PURPOSE

The Metro South Hospital and Health Service (Metro South Health) invests in research and development and partners with Queensland’s universities and research institutions to deliver practical research that benefits the community.

This Procedure identifies requirements pertaining to the:

- Management of external funding, budgets and infrastructure support.
- Implementation of the Metro South Health Research Management Compliance Framework to meet financial management requirements which include financial management, contract management and intellectual property.
- Application of a consistent and enforceable process for the budgeting of research being conducted in or in collaboration with Metro South Health.

In Metro South Health, infrastructure in research management refers to clinical research support such as facilities, resources and services used by the science community to conduct research and foster innovation.

OUTCOME

Adherence to this Procedure will ensure all research conducted within Metro South Health or undertaken in collaboration with external entities, has appropriate fiscal management strategies in place to enable the conduct of the research within 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;
- All Metro South Health employees involved in the governance or financial management of research grants; 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 funding, budgets and infrastructure support.

- The financial management of research funds is underpinned by the Metro South Health Finance Management Practice Manual (FMPM).
- There is a requirement in all research projects to identify all direct and indirect or in-kind costs associated with the proposal and have a comprehensive budget.
- All potentially fundable research proposals must demonstrate to Metro South Health a focus on health, social and economic outcomes that can deliver measurable improvements to the community within the next five (5) years and a clear link to the priorities and objectives of Metro South Health and Metro South Health strategic plans.
- Research teams conducting research within Metro South Health must provide evidence that they have proven capacity to deliver outcomes such as demonstrated experience of research outcomes on time and on budget.
- Research projects in Metro South Health must be realistic, build capacity and strengthen Metro South Health's research base.
- Where possible, Metro South Health research projects should also; involve collaboration and partnerships between Metro South Health, industry, research institutions and cross disciplinary boundaries and provide opportunities to leverage funds which will build on Metro South Health’s investment in research. Furthermore, research projects should aim to promote realistic possibilities for developing and commercialising new knowledge and health service delivery models that give Metro South Health a competitive and sustainable advantage nationally and/or internationally.
- Research projects must include an appropriate plan to communicate or otherwise make research outcomes available to the public.
- All funding agreements must include a clear plan for funding sustainability and include step down funding arrangements where required.
- All research income and expenditure must be recorded in a research cost centre to enable Metro South Health audit and review. In-kind or actual research income and expenditure is best identified in budgets as opposed to recorded in a research cost centre.
- Funding and support from Metro South Health can be provided as a direct cash or capital investment; provision of in-kind expertise and services or a mixture of direct capital and in-kind support.

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

**Regulation**

**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](#)
- [Junior Doctor Research Fellowship Funding Rules: Round Two 2016](#)
- [Health Innovation, Investment and Research Office Funding Programs](#)
- [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 Policy - 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**

**Chief Financial Officer, Metro South Health**

The Chief Financial Officer, Metro South Health has final approval of all research budgets and research site approval but may delegate a budget approval level to the relevant department/division via the relevant Business Manager and/or Cost Centre Manager. The Chief Financial Officer/Delegate, Metro South Health must acknowledge and abide by the intended purpose of research grant funds.
Research budgets and accounts comprise both internal and external funding; the Chief Financial Officer/Delegate, Metro South Health is responsible for overseeing all of these research budgets and accounts irrespective of the funding source and for authorising the allocation of Metro South Health resources (such as laboratory space), approving internal budgets and the use of internal research funds.

**Chair, Centres for Health Research**

Provides authorisation for research applications/contracts up to the value of $200,000. The Centre for Health Research also maintains research office records and databases, and generates data for use in internal reports, governmental surveys as required by key stakeholders and government bodies.

The Chair, Centres for Health Research is also responsible for ensuring the Metro South Health Research and Development report is submitted to the Queensland Chief Scientist Office on an annual basis.

**Metro South Health Research Grants Administration Office/r**

The Metro South Health Research Grants Administration Office/r is accountable and responsible for coordinating and administering research project funding grants, in accordance with the [Research Grants Administration Procedure (PR2017/119)](#), in developing, managing and administering internal funding as well as providing advice and support to researchers in the preparation of funding applications. The Metro South Health Research Grants Administration Office/r liaises with researchers and Business Managers and/or Cost Centre Managers to facilitate the appropriate tracking of research grant funding and ensure the fulfilment of associated post-award requirements including the provision of progress and final reports.

**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 and provide a recommendation for authorisation of research contracts/agreements and budget, when submitted in conjunction with a Site Specific Application (SSA), to undertake research within a Metro South Health facility.

