

# PROCEDURE

## Research Management - Research Governance (Monitoring)

PR2017/117  
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 routine monitoring and on-site monitoring, for research being conducted in or in collaboration with 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:

- Monitoring of research approved by the Metro South Health Human Research Ethics Committee (HREC) is a component of the Metro South Health Research Compliance Framework and Metro South Health's commitment to the Australian Code for the Responsible Conduct of Research 2007, National Statement on Ethical Conduct in Human Research (2007) ('National Statement'), Australian Code for the Care and Use of Animals for Scientific Purposes and the requirements of other external regulators.
- The Metro South Health HREC Office/r and Research Governance Office/r may conduct monitoring audits on approved research. Researchers must comply with any requests from the Metro South Health Research Monitoring Office/r in relation to monitoring.

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- Monitoring of approved research is conducted in accordance with principles of compliance, accountability, transparency, quality control, risk management, health and safety, environmental protection and efficiency.
- Monitoring of approved research applies to research that has been reviewed and approved by the Metro South Health HREC and is undertaken to assess that a research project is being or has been conducted in the manner proposed to, and approved by the Metro South Health HREC and in accordance with institutional requirements.

## LEGISLATION OR OTHER AUTHORITY

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### Legislation

- *Gene Technology Act 2000 (Cth)*
- *Gene Technology (Queensland) Act 2016 (Qld)*
- *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 compliance 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 [Finance Management Practice Manual \(FMPM\)](#) and [Contract Management Framework](#).

### **Departmental Directors/Clinical Trial Coordinators**

Responsible for reviewing research projects within their departments however this is separate to the Metro South Health Research Governance (Monitoring) process outlined in this procedure.

## **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**

[HREC/RGO Annual Report Form](#)

[MSF 34 Monitoring Self-Assessment Template](#)

## **DEFINITIONS**

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

## **PROCEDURE - RESEARCH GOVERNANCE (MONITORING)**

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### **Step1: Prepare an Annual Report**

Researchers are required to prepare annual progress reports and complete the [HREC/RGO Annual Report Form](#). Annual reports must be provided to the Metro South Health HREC Office/r and Metro South Health Research Governance Office/r, in accordance with the Metro South Health HREC and Research Governance approval letters.

### **Step 2: Scheduling an On-site Monitoring Visit**

The Metro South Health Research Monitoring Office/r will contact a Principal Investigator via telephone and in writing at least two (2) weeks in advance if their research project has been identified for an on-site monitoring visit. This notification will generally be by email and an [MSF 34 Monitoring Self-Assessment Template](#) will be attached to assist research team in preparation for the monitoring visit.

Research on-site monitoring visits will vary from an hour to a full day. The Metro South Health Research Monitoring Office/r will assess how much time will be required. The on-site monitoring visit will be scheduled for a mutually convenient time.

### **Step 3: Complete the Monitoring Self-Assessment Template**

The MSF 34 Monitoring Self-Assessment Template contains a list of specific information that will be reviewed on the day of the on-site monitoring visit. The Principal Investigator and research team are encouraged to complete the template in preparation for the on-site monitoring visit.

### **Step 4: Non-response to an On-site Monitoring Visit Request**

If a response is not received by the Metro South Health Research Monitoring Office/r within fourteen (14) days a reminder will be sent to the Principal Investigator, nominated contact person and site head of department. Timeframes for response will be stipulated in the reminder notice. It is a requirement of ongoing HREC approval for monitoring to take place.

### **Step 5: Final Notification for an On-site Monitoring Visit Request**

If there has been no response to the reminder request within fourteen (14) days then a final notification will be forwarded to Principal Investigator, nominated contact person and site head of department. The notification will also be forwarded to the Metro South Health HREC Chair for their consideration/necessary action.

### **Step 6: On-site Monitoring Visit**

The on-site monitoring visit will involve a meeting with the Principal Investigator and research project personnel to discuss matters relating to the research and its conduct. At the commencement of the meeting the Metro South Health Research Monitoring Officer will introduce the purpose of the on-site monitoring visit, ask general questions regarding the research project, note any relevant delegations and answer any questions regarding the on-site monitoring process.

