Metro South Health

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Research Administration and Compliance Handbook

Metro South Research

V0.1 Date: December 2023

ICARE² values

INTEGRITY COMPASSION ACCOUNTABILITY RESPECT ENGAGEMENT EXCELLENCE

Queensland Government

Contents

Purpose

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

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

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

MSH executive, Principal Investigators, researchers and Metro South Research have responsibilities for research administration and compliance, some of which are delegated on behalf of the Health Service Chief Executive (HSCE), MSH. This Handbook, which is attached to MSH procedure PR2023-413 Research administration and compliance, aims to outline the standards and principles which MSH must comply with, to:

- Ensure collaborative, harmonised, clear and detailed publicly available policies and procedures are in place for the ethical and scientific review of all MSH research.
- Provide research administration services to MSH and ensure compliance with relevant legislation and standards.
- Maintain NHMRC certification of the Metro South Human Research Ethics Committee (MSHREC) registration number EC00167.
- Monitor research to ensure compliance with the Research Policy Framework.
- Ensure researchers adhere to, be aware of and comply with the Research Policy Framework when conducting research in MSH.

The Research Administration and Compliance Handbook is to be read alongside MSH procedure PR2023-413 Research administration and compliance, related work instructions and guidelines.

1.0 Overview

MSH refers to and relies on the Researcher User Guide – Queensland Health July 2023 as part of the research administration and compliance processes. Please refer to the User Guide directly to find information relevant to ethical and scientific review of research, and site-specific assessment and authorisation. The below is information specific to MSH.

1.1 Conflicts of interest

Identification and management of perceived, potential and actual conflicts of interest relevant to the ethical and scientific review of research, site-specific assessment, and other research activities will be in accordance with MSH work instruction WI2023-287 Research integrity. If any person believes they may have a conflict of interest in relation to research, the conflict must be declared and detailed prior to submission of applications for ethical and scientific review of research, or site-specific assessment.

Conflicts of interest in this context may include a principal investigator, who may:

- be approving their own research within their related department and/or
- have a family member involved in the research project where he/she is providing head of department approval.

In the event of a conflict of interest of this nature, the Principal Investigator will be required to escalate the matter to their line manager or relevant delegate.

1.2 Administration Fees

Research administration fees are charged for new research project applications and amendments to approved research projects for Metro South Human Research Ethics Committee (MSHREC) review and Site Specific Assessment (SSA).

Research administration fees vary depending on the type of submission and the research project sponsor/funding type.

MSH Executive provide funds to enable research administration fees to be subsidised for MSH or Queensland Health (QH) employees whose usual reporting line is through a MSH facility or service.

Funds received from research administration fees enable the support of research and are used to:

- ensure that the MSH HREC is able to fulfil its obligations as directed by the National Statement on Ethical Conduct in Human Research (2023) ('National Statement');
- ensure that MSH is able to fulfil its obligations in accordance with the legislative framework that supports research and as directed by MSH policies and procedures;
- partially offset the cost of the administrative support for the MSH HREC and personnel involved in SSA authorisation; and
- promote excellence in research and underpin MSH's Strategic Plan and Research Strategy.

1.2.1 Schedule of research administration fees

A Schedule of Research Administration Fees (Attachment 2) have been endorsed by MSH Executive and implemented in order to provide assistance to support the administration of research conducted in, or in association with MSH.

The Schedule of Fees will be reviewed bi-annually and approved by MSH Executive. Note: when published or distributed, all fees must show or include GST in accordance with relevant legislation.

1.2.2 Invoicing

Principal Investigators must ensure appropriate invoicing details are submitted with their research applications, on the Metro South Research Administration Fees Form (Attachment 3).

2.0 Ethical and Scientific Review of Human Research

2.1 Types of research and ethical review requirements

In accordance with the National Statement, human research must be ethically and scientifically reviewed and approved by a Human Research Ethics Committee (HREC) before they take place in a HHS. All applications to MSHREC should be submitted via a Human Research Ethics Application (HREA) form via Ethical Review Manager (ERM).

National Statement, Chapter 2.1 Risk and benefit aims to help researchers and reviewers to understand and describe the level of risk involved in the planned research, and how to minimise, justify and manage that risk, and (with reference to Chapter 5.1) what level of ethical review is suitable.

A continuum-based model (high risk to minimal risk has been introduced to assist researchers and reviewers to understand and apply the continuum-based model.

