Metro South Health

Quality healthcare every day

Research Support and Management Handbook

Metro South Research

V1.0 Date: December 2023

ICARE² values

INTEGRITY COMPASSION ACCOUNTABILITY RESPECT ENGAGEMENT EXCELLENCE

Queensland Government

Contents

Purpose

Metro South Health (MSH) uses policies and procedures to mandate and direct specific business activity across the Hospital and Health Service (HHS). The MSH Policy Framework ensures appropriate governance and consistency for policy development and supports the management of policy through the policy life cycle.

The Research Policy Framework forms part of the MSH Policy Framework and the processes outlined in this document comply with the MSH Policy Framework.

The PL2023-92 Research Policy encompasses more than just the management of research in MSH. The Research Policy aims to embed MSH's commitment conducting research that advances knowledge and innovation and enhances our ability to serve our community. MSH believes in conducting research with integrity, respect for participants, and in compliance with ethical and legislative standards.

MSH executive, Metro South Research, principal investigators and researchers have responsibilities for research support and management, some of which are delegated by the MSH Health Service Chief Executive (HSCE). This Handbook, which is attached to MSH procedure PR2023-412 Research Support and Management Procedure, aims to outline the standards and principles which MSH must comply with to:

- Ensure collaborative, harmonised, clear and detailed publicly available policies and procedures are in place for the ethical and scientific review of all MSH research.
- Provide research support and management services to MSH.
- Ensure researchers adhere, be aware of and comply with the Research Policy Framework when conducting research in MSH.

The Research Support and Management Handbook is to be read alongside MSH procedure PR2023-412 Research support and management, related work instructions and guidelines.

1.0 Research Policy Framework and research committees

The following key principles guide MSH in utilising the Research Policy Framework.

- The Research Policy Framework specifies the roles, responsibilities and accountability of all involved and provides principles in which research is assessed for ethical acceptability, quality, safety, privacy, risk management and financial management, including legal considerations.
- The Research Policy Framework outlines fundamental principles of compliance/governance, funding/grants/contracts, integrity/quality/reporting. It also outlines systems for the Clinical Research Facility (CRF) and research biobanks in MSH.
- The Research Policy Framework:
    - adopts the governance practices outlined in MSH corporate governance processes.
    - sets out governance and compliance principles and standards that apply to all research disciplines.
    - clarifies roles and responsibilities of people and organisational structures involved in research management in MSH.
    - supports and promotes research quality and good research practices.

- aims to prevent adverse incidents, breaches of guidelines and codes, and research misconduct.

- Good institutional governance, compliance and management practices encourage responsible research practices. These practices promote quality in research, enhance the reputation of the institution and its researchers, and minimise the risk of harm to humans, animals and the environment.

1.1 International, national and state regulation, accountability and best practice principles

MSH's research practices must operate within applicable laws, regulations, guidelines and codes of practice, as well as Hospital and Health Service policies, procedures and guidelines. The ethical, legal and scientific review of human research is regulated by a number of international, national and state laws, legislation, regulations, ethical guidelines, instruments, codes, guidelines institutional requirements and standards.

MSH has a statutory obligation to ensure all human research is managed scientifically and is conducted in a legally and ethically appropriately manner. Common law obligations may arise from the relationships between institutions, researchers and participants, while contractual arrangements may impose further obligations.

1.1.1 Legislated requirements

Research management compliance practices must be consistent with state legislation, including but not limited to:

- The *Public Health Act 2005 (Qld)* aims to protect and promote the health of the Queensland public by preventing, controlling and reducing risks to public health and collecting and managing particular health information, and establishing mechanisms for health information held by a health agency to be accessed for appropriate research.

- The *Information Privacy Act 2009 (Qld)* and Information Privacy Regulation 2009 (Qld) regulates how Queensland government agencies, including MSH, must manage personal information and provides a right for individuals to apply for access and amendment of their personal information. MSH is required to comply with Privacy Principles outlined in the *Information Privacy Act 2009 (Qld),* in particular, the Australian Privacy Principles. These privacy principles include rules about the collection, use, quality, security and disclosure of personal information. They also provide conditions under which personal information may be transferred outside of Australia and rules regarding contracted service providers.
- The *Hospital and Health Boards Act 2011 (Qld)* gives effect to the principles and objectives of the national health system and hospital and health services. It applies to the collection of confidential information (including public and private hospital data) regarding users of the health system (Part 7 Confidentiality).
- The *Human Rights Act 2019 (Qld)* outlines the obligation to act compatibly with the human rights identified in the Act. The Act applies to day-to-day work decisions and actions that impact individuals in Queensland. Our work as public service employees can impact individuals' human rights—sometimes positively and sometimes negatively. This may be when employees deal directly with patients in a clinical setting or members of the public more generally in a non-clinical setting.

  The Metro South Hospital and Health Service is committed to respecting, protecting and promoting human rights. Under the *Human Rights Act 2019*, MSH 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 compliance, decision-makers must comply with that obligation.

- The *Transplantation and Anatomy Act 1979 (Qld)* regulates the removal and use of tissue in certain circumstances including for the purpose of transplantation. The Transplantation and Anatomy Regulation 2004 (Qld) and Explanatory Notes provides additional information relevant to the removal and use of tissue.
- The *Gene Technology (Queensland) Act 2016 (Qld)* protects the health and safety of people and the environment, by identifying risks posed by, or as a result of, gene technology. It does this by managing risks through regulating certain dealings with genetically modified organisms. The Act applies Commonwealth gene technology laws and ensures application is administered on a uniform basis by the Commonwealth as if they constituted a single law of the Commonwealth.

MSH is also required to comply with Federal laws, codes and institutional requirements that exist in Australia:

- The *Privacy Act 1988 (Cth)* promotes the protection of the privacy of individuals and the handling of personal information. The Ten National Privacy Principles (NPPs) contained in Schedule 3 of the *Privacy Act 1988 (Cth)* regulates how large businesses, all health service providers and some small businesses and non-government organisations handle individuals' personal information. Additionally, guidelines have been approved under Section 95 and 95A of the *Privacy Act 1988 (Cth).*
- The *Therapeutic Goods Act 1989 (Cth)*, Therapeutic Goods Regulations 1990 (Cth) and Therapeutic Good (Medical Devices) Regulations 2002 (Cth) details the legal requirements for the import, export, manufacture and supply of therapeutic goods in Australia. The meaning of a 'biological' is also included under Section 32A *Therapeutic Goods Act 1989 (Cth)*.
- The *Gene Technology Act 2000 (Cth)*, Gene Technology Regulations 2001 (Cth) protects the health and safety of people and the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with Genetically Modified Organisms (GMO).
- The *Defence Trade Controls Act 2012 (Cth)* regulates dealings in certain goods, services and technologies.

