Planning a research project

PURPOSE

This guideline provides an introduction to planning a research project and helpful information to assist with navigating various pathways and administrative processes which you may come across at the beginning of your research journey in Metro South Health (MSH).

OUTCOME

This guideline aims to:

- Provide researchers with helpful information to assist with navigating various pathways which you may come across at the beginning of your research journey in MSH.
- Outline information, predominantly at the initiation and planning stages, in order to enable researchers to conduct research with quality and integrity.

Whilst this document may not capture all the intricacies and requirements which form parts of the research administration process it is aimed at providing information, predominantly at the initiation and planning stages, to enable novice researchers to conduct research with quality and integrity. Metro South Research acknowledges that the 'research journey' is not always linear and that there are sometimes diversions or forks in the road. Keeping this in mind, this document aims to highlight what a simple or basic process may look like.

SCOPE

This guideline applies to all MSH employees who conduct human research within or in association with MSH, or through access to MSH participants, health records or data.

GUIDELINE

1. INITIATING AND PLANNING A RESEARCH PROJECT

- Before getting started its important to review existing education and support available in MSH.
- There are a variety of research related education and training resources available to people starting out in research.
- See our website for more information: https://metrosouth.health.qld.gov.au/research/education

1.1 Terminology

- To understand what you need to know about conducting research in MSH, find an outline of some key terms which are used frequently throughout the Metro South Research website and documents:

Table 1: Key terms

Term	Definition
HREC	Human Research Ethics Committees (HRECs) play a central role in the Australian system of ethical oversight of research involving humans. HRECs review research proposals involving human participants to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines. There are more than 200 HRECs in institutions and organisations across Australia. Many other countries have similar systems. In undertaking this role, HRECs are guided by relevant standards. Standards include those in the National Statement on Ethical Conduct in Human Research (2023) ('National Statement') issued by National Health and Medical Research Council (NHMRC). The National Statement sets out the requirements for the composition of a HREC and the relevant ethical principles and values by which research should be designed and conducted by researchers and to which HRECs should refer when reviewing research proposals. Read more about the Metro South Human Research Ethics Committee (MSHREC) on our website.
Clinical Trial	Clinical Trials are not just pharmaceutical trials but any research investigations involving human participants to test new treatments, interventions or tests. These types of studies would ordinarily require full ethical review by a NHMRC Certified HREC.
Ethical clearance	All proposed research projects must include ethical considerations at the initiating and planning, setup, implementation and maintenance stages. All research applications must be submitted to the HREC via completion of a Human Research Ethics Application (HREA) and receive 'ethical clearance' from a HREC prior to commencement of a project. Read more about ethical clearance in MSH work instruction WI2023-299 Ethical and scientific review of research.
PICF	A Participant Information and Consent Form (PICF) provides information about a research project to prospective participants and is a mechanism for obtaining their written consent to participate. The information should include details such as the projects purpose, duration, required procedures, risks and potential benefits.
SSA authorisation	Research governance refers to the framework used by institutions to ensure that they are accountable for the research conducted under their auspices. Elements of research governance include ethical clearance, compliance with legislation, regulations, guidelines and codes of practice. Research governance ensures that all documentation is appropriate for site assessment so that a decision can be made by an organisation to either conduct or not conduct the research. To receive research governance authorisation, you must: • complete the Site Specific Assessment (SSA)

	• provide relevant supporting documentation - including MSH site and department acceptance Read more about SSA authorisation on MSH work instruction WI2023-301 Site specific assessment of research.
Research	The *Public Health Act 2005 (Qld)* defines research as the systematic investigation for the purpose of adding to knowledge about human health and well-being and includes: • biomedical studies • clinical and applied studies • epidemiological studies • valuation and planning studies • monitoring and surveillance studies
Therapeutic Goods Administration (TGA) Note for Guidance on Good Clinical Practice (GCP)	TGA ICH Guideline for Good Clinical Practice is an internationally accepted standard for designing, conducting, recording and reporting of clinical trials. These guidelines may be overridden by national legal requirements and the requirements of individual regulatory agencies as appropriate, to address matters relevant to local conditions or culture. Read more about clinical trials in MSH guideline GL2021-77 Clinical trials.

