

# PROCEDURE

## Research Management - Research Governance (Site Specific Assessment)

PR2017/116  
Version No. 1.0

### PURPOSE

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The Metro South Hospital and Health Service (Metro South Health) is committed to the highest standards and practices in the assessment, authorisation, oversight and conduct of research. This Procedure identifies consistent and enforceable research governance processes, pertaining specifically to Site Specific Assessment (SSA), for research being conducted in or in collaboration within Metro South Health.

### OUTCOME

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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.

### KEY PRINCIPLES

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The following key principles guide Metro South Health research in the assessment, authorisation, oversight and conduct of research:

- Research governance is a framework through which Metro South Health is accountable for the research it authorises to be conducted within any one of its facilities.
- Research governance involves cooperation between the research project Principal Investigator, Coordinating Principal Investigator and the Metro South Health Research Governance Office/r.
- Research governance is intended to ensure that research project documentation is appropriate for Site Specific Assessment (SSA) so that a decision can be made by an organisation to either conduct or not conduct the research.
- Research governance covers areas such as finance, intellectual property, contracts and site resource utilisation.

- Information contained within Procedure provisions applies to all research projects conducted at/within or by Metro South Health, irrespective of whether the Metro South Human Research Ethics Committee (HREC) has provided ethical review for the research project.
- Research governance must be undertaken in parallel with Metro South Health HREC review using the [Australia Online Forms for Research](#) internet site.
- Research may not commence until HREC review and governance processes are completed and the research project has received written authorisation from the Metro South Health Chief Executive Officer or delegate.
- All research activities will be registered on AU-RED (Australian Research Ethics Database) when approved by a HREC. A recommendation for Metro South Health Chief Executive Officer or delegate approval to conduct research will not be made unless evidence of consultation with supporting departments has been provided and financial, legal and indemnity issues have been addressed.

## LEGISLATION OR OTHER AUTHORITY

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### 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

- Australian Radiation Protection and Nuclear Safety Agency (ARPANSA): [Code of Practice - Exposure of Humans to Ionizing Radiation for Research Purposes](#)
- 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](#)
- Queensland Health:
  - [Fee Schedule and Site Information for Commercially Sponsored Research 2010](#)
  - [Health Service Directive: Research Ethics and Governance HSD-035:2016](#)
  - [Junior Doctor Research Fellowship Funding Rules: Round Two 2016](#)
  - [Research Fellowship Funding Agreement Rules](#)
  - [Researcher User Guide \(RUG\) 2010](#)

- [Standard Operating Procedures for Queensland Health HREC Administrators 2013](#)
- [Standard Operating Procedures for Queensland Health Research Governance Officers 2013](#)
- 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 \(PL 2014/0038\)](#)
- [Research Biorepositories Policy \(PL2017/53\)](#)
- [Risk Assessment Guide \(V12 6-11-2013\)](#)
- [Risk Management Policy \(PL2013-06\)](#)

## **RESPONSIBILITIES**

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### **Executive Management Team**

Ensure collaborative, harmonised, clear and detailed publicly available Policies and Procedures are in place for the ethical, scientific and governance review of research of all research conducted within Metro South Health.

### **Metro South Human Research Ethics Committee (HREC)**

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 Metro South Health strategic requirements and ethical and responsible decision-making which respects the rights of Metro South Health participants.

### **Centres for Health Research**

Update Metro South Health research governance documents in accordance with Metro South Health requirements. Provision of secretariat/administrative support to maintain and uphold principles outlined in the [Metro South Health Research Management Policy](#) and related Procedures. Complete due diligence by ensuring adherence to legislative and institutional policy requirements and recommend authorisation by the Metro South Health Chief Executive Officer or delegate as appropriate.

### **Metro South Health Chief Executive Officer or Delegate**

Provide authorisation on research applications and contracts according to the Metro South Health [Finance Management Practice Manual \(FMPM\)](#) and the [Contract Management Framework](#)

### **Principal Investigators/Research Team**

Conduct research in accordance with national guidelines and the Metro South Health Research Management Compliance 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.

Only conduct clinical intervention studies with the essential approved credentialing privileges and clinical experience. Adhere to all relevant Policies, Procedures, Research Protocols and Standard Operating Procedures (SOPs) when conducting research.

### **All Metro South Health Employees**

Are required to be aware of and comply with this Procedure when conducting research.

