PROCEDURE

Research Management - Research Contracts and Study Execution

PR2017/122
Version No. 1.0

PURPOSE

The purpose of this Procedure is to outline requirements for research contracts when agreements are required for research project activities and study execution. All research or research related activities that involve an external/third-party must have a written research agreement in order to define the obligations of involved parties, ensure that Intellectual Property (IP) is protected, indemnity provisions are considered and risks are managed for the Metro South Hospital and Health Service (Metro South Health).

OUTCOME

Adherence to this Procedure will ensure all research conducted within Metro South Health or in collaboration with external entities, is of the highest ethical and scientific standard and is compliant with relevant legislation, standards and guidelines.

This Procedure applies to:

- All Metro South Health employees who conduct human research within or in association with Metro South Health facilities, or through access to Metro South Health participants; and
- All personnel (including researchers, students and visitors) involved in all aspects of human research in or in association with Metro South Health.

Failure to comply with this Procedure may amount to research misconduct on the part of the responsible individual. This Procedure must be read in conjunction with other Metro South Health Research Management Procedures and the Metro South Health Contract Management Framework.

KEY PRINCIPLES

The following key principles guide Metro South Health in the management of research contracts and study execution.

- All research involving Metro South Health employees, premises, resources or patients must be subject of a written research contract, also known as a research agreement, where a ‘third-party’, external to Metro South Health is involved.
- To facilitate research contract negotiations Metro South Health has adopted the Medicines Australia Research Agreements Template as mandatory for all commercially sponsored clinical studies in Metro South Health facilities and is party to a number of standardised agreement templates.

- All research contracts in Metro South Health must include a set of fundamental principles and clauses as outlined in this Procedure.
- Metro South Health maintains details of research funding, research contracts, ethics, research outputs and impact through the Australian Research Ethics Database (AU RED).
- Metro South Health is subject to reviews, audits and investigations instigated by the various external regulatory bodies.
- Researchers must ensure that research contracts are formalised and signed by the Metro South Health delegate, as identified in the Finance Management Practice Manual (FMPM), before engagement with any research partner.

LEGISLATION OR OTHER AUTHORITY

Legislation

- *Gene Technology (Queensland) Act 2016 (Qld)*
- *Gene Technology Act 2000 (Cth)*
- *Hospital and Health Boards Act 2011 (Qld)*
- *Information Privacy Act 2009 (Qld)*
- *Privacy Act 1988 (Cth)*
- *Public Health Act 2005 (Qld)*
- *Statutory Bodies Financial Management Act (1982)*
- *Therapeutic Goods Act 1989 (Cth)*

Regulation

- Hospital and Health Boards Regulation 2012 (Qld)
- Information Privacy Regulation 2009 (Qld)

Statements, Papers and Guidelines

- National Health and Medical Research Council (NHMRC):
  - Australian Code for the Responsible Conduct of Research 2007
  - National Statement on Ethical Conduct in Human Research (2007) - Updated May 2015
  - Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods
  - Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research 2003
  - Research Governance Handbook: Guidance for the national approach to single ethical review 2011
  - Medicines Australia - Clinical Trial Agreements
- Queensland Health:
  - Health Service Directive: Research Ethics and Governance HSD-035:2016
  - Researcher User Guide (RUG) 2010
  - Standard Operating Procedures for Queensland Health HREC Administrators 2013
  - Standard Operating Procedures for Queensland Health Research Governance Officers 2013
  - Retention and Disposal of Clinical Records Standard QH-IMP-280-1:2014
- Therapeutic Goods Administration: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) 2000 - Annotated with TGA Comments

Metro South Health Policies, Procedures, Manuals, Frameworks etc.

- Contract Management Framework
- Finance Management Practice Manual (FMPM)
- Integrated Risk Management Framework
- Management of Conflict of Interest - All Staff Procedure (PR2016-66)
- Management of Conflict of Interest Policy (PL 2014/0038)
- Risk Assessment Guide (V12 6-11-2013)
- Risk Management Policy (PL2013-06)

RESPONSIBILITIES

Metro South Health Legal Representatives

Review research contracts and provide legal support to the Metro South Health Research Governance Office/r (when required).