1.2 Research questions

- Research may be initiated from a variety of different areas:
    - You – as the researcher
    - Your team or line manager
    - Clinical data or metrics
    - Principal investigator (PI)/trial coordinator
    - MSH (sponsor)
    - Other Hospital and Health Services
    - Universities
    - Commercial sponsors/ Pharmaceutical companies
    - International sponsors
        - *Note: must have an Australian sponsor associated with an ABN and address*
    - Private industry
- Establishing a research question requires rigorous review of literature to ensure there is an unmet need. Conducting a search of the literature will help to determine the current knowledge on the topic of interest.

- This can also assist in clarifying a research question and identifying the tools and resources needed to conduct the research. MSH libraries can offer training and support in conducting a literature search and using referencing software.
    - Princess Alexandra Hospital
    - QEII Hospital
    - Logan Hospital
    - Redland Hospital
- The literature review should evaluate and analyse previous research, demonstrating where the proposed research fits into the current body of knowledge.
- The research question, when appropriately written, will guide you and assist in the construction of a logical argument. The research question should be a clear, focused question that summarises the issue that you will investigate. Researchers may find the below table to be of assistance when developing a research question.

Table 2: Developing a research question

Step	Recommended approach
Clinical area and/or research topic	Researchers should begin by identifying a broader subject of interest that lends itself to investigation. For example, a researcher may be interested in lung cancer.
Undertake preliminary research	Find out what research has already been done and what literature already exists – discuss with a MSH Library. How much research has been done on the topic? What types of research projects have already occurred? Is there a unique area that is yet to be investigated or is there a particular question that may be worth replicating?
Develop a research question	Narrow the topic by asking open-ended "how" and "why" questions. For example, a researcher may want to consider the factors that are contributing to lung cancer or the success rate of early detection programs. Create a list of potential questions for consideration and choose one which is of interest and provides an opportunity for exploration.
Evaluate the question	Is the research question one that is of interest to the researcher and potentially to others? Is it a new issue or problem that needs to be solved or is it attempting to shed light on previously researched topic? Is the research question researchable? Consider the available timeframe and the required resources. Is the methodology to conduct the research feasible?

	Is the research question measurable and will the process produce data that can be supported or contradicted? Is the research question too broad or too narrow?

Adapted from the Centre for Innovation in Research and Teaching.

- A variety of education sessions are available to researchers in MSH. Furthermore, it is mandatory that Good Clinical Practice (GCP) Training and Research Integrity Training is completed when MSH employees are conducting research.
- **Note: If you are unsure if your work activity or project pertains to research it is recommended to contact Metro South Research to discuss further.**

1.3 Consultation

- When initiating and planning a research project, consider making contact with the MSH HREC Office and Research Governance Office to discuss submission requirements include identification of risk level.
- MSH strongly recommends all researchers also contact the Metro South Research to seek assistance and support regarding:
    - PowerTrials
    - Research grants
    - Clinical Research Facility (CRF)
    - Research biorepositories
    - Biostatistics service
- See Metro South Research website for information regarding available assistance and support.

1.4 Policy and procedure review

- During the planning and initiation phase it is important to familiarise yourself with our MSH Research Policy Framework.
- The Research Policy Framework aims to ensure that consistent, clear, and detailed publicly available policies, procedures and supporting documentation, are in place to inform and guide MSH researchers in the pursuit of research excellence.
- All those who participate in the regulatory steps required for research should familiarise themselves with our processes and practices outlined on our site, and a unified approach among relevant parties is encouraged.
- It is also important to:
    - Identify any Conflicts of Interest (COI) and ensure they are managed in accordance with MSH policies and procedures. Refer to MSH work instruction Research integrity for more information
    - Plan all supporting documentation requirements (more information below)
    - Create a ‘master file’ to help you manage documentation (especially version control) pertaining to your research project (more information below).