Figure 1: Risk profiles of research

Lower risk		**Higher risk** (Individual, group, community, societal or global)	
Minimal	**Low**	**Greater than low**	**High**
No risk of harm or discomfort; potential for minor burden or inconvenience*	No risk of harm; risk of discomfort (+/- foreseeable burden)	Risk of harm (+/- foreseeable burden)	Risk of significant harm (+/- foreseeable burden)

*Burden and inconvenience are discussed below

National Statement on Ethical Conduct in Human Research 2023

The continuum-based model differentiates between ‘harm’ (which can be experienced individually or collectively), 'discomfort', 'burden', and 'inconvenience'. It also provides the following additional guidance to assist the assessment of these risks:

- Types of harm: The National Statement explicitly recognises the risk of death as a physical harm and the risk of anxiety-related psychological harm such as re-traumatisation; introduces the concept of cultural harm, which includes misunderstanding, misrepresenting or misappropriating cultural beliefs, customs or practices; and recognises the unauthorised disclosure of personal information as a social harm.
- Vulnerability to harm: It also recognises that some participants, by reason of the design study or their specific attributes, may be at higher risk of harm or discomfort from research. This risk of harm or discomfort can express itself in different ways, and at different times and degrees.
- Burden and inconvenience: Participation in research can also impose burdens or inconvenience on those involved in research. The National Statement makes clear that neither burden nor inconvenience should be considered a type of harm or discomfort (and therefore should not be viewed as a risk). It also makes clear that in designing, reviewing and conducting research, researchers and ethics review bodies should consider the impact of any burdens or inconvenience on participants and balance them against the potential benefits of the research.

The National Statement emphasises to researchers, institutions, and HRECs that the assessment of risk informs the determination of the appropriate level of review for a research project by the institution. It also informs reviewers’ judgments about whether risks are justified by potential benefits. It specifically provides that research in which the only foreseeable risk is discomfort will be classified as lower risk. Higher risk will require review by a Human Research Ethics Committee (HREC).

Refer to MSH work instructions WI2023-292 Assessing and managing risk in research and WI2023-299 Ethical and scientific review of research for more information.

2.2 MSHREC

MSH operates a HREC which gives ethical clearance to research projects. The MSHREC reviews the ethical and scientific validity of proposed research within MSH and can provide ethical clearance for research projects conducted at any public health organisation as well as research project conducted in Queensland, New South Wales, Victoria and South Australia, with the exception of Tasmania and the Northern Territory.

MSHREC meetings currently occur monthly (except January) throughout the year. The Metro South HREC is a NHMRC certified HREC Registration No: EC00167 and is constituted and functions in accordance with the National Statement.

The MSHREC aims to:

- protect the mental and physical welfare, rights, dignity and safety of research participants;
- facilitate and promote high caliber ethical research through efficient and effective review processes; and
- ensure that all clinical and ethical research is conducted responsibly.

Please review MSHREC Terms of Reference for further information.

2.2.1 HREC Membership

As per Section 5.1.30 of the National Statement, the membership of the MSHREC includes:

- a chairperson, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement
- at least two (2) lay people, one man and one woman, who have no affiliation with MSH and do not currently engage in medical, scientific, legal or academic work
- at least one (1) person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional
- at least one (1) person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion
- at least one (1) lawyer, where possible one who is not engaged to advise MSH and
- at least two (2) people with current research experience that is relevant to research proposals to be considered at the meetings they attend. These two (2) members may be selected, according to need, from an established pool of inducted members with relevant expertise.

Please see the MSHREC internet page for more information regarding meeting dates and categories of membership.

Identification and management of perceived, potential, and actual conflicts of interest will be in accordance with MSH procedure PR2023-411Research excellence. If a member of the MSHREC believes they may have a conflict of interest in relation to any application, that conflict must be declared and detailed prior to any consideration of applications.

Conflicts of interest in this context may include a material connection to an application or researcher, which could bias the assessment of that application. In the event of a conflict of interest, a MSHREC member may be required to absent themselves from consideration of the relevant application.

2.3 Research project classification

In MSH, research projects which appear to contain low and negligible risk levels (inconvenience only), involving the use of existing collection of data or records that contain only non-identifiable data, currently requires ethical oversight to determine if there are any ethical implications. The co-ordinating principal investigator must consult the MSHREC Co-ordinator to determine if the research project can be classified as low risk research. The MSHREC Co-ordinator has the discretion to request that the research project is submitted for full HREC review if they consider the risk to participants to be greater than low risk.

Applications for expedited review of research with low risk to participants by the MSHREC must be made by the co-ordinating principal investigator using the HREA form. All human research as defined by the National Statement as being greater than low and negligible risk, conducted in or accessing patients, data, facilities and/or staff in MSH must, at a minimum, be reviewed and approved by a HREC.

Requests for additional information or amendments made by the MSHREC to a researcher will be provided in a timely manner to ensure prompt review and resolution. Delays in providing information to the MSHREC may result in a research protocol being withdrawn from MSHREC review. The MSHREC has the discretion to request a full HREC review following assessment of the application for expedited review if it considers the risk to participants to be greater than low or negligible risk.

2.4 Research sponsor

All research conducted within Australia must have an identified research sponsor. The National Statement identifies the sponsor as '*An individual, company, institution or organisation that takes responsibility for the initiation, management, and/or financing of research'.*

MSHREC requires the identification of the research sponsor as part of the application for ethical and scientific review.