## **SUPPORTING DOCUMENTS**

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### **Attachments**

Attachment 1 - [Application](#)

### **Forms**

[Metro South Research Contracts Approval and Study Execution Form](#)

[HREC/RGO Annual Report Form](#)

[MSF11 Notification of Commencement Form](#)

[MSF19: Metro South HREC Serious Adverse Event \(SAE\)/Suspected Unexpected Serious Adverse Reaction \(SUSAR\) Report](#)

[MSF31 Metro South HREC and Governance Standard Risk Submission Checklist Form](#)

[MSF49 Metro South Amendment Form](#)

Multi-centre Research Projects only – [Accepting Site Guidance](#) (when Metro South Health HREC is the reviewing HREC)

Multi-centre Research Projects only – [Accepting Site Guidance](#) (when Metro South Health HREC is **not** the reviewing HREC)

Multi-centre Research Projects only – [Lead Site Guidance](#)

## **DEFINITIONS**

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See the [Metro South Health Research Management Glossary](#)

### SITE SPECIFIC ASSESSMENT PRE-AUTHORISATION

#### **Step 1: Commencing the Site Specific Assessment - Human Research Ethics Committee Review**

It is strongly recommended to commence completion and collation of Site Specific Assessment (SSA) documentation at the same time as the Human Research Ethics Committee (HREC) review process. Please see [Ethical and Scientific Review of Human Research Procedure \(PR2017/113\)](#) for more information.

#### **Step 2: Commencing the Site Specific Assessment - Conflicts of Interest**

If any person believes they may have a Conflict of Interest in relation to a Site Specific Assessment, the conflict must be declared and detailed prior to submission of Site Specific Assessment (SSA) documentation. The Principal Investigator must escalate; approval of the Site Specific Assessment (SSA) documents and signing of the [Metro South Research Contracts Approval and Study Execution Form](#) to a relevant line manager or delegate.

#### **Step 3: Preparing the Site Specific Assessment – Specific Components**

In order to fulfil Site Specific Assessment (SSA) requirements the following specific components must be prepared.

##### ***3.a Cover Letter and/or HREC Governance Standard Risk Submission Checklist Form***

A cover letter outlining the reason for submission and itemising all supporting documentation and/or complete the [MSF31 Metro South HREC and Governance Standard Risk Submission Checklist Form](#). Ensure the cover letter and/or [MSF31 Metro South HREC and Governance Standard Risk Submission Checklist Form](#) is signed/approved by the Principal Investigator.

##### ***3.b Metro South Research Contracts Approval and Study Execution Form***

Researchers must only complete Part A of the [Metro South Research Contracts Approval and Study Execution Form](#). As the [Metro South Research Contracts Approval and Study Execution Form](#) must be completed for **all** research projects occurring within Metro South Health, the authorising signatories must be employees of Metro South Health.

- For research projects that involve more than one (1) Metro South Health facility, a signature from the authorised representative of the facility is required.
- The Metro South Health Principal Investigator is only required to sign when assuming full responsibility for the conduct of the research project at the site and ownership of the research contract/agreement (if applicable).
- The head of department at the initiating site in which the research project is to be conducted, normally the director of the department. This delegate must not be a member of the research team. If necessary, researchers must seek approval from the Executive Director of the department. Their signature indicates that they support the conduct of the research project within the department.
- The Business Manager/Financial Officer of the department in which the research project is to be conducted. Their signature indicates that there are sufficient resources available to conduct the research project.

Part B is to be completed by the Metro South Health Research Governance Office/r.

### **3.c Site Specific Assessment (SSA) Form**

The online Site Specific Assessment (SSA) form, available on the [Australia Online Forms for Research](#) internet site, must be completed as it relates to information about research activities that are occurring within a Metro South Health facility. *Note:* Only 1 (one) Site Specific Assessment (SSA) form is required for research projects that involve multiple Metro South Health facilities.

It is important to note that the online Site Specific Assessment (SSA) form can be saved and updated throughout the preparation process.

All supporting documents must be uploaded electronically against the online Site Specific Assessment (SSA) form. See [Step 4: Preparing the Site Specific Assessment – Supporting Documents](#) below for more information on required supporting documentation.

### **Step 4: Preparing the Site Specific Assessment – Supporting Documents**

In addition to the above specific components, the following associated supporting documents may also be required based on research project requirements. All supporting documents must be prepared and uploaded against the research project's online Site Specific Assessment (SSA) form available on the [Australia Online Forms for Research](#) internet site.