1.5 Specific human and animal ethical and scientific review requirements

- When developing a research question, it is important to ascertain if specific human and animal ethical and scientific review will be required in addition to HREC approval. This includes research pertaining to:
    - gene technologies and related therapies
    - ionising radiation
    - use of approved and unapproved medicines and medical devices; access to coronial material for research purposes
    - research involving adults with impaired capacity to consent
    - research involving persons in custody and/or employees of Department of Justice and Attorney-General
    - research that may affect the health and wellbeing of Aboriginal and Torres Strait Islander people and communities
    - research requiring access to state-wide data collections
    - clinical trials with persons unable to provide consent
    - use of animals.

1.6 Research proposal and protocol

- The development of a research protocol is an important step in the research process as:
    - it states the research question to be addressed
    - it encourages adequate consideration and planning of research project detail before commencement
    - it allows co-investigators or peers a living and dynamic document for contribution and early review prior to its completion
    - it acts as a record and reminder for the researchers (co-investigator or co-worker) of the initial research project aims and stated procedures (this record also enables monitoring of research project progress)
    - it provides the basis for funding of HREA.
- All research protocols submitted to the MSHREC must be presented on the HREA available on the Ethical Review Manager (ERM) https://au.ethicsform.org/SignIn.aspx.
- MSH research protocol guides and templates have been developed to assist researchers.
    - Attachment 1: MSH Research Protocol Template
    - Attachment 2: MSH Clinical Trial Protocol Template
    - Attachment 3: MSH Research Protocol Template - Retrospective Study
- When revisions occur during research, researchers must submit a revised research protocol as an amendment. Refer to MSH work instruction WI2023-306 Post approval – research amendments, reporting and closure for more information.

1.7 Risk

- It's important to assess risk as part of research planning, refer to WI2023-292 Assessing and managing risk in research for more information.

1.8 Research mentor and clinical team

- Some of the best clinical research questions are those which stem from a clinical need, or a limitation identified by a MSH facility or service. It is recommended for discussions regarding the research question to occur with colleagues, supervisions/line managers, collaborating departments and Divisional/Department heads to determine whether it is a clinical priority and can be supported by the Division/Department.
- Early in the process the research mentor and trainee should create an agreement delineating the amount of time they will devote to each other, ownership of data and so forth, so as to maintain a healthy working environment.
- A research mentor and/or clinical team may be able to provide you with assistance:
    - in developing and refining a research idea and question
    - providing direction to key research literature related to the research question
    - developing the most appropriate research plan and methodology to answer the research question.
- Researchers should also consider aligning the research idea/question with the Division/Department's strategic plan or Key Performance Indicators (KPIs).
- Support may also be provided by discipline specific areas.

1.9 Communication

- Both before and after ethical clearance and research governance authorisation, it is essential to ensure good communication between all parties. All parties involved need to establish open lines of communication from the inception and initiation of the research project.
- If the processes are not discussed and coordinated correctly at the beginning, then the streamlined ethical review and clearance system will not operate to its full potential.

1.10 Partnerships

- External researchers regularly seek assistance from MSH employees for the inclusion of MSH as an additional site for a larger research project. This may involve MSH employees as associate investigators or simply as a site contact to facilitate recruitment or data extraction.
- If you are contacted by someone who is interested in collaboration or partnership for a research project, it is important to identify:
    - if it is a collaboration (e.g., between two or more Hospital and Health Services - also called multi-site research)
    - if it is sponsor driven (e.g., by a commercial sponsor)
    - if it is a MSH sponsored research project (e.g., funded by MSH Research Support Scheme (MSH RSS)

- if any MSH Intellectual Property (IP) will be utilised
- required legal contracts between collaborators/partnerships
- if MSH HREC fees will be applicable.