MSHREC consideration of MSH-sponsored CTN trials will be in accordance with MSH work instruction WI2023-303 Metro South Health Sponsorship of Clinical Trial Notification (CTN) scheme trials. Where the application for ethical and scientific review identifies MSH as sponsor for a Clinical Trial Notification (CTN) scheme trial, the Principal Investigator will be required to provide evidence of the following, prior to consideration of the application:

- Approval for MSH to act as sponsor from the relevant MSH delegate.
- Safety, data management and monitoring plans appropriate for the proposed research risk.

2.5 Specific human research ethical and scientific review requirements

Certain human research projects must satisfy specific ethical and scientific review requirements in addition to review by a local or lead HREC, before they take place in MSH, as detailed in sections 2.5.1-2.5.7 below. The purpose of this procedure is to ensure that all specific human and animal research conducted within or supported by MSH complies with NHMRC guidelines relating to medical and health research.

In addition to the ethical considerations pertaining to all human research participants, specific issues arise in the design, conduct and ethical review of research involving specific categories of participants. The impact of research on wider populations is an important ethical consideration in the design, review and conduct of human research.

Whilst ethical review by an accredited HREC is required for any human research, additional ethical and scientific review may also be required as dependent on the research project. Where other guidelines and codes of practice in particular research fields are consistent with the National Statement, researchers and members of ethical review bodies should draw on them when necessary to clarify researchers' ethical obligations in particular contexts.

If a research project requires specific human and animal research review, the Coordinating principal investigator/principal investigator is responsible for identifying an appropriate reviewing body. To assist researchers in this process the below table identifies relevant review bodies which pertain to specific ethical and scientific review requirements:

Type of research	Review body	Timing relative to MSHREC Review
Gene Technologies and Related Therapies Security Sensitive Biological Agents (SSBA)	UQ Institutional Biosafety Committee (UQ IBC)	Prior
Ionising Radiation	Queensland Health Radiation Safety Unit	Prior
Use of Approved and Unapproved Medicines and Medical Devices	Therapeutic Goods Administration (TGA)	N/A
Access to Coronial Material for Research Purposes	Queensland Health Forensic and Scientific Services Human Research Ethics Committee (FSS-HREC)	Not Required
Research Involving Adults with Impaired Capacity or Unable to Consent	Queensland Civil and Administrative Tribunal (QCAT)	Post
Research Involving Persons in Custody and/or Staff of Department of Justice and Attorney-General	Queensland Department of Justice HREC	Parallel
Research that May Affect the Health and Wellbeing of Aboriginal People and Communities	Aboriginal Health and Medical Research Council (AH&MRC) Ethics Committee	Prior
Research Requiring Access to State-wide Data Collections	Queensland Population and Health Services Research HREC Queensland Central Cancer Registry	Prior
Animal Research	Department of Agriculture and Fisheries Animal Ethics Committee UQ's Animal Ethics Committees	Prior

2.5.1 Regulation of gene technologies and related therapies and Security Sensitive Biological Agents (SSBA)

MSH researchers are required by law to abide by the Commonwealth scheme for the regulation of Genetically Modified Organisms (GMOs) in Australia as defined in the Gene Technology Act 2000 (Cth) and the Gene Technology Regulations 2001. MSH facilities in which researchers are using gene technology or undertaking dealings (as defined in the legislation) must be accredited and maintained, or have an established link with, a properly constituted Institutional Biosafety Committee (IBC) within a collaborating organisation. The research should be assessed and comply with recommendations made by the NHMRC Cellular Therapies Advisory Committee (CTAC), and the IBC prior to review and approval from a HREC.

Research using SSBAs is not routinely undertaken by MSH and is usually conducted under the auspices of university partners. In these circumstances researchers must contact the relevant university partner to ensure their research in undertaken in accordance with partner's relevant SSBA standards, policies and procedures.

If research using SSBAs were to be conducted under MSH sponsorship, it would be reviewed by the MSHREC and referred to a relevant IBC (e.g., the University of Queensland Institutional Biosafety Committee (UQ IBC) which is able to assess and approve GMOs and SSBA research proposals.

2.5.2 Use of approved and unapproved medicines and medical devices

Research within MSH that involves the use of approved or unapproved medicines, medical devices, blood, tissues and chemicals must be compliant with the legislation, regulations and guidelines of the Therapeutic Goods Administration (TGA).

2.5.3 Access to coronial material for research purposes

Under Section 53 of the *Coroners Act 2003 (Qld),* research involving access to coronial material must be referred to the Queensland Health Forensic and Scientific Services Human Research Ethics Committee (FSS-HREC) for ethical and legal approvals by the State Coroner.

2.5.4 Research involving persons in custody and/or staff of Department of Justice and Attorney-General

All research projects involving persons in custody in Queensland and/or staff of Department of Justice and Attorney-General requires review by the Queensland Department of Justice HREC.

Research projects **only** involving persons in custody and/or staff of Department of Justice and Attorney-General will be reviewed by the Queensland Department of Justice HREC **alone**. Research projects that also involve other participants should be reviewed by the Queensland Department of Justice HREC and other appropriate institutional HRECs.

2.5.5 Research that may affect the health and wellbeing of Aboriginal and Torres Strait Islander peoples and communities

It is acknowledged that research with Aboriginal and Torres Strait Islander peoples spans many methodologies and disciplines. There are wide variations in the ways in which Aboriginal and Torres Strait Islander individuals, communities or groups are involved in, or affected by, research.

