# Ethical and scientific review of human research

## PURPOSE

This work instruction identifies a consistent and enforceable process for ethical and scientific review of human research being conducted within or in collaboration with Metro South Health (MSH).

## OUTCOME

This work instruction aims to:

- Ensure all research conducted within MSH or in collaboration with external entities, is of the highest ethical and scientific standard and is compliant with relevant legislation, standards, and guidelines.
- Protect human participants, their data and/or biospecimens in research in accordance with the National Statement on Ethical Conduct in Human Research (2023) ('National Statement') by ensuring all research projects undertaken, within or in collaboration with MSH, undergo ethical and scientific review, approval and monitoring by a National Health and Medical Research Council (NHMRC) certified HREC or ethical review body.
- Outline Metro South Human Research Ethics Committee (MSHREC) review and approval 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 all MSH employees and collaborators who conduct human research within or in association with MSH, or through access to MSH participants, health records or data.

## WORK INSTRUCTION

### 1. STEP 1: COMMENCE THE ETHICAL REVIEW PROCESS

- Develop the research protocol and study documents ensuring adherence to the National Statement. Refer to MSH guideline GL2023-99 Planning a research project for more information.
- Human Research Ethics Applications (HREAs) are made online via Ethical Review Manager (ERM).
- All supporting documentation (which may include, but is not limited to, a research protocol, questionnaires, surveys, Curriculum Vitaes (CVs), Good Clinical Practice (GCP) certification, research risk assessment and management plan, research data risk assessment and management plan and Participant Information and Consent Forms (PICFs) must be uploaded and submitted with the HREA through ERM.
    - Please see Attachment 1: Ethical Review Guidance Document and Checklist for more information.
- It is strongly recommended to commence the ethical review pross and Site Specific Assessment (SSA) application simultaneously. Refer to MSH work instruction WI2023-301 Site specific assessment of research for more information.

### 1.1 Considerations for single site and multi-site research

- As the MSHREC is a NHMRC Certified Committee, it can provide single ethical review for multi-site research projects that participate in the National Mutual Acceptance (NMA) model.
- To understand what kind of ethical and scientific clearance is required it is important for researchers to identify if the research project is considered either single site or multi-site research, and if there will be any specific human ethical and scientific review requirements.
- For multi-site research, all ethical submissions must be coordinated via a lead site.

### 1.2 Consider review pathways

- During the initiation and planning of a research project, researchers are encouraged to contact the MSHREC Co-ordinator via telephone (07) 3443 8049 or email MSH-Ethics@health.qld.gov.au to discuss the proposed research project and identify whether the research project is suitable for an alternative review other than a full HREC review based on the level of risk and the activity undertaken.
- A research project may be granted an exemption from full HREC review or categorised as lower risk and offered an alternative review process. Refer to WI2023-300 Exemptions from research review for more information.

### 1.3 Risk profiles of research

- National Statement, Chapter 2.1 Risk and benefit aims to help researchers and reviewers to understand and describe the level of risk involved in the planned research, and how to minimise, justify and manage that risk, and (with reference to Chapter 5.1) what level of ethical review is suitable.
- Risks identified through a Research Risk Assessment and Management Plan and/or Research data risk assessment and management plan must be considered as part of the ethical review process.
- Refer to MSH work instructions WI2023-292 Assessing and managing risk in research and WI2023-289 Research data and privacy for more information.

## STEP 2: LOWER RISK RESEARCH REVIEW

### 2.1 Submit via ERM

- Lower risk applications can be submitted at any time by completing the HREA form via ERM.
- Submit the HREA and upload supporting documents noting that all applications must be submitted via the ERM website as Metro South Research cannot process emailed or faxed submissions.
- The researcher will be advised if the research project is lower risk or higher risk in accordance with the National Statement Section 2.1. The MSHREC will, on certain occasions, accept a right of reply in respect to the decision.

### 2.2 Review research administration fees

- MSH research administration fees are outlined in MSH procedure PR2023-413 Research administration and compliance.
- Appropriate invoicing details must be included in the initial submission.

### 1.4 Waiver of consent

- Researchers must indicate via the research protocol and the HREA the justification for a waiver of consent according to the National Statement section 2.3.10 a – i.
- Before deciding to waive the requirement for consent the MSHREC must be satisfied that:
    - involvement in the research carries no more than low risk to participants.
    - the benefits from the research justify any risks of harm associated with not seeking consent.
    - it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records).
    - there is no known or likely reason for thinking that participants would not have consented if they had been asked.
    - there is sufficient protection of their privacy.
    - there is an adequate plan to protect the confidentiality of data.
    - in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media).
    - the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled.
    - the waiver is not prohibited by State, federal, or international law.