**Principal Investigator**

The Principal Investigator, in collaboration with the relevant Business Manager, is required to have identified a research cost centre within Metro South Health to manage the funds received as a result of conducting research. A Principal Investigator must have a recognised stature in his/her clinical/scientific discipline and have the demonstrated ability to ensure quality control and adherence to relevant guidelines and legislation that underpin the conduct of research and to administer and integrate all components of the research project. Principal Investigators are required to ensure:

- the entire research team is eligible to undertake research and comply with all the relevant Metro South Health Policies and Procedures;
- expenditure of research funds are in accordance with the approved funding agreement and budget and within the timeframes outlined in the funding agreement or funding agreement variations approved by the funder;
- expenditure, including salary related costs, is allocated to the correct research project account in a timely manner;
- support is provided by their line manager;
• budget approval and research initiative endorsement is received from the relevant Business Manager and Head of Department via the Metro South Research Contract Approval and Study Execution Form; and

• appropriate documentation is obtained in support of the expenditure of research funds.

**Research Project Liaison Officer/s and Clinical Research Coordinators**

Research Project Liaison Officer/s and Clinical Research Coordinators are responsible for liaising between the Principal Investigator, Metro South Human Research Ethics Committee (HREC) Office/r and Metro South Health Research Governance Office/r.

Research Project Liaison Officer/s and Clinical Research Coordinators also facilitate 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) form, whilst liaising with the Principal Investigator and research sponsor (if applicable) regarding the management, monitoring and financial reporting of the research project.

**Business Manager and/or Cost Centre Manager**

Business Managers and/or Cost Centre Managers are accountable and responsible for; creating research cost centres; maintaining and monitoring of research cost centre balances, expenditure, receipting and transfer of fund surpluses. Business Managers and/or Cost Centre Managers are also able to assist in budget development and funding use identification. Additionally, Business Managers and/or Cost Centre Managers are responsible for identifying a lack of, or no activity in research cost centres within their division/department and overdrawn balances as well as implementing consistent GST treatments for research grant income received and paid to external parties. They must also ensure adequate supporting documentation is provided in relation to salary and wage costs.

Business Managers and/or Cost Centre Managers must also provide information to the Chair, Centres for Health Research, when required/requested, to assist in preparing Metro South Health information for the Queensland Chief Scientist Office annual report.

**Researchers and Research Personnel**

Researchers and research personnel are required to obtain appropriate clearances for the expenditure of any research project funds; and provide appropriate documentation in support of expenditure of research funds in a timely manner.

**SUPPORTING DOCUMENTS**

**Attachments**

Attachment 1 - Application

Attachment 2 - Metro South Health Financial Processes Flowchart

**Forms**

Request for Funds Form

HREC/RGO Annual Progress Report/Final Report

Metro South Research Contract Approval and Study Execution Form
DEFINITIONS

See the Metro South Health Research Management Glossary

PROCEDURE - RESEARCH FUNDING, BUDGETS AND INFRASTRUCTURE SUPPORT

STEP 1: Determine Research Project Funding, Budgets and Infrastructure Requirements

Principal Investigators must identify and document the support needed for their research project. It is the responsibility of the Principal Investigator to identify the items associated with their research project that could incur costs (refer to Section 1.3 Research Costs below for further information).

Any research project that requires financial support (from any source) must be supported by a research project costing and budget.

The online Site Specific Assessment (SSA) form, available on the Australia Online Forms for Research internet site includes an example of a completed Site Finance Management Table. Relevant Business Managers and/or Cost Centre Managers may support the costing of any research project and will be involved in the costing for research projects requiring substantial resources.

STEP 2: Site Specific Assessment (SSA) Application

Research projects may be either externally funded (via research grants, commercial contracts etc.) or internally funded by Metro South Health. All research projects must be costed before a site specific application is submitted and before being submitted for approval by the Metro South Health delegate. A Site Specific Assessment (SSA) application is required as validity of needs and as a condition of submission to the Metro South Health Research Governance Office/r.

The Principal Investigator must forward the approved research project budget along with the competed Site Specific Assessment (SSA) to the Metro South Health Research Governance Office/r. Please note the Metro South Health Research Governance Office/r only needs to sight the final research project budget which has been approved by the relevant Finance/Business Manager and/or Cost Centre Manager. Finance/Business Manager and/or Cost Centre Manager approval indicates that the research project final budget workup is accurate, costed appropriately and is supported.

The Principal Investigator must advise in the budget workup how the funding will be obtained (i.e. a lump sum payment or research payments on a participant recruitment basis). Please see Research Governance (Site Specific Assessment) Procedure (PR2017/116) for more information.

STEP 3: Research Cost Centre Creation

Following Site Specific Assessment (SSA) authorisation, the Metro South Health Research Governance Office/r will forward relevant information to the identified Business Manager and/or Cost Centre Manager. The Business Manager and/or Cost Centre Manager will review the following prior to establishing a research cost centre:

- Research Governance Authorisation from the Metro South Health delegate via the Metro South Research Governance Office/r.
- Copy of the research contract (if applicable); please see Research Contracts and Study Execution Procedure (PR2017/122) for more information.
• Detailed budget workup including Metro South Health contributions for expenses and where research revenue is to be spent.

• Copy of the Research Protocol.

If funds have been received as a result of the Metro South Health Research Support Scheme (RSS) please see Step 4 below, otherwise please proceed to Step 5.

