

PROCEDURE

Research Management - Quality Framework and Reporting

PR2017/126
Version No. 1.0

PURPOSE

The Metro South Hospital and Health Service (Metro South Health) is committed to ensuring that resources provided to carry out research are directed to areas of research excellence and public benefit. The aim of this Procedure is to develop a basis for an improved assessment of the quality and impact of research within Metro South Health and to establish an effective process to achieve this.

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 its research management quality framework and reporting requirements:

- Research quality frameworks must aim to drive positive research behaviours, encouraging researchers and research organisations to focus on the quality and impact of their research.
- In Metro South Health, research management quality frameworks and subsequent reporting requirements aim to establish greater transparency of the quality of research arising from public investment for Metro South Health, taxpayers, researchers and other end-users, in addition to providing evidence of the merits of investment in research.
- A clear rationale for examining the quality and impact of research is that high quality research has the best chance of success in a global market and that will ensure a further deepening of Metro South Health's innovation base.

- In Metro South Health, the core expectations pertaining to research quality and reporting are as follows:
 - Compliance with legal and regulatory requirements applicable to the organisation.
 - Carrying out activities that are in line with the needs of the interest groups, taking into account the growing perspectives and the changing needs in science and technology, always in line with the [Metro South Health Research Management Policy \(PL2017/55\)](#).
 - Establishment of an ongoing process and activities improvements, to achieve the objectives and targets set by each research group or innovation centre within Metro South Health.
 - Ensuring that activities are perceived as reliable, effective and efficient for all interest groups.
 - Involvement, motivation and engagement staff in order to seek their participation in the management, development and implementation of research management quality frameworks in Metro South Health.
 - Provision of technical, material and human resources for each research group and innovation centre.
 - Definition and implementation of training needs to maintain and improve the professional skills of the research group's staff and innovation centres.
 - Development of a structural coordination with other entities to respond to any circumstantial needs that may arise.

LEGISLATION OR OTHER AUTHORITY

Legislation

- *Defence Trade Controls Act 2012 (Cth)*
- *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)*
- *Therapeutic Goods Act 1989 (Cth)*

Regulations and Standards

- Gene Technology Regulations 2001 (Cth)
- Information Privacy Regulation 2009 (Qld)
- Therapeutic Good (Medical Devices) Regulations 2002 (Cth)
- Therapeutic Goods Regulations 1990 (Cth)

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](#)
 - [Research Governance Handbook: Guidance for the national approach to single ethical review 2011](#)

- [Standardised Participant Information and Consent Forms](#)
- [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](#)
- [Ethical Considerations in Quality Assurance and Evaluation Activities 2004](#)
- Queensland Health: [Health Service Directive: Research Ethics and Governance HSD-035:2016](#)
- Queensland Government: [Queensland Biotechnology Code of Ethics: Update of the Code of Ethical Practice for Biotechnology in Queensland \(2006\)](#)
- 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.

- [Finance Management Practice Manual \(FMPPM\)](#)
- [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

Metro South Health Research Committee

Responsible for providing advice and oversight of Metro South Health Procedures relating to research and innovation (including research conduct), commercialisation and research higher degree training (including issues of quality) and reports to Metro South Health Executive on these matters at least annually.

Executive Management Team

Responsible for implementation of the research compliance framework and for fostering good research governance practices.

Centres for Health Research

Responsible for:

- The implementation of the Metro South Health Research Management Compliance Framework and for fostering good research governance practices;
- Provision of information resources and services pertaining to research to Metro South Health;
- Strategic oversight of research development in Metro South Health;
- Leadership and for embedding a culture of responsible research conduct;
- Ensuring the administrative processes for ethical approval and governance of all human, animal and biological related research are in place and promotes research integrity;

- Assisting researchers with applications for funding and finances and in developing, costing and negotiating consultancies and commercial contract research; and
- Assessing the adequacy and effectiveness of Metro South Health’s internal controls, including the risk management and compliance frameworks.

Principal Investigator – Responsible Officer

Ensure quality is considered when developing research protocols and processes and that Quality Assurance (QA) and Quality Control (QC) programs are in compliance with the Metro South Health Research Management Compliance Framework.

Employees and Researchers

Share responsibility and accountability for Metro South Health’s research being conducted according to appropriate regulatory, ethical and scientific standards.

