# Research administration and compliance

## PURPOSE

This procedure describes the processes for research administration and compliance to ensure the effective management and oversight of research activities in Metro South Health (MSH).

## OUTCOME

The intended outcome of this procedure is to:

- Promote the consideration of ethical implications (including scientific considerations) of human research, the appropriate review of research in accordance with national frameworks and ensure appropriate action is taken so that research is conducted in an ethical and scientifically robust manner by upholding principles outlined within the PL2023-92 Research Policy.
- Outline the MSH-wide process to ensure:
    - All research projects undertaken in MSH or involving MSH participants and/or resources are submitted for ethical review and approval.
    - Research governance review is undertaken, including Site-specific Assessment (SSA) of each research project. Site-specific authorisation includes contractual and financial management of research and authorisation by the relevant authority.
    - Consistency in monitoring research activities to maintain compliance with relevant regulations, laws, and guidelines related to informed consent, confidentiality and protection of human participants. It also includes requirements when collaborating with external organisations and individuals including joint research projects and data sharing.
    - Maintain compliance with relevant legislation, international and national guidelines, policies, procedures and standards including but not limited to National Clinical Trials Governance Framework (NCTGF) to safeguard and protect participants, ensure scientific validity, comply with regulations, build public trust, and mitigate legal and liability risks associated with clinical trials in MSH.
- Uphold principles outlined within Attachment 1: Research Administration and Compliance Handbook.
- Outline research administration and compliance research administration fees within Attachment 2: Schedule of Research Administration Fees.

## 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

## 1. RESEARCH PLANNING AND PROPOSAL DEVELOPMENT

- Researchers may identify research areas of interest and develop research proposals and protocols and seek collaboration with other researchers or research institutions.
- Researchers should also consider partnering with consumers as part of the research planning process.
- For more information refer to MSH guidelines:
    - GL2021-75 Partnering with consumers in research
    - GL2023-97 Aboriginal and Torres Strait Islander health research

### 1.1 Develop the research proposal, protocol and study documents

- Proposal and protocol development may involve literature reviews, research design, budgeting, and identification of funding opportunities.
    - A **research proposal** is a document prepared by researchers to outline the planned research project. It is usually submitted to funding agencies, research institutions, or academic committees to seek approval and secure resources, such as grants or permissions, necessary to conduct the research.
    - A **research protocol**, also known as a research plan or study protocol, is a detailed document that provides a roadmap for carrying out a specific research project. It is typically developed after the research proposal has been approved and serves as a guide for the research team during the implementation phase of the project. Preparation of a research protocol is mandatory. Researchers may utilise MSH research protocol guides and templates however, it is important to note that not all fields are required.
- Researchers may also need to develop an appropriate Participant Information sheet and Consent (PICF) and other associated supporting documents relevant to the research project.
- For more information refer to MSH guidelines:
    - GL2023-99 Planning a research project
    - GL2023-100 Research Participant Information and Consent Form (PICF)

### 1.2 Risk assessment and management

- Researchers must continuously assess risk as part of research as it's essential to prioritise participant safety, uphold ethical principles, ensure informed consent, guide study design and methodology, comply with regulations, enhance research quality, and maintain researcher and institutional reputation. It is also a fundamental aspect of responsible and ethical research conduct.
- Refer to MSH work instruction WI2023-292 Assessing and managing risk in research for more information.

### 1.3 Data risk assessment and management

- Researchers must consider data collection methods, the types of data required, data linkages required and sources of data when planning and starting a research project.

- Data risk assessment and management in research involves evaluating potential risks associated with the collection, storage, and handling of research data. It aims to identify and mitigate threats to the confidentiality, integrity, and availability of data and helps researchers anticipate and address privacy concerns, data breaches, and other risks to ensure ethical and secure research practices.
- Refer to MSH work instruction WI2023-289 Data and privacy for more information.

## 2. FUNDING AND GRANT APPLICATIONS

### 2.1 Funding and budgets

- Principal Investigators must identify and document the financial support needed for their research project.
- Any research project that requires financial support (from any source including actual financial support or in-kind support) must be supported by a research project costing and budget (Health Service Directive: Research Ethics and Governance Directive QH-HSD-035:2023).
- Research costs can include clinician/researcher time, use of MSH facilities and resources, printing, postage, consumer engagement, access to internal or external expertise (e.g., biostatisticians), diagnostic procedures and publication.
- Refer to MSH procedure PR2023-412 Research support and management for more information.