STEP 4: Metro South Health Research Support Scheme (RSS) Requirements (If Applicable)

Recipients of research funds from the Metro South Health Research Support Scheme (RSS) recipients must prepare a direct journal request/tax invoice for the transfer of funds from the Study Education and Research Trust Account. The following documents must be provided by the recipient:

• Request for Funds Form - signed; and

• Notification of Award (signed by the Chair, Centres for Health Research and/or a representative of the funding body) - new recipients.

Recipients must check details provided on the Request for Funds Form (with the exception of the Metro South Health research cost centre) match those stated in the Notification of Award.

A direct journal request should be prepared (Metro South Study, Education, Research and Travel Account (SERTA) funded awards) or tax invoice request (Princess Alexandra Research Foundation (PARF) funded awards) using information provided in the Request for Funds Form. The text of the journal/invoice must be worded as stated in the Notification of Award.

For both PARF, tax invoices are to be addressed to the PA Research Foundation (Ground Floor, Building 1, 199 Ipswich Road, Woolloongabba, QLD, 4102). The following documents must be emailed to the Metro South Health Research Grants Administration Office/r at CHR@health.qld.gov.au:

• the direct journal request/tax invoice;

• Notification of Award and completed HREC/RGO Annual Progress Report/Final Report; and

• completed Request for Funds Form.

If the conditions of the award have been met, the direct journal request/tax invoice will be forwarded to the funding body.

Once a Metro South Health SERTA payment has been transferred into a Metro South Health research cost centre, the funds may be used to purchase services upon receipt of a detailed itemised invoice from an external organisation. Metro South Health purchasing rules apply.

Enquiries regarding award payments should be directed as follows:

• Metro South Health SERTA funded awards – Metro South Health finance department

• PARF funded awards – PA Research Foundation Bookkeeper/Accounts Manager:
  o Ms Kerstin Petrick, PA Research Foundation, 199 Ipswich Road, Woolloongabba QLD 4102, Kerstin@pafoundation.org.au (07) 3176 5022

STEP 5: Budget Management

Throughout the duration of the research project Business Managers and/or Cost Centre Managers will:

• Assist with arranging an invoice to the relevant funding providers (where applicable).
• Assist in ensuring funds are deposited into the correct research cost centre.
• Assist with advice on Workforce Services/Payroll Services requirements if any labour is to go to the research cost centre.
• Arrange for a research cost centre to be established in FAMMIS.
• Advise purchasing of the delivery address setup for non-labour items.
• Advise the Principal Investigator in relation to requirements for business cases/other approvals for purchase of assets (there must be compliance with Health Service Policies and Procedures and the Finance Management Practice Manual (FMPM) for all financial transactions, including purchasing). Where information technology equipment is to be purchased this should occur in consultation with the relevant delegate of Clinical Informatics.
• Assist with the acquisition of supplied/equipment via FAMMIS requisitioning/ordering.
• Advise the Principal Investigator in relation to Workforce Services/Payroll Services, position/support requirements including business cases and delegated approvals for positions.

**STEP 6: Research Project Team Recruitment**

If allocated, the Principal Investigator is responsible for confirming with Workforce Services/Payroll Services position/support recruitment requirements (if any) and follow-up delegated approvals for positions/advertising etc.

The Principal Investigator is responsible for ensuring the employment eligibility of the research team in accordance with funding guidelines.

**STEP 7: Reporting**

Principal Investigators and/or research project contacts must meet with their respective Business Manager and/or Cost Centre Manager at least quarterly to monitor research cost centre expenditure. It is advisable to meet in May of each year applicable to allow effective planning for the new financial year if appropriate.

**STEP 8: Requests for Increased Budgets**

Research projects are expected to be completed within the agreed budget, in exceptional cases the relevant Metro South Health delegate may approve an increase in the budget for a research project where a strong justification made. For research projects that require agreements with third party entities, a contract variation will need to be submitted to the Metro South Research Governance Office/r for authorisation and execution prior to funds being transferred.

**STEP 9: Conclusion of a Research Project and Unused Funds**

At the end of a research project all surplus funds, including those managed via the General Trust Fund or the Health Service Operating Funds, will be retained intact by the Metro South Health with one (1) exception:

1. The business rules specifically state that in certain cases in which the conditions of the research project sponsor pre-determines that any excess funds be returned to them, this condition will apply.
Following discussions between the Principal Investigator and the Business Manager and/or Cost Centre Manager funds retained by the Metro South Health will be allocated for that financial year within the department/division of the individual Principal Investigator to be used for the following purposes:

- further research; or
- training and development of research staff (additional to require training); or
- publication or presentation of the research results; or
- other research purposes agreed to by the Principal Investigator and Business Manager and/or Cost Centre Manager.
PROCEDURE DETAILS

Procedure Number
PR2017/121

Procedure Name
Metro South Health Research Management - Research Funding, Budgets and Infrastructure Support

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

Metro South Health manages funding investment for all research and research infrastructure it supports by:

- Utilising the Queensland Government R.E.D.S. Decision Rules (Real future impact, External commitment, Distinctive angle and Scaling toward critical mass) to assess and guide all decisions to fund and support research projects/infrastructure.
- Assessing funding proposals against guidelines specific to a funding program (where applicable).
- Exploring all possible funding options and ensuring that when support is provided it is time-limited.
- Using research funding contracts that include information about intellectual property, research outcomes, timeframes, progress reports, agreed funding amounts, financial reporting, payment methods, performance indicators, evaluation criteria and which are time limited and include clear exit points for Metro South Health.
- Liaising with Business Managers and/or Cost Centre Managers for matters relating to infrastructure planning and development and utilising the Finance Management Practice Manual (FMPM).