1.1.2 Other mandatory requirements

Additionally, national guidelines exist to assist with implementing best practice principles including but not limited to:

National Health and Medical Research Council (NHMRC)	
National Statement on Ethical Conduct in Human Research (2007) - Updated 2023 (as amended from time to time)	Promotes ethically good human research. Fulfilment of this purpose requires that participants be accorded the respect and protection that is due to them. It also involves the fostering of research that is of benefit to the community. The National Statement is therefore designed to clarify the responsibilities of institutions and researchers for the ethical design, conduct and dissemination of results of human research and review bodies in the ethical review of research.
Australian Code of the Responsible Conduct of Research, 2018 (the Code)	Provides a framework for managing breaches of the Code and allegations of research misconduct, managing research data and materials, publishing and disseminating research findings, including proper attribution of authorship, conducting effective peer review and managing conflicts of interest. It also explains

	the responsibilities and rights of researchers if they witness research misconduct.
Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities	Provides guidance for researchers and stakeholders provides a set of principles to ensure research is safe, respectful, responsible, high quality and of benefit to Aboriginal and Torres Strait Islander people and communities.
Statement on Consumer and Community Involvement in Health and Medical Research (2016)	The aims to guide research institutions, researchers, consumers and community members in the active involvement of consumers and community members in all aspects of health and medical research.
NHMRC Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods	Clarifies the responsibilities of those involved in clinical trials to monitor and report adverse events and other safety issues.
National Safety and Quality Health Service (NSQHS)	
NSQHS Standards 2017 2nd Edition	Were developed by the Commission in collaboration with the Australian Government, states and territories, private sector providers, clinical experts, patients and carers. The primary aims of the NSQHS Standards are to protect the public from harm and to improve the quality of health service provision.
National Clinical Trials Governance Framework (NCTGF)	All clinical trials being undertaken in MSH must adhere to the NCTGF, specifically NSQHS Standards: o Standard 1: Clinical Governance and o Standard 2: Partnering with Consumers.
Office of the Gene Technology Regulator	
National Framework of Ethical Principles in Gene Technology' (2012)	The Gene Technology Ethics and Community Consultative Committee is a set of principles which Australian scientists and researchers are expected to abide by when dealing with gene technology and Genetically Modified Organisms (GMOs) at all times. It is a means to encourage ethical conduct in gene technology – in particular where it relates to human health, the environment, genetically modified organisms and products.
Therapeutic Goods Administration (TGA)	
Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)	The TGA has adopted the 'Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)' which is internationally accepted standard for the designing, conducting, recording and reporting of clinical trials.
Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2) ('GCP Guideline	Replaces the Guidelines for Good Clinical Research Practice (GCRP) in Australia, but at the same time has recognised that some elements are, by necessity, overridden by the National Statement (and therefore not adopted) and that others require explanation in terms of 'local regulatory requirements'.
Australian clinical trial handbook	Provides guidance on the legislative, regulatory and Good Clinical Practice (GCP) requirements when conducting clinical trials in

	Australia using 'unapproved' therapeutic goods. It assists trial sponsors, Human Research Ethics Committees (HRECs), investigators and approving authorities (institutions) to understand their roles and responsibilities under the therapeutic goods legislation.

1.1.3 Guidelines and standards

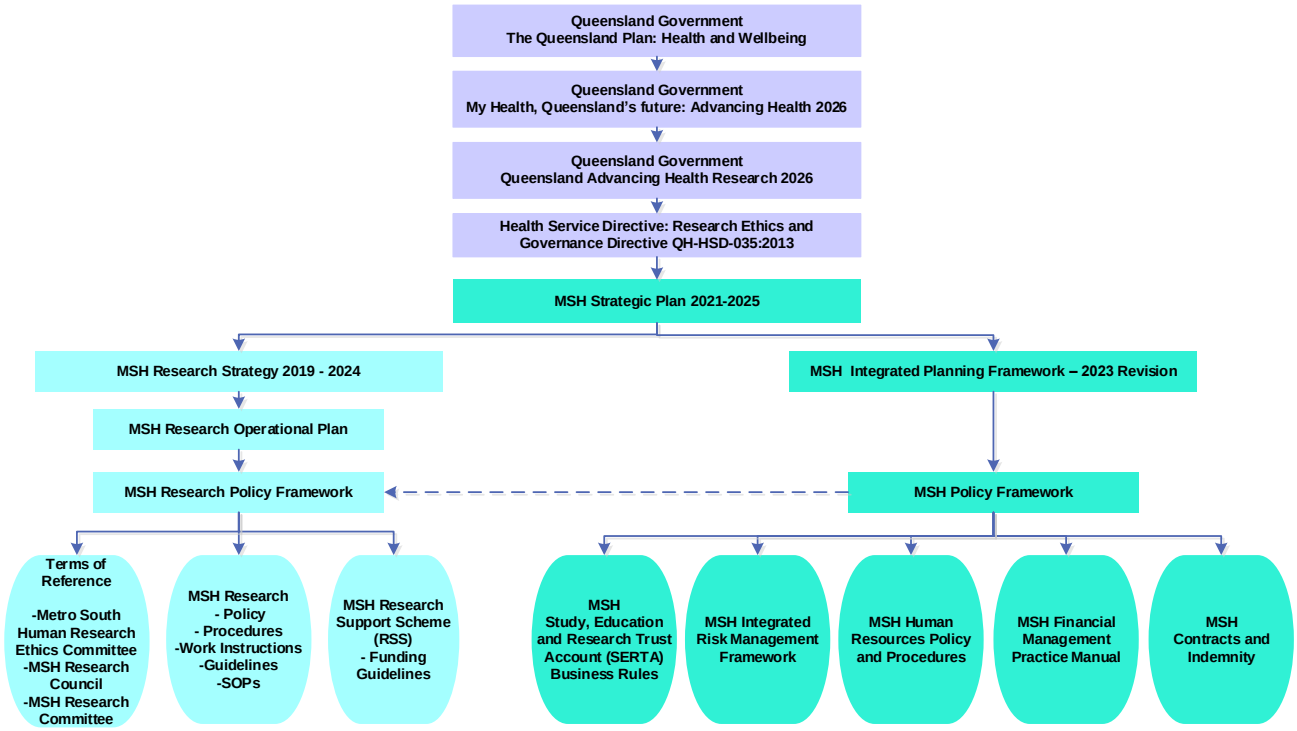
Additionally, international guidelines exist to assist with implementing best practice principles including but not limited to:

- 'Singapore Statement on Research Integrity' (2010) is intended to challenge governments, organisations and researchers to develop more comprehensive standards, codes and policies to promote research integrity both locally and on a global basis.
- The 'Hong Kong Principles' for assessing researchers were formulated and endorsed at the 6th World Conference on Research Integrity, June 2019 in Hong Kong. These principles will help research institutions that adopt them to minimise perverse incentives that invite to engage in questionable research practices or worse.