### 2.3 Lower risk research approval

- The MSHREC Co-ordinator will advise an outcome of the review in a formal letter from the MSHREC sent via the ERM correspondence function.

### 2.4 Ensure SSA authorisation prior to commencement of research

- The research project may only proceed upon receipt of SSA authorisation in accordance with MSH work instruction WI2023-301 Site specific assessment of research.

## STEP 3: HIGHER RISK - FULL HREC REVIEW

### 3.1 Review closing dates

- Researchers are required to submit their research applications for full MSHREC review to the MSHREC Co-ordinator by the appropriate closing date.
- Please see MSHREC Terms of Reference and Attachment 2: MSH HREC Meeting Dates (as updated from time to time). Note: the submission deadline is **always** 12pm/noon.

### 1.2 Submit via ERM Applications

- Submit the HREA and upload supporting documents via ERM. Note: this is a different HREA than that used by Universities.
- Applications must be submitted via the ERM website as the MSHREC Co-ordinator cannot process emailed or faxed submissions.

### 3.3 Review research administration fees

- MSH research administration fees are outlined in MSH procedure PR2023-413 Research administration and compliance.
- Appropriate invoicing details must be included in the initial submission.

### 3.4 Full HREC review determination

- The MSHREC Co-ordinator will advise an outcome of the review in a formal letter from the MSHREC sent via the ERM correspondence function.
- If further information is requested to make a final determination, this must be supplied to the MSHREC Co-ordinator by no later than three meetings/four calendar months.
- Failure to provide this information will result in the application being withdrawn by the MSHREC Co-ordinator, with a new application required to reinstate the research project.

### 3.5 Ensure SSA authorisation prior to commencement of research

- The research project may only proceed upon receipt of SSA authorisation in accordance with MSH work instruction WI2023-301 Site specific assessment of research.

## STEP 4: POST APPROVAL – RESEARCH AMENDMENT, REPORTING AND CLOSURE

- Refer to MSH work instruction WI2023-306 Post approval – research amendments, reporting and closure for more information regarding:
    - Amendments
    - Serious Adverse Event (SAE)/Suspected Unexpected Serious Adverse Reaction (SUSAR) Reports
    - Annual progress reporting
    - Grant funded research
    - Suspension or termination of a research project
    - Completion of a study.

# RESPONSIBILITIES

| Position | Responsibility | Audit criteria |
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| 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. | N/A |

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| | • Promote MSH strategic requirements and ethical and responsible decision-making which respects the rights of MSH participants. | |
| Metro South Research | • Update MSH ethical and scientific review internal documents in accordance with MSHREC requirements.<br>• Provision of secretariat/administrative support to maintain and uphold principles outlined in the Research Policy Framework and related procedures. | N/A |
| Principal Investigator (PI)/ Coordinating Principal Investigator (CPI) - responsible officer | • Ultimately responsible for all elements of the research project—from initial application to final report. | 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 |
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| Adverse drug reaction (ADR) | Adverse drug reactions concern noxious and unintended responses to a medicinal product. |
| Adverse event (AE) | Any untoward medical occurrence in a patient administered a medicinal product and which does not necessarily have to have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign (for example, an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether considered related to this medicinal product or not. |
| Clinical Trial<br>*(National Clinical Trials Governance Framework definition)* | A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects o health outcomes. Clinical trials include but are not limited to:<br>• Surgical and medical treatments and procedures<br>• Experimental drugs<br>• Biological products<br>• Medical devices<br>• Health-related service changes |

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| | • Health-related preventative strategies<br>• Health-related educational interventions. |
| Collaborative Research Group Clinical Trials Research Agreement (CRG CTRA) | An agreement template that is to be used where a Hospital and Health Service (HHS) acts as and assumes all the responsibilities of a commercial sponsor. |
| Good Clinical Practice (GCP) | A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected. |
| Investigator-initiated trial | A clinical trial that has the following characteristics:<br>• A pharmaceutical/device company is not acting as the sponsor for the purposes of the CTN application.<br>• A pharmaceutical/device company is not fully funding the conduct of the study, that is, making payment to the relevant hospital or investigator.<br>• The clinical trial addresses relevant clinical questions and not industry needs.<br>The Principal Investigator (PI)/Coordinating Principal Investigator (CPI) or the Hospital/Institution is the primary author and custodian of the clinical trial protocol. |
| Multi-site research | Research will be undertaken in multiple sites/areas/centres. |
| Research Monitoring | ICH GCP defines monitoring as the act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating procedures (SOPs), GCP, and the applicable regulatory requirement(s). |
| Principal Investigator (PI)/Coordinating Principal Investigator (CPI) | An individual responsible for the conduct of a clinical trial at a trial site ensuring that it complies with GCP guidelines. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the CPI/PI In this instance they may delegate tasks to other team members. |
| Serious adverse event (SAE) | Any untoward medical occurrence that at any dose:<br>• results in death<br>• is life-threatening<br>(NOTE: The term ‘life-threatening’ in the definition of ‘serious’ refers to an event/reaction in which the patient was at risk of death at the time of the event/reaction; it does not refer to an event/ reaction which hypothetically might have caused death if it were more severe). |