- Consideration must be given to collaborations before planning and designing the research project and before seeking ethical clearance. Collaborative research projects with a pre-existing HREC ethical clearance from another Committee may not require an ethics application due to pre-existing reciprocal arrangements.

1.11 Partnering with Consumers in Research

- Refer to MSH guideline GL2021-75 Partnering with consumers in research for more information.

1.12 Aboriginal and Torres Strait Islander health research

- Refer to MSH Guideline GL2023-97 Aboriginal and Torres Strait Islander health research for more information.

2. RESEARCH EXCELLENCE

- Refer to MSH procedure PR2023-411 Research excellence for more information.

2.1 Conflicts of Interest (COI)

- During the initiation and planning phase any (perceived or actual) Conflicts of Interest (COI) including unresolved personal, professional, or financial matters, must be identified and managed. In research COI may include a convergence between the individual interests of a person and their professional or other (such as personal, commercial or other professional) responsibilities, such that an independent observer might reasonably conclude that the professional actions of that person are unduly influenced by their own interests.
- A COI may compromise the research process itself and/or the institutional processes governing research and may lead researchers or institutions to base decisions about the research on factors outside research requirements.
- Such compromises could undermine community trust in research. Information for managing perceived and actual COI involving MSH, researchers and the MSH HREC members or advisors are included in the following MSH work instruction WI2023-287 Research integrity.

2.1 Research integrity

- Responsible research conduct is critical to the success of, and maintaining community confidence in, our research efforts. Whilst ethics and research governance processes are in place to uphold and promote ethically good human research, it is vital that MSH researchers take personal responsibility to ensure all their research activities are conducted with:
    - honesty - conveying information truthfully
    - accuracy - avoiding research errors and reporting research findings precisely and
    - objectivity - avoidance of inappropriate bias and presentation of research findings completely and impartially.

- Complaints and matters pertaining to research misconduct are treated seriously by MSH as part of research integrity. See the Research feedback webpage for more information.
- Refer to MSH work instruction WI2023-287 Research integrity for more information.

3. DOCUMENTATION

3.1 Research proposal and protocol

- **Research proposal** - 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. The primary purpose of a research proposal is to convince the intended audience that the proposed study is significant, feasible, and worth pursuing. It typically includes the following elements:
    - Introduction: Background information, research problem statement, and research questions
    - Literature Review: Review of existing research and relevant theories
    - Objectives: Clear and specific research objectives or goals
    - Methodology: Overview of research design, methods, data collection, and analysis procedures
    - Expected Outcomes: Anticipated results and their potential impact or contribution
    - Timeline: Proposed timeline or schedule for conducting the research
    - Budget: Estimated costs and resources required for the research project
    - References: List of cited sources.
- The research proposal is generally more comprehensive, focusing on the theoretical and conceptual aspects of the study. It highlights the significance of the research, demonstrates the researcher's knowledge of the subject area, and presents a persuasive argument for why the research should be funded and conducted.
- **Research Protocol** - 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. The research protocol contains more operational and technical details and is intended for internal use within the research team or institution. It includes the following elements:
    - Research Objectives: Clear and specific objectives that align with the approved research proposal.
    - Study Design: Detailed description of the research design, including the study type (e.g., observational, experimental), sample size determination, and data collection methods
    - Data Collection and Analysis: Specific procedures and tools for data collection, measurements, and statistical analysis
    - Ethical Considerations: Information on how ethical standards and guidelines will be addressed, such as informed consent, participant privacy, and data protection

