Assessing and managing risk in research

PURPOSE

This work instruction describes the processes for identifying, assessing and managing risk in research projects to ensure potential issues are identified and managed effectively in Metro South Health (MSH).

OUTCOME

This work instruction aims to:

- Provide helpful information to assist with identifying and assessing risk which researchers will come across as part of the research journey in MSH.
- Outline information, about how to categorise and manage/mitigate research risks utilising existing MSH risk assessment and management processes.
- Support the implementation of the *National Statement on Ethical Conduct in Human Research 2023* ('National Statement') by ensuring that the risk and benefit of research be assessed and that any risks are effectively minimised, mitigated or managed.
- Integrate risk assessment in research into the current MSH Risk Management Framework aligning research governance systems with clinical governance systems.

This work instruction outlines processes described MSH procedure PR2023-411 Research excellence and upholds principles outlined within the Research Excellence 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: RISK ASSESSMENT IN RESEARCH

- Assessing risk is a fundamental aspect of responsible and ethical research conduct and a crucial component of research for several important reasons:
    - **Participant safety**: Risk assessment helps to identify potential hazards and minimise the risk of harm to research participants. Researchers need to evaluate the potential physical, psychological, and social risks associated with the research procedures and interventions. By identifying and mitigating risks, researchers can prioritise participant safety and well-being.
    - **Ethical considerations**: Risk assessment is closely linked to ethical considerations in research. It ensures that the potential benefits of the research justify any potential risks to participants. Ethical principles, such as respect for autonomy and beneficence, require researchers to carefully weigh

the risks and benefits of the research and ensure that the potential harms are minimised and justified.

- **Consent**: Accurate risk assessment is essential for providing comprehensive information to research participants during the informed consent process. Participants have the right to be fully informed about the potential risks they may encounter by participating in the research. Transparent communication of risks enables participants to make informed decisions about their voluntary participation and gives them the opportunity to ask questions or express concerns.
- **Study design and methodology**: Risk assessment helps researchers in designing and selecting appropriate research methods and procedures. By identifying potential risks and challenges, researchers can develop strategies to minimise or manage those risks effectively. This includes selecting appropriate study populations, determining sample sizes, implementing appropriate data collection and analysis methods, and implementing safeguards to protect participant privacy and confidentiality.
- **Regulatory compliance**: Many research institutions like MSH and funding agencies require researchers to conduct risk assessments as part of the research protocol review process. Demonstrating that potential risks have been identified and adequately addressed is a requirement for obtaining ethical approval and often a pre-requisite for funding. Compliance with regulatory guidelines and standards ensures that research is conducted responsibly and meets the necessary legal and ethical requirements.
- **Quality and validity of research**: Assessing risks helps to ensure the quality and validity of research outcomes. By identifying potential confounding factors or sources of bias, researchers can take appropriate measures to control for them. This enhances the reliability and validity of the research findings, making them more credible and meaningful.
- **Researcher and MSH reputation**: Conducting thorough risk assessments contributes to the overall reputation and credibility of researchers and institutions. Adhering to best practices in risk assessment demonstrates a commitment to responsible research conduct and participant welfare. This enhances the trust and confidence of the scientific community, funding agencies, and the public in the integrity and quality of the research.

2. STEP 2: MSH RISK MANAGEMENT

- MSH has an established Risk Management Framework and policy and procedures which outlines processes the MSH must follow when identifying, assessing and managing risk.
- When conducting a risk assessment for a research project refer to the following documents and resources available via the MSH Risk Management intranet page:
    - MSH Risk Management Framework
    - PL2018-62 Risk Management Policy
    - MSH Risk Appetite Statement
    - PR2018-97 MSH Risk Management Procedure
    - MSH Risk Assessment Tool

- Risk Action Plan (RAP)[1]
- Risk Register - CAMMS
- CAMMS Data Definitions.

3. STEP 3: RESEARCH IDENTIFICATION AND CATEGORISATION

- To assist researchers, a Research risk assessment and management plan template (Attachment 1: Research risk assessment and management plan) has been developed which can be used whilst referring to the MSH Risk Management Framework.
    - Note: High and Very High risk research projects records may need to be transferred to the MSH Risk Action Plan (RAP) template which is included as part of the MSH Risk Management Framework and recorded within the MSH Risk Register (CAMMS).
- When completing the template:
    - Include all relevant research project details (i.e., ERM Reference Number and short project name)
    - Ensure the research project objectives and scope are clearly defined – this must also be included in the research protocol
    - Identify the number and location of research sites within MSH, the nature of the project and potential benefits to MSH patients/participants
    - Also include the research project's proposed start and end date as the plan is a living document that should be reviewed and revised throughout the project.