Approval from the Aboriginal Health and Medical Research Council (AH&MRC) Ethics Committee is required where the research project involves research in, or concerning, MSH and any one of the following applies:

- the experience of Aboriginal people is an explicit focus of all or part of the research;

- data collection is explicitly directed at Aboriginal people;
- Aboriginal peoples, as a group, are to be examined in the results;
- the information has an impact on one or more Aboriginal communities; and/or
- Aboriginal health funds are a source of funding.

One of AH&MRC Ethics Committee's major criteria in assessing an application is to ensure that there is Aboriginal community involvement in, and control over, the research. Principal investigators will need to show evidence that they have the support of each local Aboriginal Community Controlled Health Service (ACCHS) or an alternative appropriate Aboriginal organisation, subject to the agreement of the HREC, where the research is being conducted.

The AH&MRC Ethics Committee reviews applications from the perspective of the impact on Aboriginal people. The review is required in addition to review by a lead or local HREC. The AH&MRC Ethics Committee accepts applications at any stage in their progress through another HREC. Each principal investigator can decide whether they will seek AH&MRC Ethics Committee approval before submitting to other HRECs, or after approval by other HRECs, or simultaneously.

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

2.5.6 Research requiring access to state-wide data collections

All research projects requiring access (including linkage) to state-wide data collections owned or managed by QH or Queensland Central Cancer Registry must be reviewed by the Queensland Population and Health Services Research HREC. Prior to making a submission to the Queensland Population and Health Services Research HREC, researchers are required to complete a 'Data Custodian Sign-off Form' and submit this with their research proposal to the relevant Data Custodian for review and sign-off.

Researchers wishing to access data from the Queensland Central Cancer Registry are required to complete the 'Data Request Form' and submit it to the Queensland Central Cancer Registry Data Custodian together with the above documentation.

If the research project involves data linkage by the Centre for Health Record Linkage, researchers are required to obtain a letter of support (for technical feasibility) from the Centre for Health Record Linkage prior to HREC review.

Under Section 72 of the *Guardianship and Administration Act 2000 (Qld)*, where a person is over the legal age of consent but is unable to give consent, written application to the Queensland Civil and Administrative Tribunal (QCAT) must be undertaken post HREC approval by the researcher.

2.5.7 Animal Research

Research projects that involve animals must be reviewed by an appropriate animal ethics reviewing body. Note that MSHREC only reviews human research.

2.6 Other supporting documents

Other supporting documents which may be required to be submitted with a MSHREC application include:

- Therapeutic Goods Administration Clinical Trial Application (CTA)and Clinical Trial Notification (CTN) Schemes.

- 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.
- GCP Certificate (evidence of completion).
- Any advertising or marketing material that is to be given to participants (e.g., brochure or leaflet).
- Data collection tool(s) or forms (e.g., case report form).
- Questionnaires, surveys (e.g., survey monkey) or other instruments.
- Letter of invitation/letter to GP etc.
- Participant diaries and participant wallet card.
- Other correspondence, e.g., Food and Drug Administration (FDA) reviews, correspondence from other HRECs, expert independent reviews, peer reviews, etc.
- 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.

3.0 Site-Specific Assessment

Commencement of research within MSH can only occur after site-specific assessment (SSA) and authorisation. The SSA process considers the following:

- Appropriate, available resources (financial, human, equipment, and infrastructure) required for the research to proceed at the site.
- Researchers have the necessary expertise and experience.
- Compliance with relevant laws, policies and codes of conduct relating to matters such as privacy, confidentiality, consent, biosafety, professional standards, and radiation safety.
- Requirement for and appropriate development of contracts.

The MSH ED Research is responsible for authorising the conduct of research at all MSH locations.

3.1 Research Resources

Discussions should take place as early as possible with the relevant MSH heads of department regarding the availability of appropriate resources to enable and support the proposed research. Expectations should be clarified from the research protocol and detailed when completing the SSA form.

Important factors when completing the SSA form include:

- ***Heads of supporting departments' endorsement -*** If the research project will require input, services or assistance from another department, researchers must obtain endorsement from the head of that supporting department. Departments often involved in a supporting role include Health Information Management Services (HIMS), Pathology, Diagnostic Imaging and Pharmacy.
- Applications for research projects at any other MSH (excluding PAH) facilities must be directed to the relevant Executive Director of Medical Services/Facility Manager for site approval/authorisation.

3.1.1 Internal financial considerations

Principal Investigators are required to contact the nominated Business Manager/Finance Officer and/or Cost Centre Manager for budget discussions and internal processes for:

- mandatory nomination of research cost centre code and Internal Order Number (ION)
- tracking of expenditure
- purchase (compliance with MSH procurement processes) of equipment
- employee wage recoupment and
- nominated 'in-kind' value.

