Metro South Health | Metro South Research

Research Journey

An introduction to the research administrative process for Metro South Health novice researchers

V1.0

We care about you

Queensland Government

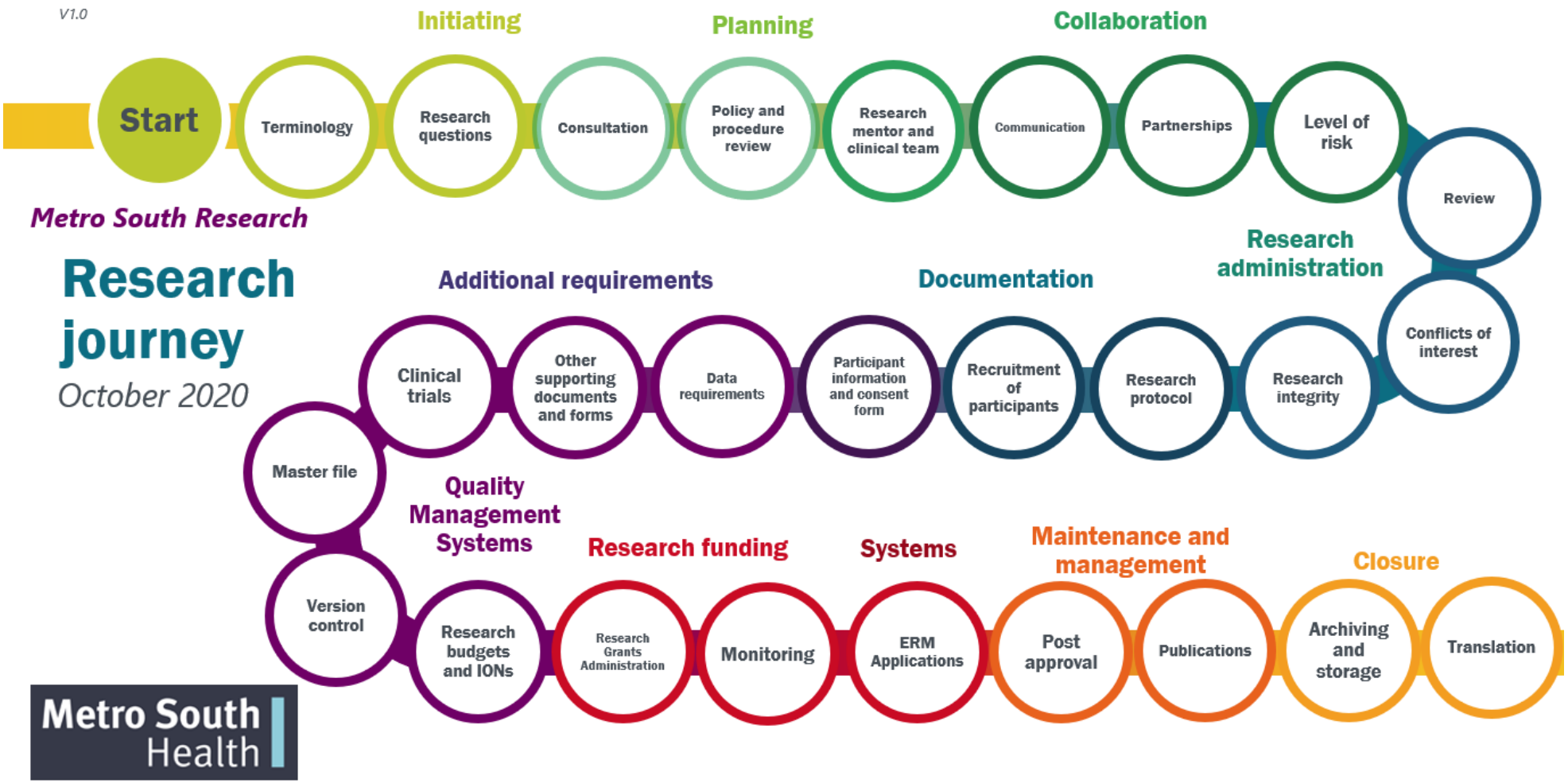
Published by the State of Queensland (Metro South Health), October 2020

For more information, contact:

Metro South Research, Metro South Health, Level 7, Translational Research Institute, 37 Ken Street, Woolloongabba, QLD 4102, email MSH-Research@health.qld.gov.au, phone 3447 8065 for Metro South Rsearch.