Following the introduction the Metro South Health Research Monitoring Officer may request to see/review/verify the following in relation to the research project:

- Trial Master File (TMF) and/or Investigator Site File (ISF) – contains specific/regulatory essential documents relevant to the research project. These are documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced.
- Source Data including but not limited to:
  - Participant Information and Consent Forms (PICFs);
  - the process for obtaining informed consent;
  - hospital charts and/or electronic records to verify eligibility;
  - research project treatment and follow up as per Research Protocol;
  - the reporting of serious adverse events (SAE) and suspected unexpected serious adverse reactions (SUSAR);
  - data storage and protection;
  - investigational product storage and accountability (if applicable); and/or
  - the participant recruitment process.

For smaller research projects, the above will be assessed for every research project participant. For larger studies, the Metro South Health Research Monitoring Officer will nominate a reasonable sample of research project participants for assessment. This sample will be randomly selected but consideration may be given to assessing an equal number of participants from different treatment groups and/or including participants who did not complete the Research Protocol.

## **Step 7: On-site Monitoring Findings**

During the on-site monitoring visit the Metro South Health Research Monitoring Officer will discuss findings with the Principal Investigator and research project personnel including recommendations and/or gaps in compliance. These may include:

- regulatory requirements;
- employees and delegated responsibilities;
- Research Protocol and amendments;
- process for taking informed consent;
- research project participant recruitment processes;
- data and/or Case Report Form recording;
- investigational product retention or accountability issues (if applicable); and/or
- data protection.

## **Step 7: Completion of Monitoring**

The Metro South Health Research Monitoring Officer will prepare a Monitoring Visit Report and formal correspondence. On-site Monitoring Visit findings can be considered as major, moderate or minor. The On-site Monitoring Visit Report will outline the findings of the on-site monitoring visit which will include a list of recommendations or actions to be completed. The formal letter and On-site Monitoring Visit Report will be issued within two (2) weeks of the on-site monitoring visit.

Copies of the Monitoring Visit Report and formal correspondence will be sent to the:

- Principal Investigator;
- Research project coordinator and members of the research project team (as agreed with the Principal Investigator);
- relevant head of department (as appropriate);
- Metro South Health HREC Chair and Metro South Health HREC Office/r for noting at the Metro South Health HREC meeting; and
- Metro South Health Research Governance Office/r.

A copy of the On-site Monitoring Visit Report and formal correspondence will be filed in the HREC file. The Metro South Health Research Monitoring Office/r will retain all relevant documentation including correspondence and resolution of findings.

## **Step 8: Follow-Up Actions**

It is the Principal Investigator's responsibility to ensure any necessary changes are implemented. If any advice or assistance is required the Metro South Health Research Monitoring Office/r will be available to provide assistance. The Principal Investigator of the research project is obliged to respond to required actions within an agreed and timely manner, generally a period of (3) three months or sooner. If issues are not resolved the matter will be referred to the Metro South Health HREC Chair and the Metro South Health Research Governance Office/r.

## PROCEDURE DETAILS

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**Procedure Number**

PR2017/117

**Procedure Name**

Metro South Health Research Management -  
Research Governance (Monitoring) 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 Site Specific Assessment (SSA) process please see [Research Governance \(Site Specific Assessment\) Procedure \(PR2017/116\)](#).

### 1.1 Monitoring Requirements

Metro South Health Centres for Health Research has a responsibility to monitor research in accordance with the [Australian Code for the Responsible Conduct of Research](#) and the [National Statement on Ethics Conduct in Human Research \(2007\)](#) (“National Statement”) on behalf of the Metro South Health HREC.

The Centres for Health Research has a comprehensive monitoring program that aims to:

- ensure patient and staff safety;
- ensure the use of high quality data; and
- promote research best practice.

Specifically, the National Statement Chapter 5.5.1 states each institution has ultimate responsibility for ensuring, via its research governance arrangements, that all its approved research is monitored and (National Statement, Chapter 5.5.2) that the frequency and type of monitoring should reflect the degree of risk to research participants.

The Metro South Health in its research monitoring program will focus on matters that directly impact on participant rights and safety (such as informed consent, eligibility criteria, adverse event reporting) and regulatory compliance.

