Site specific assessment of research

PURPOSE

This work instruction identifies a consistent and enforceable process for Site-Specific Assessment (SSA) authorisation for research being conducted in or in collaboration within Metro South Health (MSH).

OUTCOME

This work instruction aims to:

- Ensure all research conducted within MSH or in collaboration with external entities is of the highest standards and practices in the assessment, authorisation, oversight and conduct of research and is compliant with relevant legislation, standards, and guidelines.
- Outline the SSA framework through which MSH is accountable for the research it authorises to be conducted within any one of its facilities/services. It addresses financial accountability and transparency, intellectual property, mandated legal obligations, site resource utilisation/implication and site suitability.
- Enable cooperation between the research project Principal Investigator, Coordinating Principal Investigator and the Metro South Research Governance Office (MSRGO).
- Ensure research project documentation provided through SSA is appropriate, so that a decision can be made to approve or reject conduct of the research at the MSH site.

This work instruction outlines processes described in MSH procedure PR2023-413 Research administration and compliance and upholds principles outlined within the Research Administration and Compliance Handbook.

SCOPE

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

WORK INSTRUCTION

1. STEP 1: COMMENCE THE ETHICAL REVIEW AND SSA PROCESS

1.1 HREC review and SSA pre-authorisation

- It is recommended to commence the SSA application in parallel with the Human Research Ethics Committee (HREC) submission using the Ethics Review Manager (ERM) applications portal.
- Completion of the SSA form, via ERM, may be commenced whilst awaiting HREC approval, however approval is contingent on receipt of ethical clearance.

- Refer to MSH work instruction WI2023-299 Ethical and scientific review of research for more information.

1.2 Commencing the SSA - conflicts of interest

- If any person believes they may have a conflict of interest in relation to a SSA, the conflict must be declared and detailed preceding submission of SSA documentation.
- Refer to MSH work instruction WI2023-287 Research integrity for more information.

2. STEP 2: SSA SPECIFIC COMPONENTS

2.1 SSA created in ERM

- The SSA is created in the nominated online submission system known as ERM, when it is a MSH multi-site study only one (1) SSA is required for the multiple MSH sites.
- All supporting documents must be uploaded electronically against the online SSA form.
- The Principal Investigator is required to sign when assuming full responsibility for the conduct of the research project at the site. This signature is required in ERM via SSA.
- It is important to note that the online SSA form can be saved and updated throughout the preparation process in ERM.

2.2 SSA – supporting documents

- Based on the research project requirements associated supporting documents may also be required, to provide additional information for the governance review.
- All supporting documents must be prepared and uploaded against the research project's online SSA form available on ERM.
- For document control purposes, all supporting documents must have version control number and date in the footer.
    - For example: Date_DocumentTitle_MasterVersion = 230531_Research_Guide_PICF_v3.0

2.3 Ethical clearance/approval letter

- The ethical clearance/approval letter is a mandatory requirement and must be provided prior to SSA authorisation.
- Research projects that are approved by an external HREC (i.e., not the Metro South Human Research Ethics Committee (MSHREC)) require the following additional supporting documents:
    - Research Protocol
    - HREA (PDF version downloadable from ERM)
    - HREC Approval
    - Participant Information & Consent Form (PICF):
        - master PICF for multi-centre research projects only or
        - site specific PICF which contains site contact details and site logo

- confirmation of Research Integrity and Good Clinical Practice (GCP) certification for research team (e.g., provision of a Transcelerate accredited GCP Training Certificate and Research Integrity Training Certificate).
- all relevant supporting documents (i.e., Curriculum Vitaes, research risk assessment and management plan and research data risk assessment and management plan).

2.4 Research contract/agreement (as applicable)

- Research contract/agreements are typically required when a third (3rd) party entity such as a commercial sponsor / not-for-profit organisation is involved in the collaboration or when a university student is undertaking research under their university affiliation as part of the research team.
- Refer to MSH work instruction WI2023-302 Research contracts and study execution for more information.
- Researchers are encouraged to consult with the MSRGO via email MSH-RGO@health.qld.gov.au to ascertain the required research contract/agreement.
- The Research Contract Study Execution Form (RCASE Form) is used to obtain signatures and provide information regarding the study. Refer to MSH work instruction WI2023-302 Research contracts and study execution for more information.

2.5 Other supporting documents

2.5.1 Medicines Australia clinical trial agreement and standard indemnity

- Researchers must provide the relevant Medicines Australia Agreement for commercially sponsored research projects along with the Medicines Australia Indemnity accessible via the Medicines Australia website.

