Research contracts and study execution

PURPOSE

This work instruction describes the processes for research contracts when agreements are required for research activities and execution of research being conducted within or in collaboration with Metro South Health (MSH).

OUTCOME

The work instruction aims to:

- Ensure that all research involving MSH premises, resources or patients are the subject of a written research contract, also known as a research agreement, where a 'third-party', external to MSH is involved.
- Assist in facilitating research contract negotiations through the adoption of the Medicines Australia Research Agreements Template as mandatory for all commercially sponsored clinical studies in MSH facilities and is party to a number of standardised agreement templates.
- Outline a fundamental set of principles and clauses and ensure details of research funding, research contracts, ethics, research outputs and impact are maintained through the Ethics Review Manager (ERM) application.
- Ensure that there is a MSH wide process if/when MSH is subject to reviews, audits and investigations instigated by the various external regulatory bodies.

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: CONTRACT DEVELOPMENT

- All research or research related activities that involve an external/third-party must have a written research agreement in order to define the legal obligations of parties involved, ensure that Intellectual Property (IP) is protected, indemnity provisions are considered, and risks are managed on behalf of MSH.

- Researchers are advised to contact the Metro South Research at the earliest opportunity to facilitate appropriate agreement negotiation and provide contract/agreement assistance (see Appendix 1: Signature workflow diagram).

1.1 Contract requirement

- During the Site-Specific Assessment (SSA) application process, as outlined in MSH work instruction WI2023-301 Site specific assessment of research, researchers must identify if MSH employees, premises, resources or patients will be utilised in conjunction with an external and/or third party.
- All research contracts will be reviewed to identify that they comply with relevant applicable laws, regulations, guidelines and provisions outlined within this work instruction.

1.2 Development and negotiation

- MSH has a suite of approved agreement templates which are suitable for use as research contracts:
    - Clinical Trial Research Agreements – Medicines Australia
    - Medical Technology Association of Australia Clinical Investigation Research Agreement
    - Health Translation Queensland Research Passport Agreement
    - Collaborative research agreement template – for projects not involving clinical trials
- A written research contract must be initiated in consultation with the Metro South Research Governance Office (MSRGO) via email MSH-RGO@health.qld.gov.au.
- All research contracts are negotiated on behalf of the Health Service Chief Executive, by the MSRGO.
    - Note: if a Clinical Trials Research Agreement is unapproved, the MSH Legal team will be engaged for additional review, and legal review costs may be met by the third party.

2. STEP 2: RESEARCH CONTRACT FUNDAMENTAL PRINCIPLES AND CLAUSES

- Researchers must check the fundamental principles and clauses of the proposed research contract to ensure compliance with this work instruction as listed below.
- Refer to MSH guideline GL2023-101 Research contract clauses for more information.

2.1 Research data ownership, conflicts of interests and informed consent

- MSH researchers must not negotiate, accept any arrangement or offer of financial or other support from a source, for the development, protection, patenting or licensing of IP on behalf of MSH without involving MSRGO.
- Researchers must not engage in the transfer of any MSH materials or MSH confidential information to a non-MSH individual or entity without involving the MSRGO.
- MSRGO will review and provide recommendation to the Authorised signatory to approve all Confidentiality Disclosure Agreements (CDAs)/Non-Disclosure Agreements (NDAs) governing the disclosure of any MSH confidential or proprietary information to non-MSH external/third parties.

2.3 Material Transfer Agreements

- The MSRGO will review and provide recommendation to the Authorised signatory to approve relevant Material Transfer Agreements (MTAs) involving the transfer of research reagents, clinical samples, equipment or data to or from any external academic/research organisation or private sector research partner.

3. STEP 3: RESEARCH CONTRACTS AND STUDY EXECUTION

- The Research Contracts Approval and Study Execution Form (RCASE Form) must be completed by the researcher during the SSA application process for all studies.
    - Attachment 1: Research Contract Study Execution Form (RCASE Form) – single site
    - Attachment 2: Research Contract Study Execution Form (RCASE Form) – multi-site
- On the RCASE Form the researcher must provide:
    - Study information
    - Purpose of submission
    - Supporting documentation
    - Financial information (mandatory).
        - Note: Internal order number (ION) is provided by the finance delegate.
        - Project FTE generally includes the approximate hours per week converted to FTE.
        - In-kind costs include total non-cash contribution of MSH goods or services.
        - A detailed budget is required refer to MSH work instruction WI2023-293 Research funding, budgets, and infrastructure support.
- The following fields are completed based on the **Overall level of risk** identified when completing the Research risk assessment and management plan for the research project in accordance with MSH work instruction WI2023-292 Assessing and managing risk in research.
    - Principal Investigator signature
    - Head of Department signature
    - Finance/Business Manager (or PAH Divisional Director) signature >$10,000
    - Facility/Service Executive Director signature
    - Chief Operating Officer signature.
- For research projects that involve more than one (1) MSH facility, the relevant signature from each designated authorised representative of the MSH facility is required.
- The name of the contracted external/third-party, ABN, type of contract, contract value and in-kind value, compliance, legal advice is included by the MSRGO.
- Should the research contract be a non-standard agreement the RCASE Form, Legal review briefing, Protocol and HREC approval will be sent to the MSH Legal Team for review and approval PRIOR to recommendation for authorisation and execution.

- MSRGO will facilitate signature with the Health Service Chief Executive/Delegate, Chief People, Engagement and Research Officer or Executive Director, Metro South Research.

3.1 Use of electronic signatures in research contracts

- To execute a research contract refer to MSH guideline GL2023-102 Use of electronic signatures in research contracts for more information.