### 1.2 Routine Monitoring

All research projects being conducted within Metro South Health are eligible for routine monitoring by the Metro South Health Research Monitoring Office/r. All research projects could be monitored routinely within the following scheduling priority:



- research projects where a complaint has been received by the Metro South Health HREC Office/r and/or Metro South Health Research Governance Office/r from researchers and/or participants;
- reportable safety events that are numerous or of interest;
- research projects without identified oversight by an external sponsor that are classified as 'interventional'; and/or
- Principal Investigator initiated research projects sponsored by Metro South Health.

The Metro South Health Research Monitoring Office/r may also be alerted to any local events that require monitoring by the Metro South Health HREC Chair. Alternatively, a systematic review of currently approved research will identify research projects that are to be monitored.

Monitoring occurs through a variety of mechanisms including:

- Annual Progress Reporting via the [HREC/RGO Annual Report Form](#);
- review of deviations from the proposed research project plan;
- review of reports from researchers and safety monitoring boards;
- review of adverse event reports;
- feedback from research project participants; and/or
- on-site monitoring (including review of research project files, consent documentation, source documents and data).

### **1.3 HREC/RGO Annual Reports**

In accordance with the National Statement Section 5.5.5, Metro South Health HREC requires at least annual reporting on the status of the research project. This requirement is a condition of ongoing Metro South Health HREC approval/clearance which is articulated in the Metro South Health HREC Approval Letter.

An [HREC/RGO Annual Report Form](#) must be submitted which demonstrates progress to date of the research project, details any issues with the research project, maintenance and security of records and compliance with the approved Research Protocol and any other condition of approval.

In addition, the Principal Investigator is responsible for reporting to the Metro South Health HREC:

- Information that materially impacts the continued ethical acceptability of the trial or requires, or indicates the need for, a change to the trial protocol.
- At least annually - an updated investigator brochure or current approved product information, if appropriate. This should include sponsor and investigator comment as to whether action is planned for the trial on the basis of the reports.
- Other reports consistent with section 5.5.5 of the National Statement and Good Clinical Practice (GCP) as adopted by the Therapeutic Goods Administration (TGA).

Researchers are also responsible for managing the costs associated with their research and for reporting financial outcomes.

Financial management processes and reporting templates are currently being developed. The [HREC/RGO Annual Report Form](#) must also be completed and submitted to [EthicsResearch.PAH@health.qld.gov.au](mailto:EthicsResearch.PAH@health.qld.gov.au) and [PAH-Research@health.qld.gov.au](mailto:PAH-Research@health.qld.gov.au).

## 2.0 On-Site Monitoring

The Metro South Health Research Monitoring Office/r regularly conducts short audits of a range of research projects that have been authorised by the Metro South Health Research Governance Office/r. On-site monitoring of research is a tool to ensure patient safety, as well as high data quality, by promoting best research practices. The purpose of an onsite research monitoring visit is to:

- ensure participant safety;
- assist researchers with regulatory compliance requirements and Metro South Health Policy;
- educate and develop researchers by sharing best practice and improving research systems and data quality;
- prepare researchers for external audit processes e.g. by funding bodies; and
- demonstrate robust research processes to external funders and industry.

On-site monitoring involves meeting with researchers to:

- examine relevant documentation including signed consent forms, completed Case Report Forms, data spreadsheets, medical records, and approval certificates;
- regulatory documents which include HREC and research governance approvals and all relevant correspondence;
- check on the arrangements to protect privacy and confidentiality of participant data; and/or
- check source data.

The Metro South Health Research Monitoring Office/r will contact researchers a month before the audit to set up a mutually convenient time and to provide researchers with a list of prospective questions via the [MSF 34 Monitoring Self-Assessment Template](#).

### 2.1 Scheduled On-site Monitoring Visit

The visit itself may take up to a full day depending on the complexity of the research project being audited. Within fourteen days (14) of completion of the audit, researchers will receive by email, an On-site Monitoring Visit Report including a summary of the main findings and a list of items that require action in order to comply with guidelines for good clinical practice.

Researchers are expected to take appropriate action and respond to the Metro South Health Research Monitoring Office/r within a month of receiving the report. If the response is appropriate the on-site monitoring process will be considered closed.

If this is not satisfactory the researcher may need to discuss the issues with the Metro South Health Research Monitoring Office/r, the health of department and/or nominated members of the Metro South Health HREC, who can assist with resolving specific issues.

The research project may require a follow-up monitoring to ensure that the appropriate action has occurred and the researchers will be notified promptly if this is the case.