1.2 Research Policy Framework

The MSH Research Policy Framework illustrates a quality system by which research in MSH is directed and managed. It also illustrates effective governance and tools for addressing governance risk, oversight and management responsibilities.

Metro South Research Strategic Alignment



The Research Policy Framework provides structure to research policy, procedures, work instructions, guidelines and SOPs and also assists in clarifying roles and responsibilities in fulfilling MSH objectives from a corporate governance perspective. All MSH employees must abide by operational governance and quality assurance procedures contained within the Research Policy Framework. The framework influences how the objectives of MSH are set and achieved, how risk is monitored and assessed and how performance is optimised. Metro South Research is responsible for providing oversight and maintaining the Research Policy Framework. The following documents are included as part of the

Research Policy Framework:

Policy	The MSH Research Policy has been issued to influence and reflect MSH's strategic direction pertaining to research conducted in MSH.
Procedures	A series of procedures have been developed which describe the process for a particular research practice.
Work instructions	MSH work instructions include process and guidance information to assist in establishing the direction and application for each required process.
Guidelines	A document used to provide guidance on a topic area and does not contain mandatory processes.
Standard Operating Procedures (SOPs)	Are uniformly written local operating procedures, with detailed instructions to record routine operations, processes and practices followed within a business organisation. In clinical research, SOPs help define standard practices, procedures and daily processes conducted to assure execution of research tasks in accordance with institutional, state and federal guidance. The GCP Guideline 1.55 defines Standard Operating Procedures (SOPs) as: Detailed, written instructions to achieve uniformity of the performance of a specific function.
Manuals, tools, templates, checklists, quick reference guides and forms	Supporting documents which are attached to compliance framework documents to assist the reader in understanding the process and to facilitate in compliance and consistent processes.

1.2.1 Risk and quality management

MSH is committed to the management of its compliance obligations as an integral and embedded part of all its activities. Effective management of MSH's compliance obligations, through a risk-based approach, ensures that the Health Service's strategic direction and corporate objectives are pursued in a lawful and sustainable manner.

Consistent with principles of good governance, MSH has a responsibility to identify and comply with all relevant laws, regulations and other externally imposed requirements, (e.g., codes of relevant industry or regulatory bodies). MSH achieves this through the implementation of MSH's Risk Management Policy and Integrated Risk Management Framework (MSH staff access only) which sets out process for risk management.

The MSH Risk Management Policy and Integrated Risk Management Framework applies to all MSH research activities to which external compliance obligations are relevant.

At the time of occurrence, all incidents of non-compliance must be assessed. Where a non-compliance incident is assessed as having moderate or major consequences (as described in the Integrated Risk Management Framework) the issue must be reported to Metro South Research.

Metro South Research will determine if adjustments to Research Policy Framework documents and risk treatments are required, and whether an ad hoc report should be made to the MSH Audit and Risk Management Committee.

Metro South Research is also required to oversee and monitor any remedial action or adjustments to compliance risk management activities (including policies, procedures and processes) which may be required in light of the non-compliance incident.

Risk management, finance, budgeting, contracts and intellectual property considerations must be embedded and regularly reviewed throughout the lifecycle of a research project/activity. Refer to MSH procedure PR2023-411 Research excellence for more information.

MSH has an internal auditing process to examine and evaluate the adequacy, economy, effectiveness and efficiency of risk management, systems of internal control and the quality of management. Incidents of non-compliance must be reported to Metro South Research. Ad hoc reports may be made to the MSH Audit and Risk Management Committee as required. Health, safety and environmental considerations must be embedded and regularly reviewed throughout the lifecycle of research projects.

1.3 Research Committee Structure

The MSH Research Corporate Governance Committee Structure and the Research Policy Framework are administered in the spirit of:

- the Ten Essential Principles outlined in the 'Principles of Good Corporate Governance and Best Practice' published by Australian Stock Exchange (ASX) Corporate Governance Council
- the Six Essential Principles of the 'OECD Principles of Corporate Governance'.

MSH considers management as dealing with the day-to-day activities of research activities and projects, while corporate governance involves the provision of strategic advisory and oversight of matters relating to research in MSH and within partner institutions.

Refer to MSH procedure PR20412 Research Support and management Appendix 1 for more information.

1.3.1 Safety reporting and biosafety

Specific concerns or matters pertaining to the storage, processing or use of specific biospecimens may be raised with the MSH biosafety representative on the relevant work health and safety committee. Work health and safety committees may discuss specific MSH biosafety or biosecurity SOPs and assist in the development and amendment of procedural documents.

Examples of relevant work health and safety committees include:

- Princess Alexandra Hospital Work Health and Safety Committee discusses matters which pertain specifically Princess Alexandra Hospital biosafety matters.
- Translational Research Institute Work Health and Safety Committee discusses matters which pertain specifically to laboratory biosafety matters within the Translational Research Institute facilities safety@TRI.edu.au.

MSH employees also have access to the University of Queensland Institutional Biosafety Committee (UQ IBC) which is able to assess and approve Genetically Modified Organisms (GMOs) and Security Sensitive Biological Agents (SSBA) Regulatory research proposals.

MSH conforms to the NHMRC Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods November 2016. Refer to MSH work instruction WI2023-306 Post approval – amendments, reporting and closure for more information.

2.0 Funding, budgets and infrastructure support

Sufficient funding is essential to support the conduct of research. Adequate financial resources enable the implementation of robust protocols, ethical review processes, and necessary safeguards for research participants. Funding ensures that researchers have the necessary resources to conduct studies ethically, maintain data integrity, protect participant privacy, and address any potential conflicts of interest.

A robust infrastructure is essential for the ethical conduct of research in MSH. This includes having appropriate physical facilities, laboratory spaces, equipment, and technology infrastructure to support data management, storage, and analysis. Adequate infrastructure ensures that research is conducted in a safe and secure environment, with the necessary resources and tools to maintain research integrity

and protect the welfare of participants. Management of all research project funds, budgets and revenue within MSH must be compliant the MSH Finance Management and Practice Manual (FMPM).

The management of research funds comprises a series of stages commencing with the preparation for any funding application and concluding with the acquittal of the funding agreements and the closing of the research funding account. The management of research funds is a shared responsibility comprising of planning, day to day management, governance, and accounting.

Responsibility for the management of funds, including the identification, management, and mitigation of risks, is to be devolved down to the most practical level. The most practical level is that at which actions can be performed, verified, controlled, and rectified.

MSH reserves its right to take carriage of any aspect of the management of research funds to fulfil its legal and contractual responsibilities to government or to any funding body. This will occur only when there is reason to believe that if such action were not taken MSH would be in breach of its legal or contractual obligations.