    - Timeline: Detailed schedule and milestones for each phase of the research
    - Budget: Detailed breakdown of costs and resources required for the research project, including personnel, equipment, and materials
    - References: Relevant literature cited to support the research plan.
- If requesting a Waiver of Consent it is important to provide a justification for the request in accordance with the National Statement section 2.3.10 (a to i):
    - involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7, page 18) to participants
    - the benefits from the research justify any risks of harm associated with not seeking consent
    - it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records)
    - there is no known or likely reason for thinking that participants would not have consented if they had been asked
    - there is sufficient protection of their privacy
    - there is an adequate plan to protect the confidentiality of data
    - in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media)
    - the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled
    - the waiver is not prohibited by State, federal, or international law.
- The research protocol provides a comprehensive operational plan, ensuring that the research is carried out systematically, adheres to ethical guidelines, and maintains consistency in data collection and analysis. It serves as a reference document for researchers involved in the project and helps ensure that the study is conducted as planned.
- The preparation of a research protocol is mandatory for all research projects.
- The following MSH research protocol templates are available for use however it is important to note that not all fields are required:
    - Attachment 1: MSH Research Protocol Template
    - Attachment 2: MSH Clinical Trial Protocol Template
    - Attachment 3: MSH Research Protocol Template - Retrospective Study
- Clinicians and researchers are encouraged to contact the MSHREC Office to determine the most appropriate template to use when preparing a research protocol.

3.2 Recruitment of participants

- There are firm guidelines around the way potential participants may be approached, as well as the format and content of participant information. The informed consent process places the onus on the

researcher to ensure participation is entirely voluntary and participants are well informed of their rights and responsibilities.

- Refer to MSH work instruction WI2023-299 Ethical and scientific review of research and MSH guideline GL2023-100 Research Participant Information and Consent Form (PICF) for more information regarding recruitment and informed consent requirements.

3.3 Patient Information and Consent Form (PICF)

- An appropriate PICF and other associated supporting documents relevant to the recruitment of participants for the research project must also be developed (if required).
- The MSHREC Office recommends the use of the NHMRC endorsed standardised PICFs templates. Extensive information about informed consent is also available on the National PICF ABC website.
- ****Note the NHMRC standardised PICFs templates are mandatory in some states in Australia. If your research project is multi-site consider using these templates****

3.4 Data requirements

- If the research question requires access to data consider planning the following:
    - plan the type of research data
    - plan the methodology
    - plan the sampling: sample size and population, calculation or justification
    - data points/variables (should include a complete list including any demographics being collected)
    - plan data analysis techniques
    - data timeframe (should be specific such as 1 January 2024 to 31 December 2024 and should be retrospective to the submission date of the project if a retrospective data study); and
    - identify data required for analyse to meet outcomes.
- The data format should be re-identifiable or nonidentifiable, the term de-identified can be misleading. If it is re-identifiable, information on the linkage file will need to be provided.
- The data source should be identified (i.e., iEMR, a departmental database, a registry etc.)
- Retention period + disposal should be either 7 years or 5 years post publication for most low-risk studies.
- The storage location should be specific such as in a password protected folder on the Queensland Health drive only accessible by named investigators, cannot be on a USB or hard drive)
- If your project will also have hard copy files, a separate storage method for these should be outlined.
- Refer to MSH work instruction WI2023-289 Research data and privacy for more information.

4. ADDITIONAL REQUIREMENTS

4.1 Other supporting documents and forms

Below are examples of some study documents which may be included as part of a research project:

Table 3: Study documents

Ref	Document type
a.	HREA via ERM (Ethical Review Manager) Applications
b.	Research proposal, research protocol and PICF (including version control)
c.	Questionnaires/surveys (e.g., Survey Monkey)
d.	Participant diary
e.	Advertising material (e.g., brochure or leaflet)
f.	Data collection form
g.	Curriculum Vitae (CV) of Coordinating Principal Investigator or Principal Investigator, as relevant
h.	Good Clinical Practice (GCP) Certificate
i.	Other supporting documentation. Note: Dear Investigator Letters (DIL), Independent Data Monitoring Committee (IDMC) outcome letters where study can continue as planned and protocol deviations are not required by the MSHREC unless they have a bearing on the ongoing ethical and scientific validity of a study.
j.	For research using radiological procedures that are performed specifically for research - independent assessment report or verification by a medical physicist (or radiation safety officer) of the total effective dose and relevant organ doses for those radiological procedures that are performed specifically for the research protocol. Ensure your request to Biomedical Technology Services at MSH is supported by the inclusion of the Participant Information and Consent Form for the study which you wish to have assessed.

