Exemptions from research review

PURPOSE

Exemptions may be requested from a Human Research Ethics Committee (HREC) for quality initiatives (audit, quality improvement project) and research exempt from ethical review (systematic reviews, studies that use data publicly available). This work instruction identifies a consistent and enforceable procedure for the processing, reviewing and approving of non-research or research exempt projects from Metro South Human Research Ethics Committee (MSHREC).

OUTCOME

This work instruction aims to:

- Ensure all research conducted within Metro South Health (MSH) or in collaboration with external entities, is of the highest ethical and scientific standard and is compliant with relevant legislation, standards, and guidelines.
- Ensure ethical considerations in quality assurance and evaluation activities are enabled for all non-research projects in accordance with the:
    - National Statement on Ethical Conduct in Human Research (2023) ('National Statement') – Chapters 2.3 and 5.1.22.
    - Ethical Considerations in Quality Assurance and Evaluation Activities March 2014.
- Outline Metro South Human Research Ethics Committee (MSHREC) exemption process when the MSHREC Chair or Deputy Chair, or the Manager of Research Integrity and Compliance, grants an exemption from full HREC review or categorise the research project as a lower risk and offer an alternative review process.

This work instruction outlines processes described in MSH procedure PR2023-413 Research administration and compliance and upholds principles outlined within the Research Administration and Compliance Handbook.

SCOPE

This work instruction applies to MSH employees who conduct quality assurance activities or case studies within or in association with MSH, or through access to MSH participants, health records or data, where they require evidence of a HREC exemption. This may be required either to access the necessary data or to publish the project.

WORK INSTRUCTION

1. STEP 1: EXEMPTION SUBMISSION PROCESS

- Submissions of projects that are exempt from ethical review are made online via the Ethical Review Manager (ERM) using the QLD Exemption Form.
    - Please discuss with the MSHREC Office if unsure if a project meets exemption requirements prior to submitting.
    - An email can be sent to MSH-Ethics@health.qld.gov.au with a draft protocol for advice on whether the exemption pathway is right for the project.
    - Refer to MSH work instruction WI2023-299 Ethical and scientific review of research for more information.
- Create the QLD Exemption Form in ERM and complete the required questions and upload the required documents.

1.1 Exemption – required documents

- Project description - Utilise the Attachment 1: MSH Exemption – Project Description Template to provide all relevant information about the project/request for exemption ensuring the following are included:
    - Descriptive title: of the activity, staff involved, literature review including standards of care and relevant indicators.
    - Aim and background: for example, Why is this activity being undertaken? What are the standards of care that apply in this case? If standards are not known, what is to be determined? How will the results be used?
    - Method: Details on participants, or data, to be included (inclusion / exclusion criteria, numbers involved, relevant time periods). What, if anything, participants will be asked to do; variables to be reported on, including outcomes of interest; method of data collection and storage (e.g., chart review); methods used to maintain confidentiality/anonymity, data/list of variables to be collected; methods used to maintain confidentiality / anonymity; the form the results will take (e.g., descriptive statistics); activity/study timelines; how the results might be fed back into an audit or quality improvement cycle; where the results are anticipated to be presented external to the institution; references (where relevant).
    - Associated documents if applicable: such as Patient Satisfaction Questionnaires, Data Collection Sheet, etc.
- Head of Department (HoD) Support – accompanied by evidence of support from the HoD's line manager:
    - Evidence of HoD support is required for all exemption submissions.

- This can be either a letter or an email trail showing that the HoD is aware of and in support of the project as a quality assurance activity or a case study. If it is an email trail, please ensure the HoD has their position title in their email signature.

- For case studies, confirmation of consent is required:
  - The NHMRC has a Participant Information and Consent Form (PICF) template for Case Studies.
  - Depending on the type of case study, consent may also be given verbally, a Participant Information Sheet (PIS) may be required.
  - Consent may also be given by a substitute decision maker, in which case a PICF for a substitute decision maker may be required.
  - The project description should outline how consent has been obtained and that it is recorded in the patient's medical record. If a PICF or PIS was used, this document should be submitted. Please ensure that the submitted document is not the signed version showing identifiable patient details.
- Once completed, upload the final documents to ERM under the documents section.
- Sign the form and click the submit button.

2. STEP 2: EXEMPTION REVIEW PROCESS

- The MSHREC Office will review the Project Description and supporting documents (if required) via ERM.
- If the submission is missing one of the necessary documents or there is not enough information in the project description, it is marked as further information requested and a request for the missing item will be provided to the contact person via the correspondence tab in ERM.
- This must be revised and uploaded to ERM before the review process can proceed.

3. STEP 3: EXEMPTION APPROVAL

- The contact person will be formally notified via ERM if the project:
  - Requires further information.
  - Is deemed exempt from ethical review:
    - The Site Specific Assessment (SSA) authorisation process is not required for exemptions.
    - Annual progress and/or final reports are not required for exemptions.
    - All projects deemed exempt from ethical review must register with the institution's Safety and Quality Unit before commencing.