2.5.2 Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) radiation Risk Assessment

- A copy of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Radiation Risk Assessment is required for research projects involving ionising radiation as a specific component of the Research Protocol.

2.5.3 Risk versus benefit letter

- The risk versus benefit letter is required for clinical trials or clinical interventional trials where MSH is acting as the research project sponsor. The letter must be signed by an appropriate delegate.
- Refer to MSH work instruction WI2023-303 Metro South Health sponsorship of Clinical Trial Notification (CTN) scheme trials for more information.

2.5.4 Quotes and approvals

- Quotes and approvals from departments providing a service to support the research project (i.e., Pharmacy, Radiology and Pathology etc) must be included and be reflected in any contract provided for the study.

2.5.5 Clinical Trial Notification (CTN) Form

- A copy of the electronic acknowledgement is which has been submitted to the Therapeutic Goods Administration (TGA). Additionally, provided for our records, if available.

2.5.6 Invoicing details

- Invoicing details are required for the sponsor of research projects that attract a fee as per MSH procedure PR2023-413 Research administration and compliance.

2.5.7 Health Support Queensland (HSQ) Pathology or Coronial Material Approval

- Depending on the research project, researchers seeking access to HSQ resources (e.g., data, equipment, biospecimens, biological materials, tissue blocks and slides, etc) are required to seek approval from the relevant director or delegate.

2.5.8 *Public Health Act 2005* (Qld) approval

- The Public Health Act (PHA) applies to all researchers (internal and external to Queensland Health) who are undertaking research using identifiable or potentially re-identifiable health information for which the researchers are unable to obtain participant consent to use personal or identifying information for a clearly specified research study.
- The relevant data custodian must be contacted and the completed PHA – Application and Information for Researchers form must be submitted (see instructions on page 4). Researchers must ensure when *Public Health Act 2005* (Qld) approval is received it is uploaded to the SSA.

2.5.9 Additional documentation

- The research protocol/study plan and additional documents used for the study are provided for information reference only, enabling the MSRGO to determine any additional requirements.

2.6 Documentation no longer required

- The MSRGO no longer requires submission of documents which do not have an impact on ongoing site acceptability (see note below).
- Master PICFs and the Protocol may be requested for the initial SSA review for information purposes only.
- Documentation not required:
  - Site specific PICFs
  - *Dear Investigator Letters (DIL)
  - *Independent Data Monitoring Committee (IDMC) outcome letters where study can continue as planned
  - Suspected Unexpected Serious Adverse Reactions (SUSAR) notifications
  - Serious Adverse Event (SAE) notifications
  - Data Safety Update Reports (DSUR)
  - Safety reports (including line listings)
  - *Protocol deviations

- Research protocols/protocol amendments
- Investigator brochures/investigator brochure amendments
- Synopsis
- Case Study
- Curriculum Vitae

- Please note: Items marked with an Asterix (*) are also not required by the MSHREC unless they have a bearing on the ongoing ethical and scientific validity of a study.
    - Note: This is not applicable to research projects being conducted under the TeleTrials Model at this time.

2.7 Risk profiles of research

- 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.
- Risks identified through a Research Risk Assessment and Management Plan and/or Research data risk assessment and management plan must be considered as part of the SSA process.
- Refer to MSH work instructions WI2023-292 Assessing and managing risk in research and WI2023-289 Research data and privacy for more information.

2.8 Submitting the completed SSA

- Ensure all fields of the SSA are completed and upload all relevant documents, as outlined above, via ERM.
- Once completed online, the SSA form is submitted electronically and a SSA reference number is generated. This will be the five (5) digit number in ERM.
- Once submitted it will be immediately accessible for review by the MSRGO.

3. STEP 3: SSA AUTHORISATION

3.1 Authorisation and review

- Recommendation of authorisation of the research project will not occur until all regulatory, legislative and institutional (MSH) requirements are met including legal review and acceptance of indemnity provisions. Only research projects approved by a NHMRC certified HREC will be considered for SSA authorisation.
- It is not permissible to commence research until all SSA requirements are met.
- The MSRGO will review all submitted documentation and request further information if/when required via ERM correspondence or email where appropriate.
    - Note: When corresponding with Metro South Research its important to include the ERM number in the subject line. Please send separate emails for each study (i.e., avoid discussing more than one study in an email).

3.2 Acknowledgement

- Formal acknowledgment/confirmation of receipt of the submitted SSA will be sent from the MSRGO via ERM correspondence.
- Relevant SSA documentation will be uploaded to relevant Metro South Research files for record keeping purposes.

