MEMORANDUM

To: Metro South Research Community

Copies to: Metro South Health Executive Directors, Divisional Chairs, Research Directors and Research Managers

From: Executive Director, Metro South Research

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Subject: Metro South Research Policy Framework

Date: 21/12/2023

In June 2023, the revised Research Policy was published on the Metro South Health (MSH) Policy Index.[1] The Research Policy brought Metro South Research into alignment with the MSH overarching policy framework and MSH Research Strategy 2019-2024 and set the foundation for implementing the National Clinical Trials Governance Framework (NCTGF) in MSH.

Since its release an extensive review and consultation process has been undertaken to revise all supporting procedures, work instructions and guidelines. From December 2023, all revised Research Policy Framework (Attachment 1) documents (inclusive of forms, tools and templates) will be published on the MSH Policy Index and Metro South Research website.

In consideration of the recently released National Statement on Ethical Conduct in Human Research 2023[2], NCTGF[3] and Queensland Health Researcher User Guide July 2023[4] there will be changes to the way research is managed in MSH. To assist researchers, outlined below are some key changes that will come into effect from 1 January 2024.

Assessing and managing risk in research

- All research projects undertaken within MSH must complete a Risk assessment and management plan and identify an overall risk rating for the study.
- The completed plan must be included as a supporting document to both the Human Research Ethics Application (HREA) and Site Specific Assessment (SSA) in the Ethical Review Manager (ERM) application.
- The overall risk rating must be included in the research protocol.
- The overall risk rating will also be used to determine signatures on the Research Contracts Approval and Study Execution (RCASE) form for both single site and multi-site studies.
- MSH work instruction WI2023-292 Assessing and managing risk in research outlines the process required to undertake this risk assessment.
- The Metro South Human Research Ethics Committee (HREC) and Metro South Research will review risk ratings.
- The HREC Chair and Deputy-Chair and Metro South Research may provide guidance in cases where adjustment to the risk rating is considered appropriate.

[1] PL2023-92 Research Policy https://docs.sth.health.qld.gov.au/documents/metro-south-health/pl2023-92
[2] National Statement 2023 https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023
[3] NCTGF https://www.safetyandquality.gov.au/standards/national-clinical-trials-governance-framework
[4] User Guide https://www.health.qld.gov.au/__data/assets/pdf_file/0027/1247724/qld-health-researcher-user-guide.pdf

Research data risk assessment and management plan

- Similar to a general research project risk assessment, a separate Research data risk assessment and management plan is also required to be uploaded as a supporting document to ERM.
- This process aims to assist researchers, reviewers and delegates to understand and manage the risks around data and privacy for research participants.
- MSH work instruction WI2023-289 Research data and privacy outlines the process required to complete a Research data risk assessment and management plan.

Research contracts and study execution (RCASE)

- The RCASE form has been revised to reflect the risk assessment and management process, streamline signatures and clarify requirements around budgets and funding.
- Two RCASE forms are available for single site and multi-site projects.
    - The multi-site form enables Facility/Service Line endorsement from multiple participating MSH sites.
- Some key changes to the RCASE form are as follows:
    - Inclusion of overall risk rating.
    - Required supporting documentation (i.e., research protocol).
    - Financial information (i.e., Operational Cost Centre Code/Research ION and FTE assigned to the project).
        - MSH work instruction WI2023-93 Research funding, budgets and infrastructure support and budget templates aims to assist researchers completing the financial information section.
        - Researchers must contact their Business Manager and/or Cost Centre Manager to help identify and provide relevant financial information.
    - Endorsement and collation of appropriate signatures based on risk.
        - Low risk studies only require Principal Investigator (PI) and Head of Department (HoD) signatures.
        - For projects over $10,000 Finance/Business Manager signature is required.
        - Medium risk and higher studies require PI, HoD, Finance/Business Manager and Clinical Lead (above HoD) signature (leave other signatories blank).
        - High and very high risk studies require PI, HoD, Finance/Business Manager and Clinical Lead (above HoD) and Facility/Service Executive Director signatures (leave other signatory blank).
        - Very high-risk studies require PI, HoD, Finance/Business Manager and Clinical Lead (above HoD) and Facility/Service Executive Director and Chief Operating Officer signatures (all signatures are required).
    - For multi-site studies, the first page is completed by the lead site and an additional signatory section has been included for participating facility/service authorisation.
    - The Metro South Research Governance Office (MSRGO) will complete a review and submit to the relevant MSH delegate for authorisation.
- Researchers who are unsure about any of the above RCASE form changes (e.g., assistance in identifying the relevant delegate) are encouraged to contact MSH-research@health.qld.gov.au.
- Whilst the revised RCASE Forms will be utilised from 1 January 2024, there is ongoing opportunity to amend the fields/content as required.