For document control purposes, all supporting documents must have version control number and date in the footer. For example the site specific Participant Information and Consent Form (PICF) must include the following:

Master Version x dated XX

Site Specific Version x dated XX

#### **4.a Metro South Health HREC Clearance/Approval Letter**

The Metro South Health HREC Clearance/Approval Letter is a mandatory requirement and must be provided prior to authorisation

#### **4.b Research Contract/Agreement (as applicable)**

Researchers are encouraged consult with the Metro South Health Research Governance Office/r via email [PAH-Research@health.qld.gov.au](mailto:PAH-Research@health.qld.gov.au) to ascertain if there is a requirement for a research contract/agreement.

Research contract/agreements are typically required when a third (3<sup>rd</sup>) party entity is involved in the collaboration or when a student is undertaking a research higher degree as part of the research team. Please see Research Contracts and Study Execution Procedure (PR2017/122) for more information.

#### **4.c Medicines Australia Standard Indemnity**

Researchers must complete the Medicines Australia [Standard Indemnity](#), in addition to the Medicines Australia Agreement, for commercially sponsored research projects.

#### **4.d 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.

#### **4.e Risk Versus Benefit Letter**

The Risk Versus Benefit Letter is required for clinical trials or clinical interventional trials where Metro South Health is acting as the research project sponsor. The letter must be signed by an appropriate delegate.

#### **4.f 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.

#### **4.g Clinical Trial Notification (CTN) Form**

As supplied by the commercial sponsor a copy of [Clinical Trial Notification \(CTN\) Form](#) (in pdf) which has been submitted to the Therapeutic Goods Administration (TGA). Additionally, if available, a copy of the TGA acknowledgement letter in respect of the CTN notification.

#### **4.h Invoicing Details**

Invoicing details are required for research projects that attract a fee as per Research Fees Procedure (PR2017/123).

#### **4.i External HREC Approval**

Research projects that are approved by an external HREC (i.e. non-Metro South Health HREC) require the following additional supporting documents:

- Research Protocol;
- printed Human Research Ethics Application (HREA)/Low and Negligible Risk Application Form (LNA Form) available on the [Australia Online Forms for Research](#) internet site;
- PICF:
  - master PICF for multi-centre research projects only; or
  - site specific PICF which contains site contact details and site logo;
- current Curriculum Vitae (CV) of research personnel (if not already supplied within the previous two (2) years); and
- confirmation of Good Clinical Practice (GCP) certification; for clinical trials - mandatory requirement or for all other types of research - strongly recommended.

#### **4.j 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.

#### 4.k Public Health Act 2005 (Qld) Approval

Depending on the research project, *Public Health Act 2005 (Qld)* approval is required where confidential patient medical information is to be obtained without consent.

Please contact the relevant data custodian and complete and submit the [Public Health Act – Application and Information for Researchers](#) Form. Researchers must ensure when *Public Health Act 2005 (Qld)* approval is received it is immediately forwarded to [PAH-Research@health.qld.gov.au](mailto:PAH-Research@health.qld.gov.au).

#### Step 5: Submitting the Completed Site Specific Assessment

Once completed online, the Site Specific Assessment (SSA) form is submitted electronically and a Site Specific Assessment (SSA) reference number is generated. Researchers must print the completed Site Specific Assessment (SSA) form from the [Australia Online Forms for Research](#) internet site and include the Site Specific Assessment (SSA) reference number on the [Metro South Research Contracts Approval and Study Execution Form](#). *Note: No* signatures are required on the printed version of the online Site Specific Assessment (SSA) form.

Only research projects approved by a NHMRC certified HREC will be considered for Site Specific Assessment (SSA) authorisation. Researchers must ensure approval is received prior to submitting Site Specific Assessment (SSA) documentation. The following documents must be submitted in hard copy to the Metro South Health Research Governance Office/r:

Metro South Health Research Governance Office  
Centres for Health Research  
Level 7, Translational Research Institute  
37 Kent Street  
Woolloongabba QLD 4102

Ref.	Document Type	Hard Copy Req.
a.	Cover Letter and/or <a href="#">MSF31 Metro South HREC and Governance Standard Risk Submission Checklist Form</a>	1 copy
b.	<a href="#">Metro South Research Contracts Approval and Study Execution Form</a>	1 copy
c.	Site Specific Assessment (SSA) Form <ul style="list-style-type: none"><li>available on the <a href="#">Australia Online Forms for Research</a> internet site</li><li>note submission code</li><li>printed and scanned from online site</li></ul>	1 copy

Please note, the original (hardcopy) applications must be submitted as the Metro South Health Research Governance Office/r cannot process emailed or faxed copies.