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

3.1.2 SSA financial requirements

All SSA applications must include a budget to confirm the costs associated with the research project and specify the type of costs to be covered (e.g., revenue, expenses and 'in-kind' contributions). The key financial components for SSA applications are:

- actual costs have been provided;
- justification for covering costs in-kind (including benefits to MSH and/or participants) have been outlined; and
- evidence that review of the finalised budget has been endorsed by the relevant departments finance team – please note that finance managers are not delegated authorise expenditure.

For complex studies (e.g., clinical trials) a separate more detailed budget to that provided in the SSA should be used. Researchers who need to complete a more detailed budget should contact their Business Manager/Finance Officer and/or Cost Centre Manager for advice and assistance.

3.1.3 MSH sponsored research

Where MSH is identified as the research sponsor, the Principal Investigator will be required to provide evidence that organisational requirements for safety and data management, monitoring and reporting can be appropriately managed by the research team, or delegated to another group that has the necessary resources and capability.

Research projects which are sponsored by MSH are managed in accordance with MSH work instruction WI2023-303 Metro South Health sponsorship of Clinical Trial Notification (CTN) scheme trials.

3.1.4 Multi-centre research

In cases where MSH is involved in a multi-centre research project, a SSA will be conducted to determine what resources are required for the support and successful completion of the research at the relevant locations. This will include identification of actual and 'in kind' costs associated with the conduct of the research at each site.

Where multiple MSH sites (Princess Alexandra Hospital, QEII Hospital and Logan Hospital etc) are involved with the research project, one (1) SSA form can be completed, and one (1) Research Contracts Approval and Study Execution form is required. Signatures on the Research Contract Approval and Study Execution Form are to be obtained from the **initiating** department/delegate.

3.2 Research training

The Principal Investigator is responsible for ensuring all members of the research team are suitably qualified to perform the roles delegated to them within the project.

MSH has mandated the training for research team members:

- Good Clinical Practice (GCP) Training
- Research Integrity Training.

The Principal Investigator is required to verify training is up to date when submitting the SSA.

3.3 Legislative, Policy and Standards Compliance

The Principal Investigator is responsible for ensuring all members of the research team are aware of requirements under the National Statement, the Code, MSH policy and procedures, and relevant legislation and standards.

The Principal Investigator is responsible for ensuring that provisions are made for adequate supervision of all research team members.

3.4 Research Contracts

A research contract is a legally enforceable agreement between two (2) or more parties. It should contain all of the terms on which the parties have agreed to conduct the research project. Contractual terms must be appropriate and acceptable to MSH and consistent with MSH Contract Management Framework and its research and development objectives, as the conduct of research may otherwise expose MSH to significant legal liability and risk.

Depending on the type of research and the collaborations that exist with external organisations a research agreement may be required to be submitted with a SSA application. Medicines Australia has provided some standard agreements for use in clinical research. If these agreements are not relevant to the type of research being undertaken, a non-standard agreement can be developed. Some agreements may need to undergo appropriate review by members of the Metro South Legal team, and this is organised by the MSRGO.

The MSRGO should be the first point of contact for any questions about the process for preparing a research agreement. Refer to MSH work instruction WI2023-302 Research contracts and study execution for more information.

3.4.1 Research contract delegations

Within MSH, the delegation and the authority for signing of research contracts on behalf of the Health Service is the Chief Executive Officer, MSH or delegate. Please see the Financial Delegations Framework and Schedule for more information. For research projects which involve funds less than $500,000, the appropriate delegate is the Executive Director, Metro South Research. For research that involves funds greater than $500,000, the appropriate delegate is the Chief, People Engagement and Research.

Research contract signing must take place following review of the final document by MSRGO and on recommendation from the Manager, Research Integrity and Compliance, Metro South Research that the research project be authorised to commence.

MSH officers involved in research contract negotiation must make other parties aware that they are not authorised to bind the organisation and that no research contract will be formed until a final written agreement had been signed by the appropriate MSH research contract delegate.

3.4.2 Agreement options

Health Translational Queensland (HTQ) Research Passport Agreement	The HTQ Research Passport Agreement acts as an umbrella agreement for any research projects that might be between any given partner institution listed above. HTQ, which includes MSH, must provide a relevant schedule that is an appendage to the HTQ Research Passport Agreement.
Clinical trial research contract/agreement	Whenever possible, the Sponsor (eg pharmaceutical company), Contract Research Organisation (CRO) or collaborative not-for-profit organisations must provide a Clinical Trial Research Agreement using the latest version of the Medicines Australia Research Agreements Template. Or the Medical Technology Association of Australia (MTAA) Clinical Investigation Research Agreements - MTAA
Investigator initiated study between institutions	The Medicines Australia Research Agreements Template should also be encouraged or a pre-agreed collaborative agreement in relation to principal investigator-initiated research projects between institutions.
University led research projects	For research projects undertaken by a university employee or student, the university employee or student must contact their University Legal Representative to request that a preferred contractual arrangement be put in place.
Material Transfer Agreements (MTA)	An MTA may also be required in addition to a Research Contract. An MTA is a legal agreement that governs the transfer of research material (including biospecimen and data) or equipment from MSH to another non-MSH entity or individual (and vice versa). The MTA names the sender and the intended recipient, specifies the nature of the material/equipment transferred and establishes ownership and the constraints on its use, including a descriptor of permissible research to be performed with the transferred material/equipment.
Multi-Institution Agreement (MIA)	For multi-centre research projects, the NHMRC requires that all research grants with chief investigators (CIs) collaborating with CIs from other institutions or organisations (including international organisations), have a collaborative agreement in place, even if there are no funds being shared. This agreement is written as part of a NHMRC MIA.