3.1 Risk identification

- Risk identification is the most critical step in assessing risk. Identify risks by:
    - Reviewing historical data from similar projects
    - Brainstorming with the project team and stakeholders
    - Conducting a literature review to understand therapeutic/disease specific risks
    - Analysing project documentation, data and plans
    - Reviewing Investigation/Product Brochures and medical device related material.
    - Considering potential harms in or from research as identified in the *National Statement Chapter 2.1 – Risk and benefit.*
- Even research projects which may be considered lower risk in accordance with the National Statement must undergo a risk identification and assessment process utilising the Research risk assessment and management plan template.
- To assist in risk identification, include members in the research team or identify stakeholders who can provide the necessary expertise to identify and assess the risk effectively. When identifying

[1] To be used for High or Very High risks

stakeholders (i.e., sponsors, collaborators and end-users) be sure to understand their interests and expectations related to the project as these can influence the perception of risk.

- Included in the Research risk assessment and management plan template are some examples of risks (including threats, vulnerabilities and consequences) which may assist and guide in identifying risks relevant to the study. Only identify risks that are relevant to the project.

3.2 Categories/areas

- Identified internal and external research project risks should be categorised into different types such as (but not limited to):
    - Participant consent, rights and confidentiality
    - Reliability of research results
    - Legal and regulatory compliance
    - Operational - facilities, equipment and resources (including staff)
    - Financial
    - Procedures or investigations
    - Health Intervention
    - Observational/educations
    - General health, safety and security
    - Business continuity planning[2].
- This categorisation helps in prioritising and managing risks effectively. See the template for examples of how risks can be categorised.

3.3 Existing controls and their effectiveness

- Include any existing risk mitigation already in place either through the hospital or research project design and implementation for each identified risk.
    - For example: Research data risk assessment and management plan will be followed and will manage/mitigate a breach of participant confidentiality.

3.4 Existing risks and their relevance

- Include any existing risks registered that might be relevant to research risk development for example: Risk #822 Cyber and Information Security.

4. STEP 4: RISK ASSESSMENT

- The risk assessment process must occur in accordance with the MSH Risk Assessment Tool:

[2] For example, if an external research partner is subject to a cyber-attack or other disruption how will that be managed to enable the research activity to continue, or to minimise the impact on MSH.

- Step 4.1: Use the Consequence Table to determine potential consequence rating for each identified risk. Select the highest likely consequence as a result of the risk identified.
    - In the template: select the chosen consequence rating.
- Step 4.2: Use the Likelihood Table to rate how likely/how often a risk is expected to occur. When assessing the likelihood rating—use “clinical” frequency for any risk categories that have a clinical impact; use “non-clinical” frequency column for risk categories that have a non-clinical impact. Alternately consider the description or probability of this risk occurring at an organisation-wide level to determine likelihood rating.
    - In the template: select the chosen likelihood.
- Step 4.3: Use the Risk Heatmap to determine the risk rating based on the consequence rating and likelihood assessment for the **Current** and **Target** risks. The numeric value assists with prioritising risks which are rated in the same word category.
    - In the template: Select the chosen consequence rating and risk matrix rating.
- Low and medium risks are managed by the research team and are submitted as part of the ERM application for ethical review and/or site-specific assessment.
- For any risks that are identified through the above process as High and Very High rating, the research team will be required to complete a MSH Risk Assessment Plan and enter the risk in the MSH Risk Register (CAMMS).
    - This enables appropriate MSH executive and Board awareness and oversight of High and Very High risks associated with research projects.

5. STEP 5: RISK MANAGEMENT

- It is vital to develop risk mitigation strategies to manage, action or control identified risks. These strategies may include:
    - Risk avoidance. Terminate the risk by changing project scope or approach or deciding not to conduct the research activity to eliminate the risk.
    - Risk reduction. Treat the risk by implementing preventive measures (treatments) to reduce the likelihood or impact.
    - Risk transfer. Transfer the risk by shifting responsibility or liability to a third party, (e.g., through insurance or by contract.
    - Risk acceptance. Tolerate the risk by acknowledging and accepting the risk but deciding not to take any action. This is applicable if it is not reasonably practicable to achieve the Target Risk Rating.
- In the template, document potential risk exposures that need to be managed and actioned relevant to the study.

