Research contract clauses

PURPOSE

This guideline provides information and guidance around the fundamental principles and clauses for all research contracts executed in Metro South Health (MSH).

OUTCOME

The guideline aims to identify the intended outcomes of this guideline is to enable consistency in terminology and content included in research contracts.

SCOPE

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

GUIDELINE

1. RESEARCH CONTRACT SPECIFIC DETAILS

All contracts used in research have specific details which are required. To enable consistency please refer to and copy and paste the specific details outlined below (if applicable):

1.1 Legal entity - institution business name, address and ABN:

- The research contract must include the correct reference to MSH's legal entity name as outlined in the table example below.
    - The legal entity entering into the research contract is the 'Metro South Hospital and Health Service' via the Name of the Institution (i.e. the Princess Alexandra Hospital, Redland Hospital, QEII Hospital, Logan Hospital or Communities).
    - ABN for all sites is listed as 86 834 068 616
    - **Note:** The Hospital in itself is not a legal entity.

Name of Institution:	Metro South Hospital and Health Service via the Princess Alexandra Hospital
Address:	199 Ipswich Road, Woolloongabba, QLD, 4102
ABN:	86 834 068 616
Contact for Notices:	Manager, Research Integrity and Compliance, Metro South Research, Level 7, Translational Research Institute
Fax for Notices:	+61 7 3443 8003

Phone Number	+61 7 3443 8050

- The role and responsibilities of MSH, the facility or institution, participants, principal investigator (PI), sponsor, CRO and/or any collaborating organisations must also be outlined.

1.2 Sponsor details

- The research contract must identify the legal business name and registered address of the sponsor, Contract Research Organisation (CRO), Institution or University (including ACN/ABN).
- Researchers must check the sponsor/CRO's legal entity title against their ABN using Australian Business Register Lookup Internet Site.
- The legal entity entering into agreement with MSH for clinical trials must be an Australian company. If the Sponsor is a global company, they will need to engage a CRO located in Australia.

1.3 Researcher details

- The researcher is usually defined as the **investigator** conducting the research project on behalf of the correct legal entity.

2. SECTION GUIDANCE

2.1 Definitions section

- Definitions are normally placed prior to terms found in the research contract and must be clearly defined.

2.2 Effective date

- The research contract must include an effective date. This date is not necessarily the date when the research contract is signed but rather the date from which all the contractual rights and obligations begin, and from which point the term of the research contract will commence unless specified otherwise.

2.3 Clauses

- All research contracts must generally include clauses that deal with the following issues:

2.3.1 Parties

- The research contract must correctly identify the parties to the contract. External/third parties must include their full legal number including their registered address and ABN.

2.3.2 Payments, GST and Invoicing

- Details must be included in the research contract regarding the following:
    - Payee details
    - Invoicing details
    - Method of any payments to or by MSH (where applicable). Generally, GST will apply to all payments.
    - Timing

- The sponsor or CRO must arrange payment of the fee including GST, agreed with MSH (via the researcher) for performance of research project tasks.

- The research contract must specify that funds will be paid using electronic transfer.
- An appropriate MSH research Internal Order Number (ION) must be identified in accordance with MSH work instruction WI2023-293 Research funding, budgets, and infrastructure support.

2.3.3 Obligations, roles and responsibilities of each party

- The research contract must set out, with as much detail as possible, the roles and responsibilities of each party in relation to the conduct of the research project.
- The research contract should oblige all parties to comply with Laws of Queensland as a precedence or Australian law as an alternative, and relevant regulations, as well as national guidelines and standards regarding research.
- The research contract must include clauses regarding each party's responsibilities for reporting and management of adverse events, records managements and provision of equipment or research project material, completion of case forms or reports, and retention and access requirements to research project related material.