The supporting documents must be uploaded and submitted electronically via the [Australia Online Forms for Research](#) internet site. See [Step 4: Preparing the Site Specific Assessment – Supporting Documents](#) for more information.

Once received, the research project submission will be reviewed by the Metro South Health Research Governance Office/r.



## SITE SPECIFIC ASSESSMENT AUTHORISATION

### Step 1: Authorisation and Review

Recommendation of authorisation of the research project will not occur until all regulatory, legislative and institutional (Metro South Health) requirements are met including legal review and acceptance of indemnity provisions. It is not permissible to commence research until **all** research governance requirements are met.

The Metro South Health Research Governance Office/r will review all submitted documentation and request further information if/when required (in line with specifications as set in the Health Service Directive – Research Ethics and Governance QH-HSD-035:2016) via email correspondence.

### Step 2: Acknowledgement

Formal acknowledgment/confirmation of receipt will be sent from the Metro South Health Research Governance Office/r when relevant supporting documents are received. Relevant Site Specific Assessment (SSA) documentation will be uploaded to relevant Centres for Health Research databases and filed for record keeping purposes.

### Step 3: Metro South Health Chief Executive Officer or Delegate Review

All Site Specific Assessment (SSA) documents requiring Metro South Health Chief Executive Officer or delegate review and/or authorisation will be forwarded by the Metro South Health Research Governance Office/r to the nominated delegate as per the Metro South Health Financial Delegations Schedule. This includes Metro South Health Sponsored research projects.

Following requires Metro South Health Chief Executive Officer or delegate authorisation:

#### 1. *Research Projects WITHOUT a Research Contract*

The Site Specific Assessment (SSA) Authorisation letter and [MSF11 Notification of Commencement Form](#) will be sent to the Metro South Health Principal Investigator and nominated contact person as well as the Power Trials Support Team via the generic email address: [powertrialssupportPAH@health.qld.gov.au](mailto:powertrialssupportPAH@health.qld.gov.au).

#### 2. *Research Projects WITH a Research Contract*

In addition to the above, the Business Manager 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 the generic email address: [MSHCentralContractsRegister@health.qld.gov.au](mailto:MSHCentralContractsRegister@health.qld.gov.au) as well as the Power Trials Support Team via the generic email address: [powertrialssupportPAH@health.qld.gov.au](mailto:powertrialssupportPAH@health.qld.gov.au).

Please see Research Contracts and Study Execution Procedure (PR2017/122) and [PowerTrials - Electronic Medical Record Research Support Module Procedure \(PR2017/118\)](#) for more information.

### Step 4: Approval

Researchers will be formally notified of Metro South Health Research Governance Office/r authorisation by written correspondence. The Authorisation Letter will be sent in a pdf form via email to the Principal Investigator and nominated contact person. The time to reach approval will not take more than NHMRC benchmark of twenty-five (25) days. Registration of the Metro South Health Research Governance Office/r authorisation of the research is documented within AU-RED and the Metro South Health Research Ethics and Governance SharePoint site. Researchers are responsible for ensuring research project activities do not commence prior to receiving Site Specific Assessment (SSA) authorisation.

### **Step 5: Notification of Commencement**

Following Site Specific Assessment (SSA) authorisation, Metro South Health requires that the Metro South Health Research Governance Office/r is provided the start date of the research project via the [MSF11 Notification of Commencement Form](#).

Researchers must complete the [MSF11 Notification of Commencement Form](#) and send to either [PAH-Research@health.qld.gov.au](mailto:PAH-Research@health.qld.gov.au) and/or [EthicsResearch.PAH@health.qld.gov.au](mailto:EthicsResearch.PAH@health.qld.gov.au) prior to commencing the research project.

### **Step 7: Commence Research/Publish**

The research project may only proceed upon receipt of advice/confirmation in writing from the Metro South Health Research Governance Office/r.

## **SITE SPECIFIC ASSESSMENT POST-AUTHORISATION**

### **Step 1: Annual Reporting**

Principal Investigators and research teams are required to submit a [HREC/RGO Annual Report Form](#) for each research project:

- twelve (12) months after the HREC Approval date; and
- every twelve (12) months thereafter (unless otherwise advised).

### **Step 2: Suspension or Termination of a Research Project**

If a decision is made by the Principal Investigator to either suspend or cease a research project (prior to the expected date of completion) a completed [HREC/RGO Annual Report Form](#) must be forwarded to the Metro South Health HREC Office/r and Metro South Health Research Governance Office/r via either [PAH-Research@health.qld.gov.au](mailto:PAH-Research@health.qld.gov.au) and/or [EthicsResearch.PAH@health.qld.gov.au](mailto:EthicsResearch.PAH@health.qld.gov.au).