3.4.3 Applicability

Research contracts, as defined in this procedure, are not required for:

- Donations and gifts administered through charitable foundations.
- Employment, independent contractor, or other personnel arrangements that are administered through MSH Human Resources (HR).

For the purposes of this procedure, an external/third party is a corporation or agency other than MSH or an individual who is not an MSH/QH employee.

4.0 Research Records in the iEMR

4.1 iEMR Research Module Overview

MSH facilities are fully digital hospitals with all patients' medical records now available in an electronic format. PowerTrials is the ieMR research support module that supports visibility of research activities in the patients' medical record.

MSH has mandated that all interventional research (clinical trials) that involve consent of MSH patients must be recorded in PowerTrials. Researchers must be mindful of the confidentiality of patient, staff and organisational information in accordance with relevant MSH policies and procedures.

4.1.1 Benefits of PowerTrials

The iEMR research module PowerTrials includes benefits for research participants, researchers and MSH, by ensuring clinical trials information is available at the point of care and which supports integration of research activities into patient health care management leading to improved communication between clinicians and researchers.

- Patient Safety - PowerTrials enables:
    - Access to research project information at the point of care fostering wholistic patient centred care.
    - If a participant on a research project presents to an Emergency Department, clinicians can see the research project's information on the patient's record; and the presentation of the participant to the Emergency Department is automatically communicated to the nominated contact person within PowerTrials via the Message Centre within PowerChart.
    - Customised protocol specific PowerPlans built for research projects within MSH outline the clinical requirements for a patient's participation in a research project.
- Recruitment - PowerTrials facilitates patient recruitment:
    - The process of identifying and recruiting patients as participants for research projects utilises electronic data to gather and analyse patient information creating efficiencies.
    - Researchers can utilise PowerTrials to determine which patients may be suitable for a research project and liaise directly with the clinicians who are caring for those participants.
    - Clinicians have increased visibility of existing PowerTrials within MSH and can use the pre-screening functionality within PowerChart for suitability assessment.
- Compliance - Compliance of research project documentation and access are improved through/by:
    - Ensuring supporting research documents (such as ethically approved protocol and participant information sheet) is clearly visible in PowerChart for participating patients, providing efficient access to research information for treating clinicians.
    - Efficient access to research project documentation is provided to auditors to verify project findings and outcomes for the relevant external agencies.

- Improved ability for researcher to generate reports on research projects being conducted with MSH.

4.1.2 Access requirements

All MSH staff with access to the ieMR, will have access to PowerTrials.

Researchers who are not an employee of MSH will need to delegate the access of the ieMR for research purposes to a member of the research team that is a MSH employee.

4.1.3 Build requirements

All interventional research (clinical trials) requiring MSH patient consent must be built into PowerTrials. Mandatory requirements include provision of MSH Research Governance approved pdf versions of:

- the research protocol
- Participant Information Sheet and Consent Form (PICF)
- other project related documents as required.

The Metro South Research Compliance Officer will liaise with the research team on gathering the required information for the PowerTrials build. Any updates to the study, including study documentation (e.g. consent forms or protocol), are to be managed by the research team using the quick reference guides or contacting the Metro South Research Compliance Officer for support as needed. Please see available Quick Reference Guides on the MSH Digital Website for information.

5.0 Compliance Monitoring

5.1 Monitoring

Monitoring of research is a quality measure and is a requirement of the National Statement, GCP and Clinical Trial Notification (CTN) process. The purpose of monitoring is to verify that:

- The rights and well-being of participants are protected.
- The reported data are accurate, complete, and verifiable from source documents.
- The conduct of the research complies with the currently approved protocol, approved amendment(s), GCP guidelines, and applicable regulatory requirement(s).

5.1.1 Risk-based approach

Traditionally commercially sponsored clinical trials have undergone 100% Source Data Verification (SDV). More recently however, the industry has recognised that risk-based monitoring is a time and cost-effective way to monitor studies.

The National Statement permits monitoring arrangements to be commensurate to the risk, size and complexity of the clinical trial. A clinical trial specific risk-based monitoring approach increases the likelihood of the monitoring plan to identifying conformance to key requirements as outlined in the:

- NHMRC guidance Safety monitoring and reporting in clinical trials involving therapeutic goods.
- Australian Clinical Trials Handbook.

A risk assessment must be completed in preparation for completion of the clinical trial study procedure manual and monitoring plan. Refer to MSH work instruction WI2023-292 Assessing and managing risk in research for more information.