2.3.4 Indemnities

- An indemnity is a contractual promise by one party to protect the other party from and against certain specified actions, claims or losses.
- Universities may include a clause whereby each of the institutions involved in the research project will indemnify themselves (MSH cannot provide indemnity pursuant to the *Statutory Bodies Financial Management Act* (1982) without Chief Financial Officer, MSH approval).
- In research projects that are PI initiated, collaborative or involve funding from non-profit organisations, it is more appropriate for the indemnity clauses to be mutual. The Medicines Australia Collaborative Research Agreement encompasses mutual indemnity in Clause 11 and is the preferred indemnity arrangement where each party indemnifies themselves, removing the requirement for a formal indemnity agreement.
- MSH is a statutory body under the *Statutory Bodies Financial Management Act* (1982) and is therefore unable to enter into a 'Type 1' financial arrangement unless approval is obtained via the Chief Financial Officer, MSH.
- If the research project is a Sponsored clinical trial commercial sponsors/pharmaceutical entities or contract research organisations proposing to engage in clinical trials using unapproved therapeutic goods or devices must fully indemnify MSH by using the Medicines Australia Standard Form of Indemnity for Clinical Trials available at the Medicines Australia website or the Medical Technology Australia website (these documents cannot be altered).

2.3.5 Insurance

- The research contract must include a clause requiring any party who is providing an indemnity under the research contract to have and maintain appropriate insurance.
- A current Public/Products Liability Certificate of Insurance from the Commercial Sponsor must be provided before final approval for the research contract can be given.
- It must name the insured corporate entity acting as the Commercial Sponsor. Insurance must contain coverage for a minimum amount of AUD$10,000,000 for anyone (1) occurrence and in annual aggregate.

2.3.4 Intellectual Property

- Intellectual Property (IP) rights must be clearly identified. The research contract must specifically state the arrangements for use of existing proprietary background intellectual property and for ownership and use of all data, research, methodologies and process results and IP resulting from the research.
- Research conducted within MSH must comply with Queensland Health as well as the Queensland Government IP guidelines published by the Department of Employment, Economic Development and Innovation.
- Research contracts must state the arrangements for use of existing IP and the party's rights in relation to ownership and use of all new IP development through the research project.
- Patient medical records must remain the property of MSH. These provisions must be at least equal to the National Health and Medical Research Council (NHMRC) Mutual Institutional Agreement.

2.3.5 Confidentiality and Privacy

- Access levels to confidential information must be identified in the research contract. Research contracts must include clauses that require the parties to maintain the confidentiality of any 'confidential information' that they have access to in the course of performing the research project.
- The term 'confidential information' must always be specifically and carefully defined in the research contract. MSH must ensure that patient data and clinical records are defined as confidential. Through the research contract, MSH must impose obligations on external parties regarding the use, handling and disclosure of 'personal information' (which must be defined) consistent with MSH privacy obligations under the *Information Privacy Act 2009* (Qld) and the research provisions of the *Public Health Act 2005* (Qld). The Sponsor or CRO will have access to all information created during research project and MSH will require access to information related to the safety and care of the patient.
- A Confidentiality Disclosure Agreement/Non-Disclosure Agreement (CDA/NDA) is legal agreement between MSH and an external/third party (e.g., company or individual) governing the disclosure and/or transfer and/or exchange of confidential information. There must be provisions requiring that all employees or agents of the Sponsor or Contract Research Organisation who become aware of any patient information must comply with all Queensland/applicable laws.

2.3.4 Assignment

- Neither party should be entitled to assign or transfer any rights or obligations under the research contract without the prior written consent of the other.

2.3.5 Force majeure

- A clause regarding force majeure must be included in the research contract, stipulating conditions pertaining to a Force Majeure.

2.3.6 Publications

- The research contract must include provisions regarding the publication rights of the parties. All research results must be published, subject only to short delays in publication to allow for a party to seek protection of valuable IP or to make amendment to remove any confidential information.
- The parties must be required to obtain the prior written permission of the other party to the use of a party's name in any publications or promotional material. Information regarding publication must be negotiated by the PI. Their approval of this clause is sufficient.