### **Step 3: Amendments to Research Protocols**

Any changes to the research project, in respect of aims, design and anticipated outcomes, which have previously been approved by the Metro South Health HREC, must be formally submitted as an amendment, for review and approval by the Metro South Health HREC via the [MSF49 Amendment Form](#). Please see [Ethical and Scientific Review of Human Research Procedure \(PR2017/113\)](#) for more information.

Once approved by the Metro South Health HREC, amendments to the research project must be provided to the Metro South Health Research Governance Office/r for authorisation especially where there is an implication to the ongoing site acceptability.

Researchers must submit the completed [MSF49 Metro South Amendment Form](#) to the Metro South Health Research Governance Office/r via email [PAH-Research@health.qld.gov.au](mailto:PAH-Research@health.qld.gov.au). The completed form must include the following details:

- a brief description of the changes;
- the rationale for the changes;
- any implications for the ongoing conduct of the research project; and
- Head of department and Business Manager/Finance Officer and/or Cost Centre Manager approval to support the ongoing conduct of the research project within the department (this can be provided by email or via letter of support).

Researchers must ensure a copy of the HREC Approval Letter is included with the amendment submission. Amendment submissions must include relevant supporting documentation which has been changed as a result of the amendment. Examples of amendments may include:

- updated insurance certificates;
- variations to Research Contracts/Agreements including changes to the legal name of the third (3<sup>rd</sup>) party entity;
- changes to the [Clinical Trial Exemption Form \(CTX\)](#) or [Clinical Trial Notification Form \(CTN\)](#);
- Pathology/Radiology/Pharmacy costing changes;
- research project budget updates or other changes which may have financial or other resource implications for Metro South Health;
- Principal Investigator or change in research personnel involved in the research project/s; and/or
- any other matters which may impact on the conduct of the research project in Metro South Health.

The following documents must be submitted electronically and in hard copy to the Metro South Health Research Governance Office/r via email [PAH-Research@health.qld.gov.au](mailto:PAH-Research@health.qld.gov.au) and:

Metro South Health Research Governance Office  
Centres for Health Research  
Level 7, Translational Research Institute  
37 Kent Street  
Woolloongabba QLD 4102

Ref.	Document Type	Hard Copy Req.
a.	<a href="#">MSF49 Metro South Amendment Form</a>	1 copy
b.	HREC Approval Letter	1 copy
c.	Supporting Documentation <ul style="list-style-type: none"> <li>• updates/changes to relevant documents</li> </ul>	1 copy

*Note:* There is no specific deadline for amendments.

Further assessment/more information may be required by the Metro South Health Research Governance Office/r.

Principal Investigators will be formally advised by the Metro South Health Research Governance Office/r when the research project amendments have been approved.

#### **Step 4: Serious Adverse Event (SAE)/Suspected Unexpected Serious Adverse Reaction (SUSAR) Report**

Researchers must report serious adverse events (SAE) and suspected unexpected serious adverse reactions (SUSAR) to the Metro South Health HREC and/or the Metro South Health Research Governance Office/r.

This applies to all research including investigator initiated research projects, university and student research.

In the event of a serious adverse event, the Principal Investigator must:

- report the event to the sponsor immediately (within twenty-four (24) hours); and
- complete and sign an [MSF19: Metro South HREC Serious Adverse Event \(SAE\)/Suspected Unexpected Serious Adverse Reaction \(SUSAR\) Report](#) within forty-eight (48) hours of notification.

Completed documentation must be submitted to the Metro South Health HREC Office/r and Metro South Health Research Governance Office/r via either [PAH-Research@health.qld.gov.au](mailto:PAH-Research@health.qld.gov.au) and/or [EthicsResearch.PAH@health.qld.gov.au](mailto:EthicsResearch.PAH@health.qld.gov.au).

If a multi-centre research project, serious adverse events (SAE) and suspected unexpected serious adverse reactions (SUSAR) must be submitted in accordance with the below guidance notices:

- Multi-centre Research Projects only - [Lead Site Guidance](#);
- Multi-centre Research Projects only - [Accepting Site Guidance](#) (when Metro South Health HREC is the reviewing HREC); or
- Multi-centre Research Projects only - [Accepting Site Guidance](#) (when Metro South Health HREC is **not** the reviewing HREC).

