

# Research support and management

## PURPOSE

This procedure describes the processes for research support and management in Metro South Health (MSH) to ensure all research conducted within MSH facilities, or involving MSH personnel, is conducted in a safe and responsible manner with the appropriate use of resources.

## OUTCOME

The intended outcome of this procedure is to:

- Promote integrity in research, respect for participants and compliance with ethical and legislative standards, by upholding principles outlined within the MSH policy PL2023-92 Research Policy.
- Ensure the safety of participants and minimise the risk of harm for all involved in research.
- Outline the MSH-wide process to ensure:
  - good institutional corporate governance, compliance and management practices encourage responsible research practices.
  - processes/arrangements by which research in MSH is administered is promoted and accessible.
  - roles, responsibilities and accountability of all involved in a research project are specified to ensure research is assessed for ethical acceptability, quality, safety, privacy, risk management and financial management including legal considerations.
  - Support services for researchers is accessible and available.
- Enhance MSH's reputation through appropriate governance, support and custodianship of research.
- Uphold principles outlined within Attachment 1: Research Support and Management Handbook.

## SCOPE

This procedure applies to all MSH employees and collaborators who conduct human research within or in association with MSH, or through access to MSH participants, health records or data. Adherence to this procedure will ensure all research conducted within MSH or in collaboration with external entities/organisations is of the highest ethical and scientific standard and is compliant with relevant legislation, standards, and guidelines. Failure to comply with this procedure may constitute professional or research misconduct on the part of the responsible individual.

# PROCEDURE

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## 1. RESEARCH POLICY FRAMEWORK AND RESEARCH CORPORATE GOVERNANCE

- Corporate governance is vital in research support and management for MSH, as it ensures ethical conduct, compliance with regulations, risk management, accountability, transparency, stakeholder confidence, strategic alignment, and quality/integrity.
- MSH research corporate governance structures establish frameworks and practices that upholds ethical principles, protects research participants, ensures compliance with laws and regulations and aligns research activities with organisational objectives.

### 1.1 Research Policy Framework

- The Research Policy Framework, underpinned by PL2023-92 Research Policy (endorsed by the MSH Executive Strategic Governance Committee), upholds MSH corporate governance processes, compliance principles and standards that apply to all research disciplines.
- See Research Support and Management Handbook (Attachment 1) for more information.

### 1.2 Research Committee Structure

- The MSH research corporate governance committee structure, which forms part of research corporate governance processes, ensures MSH operates in an efficient, effective, and safe manner aligned to MSH corporate governance frameworks.
- MSH research committees form part of the MSH Organisational Committee Structure. See Appendix 1 for a diagram of the MSH Research Corporate Governance Committee Structure.
  - MSH Research Council (Tier 3 – Strategic Committee)
  - Metro South Human Research Ethics Committee (Tier 5)
  - MSH Research Grants Committee (Tier 7)
  - Facility/Service Research Committee (Tier 5 – Operational Committees)
- The Metro South Health Human Research Ethics Committee (MSHREC) operates in accordance with National Health and Medical Research Council (NHMRC) certification requirements (registration number EC00167).
- Within MSH, laboratory work health and safety, general biosafety and biosecurity issues are discussed at relevant work health and safety committees (e.g., Translational Research Institute (TRI) Work Health and Safety Committee).
- Attached to this procedure are the following Terms of Reference (TOR):
  - Attachment 2: MSH Research Council TOR
  - Attachment 3: Metro South Human Research Ethics Committee TOR
  - Attachment 4: MSH Research Grants Committee TOR
  - Attachment 5: Facility/Service Research Committee TOR Template.