2.3.7 Term and termination

- The term of the research contract must be stated. The research contract must also expressly state the circumstances in which a party may terminate the research contract and suitable mechanisms for termination. For termination before completion, written notice by the terminating party must be required.
- The research contract must be able to be terminated by MSH with immediate effect if MSH is unable to complete the research project due to circumstances beyond its control, or the PI or Metro South Research Governance Office (MSRGO) determines that it is unsafe to continue.
- MSH must ensure that it has the right to terminate if it forms the view at any time that patient safety necessitates the cessation of the research project.
- Clauses must also be included regarding the consequences of the terminations (including for example, obligations to finalise and submit reports, payment of all funds due and owing up until the date of termination and arrangements for ongoing medical care of the patients). Upon termination MSH must be paid for all costs incurred or committed up to the date of termination, including cost of closing the project (e.g., staff contracts, leases, etc.).

2.4 Records maintenance and inspection

- A records maintenance and inspection clause must be negotiated by the PI and third party prior to inclusion in a research contract.
- Approval and agreement to this clause by all parties is sufficient. The research contract should stipulate how records and related materials are to be stored, by whom, for how long and how they will be disposed of, also clearly stating who will have access to and or administer the stored information.
- All clinical trial related records and materials must be stored in accordance with the Department of Health Retention and Disposal of Clinical Records Standard QH-IMP-280-1:2014.

2.5 Use of party's names

- No party to the research contract will use the other party's name in connection with any public announcement, advertising publication or promotion without prior written permission.

2.6 Considerations

- Consideration is the exchange of promises by the parties to the research contract. It can be the payment of money or the promise to do or not do a particular thing. A clinical drug trial research contract must specify in detail the:
    - Outputs/and or outcomes the sponsor or CRO wants to achieve.
    - Tasks the institution/researcher agrees to carry out and resources (including funds) to be made available by each party.

2.7 Conformance with law

- The research contract must also indicate that all activities as set out in the protocol will be undertaken in conformance with all applicable Queensland law or Australian law as an alternative. Including but not limited to regulations and requirements of NHMRC, Therapeutic Goods Administration (TGA) and Office of Gene Technology Regulator (OGTR) and the applicable laws of any other to which the sponsor or Contract Research Organisation is accountable (e.g., United States Food and Drug Administration (FDA).

3. OTHER REQUIREMENTS

3.1 Template research contracts

- The type of research contract required and the nature of the clauses to be included in the contract will be determined by the type of research activity being undertaken.
- MSH has endorsed several template research contracts for use in circumstances involving common types of research activity. These templates can be accessed via contacting the MSRGO via MSH-Research@health.qld.gov.au

3.2 Variation to a research protocol

- When there is a research protocol modification agreed to by all parties and the respective Human Research Ethics Committee (HREC) has approved this variation, if the changes involve protocol name change, affect the costs incurred by any MSH division/department these changes must be appropriately compensated, for additional costs, recruitment levels, change to PI or Associate Investigators, addition of sites, an amendment to the research contract must be provided.

3.3 Adverse events - sponsor and CRO obligation to monitor and report

- The sponsor and CRO must agree to monitor the application of the specific drug, device or treatment under study in other places (including any other country). Any cessation of any relevant trial elsewhere or the withdrawal of the drug or treatment from any other market for safety reasons must be advised to the PI in the first instance.
- The NHMRC Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods November 2016 has been adopted by MSH and it is recommended that all research personnel are familiar with the requirements.

3.4 Signatures and approval

- PI/s must provide their signature acknowledgement only, post the external party's (ie sponsor) signature being obtained and prior to MSH delegate execution. The signature constitutes an

acceptance of the research contracts terms and conditions covering technical and scientific performance of the research project ownership, reporting and publication of the results.

- The external/third party must provide their signatures on the research contract prior to MSH delegate execution. The signatures of the representatives of the third party constitute final agreement with the terms and conditions of the research contract/agreement including schedules.
- The Research Governance Office will provide the research contract executed by the Sponsor and the PI to be signed by the MSH and/or delegate. The signature of the MSH delegate constitutes:
    - Final agreement to undertake the research project.
    - An assurance that the research project is consistent with MSH research management priorities.
    - An assurance that undertaking the research project will not conflict with the service delivery responsibilities of MSH.
- Non-clinical trial contracts may only require the sponsor and the institutions signature, in this case the Sponsor will sign prior to MSHHS delegate execution.