#### **Step 5: Completion of Study**

Upon completion of the research on the expected completion date, a completed [HREC/RGO Annual Report Form](#) must be forwarded to the Metro South Health HREC Office/r and Metro South Health Research Governance Office/r via either [PAH-Research@health.qld.gov.au](mailto:PAH-Research@health.qld.gov.au) and/or [EthicsResearch.PAH@health.qld.gov.au](mailto:EthicsResearch.PAH@health.qld.gov.au).

## PROCEDURE DETAILS

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**Procedure Number**

PR2017/116

**Procedure Name**

Metro South Health Research Management -  
Research Governance (Site Specific  
Assessment) Procedure

**Policy Reference**

PL2017/55

Metro South Health Research Management  
Policy

**Supersedes**

Nil

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**Approving Date**

30 June 2017

**Effective From**

30 June 2017

**Date of Last Review**

30 June 2017

**Date of Next Review**

30 June 2020

## ATTACHMENT 1 - APPLICATION

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### 1.0 Research Governance

Research Governance is the framework used by Metro South Health for the assessment, authorisation, oversight and monitoring of research conducted within the facilities under its auspices. It comprises a raft of overarching responsibilities built around Australian and international codes of research conduct that encompass four (4) specific areas including:

1. Site Specific Assessment Pre-Authorisation
2. Site Specific Assessment Authorisation
3. Site Specific Assessment Post-Authorisation
4. Monitoring

For more information regarding the monitoring process please see [Research Governance \(Monitoring\) Procedure \(PR2017/117\)](#).

#### 1.1 Site Specific Assessment (SSA) Authorisation Process

Site Specific Assessment (SSA) authorisation is a process by which research projects are reviewed to ensure that Metro South Health has the resources to support the research (e.g. funding, personnel, equipment and infrastructure). Not all research projects that are deemed ethically sound can be supported by Metro South Health. It is important that applicants engage in discussions with all departments involved in the research before applying for approval to minimise the possibility of research projects not receiving approval at this stage.

Once Metro South Health HREC and any additional approvals have been granted applicants will be required to obtain Site Specific Assessment (SSA) authorisation before commencing the research in Metro South Health.

Only research applications approved by a NHMRC registered HREC i.e. Metro South Health HREC, with a complete Site Specific Assessment (SSA) form will be considered for authorisation by the Metro South Health Chief Executive Officer or delegate.

#### 2.0 Site Specific Assessment Pre-Authorisation

Applications for research governance are to be made using the online Site Specific Assessment (SSA) form which may be found under the Site Specific Assessment (SSA) tab of the [Australia Online Forms for Research](#) internet site. Completion of this form may be commenced whilst awaiting Metro South Health HREC approval.

## **2.1 Conflicts of Interest in Completing the Site Specific Assessment**

Identification and management of perceived, potential and actual conflicts of interest will be in accordance with the Metro South Health [Management of Conflict of Interest Policy \(PL2014/0038\)](#) and [Management of Conflict of Interest - All Staff Procedure \(PR2016-66\)](#).

If any person believes they may have a Conflict of Interest in relation to a Site Specific Assessment (SSA), the conflict must be declared and detailed prior to submission.

Conflicts of Interest in this context may include a Principal Investigator, who may:

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

In the event of a Conflict of Interest of this nature, the Principal Investigator will be required to escalate approval of the Site Specific Assessment (SSA) documents to their relevant line manager or delegate.

## **2.2 Metro South Health Sponsored Research Projects**

Research projects which are sponsored/funded by Metro South Health will be reviewed by the Metro South Health Research Committee. Please [Metro South Health Research Support Scheme \(RSS\) Procedure \(PR2017/120\)](#) for more information.

## **2.3 Site Specific Assessment Financial Requirements**

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

- actual costs have been provided;
- justification for covering costs in-kind (including benefits to Metro South Health and/or participants) have been outlined; and
- evidence that finance authorisation has been obtained.

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

## **2.4 Internal Financial Considerations**

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

- mandatory nomination of research cost centre code;
- tracking of expenditure;
- purchase (procurement processes) of equipment;
- employee wage recoupment; and
- nominated 'in-kind' value.

Budget breakdown tools (accessible from relevant Business Managers/Finance Officers and/or Cost Centre Managers) can be used where a more detailed account is required however this does not need to be sent to the Metro South Health Research Governance Office/r with Site Specific Assessment (SSA) documentation.

Please [Research Grants Administration Procedure \(PR2017/119\)](#) for more information.

## **2.5 Authorisations**

Discussions should take place as early as possible with the relevant Metro South Health heads of department regarding the research. Expectations should be clarified from the Research Protocol and detailed when completing the Site Specific Assessment (SSA) form.