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### 1.3 MSH Research Council

- The purpose of the MSH Research Council is to provide strategic advice and make recommendations to the Health Service Chief Executive (HSCE) or delegate that will enable and facilitate the achievement of MSH's strategic intents in relation to research. Refer to the Metro South Health Research Strategy for more information.
- The MSH Research Council establishes management practices for the responsible conduct of research (including clinical trials) across MSH.
- MSH Research Council is responsible for ensuring quality systems and processes are in place to ensure that staff work to appropriate guidelines and standards and that processes are in place for continuing professional development including but not limited to, Good Clinical Practice (GCP): Research Integrity and training for staff, to retain a competent and appropriately skilled research workforce.

### 1.4 National Clinical Trials Governance Framework (NCTGF)

- MSH has identified roles and functions to facilitate compliance with the NCTGF.
- MSH Research Council will oversee the implementation of strategies, actions and plans to facilitate compliance with NCTGF requirements.
- MSH Executive Strategic Governance Committee, MSH Executive Safety and Quality Committee, and MSH Research Council have reporting processes to the MSH Board, in accordance with the NCTGF.
- See Appendix 2: Metro South Health Research Corporate Performance and Clinical Incident Reporting Committee Structure.

## 2. FUNDING, BUDGETS AND INFRASTRUCTURE SUPPORT

- The financial management of research funds is underpinned by the MSH Finance Management and Practice Manual (FMPM). The FMPM promotes accountability, transparency, and defensibility with a view to efficient, effective, judicious and economical use of public monies. Adherence to the FMPM facilitates compliance with financial, legislative, reporting and policy requirements.
- Refer to Attachment 1 Research Management and Support Handbook and MSH work instruction WI2023-293 Research funding, budgets, and infrastructure support for more information.

### 2.1 Open access journal publications

- MSH supports the underlying principles of open access by making publications freely available online as soon as possible or within twelve (12) months of publication.
- Provisions for open access journal publication should be included in all research budgets.
- For externally funded research projects, the costs associated with the publication should be met from the external funding source. Payments will be made in accordance with the external funding organisation's policies and procedures.
- For internally funded research projects, MSH may consider providing funding support to publish research findings through reimbursement of the open access journal article processing charge/fee.

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- MSH funding may only be applied to the publishing of a research article in a high-quality, peer reviewed, fully open access journal, with articles required to have a CC-BY (Creative Commons Attribution) licence.
- Refer to MSH work instruction WI2022-226 Open access journal publications in research for more information.

### 3. GRANTS ADMINISTRATION SERVICES

- A consistent administrative process for preparation and evaluation of research grant applications and management of research grant funds within MSH has been established.
- Metro South Research Office/Directorate must be involved in the research grants application process if it is proposed for MSH to be identified as the grant administering institution, or a partner in a collaborative application.
- To further support researchers, Metro South Research may be able to:
  - provide guidance on grant opportunities, assists in preparing grant applications, and ensures compliance with application requirements and deadlines.
  - identify suitable funding sources for their research projects by maintaining knowledge of available grants, funding cycles, and eligibility criteria, providing researchers with information on funding opportunities that align with their research interests and objectives.
  - assist researchers in developing strong research proposals that effectively communicate their objectives, methods, and expected outcomes. It may offer guidance on structuring proposals, refining research questions, and ensuring alignment with funding agency priorities. This support enhances the quality and competitiveness of researchers' grant proposals.
  - aid researchers in budgeting their research projects. It helps identify allowable expenses, provides guidance on cost estimation, and ensures compliance with funding agency financial requirements. This assistance ensures that researchers have a clear and realistic budget that maximises the utilisation of available funding.
  - help researchers navigate the compliance and reporting requirements associated with research grants. It ensures that researchers adhere to funding agency guidelines, ethics requirements, and reporting obligations throughout the research project. This support helps researchers maintain reporting compliance, uphold research integrity, and fulfill their contractual obligations.
- Once researchers receive funding, the grants administration service provides ongoing support for post-award management. This includes managing grant agreements, monitoring expenditure, facilitating budget revisions, and assisting with reporting and progress updates. Researchers can rely on the service to navigate administrative processes effectively, allowing them to focus on conducting their research.
- Training and Workshops: Some grants administration services offer training sessions and workshops to build researchers' capacity in grant writing, budgeting, compliance, and other related areas. These learning opportunities equip researchers with valuable skills and knowledge to enhance their success in securing funding and managing grants.
- Refer to MSH work instruction WI2023-294 Research grants administration for more information.