Metro South Health Research Governance Office/r

It is the responsibility of the Metro South Research Governance Office/r, within the Centres for Health Research, to review research contracts/agreements, when submitted in conjunction with a Site Specific Application (SSA), to undertake research within a Metro South Health facility.

The Metro South Health Research Governance Office/r is responsible for:

- Working with the Principal Investigator to determine which research or research related an activity, involving an external/third party, requires a research agreement.
- Negotiating terms of all research contracts in accordance with applicable law, regulations, guidelines and Metro South Health Policies and Procedures.
- Consulting with the relevant researcher and agree negotiated terms with Metro South Health Legal Representatives.
- Submitting final research agreements for execution in accordance with Metro South Health delegation requirements.

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.

Principal Investigators

Principal Investigators are responsible for maintaining familiarity with current regulatory requirements, Metro South Health Policies and Procedures and contacting the Metro South Health Research Governance Office/r regarding all research or research related activities involving an external party.

Research Project Liaison Officer/s, Clinical Research Coordinator/s and Relevant Other Personnel

Facilitating arrangements for the research team to access Metro South Health resources and support as agreed in the research contract (if applicable) and identified on the Site Specific Assessment (SSA) application.

SUPPORTING DOCUMENTS

Attachments

Attachment 1 - Application

Forms

Metro South Research Contracts Approval and Study Execution Form

Medicines Australia Research Agreements Template

DEFINITIONS

See the Metro South Health Research Management Glossary

PROCEDURE - RESEARCH CONTRACTS AND STUDY EXECUTION

STEP 1: Identification of Requirement for Research Contract

During the Site Specific Assessment (SSA) application process, as outlined in Research Governance (Site Specific Assessment) Procedure (PR2017/116), researchers must identify if Metro South Health employees, premises, resources or patients will be utilised in conjunction with an external and/or third party. Where this is identified, a written research contract must be initiated in consultation with the Metro South Health Research Governance Office/r.

STEP 2: Development and Negotiation

The Medicines Australia Research Agreements Template or other suitable agreement must be utilised when developing a research contract in Metro South Health. Researchers are advised to contact the Metro South Research Governance Office at the earliest opportunity to facilitate appropriate agreement negotiation.

All research contracts must comply with all applicable laws, regulations, guidelines and provisions outlined within this Procedure. All research contracts are negotiated on behalf of the Chief Executive Officer, Metro South Health by Legal Representatives and the Metro South Health Research Governance Office/r. Please note if an unapproved Clinical Trials Research Agreement is to be used then legal review costs may be met by the third party.

STEP 3: Research Contract Fundamental Principles and Clauses

Researchers must check the fundamental principles and clauses of the proposed research contract to ensure compliance with this Procedure. See Section 2.0 Fundamental Principles and Clauses for all Research Contracts below for more information.

STEP 4: Indemnification

The Metro South Health Research Governance Office/r must enter information regarding: dates, division/department where the research contract is kept, beneficiary of indemnity, Site Specific Assessment (SSA) reference, specific terms of indemnity, type and purpose of research contract, insurance coverage and risk management level into the Metro South Health Share Point Indemnity Register. This is then printed and retained for record keeping purposes.

STEP 5: Research Data Ownership, Conflicts of Interests and Informed Consent

Metro South Health researchers must not negotiate, accept any arrangement or offer of financial or other support from a source, other than Metro South Health, for the development, protection, patenting or licensing of Intellectual Property (IP). Researcher must also not engage in the transfer of any Metro South Health materials or Metro South Health confidential information to a non-Metro South Health individual or entity without involving the Metro South Research Governance Office/r.

Metro South Health Research Governance Office/r must review and approve all Confidentiality Disclosure Agreements (CDAs)/Non-Disclosure Agreements (NDAs) governing the disclosure of any Metro South Health confidential or proprietary information to non-Metro South Health external/third parties.

STEP 6: Material Transfer Agreements

The Metro South Health Research Governance Office/r must review and approve all 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.

STEP 7: Research Contracts and Study Execution Form, Contract Management Requirements

The Metro South Research Contracts Approval and Study Execution Form - PART A must be completed by the researcher during the Site Specific Assessment (SSA) application process. PART B of the Metro South Research Contracts Approval and Study Execution Form is completed by the Metro South Research Governance Office/r. The name of the contracted external/third-party, ABN, type of contract, contract value and compliance information details must be included within PART B.