### 2.2 Metro South Research Administration Fees

- Prior to submitting a HREC or SSA application, or amendment, researchers must review all MSH research administration fees as outlined in Attachment 2: Schedule of Research Administration Fees (e.g., HREC and SSA review).
- Researchers must include research administration fees as part of research project budget preparation as relevant.
- The Principal Investigator/Coordinating Principal Investigator (PI/CPI), for multi-centre research projects, or research project coordinator/contact person must provide the invoicing details with their HREC/SSA submission. These details must be provided on Attachment 3: Metro South Research Administration Fees Form.
- The PI/CPI and/or relevant research project contact person (where nominated) will be contacted to obtain any missing details.
- For more information regarding principles which guide MSH in the management of research please see Attachment 1: Research Administration and Compliance Handbook and Researcher User Guide – Queensland Health July 2023.

### 2.3 Grant Applications

- Researchers must also identify appropriate funding opportunities based on their research proposal.
- The research proposal can be used to prepare grant applications, which include a detailed description of the research project, budget, and any additional documentation required by the funding body.
- Grant applications are submitted to funding agencies or institutions following their guidelines and deadlines.

- Refer to MSH procedure PR2023-412 Research support and management for more information.

## 3. ETHICAL AND SCIENTIFIC REVIEW OF RESEARCH

- Researchers must submit their research protocols to the relevant Human Research Ethics Committee (HREC). In Queensland this is done via a Human Research Ethics Application (HREA) through Ethics Review Manager (ERM).
- The HREC reviews the proposals to ensure compliance with ethical standards, human subject protection, and the welfare of participants.
- Researchers may need to make revisions based on feedback from the HREC before obtaining approval.
- Refer to MSH work instruction WI2023-299 Ethical and scientific review of research for more information.

### 3.1 Exemptions

- Some studies may be exempt from ethical review.
- Refer to MSH work instruction WI2023-300 Exemptions from research review for more information.

## 4. SITE SPECIFIC ASSESSMENT (SSA)

- Researchers must submit a SSA application via the SSA Form on ERM with relevant study documents including but not limited to:
    - Research Contracts and Study Execution Form (RCASE Form)
    - HREC approval letter
    - Supporting documentation - updates/changes to relevant document.
- Refer to MSH work instruction WI2023-301 Site specific assessment in research for more information.

### 4.1 Research contract/agreement (as applicable)

- Research contract/agreements are typically required when a third (3rd) party entity as in commercially sponsored study/non-for-profit organisation is involved in the collaboration or when a university student is undertaking research under their university affiliation as part of the research team.
- Refer to the following MSH work instruction and guidelines for more information:
    - WI2023-302 Research contracts and study execution
    - GL2023-101 Research contract clauses
    - GL2023-102 Use of electronic signatures in research contracts

### 4.2 Clinical Trials

- There are additional requirements for clinical trials in MSH including if requesting for MSH to act as Sponsor.
- Refer to the following MSH work instruction and guideline for more information:
    - WI2023-303 Metro South Health sponsorship of Clinical Trial Notification (CTN) scheme trials

- GL2021-77 Clinical trials.

### 4.2 PowerTrials

- PowerTrials is the ieMR research support module that supports visibility of research activities into the patients' medical record. All MSH staff with access to the ieMR, will have access to PowerTrials.
- This may be required to be completed in certain research projects as advised by Metro South Research as part of the SSA authorisation process.
- Refer to MSH work instruction WI2023-304 PowerTrials - ieMR research support module for more information.

## 5. COMPLIANCE MONITORING

- Monitoring of research is a quality measure and is a requirement of the National Statement on Ethical Conduct in Human Research (2023) ('National Statement'), Good Clinical Practice (GCP) and Clinical Trial Notification (CTN) process.
- There may be research fees associated with research monitoring.
- Refer to MSH work instruction WI2023-305 Research monitoring for more information.

## 6. POST APPROVAL – AMENDMENTS, REPORTING AND CLOSURE

- There are research administration processes and fees in place for amendments and closure (if applicable). Please see Attachment 2: Schedule of Research Administration Fees for more information.
- Researchers must prepare reports detailing the findings and outcomes of their research project.
- Refer to MSH work instruction WI2023-306 Post approval – research amendments, reporting and closure for more information.