3.3 MSH delegate review

- All SSA documents requiring Health Service Chief Executive or delegate review and/or authorisation will be forwarded by the MSRGO to the nominated delegate as per the MSH Financial Delegations Schedule. This includes MSH Sponsored research projects.

3.4 Research projects WITHOUT a research contract

- A SSA Authorisation letter may be sent to the MSH Principal Investigator and nominated contact person via ERM correspondence.

3.5 Research projects WITH a research contract

- In addition to the above, the Business Managers and/or Cost Centre Managers of the department and the Central Contract Registration Team must be notified to facilitate uploading of relevant documents onto the central contract register (Q Contracts) via email address: MSHCentralContractsRegister@health.qld.gov.au
- Refer to MSH work instruction WI2023-302 Research contracts and study execution for more information.

3.6 Approval

- HREC approval does not automatically grant authorisation for the research project. Should the Health Service Chief Executive or delegate decide not to authorise a research project, a formal letter is sent to the Principal Investigator.
- If applicable, researchers will be formally notified of MSHRGO authorisation of the SSA via correspondence in a pdf form via ERM, to the Principal Investigator and nominated contact person. MSRGO approval documentation will sit within ERM correspondence.
- Researchers are responsible for ensuring research project activities do not commence prior to receiving SSA authorisation. Researchers/coordinators engaged in research activities must ensure adherence to the procedures outlined in the research application/research protocol, as approved by the HREC and MSRGO.
- Once approval has been obtained and if applicable, Clinical Trials that meet Power Trials Criteria must be built into Power Trials.
    - Documents required are the Study Protocol – Most recent version approved by the reviewing HREC (clean copy only) in PDF format.
    - Site Specific PICFs or equivalent (clean copy only) in PDF format.
- Refer to MSH work instruction WI2023-304 PowerTrials - ieMR research support module for more information.

4. STEP 4: SSA POST-AUTHORISATION

- Refer to MSH work instruction WI2023-306 Post approval – research amendments, reporting and closure for more information.

RESPONSIBILITIES

Position	Responsibility	Audit criteria
Health Service Chief Executive or delegate	• Provide authorisation on research SSA applications and contracts according to the MSH Finance Management Practice Manual (FMPM) and the Contract Management Framework.	N/A
Executive Management Team	• Ensure collaborative, harmonised, clear and detailed publicly available policies and procedures are in place for the ethical, scientific and SSA review of research of all research conducted within MSH.	N/A
Metro South Human Research Ethics Committee (MSHREC)	• Provide oversight of the ethical and scientific review of human research by keeping abreast of international, national and state-wide legislation, regulations and guidelines. • Promote MSH strategic requirements and ethical and responsible decision-making which respects the rights of MSH participants.	N/A
Metro South Research	• Metro South Research provides oversight and completes due diligence in line with state legislation, regulation, guidelines and in accordance with MSH SSA requirements. • Recommendation is provided by the MSRGO for authorisation by the Health Service Chief Executive or delegate as appropriate.	N/A
Principal Investigator/ Coordinating Principal Investigator - responsible officer	• Conduct research in accordance with national guidelines and the MSH Research Policy Framework. • Ensure research practices reflect current professional (ethical and legal) standards for research, including promptly responding to reporting and monitoring requirements. • Ensure compliance with the approval given by a HREC, legislative and policy requirements for participant contact, consent and confidentiality of participant information.	N/A

	• Only conduct clinical intervention studies with the essential approved credentialing privileges and clinical experience. • Are required to be aware of and comply with this procedure when conducting research.	
Employees, researchers, research student supervisors and students	• Adhere, be aware of and comply with all relevant policies, procedures, guidelines, work instruction, research protocols and Standing Operating Procedures (SOPs) when conducting research.	N/A

DEFINITIONS

Term	Definition
Adverse drug reaction (ADR)	Adverse drug reactions concern noxious and unintended responses to a medicinal product.
Adverse event (AE)	Any untoward medical occurrence in a patient administered a medicinal product and which does not necessarily have to have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign (for example, an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether considered related to this medicinal product or not.
Clinical Trial *(National Clinical Trials Governance Framework)*	A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials include but are not limited to: • Surgical and medical treatments and procedures • Experimental drugs • Biological products • Medical devices • Health-related service changes • Health-related preventative strategies • Health-related educational interventions.
Collaborative Research Group Clinical Trials Research Agreement (CRG CTRA)	An agreement template that is to be used where a Hospital and Health Service (HHS) acts as and assumes all the responsibilities of a commercial sponsor.