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### 3.1 Grant application certification and letters of support

- Major external funding organisations require the certification of research applications on behalf of the administering institution. Certification on behalf of MSH is undertaken by Metro South Research Office/Directorate.
- Refer to MSH work instruction WI2023-295 Letters of support for more information.

## 4. MSH RESEARCH SUPPORT SCHEME (MSH RSS)

- Key processes and internal controls in place to provide effective administrative processes and a reporting framework for the management of MSH research funds as part of the MSH RSS has been established.
- Refer to MSH work instruction WI2023-296 Metro South Health Research Support Scheme (MSHRSS) for more information.

## 5. OTHER RESEARCH SUPPORT

### 5.1 Provision of gift cards for research purposes

- The MSH Chief Finance Officer has approved the use of gift cards with monetary value, under limited circumstance as compensation for research participants and volunteers/research consumer advisors (see s6.4.1, Page 25, FMPM).
- The Metro South Human Research Ethics Committee (MSHREC) has identified that provision of gift cards as the preferred method of providing research participants with reimbursement of payment for their participants.
- This takes into account the National Statement on Ethical Conduct in Human Research 2023 and that the restricted range of goods and services can be purchased using gift cards – thereby contributing to harm minimisation. In particulate, the MSHREC does not endorse the use of cash or electronic funds transfer for research participants.
- The use of gift cards for reimbursement or payment of research consumer advisors must be in accordance with the below:
  - MSH guideline GL2021-75 Partnering with consumers in research
  - MSH work instruction WI2023-297 Gift cards (for use as research incentives).

### 5.2 Support initiatives

- From time to time, MSH may enter arrangements to support research within the Health Service. Refer to MSH work instruction WI2023-298 Scientists in the Clinic (MSH/TRI) as an example.

## RESPONSIBILITIES

| Position  | Responsibility   | Audit criteria  |
|---|--|---|
| Executive Director, Metro South Research and Director, Research Development, Metro South Research | <ul style="list-style-type: none"> <li>Establish and maintain corporate governance frameworks which support research in MSH.</li> </ul>              | <ul style="list-style-type: none"> <li>MSH Research Council</li> </ul>  |
| Research Support Coordinator, Metro South Research  | <ul style="list-style-type: none"> <li>Facilitate through MSH SERTA the provision of research support through the MSH RSS.</li> </ul>                | <ul style="list-style-type: none"> <li>MSH RSS annual process</li> </ul>  |
| Researchers   | <ul style="list-style-type: none"> <li>Adhere, be aware of and comply with the Research Policy Framework when conducting research in MSH.</li> </ul> | <ul style="list-style-type: none"> <li>Completion of MSH Orientation (mandatory), Research Induction and relevant training</li> </ul> |

## DEFINITIONS

| Term                   | Definition   |
|------------------------|--|
| Clinical trial         | <p>A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.<sup>81</sup></p> <p>Clinical trials include but are not limited to:</p> <ul style="list-style-type: none"> <li>Surgical and medical treatments and procedures</li> <li>Experimental drugs</li> <li>Biological products</li> <li>Medical devices</li> <li>Health-related service changes</li> <li>Health-related preventative strategies</li> <li>Health-related educational interventions.</li> </ul>  |
| Governance (corporate) | <p>Governance is a set of relationships and responsibilities established by a health service organisation between its executive, workforce and stakeholders (including patients and consumers). Governance incorporates the processes, customs, policy directives, laws and conventions affecting the way an organisation is directed, administered or controlled. Governance arrangements provide the structure for setting the corporate objectives (social, fiscal, legal and HR) of the organisation and the means to achieve the objectives. They also specify the mechanisms for monitoring performance. Effective governance provides a clear statement of individual accountabilities within the organisation to help align the roles, interests and actions of the different participants in the organisation to achieve the organisation's objectives.</p> |