## 7. RESEARCH EXECUTION

- Researchers must carry out the research activities according to the approved protocols and methodologies.
- Refer to MSH procedures, work instructions and guidelines for more information:
    - PR2023-411 Research excellence
    - WI2023-287 Research integrity
    - WI2023-288 Research quality management systems
    - WI2023-289 Research data and privacy
    - WI2023-290 Research authorship, peer review and publication
    - WI2023-291 Research complaints and misconduct
    - WI2023-292 Assessing and managing risk in research
    - GL2023-98 Research translation and impact.

## RESPONSIBILITIES

| Position | Responsibility | Audit Criteria |
|---|---|---|
| Manager, Research Integrity and Compliance, Metro South Research | • Monitor and assess compliance with all relevant legislation, policies, guidelines and procedures to receive funding by National Health and Medical Research Council (NHMRC) or Australian Research Council (ARC). | • MSHREC maintains NHMRC certification |
| Research Monitor, Metro South Research | • Monitors research to ensure compliance with the Research Policy Framework. | • Research monitoring - site initiation and visits |
| Researchers | • Adhere, be aware of and comply with the Research Policy Framework when conducting research in MSH. | • HREC and SSA applications |

## DEFINITIONS

| Term | Definition |
|---|---|
| Ethical review | Ethical review of research refers to the process of evaluating research protocols to ensure that they meet established ethical standards for conducting research with human subjects. The primary purpose of ethical review is to protect the rights and welfare of research participants, while also ensuring that the research is conducted in a scientifically valid and responsible manner. |
| Monitoring | Research monitoring refers to the process of tracking and reviewing a research study's progress to ensure that the study is conducted according to the protocol and ethical standards. The monitoring process can help to identify and address issues that arise during the study, such as deviations from the protocol, noncompliance with ethical standards, or problems with data collection. |
| Research Policy Framework | A framework inclusive of policy, procedures, work instructions, guidelines and supporting documents, aligned to MSH research practices. |
| Policy framework documents | Policy documents include policies, procedures, work instructions and guidelines – PR2013-01 Policy Document Management Procedure. |
| Quality | Quality standards in research refer to the criteria used to evaluate the quality and validity of research studies. These standards are important to ensure that research studies are conducted in a rigorous and transparent manner, and that the findings can be trusted and used to inform decision-making. |
| Research | Clinical research - A type of scientific research that is conducted with human participants to understand, diagnose, prevent, or treat medical conditions or diseases. It involves the study of human biology, physiology, pharmacology, and psychology, among other disciplines, in order to improve our understanding of health and disease. Clinical research can take many forms, |

| Term | Definition |
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| | including observational studies, randomised controlled trials, and retrospective analyses of patient data. In some cases, clinical research involves testing new drugs, medical devices, or other interventions in human subjects to evaluate their safety and efficacy. Clinical research is typically conducted in a controlled environment, such as a hospital, and is overseen by a team of researchers, including physicians, nurses, and other healthcare professionals. The goal of clinical research is to generate new knowledge that can improve patient outcomes, inform clinical practice, and advance medical science.<br><br>Non-clinical research - The concept of research is broad and includes the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies, inventions and understandings. This could include synthesis and analysis of previous research to the extent that it is new and creative. |
| Research governance review | Research governance/site-specific authorisation includes contractual and financial management of research and research authorisation by the relevant authority. |
| Sponsor | A sponsor is an individual, organisation, or company that takes responsibility for initiating, managing, and financing a research project or clinical trial. The sponsor is typically the organisation that has developed the new drug, medical device, or other intervention being tested in the project. |

## RELATED AND SUPPORTING DOCUMENTS

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|---|---|
| **Legislation and other Authority** | **Legislation (as updated and replaced from time to time)**<br>• *Australian Research Council Act 2001* (Cth)<br>• *Hospital and Health Boards Act 2011* (Qld)<br>• *Financial Accountability Act 2009* (Qld)<br>• *National Health and Medical Research Council Act 1992* (Cth)<br>• *Public Health Act 2005* (Qld)<br>• *Public Sector Act 2022* (Qld)<br>• *Public Sector Ethics Act 1994* (Qld)<br>• *Research Involving Human Embryos Act 2002* (Cth)<br>• *Therapeutic Goods Act 1989* (Cth)<br>**Regulations**<br>• *Financial Accountability Regulation 2009* (Qld)<br>• *Financial and Performance Management Standard 2009* (Qld)<br>• *Hospital and Health Boards Regulation 2012* (Qld) |