5.1 Overall risk rating

- The **overall risk rating** should be based on the highest rating calculated for your research project (i.e., if Procedures or Investigations/Clinical Safety is high and all others are low the overall risk rating is high.

5.2 Action

- Refer to the MSH Risk Appetite Statement to assist in identifying an appropriate action for each identified risk. Note MSH's risk appetite for research is **Eager**.
- The **Eager** appetite for research risks needs to be balanced with the related risk appetites found in the Risk Appetite Statement and Risk Assessment Tool that may apply to the activity including an **Averse** risk appetite for Consumer/Patient Safety.
- Therefore, if the primary risk domain[3] is Consumer/Patient Safety, or other risk domain, then the risk should be linked to that risk domain and it's associated risk appetite.
- Any risks rated as Very High or High pose the most significant threats to the research project's success or MSH and must:
    - Be actioned in accordance with the MSH Risk Management Framework
    - Indicate the risk owner – noting that only Executive Directors in MSH have the authority to create and close risks in MSH
    - Be referred to MSH-Research@health.qld.gov.au for consideration/review.

5.2 Risk Management Plan

- The Research risk assessment and management plan is a living document and should be periodically reviewed and updated throughout the lifecycle of the project.
- As part of the ongoing risk assessment and management process researchers must:
    - Identify any new risks which may emerge, and the likelihood and consequence of existing risks may change
    - Implement a robust monitoring and reporting system to keep track of identified risks throughout the project's lifecycle
    - Develop contingency plans for high and medium-high risks. These plans outline specific actions to be taken if a risk materialises
    - Regularly update stakeholders on the status of risks and including Controls and Treatments status
    - Ensure that all risk assessments, mitigation strategies, and contingency plans are well-documented and communicated to the project team and stakeholders.
    - After the project is completed, conduct a post-project review to assess how well risks were managed and identify opportunities for improvement in future research projects.
- Risk assessment is an ongoing process, and it should be integrated into the research project quality management process to ensure that potential issues are continuously monitored and addressed throughout the research project's lifecycle.

[3] Found in the MSH Risk Appetite Statement

6. STEP 6: ETHICAL REVIEW AND LEVEL OF RISK

- After completing the risk assessment template and management plan the researcher must include the **overall risk rating** for the research project in the research protocol.
    - If the project includes **<u>any</u> Medium to Very High risk ratings**, the project is likely to require full Human Research Ethics Committee (HREC) review.
    - If the project includes only low risk ratings, then the project might be eligible for review via the lower risk review pathway.
        - Note: when the Metro South Human Research Ethics Committee (MSHREC) is not the approving HREC the completed Research risk assessment and management plan must be attached to the SSA in the Ethical Review Manager (ERM) application.
    - See MSH work instruction the WI2023-299 Ethical and scientific review of research for information regarding:
        - Types of research that may not require full HREC review – i.e., lower risk review.
        - Types of research requiring full HREC review.
    - Researchers are encouraged to contact MSH-Ethics@health.qld.gov.au when determining relevant ethical and scientific review requirements for the ethical clearance and MSH-RGO@health.qld.gov.au for site specific assessment and authorisation of research.

7. STEP 7: RESEARCH CONTRACTS AND STUDY EXECUTION

- The Research Contracts Approval and Study Execution Form (RCASE Form) – single and mutli-site is completed based on the overall risk rating for the research project.
- Refer to MSH work instruction WI2023-302 Research contracts and study execution for more information about how to complete the relevant RCASE Form.

8. STEP 8: RESEARCH RISK SUPPORT

- The MSH Risk and Compliance team is available to support research risk development. This includes RiskMan and CAMMS data searches and information.
- The Risk and Compliance team can be contacted at msh.risk@health.qld.gov.au

RESPONSIBILITIES

Position	Responsibility	Audit criteria
Metro South Research	Provide tools and guidance to assist researchers in assessing risks in research.	N/A
Principal Investigators	Undertake a risk assessment utilising the Research Project Risk Assessment and Management Plan template.	N/A

Risk Owner	As identified in the Research Project Risk Assessment and Management Plan – responsible for the management and action for an identified risk.	N/A

