

PROCEDURE

Research Management - Research Fees

PR2017/123
Version No. 1.0

PURPOSE

This Procedure describes the processes for the management of research fees in the Metro South Hospital and Health Service (Metro South Health). It is the responsibility of the Metro South Health Human Research Ethics Committee (HREC) Office/r and Metro South Health Research Governance Office/r to ensure that appropriate fees are invoiced to a commercial entity, collaborative group, University or external Principal Investigator initiated research projects.

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.

KEY PRINCIPLES

The following key principles guide Metro South Health in the management of research fees.

- Research application fees have been endorsed by Metro South Health Executive and implemented in order to provide assistance to support the administration of both the Metro South Human Research Ethics Committee (HREC) Office/r and the Metro South Research Governance Office/r located within the Centres for Health Research, Metro South Health.
- The funds received supplement the support provided by Centres for Health Research and are used to:
 - Assist with the cost of the Metro South Health HREC Office/r which provides administrative support for the Metro South Health HREC.
 - Assist in the cost of administrative support and assistance provided by the Metro South Health Research Governance Office/r to researchers preparing applications.

Page 1 of 7

- Facilitate the ongoing education of researchers and Metro South Health HREC members through research forums, workshops and individual support for researchers.
- Ensure that the Metro South Health HREC is able to fulfil its obligations as directed by the National Health and Medical Research Council (NHMRC), '[National Statement on Ethical Conduct in Human Research \(2007\) - Updated May 2015](#)', including the provision of on-site monitoring and training.
- Ensure that the Metro South Health Research Governance Office/r is able to fulfil its obligations as directed by Metro South Health Policies and Procedures and the legislative framework that supports research.
- Promote excellence in research and underpin Metro South Health's Strategic Plan for research.
- Research application fees are charged for new applications and amendments to approved research projects for both ethics and governance review.
- Research application fees vary depending on the type of submission and the research project sponsor/funding type.
- Research application fees do not apply to employees of Metro South Health.

LEGISLATION OR OTHER AUTHORITY

Legislation

- *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)*

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](#)
- Queensland Health:
 - [Health Service Directive: Research Ethics and Governance HSD-035:2016](#)
 - [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](#)
- Research Funding, Budgets and Infrastructure Support Procedure (PR2017/121)
- [Finance Management Practice Manual \(FMPM\)](#)
- [Integrated Risk Management Framework](#)
- [Management of Conflict of Interest - All Staff Procedure \(PR2016-66\)](#)

RESPONSIBILITIES

Centres for Health Research

The Centres for Health research is responsible for establishing appropriate research fee structures by benchmarking against other leading research institutions across Victoria, New South Wales and Queensland. The Centres for Health research must also communicate changes in fee structures to Metro South Health researchers when required.

Metro South Health Human Research Ethics Committee (HREC) Office/r

It is the responsibility of the Metro South Health HREC Office/r to ensure that research application fees are invoiced appropriately and in accordance with provisions in this Procedure.

Metro South Health Research Governance Office/r

It is the responsibility of Metro South Health Research Governance Office/r to ensure that appropriate research fees are invoiced to a commercial entity, collaborative group, and external University or Principal Investigator initiated research projects in accordance with provisions in this Procedure.

Principal Investigators

It is the responsibility of the relevant Principal Investigator to ensure that relevant research project invoicing details are listed on the [MSF31 Metro South HREC and Governance Standard Risk Submission Checklist Form](#) and included as part of research project budget planning. Please see Research Funding, Budgets and Infrastructure Support Procedure (PR2017/121) for more information.

Researchers and Research Personnel

Researchers and research personnel are required to obtain appropriate clearances for the expenditure of any research project funds and abide by provisions outlined within this Procedure.

SUPPORTING DOCUMENTS

Attachment

Attachment 1 - [Application](#)

Forms

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

[MSF49 Amendment Form](#)

MSF21 Schedule of Fees and Requisition of Invoices for Ethics and Research Governance Review

DEFINITIONS

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

PROCEDURE - RESEARCH FEES

STEP 1: Review Research Application Fees

Prior to submitting an application to the Metro South Health HREC Office/r and Metro South Health Research Governance Office/r, researchers must review all Metro South Health research application fees as outlined in the Research Fee Structure detailed in this Procedure (or on the website).

STEP 2: Research Project Budget Preparation

The Principal Investigator must include Research Fees as part of research project budget preparation in accordance with the Research Funding, Budgets and Infrastructure Support Procedure (PR2017/121).

STEP 3: Generate an Invoice

The Principal Investigator, Coordinating Principal Investigator for multi-centre research projects, or Research Project Coordinator/Contact Person must provide the invoicing details to the Metro South HREC Office/r and/or Research Governance Office using the:

- [MSF31 Metro South HREC and Governance Standard Risk Submission Checklist Form](#); or
- [MSF49 Amendment Form](#).

The Principal Investigator and/or relevant research project contact person (where nominated) will be contacted to obtain any missing details.