1.0 Funding Requirements

Research applicants are required to provide a written proposal addressing relevant Criteria for Investment. Metro South Health work areas proposing to fund research projects/infrastructure must also use these criteria to inform funding decisions.

1.1 Criteria for Investment

1. Funding options are explored which means that evidence must be provided that appropriate/relevant non-Metro South Health funding options have been investigated.

2. There are clearly identifiable and measurable outcomes in that all potentially fundable research proposals must demonstrate to Metro South Health that there is:
   - A focus on health, social and economic outcomes that can deliver measurable improvements to the community within the next five (5) years; and
   - A clear link to the priorities and objectives of Metro South Health and Metro South Health strategic plans.

3. There is evidence that the research team has a proven capacity to deliver outcomes through:
   - Applicants demonstrating experience of delivery of research outcomes on time and on budget;
   - Novice applicants being mentored by experienced supervisors who can demonstrate delivery of research outcomes on time and on budget;
   - The research project/program has a comprehensive budget; and
   - Where continued funding is requested, applicants must provide research project specific historical funding expenditure versus research outcomes data along with a comprehensive budget and project plan for ongoing funding. Business Manager and/or Cost Centre Managers are able to assist in the development of research budgets and project plans.
4. The research is realistic, builds capacity and strengthens Metro South Health’s research base by meeting the following:
   o Involves collaboration and partnerships between Metro South Health, industry, research institutions and cross disciplinary boundaries;
   o Provides opportunities to leverage funds which will build on Metro South Health’s investment in research;
   o Promotes a competitive strength with a realistic possibility of developing and commercialising new knowledge and health service delivery models that give Metro South Health a competitive and sustainable advantage nationally and/or internationally; and
   o A plan to communicate or otherwise make research outcomes available to the public.

5. There is planning for funding sustainability in that funding contracts include a clear plan for funding sustainability and include step down funding arrangements where required and all research income and expenditure is recorded in a research cost centre to enable audit and review.

1.2 Form and Duration of Support

Funding and support from Metro South Health and/or universities, research institutions or commercial/third-party entities can be provided as:

- a direct capital investment;
- provision of in-kind expertise and services; or
- a mixture of direct capital and in-kind support.

Principal Investigators and researchers should consider expected future funding opportunities which may include the amount of revenue not yet received, supported by a third-party document stating the amount and period, and for which there is reasonable assurance of collection.

1.3 Research Costs

Research costs could include, but are not limited to (note; this list is intended to give examples and is not intended to be a comprehensive list of items that will be funded):

- Consumables: stationery, printing costs associated with questionnaires, case report forms, postage, sample transportation/packaging/tracking etc. Laboratory consumables needed specifically for the research project, such as; reagents, test kits, pipette tips, plastic and glassware. Single use clinical items, such as blood tubes, swabs etc.

- Devices and drugs: this includes any materials needed to undertake the research project including placebos. Fees from registration with the [Therapeutic Goods Administration](https://www.tga.gov.au) for studies being conducted under the Clinical Trials Notification Scheme, should also be included as applicable

- Equipment and other capital items: this includes items having a useful life of more than one (1) year. For internally funded projects the Metro South Health definition of capital cost will be used, for externally funded research projects the limit and terms specified by the funding body will be used. This also includes the provision of computers, laptops and other IT related hardware that is required to support the research project. Software should be included where the cost of this exceeds the funding limits described above.
• Insurance: some clinical trial sites require specific research project insurance; the cost of this should be met from research funding.

• Principal Investigator costs: (externally funded research projects) the time that the Principal Investigator will spend on the research project, providing leadership through team meetings, research project discussions with team members, time taken to perform additional patient evaluations and tests, oversight and authorisation of case report forms, etc. Principal Investigator time is not usually funded for internally funded research projects, however, the Metro South Health Research Committee may agree to fund investigator time in exceptional circumstances where the research project warrants significant direct investigator input where this cannot be undertaken through other means such as locum support, and where the Principal Investigators input is undertaken outside of normal working hours. For example, a blinded evaluation of patient images that are additional to those undertaken as part of patient care could qualify for this support.

• Manpower: research assistant(s), research nurses, administrators, scientists, technicians and project managers etc.