5.2 MSH monitoring requirements

Metro South Research has a responsibility to monitor research in accordance with the Code and the National Statement on behalf of the MSHREC.

Metro South Research has a risk-based monitoring program that aims to:

- ensure patient and staff safety;
- ensure the use of high-quality data; and
- promote research best practice.

Specifically, the National Statement Chapter 5.5.1 states each institution has ultimate responsibility for ensuring, via its SSA arrangements, that all its approved research is monitored and (National Statement, Chapter 5.5.2) that the frequency and type of monitoring should reflect the degree of risk to research participants.

The MSH in its research monitoring program will focus on matters that directly impact on participant rights and safety (such as informed consent, eligibility criteria, adverse event reporting) and regulatory compliance.

5.2.1 Types of monitoring visits

Site initiation visit	This is not usually classed as a monitoring visit. The purpose of the site initiation visit is to confirm that all elements required to conduct the project are in place and ready for the project to start and include - the issue of all project approvals, the site processes are appropriate study specific process have been established, delegations and training have been completed. For further information on site initiation visits refer to National Clinical Trials SOP 00X Site Initiation and Close Out.
Interim Monitoring Visits	Are visits scheduled between the site initiation visit and close out visit. Interim monitoring visits may be scheduled on-site visits or a combination of on-site visits and remote visits. Remote monitoring, also termed centralised monitoring, includes the review of information that is routinely provided to/requested by the Sponsor. Remote monitoring is generally conducted off-site (i.e. at the sponsors site). Where remote monitoring visits are scheduled in the monitoring plan, the Sponsor should ensure: • That the site is aware of the extra procedures that may be involved for remote monitoring and may include PI/study team training, regular meetings, Standard Operating Procedures (SOPs) including for the forwarding documentation to the monitor and answering queries. • The study agreement includes clauses that adequately describe the provision of associated procedures. Note: while remote monitoring may reduce the need for onsite visits, it is recognised that remote monitoring does not entirely replace on-site monitoring completely. Most importantly information about the site function and processes as well as building a good rapport with site study team are critical outcomes of onsite monitoring. Further, remote monitoring of complex studies may not be possible for all elements of monitoring functions.

For-cause visits	Monitoring visits conducted in response to an event (i.e., a safety event or serious).
Close out visits	Are visits scheduled at the end of the study and must be completed before the study is closed. The purpose of the close out visit is to ensure that all study activities and documentation have been satisfactorily completed prior to closing the study.

5.2.2 Routine monitoring

All research projects being conducted within MSH are eligible for routine monitoring by the Metro South Research Compliance team. All research projects could be monitored routinely within the following scheduling priority:

- Principal investigator-initiated research projects sponsored by MSH.
- research projects where a complaint has been received by the MSHREC Office and/or Metro South MSRGO from researchers and/or participants.
- reportable safety events that are numerous or of interest.
- research projects without identified oversight by an external sponsor that are classified as ‘interventional’.

Metro South Research may also be alerted to any local events that require monitoring by the MSHREC Chair. Alternatively, a systematic review of currently approved research will identify research projects that are to be monitored. Monitoring occurs through a variety of mechanisms including:

- Annual Progress Reporting via the HREC/RGO Annual Report Form
- review of deviations from the proposed research project plan
- review of reports from researchers and safety monitoring boards
- review of adverse event reports
- feedback from research project participants and/or
- on-site monitoring (including review of research project files, consent documentation, source documents and data).

5.3 On-site monitoring

Metro South Research regularly conducts short audits of a range of research projects that have been authorised by the MSRGO. On-site monitoring of research is a tool to ensure patient safety, as well as high data quality, by promoting best research practices. The purpose of an onsite research monitoring visit is to:

- ensure participant safety.
- assist researchers with regulatory compliance requirements and MSH policy.
- educate and develop researchers by sharing best practice and improving research systems and data quality.
- prepare researchers for external audit processes (e.g., by funding bodies).
- demonstrate robust research processes to external funders and industry.

On-site monitoring involves meeting with researchers to:

- examine relevant documentation including signed consent forms, completed Case Report Forms, data spreadsheets, medical records, and approval certificates.
- regulatory documents which include HREC and SSA approvals and all relevant correspondence.
- check on the arrangements to protect privacy and confidentiality of participant data.
- check source data.

Metro South Research will contact researchers a reasonable period before the audit to set up a mutually convenient time and to provide researchers with a list of prospective questions.

5.3.1 Scheduled on-site monitoring visit

The visit itself may take up to a full day depending on the complexity of the research project being audited. Following completion of the audit, researchers will receive by email, an On-site Monitoring Visit Report including a summary of the main findings and a list of items that require action in order to comply with guidelines for good clinical practice.

Researchers are expected to take appropriate action and respond to the MSH Research Monitoring Office/r within a month of receiving the report. If the response is appropriate the on-site monitoring process will be considered closed.

If this is not satisfactory the researcher may need to discuss the issues with Metro South Research, the health of department and/or nominated members of the MSHREC, who can assist with resolving specific issues.