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|---|---|
| | • *Public Health Regulation 2018* (Qld)<br>• *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth)<br>• *Therapeutic Goods Regulations 1990* (Cth)<br>**National Health and Medical Research Council (NHMRC)**<br>• National Statement on Ethical Conduct in Human Research (2023)<br>• NHMRC Certification Handbook, National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-centre Research 2012<br>• NHMRC ethical issues and resources<br>• Payment of participants in research: information for researchers, HRECs and other ethics review bodies (2019)<br>• Research Governance Handbook: Guidance for national approach to single ethical review December 2011<br>**Department of Health**<br>• Health Service Directive: Research Ethics and Governance Directive QH-HSD-035:2023<br>• Research Management Guideline: external funding and infrastructure support QH-GDL-013-1:2022<br>• Research Management Policy QH-POL-013:2022<br>• Research Management Standard QH-IMP-013:1:2022<br>• Researcher User Guide - Queensland Health<br>• Standard Operating Procedures for Queensland Health HREC Administrators<br>• Standard Operating Procedures for Queensland Health RGOs |
| **Standards** | • National Clinical Trials Governance Framework<br>• National Safety and Quality Health Service (NSQHS) Standards 2nd Ed.<br>  ○ Standard 1 – Clinical Governance<br>  ○ Standard 2 – Partnering with Consumers |
| **Supporting documents** | **Metro South Health**<br>• Metro South Health Research Strategy<br>• Finance Management Practice Manual (FMPM)<br>• Contract Management Framework<br>• MSH Risk Management Framework<br>**Policies and procedures**<br>• PR2023-411 Research excellence<br>• PR2023-412 Research support and management<br>**Work Instructions** |

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| | • WI2023-287 Research integrity<br>• WI2023-288 Research quality management systems<br>• WI2023-289 Research data and privacy<br>• WI2023-292 Assessing and managing risk in research<br>• WI2023-299 Ethical and scientific review of research<br>• WI2023-300 Exemptions from research review<br>• WI2023-301 Site specific assessment of research<br>• WI2023-302 Research contracts and study execution<br>• WI2023-303 Metro South Health sponsorship of Clinical Trial Notification (CTN) scheme trials<br>• WI2023-304 PowerTrials - ieMR research support module<br>• WI2023-305 Research monitoring<br>• WI2023-306 Post approval – research amendments, reporting and closure<br>**Guidelines**<br>• GL2021-75 Partnering with consumers in research<br>• GL2023-97 Aboriginal and Torres Strait Islander health research<br>• GL2023-98 Research translation and impact<br>• GL2023-99 Planning a research project<br>• GL2023-100 Research Participant Information and Consent Form (PICF)<br>• GL2023-101 Research contract clauses<br>• GL2023-102 Use of electronic signatures in research contracts<br>• GL2021-77 Clinical trials<br>• GL2023-103 TeleTrials<br>**Attachments**<br>• Attachment 1: Research Administration and Compliance Handbook<br>• Attachment 2: Schedule of Research Administration Fees<br>• Attachment 3: Research Administration Fees Form |

## 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

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|---|---|
| **Consequence category** | Health Service Delivery |
| **Level of consequence** | Moderate |
| **What will be monitored** | Research administration and compliance processes |
| **How (method or tool)** | • MSHREC maintains certification by the NHMRC (registration number EC00167)<br>• Research monitoring - site initiation and visits<br>• HREC and SSA applications |
| **Frequency** | Annually |
| **Responsible officer** | Executive Director, Metro South Research |
| **Reporting to** | Metro South Health Research Council |

## PROCEDURE DETAILS

| | |
|---|---|
| **Procedure Name** | Research administration and compliance |
| **Procedure Number** | PR2023-413 |
| **Current Version** | V1.0 |
| **Keywords** | Ethical and Scientific Review of Research, Exemptions, Site Specific Assessment, Research Contracts and Study Execution, Clinical Trial Notification (CTN) – Sponsor Responsibilities, ieMR Research Support Module (PowerTrials), Monitoring, Post Approval – Amendments, Reporting and Closure |
| **Primary Policy Reference** | PL2023-92 Research Policy |
| **Risk Consequence Rating** | Moderate |
| **Executive Sponsor** | Chief People, Engagement and Research Officer |
| **Endorsing Committee / Authority** | Metro South Health Research Council |
| **Document Author** | Manager, Research Development, Metro South Research |
| **Next Review Date** | December 2026 |

## REVIEW HISTORY

| Version | Approval date | Effective from | Authority | Comment |
|---|---|---|---|---|
| 1.0 | 5/12/2023 | 13/12/2023 | Chief People, Engagement and Research Officer | New MSH procedure: links together research administration and compliance principles. |