• Overhead costs: all externally funded research projects should include institutional overheads, for many research grant funding bodies the level of overheads will be determined by the awarding body. For commercial research projects overheads of up to 20% can be sought, the actual level will be agreed through the negotiation processes. Research finance is authorised by Business Managers and/or Cost Centre Managers to agree overhead rates for commercial research projects on a case by case basis.

• Indirect Costs: applicable for the externally funded research projects. These are general costs that cannot be clearly identified with a specific research project budget, but are nonetheless necessary to the research project. For example, costs of maintaining a building, utilising different facilities and administrative expenses required throughout the research project period. Indirect costs, based on rates approved, should be included in the approved research project budget. These are then charged to specific contract/research grant accounts in accordance with the terms of the agreement. Indirect budget is disbursed (in accordance with approvals from the delegate) according to the effort level of various departments involved in the research project management and a portion of which is deposited in Metro South Health cost centres for supporting Metro South Health’s unbudgeted research programs and workshops and also to provide financial backup for any external research project that is running short of funds due to unforeseen issues (in accordance with approvals from the relevant delegate).

• Patient travel: any costs associated with the patient travelling to the research centre location. These could be the costs associated with standard care visits or just those that are additional to standard care, the categorisation of the visit type and associated costs should be clear in the research project budget request. The reimbursements available will be in accordance with the finance policies in force at the time that research project approval is given. Any reimbursements made to patients as a result of their participation in clinical research must be declared to the HREC as possible inducements to research project participation. See Ethical and Scientific Review of Human Research Procedure (PR2017/113) for more information.
• Publication costs and conference fees: (externally funded research projects) these should be included in the research project costing for externally funded research projects. Internal research projects costings should not include these fees but these costs are covered separately, refer to the publication section below.

• Research evaluations: the costs associated with patient/participant and/or laboratory tests or analyses, the costs associated with the development of new analyses for the purpose of conducting the research project. This could include, for example; patient imaging tests, safety analyses etc.

• Translation costs: the costs associated with translating any research project documentation such as Participant Information and Consent Forms (PICFs), Research Protocols and case report forms etc.

• Travel costs: the costs associated with collaborating with external researchers for the conduct of the research project. For external research grants the costs associated with travel for conference presentations must be included in the research grant application (if allowed by the research grant awarding body). Note for internally funded research projects the research project costing should not include the costs of travel for conferences as this is covered separately.

• Metro South Research Ethics and Governance Office/r review fees: please see Research Fees Procedure (PR2017/123) for more information.

1.4 Additional Costs
On occasions there are costs associated with an activity that would happen as part of the standard of care for patients/participants, but additional costs are incurred because the activity is associated with research, for instance:

• Drug supply: the supply of drugs for clinical trials can involve additional steps to the supply for standard care, these might include; additional packaging to ‘blind’ drug supplies, operation of randomisation processes, development, storage and use of code breaks, recording of batch numbers and maintenance of an audit trail of research project dispensing, reconciliation of drug returns and drug dispenses.

• CT / MRI imaging: may need additional Quality Assurance (QA) steps in order to ensure uniformity across all research project sites.

• Blood tests: may be required outside of normal service hours so that patient/participant safety is assured.

• Additional medical or nursing cover: may be required to ensure patient safety.

• Archiving costs: for patient records to ensure that source documentation is maintained so that the research project audit trail including any deficits is complete. A deficit is the balance in a research project fund when the expenses recorded exceed the revenues recorded.

1.5 Documentation
In relation to research funding, budgets and infrastructure support documentation pertains to all records, in any form (such as written, electronic, magnetic and optical records; and scans, x-rays, and electrocardiograms, etc.) that contain information pertinent to the activities under review. Relevant records include but are not limited to:

• research subject health records;
• Metro South Health administrative documentation such as finance, research contracts/agreements;
• HREC documents;
• research site documentation such as research project documents, scheduling, assignments, CV's and lab notebooks; and
• external service provider documentation such as quality records, production, shipping and Standard Operating Procedures (SOPs).

2.0 Research Budgeting

Following discussions between the Principal Investigator and the Chief Executive Officer, Metro South Health and/or delegate, funds retained by the Health Service will be allocated for that financial year within the department of the individual Principal Investigator to be used for the following purposes:

• further research; or
• training and development of research staff (additional to require training); or
• publication or presentation of the research results; or
• other research purposes agreed to by the Principal Investigator and the Chief Executive Officer, Metro South Health.

The above also applies to both pre-existing research funds transferred from General Trust Funds to Health Service Operating Funds.

It must be noted that the above treatment of budget surpluses is not relevant in certain cases where the research project sponsor's condition is that any excess funds are to be returned to the sponsor (e.g. National Health and Medical Research Council (NHMRC), Queensland Cancer Fund (QCF) and/or Australian Research Council (ARC) etc.).

General Trust Fund cannot manage research funds; it is prohibited under Metro South Health business rules unless received as a bequest or donation.