Everyone responsible for an aspect of the management of research funds for a research project must act to support the governance, management and accounting of those research funds and supply information and documentation as required to the relevant personnel in a timely manner.

MSH is required to have a robust and transparent governance process in place that provides assurance that the standards of financial management meet public expectations and administers research funds with integrity.

2.1 Criteria for investment

Research applicants are required to provide a written proposal addressing relevant criteria for investment. MSH work areas proposing to fund research projects/infrastructure must also use these criteria to inform funding decisions.

1. All funding agreements must include a clear plan for funding sustainability and include step down funding arrangements where required.
2. Unless otherwise authorised in writing by an authorised delegate, all research grant income and expenditure are recorded in a research Internal Order Number (ION) to enable audit and review.
3. Funding options are explored which means that evidence must be provided that appropriate/relevant non-MSH funding options have been investigated.
4. There are clearly identifiable and measurable outcomes in that all potentially fundable research proposals must demonstrate to MSH that there is:
    - a focus on health, social and economic outcomes that can deliver measurable improvements to the community; and
    - a clear link to the priorities and objectives of MSH and Health Service strategic plans.
5. There is evidence that the research team has a proven capacity to deliver outcomes through:
    - applicants demonstrating experience of delivery of research outcomes on time and on budget.
    - novice applicants being mentored by experienced supervisors who can demonstrate delivery of research outcomes on time and on budget.
    - the research project/program has a comprehensive budget.

- where continued funding is requested, applicants must provide research project specific historical funding expenditure versus research outcomes data along with a comprehensive budget and project plan for ongoing funding - Business Manager and/or Cost Centre Managers are able to assist in the development of research budgets and project plans.

6. The research is feasible, builds capacity and strengthens MSH's research base as it:
    - involves collaboration and partnerships between MSH, industry, research institutions and cross disciplinary boundaries and provides opportunities to leverage funds which will build on MSH's investment in research.
    - promotes a competitive strength with a realistic possibility of developing and commercialising new knowledge and health service delivery models that give MSH a competitive and sustainable advantage nationally and/or internationally.
    - explores possibilities for developing and commercialising new knowledge and health service delivery models that give MSH a competitive and sustainable advantage nationally and/or internationally.
    - includes a plan to communicate or otherwise make research outcomes available to the public.

2.1.2 Type and duration of support

There is a requirement in all research projects to identify all direct and indirect or in-kind costs associated with the proposal and have a comprehensive budget. Funding and support from MSH and/or universities, research institutions or commercial/third-party entities can be provided as:

- a direct cash contribution or capital investment
- provision of in-kind expertise and services; or
- a mixture of direct cash, capital and in-kind support.

Principal Investigators and researchers should consider expected future funding opportunities which may include the amount of revenue not yet received, supported by a third-party document stating the amount and period, and for which there is reasonable assurance of collection.

2.2 Research costs

Research costs could include, but are not limited to (note- this list is intended to give examples and is not intended to be a comprehensive list of items that will be funded):

- Consumables: stationery, printing costs associated with questionnaires, case report forms, postage, sample transportation/packaging/tracking etc. Laboratory consumables needed specifically for the research project, such as reagents, test kits, pipette tips, plastic, and glassware. Single use clinical items, such as blood tubes, swabs etc.
- Devices and drugs: this includes any materials needed to undertake the research project including placebos. Fees from registration with the Therapeutic Goods Administration for studies being conducted under the Clinical Trials Notification (CTN) Scheme, should also be included as applicable.
- Equipment and other capital items: this includes items having a useful life of more than one (1) year. For internally funded projects the MSH definition of capital cost will be used, for externally funded research projects the limit and terms specified by the funding body will be used. This also includes the provision of computers, laptops and other IT related hardware that is required to

support the research project. Software should be included where the cost of this exceeds the funding limits described above.

- Insurance: some clinical trial sites require specific research project insurance; the cost of this should be met from research funding.
- Principal Investigator and research team costs: (externally funded research projects) the time that the Principal Investigator will spend on the research project, providing leadership through team meetings, research project discussions with team members, time taken to perform additional patient evaluations and tests, oversight, and authorisation of case report forms, etc.

Principal Investigator time is not usually funded for internally funded research projects, however, the MSH delegate may agree to fund investigator time in exceptional circumstances where the research project warrants significant direct investigator input where this cannot be undertaken through other means such as locum support, and where the Principal Investigator's input is undertaken outside of normal working hours.

For example, a blinded evaluation of patient images that are additional to those undertaken as part of patient care could qualify for this support.

- Manpower: research assistant(s), research nurses, administrators, scientists, technicians and project managers etc.
- In-kind support: to be costed as accurately as possible.
- Overhead costs: all externally funded research projects should include institutional overheads, for many research grant funding bodies the level of overheads will be determined by the awarding body. For commercial research projects overheads of up to 30% can be sought, the actual level will be agreed through the negotiation processes. Research finance is authorised by Business Managers and/or Cost Centre Managers to agree overhead rates for commercial research projects on a case-by-case basis.
- Indirect Costs: applicable for the externally funded research projects. These are general costs that cannot be clearly identified with a specific research project budget but are nonetheless necessary to the research project. For example, costs of maintaining a building, utilising different facilities and administrative expenses required throughout the research project period. Indirect costs, based on rates approved, should be included in the approved research project budget. These are then charged to specific contract/research grant accounts in accordance with the terms of the agreement. Indirect budget is disbursed (in accordance with approvals from the delegate) according to the effort level of various departments involved in the research project management and a portion of which is deposited in MSH cost centres for supporting MSH's unbudgeted research programs and workshops and also to provide financial backup for any external research project that is running short of funds due to unforeseen issues (in accordance with approvals from the relevant delegate).
- Patient travel: any costs associated with the patient travelling to the research centre location. These could be the costs associated with standard care visits or just those that are additional to standard care, the categorisation of the visit type and associated costs should be clear in the research project budget request. The reimbursements available will be in accordance with the finance policies in force at the time that research project approval is given. Any reimbursements made to patients as a result of their participation in clinical research must be declared to the HREC as possible inducements to research project participation.

- Open access publication costs and conference fees: (externally funded research projects) these should be included in the research project costing for externally funded research projects. Internal research projects costings should not include these fees, but these costs are covered separately.
- Research evaluations: the costs associated with patient/participant and/or laboratory tests or analyses; the costs associated with the development of new analyses for the purpose of conducting the research project. This could include, for example patient imaging tests, safety analyses etc.
- Translation costs: the costs associated with translating any research project documentation such as Participant Information and Consent Forms (PICFs), research protocols and case report forms etc.
- Travel costs: the costs associated with collaborating with external researchers for the conduct of the research project. For external research grants the costs associated with travel for conference presentations must be included in the research grant application (if allowed by the research grant awarding body).
- Metro South Research administration review fees (encompassing both HREC and Site Specific Assessment (SSA) fees).