Important factors when completing the Site Specific Assessment (SSA) form include:

- ***Head of Supporting Department Authorisation***

If the research project will require input, services or assistance from another department, researchers must obtain authorisation from the head of that supporting department. Departments often involved in a supporting role include Health Information Management Services (HIMS), Pathology, Medical Imaging and Pharmacy.

Applications for research projects at any other Metro South Health (excluding PAH) facilities must be directed to the relevant Executive Director of Medical Services/Facility Manager for site approval/authorisation.

- ***Budgets and Financial Authorisation***

All research projects (whether externally funded or not) must include a budget to confirm the costs associated with the research project and whether any costs are to be covered in-kind. The research project budget must be approved by the relevant Business Manager/Finance Officer and/or Cost Centre Manager and the research cost centre code assigned to the research project. In-kind contributions must be quantified, thus allowing Metro South Health to calculate the actual cost of research. Business Managers/Finance Officers and/or Cost Centre Manager can assist in determining salary costs along with other queries relating to research project budgets.

It is recognised that while some research projects will have an associated cost for Metro South Health, there may be additional benefits resulting from the research that need to be considered as part of the Research Governance review process. Researchers are encouraged to provide a justification of the benefits in the budget section of the Site Specific Assessment (SSA) form, where indicated. Where wage reimbursement or purchases are expected, further discussions should be held with relevant Business Managers/Finance Officers and/or Cost Centre Managers.

## **2.6 Research Contract/Agreements and Collaborations**

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



The Metro South Health Research Governance Office/r should be the first point of contact for any questions about the process for preparing a research agreement. Please see Research Contracts and Study Execution Procedure (PR2017/122) for more information.

## **2.7 Multi-centre Research**

At each site where a multi-centre research project is being undertaken, a Site Specific Assessment (SSA) will be conducted to determine what resources are required for the support and successful completion of the research at that site. This will include identification of actual and 'in kind' costs associated with the conduct of the research at each site. Where multiple Metro South Health sites (Princess Alexandra Hospital, QEII Hospital and Logan Hospital etc.) are involved with the research project, one (1) Site Specific Assessment (SSA) form can be completed and one (1) Research Contract Approval and Study Execution form is required. Signatures on the Research Contract Approval and Study Execution Form are to be obtained from the **initiating** department

## **2.8 Low and Negligible Risk**

For completion of records, low and negligible risk research requires a Site Specific Assessment (SSA) form to be completed and submitted at the same time as the HREC submission.

## **3.0 Site Specific Assessment Authorisation**

### **3.1 Timeframes**

The NHRMC has stipulated a twenty-five (25) day benchmark for Site Specific Assessment (SSA) approval processes. The review time does not include the time taken for the Principal Investigator to; attend to the requested amendments or provide additional information to the Metro South Health Research Governance Office/r.

If, due to complexity of the research project, the research governance review may be compromised by the twenty-five (25) day completion time, the Metro South Health Research Governance Office/r may extend the time taken to complete the research governance review process. The Metro South Health Research Governance Office/r must notify the site Principal Investigator why the twenty-five (25) day benchmark will be exceeded.

### **3.2 Commencement**

The Metro South Health Research Governance Office/r will formally advise the Principal Investigator once approval has been received.

## **4.0 Site Specific Assessment Post Authorisation**

Research may commence once a letter of authorisation has been received, signed by the Metro South Health Chief Executive Officer or delegate. Personnel engaged in research activities must ensure adherence to the procedures outlined in the research application/Research Protocol, as approved by the Metro South Health HREC and the Metro South Health Research Governance Office/r.

The Metro South Health Research Governance Office/r will load these authorisation documents onto the AU-RED system for review and storage. Staff engaged in research activities must ensure adherence to the procedures outlined in the research application/Research Protocol, as approved by the Metro South Health HREC and Metro South Health Research Governance Office/r. Note: HREC approval does not automatically grant authorisation for the research project. Should the Metro South Health Chief Executive Officer or delegate decide not to authorise a research project, a formal letter is sent to the Principal Investigator.

#### **4.1 Site Specific Assessment Registered onto AU-RED**

Once Site Specific Assessment authorisation has been received, the Metro South Health Research Governance Office/r will upload and register the Site Specific Assessment (SSA) into the National database AU-RED using the 'submission code' found on the far right hand bottom corner of the Site Specific Assessment (AU/.../...). The Site Specific Assessment (SSA) can only be 'validated' on AU-RED when all project documents have been received and the application is complete. AU-RED will allocate a research project Site Specific Assessment reference number (SSA/year/QPAH/number) which will be quoted on research project correspondence.