2.1 Financial Management of Research

This section of the Procedure applies to the management of all funds received by Metro South Health, or Metro South Health employees, in relation to research, irrespective of whether identified as a fee-for-service, funded research (e.g. NHMRC, QCF, ARC and/or research for higher degrees) or as a donation or bequest. Management of all research project funds and revenue within Metro South Health must be compliant with this Procedure and applicable legislation.

To comply, revenue in relation to research projects (e.g. sponsored trials, ARC or research for higher degrees), which is a fee-for-service, nature, must be managed via Metro South Health research funds and not General Trust Funds (GTFs). However, funding received as bequests and donations must remain in, and be administered via, General Trust Funds.

Budgets for all commercially sponsored research are to be developed by the researcher, in negotiation with the relevant supporting departments. Funding received for all new research projects that are of a ‘fee for service nature’ will be managed by the relevant departments Business Manager and/or Cost Centre Manager.
Business Managers and/or Cost Centre Managers will undertake the steps to ensure compliance, however, it is the Principal Investigator’s responsibility to ensure that all incoming research funds for their research projects (excluding those from bequests/donation) are identified appropriately and placed into quarantined research cost centres with the departments operating funds.

Research project budgets should automatically be adjusted for the coordinating Principal Investigator on the anniversary of the date of the contract’s signing by the Business Managers and/or Cost Centre Managers. Regular cost centre reviews must be carried out by Metro South Health to ensure that research cost centres are properly set up with the correct fund code. As part of the reporting process, Metro South Health is to report on research funds in financial statements.

2.2 Site Specific Assessment (SSA)

All researchers must complete a Site Specific Assessment (SSA) in addition to the application submitted to the HREC for each research project. Metro South Health has responsibility for the considering matters of research governance. Please see Ethical and Scientific Review of Human Research Procedure (PR2017/113) and Research Governance (Site Specific Assessment) Procedure (PR2017/116) for more information.

The Site Specific Assessment (SSA) application must be completed and authorisation obtained from the Metro South Health Delegate for the conduct of the research by the Principal Investigator to begin within Metro South Health. The Site Specific Assessment (SSA) must detail the actual monetary and/or in-kind cost of the research project being conducted at a Metro South Health site or facility as well as approval by the Head of Department and relevant Business Manager and/or Cost Centre Manager via completion of the Metro South Research Contract Approval and Study Execution Form.

Authorisation to commence the research project will only be granted when:

- An authorised HREC has granted ethical clearance for the research protocol; and
- A Site Specific Assessment (SSA) has been completed and the Metro South Health Research Governance Office/r has recommended authorisation by the Metro South Health delegate.

The Metro South Health delegate retains the right to not authorise the commencement of research projects within Metro South Health, even if a HREC has granted ethical clearance.

2.3 Financial Management of Research Funds

Management of all research project funds and revenue within Metro South Health must be compliant with this Procedure and relevant legislative requirements. Budgets for all research projects are to be developed, and approved by the relevant Business Manager and/or Cost Centre Manager. In-kind support is to be costed as far as possible and included in the budget spreadsheet. A budget spreadsheet template may be accessible from relevant Business Managers and/or Cost Centre Managers.

Research project budgets should be adjusted according to the Consumer Price Index (CPI) on the anniversary of the contract execution date. Research that is funded, regardless of the source of funding, should have an individual cost centre number or other means of identification for auditing purposes.

The management of research funds comprises a series of stages commencing with the preparation for any funding application and concluding with the acquittal of the funding agreements and the closing of the research funding account. The management of research funds is a shared responsibility comprising of planning, day to day management, governance and accounting.
Responsibility for the management of funds, including the identification, management and mitigation of risks, is to be devolved down to the most practical level. The most practical level is that at which actions can be performed, verified, controlled and rectified.

Metro South Health reserves its right to take carriage of any aspect of the management of research funds in order to fulfil its legal and contractual responsibilities to government or to any funding body. This will occur only when there is reason to believe that if such action were not taken Metro South Health would be in breach of its legal or contractual obligations.

Everyone responsible for an aspect of the management of research funds for a research project will and must act to support the governance, management and accounting of those research funds. They must supply information and documentation as required to the relevant personnel in a timely manner.

Metro South Health is required to have a robust and transparent governance process in place that provides assurance that the standards of financial management meet public expectations.

Metro South is required to provide the infrastructure to administer research funds with integrity. To this end, the Business Manager and/or Cost Centre Managers will:

- Establish separate research project account(s), for each new research agreement within the finance system.
- Make research project reports available detailing all financial transactions and summarising the financial status of individual research projects.
- Prepare invoices to Funding Bodies in accordance with funding agreements.
- Prepare financial acquittals for Funding Bodies and other Funding Partners as required under funding agreements.
- Co-ordinate independent audits of research funds as required under funding agreements.
- Assist in the conduct of internal audits of research funds as initiated under the Internal Audit Program.
- Conduct audits as required and in accordance with Metro South Health Risk Management Policy (PL2013-06), Risk Assessment Guide (V12 6-11-2013) and Integrated Risk Management Framework.
- Ensure all research funds are linked to a research project that is authorised by the Metro South Health delegate.
- Complete audit requirements for submission to the Chief Scientist – Queensland Health via Metro South Health Finance.