Research integrity training mandatory

- As advised in memorandum[5] dated 17 August 2023, completion of all three MSH Research Integrity Training online modules is mandatory for all MSH employees undertaking research in MSH from 1 January 2024.

[5] Memorandum Research Integrity https://metrosouth.health.qld.gov.au/sites/default/files/content/ri_memo_2023.pdf

- As part of this mandate, all researchers seeking authorisation of research from 1 January 2024 must provide evidence of Research Integrity Training completion (i.e., a valid Research Integrity Training Certificate), as part of the SSA process.
- The Metro South Research Governance Office (MSRGO) will not authorise any SSAs without sighting accompanying certificates for Research Integrity and Good Clinical Practice (GCP) for all members of the research team.
- MSH researchers can access research integrity and GCP online modules via MSHLearn.
    - Researchers external to MSH may request to access MSH research integrity and GCP online modules via MSH-research@health.qld.gov.au.

MSH sponsorship of Clinical Trial Notification (CTN) scheme trials

- MSH has implemented an appropriate MSH-wide process to grant sponsorship, by MSH, for CTN Scheme investigator-initiated clinical trials.
- Principal Investigators/Coordinating Principal Investigators (PI/CPI) and an identified 'Sponsor Representative' must be aware of MSH sponsor responsibilities and maintain consistency with the Therapeutic Goods Administration's (TGA) GCP Inspection Program.
- MSH work instruction WI2023-301 Metro South Health sponsorship of Clinical Trial Notification (CTN) scheme trials provides more information on this process.

Metro South Research acknowledges that understanding new and revised processes is a challenge in a complex Hospital and Health Service. From early 2024, education sessions centred around the above changes will be made available to all MSH researchers.

Attached to this memorandum is the current Research Policy Framework inclusive of relevant hyperlinks. We hope that the framework assists researchers in finding relevant information, forms, tools and templates.

Metro South Research would like to seek support from the MSH Research Community during this period of change. Whilst the revised Research Policy Framework required a significant contribution from relevant key stakeholders across MSH there may be areas which could be fine-tuned or improved over time. We would like to encourage all researchers to provide feedback to MSH-research@health.qld.gov.au on any documents contained within the Research Policy Framework.

Finally, I'd like to personally thank all those who contributed to the review of these documents.

Professor John Upham
Executive Director
Metro South Research
21/12/2023

Attachment 1: Metro South Research Policy Framework

Policy	PL2023-92 Research Policy				
Procedures	PR2023-411 Research excellence	PR2023-412 Research support and management	PR2023-413 Research administration and compliance	Research biobanks	Clinical Research Facility (CRF)
Work Instructions	WI2023-287 Research integrity WI2023-288 Research quality management systems WI2023-289 Research data and privacy WI2023-290 Research authorship, peer review and publication WI2023-291 Research complaints and misconduct WI2023-292 Assessing and managing risk in research	WI2023-293 Research funding, budgets and infrastructure support WI2022-226 Open access journal publications in research WI2023-294 Research grants administration WI2023-295 Research letters of support WI2023-296 Metro South Health Research Support Scheme (MSH RSS) WI2023-297 Gift cards (for use as research incentives)	WI2023-299 Ethical and scientific review of research WI2023-300 Exemptions from research review WI2023-301 Site specific assessment of research WI2023-302 Research contracts and study execution WI2023-303 Metro South Health sponsorship of Clinical Trial Notification (CTN) scheme trials WI2023-304 PowerTrials - ieMR research support module WI2023-305 Research monitoring WI2023-306 Post approval – research amendments, reporting and closure	Coming 2024	Coming 2024
Guidelines	GL2021-75 Partnering with consumers in research GL2023-97 Aboriginal and Torres Strait Islander health research GL2023-98 Research translation and impact		GL2023-99 Planning a research project GL2023-100 Research Participant Information and Consent Form (PICF) GL2023-101 Research contract clauses GL2023-102 Use of electronic signatures in research contracts GL2021-77 Clinical trials GL2023-103 Teletrial Support Program (TSP) funding		