Budgets for all research projects are to be developed and approved by the relevant Business Manager and/or Cost Centre Manager. Research project budgets should be adjusted according to the Consumer Price Index (CPI) on the anniversary of the contract execution date. Research that is funded, regardless of the source of funding, should have an individual cost centre number or other means of identification for auditing purposes.

2.2.1 Additional costs

On occasions there are costs associated with an activity that would happen as part of the standard of care for patients/participants, but additional costs are incurred because the activity is associated with research, for instance:

- Drug supply: the supply of drugs for clinical trials can involve additional steps to the supply for standard care, these might include; additional packaging to ‘blind’ drug supplies, operation of randomisation processes, development, storage and use of code breaks, recording of batch numbers and maintenance of an audit trail of research project dispensing, reconciliation of drug returns and drug dispenses.
- CT/MRI imaging: may need additional Quality Assurance (QA) steps in order to ensure uniformity across all research project sites.
- Blood tests: may be required outside of normal service hours so that patient/participant safety is assured.
- Additional medical or nursing cover: may be required to ensure patient safety.
- Archiving costs: for patient records to ensure that source documentation is maintained so that the research project audit trail including any deficits is complete. A deficit is the balance in a research project fund when the expenses recorded exceed the revenues recorded.

2.2.2 Documentation

In relation to research funding, budgets and infrastructure support documentation pertains to all records, in any form (such as written, electronic, magnetic and optical records; and scans, x-rays, and electrocardiograms, etc) that contain information pertinent to the activities under review. Relevant records include but are not limited to:

- research subject electronic health records;
- MSH administrative documentation such as finance, research contracts/agreements and HREC documents;
- research site documentation such as research project documents, scheduling, assignments, CV's and lab notebooks; and
- external service provider documentation such as quality records, production, shipping, and Standard Operating Procedures (SOPs).

2.2.3 Research budgeting

Effective budgeting ensures that resources are allocated appropriately for research-related expenses, such as participant recruitment, data collection and analysis, equipment, training, and dissemination of research findings. Proper budgeting ensures that ethical considerations, such as obtaining informed consent, protecting participant confidentiality, and addressing any potential risks, are adequately accounted for and addressed.

A budget spreadsheet template may be accessible from relevant Business Managers and/or Cost Centre Managers. Following discussions between the Principal Investigator and the Chief Finance Officer, MSH and/or delegate, funds retained by the Health Service will be allocated for that financial year within the department of the individual Principal Investigator to be used for the following purposes:

- further research; or
- training and development of research staff (additional to require training); or
- publication or presentation of the research results; or
- other research purposes agreed to by the Principal Investigator and the Chief Finance Officer, MSH and/or delegate.

The above also applies to both pre-existing research funds transferred from General Trust Funds to Health Service Operating Funds.

2.3 Financial management of research

This section of the procedure applies to the management of all funds received by MSH, or MSH employees, in relation to research, irrespective of whether identified as a fee-for service, funded research (e.g., NHMRC, Queensland Cancer Fund (QCF), Australian Research Council (ARC) and/or research for higher degrees) or as a donation or bequest. Management of all research project funds and revenue within MSH must be compliant with this procedure and applicable legislation.

To comply, revenue in relation to research projects (e.g., sponsored trials, ARC or research for higher degrees), which is of a fee-for service nature must be managed via MSH research fund cost centres and not General Trust Funds (GTFs). However, funding received as bequests and donations must remain in, and be administered via, General Trust Funds.

Budgets for all commercially sponsored research are to be developed by the researcher and Business Manager, in negotiation with the relevant supporting departments. Funding received for all new research projects that are of a ‘fee for service nature’ will be managed by the relevant departments Business Manager and/or Cost Centre Manager.

Business Managers and/or Cost Centre Managers will undertake the steps to ensure compliance, however, it is the Principal Investigator’s responsibility to ensure that all incoming research funds for their

research projects (excluding those from bequests/donation) are identified appropriately and placed into quarantined research cost centres with the departments operating funds.

Regular ION reviews must be carried out by MSH to ensure that research IONs are properly set up with the correct fund code. As part of the reporting process, MSH is to report on research funds in financial statements.

MSH intent is that operational funds allocated for patient care are not diverted to research. In line with this, transfer of operational funds to research cost centres is not permitted. Budget over-runs in research cost centres must be met by research funds within the department/division/facility.

2.3.1 Site Specific Assessment (SSA)

The SSA must detail the actual monetary and/or in-kind cost of the research project being conducted at a MSH site or facility as well as approval by the Head of Department and relevant Business Manager and/or Cost Centre Manager. Refer to MSH work instruction WI2023-301 Site specific assessment of research for more information.

2.3.2 Payments to service providers

The principle is that any provider of services for research purposes must only be paid once for any research activity, so activities funded through research grants cannot also be funded from other sources – whether internal or external grants or allocations (i.e., no double-dipping).

The same principle applies to providers of services to patients participating in research, which ensures any costs that are met through other payment provisions (such as health insurance) are not also charged to research.

Note there are occasions where an activity that is provided as standard of care incurs additional costs for the provision of the service in the research setting; these additional costs should be met from research funding (see below for more information). Researchers must note special conditions for MSH Study Education and Research Trust Account (SERTA) funds.

2.3.3 Payments to research project personnel

The same principle applies to research project personnel time spent on research projects. Research project personnel cannot be paid twice for the working the same hours on research projects and their salaried activities. That is, they cannot get paid through their usual salary and through research grant incomes for work undertaken during normal working hours.

Principal Investigators must provide evidence that any paid activities, are undertaken outside of normal working hours in order to receive payment in addition to their normal salary (this includes investigator and supporting staff payments). Consideration should be given to conflicts of interest in accordance with MSH procedure PR2023-411 Research excellence.

2.4 Funding sources – specific requirements

Research grant funded research projects should be costed so that they comply with the requirements of the relevant funding body. Metro South Research will decide on a case-by-case basis, the management of discrepancies between MSH policies and procedures and those of the funding body. Business Managers and/or Cost Centre Managers will perform research project costing, budget review and finalisation in coordination with relevant requirements. Refer to MSH work instruction WI2023-294 Research grants administration for more information.

2.4.1 Externally funded research projects

External research grant applications that have the requirement of matched funding or a cash (Recipient or Partner Organisation) co-contribution from MSH should demonstrate the potential to build research capability, increase research capability and deliver measurable improvements in health care for the MSH community through excellence in translational research.

MSH SERTA Committee may consider requests for support in the instance where an external research grant application has the requirement for the Recipient or Partner Organisation to match funding by the funding body or commit a cash co-contribution.