- As part ethical clearance and research governance authorisation of research processes other supporting documents may be required. Researchers are encouraged to contact Metro South Research when identifying and determining relevant requirements for supporting documents and forms.
- Refer to MSH work instructions WI2023-299 Ethical and scientific review of research and WI2023-301 Site specific assessment of research for more information.

5. QUALITY MANAGEMENT SYSTEMS

5.1 Master file

- It is recommended that a master file is created to assist you in maintaining and monitoring all of your essential research project documentation. If you would like guidance in creating a master file contact Metro South Research for more information.

5.2 Site master file maintenance

- MSH recommends that a site master file is established during the Initiating and planning a research project stage and maintained throughout the life of the research project. The site master file should contain all essential documents pertaining to the research project and be accessible for review by the sponsor’s representatives (e.g., Metro South Research - Monitor).

- **Note**: that PowerTrials has a document management component within the Protocol Office Manager application.

- Refer to MSH guideline WI2023-288 Research quality management systems for more information.

6. RESEARCH FUNDING

6.1 Research budgets and Internal Order Numbers (ION)

- Clinicians, researchers and PI must identify and document the financial support needed for their research project. It is the responsibility of the PI to identify the items associated with their research project that could incur costs. Research costs can include clinician/researcher time, use of MSH facilities and resources, printing, postage, access to internal or external expertise (e.g., biostatisticians), diagnostic procedures and publication. Any research project that requires financial support (from any source) must be supported by a research project costing and budget.
- The SSA form, available on ERM, includes an example of a completed Site Finance Management Table. Relevant business/finance managers may support the costing of any research project and will be involved in the costing for research projects requiring substantial resources.
- More information regarding MSH research budgets and ION management can be found in MSH procedure PR2023-412 Research support and management. As part of the setting up process you should consider costs associated with:
    - Novell and ieMR access
    - Consumables
    - Devices and drugs
    - Equipment and other capital items
    - Insurance
    - PI costs
    - Resourcing
    - Overhead costs
    - Indirect costs
    - Patient travel
    - Publication costs and conference fees
    - Research evaluations
    - Travel costs
    - Translation costs
    - Biostatistics services
    - Clinical Research Facility (CRF) fees
    - Cancer Collaborative Biobank (CCB) fees
    - MSH submission fees.

- Relevant business/finance managers may support the costing of any research project and will be involved in the costing for research projects requiring substantial resources. MSH research submission fees pertaining to the administration of the MSHREC and MSRGO have been endorsed by MSH Executive.
- Refer to MSH procedure PR2023-413 Research administration and compliance for more information.

6.2 Research Grants Administration

- Metro South Research facilitates internal – via the annual MSH RSS grant funding program - and external research grants administration services through its role as a NHMRC administering institution for any research grant where MSH is named as the administering institution. This includes providing advice and support in relation to:
    - research grant application development and submission
    - accepting and managing research grants
    - reporting requirements
    - varying or transferring research grants.
- Metro South Research must be involved in the research grant application process if it is proposed for MSH to be identified as the grant administering institution.
- The review, authorisation and certification processes are aimed at ensuring compliance with MSH corporate requirements and the funding body's application guidelines (i.e., it is not a review of the quality of the research proposal).
- During the review process the Metro South Research Support Coordinator (MSRSC) will assess:
    - compliance with the funding body's funding guidelines
    - requirements for Letters of Support and Certification of the application by an authorised delegate
    - evidence of Head of Department endorsement of the application
    - evidence of consultation with the Business Manager in respect to the budget build.
- Where a research grant application requires a Letter of Support and/or certification by a MSH authorised representative the MSRSC will facilitate this process.
- Refer to the following work instructions for more information:
    - WI2023-293 Research funding, budgets, and infrastructure support
    - WI2023-294 Research grants administration
    - WI2023-295 Research letters of support
    - WI2023-296 Metro South Health Research Support Scheme (MSHRSS)