#### **4.2 Contracts and Other Legal Documents**

Please see Research Contracts and Study Execution Procedure (PR2017/122) for more information.

### **5.0 Ongoing Maintenance of Approved Research**

#### **5.1 Reporting of Adverse Events and Serious Adverse Events to Metro South Research Governance.**

The Metro South Research Governance Office/r has adopted the NHMRC Position Statement: Monitoring and Reporting of Safety for Clinical Trials. Any other events that affect the ongoing site acceptability of a study within Metro South Health should be reported via the [MSF49 Metro South Amendment Form](#).

#### **5.2 Approval Period**

The length of HREC approval for a research project will be documented clearly on the HREC approval letter. If a research project will extend beyond this date the researcher must apply to the HREC to extend the HREC approval period **before** the approval date expires. Once an extension has been granted the request and HREC approval should be submitted to the Metro South Research Governance Office/r.

#### **5.3 Changes and Amendments to the Research Protocol**

Changes to a research project must be re-submitted to the Metro South Health HREC for approval prior to introducing the changes. Researchers may also be required to re-submit these changes for Metro South Health Research Governance Office/r authorisation.

Researchers may consult with the Metro South Health HREC Office/r or Metro South Health Research Governance Office/r if there are any concerns about how to manage changes and amendments to research projects.

Common changes that will require submission to the Metro South Health HREC Office/r and Metro South Health Research Governance Office/r include:

- eligibility or changes to the participant group;
- process for obtaining participant consent (where appropriate);
- data being collected;
- process for collecting data;
- facilities/hospitals involved in the research project; or
- investigators.

Amendments to research projects may affect the ongoing ethical acceptability of the research project. The suitability of the research site must be submitted to the Metro South Health HREC for review.

Research project amendments that may **affect both the ongoing ethical acceptability AND the site acceptability** of the research must be submitted to the Metro South Health HREC Office/r for review by the Metro South Health HREC and, once HREC approval has been granted, are submitted to the Metro South Health Research Governance Office/r for final authorisation.

Research project amendments that only **affect the site acceptability** of the research must be submitted to the Metro South Health Research Governance Office/r.

Research project amendments that **do not affect the ongoing ethical acceptability OR the site acceptability** of the research (e.g. typographical errors) must be submitted in hard copy to the Metro South Health HREC Office/r.

For research projects that are externally HREC approved, the researcher must submit the HREC approval of the amendment along with any updated site specific changes to the Metro South Health HREC Office/r.

### **5.5 Site Acceptability Amendments to Research Protocols**

Amendments that affect site specific resources or site specific documentation (i.e. PICFS, advertisement flyer etc.) should be submitted to the Metro South Health Research Governance Office/r for review and approval accompanied with the relevant reviewing HREC approval letter.

Note: A protocol deviation should be submitted to the relevant HREC.

A revised quote should be provided where the resources of services departments within Metro South Health which are impacted financially. If there is additional department or services involved in the project, this will required head of department signature and approval form these new departments or services.

Research contract amendments should be submitted to the Metro South Health Research Governance Office/r for review and execution. Should the agreement impact on the budget, the relevant departmental Business Managers/Finance Officers and/or Cost Centre Managers are to be informed and their approval provided.

Researchers must consider relevant amendment fees prior to submitting amendment documentation. Please see Research Fees Procedure (PR2017/123) for more information.

### **5.8 Termination of research by Principal Investigator**

In circumstances where the Principal Investigator decides to terminate the research project, the Principal Investigator must consult with the Metro South Health HREC first to ensure the safety and welfare of the research participants that may be involved in the research. The Principal Investigator is required to immediately notify the Coordinating Principal Investigator (if applicable) and the reviewing HREC and Metro South Health Research Governance Office/r.

### **5.9 Withdrawal of an Application**

This may be done at any time by the Principal Investigator for the site or Coordinating Principal Investigator. This information is recorded in the ethics database on the common drive and in AU-RED.

### **5.10 Suspension/Withdrawal of Governance Authorisation to Conduct Research**

A Principal Investigator cannot continue with the research if the Metro South Health Chief Executive Officer or delegate has suspended or withdrawn authorisation for the research to be conducted at that site. It is the responsibility of the Metro South Health Research Governance Office/r to update the AU-RED application tracing and management system accordingly.

### **5.11 Monitoring**

Please see [Research Governance \(Monitoring\) Procedure \(PR2017/117\)](#) for more information.