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| Term                      | Definition  |
|---------------------------|---|
| Governing body            | The governing body is a board, chief executive officer, organisation owner, partnership or other highest level of governance (individual or group of individuals) that has ultimate responsibility for strategic and operational decisions affecting safety and quality in a health service organisation. |
| Infrastructure            | The basic facilities, equipment, or underlying framework that is necessary for a system or organisation to function.  |
| Research Policy Framework | A framework inclusive of policy, procedures, work instructions, guidelines and supporting documents, aligned to MSH research practices.   |
| Policy documents          | Policy documents include policies, procedures, work instructions and guidelines. Refer to MSH procedure PR2013-01 Policy document management.   |

## RELATED AND SUPPORTING DOCUMENTS

|  |  |
|--|--|
| <b>Legislation and other Authority</b> | <p><b>Legislation (as updated and replaced from time to time)</b></p> <ul style="list-style-type: none"> <li>• <i>Australian Research Council Act 2001 (Cth)</i></li> <li>• <i>Hospital and Health Boards Act 2011 (Qld)</i></li> <li>• <i>Financial Accountability Act 2009 (Qld)</i></li> <li>• <i>National Health and Medical Research Council Act 1992 (Cth)</i></li> <li>• <i>Public Health Act 2005 (Qld)</i></li> <li>• <i>Public Sector Act 2022 (Qld)</i></li> <li>• <i>Public Sector Ethics Act 1994 (Qld)</i></li> <li>• <i>Research Involving Human Embryos Act 2002 (Cth)</i></li> <li>• <i>Therapeutic Goods Act 1989 (Cth)</i></li> </ul> <p>Regulations</p> <ul style="list-style-type: none"> <li>• Financial Accountability Regulation 2009 (Qld)</li> <li>• Financial and Performance Management Standard 2009 (Qld)</li> <li>• Hospital and Health Boards Regulation 2012 (Qld)</li> <li>• Public Health Regulation 2018 (Qld)</li> <li>• Therapeutic Goods (Medical Devices) Regulations 2002 (Cth)</li> <li>• Therapeutic Goods Regulations 1990 (Cth)</li> </ul> <p><b>National Health and Medical Research Council (NHMRC)</b></p> <ul style="list-style-type: none"> <li>• National Statement on Ethical Conduct in Human Research 2023</li> <li>• Australian Code for the Responsible Conduct of Research 2018</li> </ul> <p><b>Department of Health</b></p> |
|--|--|