Should the research contract be a non-standard agreement the Metro South Research Contracts Approval and Study Execution Form along with the research contract must be sent to Metro South Health Research Governance Office/r for review PRIOR to recommendation for authorisation and execution.

STEP 8: Metro South Health Central Contract Register

Once the research contract has been executed by the Metro South Health delegate, the executed research contract is emailed to MSHCentralContractsRegister@health.qld.gov.au. The Central Contract Register Team register the agreement and supporting documentation in the Metro South Health Central Contracts Register, Note: The Central Contract Register Team will notify the Metro South Health Research Governance Office/r 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 contact and is loaded to the SharePoint Research Ethics and Governance Register.

STEP 9: 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 Metro South Health Research Governance Office/r, including but not limited to:

- Evidence of HREC approval of the amendment. See Ethical and Scientific Review of Human Research Procedure (PR2017/113) for more information.
- A memorandum which includes notification of the change and highlights the variation to the research contract.
- A revised research contract (3 copies). Please note if provided in hard copy then original signatures are required however if supplied in PDF then a scanned version of original signatures are acceptable.
- Metro South Research Contracts Approval and Study Execution Form with the Department Head and Finance Managers support for the change.

As required, legal advice may be sought from Metro South Health Legal Representatives. As all research contracts must be signed off by the Chief Executive Officer, Metro South Health and/or delegate, the Metro South Health Research Governance Office/r will seek required endorsement of the requested amendment.

Step 10: Records

Research contracts are to be maintained in the Metro South Health Central Contract Register with a copy retained by the Metro South Health Research Governance Office/r and Business Manager and/or Cost Centre Manager (if applicable).

PROCEDURE DETAILS

Procedure Number
PR2017/122

Procedure Name
Metro South Health Research Management - Research Contracts and Study Execution

Policy Reference
PL2017/55
Metro South Health Research Management Policy

Supersedes
Nil

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Approving Date
25/10/2017

Effective From
30/10/2017

Date of Last Review
30/10/2017

Date of Next Review
30/10/2020

Attachment 1 - Application

1.0 Research Contract Management

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. Contractually terms must be appropriate and acceptable to Metro South Health and consistent with Metro South Health Contract Management Framework and its research and development objectives, as the conduct of research may otherwise expose Metro South Health to significant legal liability and risk.

1.1 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 Metro South Health Workforce Services.

For the purposes of this Procedure, an external/third party is a corporation or agency other than Metro South Health or an individual who is not a Metro South Health employee.

1.2 Authority

Within Metro South Health, the delegation and the authority for signing of research contracts on behalf of the Health Service is the Chief Executive Officer, Metro South Health or delegate. Please see the Financial Management Practice Manual (FMPM) for more information. For research projects which involve funds less than $200,000, the appropriate delegate is the Chair, Centres for Health Research, Metro South Health. For research that involves funds greater than $200,000, the appropriate delegate is the Executive Director for the facility/service i.e. Executive Director, PAH-QEII Network, Metro South Health.

Research contract signing must take place following review of the final document by Metro South Health Research Governance Office/r and on recommendation from the Manager, Research Compliance, Centres for Health Research, Metro South Health that the research project be authorised to commence.

Metro South Health 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 Metro South Health research contract delegate.

1.3 Brisbane Diamantina Health Partners (BDHP) Research Passport Agreement

The Brisbane Diamantina Health Partners (BDHP) Research Passport Agreement has been adopted by Metro South Health, Metro North Health, Mater Health Services, Children's Health Queensland, Translational Research Institute (TRI), QIMR Berghofer Medical Research Institution, the University of Queensland and Queensland University of Technology. The BDHP Research Passport Agreement acts as an umbrella agreement for any research projects that might be between any given partner institution listed above. BDHP, which includes Metro South Health, must provide a relevant Schedule that is an appendage to the BDHP Research Passport Agreement.

1.4 Clinical Trial Research Contract/Agreement

Whenever possible, the Sponsor (e.g. 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.

1.5 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.

1.6 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 the correct contractual arrangements be put in place.