SUPPORTING DOCUMENTS

Attachments

Attachment 1 - [Application](#)

Forms

[HREC/RGO Annual Progress Report/Final Report](#)

DEFINITIONS

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

PROCEDURE - QUALITY FRAMEWORK AND REPORTING

STEP 1: Research Protocols and Compliance

Principal investigators must ensure that that consideration is given to quality and reporting requirements, as outlined within the Metro South Health Research Management Compliance Framework, when developing research protocols for research projects. Please see [Compliance Framework Procedure \(PR2017/112\)](#) for more information.

STEP 2: Quality Frameworks

Principal investigators and researchers must implement appropriate quality frameworks that maintains participant confidentiality and complies with ethical review requirements. Please see [Ethical and Scientific Review of Human Research Procedure \(PR2017/113\)](#) for more information.

Established quality provisions must also comply with the [Note for Guidance on Good Clinical Practice \(CPMP/ICH/135/95\) 2000 - Annotated with TGA Comments](#) and the [National Statement on Ethical Conduct in Human Research \(2007\) - Updated May 2015](#).

STEP 3: Collection and Use of Data for Quality Assurance (QA) and/or Evaluation

Principal investigators and researchers must comply with the Research Data Integrity and Information Procedure (PR2017/125) in the collection and use of data for Quality Assurance (QA) and/or evaluation purposes.

STEP 4: Conduct of Research

Researchers must ensure research is conducted in accordance with the [Metro South Health Research Management Policy \(PL2017/55\)](#) and Research Complaints and Misconduct Procedure (PR2017/124).

STEP 5: Monitoring

Research projects must be monitored in accordance with [Research Governance \(Monitoring\) Procedure \(PR2017/117\)](#).

STEP 6: Reporting

Researchers are responsible for ensuring that the [HREC/RGO Annual Progress Report/Final Report](#) is submitted prior to the Metro South Health HREC clearance anniversary (or sooner as required), to comply with Metro South Health HREC clearance requirements. Please see [Ethical and Scientific Review of Human Research Procedure \(PR2017/113\)](#) and [Research Governance \(Site Specific Assessment\) Procedure \(PR2017/116\)](#) for more information.

PROCEDURE DETAILS

Procedure Number

PR2017/126

Procedure Name

Research Management - Quality Framework and Reporting Procedure

Policy Reference

PL2017/55

Metro South Health Research Management Policy

Supersedes

Nil

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30/10/2017

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30/10/2017

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30/10/2020

1.0 Rationale for Research Management - Quality Framework and Reporting

Currently, no practical and universally accepted mechanisms or procedures have been identified to consistently assess the quality of publicly funded research in Australia, or the impacts and benefits that result from the public investment in that research.

Metro South Health however has decided to implement key principles which underpin a quality framework with the aim to provide a more consistent and comprehensive approach to assessing the quality and impact of research projects within the Health Service.

1.1 Research and Experimental Development

Research management quality framework and reporting is intended to apply to all aspects of basic and applied research and to experimental development research insofar as it directly relates to original basic and applied research. A quality framework and reporting will be framed around the principles of:

- transparency,
- acceptability;
- effectiveness; and
- encouraging positive behaviours.

1.2 Transparency

The implementation of a research management quality framework, in its application and measures, enables openness and transparency to Government, Metro South Health, stakeholders and collaborators alike so that they are better informed about the results of public investment in research. This includes the use of reliable/repeatable measures/metrics. Examples of transparency in process would be the publication of guidelines for expert review, consistency, and neutrality in presenting information. These form key elements for the credibility of Metro South Health's research management quality frameworks and reporting.

1.3 Acceptability

A research management quality framework and its measures should be acceptable to the organisations and agencies to which it is to be applied as well as meeting the needs of Metro South Health. Additionally, quality frameworks should provide transparent, reliable and timely assessments of research quality. It should also ensure that it encourages positive behaviours and is also able to take account of differences across disciplines, while identifying common elements to enable appropriate cross-disciplinary application.