An electronic version of this document is available at https://metrosouth.health.qld.gov.au/research

Figure 1 – Research journey



Contents

Introduction

This document is intended to provide novice researchers with helpful information to assist with navigating various pathways which you may come across at the beginning of your research journey in Metro South Health. 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, in order 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.

The Metro South Research team is available to answer any questions throughout the journey and can provide tailored advice for your needs.

The Research Journey has been included as Figure 1 at the beginning of this document. This document will break each component of the journey down and provide relevant links to our website, procedures, external resources and tools. Metro South Research would like to continuously develop and evolve this resource over time. Feedback is welcomed and can be provided via email to MSH-Research@health.qld.gov.au.

1.0 Initiating and planning a research project

1.1 Terminology

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

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 2007-(Updated 2018) ('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 MSH HREC 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.

Term	Definition
	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 on our website.
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.
Research governance 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. In order 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 research governance authorisation on our website.
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 on our website.

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/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

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

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.

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.

Step	Recommended approach
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 is completed when MSH employees are conducting clinical trials.

If you are unsure if your work activity or project pertains to research it is recommended to contact the MSH HREC Office 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 following teams to seek assistance and support:

- PowerTrials Support
- Metro South Research Support Coordinator
- 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 Metro South Research policies and procedures:

- Research Management Compliance Framework
- Clinical Research Facility Policy Framework (in development)
- Research Biorepositories Governance Framework

The Research Management Compliance 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 (Research Integrity Procedure).
- 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).

2.0 Collaboration

2.1 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. Please see our Research areas page for more information.

2.2 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.

2.3 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 (eg between two or more Hospital and Health Services - also called multi-centre research)
- if it is sponsor driven (eg by a commercial sponsor)
- if it is a MSH sponsored research project (eg funded by MSH Research Support Scheme (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.

3.0 Research administration

3.1 Level of risk

If you are initiating a research project, it is important to identify the level of risk to participants during initiation and planning. A risk is a potential for harm, discomfort or inconvenience (discussed below). It involves:

- the likelihood that a harm (or discomfort or inconvenience) will occur
- the severity of the harm, including its consequences.

The research team is responsible for conducting an assessment of risk for research projects by:

- identifying any risks
- gauging their probability and severity
- assessing the extent to which they can be minimised
- determining whether they are justified by the potential benefits of the research
- determining how they can be managed.

Please see the Ethical and Scientific Review of Human Research Procedure for information regarding:

- Types of research that may not require full HREC review – ie Low and negligible risk review
- Types of research requiring full HREC review - ie Greater than low risk (standard risk)

For more information regarding the process for low and negligible risk review and greater than low risk (standard risk) review please see the Ethical clearance webpage.

Requirements for the ethical review of negligible risk and low risk research are explained in the National Statement paragraphs 5.1.18- 5.1.21.

Why is this important?

It is recommended that researchers contact the MSH HREC Office to seek assistance in determining the correct level of risk for the research project at initiation. This is vitally important because it will assist you in determining your research project design and planning requirements. If you have any questions about a research question, project or activity, including if you are unsure if your work requires ethical review and clearance, please contact the MSH HREC Office and/or MS Research Governance Office.

3.2 Review

The ethical review of research, as defined by the NHMRC, provides guidelines on ethical considerations that must be addressed when preparing research materials and documents for the ethical and scientific review of research. 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 that may affect the health and wellbeing of Aboriginal people and communities
- research Involving persons in custody and/or employees of Department of Justice and Attorney-General
- research requiring access to state-wide data collections
- clinical trials with persons unable to provide consent
- use of animals **see note below**

Please note:

- Aboriginal and Torres Strait Islander Research requires additional consideration around cultural implications and engagement of community juries - for instance Inala Indigenous Services has a Research Jury and a letter of support must be provided.
- **MSH does not host an Animal Ethics Committee (AEC) or provide information on the use of animals in research.**

Researchers are encouraged to contact the MSH HREC Office and MS Research Governance Office when determining relevant ethical and scientific review requirements for the ethical clearance and SSA authorisation of research.