DEFINITIONS

Term	Definition
Consequence	The outcome or impact of an event on objectives.
Control	Measure that is modifying a risk. Processes or methods in place to reduce the likelihood or the consequence of a risk. Controls may include policies, standards, procedures or physical actions. A Key Control is one that will undoubtedly affect the likelihood or consequence of a risk event occurring if it is significantly changed or stopped altogether.
Current Risk Rating	The risk which has been rated in its current state with existing controls considered.
Issue	A known and recognised problem or event requiring immediate resolution and/or action. There is no uncertainty regarding the likelihood as an issue is already in train. Issues are usually described in the present or past tense. An issue may be an indicator of a deeper risk if the cause is not resolved and there is a credible chance of recurrence with impacts to organisational objectives.
Likelihood	A description of the probability or frequency that a risk will occur resulting in the consequence.
Objectives	Measurable and achievable goals which relate to the portfolio, a division, business unit or an aspect of one of these.
Operational Risks	Operational risks are those which could have a significant impact on the achievement of: • MSH's strategic objectives (as documented in the strategic plan) from the perspective of the actions undertaken by a particular directorate, division, or work unit, or • the individual programs or project management objectives. Operational risks generally require management by the relevant senior officer responsible for the directorate, division, or work unit, or by the relevant program or project board. In extreme instances, these risks may require escalation to executive management.
Risk Owner	Person or entity with the accountability and MSH authority/ delegation to manage a treatment action. Person or entity with the accountability and MSH authority/ delegation to manage risk.

Risk	The effect of uncertainty on objectives. (Risk is the chance of something happening that will have an impact on objectives. It is measured in terms of a combination of the consequences of an event and their likelihood).
Risk Analysis	The process to comprehend the nature of risk and to determine the level of risk.
Risk Identification	The process of finding, recognising and describing risk.
Risk Management	Coordinated activities to direct and control MSH with regard to risk. It is the process of identifying, assessing and responding to risks, and communicating the outcomes of these processes to the appropriate parties in a timely manner. The Principal Investigator holds primary responsibility for any of these activities relevant to the research project.
Risk Reduction	A risk treatment action aimed at limiting either the likelihood of the risk event and consequences occurring or the severity of consequences. Risk Register A formal record of identified risks. The risk register includes all information related to a risk.
Risk Treatment	Processes or methods to be implemented to reduce the likelihood or the consequence of a risk. Treatments may include policies, standards, procedures or physical actions.
Stakeholder	Person or organisation that can affect, be affected by, or perceive themselves to be affected by a decision or activity.
Terminate	One of four risk responses: Indicates management are not comfortable with the level of risk and no risk treatment actions can be implemented to reduce the risk to a tolerable level. Consequently, the activities leading to the risk are discontinued.
Tolerate	One of four risk responses: Indicates management are comfortable with the level of risk (risk rating) and no further action is required.
Transfer	One of four risk responses: Indicates management are planning or have transferred the risk to another party, through the use of insurance, contractors or other methods.
Treat	One of four risk responses: Indicates management are not comfortable with the level of risk (risk rating) and that risk treatment actions should be implemented to reduce the risk to a level which management is comfortable with (treatment actions should have already been identified and submitted for consideration)

RELATED AND SUPPORTING DOCUMENTS

Legislation and other Authority	**Legislation (as updated and replaced from time to time)** • *Financial Accountability Act 2009* (Qld)

	• *Financial and Performance Management Standard 2019* (Qld) • *Hospital and Health Boards Act 2011* (Qld) • *Hospital and Health Boards Regulation 2012* (Qld) • *Human Rights Act 2019* (Qld) **Other authority** • *National Statement on Ethical Conduct in Human Research* (2023) • ISO 31000:2018 Risk Management Guidelines • Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2) (2016) **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 • MSH Risk Management Framework • MSH Risk Assessment Tool • MSH Risk Appetite Statement • Risk Register - CAMMS • CAMMS Data Definitions

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	**Policies and procedures** • PL2018-62 Risk Management Policy • PR2018-97 MSH Risk Management Procedure • PR2023-411 Research excellence • PR2023-412 Research support and management • PR2023-413 Research administration and compliance **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 publications • WI2023-291 Research complaints and misconduct • 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 • GL2023-99 Planning a research project **Guidelines** • GL2021-75 Partnering with consumers in research • GL2023-97 Aboriginal and Torres Strait Islander health research • GL2023-98 Research translation and impact **Attachments** • Attachment 1: Research risk assessment and management plan

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.

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