1.7 Material Transfer Agreements (MTA)

A Material Transfer Agreements (MTA) may also be required in addition to a Research Contract. A Material Transfer Agreement (MTA) is a legal agreement that governs the transfer of research material (including biospecimen and data) or equipment from Metro South Health to another non-Metro South Health entity or individual (and vice versa). The Material Transfer Agreement 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.

2.0 Fundamental Principles and Clauses for all Research Contracts

2.1 Specific Details

Legal Entity - Institution Business Name, Address and ABN: The research contract must include the correct reference to Metro South Health's legal entity name as outlined in the table 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 or Logan Hospital. Note: The Hospital in itself is not a legal entity.

Fields	Specific Details
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 Compliance, Centres for Health Research, Level 7, Translational Research Institute
Fax for Notices:	+61 7 3443 8003
Phone Number	+61 7 3443 8050

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

Researcher Details: The researcher is usually defined as the INVESTIGATOR conducting the research project on behalf of the correct legal entity (usually defined as the "INSTITUTION").

2.2 Definitions Section

Definitions and terms must be clearly defined in the 'Definitions' section of the research contract. The definition, role and responsibilities of Metro South Health, the facility or institution, participants, Principal Investigator, Sponsor, Contract Research Organisation and/or any collaborating organisations must also be outlined.

2.3 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.

2.4 Clauses

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

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. Metro South Health must be identified as: *Metro South Hospital and Health Service acting via "insert relevant facility" ABN 86 834 068 616 at "insert facility address".*

Payments, GST and Invoicing: Details must be included in the research contract regarding the timing and method of any payments to or by Metro South Health (where applicable). Generally GST will apply to all payments. The Sponsor or Contract Research Organisation must arrange payment of the fee including GST, agreed with Metro South Health (via the researcher) for performance of research project tasks. The research contract must specify the manner in which Metro South Health will be paid via cheque or funds can be paid using electronic transfer. An appropriate Metro South Health research cost code must be identified in accordance with Research Funding, Budgets and Infrastructure Support Procedure (PR2017/121).

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 all applicable Australian Laws and 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 formes or reports, and retention and access requirements to research project related material.

Indemnities: If the research project is a Sponsored clinical trial, the Sponsor or Clinical Research Organisation (engaged to act on behalf of the Sponsor) must indemnify Metro South Health against claims by patients/participants arising from the research project in terms consistent with the Medicines Australia Standard Forms of Indemnity. In research projects that are Principal Investigator initiated, collaborative or involve funding from non-profit organisations, it is more appropriate for the indemnity clauses to be mutual. Metro South Health 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, Metro South Health. Clause 11 from the Medicines Australia Collaborative Research Agreement is the preferred indemnity arrangement where each party indemnifies themselves.

Indemnity and 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. An indemnity is a contractual promise by one party to protect the other party from and against certain specified actions, claims or losses.

Commercial Sponsors/Pharmaceutical entities or Contract Research Organisations proposing to engage in clinical trials using unapproved therapeutic goods must fully indemnify Metro South Health 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).

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 any one (1) occurrence and in annual aggregate.

A non-for-profit-organisation will make provision for a collaborative indemnity covered under the collaborative research contract/agreement. Universities may include a clause whereby each of the institutions involved in the research project will indemnify themselves (Metro South Health cannot provide indemnity pursuant to the *Statutory Bodies Financial Management Act (1982)* without Chief Financial Officer, Metro South Health approval).

Intellectual Property: Intellectual property 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 Intellectual Property (IP) resulting from the research.

Research conducted within Metro South Health must comply with Queensland Health and Metro South Health Intellectual Property (IP) Policies, Procedures and principles, as well as the Queensland Government Intellectual Property (IP) Guidelines published by the Department of Employment, Economic Development and Innovation. Research contracts must state the arrangements for use of existing Intellectual Property (IP) and the party's rights in relation to ownership and use of all new Intellectual Property (IP) development through the research project.

Patient medical records must remain the property of Metro South Health. These provisions must be at least equal to the NHMRC Mutual Institutional Agreement.

Confidentiality and Privacy: Access levels to confidential information must be identified in the research contract. Research contracts must include clauses that require the party's 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. Metro South Health must ensure that patient data and clinical records are defined as confidential. Through the research contract, Metro South Health must impose obligations on external parties regarding the use, handling and disclosure of ‘personal information’ (which must be defined) consistent with Metro South Health privacy obligations under the Information *Privacy Act 2009 (Qld)* and the research provisions of the *Public Health Act 2005 (Qld)*.

