro South Research will provide secretariat support to the Committee.

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 MSH HREC
2.0	15/09/2022	Endorsed	Metro South Research	Dr Mary Boyde, Chair MSH HREC

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 MSH Common Arrangements for Tier 3 to 7 Committees document ('the common arrangements') which set out the common administrative arrangements of all MSH 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.....  Date 15.09.2022

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 HREC Members for their consideration to allow for the views of Members to be discussed at the next scheduled meeting of the HREC for ratification.
- Proposed amendments may be made by a member of the HREC or Metro South Research Administration team; in conjunction with the HREC Chair.
- The amended terms of reference will be sent by the HREC Chair to the Chief, People, Engagement and Research Officer, for ratification.

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 9 September 2022)
- 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.safetyandquality.gov.au/standards/nsqhs-standards> (Accessed 9 September 2022)
- Hospital and Health Boards Act 2011 available at <https://www.legislation.qld.gov.au/view/pdf/inforce/current/act-2011-032> (Accessed 9 September 2022)
- Human Rights Act 2019 Act no 5 of 2019 available at <https://www.legislation.qld.gov.au/view/pdf/asmade/act-2019-005> (Accessed 9 September 2022)
- 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 9 September 2022)
- Metro South Health Research Management Policy (2020) PL2017/55 V2.0
<https://docs.sth.health.qld.gov.au/documents/metro-south-health/pl2017-55> (Accessed 9 September 2022)
- National Statement on Ethical Conduct in Human Research 2007 (Updated 2018). The National Health and Medical Research Council, the Australian Research Council and Universities Australia. Commonwealth of Australia, Canberra, Australia
https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__2102 (Accessed 9 September 2022)
- Queensland Health: Research, Ethics and Governance Health Service Directive (2022) (QH-HSD-035:2013) V 3.0 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 9 September 2022)