|                             |   |
|-----------------------------|---|
|                             | <ul style="list-style-type: none"> <li>• Health Service Directive: Research Ethics and Governance Directive QH-HSD-035:2023</li> <li>• Research Management Guideline: external funding and infrastructure support QH-GDL-013-1:2022</li> <li>• Research Management Policy QH-POL-013:2022</li> <li>• Research Management Standard QH-IMP-013:1:2022</li> </ul> <p><b>Metro South Health</b></p> <ul style="list-style-type: none"> <li>• Metro South Health Research Strategy</li> <li>• Finance Management Practice Manual (FMPM)</li> <li>• Contract Management Framework</li> </ul>  |
| <b>Standards</b>            | <ul style="list-style-type: none"> <li>• National Clinical Trials Governance Framework</li> <li>• National Safety and Quality Health Service (NSQHS) Standards 2<sup>nd</sup> Ed. <ul style="list-style-type: none"> <li>○ Standard 1 – Clinical Governance</li> <li>○ Standard 2 – Partnering with Consumers</li> </ul> </li> </ul>  |
| <b>Supporting documents</b> | <p><b>Policies and procedures</b></p> <ul style="list-style-type: none"> <li>• PL2018-62 Risk Management</li> <li>• PR2018-97 Risk management</li> <li>• PR2023-411 Research excellence</li> <li>• PR2023-413 Research administration and compliance</li> </ul> <p>Work Instructions</p> <ul style="list-style-type: none"> <li>• WI2023-293 Research funding, budgets, and infrastructure support</li> <li>• WI2022-226 Open access journal publications in research</li> <li>• WI2023-294 Research grants administration</li> <li>• WI2023-295 Research letters of support</li> <li>• WI2023-296 Metro South Health Research Support Scheme (MSHRSS)</li> <li>• WI2023-297 Gift cards (for use as research incentives)</li> <li>• WI2023-298 Scientists in the Clinic (MSH/TRI)</li> </ul> <p>Attachments</p> <ul style="list-style-type: none"> <li>• Attachment 1 Research Support and Management Handbook</li> <li>• Attachment 2: MSH Research Council TOR</li> <li>• Attachment 3: Metro South Human Research Ethics Committee TOR</li> <li>• Attachment 4: MSH Research Grants Committee TOR</li> <li>• Attachment 5: Facility/Service Research Committee TOR Template</li> </ul> |



## HUMAN RIGHTS ACT 2019

Metro South Hospital and Health Service is committed to respecting, protecting and promoting human rights. Under the *Human Rights Act 2019*, Metro South Health has an obligation to act and make decisions in a way that is compatible with human rights and, when making a decision, to give proper consideration to human rights. When making a decision about research, decision-makers must comply with that obligation. Further information about the *Human Rights Act 2019* is available at: <https://www.forgov.qld.gov.au/humanrights>.

## CONSEQUENCE CATEGORY

|                               |  |
|-------------------------------|--|
| <b>Consequence category</b>   | Business Operations  |
| <b>Level of consequence</b>   | Moderate   |
| <b>What will be monitored</b> | Research support and management processes  |
| <b>How (method or tool)</b>   | <ul style="list-style-type: none"><li>• MSH Research Council TOR published</li><li>• MSH RSS annual process</li><li>• Completion of MSH Orientation (mandatory) and Research Induction</li></ul> |
| <b>Frequency</b>              | Annually   |
| <b>Responsible officer</b>    | Executive Director, Metro South Research   |
| <b>Reporting to</b>           | Metro South Health Research Council  |

## PROCEDURE DETAILS

|  |   |
|--|---|
| <b>Procedure Name</b>                  | Research support and management   |
| <b>Procedure Number</b>                | PR2023-412  |
| <b>Current Version</b>                 | V1.0  |
| <b>Keywords</b>                        | Research Funding, Budgets and Infrastructure Support, Research Grants Administration, Metro South Health Research Support Scheme, MSH Research Council, corporate governance, National Clinical Trials Governance Framework (NCTGF) |
| <b>Primary Policy Reference</b>        | PL2023-92 Research Policy   |
| <b>Risk Consequence Rating</b>         | Moderate  |
| <b>Executive Sponsor</b>               | Chief People, Engagement and Research Officer, Metro South Health   |
| <b>Endorsing Committee / Authority</b> | Metro South Health Research Council   |
| <b>Document Author</b>                 | Manager, Research Development, Metro South Research   |

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|                         |               |
|-------------------------|---------------|
| <b>Next Review Date</b> | December 2026 |
|-------------------------|---------------|