Good Clinical Practice (GCP)	A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.
Investigator initiated trial	A clinical trial that has the following characteristics: • A pharmaceutical/device company is not acting as the sponsor for the purposes of the CTN application. • A pharmaceutical/device company is not fully funding the conduct of the study, that is, making payment to the relevant hospital or investigator. • The clinical trial addresses relevant clinical questions and not industry needs. The CPI/PI or the Hospital/Institution is the primary author and custodian of the clinical trial protocol.
Principal Investigator (PI)/ Coordinating Principal Investigator (CPI)	An individual responsible for the conduct of a clinical trial at a trial site ensuring that it complies with GCP guidelines. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the CPI/PI In this instance they may delegate tasks to other team members.
Serious adverse event (SAE)	Any untoward medical occurrence that at any dose: • Results in death. • Is life-threatening (NOTE: The term 'life-threatening' in the definition of 'serious' refers to an event/reaction in which the patient was at risk of death at the time of the event/reaction; it does not refer to an event/ reaction which hypothetically might have caused death if it were more severe). • Requires inpatient hospitalisation or results in prolongation of existing hospitalisation. • Results in persistent or significant disability/incapacity. • Is a congenital anomaly/birth defect. Is a medically important event or reaction.
Sponsor	The Sponsor is responsible for ensuring that the clinical trial is conducted in accordance with the protocol, GCP and applicable regulatory requirements. Specifically, MSH is the Sponsor for investigator initiated clinical trials where MSH personnel has written the protocol, data is owned by MSH and/or is named on the CTN (as applicable).

RELATED AND SUPPORTING DOCUMENTS

Legislation and other Authority	**Legislation** • *Hospital and Health Boards Act 2011* (Qld) • *Information Privacy Act 2009* (Qld) • *Privacy Act 1988* (Cth) • *Public Health Act 2005* (Qld) • *Statutory Bodies Financial Arrangements Act 1982* (Qld) • *Therapeutic Goods Act 1989* (Cth) • *Gene Technology (Licence Charges) Act 2000* (Cth) • *Gene Technology (Queensland) Act 2016* (Qld) • *Gene Technology Act 2000* (Cth) • *National Health and Medical Research Council Act 1992* (Cth) • *National Safety and Quality Health Service Standards 2nd Edition ACSQHC 2017* (Cth) • *Therapeutic Good (Medical Devices) Regulations 2002* (Cth) • *Therapeutic Goods Regulations 1990* (Cth) **Regulations** • *Hospital and Health Boards Regulation 2012* (Qld) • *Information Privacy Regulation 2009* (Qld) • *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) **Other authority** • National Statement on Ethical Conduct in Human Research (2023) • Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2) • ICH Quality Guidelines • ISO 9001:2015 Quality management systems - Requirements **Department of Health** • Health Service Directive: Research Ethics and Governance Directive QH-HSD-035:2023 • Research Management Policy QH-POL-013:2022 • Research Management Standard QH-IMP-013:1:2022 **Metro South Health** • Metro South Health Research Strategy • Finance Management Practice Manual (FMPM) • Human Resources (HR) Delegations Matrix and Schedule • Metro South Financial Delegation Schedule and Framework • MSH Risk Management Framework

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

Supporting documents	**Procedures** • PR2023-411 Research excellence • PR2023-412 Research support and management • PR2023-413 Research administration and compliance **Work instructions** • WI2023-299 Ethical and scientific review of research • WI2023-300 Exemptions from research review • WI2023-302 Research contracts and study execution • WI2023-303 Metro South Health sponsorship of Clinical Trial Notification (CTN) scheme trials • WI2023-304 PowerTrials - ieMR research support module • WI2023-305 Research monitoring • WI2023-306 Post approval – research amendments, reporting and closure **Guidelines** • GL2023-99 Planning a research project • GL2023-100 Research Participant Information and Consent Form (PICF) • GL2023-101 Research contract clauses • GL2023-102 Use of electronic signatures in research contracts • GL2021-77 Clinical trials • GL2023-103 TeleTrials **Attachments** • Attachment 1: SSA Guidance Document and Checklist

HUMAN RIGHTS ACT 2019

Metro South Hospital and Health Service is committed to respecting, protecting and promoting human rights. Under the *Human Rights Act 2019*, Metro South Health has an obligation to act and make decisions in a way that is compatible with human rights and, when making a decision, to give proper consideration to human rights. When making a decision about research, decision-makers must comply with that obligation. Further information about the *Human Rights Act 2019* is available at: https://www.forgov.qld.gov.au/humanrights.

WORK INSTRUCTION DETAILS

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