3.3 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 procedures Research Complaints and Misconduct Procedure and Research Integrity Procedure.

3.4 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.

Please see the Research Integrity Procedure for more information.

4.0 Documentation

4.1 Research protocol

The preparation of a research protocol is mandatory for all research projects. MSH Research Protocol Templates may be utilised however it is important to note that not all fields are required.

Clinicians and researchers are encouraged to contact the MSH HREC Office to determine the most appropriate template to use when preparing a research protocol.

4.2 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.

Please see the Ethical and Scientific Review of Human Research Procedure and Participant Information and Consent Form (PICF) Procedure for more information regarding recruitment and informed consent requirements.

4.3 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 MSH HREC 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.

****Please note the NHMRC standardised PICFs templates are mandatory in some states in Australia. If your research project is multi-centre please consider using these templates****

Researchers may also refer to the Participant Information and Consent Form Procedure for more information and utilise the MSH PICF Template for guidance.

4.4 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

- plan data analysis techniques
- identify data required for analyse to meet outcomes

Data is available from the following sources:

- AUSLAB access - email Laboratory Information Systems
- Forensic AUSLAB data - email the Forensics and Scientific Services (FSS) HREC (HREC)
- Database of Research Activity (DORA) – search for Queensland Health human research studies

Data is also available directly from Queensland Health departments and Hospital and Health Services. It is important to note that when researchers require access to data, approval is required from the data custodian delegate. Requests for data **must** be approved by the data custodian prior to release (a fee for provision may be applicable).

View a list of Queensland Health and Hospital and Health Services data custodians. If the data custodian list is not up to date please contact us for assistance.

Depending on the research project, *Public Health Act 2005 (Qld)* approval is required where confidential patient medical information is to be obtained without participant consent. In this circumstance, please contact the relevant data custodian (as listed above) and complete and submit the *Public Health Act 2005 – Application and Information for Researchers Form*.

Researchers must ensure when *Public Health Act 2005 (Qld)* approval is received it is immediately forwarded to the MS Research Governance Office in accordance with the SSA process:

- Research Governance (Site Specific Authorisation) Procedure
- Research governance authorisation.

MSH data

MSH researchers have access to the MSH Data Hub.

Researchers who require data from MSH data custodians—Directors of Health Information Management Services (HIMS)—are required to seek approval to access relevant data.

HIMS contacts:

Facility	Contact details	Process
Princess Alexandra Hospital	T: 07 3176 2759 E: PAH_HIMS_Research@health.qld.gov.au	1. Complete the Public Health Act – Application and Information for Researchers Form (if required) 2. Email completed form and/or information about the research project to the stated email 3. HIMS will review request and approve 4. The processed from will be returned to the researcher Note: 1. This account may also be contacted when a researcher requires access to the integrated electronic Medical Record (ieMR) 2. HIMS have several documents that require completion before ieMR access is approved

Logan and Beaudesert Hospitals	T: 07 3299 8979 E: Tammy.Reese@health.qld.gov.au	1. Complete the Public Health Act – Application and Information for Researchers Form (if required) 2. Email completed form and/or information about the research project to the stated email 3. HIMS will review request and approve 4. The processed from will be returned to the researcher
QEII Hospital	T: 07 3182 6426 E: Marilla.Fraser@health.qld.gov.au	1. Complete the Public Health Act – Application and Information for Researchers Form (if required) 2. Email completed form and/or information about the research project to the stated email 3. HIMS will review request and approve 4. The processed from will be returned to the researcher
Redland and Wynnum Hospitals	T: 07 3488 3352 E: Marilla.Fraser@health.qld.gov.au	1. Complete the Public Health Act – Application and Information for Researchers Form (if required) 2. Email completed form and/or information about the research project to the stated email 3. HIMS will review request and approve 4. The processed from will be returned to the researcher
MSH Addiction and Mental Health Services (MSAMHS)	E: MSMHS_MHIM@health.qld.gov.au	1. Review MSAMHS Data Governance, Security & Access (staff intranet link) 2. Complete/submit the MSAMHS Data Access Request Form (staff intranet link) via email

5.0 Additional requirements

5.1 Other supporting documents and forms

As part ethical clearance and research governance authorisation of research processes other supporting documents may be required. Some these include:

- Research Contracts Approval and Study Execution Form (Application and Submission Form)
- Therapeutic Goods Administration (TGA) Clinical Trial Exemption Form (CTX) or Clinical Trial Notification Form (CTN)
- Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Radiation Risk Assessment
- Risk Versus Benefit Letter
- Quotes and approvals
- Invoicing details
- Health Support Queensland (HSQ) Pathology or Coronial Material Approval
- *Public Health Act 2005* – Application and Information for Researchers Form
- Indemnity arrangements (for industry sponsored studies, Medicines Australia form of indemnity may be required if the HREC is not located at a participating site)

- Curriculum Vitae (CV) of researchers who have not submitted a CV within the past two (2) years
- Any advertising or marketing material that is to be given to participants
- Data collection tool(s)—(eg case report form)
- Questionnaires or other instruments
- Letter of invitation/letter to GP etc
- Evidence of GCP Training (TransCelerate Biopharma Inc. accredited)
- Participant diaries
- Participant wallet card
- Other correspondence—(eg Food and Drug Administration (FDA) reviews, correspondence from other HRECs (HRECs), expert independent reviews, peer reviews, etc)
- Aboriginal and Torres Strait Islander Research Jury Support Letter

View our Quick links, tools, forms and templates page to access information relevant to the above supporting documents.

Researchers are encouraged to contact the MSH HREC Office and MS Research Governance Office when identifying and determining relevant requirements for supporting documents and forms.

5.2 Clinical trials

The Australian Clinical Trials Handbook provides guidance on conducting clinical trials in Australia using 'unapproved' therapeutic goods.

Please see the Clinical trials website for more information.

6.0 Quality Management Systems

6.1 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 please contact us for more information.

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 (eg MS Research Monitoring Office). Please see our Quality Management Framework and Reporting Procedure for more information.

Please note: that PowerTrials has a document management component within the Protocol Office Manager application.

6.2 Version control

MSH recommends that you have a discussion with your research team early on and agree to a consistent format for version control. This small preparation can save you many hours of searching through emails and having multiple phone conversations to ensure everyone is reviewing the most recent version of documents and that the correct versions of each document is being submitted for ethical clearance.

It can also assist if/when your research project goes through a monitoring process.

If you have no experience with this or no preferred system of version numbering, the system below may work for you, however, if you already have a system in place that works, you are welcome to keep using it—the most important thing is that the version numbers are included and match to version which has been given ethical clearance.

It may also assist to document a Standard Operating Procedure (SOP) which details the version control and numbering system to be used by the research project team. For example:

- When a document is updated following comments from the research team (see Step 2) the version number increases by decimal point (eg 0.0 to 0.1).
- When a document is updated following feedback from the MSH HREC Office and/or MS Research Governance Office (see Step 4) the version number increases by a whole number (eg 1.0 to 2.0)

Step 1: Generate the first version of your document and assign the date and version number to the footer (for the sake of example we will use a PICF).

PICF – Research Project Version 0.1 Date 01/01/2021

Step 2: Circulate this version to reviewers for changes and comments.

PICF – Research Project Version 0.**2** Date 02/01/2021

Circulate this document back to the people who need to review it and they will make further tracked changes if needed. Every time you implement the changes from your team, the document is saved as a new version number (in the decimal point) and distributed again for comment until no more changes are required.

Step 3: Once you have made the changes suggested by the team it is time to save the document with a new version number and the date in the footer.

PICF – Research Project Version **1**.0 Date 03/01/2021

In this type of version control, only versions 1.0 or 2.0 are considered 'final versions', with 1.1, and 2.2 for example considered as revisions. This final document is saved in the master file and is submitted to the MSH HREC Office and MS Research Governance Office.

Step 4: Submit the final version of your document with your cover letter for review. If the MSH HREC Office and MS Research Governance Office sends you feedback resulting in changes to the document, when you update the document also change the version number (eg the draft 1.3 will become a final 2.0). A new date will also be added.

PICF – Research Project Version **2**.0 Date 04/01/2021

Step 5: Circulate the changed document to your team and save in your master file. Only use the document as part of your research project once ethical clearance and research governance authorisation is received.

Step 6: If an amendment is required, begin the tracked changes process again. From this point on any changes made to the document based on the new round of tracked changes will now be reflected in the version number decimal points again.