The Sponsor or Contract Research Organisation will have access to all information created in the course of research project and Metro South Health 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 Metro South Health 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.

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.

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

Publications: The research contract must include provisions regarding the publication rights of the party’s. All research results must be published, subject only to short delays in publication to allow for a party to seek protection of valuable Intellectual Property (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 Principal Investigator. Their approval of this clause is sufficient.

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 Metro South Health with immediate effect if Metro South Health is unable to complete the research project due to circumstances beyond its control, or the Principal Investigator or Metro South Health Research Governance Office/r determines that it is unsafe to continue. Metro South Health 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 Metro South Health 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.).

2.5 Records Maintenance and Inspection

A Records Maintenance and Inspection clause must be negotiated by the Principal Investigator 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.

2.6 Use of Parties Names

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

2.7 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 Contract Research Organisation wants to achieve.
- Tasks the Institution/researcher agrees to carry out and resources (including funds) to be made available by each party.

2.8 Conformance with Law

The parties and the Principal Investigator must perform the research in conformance with the protocols and instructions agreed between the parties. The research contract must also indicate that all activities 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).

2.9 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. Metro South Heath has endorsed a number of template research contracts for use in circumstances involving common types of research activity. These templates can be accessed via contacting the Metro South Health Research Governance Office/r via PAH-Research@health.qld.gov.au.

2.10 Variation to a Research Protocol

There must be a mechanism allowing for Research Protocol to be modified if agreed to by all parties and the respective HREC must have approved this variation. Please see Ethical and Scientific Review of Human Research Procedure (PR2017/113) and Research Governance (Site Specific Assessment) Procedure (PR2017/116) for more information.

If such changes affect the costs incurred by any Metro South Health division/department, these changes must be appropriately compensated, an amendment to the research contract must be provided.

2.11 Adverse Events - Sponsor and Contract Research Organisation Obligation to Monitor and Report

The Sponsor and Contract Research Organisation 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 Principal Investigator in the first instance. The NHMRC Position Statement: Monitoring and Reporting of Safety for Clinical Trials has been adopted by Metro South Health and it is recommended that all research personnel are familiar with the requirements. Please see Ethical and Scientific Review of Human Research Procedure (PR2017/113) and Research Governance (Site Specific Assessment) Procedure (PR2017/116) for more information.

2.12 Signatures and Approval

The external/third party must provide their signatures on a minimum of one (1) copy of the Research Contract prior to Metro South Health 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

Principal Investigator/s must provide their signature acknowledgement only, post the external party's (i.e. Sponsor) signature being obtained and prior to Metro South Health 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 research contract must be signed by the Metro South Health and/or delegate. The signature of the Metro South Health delegate constitutes:

- Final agreement to undertake the research project.
- An assurance that the research project is consistent with Metro South Health research management priorities.
- An assurance that undertaking the research project will not conflict with the service delivery responsibilities of Metro South Health.

3.0 Schedules

Researchers must ensure all Schedules 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.

3.1 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.

3.2 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 Metro South Health Research Governance Office/r must check with Principal Investigator or Clinical Trial Co-ordinator (as appropriate).

FOR CLINICAL TRIALS ONLY:

3.4 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 Metro South Health SharePoint Indemnity Register.

3.5 Schedule 4 Insurance

The Sponsor must provide a current insurance certificate and attach this as part of the research contract.

3.6 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.

3.7 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.

3.8 Schedule 7 Special Conditions

If the Sponsor has included special conditions these must be checked against the Metro South Health approved special conditions. Researchers must discuss further with the Metro South Health Research Governance Office/r for more information regarding special conditions.

3.9 Specific Schedules for Contract Research Organisation Research Contracts

Specific schedules are required for Contract Research Organisation research contracts including:

- Schedule 1, 2 (see above section);
- Schedule 3; and
- Schedule 4 Special Conditions.

As stated above, if the Contract Research Organisation has included special conditions, these must be checked against Metro South Health approved special conditions accessible from the Metro South Health Research Governance Office/r.