Given the diversity of stakeholders and the range of institutions to which Metro South Health's research management quality framework may be applied, it is acknowledged that it may difficult to develop a framework which is acceptable to everyone. Acceptability may mean achieving compromise to acknowledge institutional diversity. It will also mean that for each and every metric/measure proposed for a quality framework, reaching consensus may not be possible. In these circumstances, acceptability will be guided by the other agreed principles.

1.4 Effectiveness

Metro South Health's research management quality framework aims to avoid a high cost of implementation and imposition of a high administration burden on research providers. It also takes into consideration cost-effectiveness of recommended measures of funding, administration, and wider considerations of constraints to creativity and innovation.

Specifically, research management quality frameworks in general must be cost effective, easy to implement, and keep compliance costs to a minimum, consistent with maintaining an acceptable level of methodological rigour. It is for this reason that full consideration must be given by Metro South Health to any additional administrative burden to existing assessment mechanisms and data collection processes.

Similarly, a research management quality framework needs to have useful outcomes in order to be effective. These may include encouraging institutional self-reflection and adjustment of strategic goals/directions to inform future policy deliberation and decision-making. Effectiveness will also be demonstrated by ensuring that research results are accessible to fellow researchers and the broader community. This is to ensure good value for money for the investment in research.

1.5 Encouraging Positive Behaviours

The overarching behaviour targeted as part of research management quality framework and reporting is to focus on improving the quality and impact of research and to further develop and support a vibrant research culture in Metro South Health. Some of the activities undertaken to support this behaviour and which may be encouraged and valued by a research management quality framework could include:

- further enhancing the quality of research-related publications;
- supporting early career researchers;
- improving the strategic planning for research activities within institutions;
- promoting collaborative linkages with industry/end-users;
- enhancing the impact of research on policy and practice;
- improving the internationalisation of Metro South Health research and researchers;
- improving inter-institutional linkages;
- facilitating trans/cross-disciplinary research; and
- encouraging access to high quality research.

2.0 Measuring the Quality of Research

When reviewing the quality of research in Metro South Health the following impact outputs may be measured:

- Publication outputs;
- Editorship of international journals;
- Involvement in international learned societies;
- Invited international lectures/other international collaborations;
- Peer recognition: Academy membership;
- Research income: Competitive Grants Schemes;
- Research income: Other Grants Schemes (incl. International);
- Other research income (other contract research);

- International linkages/collaborations/Memoranda of Understanding;
- Visiting scholars and/or postgraduate students;
- Publication citations;
- Incorporation of research results into international/national policies, codes and/or practices;
- Research graduates employed in industry;
- Industry-funded research places;
- Academic-Industry Staff exchanges;
- Research students industry placements;
- The holding of exhibitions and performances;
- Audience/attendances at exhibitions/performances;
- Media presence through articles, debates, coverage;
- Expert advice/submissions/panel membership at government inquiries;
- Patents;
- Commercial licences; and/or
- Commercial uptake.

3.0 Quality of Research

Irrespective of whether an activity is called research or Quality Assurance (QA) or evaluation, those conducting the activity must consider whether the people involved (e.g. participants, staff or the community) will be exposed to any risk, burden, inconvenience or possible breach of their privacy.

An activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation is a Quality Assurance (QA) activity. Terms such as 'peer review', 'quality assurance', 'quality improvement', 'quality activities', 'quality studies' and 'audit' are often used interchangeably.

3.1 Evaluation

Evaluation is a term that generally encompasses the systematic collection and analysis of information to make judgements, usually about the effectiveness, efficiency and/or appropriateness of an activity. The term is used in a broad sense to refer to any set of procedures, activities, resources, policies and/or strategies designed to achieve some common goals or objectives.

Importantly, Quality Assurance (QA) and evaluation commonly involve minimal risk, burden or inconvenience to participants, and, while some level of oversight is necessary, Human Research Ethics Committee (HREC) review processes are often not the optimal pathway for review of these activities.

What really matters is that:

- Participants in Quality Assurance (QA) and evaluation are afforded appropriate protections and respect;
- Quality Assurance (QA) and/or evaluation is undertaken to generate outcomes that are used to assess and/or improve service provision;
- Those who undertake Quality Assurance (QA) and/or evaluation adhere to relevant ethical principles and state, territory and Commonwealth legislation
- Organisations provide guidance and oversight to ensure activities are conducted ethically including a pathway to address concerns.