The research project may require a follow-up monitoring to ensure that the appropriate action has occurred, and the researchers will be notified promptly if this is the case.

On-site monitoring activities may include:

- Access to all requested trial related records.
- Verifying that the Principal Investigator has adequate qualifications and resources remain adequate throughout the clinical trial period; those facilities, including laboratories, equipment, and staff, are adequate to safely and properly conduct the trial and remain adequate throughout the trial period.
- Verifying, for the investigational product(s):
    - That storage times and conditions are acceptable, and that supplies are sufficient throughout the clinical trial.
    - That the investigational product(s) are supplied only to participants who are eligible to receive it and at the protocol specified dose(s).
    - That participants are provided with necessary instruction on properly using, handling, storing, and returning the investigational product(s).
    - That the receipt, use, and return of the investigational product(s) at the trial sites are controlled and documented adequately.
    - That the disposition of unused investigational product(s) at the trial sites complies with applicable regulatory requirement(s) and is in accordance with the sponsor.
- Ensuring that the Principal Investigator and trial staff are adequately informed about the trial and performing the specified trial functions, in accordance with the protocol and any other

written agreement between the sponsor and the investigator/institution and have not delegated these functions to unauthorised individuals.

- Verifying that written informed consent was obtained before each participant's participation in the trial.
- Verifying that the Principal Investigator follows the approved protocol and all approved amendment(s), if any.
- Ensuring that the Principal Investigator receives the current Investigator's Brochure, all documents, and all trial supplies needed to conduct the trial properly and to comply with the applicable regulatory requirement(s).
- Verifying that the Principal Investigator is enrolling only eligible participants and reporting the participant recruitment rate.
- Verifying that source documents and other trial records are accurate, complete, kept up-to-date and maintained in a secure manner.
- Verifying that the Principal Investigator provides all the required reports, notifications, applications, and submissions, and that these documents are accurate, complete, timely, legible, dated, and identify the trial.
- Checking the accuracy and completeness of case report form entries, source documents and other trial-related records against each other. The monitor specifically should verify that:
    - The data required by the protocol are reported accurately on the case report forms and are consistent with the source documents.
    - Any dose and/or therapy modifications are well documented for each of the trial participants.
    - Adverse events (AEs), concomitant medications and intercurrent illnesses are reported in accordance with the protocol on the case report forms.
    - Visits that the participants fail to make, tests that are not conducted, and examinations that are not performed are clearly reported as such on the case report forms.
    - All withdrawals and dropouts of enrolled participants from the trial are reported and explained on the case report forms.
- Informing the investigator of any case report form entry error, omission, or illegibility. The monitor should ensure that appropriate corrections, additions, or deletions are made, dated, explained (if necessary), and initialled by the investigator or by a member of the investigator's trial staff who is authorised to initial case report form changes for the investigator. This authorisation should be documented.
- Determining whether all AEs are appropriately reported within the time periods required by GCP, the protocol, the reviewing Ethics Committee, the Sponsor (MSH), and the applicable regulatory requirement(s).
- Determining whether the PI is maintaining the essential documents.
- Communicating deviations from the protocol, SOPs, GCP, and the applicable regulatory requirements to the investigator and taking appropriate action designed to prevent recurrence of the detected deviations.
- Signing the monitoring log.

5.3.2 PowerTrials Research auditor/monitoring

Research auditors/monitors can perform auditing requirements by gaining access to the study built in PowerTrials. Research auditors/monitors only have access to the research study they have been allocated to. This enables monitor activity to take place without needing a clinical trial coordinator present. Research auditors/monitors will not have access to PowerTrials unless the following has been undertaken:

- Consultation has taken place with the site-specific Health Information Management Service (HIMS)
- Completion of supporting document and training as per HIMS direction

The research auditor has been given a role within POManager by the research team member, access has been granted by HIMS and a login provided by the Information Technology Support (please refer to Quick Reference Guides found on Metro South Digital). The access to the PowerTrial must be removed once the auditor/monitor has completed all work.

5.3.3 Internal monitoring

The PowerTrials Research Support Module allows Metro South Research Compliance Officer or delegate to monitor the progress of open research projects periodically electronically across the Health Service. Additionally, it facilitates the monitoring process undertaken by Metro South Research Compliance. Refer to MSH work instruction WI2023-304 PowerTrials - ieMR research support module for more information.

Glossary

Agreement	An agreement used in a research setting is a formal and documented understanding or contract between parties involved in research. It outlines the terms, conditions, rights, and responsibilities related to the research project, such as collaboration, data sharing, confidentiality, funding, or any other relevant aspects. These agreements ensure clarity and compliance among involved stakeholders.
Biosafety	Biosafety refers to the principles, practices, and measures implemented to ensure the safe handling, containment, and control of biological materials and agents to prevent accidental exposure, release, or environmental contamination, thereby safeguarding human health and the environment.
Risk-based approach	Involves assessing and managing activities, decisions, or processes by considering potential risks and tailoring strategies to mitigate those risks effectively. It prioritises resources and actions based on the level of risk, aiming to optimise outcomes and enhance overall decision-making.