Commercially funded research projects should be fully costed, and the commercial income should be sufficient to cover these costs so that the research project can be undertaken. Please note a commercial/industry-sponsored research contract is an agreement to fund research from a for-profit entity. These are distinguishable from research grants in how sponsorship, publication, liability, data ownership and intellectual property are addressed.

Funding is not usually provided to ‘prop up’ externally funded research projects. In exceptional cases (such as where the external body excludes certain costs) the MSH delegate, in consultation with the relevant Business Manager and/or Cost Centre Manager, may agree to provide internal funding support – this should be agreed in advance of any research grant submission or research contract agreements being made. If the funding is to be obtained through a commercial (e.g., pharmaceutical company) or non-commercial (e.g., NHMRC, ARC, Queensland Nursing Council or Queensland Community Foundation) sponsor a MSH research ION with the funding type ‘STR’ is mandatory. The research contract must be signed by the MSH delegate before the research ION is setup.

Where research revenue is from a source other than commercial or non-commercial sponsorship it is still possible for these funds to be placed in a designated research cost centre with a nominated research internal order number (ION), however the funding type must match the source (i.e., Commonwealth Funding).

Refer to MSH work instruction WI2023-302 Research contracts and study execution for more information.

2.4.2 Internally funded research projects

MSH wishes to support the development of research, so funding is provided to enable researchers to develop their research portfolio, publish their research findings and gather pilot data to support external funding applications.

Any funding requested for internal research projects must be approved by the MSH delegate before the research project commences. The HSCE has delegated the approval of budgets up to $10,000 either in-kind or funded to the Manager, Research Integrity and Compliance for low risk research projects.

Funding will not be provided for research projects that start prior to HREC approval. Budgets will not usually be agreed for activities that start before the budget has been approved. Funds receipted must be spent within the same financial year and cannot be rolled over.

2.5 Open access publication

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.

MSH is a generator of new knowledge and contributor to scholarly outputs. It is committed to ensuring that all outputs are disseminated as broadly as possible, where legally possible. This will allow MSH to

adhere to open-access policies of state, national and international granting bodies and also ensure the results of research are made available to the public, industry and researchers worldwide, for the benefit of society.

Open access compliance requirements of funding bodies can vary significantly, and all MSH authors are contractually bound to comply with the relevant open access policies of their funding contracts where those requirements are more restrictive than this procedure. Research grant or contractual requirements may extend to the data underlying/supporting a publication being openly accessible.

2.5.1 Reporting prior to publication

Researchers are encouraged to publicise their research findings in both the academic and wider communities. However, as a general principle, research findings should not be reported in the public media before they have been reported to a research audience of experts in the field of research - preferably by publication in a peer-reviewed journal.

Where research that has not yet been subjected to peer-review is privately reported, researchers must disclose fully the unpublished status of the work and the peer-review mechanisms to which it will be subjected. It could be interpreted that some lower quality journals have set up processes to extract fees from authors, to publish material that would not be accepted elsewhere, under the guise of ‘open access publication’.

2.5.2 Identification of an appropriate eligible open access journal publications

To be eligible and in order to seek reimbursement of reasonable article processing fees/charges from MSH SERTA, the following criteria must be met:

- The journal venue of publication must be an established open-access journal, that is, a journal that does not charge readers or their institutions for unfettered access to the peer-reviewed articles it publishes.
- The journal Journals with a hybrid open-access model or delayed open-access model are not eligible.
- To be eligible, a journal must meet these additional requirements:
- It must be a full (not hybrid) open-access journal.
- The journal must be listed in the Directory of Open Access Journals (DOAJ), unless the journal is too new for DOAJ eligibility.
- The publisher must be a member of the Open Access Scholarly Publishers Association or adhere to its Code of Conduct.
- The journal must make articles open access under a Creative Commons license.
- The journal must have a publicly available article-fee schedule and the fee requested by the MSH author must conform to that standard fee schedule.
- The journal must have a policy to waive or substantially discount fees in case of economic hardship.

2.5.3 Open access publication costs

Open access publication costs must be included in research budgets and in general, funded from the funding source that supports the research project.

For externally funded research projects, the costs associated with the publication should usually be met from the external funding source. Payments will be made in accordance with the external funding organisation's policies and procedures.

MSH Research Support Scheme (RSS) applicants should include provisions for 'Open Access Journal Publication' as part of their budget (where relevant).

For other internally funded facility/service driven research projects, MSH delegates may consider and approve direct payment or reimbursement of reasonable publication processing fees/charges.

MSH SERTA funds to support open access publication are available to any MSH employee for articles resulting from their research activities, only in situations where there is no alternative funding is available.

MSH researchers, seeking reimbursement of reasonable article processing fees/charges for articles authored or co-authored by MSH researchers published in eligible open-access journals must refer to MSH work instruction WI2022-226 Open access journal publications for more information.

3.0 MSH grants administration services

Effective research grant administration supports MSH's ability to remain internationally recognised as a leader in biomedical and clinical research. Furthermore, research represents one of the most important avenues to increase its knowledge base.

Research grant funding is awarded to researchers working on individual research projects for the purpose of advancing research in their field of expertise. MSH may administer research grants from internal and external sponsoring/funding entities/organisations for approved research projects.

A grants administration service provides vital support to researchers by simplifying the funding application process, identifying suitable funding sources, assisting in proposal development, offering financial guidance, ensuring compliance, and providing ongoing post-award management support. By relieving researchers of administrative burdens, the service enables them to focus on their research, increases their chances of securing funding, and enhances the overall efficiency and effectiveness of the research enterprise.

3.1 Research grant applications

Principal Investigators, researchers and research student supervisors are responsible for undertaking appropriate planning prior to developing research grant applications. It is imperative to focus on research significance, scientific quality and feasibility, including the accurate identification of resources and expertise required to enable research to be conducted in a safe, responsible, ethical and efficient manner.

Principal Investigators and research student supervisors are responsible for:

- ensuring appropriate development and review of research grant applications;
- reading eligibility rules and guidelines and ensuring that research grants are submitted in accordance with the sponsoring/funding entity/organisation's requirements;
- consulting with the relevant Business Manager/Finance Officer and/or Cost Centre Manager to develop research grant application budget;
- obtaining appropriate statistical and other advice relevant to the research grant application; and
- obtaining all required authorisation prior to submission of research grant applications.

3.2 Grant application certification and letters of support

MSH research grant application certification process is aimed at ensuring compliance with MSH corporate requirements and application guidelines (i.e., it is not a review of the quality of the research or application). Refer to MSH work instruction WI2023-295 Letters of support for more information.