STEP 4: Raise an Invoice

The Metro South Health HREC Office/r and Metro South Health Research Governance Office/r processing the new application for review will generate a memorandum to raise an invoice utilising the MSF21 Schedule of Fees and Requisition of Invoices for Ethics and Research Governance Review form.

The completed form will be emailed to PAH_Revenue@health.qld.gov.au for processing.

STEP 5: Metro South Health Research Fees Invoice Register

The Metro South Health Research Fees Invoice Register must be updated with the relevant details for the invoice request.

STEP 6: Receiving an Invoice

Invoices generated by the relevant Metro South Health revenue department will be emailed to the Sponsor, Principal Investigator and/or relevant research project contact person and EthicsResearch.PAH@health.qld.gov.au / PAH-Research@health.qld.gov.au copied in. The Metro South Health Research Fees Invoice Register must be updated with the invoice number contained within the invoice.

STEP 7: Payment of the Invoice

The Sponsor, Principal Investigator and/or relevant research project contact person is responsible for ensuring the invoice is paid in accordance with details included.

PROCEDURE DETAILS

Procedure Number

PR2017/123

Procedure Name

Metro South Health Research Management –
Research Fees

Policy Reference

PL2017/55

Metro South Health Research Management
Policy

Supersedes

Nil

Procedure Author

Erica Wright, Project Manager, Research
Development, Centres for Health Research,
Metro South Health

Portfolio Executive Director

Professor Ken Ho, Chair, Centres for Health
Research, Metro South Health

Approving Officer

Dr Michael Cleary, A/Executive Director, PAH-
QEII Health Network, Metro South Health

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 Application Fees

Research application fees are charged for new research project applications and amendments to approved research projects for both ethics and governance review. Research application fees vary depending on the type of submission and the research project sponsor/funding type.

1.1 Provision of Support

Funds received from research application fees supplement the support provided by Centres for Health Research (Metro South Health HREC Office/r Research Governance Office/r). For more information regarding available support please see [Ethical and Scientific Review of Human Research Procedure \(PR2017/113\)](#) and [Research Governance \(Site Specific Assessment\) Procedure \(PR2017/116\)](#).

1.2 Invoicing

Applicants must ensure appropriate invoicing details are submitted within the [MSF31 Metro South HREC and Governance Standard Risk Submission Checklist Form](#).

1.3 PowerTrials

Fees may be applicable to 'maximum' PowerTrial builds within the future state. Researchers must contact PowerTrialsSupportPAH@health.qld.gov.au to discuss further.

2.0 Research Fee Structure

In order to establish an appropriate research fee structure, the Centres for Health Research will review its performance and 'stop clock days' (time for valid submission to approval) whilst benchmarking against other leading research institutions across Victoria, New South Wales and Queensland.

The below research fee structure is effective from 1 July 2016 and enables the Centres for Health Research to continue to provide a highly effective support service that ensures high quality and compliance.

A complete table of research application fees is listed below:

2.1 Commercial Studies (sponsored by a Commercial Entity)

Item	Type of Research Application	Fee
Metro South HREC Office/r Review	New Research project	\$4,500
	Addition of a Sub-study	\$2,000
	Addition of a Site	\$500
	Major Amendment	\$650
Metro South Research Governance Office/r	New Research Project	\$4,500
	Addition of a Sub-study	\$2,000

2.2 Collaborative Research Groups (a legal entity which acts as the Sponsor of the research project)

Item	Type of Research Application	Fee
Metro South HREC Office/r Review	New Research Project	\$700
	Addition of a Site	\$150
	Major Amendment	\$150
Metro South Research Governance Office/r	New Research Project	\$700

2.3 University Initiated

Item	Type of Research Application	Fee
Metro South HREC Office/r Review	New Research Project	\$150
	Major Amendment	\$50
Metro South Research Governance Office/r	New Research Project	\$150

2.4 Principal Investigator Initiated (for Non-Metro South-Led Research Projects)

Item	Type of Research Application	Fee
Metro South HREC Office/r Review	New Research Project	\$150
	Major Amendment	\$50
Metro South Research Governance Office/r	New Research Project	\$150

3.0 Amendments

As outlined in the research fees structure above a 'Major Amendment' is considered more than an administrative change and requires review by the Metro South Health HREC Chair or Deputy Chair, for example; additional safety information or changes to the research protocol.

3.1 Amendment Fees

Other than administrative changes, all amendments to previously approved pharmaceutically sponsored research projects that are submitted to the Metro South Health HREC for review are subject to a levy of \$650 (inclusive of GST).

An administrative amendment is defined as changes to the details of a research project that have no significant implications for participants or for the conduct, management or scientific value of the research project. For example:

- Correction of typographical errors in the Research Protocol or other research project documentation.
- Amended contact details for the Sponsor or research project staff.
- Appointment of new or change of support staff contact.

There is no charge for amendment/s submitted to the Metro South Health Research Governance Office/r.