PICF – Research Project Version **2**.1 Date 05/01/2021

Amendments which are sent to MSH HREC Office and MS Research Governance Office should be a final version (eg Version 3.0).

7.0 Research funding

7.1 Research budgets and Internal Order Numbers (ION)

Clinicians, researchers and principal investigators must identify and document the financial support needed for their research project. It is the responsibility of the principal investigator 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 (eg 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 the Ethics Review Manager (ERM) Applications site 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 the Research Funding, Budgets and Infrastructure Support Procedure. 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
- Principal investigator 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 MSH HREC, MS Research Governance Office and CRF have been endorsed by MSH Executive. Please see the Research Fees Procedure. Please note: fees are associated with ‘Major Amendments’ to MSH HREC ethical clearance.

7.2 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 (ie it is not a review of the quality of the research proposal).

During the review process the MS Research Support Coordinator 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 MS Research Support Coordinator will facilitate this process and requires 5-7 working days prior to the application submission date in order to do so.

Read more about the MSH RSS and external research grants on our website

8.0 Systems

8.1 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

9.0 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 (eg annual reports)
- amendments
- safety reporting
- suspension or early research project closure.

9.1 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

The Metro South Research has limited scope to check source data verification – this must be checked by the research team. See monitoring webpage for more information.

9.2 Post approval

Please see the Post approval - amendments reporting and closure webpage for more information regarding amendments, reporting and study status (ie study commencement, progress reporting, safety reporting, suspension and final report/study closure) and research funding.

Read more about clinical trial site master file maintenance.

Complaints and matters pertaining to research misconduct are treated seriously by MSH as part of research integrity. Please see the Research feedback webpage for more information.

10.0 Closure

Research projects must be formally closed with the MSH HREC and MS Research Governance Offices. Researchers who are in receipt of a research grant are required to submit progress and final reports in accordance with each funding bodies' requirements.

Please see the Post approval - amendments reporting and closure webpage for more information.

10.1 Publications

Publications are the responsibility of the researcher and approval must be sought by a relevant MSH delegate before publishing. Research may be publicised through both internal and external channels (ie via web pages, conference presentations, poster displays and multimedia displays), as well as via publication in peer-reviewed journals and/or relevant policy documents.

It is the researcher's responsibility to ensure that disseminated information is complete, accurate and unambiguous, and that the contributions of all team members are appropriately acknowledged. HREC approval or a formal ethics waiver is required for any work to be presented or disseminated outside of Queensland Health.

Tips to consider:

- discuss with the Head of Department or supervisor/line manager regarding opportunities for attending and presenting at conferences, travel support and leave processes
- link with a research mentor to determine the best methods and avenues for disseminating the research
- a research mentor may also provide assistance with the preparation of publications and/or conference presentations
- guidelines and checklists are available for you to follow when writing publications, including specific information for different types of research projects (ie case studies, literature reviews and/or cohort studies)

Please note: publications are the responsibility of the researcher and approval must be sought by a relevant MSH delegate before publishing. The MSH HREC does not take responsibility for publications and a letter of support may be requested from MSH Executive.

Please see the Publication and dissemination of research - A guide supporting the Australian Code for the Responsible Conduct of Research for more information.

10.2 Archiving and storage

Research project documentation should be maintained as specified in the Management of Data and Information in Research: A guide supporting the Australian Code for the Responsible Conduct of Research as indicated below:

- for short-term research projects that are for assessment purposes only, such as research projects completed by students, retaining research data for 12 months after the completion of the project may be sufficient
- for most clinical trials, retaining research data for 15 years or more may be necessary
- for areas such as gene therapy, research data must be retained permanently (e.g. data in the form of patient records)
- if the work has community, cultural or historical value, research data should be kept permanently, preferably within a national collection.

10.3 Translation

Research translation is the process whereby knowledge is passed anywhere along the translational pathway (ie research findings are translated into practice, policy or further research). The NHMRC provides information regarding research translation on their website.

The Murdoch Children's Research Institute also provides a useful Translation Toolkit for use in a research project however it is recommended for this toolkit to be utilised during the Initiation and planning stage. If you require assistance in translating your research, please discuss further with your department or your research mentor.