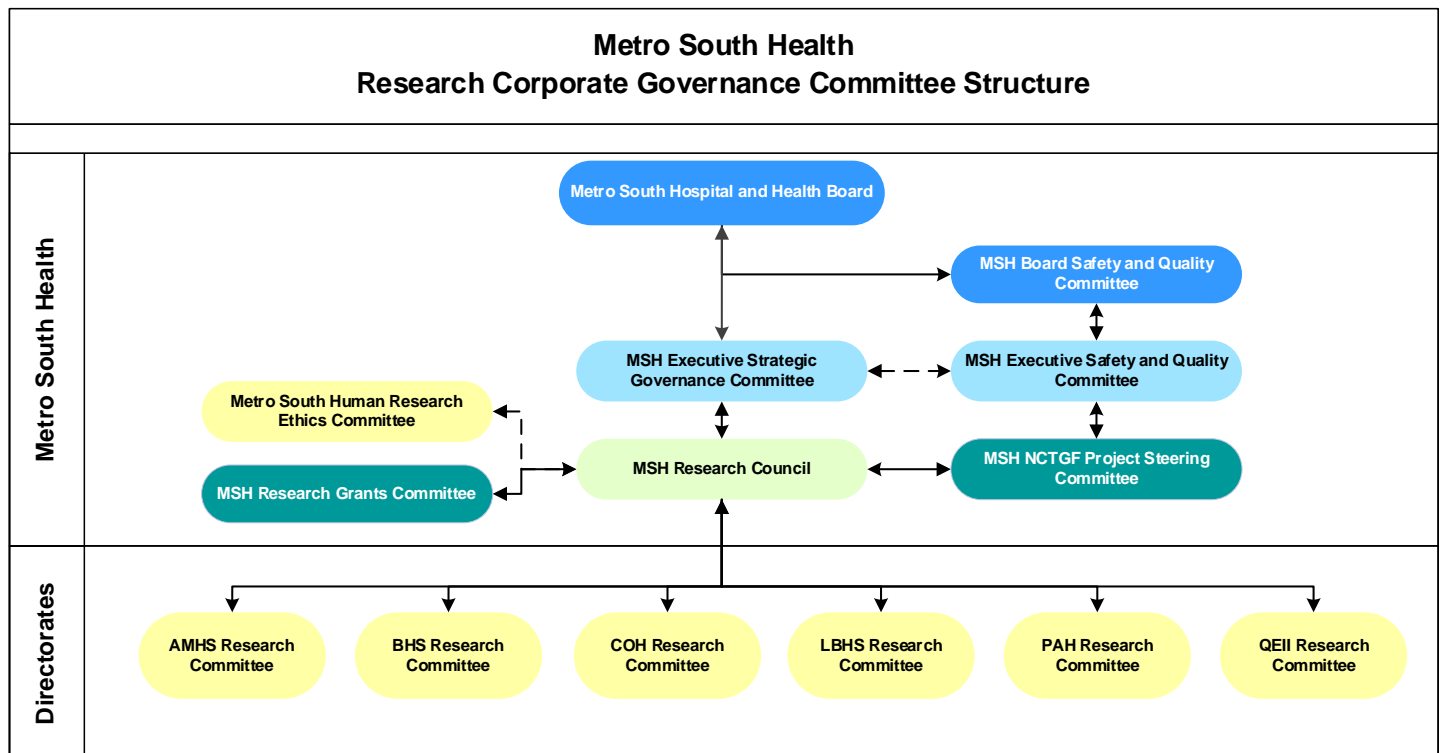
## REVIEW HISTORY

| Version | Approval date | Effective from | Authority  | Comment      |
|---------|---------------|----------------|--|--------------|
| 1.0     | 7/12/2023     | 11/12/2023     | Chief People,<br>Engagement and<br>Research Officer,<br>Metro South Health | New document |