7. SYSTEMS

7.1 ERM Applications

- ERM Applications must be used to complete the HREA and SSA forms. A number of resources are available to assist researchers in using ERM:
    - ERM submissions
    - Training & Quick guides
    - Frequently asked questions - FAQs
    - Help

8. MAINTENANCE AND MANAGEMENT

- It is vital that research projects in MSH are monitored and maintained throughout the entire life of the research project. There are several components to consider as part of the maintaining and managing a research project process:
    - monitoring
    - post approval reporting (e.g., annual reports)
    - amendments
    - safety reporting
    - suspension or early research project closure.

8.1 Monitoring

- The Monitoring process provides education, support and health/assistance, which may assist novice researchers.
- The most common errors found as a result of the monitoring process centre around:
    - PICFs signatures and dates (the PICF must be signed before the person commences participation)
    - Version control of all research project documents – the MSH HREC ethical clearance letter must reference the same version of the document which is being used by the research project
    - Contracts – must be active and be approved by all relevant delegates
    - Funding arrangements (particularly if external) – must be kept up to date and managed.
- Metro South Research has limited scope to check source data verification – this must be checked by the research team.
- Refer to MSH work instruction WI2023-305 Research monitoring for more information.

8.2 Post approval

- For more information regarding amendments, reporting and study status (i.e., study commencement, progress reporting, safety reporting, suspension and final report/study closure) and research funding.
- Refer to MSH work instruction WI2023-306 Post approval – research amendments, reporting and closure for more information.

8.3 Translation and impact

- Refer to MSH work instruction GL2023-98 Research translation and impact for more information.

9. OTHER USEFUL DOCUMENTS

- WI2023-300 Exemptions from research review
- WI2023-290 Research authorship, peer review and publication
- WI2022-226 Open access journal publications in research
- WI2023-291 Research complaints and misconduct
- WI2023-297 Gift cards (for use as research incentives)
- WI2023-302 Research contracts and study execution
- WI2023-303 Metro South Health sponsorship of Clinical Trial Notification (CTN) scheme trials
- GL2023-100 Research Participant Information and Consent Form (PICF)
- GL2023-101 Research contract clauses
- GL2023-102 Use of electronic signatures in research contracts

RESPONSIBILITIES

Position	Responsibility	Audit criteria
Principal Investigator	Is responsible for the conduct of a study, ensuring that the study complies with GCP guidelines.	N/A
Coordinating Principal Investigator	Takes overall responsibility for the study and for the coordination across all sites is if a study is conducted at more than one study site. The PI at each site will retain responsibility for the conduct of the study at their site.	N/A

DEFINITIONS

Term	Definition
Good Clinical Practice (GCP)	A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

RELATED AND SUPPORTING DOCUMENTS

Standards	• National Clinical Trials Governance Framework • National Safety and Quality Health Service (NSQHS) Standards 2nd Ed. ○ Standard 1 – Clinical Governance

	○ Standard 2 – Partnering with Consumers
Supporting documents	**Attachments** • Attachment 1 - MSH Research Protocol Template • Attachment 2 - MSH Clinical Trial Protocol Template • Attachment 3 - MSH Research Protocol Template - Retrospective Study

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.

GUIDELINE DETAILS

Guideline Name	Planning a research project
Guideline Number	GL2023-99
Current Version	V1.0
Keywords	Research, planning, protocol, quality, research administration
Primary Document Reference	PR2023-413 Research administration and compliance
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	7/12/2023	14/12/2023	Chief People, Engagement and Research Officer	New document - supersedes the ‘Research Journey’