3.3 Multi-Institution Agreement (MIA)

For multi-centre research projects, the NHMRC requires that all research grants with chief investigators (CIs) collaborating with CIs from other institutions or organisations (including international organisations), have a collaborative agreement in place, even if there are no funds being shared. This agreement is written as part of a NHMRC Multi-Institutional Agreement (MIA). Refer to MSH work instruction WI2023-302 Research contracts and study execution for more information.

3.4 MSH approval and authorisation

Principal Investigators are responsible for ensuring appropriate approval and authorisation of all research grants. It is important for researchers to note that research grant payments will not be made unless ethics and SSA approval is in place and forwarded to Metro South Research for record keeping purposes.

It is responsibility of the researcher to ensure that the research project remains compliant with ethics and SSA requirements and participates in monitoring when requested by Metro South Research.

3.4.1 Metro South Research review

During the review process the Metro South Research will ensure:

- the HREA and SSA approval is related to the research described in the research grants application;
- research grant funds are only spent on sponsoring/funding entity/organisation approved items; and
- that expenditure only occurs in the research granting period.

3.4.2 Rapid review

A Principal Investigator may request support from the MSH SERTA Committee for external research grant applications that have a cash (Recipient or Partner Organisation) co-contribution as a requirement for submission.

This process is facilitated by the Metro South Research Support Coordinator via the MSH Research Grants Committee, which may convene a Rapid Review Sub-Committee (if required). The Rapid Review Sub-Committee will include no less than three (3) reviewers who are free of conflict of interest and will provide a recommendation to the MSH SERTA Committee. Where practical the sub-committee will include a subject matter expert.

3.4.3 Certification

Official research grants must be certified by MSH. This certification is provided by Metro South Research, supported by the signatures of the research grant recipient and the delegate.

Each individual research project grant is allocated a specific ‘research project grant number’ and a central records file is retained by Metro South Research. Research project grant records are set up to record initial revenue and expenditure budget, the net effect being zero. Amounts entered are in accordance with the original research grant agreement and amended for any subsequent official variations.

3.5 Financial management of research funds

Financial management of all research funds in MSH must be in accordance with the MSH Financial Management and Practice Manual (FMPM).

All sponsoring/funding entities/organisations have their own funding rules and conditions however there are four (4) key conditions which pertain to research grant administration:

- the research project must have appropriate approvals (including HREA and SSA approvals);
- research project funds can only be used for the research described in the research grant application and therefore spent on items listed in the approved budget;
- research funds can only be used during the research granting period; and
- if there are unspent funds at the end of the research granting period, they must be returned to the funding body.

3.5.1 Funding and financial management

MSH principal investigators, and business manager/financial officer and/or cost centre managers are responsible for ensuring:

- that research that is funded, regardless of source of funding, has an individual cost centre, internal order number (ION) or other means of identification and tracking funds.
- that adequate funds per research project are maintained before expenses are approved.
- a review over all the current research project balances to ensure future obligations can be met is performed.
- where relevant, appropriate action is taken to remedy research projects with deficit balances.
- monitoring controls are enhanced to review research cost centre balances on a periodic basis for timely identification of dormant or overdrawn accounts.
- guidance on the treatment of surplus and the approval process is provided for transfer of funds to another research project.
- that amounts stated in the various monitoring reports (e.g., progress report and acquittal) are accurate and can be verified to accounting records.

3.5.2 Use of research grant funds

Principal Investigators, researchers and research student supervisors have primary responsibility for ensuring all research grant funds are used appropriately. In particular, use of research grant funds must be in accordance with all legislation, standards and guidelines relevant to the research activities. Additionally, the use of research grant funds must be in compliance with:

- the research protocol approved by a HREC.
- the SSA approved by the Metro South Research Governance Office.
- the relevant research funding agreement/s, please see the MSH FMPM.
- MSH policies and procedures pertaining to conflicts of interest.

Failure to comply with this procedure and related research management procedures may amount to research misconduct on the part of the responsible individual. Refer to MSH procedure PR2023-411 Research excellence for more information.

3.5.3 Goods and Services Tax (GST)

MSH must ensure that GST is consistently treated for research grant income received and paid to external parties and adequate supporting documentation is maintained in relation to salary and wages costs.

3.5.4 Financial acquittals

The MSH business manager/financial officer and/or cost centre manager will also assist researchers in the preparation of financial acquittals for funding bodies and other funding partners in accordance with the relevant research funding agreement. Please see the MSH FMPM for more information regarding the payments and acquittals process for research activities.

3.6 Reporting

Principal Investigators, researchers and research student supervisors have primary responsibility for ensuring all funding body reporting requirements are met within prescribed timeframes.

On request from the researcher and with sufficient notice Metro South Research may be able to facilitate a review of progress or final reports, aimed at improving the quality of the report. Progress and final reports will be stored as official records with research grant documents.

4.0 Metro South Health Research Support Scheme

The MSH RSS is a competitive internal research grant application and assessment process through which research projects are awarded funding via MSH SERTA, the PA Research Foundation, and collaborating organisations.

The MSH RSS has consistently supported high quality research since it was established in 2012. The MSH RSS was initially formed by consolidation of research funding from the Princess Alexandra Hospital (PAH) Private Practice Trust Fund (PPTF) and the PA Research Foundation.

Following the establishment of the Metro South Hospital and Health Service in 2012, as well as the MSH SERTA in 2014, the RSS was broadened to include all MSH facilities and services, as well as partner institutions. The MSH RSS is administered by Metro South Research, MSH.

Applications to the scheme open annually and Metro South Research is responsible for the management of the process in accordance with MSH work instruction WI2023-296 Metro South Health Research Support Scheme. Metro South Research notifies successful applicants of the outcome of their application via a Notification of Award email and a formal letter. The formal letter will include the Conditions of Award including reporting requirements and information regarding how to accept the awarded funds.

4.1 Objectives

The MSH RSS's objectives are aligned to the Metro South Research Strategy and as defined from time to time in the RSS Funding Guidelines for the relevant year/s.

MSH RSS process is designed to provide applicants with valuable experience in participating in a competitive process. It is envisaged that this experience can then be applied to other external research grant schemes, improving the capability of staff in securing external research grants.

4.2 MSH RSS funds

The MSH RSS is a joint initiative funded by the MSH Study, Education and Research Trust Account (SERTA) and any other funding entities/organisations that wish to participate in the scheme.

The Metro South Research Support Coordinator (MSRSC) must obtain appropriate delegate approval for the allocation of funds to the MSH RSS. The total value of research grants for the year (based on the value of each research grant and the number of research grants) will be developed following consultation with the Executive Director, Metro South Research and MSH Research Council, and endorsed by MSH Research Grants Committee.