- Is deemed research and referred for ethical review:
    - The MSHREC has the discretion to request a full review of a project if it is determined to be for research purposes rather than a quality assurance activity or case study.
    - Either the lower risk or higher risk pathway will be recommended, depending on the level of risk the project poses to participants and/or the organisation.

RESPONSIBILITIES

Position	Responsibility	Audit criteria
Executive Management Team	• Ensure collaborative, harmonised, clear and detailed publicly available policies and procedures are in place for the ethical and scientific review of all MSH research.	N/A
Metro South Human Research Ethics Committee (MSHREC)	• Provide oversight of the ethical and scientific review of MSH human research by keeping abreast of international, national and state-wide legislation, regulations and guidelines. • Promote MSH strategic requirements and ethical and responsible decision-making which respects the rights of MSH participants.	N/A
Metro South Research	• Update MSH ethical and scientific review documents in accordance with MSHREC requirements. • Provision of secretariat/administrative support to maintain and uphold principles outlined in the Research Policy Framework and related procedures.	N/A
Employees, researchers, research student supervisors and students	• Adhere, be aware of and comply with all relevant policies, procedures, guidelines, research protocols and Standing Operating Procedures (SOPs) when conducting research.	N/A

DEFINITIONS

Term	Definition
Ethical Review Manager (ERM)	Web based content manager supported by the Office of the Director General via Office of Research Innovation, Queensland Health.
Evaluation activities	Evaluation is a term that 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.
Quality assurance	In accordance with the National Health and Medical Research Council (NHMRC), 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.
QA and evaluation	Importantly, 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 these activities. What really matters is that: • Participants in QA and evaluation are afforded appropriate protections and respect. • QA and/or evaluation is undertaken to generate outcomes that are used to assess and/or improve service provision. • Those who undertake 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.

RELATED AND SUPPORTING DOCUMENTS

Legislation and other Authority	**Legislation (as updated and replaced from time to time)** • *Australian Research Council Act 2001* (Cth)

- *Hospital and Health Boards Act 2011* (Qld)
- *Financial Accountability Act 2009* (Qld)
- *National Health and Medical Research Council Act 1992* (Cth)
- *Public Health Act 2005* (Qld)
- *Public Sector Ethics Act 1994* (Qld)
- *Research Involving Human Embryos Act 2002* (Cth)
- *Therapeutic Goods Act 1989* (Cth)

Regulations

- *Financial Accountability Regulation 2009* (Qld)
- *Financial and Performance Management Standard 2009* (Qld)
- *Hospital and Health Boards Regulation 2012* (Qld)
- *Public Health Regulation 2018* (Qld)
- *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth)
- *Therapeutic Goods Regulations 1990* (Cth)

National Health and Medical Research Council (NHMRC)

- National Certification Handbook, 2012
- National Statement on Ethical Conduct in Human Research (2023)
- NHMRC Certification Handbook, National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-centre Research 2012
- NHMRC ethical issues and resources
- Payment of participants in research: information for researchers, HRECs and other ethics review bodies (2019)
- Research Governance Handbook: Guidance for national approach to single ethical review December 2011

Department of Health

- Health Service Directive: Research Ethics and Governance Directive QH-HSD-035:2023
- Research Management Guideline: external funding and infrastructure support QH-GDL-013-1:2022
- Research Management Policy QH-POL-013:2022
- Research Management Standard QH-IMP-013:1:2022
- Standard Operating Procedures for Queensland Health HREC Administrators
- Standard Operating Procedures for Queensland Health RGOs

	Metro South Health • Metro South Health Research Strategy • Finance Management Practice Manual (FMPM) • Human Resources (HR) Delegations Matrix and Schedule • Metro South Financial Delegation Schedule and Framework

Standards	• National Clinical Trials Governance Framework
	• National Safety and Quality Health Service (NSQHS) Standards 2nd Ed.
	  ○ Standard 1 – Clinical Governance
	  ○ Standard 2 – Partnering with Consumers

Supporting documents	**Procedures** • PR2023-411 Research excellence • PR2023-412 Research support and management • PR2023-413 Research administration and compliance **Work instructions** • WI2023-299 Ethical and scientific review of research • 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 **Guidelines** • 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 TeleTrials **Attachments** • Attachment 1: MSH Exemption – Project Description Template

HUMAN RIGHTS ACT 2019

Metro South Hospital and Health Service is committed to respecting, protecting and promoting human rights. Under the *Human Rights Act 2019*, Metro South Health has an obligation to act and make decisions in a way that is compatible with human rights and, when making a decision, to give proper consideration to human rights. When making a decision about research, decision-makers must comply with that obligation. Further information about the *Human Rights Act 2019* is available at: https://www.forgov.qld.gov.au/humanrights.

WORK INSTRUCTION DETAILS

Work Instruction Name	Exemptions from research review
Work Instruction Number	WI2023-300
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Executive Sponsor	Chief People, Engagement and Research Officer
Document Author	Manager, Research Development, Metro South Research
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REVIEW HISTORY

Version	Approval date	Effective from	Authority	Comment
V1.0	7/12/2023	13/12/2023	Chief People, Engagement and Research Officer	New document