4. SCHEDULES

- Researchers **must ensure all schedules** or annexures referred to in the body of the research contract are attached and marked appropriately. The following schedules may be included in research contracts and/or sponsored clinical trials research agreements.

4.1 Schedule 1 Key Information

- Key information is completed including - minimum and maximum recruitment numbers, commencement, equipment supplied and termination dates and details of the third party are applicable.

4.2 Schedule 2 Payments

- Information regarding payment information must be include and include the correct cost centre code, method of payment and banking details.
- If there are any discrepancies the MSRGO must check with PI or Clinical Trial Co-ordinator (as appropriate).

FOR CLINICAL TRIALS ONLY:

4.3 Schedule 3 Indemnity

- This schedule pertains to the standard indemnity which the Sponsor must provide. The Sponsor can provide this separately as or paste the indemnity in this schedule.
- All research contracts providing indemnification must be entered into the MSH SharePoint Indemnity Register.

4.4 Schedule 4 Insurance

- The sponsor must provide a current insurance certificate or attach this as part of the research contract.

4.5 Schedule 5 Guidelines for Compensation

- The guideline for compensation is included for the Sponsor's reference. When the Sponsor is making compensation to participants, they must abide by this guideline. The guideline can be pasted in its entirety in the schedule, or a website address to the guideline can be inserted.

4.6 Schedule 6 Research Protocol Identification

- The Sponsor must insert a reference to the research protocol document which has been submitted and approved by an authorised HREC.

4.7 Schedule 7 Special Conditions

- If the sponsor has included special conditions these must be checked against SEBS approval for the special conditions. Researchers must discuss further with the MSRGO for more information regarding special conditions.

4.8 Specific schedules for CRO research contracts

- Specific schedules are required for CRO research contracts including:
    - Schedule 1, 2 (see above section)
    - Schedule 3 and
    - Schedule 4 Special Conditions.
- As stated above, if the CRO has included special conditions, these must be checked against MSH approved special conditions accessible from the MSRGO.

RESPONSIBILITIES

Position	Responsibility	Audit criteria
External party	Provide executed research contracts in accordance with the outlined process.	N/A
Metro South Research	Review and process research contracts for signature in accordance with the Research Policy Framework.	N/A
Principal Investigators	Liaise with the Sponsor regarding the development and execution of a research contracts.	N/A
Requestor	Facilitate contract signature by external parties and MSH.	N/A

DEFINITIONS

Term	Definition

Research contract	A research contract is a legally binding agreement that governs collaborative research between MSH, the University and external organisations. The contract can be for the provision of research goods or services.
Schedule	A contract schedule is a list or description of information that is attached at the end of a contract. It is sometimes referred to as an appendix and is used to include information that would be too confusing or cumbersome to include in the main body of the agreement.

RELATED AND SUPPORTING DOCUMENTS

Legislation and other Authority	• *Electronic Transactions (Queensland) Act 2001* (Qld) • *Financial Accountability Act 2009* (Qld) • *Financial and Performance Management Standard 2019* (Qld) • *Public Sector Ethics Act 1994* (Qld) • *Public Records Act 2002* (Qld) • *Corporations Act 2001* (Cth) • *Electronic Transactions Act 1999* (Cth) • *Human Rights Act 2019* (Qld)

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	• WI2023-301 Site specific assessment of research • WI2023-302 Research contracts and study execution • WI2023-293 Research funding, budgets, and infrastructure support • GL2023-102 Use of electronic signatures in research contracts • GL2021-77 Clinical trials

HUMAN RIGHTS ACT 2019

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

GUIDELINE DETAILS

Guideline Name	Research contract clauses
Guideline Number	GL2023-101
Current Version	V1.0
Keywords	Research contract, site specific assessment
Primary Document Reference	PR2023-413 Research administration and compliance
Executive Sponsor	Chief People, Engagement and Research Officer
Endorsing Committee / Authority	Metro South Health Research Council
Document Author	Manager, Research Development, Metro South Research
Next Review Date	December 2026

REVIEW HISTORY

Version	Approval date	Effective from	Authority	Comment
1.0	7/12/2023	14/12/2023	Chief People, Engagement and Research Officer	New document