In addition to the funds allocation for research grants, the expenses associated with managing the application, assessment, award and ongoing maintenance of the MSH RSS research grants must be identified including:

- probity advice;
- advertising;
- miscellaneous expenses for an assessment committee (eg catering);
- awards ceremony expenses (venue, equipment, food and materials, entertainment, cleaning); and
- other expenses as determined from time to time.

Based on the total grants value and additional costs, a request for funds will be made to the appropriate delegate:

- SERTA funds — the Chair of the MSH SERTA Committee.
- PA Research Foundation funds — PA Research Foundation CEO.
- Other sponsoring/funding entities/organisations — nominated delegate in accordance with funding agreements.

Available funds from each source will only be considered to be confirmed when obtained in writing.

4.3 Research funds

Access to research funds is transacted between the funding body (eg MSH SERTA; PA Research Foundation; collaborating organisation) and the business unit/department/division in which the grant recipient is employed. Recipients are responsible for initiating award payments. Financial transactions are the responsibility of business managers and/or cost centre managers.

4.4 MSH RSS funding guidelines

The MSH RSS funding guidelines outline key information relevant to governance and operational requirements of the MSH RSS. Funding guidelines for the relevant year are made available to all MSH researchers and applicants and details key information such as:

- MSH RSS methodology;
- eligibility and exclusion criteria;
- application process;
- key dates and milestones;
- process for submitting an application;
- relevant contact details;
- application requirements including supporting documents, evidence and budget;
- research fund categories;

- explanation of the assessment and evaluation process; and
- MSH research committee decision-making criteria and weighting.

4.5 Criteria for the approval of funding

The approval of funding for research funds will be subject to the following criteria:

- Proposals must be project specific.
- Applications must contain a detailed budget justification in line with the budget proposal (ie money cannot be spent on unspecified or unrelated items).
- Research funds will be available for the period of the offer, with any unspent monies to be returned to the relevant funding body. The research fund end date may be extended if written in the funding rules.

The awarded funds must only be spent on the research described in the funding application.

4.6 Goods and Services Tax (GST)

MSH must ensure that GST is consistently treated for research fund income received, paid to external parties and adequate supporting documentation is maintained in relation to salary and wages costs.

4.7 MSH RSS research fund categories

The MSH RSS may provide research funds in a range of categories, as approved by the funding bodies and documented in the funding guidelines for the relevant year. Research fund categories may be updated or changed on an annual basis. Researchers must refer to the MSH RSS funding guidelines for current information for that particular year.

4.8 MSH RSS application forms

MSH RSS research funds are competitive and therefore it is in the best interest of the applicant to prepare a quality submission. Applications must not exceed the stipulated page or word limits and must be precise.

4.9 MSH RSS evaluation plan

The MSH RSS evaluation plan outlines key information relevant to governance of the assessment and evaluation process. It is made available to MSH research committee members and nominated assessors when they are sent application forms. It outlines the research fund assessment criteria, weighting and assessment process.

4.10 MSH RSS research fund assessment criteria

The MSH RSS assessment is based on a number of criteria, the weightings of which are varied dependent on the category of research fund. Research fund assessment criteria are documented in the funding guidelines for the relevant year may be updated or changed on an annual basis. Assessors must refer to the evaluation plan for current information for that year.

4.11 Assessment criteria weighting by MSH RSS research fund category

Each of the assessment criteria will be scored by the review panels as documented in the funding guidelines for the relevant year.

4.12 Special considerations

Track records will be assessed relative to opportunity.

Preference may be given to applicants demonstrating convincing ways in which their future research can be supported via external sources of funds on an ongoing basis.

Performance in relation to previous RSS grant use and reporting may be considered. Preference may be given to previous recipients who have exemplified compliance with RSS grant requirements, and failure to submit reports in accordance with requirement may disqualify applicants from future grant offers.

At the margin, priority will be given to research projects that do not involve conference travel as a major expense item.

4.13 MSH RSS awards event

A MSH RSS awards event is coordinated on an annual basis by the Metro South Research Support Coordinator. Applicants will be notified of the details pertaining to this event through MSH communication and email channels.

4.14 MSH RSS grant recipients

Successful MSH RSS grant recipients are sent a Notification of Award and formal Letter of Offer. This letter contains Conditions of Award, which must be accepted and signed by the recipient, the co-investigators/supervisors named on the application, and the head of department/division (or direct line manager) in which the research will be conducted.

Recipients are responsible for ensuring the following details (including spelling) are correct:

- recipient name;
- research project title; and
- funding type (Novice Researcher, Project Grant, Program Grant etc).

Recipients are also required to note which funding body is supporting the award (MSH SERTA or PA Research Foundation.) The funding body will affect the manner of payment. For awards funded by MSH SERTA, the transfer of funds must occur through the Business Manager and/or Cost Centre Manager of the department/division within which the recipient's research ION resides.

For awards funded by the PA Research Foundation, the transfer of funds may occur through either the Business Manager and/or Cost Centre Manager of the department/division within which the recipients research ION resides OR a Finance Officer of the academic partner university with which the recipients are affiliated.

The recipient must return the signed Conditions of Award to Metro South Research by the designated due date. Note that award payments can only be made if this signed document has been received by the Metro South Research Support Coordinator.

The recipient will then be instructed by the Metro South Research Support Coordinator to initiate the award payment by providing their Business Manager and/or Cost Centre Manager (or their delegate) with the following:

- Letter of Offer (signed by the Executive Director, Metro South Research, and a representative of the recipient's funding body);

- completed Grant Payment Request Form; and
- a copy of the budget submitted with their RSS application.

The direct journal request/tax invoice is raised by the Business Managers and/or Cost Centre Managers and forwarded with the Letter of Offer and the completed Grant Payment Request Form to the relevant funding body.

Glossary

Agreement	An agreement used in a research setting is a formal and documented understanding or contract between parties involved in research. It outlines the terms, conditions, rights, and responsibilities related to the research project, such as collaboration, data sharing, confidentiality, funding, or any other relevant aspects. These agreements ensure clarity and compliance among involved stakeholders.
Biosafety	Biosafety refers to the principles, practices, and measures implemented to ensure the safe handling, containment, and control of biological materials and agents to prevent accidental exposure, release, or environmental contamination, thereby safeguarding human health and the environment.
Corporate governance	Corporate governance is the system of rules, practices, and processes by which an organisation is directed and controlled, involving the balance of power among its various stakeholders, such as management, customers, patients, financiers, government, and the community. The aim is to ensure that the organisation operates ethically, transparently, and in the best interests of all its stakeholders.
In-kind support	In-kind support refers to non-monetary assistance provided in the form of goods, services, or resources rather than direct financial aid.
Risk-based approach	Involves assessing and managing activities, decisions, or processes by considering potential risks and tailoring strategies to mitigate those risks effectively. It prioritises resources and actions based on the level of risk, aiming to optimise outcomes and enhance overall decision-making.