STEP 4: CONTRACT MANAGEMENT REQUIREMENTS

4.1 MSH Central Contract Register

- Once the research contract has been executed by the MSH delegate, the executed research contract is emailed to MSHCentralContractsRegister@health.qld.gov.au by the MSRGO.
- The Central Contract Register Team register the agreement and supporting documentation in the MSH Central Contracts Register.
    - Note: The Central Contract Register Team will notify the MSRGO via return email when the contract/contract amendment has been included in QContracts and will include the QContracts File Reference Number.
    - The registered number is the identifier for any contract.

4.2 Amendments to executed research contracts

- From time-to-time executed research contracts may require amendments.
- This may occur when there is a change to the research protocol, payment requirements, addition to the participant level or change to the sites participating.
- When an amendment is required, relevant information must be provided to the MSRGO, including but not limited to:
    - Evidence of HREC approval of the amendment (if required). Refer to the following MSH work instructions:
        - WI2023-299 Ethical and scientific review of research
        - WI2023-306 Post approval – research amendments, reporting and closure
    - A memorandum which includes notification of the change and highlights the variation to the research contract.
    - A revised research contract in PDF.
    - RCASE Form with the Department Head and Business Managers and/or Cost Centre Managers support for the change.
- As required, legal advice may be sought from MSH Legal Representatives as all research contracts must be signed off by the Health Service Chief Executive and/or delegate.
- The MSRGO will seek required endorsement of the requested amendment.

4.3 Records

- Research contracts are to be maintained in the MSH Central Contract Register with a copy retained by the MSRGO and Business Managers and/or Cost Centre Managers (if applicable).

RESPONSIBILITIES

Position	Responsibility	Audit criteria
MSH Legal Representatives	• Review research contracts and provide legal support to the Metro South Research Governance Office (MSRGO) (when required).	N/A
MSRGO	• Review research contracts/agreements, when submitted in conjunction with a Site-Specific Application (SSA), to undertake research within a MSH facility. • Work with the Principal Investigator to determine which research or research related activity, involving an external/third party, requires a research agreement. • Negotiate terms of all research contracts in accordance with applicable law, regulations, guidelines and MSH policies and procedures. • Consult with the relevant researcher and agree negotiated terms with MSH Legal Representatives. • Submit final research agreements for execution in accordance with MSH delegation requirements.	N/A
Business Managers and/or Cost Centre Managers	• Business Managers and/or Cost Centre Managers are accountable and responsible for financial aspects of a research contract including creating a research cost centre and maintaining and monitoring research cost centre balances, expenditure, receipting and transfer of fund surpluses.	N/A
Principal Investigator (PI)/ Coordinating	• Responsible for maintaining familiarity with current regulatory requirements, MSH policies and procedures and contacting the MSRGO regarding all research or research	N/A

Principal Investigator (CPI)	related activities involving an external party. • Facilitating arrangements for the research team to access MSH resources and support as agreed in the research contract (if applicable) and identified on the SSA application.	
Researchers	• Researchers must ensure that research contracts are formalised and signed by the MSH delegate, as identified in the Financial Delegations Framework and Schedule before engagement with any research partner.	N/A

DEFINITIONS

Term	Definition
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.
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.
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 (as updated and replaced from time to time)** • *Australian Research Council Act 2001 (Cth)* • *Hospital and Health Boards Act 2011 (Qld)* • *Financial Accountability Act 2009 (Qld)* • *National Health and Medical Research Council Act 1992 (Cth* • *Public Health Act 2005 (Qld)* • *Public Sector Ethics Act 1994 (Qld)* • *Research Involving Human Embryos Act 2002 (Cth)* • *Therapeutic Goods Act 1989 (Cth)* **Regulations** • *Financial Accountability Regulation 2009* (Qld) • *Financial and Performance Management Standard 2009* (Qld) • *Hospital and Health Boards Regulation 2012* (Qld) • *Public Health Regulation 2018* (Qld) • *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) • *Therapeutic Goods Regulations 1990* (Cth) **National Health and Medical Research Council (NHMRC)** • National Certification Handbook, 2012 • National Statement on Ethical Conduct in Human Research (2023) • NHMRC Certification Handbook, National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-centre Research 2012 • Payment of participants in research: information for researchers, HRECs and other ethics review bodies (2019) • Research Governance Handbook: Guidance for national approach to single ethical review December 2011 **Department of Health** • Health Service Directive: Research Ethics and Governance Directive QH-HSD-035:2023 • Research Management Guideline: external funding and infrastructure support QH-GDL-013-1:2022 • Research Management Policy QH-POL-013:2022 • Research Management Standard QH-IMP-013:1:2022 • Standard Operating Procedures for Queensland Health HREC Administrators

	• Standard Operating Procedures for Queensland Health RGOs **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

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 • WI2023-301 Site specific assessment in research • 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: Research Contract Study Execution Form (RCASE Form) – single site • Attachment 2: Research Contract Study Execution Form (RCASE Form) – multi-site

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

Work Instruction Name	Research contracts and study execution
Work Instruction Number	WI2023-302
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Executive Sponsor	Chief People, Engagement and Research Officer
Document Author	Manager, Research Development, Metro South Research
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REVIEW HISTORY

Version	Approval date	Effective from	Authority	Comment
1.0	7/12/2023	20/12/2023	Chief People, Engagement and Research Officer	• Supersedes PR2017-122 Research Contracts & Study Execution Procedure

APPENDIX 1

1. APPENDIX 1: SIGNATURE WORKFLOW DIAGRAM