2.4 Payments to Service Providers

The principle is that any provider of services for research purposes should only be paid once for the research supporting activity, so activities funded through research grants cannot also be funded from internal awards.

The same principle applies to providers of services to patients participating in research, which ensures any costs that are met through other payment provisions (such as health insurance) are not also charged to research.
Note there are occasions where an activity that is provided as standard of care incurs additional costs for the provision of the service in the research setting; these additional costs should be met from research funding (see below for more information). Researchers must note special conditions for SERTA funds. Please see Metro South Health Research Support Scheme (RSS) Procedure (PR2017/120) for more information.

2.5 Payments to Research Project Personnel

The same principle applies to research project personnel time spent on research projects. Research project personnel cannot be paid twice for the working the same hours on research projects and their salaried activities. That is, they cannot get paid through their usual salary and through research grant incomes for work undertaken during normal working hours.

Principal Investigators must provide evidence that any paid activities, are undertaken outside of normal working hours in order to receive payment in addition to their normal salary (this includes investigator and supporting staff payments). Consideration should be given to Conflicts of Interest in accordance with the Management of Conflict of Interest Policy (PL 2014/0038) and Management of Conflict of Interest - All Staff Procedure (PR2016-66).

2.6 Workforce Services and Payroll Services

Payroll is controlled and staff salaries are paid through Payroll Services directly and hence, buying official duty hours may not be acceptable for them (no employees may be allowed to work for external researches during their official duty hours). This topic (buy-out staff time) requires high level discussion and approval from Workforce Services and Legal Departments.

2.7 Publication Costs

For externally funded research projects, the costs associated with the publication should usually be met from the external funding route. Payments will be made in accordance with the external funding organisation’s Policies and Procedures.

For internally funded research projects; Metro South Health wishes to support the publication of research therefore funding may be provided to enable researchers publish their research findings. These costs should not be included in the research project budget but should be agreed with the relevant department/division prior to any costs being incurred. It is possible for more than one (1) publication to be generated from a research project; these costs will be met so long as the criteria for the support of research publications are met.

Any of the costs associated with publications will be met. This includes for instance the costs associated with journal submissions. The Metro South Health Research Committee may establish the criteria that publications need to meet in order for publication costs to be met from Metro South Health resources, for instance there may be an impact factor requirement on any funded publications.

The publication costs for research projects and case reports will be met so long as the impact factor criteria for publications are met. Note; Metro South Health will usually only support the publication costs for manuscripts in journals with an impact factor greater than 0.5. In certain circumstances, when the journal is new or a book is being authored, a case can be submitted to Metro South Health Research Committee for approval of the publication costs.
2.8 Excess Funds

It must be noted that the treatment of budget surpluses as outlined in Step 7 is not relevant in certain cases where the research project sponsor’s condition is that any excess funds are to be returned to the sponsor (e.g. National Health and Medical Research Council, Queensland Cancer Fund).

General Trust Fund cannot manage research funds; it is prohibited under Metro South Health business rules unless received as a bequest or donation.

It is the position of Metro South Health that research not impact on patient care therefore budget overrun must be met by research funds within the Department/Division/Facility.

3.0 Funding Sources – Specific Requirements

3.1 Externally Funded Research Projects

Research grant funded research projects should be costed so that they comply with the requirements of the relevant funding body. The Metro South Health Research Grants Administration Office/r will decide, on a case by case basis, the management of discrepancies between Metro South Health Policies and Procedures and those of the funding body. Business Managers and/or Cost Centre Managers will perform research project costing, budget review and finalisation in coordination with relevant requirements. Please see Research Grants Administration Procedure (PR2017/119) for more information.

Commercially funded research projects should be fully costed and the commercial income should be sufficient to cover these costs so that the research project can be undertaken. Please note; a commercial/industry-sponsored research contract is an agreement to fund research from a for-profit entity. These are distinguishable from research grants in how sponsorship, publication, liability, data ownership and intellectual property are addressed. Please see Research Contracts and Study Execution Procedure (PR2017/122) for more information.

Funding is not usually provided to ‘prop up’ externally funded research projects, in exceptional cases (such as where the external body excludes certain costs) the Business Manager and/or Cost Centre Manager may agree to provide additional internal funding support; this should be agreed in advance of any research grant submission or research contract agreements being made. If the funding is to be obtained through a commercial (e.g. pharmaceutical company) or non-commercial (e.g. National Health and Medical Research Council, Australian Research Council, Queensland Nursing Council or Queensland Community Foundation) sponsor a Metro South Health research cost centre with the funding type ‘STR’ is mandatory. The research contract must be signed by the Metro South Health delegate before the research cost centre is setup. Please see Research Contracts and Study Execution Procedure (PR2017/122) for more information.

Where research revenue is from a source other than commercial or non-commercial sponsorship it is still possible for these funds to be placed in a designated research cost centre with a nominated research cost centre, however the funding type must match the source (i.e. Commonwealth Funding).