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| | • Requires inpatient hospitalisation or results in prolongation of existing hospitalisation.<br>• Results in persistent or significant disability/incapacity.<br>• Is a congenital anomaly/birth defect.<br>• Is a medically important event or reaction. |
| Single site research | The research will only be conducted within a single site. |
| Sponsor | An individual, company, institution, or organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial'. Note the term Sponsor is relevant to all research – not just commercially sponsored research (e.g., grant-funded, or unfunded research may be sponsored by the university or hospital that is the administering institution). |
| Ethical Review Manager (ERM) | Web based content manager supported by the Office of the Director General via Office of Research Innovation, Queensland Health. |

## RELATED AND SUPPORTING DOCUMENTS

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| **Legislation and other Authority** | **Legislation (as updated and replaced from time to time)**<br>• *Australian Research Council Act 2001* (Cth)<br>• *Hospital and Health Boards Act 2011* (Qld)<br>• *Financial Accountability Act 2009* (Qld)<br>• *National Health and Medical Research Council Act 1992* (Cth)<br>• *Public Health Act 2005* (Qld)<br>• *Public Sector Ethics Act 1994* (Qld)<br>• *Research Involving Human Embryos Act 2002* (Cth)<br>• *Therapeutic Goods Act 1989* (Cth)<br>**Regulations**<br>• *Financial Accountability Regulation 2009* (Qld)<br>• *Financial and Performance Management Standard 2009* (Qld)<br>• *Hospital and Health Boards Regulation 2012* (Qld)<br>• *Public Health Regulation 2018* (Qld)<br>• *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth)<br>• *Therapeutic Goods Regulations 1990* (Cth)<br>**National Health and Medical Research Council (NHMRC)**<br>• National Certification Handbook, 2012<br>• National Statement on Ethical Conduct in Human Research (2023) |

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| | • NHMRC Certification Handbook, National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-centre Research 2012<br>• NHMRC ethical issues and resources<br>• Payment of participants in research: information for researchers, HRECs and other ethics review bodies (2019)<br>• Research Governance Handbook: Guidance for national approach to single ethical review December 2011<br>**Department of Health**<br>• Health Service Directive: Research Ethics and Governance Directive QH-HSD-035:2023<br>• Research Management Guideline: external funding and infrastructure support QH-GDL-013-1:2022<br>• Research Management Policy QH-POL-013:2022<br>• Research Management Standard QH-IMP-013:1:2022<br>• Standard Operating Procedures for Queensland Health HREC Administrators<br>• Standard Operating Procedures for Queensland Health RGOs<br>**Metro South Health**<br>• Metro South Health Research Strategy |
| **Standards** | • National Clinical Trials Governance Framework<br>• National Safety and Quality Health Service (NSQHS) Standards 2nd Ed.<br>  ○ Standard 1 – Clinical Governance<br>  ○ Standard 2 – Partnering with Consumers |
| **Supporting documents** | **Procedures**<br>• PR2023-411 Research excellence<br>• PR2023-412 Research support and management<br>• PR2023-413 Research administration and compliance<br>**Work instructions**<br>• WI2023-300 Exemptions from research review<br>• WI2023-301 Site specific assessment of research<br>• WI2023-302 Research contracts and study execution<br>• WI2023-303 Metro South Health sponsorship of Clinical Trial Notification (CTN) scheme trials<br>• WI2023-304 PowerTrials - ieMR research support module<br>• WI2023-305 Research monitoring<br>• WI2023-306 Post approval – research amendments, reporting and closure |

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| | **Guidelines**<br>• GL2023-99 Planning a research project<br>• GL2023-100 Research Participant Information and Consent Form (PICF)<br>• GL2023-101 Research contract clauses<br>• GL2023-102 Use of electronic signatures in research contracts<br>• GL2021-77 Clinical trials<br>• GL2023-103 TeleTrials<br>• **Attachments**<br>• Attachment 1: Ethical Review Guidance Document and Checklist<br>• Attachment 2: MSHREC Meeting Dates (as updated from time to time) |

## 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

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