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# APPENDICES

## 1. APPENDIX 1: MSH RESEARCH CORPORATE GOVERNANCE COMMITTEE STRUCTURE



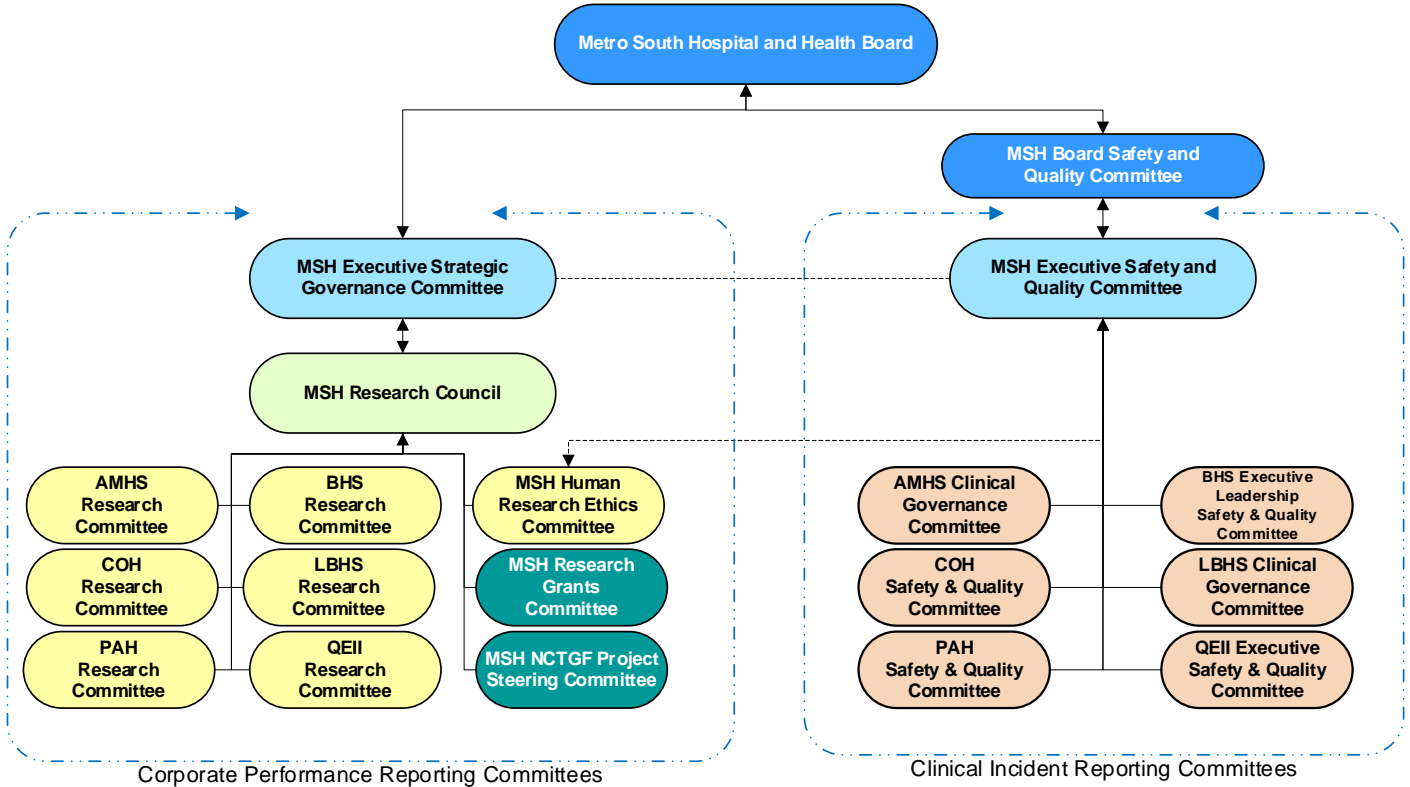
**Legend**

|              |
|--------------|
| Tier 1       |
| Tier 2       |
| Tier 3       |
| Tier 5       |
| Tier 7 (TBC) |

Formal reporting line ↔  
 Informal reporting line/information sharing - - - - -

## 2. APPENDIX 2: METRO SOUTH HEALTH RESEARCH CORPORATE PERFORMANCE AND CLINICAL INCIDENT REPORTING COMMITTEE STRUCTURE

### Metro South Health Research Corporate Performance and Clinical Incident Reporting Committee Structure



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