3.2 Internally Funded Research Projects

Metro South Health wishes to support the development of research, so funding is provided to enable researchers to develop their research portfolio, publish their research findings and gather pilot data to support external funding applications.
Any funding requested for internal research projects must be approved by the Metro South Health delegate before the research project commences. Please see Metro South Health Research Support Scheme (RSS) Procedure (PR2017/120) for more information.

The Chief Executive Officer, Metro South Health can delegate the approval of budgets up to $10,000 either in-kind or funded to the Research Compliance Manager for low risk research projects. For more information regarding low risk research projects please see Ethical and Scientific Review of Human Research Procedure (PR2017/113).

Funding will not be provided for research projects that start prior to HREC approval. Budgets will not usually be agreed for activities that start before the budget has been approved. Funds receipted must be spent within the same financial year and cannot be rolled over.

3.3 Metro South Health Research Support Scheme (RSS)

The Metro South Health Research Support Scheme (RSS) is the application and assessment process through which research awards are funded by the Metro South Health Study, Education and Research Trust Account (SERTA) and the PA Research Foundation (PARF).

Applications to the scheme open annually and the Centres for Health Research are responsible for the management of the process to select candidates for the available awards in accordance with Metro South Health Research Support Scheme (RSS) Procedure (PR2017/120). Successful candidates are endorsed by Metro South Health funding bodies i.e. Metro South Health SERTA and the PARF.

The Centres for Health Research notifies successful applicants of the outcome of their application via a Notification of Award (including conditions and acceptance) document and a formal letter. The formal letter will include GST for research fund income received and paid and provides information regarding access to and payment of instalment/year one (1) of the awarded funds.

Successful candidates are provided with information which details their award conditions and provided information regarding access to and payment of the awarded funds in instalments over a one (1) year period. Award progress is monitored by the Centres for Health Research via annual HREC/RGO Annual Progress Report/Final Report.

Similarly, current recipients are notified of the acceptance of their progress report via a HREC/RGO Annual Progress Report/Final Report which also provides information regarding access to and payment of instalment two (2) (or the subsequent year) of the awarded funds from the Metro South Health Research Grants Administration Office/r. In each instance, the award recipient is to forward their HREC/RGO Annual Progress Report/Final Report to the appropriate Business Managers and/or Cost Centre Managers, who will assist with the transfer of funds.

Recipients are responsible for initiating award payments. Transfer of funds cannot occur without provision of a signed Request for Funds Form. Financial transactions are the responsibility of Business Managers and/or Cost Centre Managers and University Finance Officer/s.

The direct journal request/tax invoice raised by the Business Managers and/or Cost Centre Managers is to be forwarded with the Notification of Award, HREC/RGO Annual Progress Report/Final Report and the completed Request for Funds Form to the relevant funding body.
3.4 Metro South Health Research Support Scheme Grant Recipients

Recipients are sent a Notification of Award which must be used to initiate instalments/year (one) 1 of the award payment. This letter contains Conditions of Award, which must be accepted and signed by the recipient, the co-investigators/supervisors named on the application, and the Head of Department/Division (or direct line manager) in which the research will be conducted. Please see Metro South Health Research Support Scheme (RSS) Procedure (PR2017/120) for more information.

Particular arrangements maybe required when the recipient of the award is from a third party and an agreement is required. Further information must be sought from the Metro South Health Research Grants Administration Office/r in these circumstances.

Recipients are responsible for ensuring the following details (including spelling) are correct:

- Recipient name;
- Research project title; and
- Funding type (Project Grant, Small Grant, New Appointment Grant, Postgraduate Scholarship etc.).

Recipients are also required to note which funding body is supporting the award (Metro South Health SERTA or PARF). The funding body will affect the manner of payment. For awards funded by Metro South Health SERTA, the transfer of funds must occur through the Business Manager and/or Cost Centre Manager of the department/division within which the recipient's research cost centre resides.

For awards funded by the PARF, the transfer of funds may occur through either the Business Manager and/or Cost Centre Manager of the department/division within which the recipients research cost centre resides OR a Finance Officer of the academic partner university with which the recipients are affiliated.

The recipient must return the signed Conditions of Award to the Centres for Health Research by the designated due date. Note that award payments can only be made if this signed document has been received by the Metro South Health Research Grants Administration Office/r.

The recipient must initiate the instalment/year (one) 1 award payment by providing their Business Manager and/or Cost Centre Manager (or their delegate) with the following:

- Notification of Award (signed by the Chair, Centres for Health Research and a representative of the recipient’s funding body);
- Completed and signed Request for Funds Form;
- Submit an annual HREC/RGO Annual Progress Report/Final Report by 30 November each year of funding;
- Initiate the instalment two (2)/subsequent year award payment by providing the Business Manager and/or Cost Centre Manager (or their delegate) with the following:
  - Request for Funds Form - completed and signed (signed by the Chair, Centres for Health Research, or a representative of the recipient’s funding body) stating additions funding has been released.