

Quality healthcare every day

# Research Excellence Handbook Metro South Research

V1.0 Date: December 2023





# Contents

Purpose	
1.0 Research integrity	4
2.0 Quality	5
2.1 Transparency	6
2.2 Acceptability	6
2.3 Cost effectiveness	6
2.4 Research effectiveness	6
2.5 Encouraging positive behaviours	6
2.6 Quality Management System (QMS)	7
2.7 Issue management	7
3.0 Data and privacy	
3.1 Data	
3.2 Privacy	9
3.3 Access and use of confidential information for the purpose of research	9
3.3.1 Consent to access confidential information	9
3.3.2 Access to confidential health information retained by Metro South	9
3.3.3 Storage and retention of confidential information	9
3.3.4 Data accessibility	
3.3.5 Disposal of research data and material	
4.0 Authorship, publication and peer review	
4.1 Authorship	11
4.1.2 Determining authorship	11
4.1.3 Recognition of contribution	11
4.1.4 Acknowledgements	
4.1.5 Affiliations	13
4.1.6 Ghost authorship	13
4.1.7 Custodianship of data	14
4.1.8 Accuracy and integrity	14
4.1.9 Research students as authors	14
4.1.10 Indigenous authorship	14
4.1.11 Formalised authorship arrangements	15
4.1.12 Authorship order	15
4.1.13 Reporting and recording of authorship	15
4.1.14 Declaration of authorship	
4.2 Peer review	
4.2.1 Participation	
4.2.2 Peer review process	
4.2.3 Acting as a peer-reviewer	17
4.3 Publication and dissemination of research	17
4.3.1 Prior to publication	
4.3.2 Delayed publications	

4.3.3 Publications that incorporate two or more projects	
4.3.4 Phishing and unsolicited email invitations	
4.3.5 Journal metrics (impact factor)	
4.3.6 Ethics approval	
4.3.7 Dispute resolution	
5.0 Research Complaints and misconduct	
5.1 Breaches of the Code	21
5.2 Other MSH processes	21
5.4 Participant Information and Consent Form (PICF)	
5.5 Initial receipt of complaints	
5.6 Corrupt conduct and/or criminal behaviour	
5.7 Other considerations	
5.8 Frivolous and vexatious complaints	
5.9 Collaborative research	
6.0 Risk assessment and management	
7.0 Guidelines	
Glossary	

# Purpose

Metro South Health (MSH) uses policies and procedures to mandate and direct specific business activity across the Hospital and Health Service (HHS). The MSH Policy Framework ensures appropriate governance and consistency for policy development and supports the management of policy through the policy life cycle.

The PL2023-92 Research Policy conveys MSH's commitment to conducting research that advances knowledge and innovation, enhancing our ability to serve our community. MSH believes in conducting research with integrity, respect for participants, and in compliance with ethical and legislative standards. Metro South Research is responsible for research support and management on behalf of the Health Service Chief Executive, MSH.

This Handbook is intended to present the standards and principles which MSH must comply with to uphold and promote the Australian Code for the Responsible Conduct of Research 2018 ('the Code'). It also outlines processes for the conduct of research in MSH or research conducted under the auspices of MSH facilities/services.

The Research Excellence Handbook is to be read alongside MSH procedure PR2023-411 Research excellence, related work instructions and guidelines.

# 1.0 Research integrity

The community and those responsible for funding research, expect research to be conducted responsibly, ethically, and with integrity. Research integrity means conducting research in such a way that others can trust the methods used and the results obtained from them. To facilitate this confidence, Metro South Health (MSH) employees involved in research must be aware of and abide by the Australian Code for the Responsible Conduct of Research 2018 ('the Code'). The Code articulates the broad principles that characterise an honest, ethical, and conscientious research culture.

In compliance with the Code, MSH is committed to upholding the Code's eight Principles of responsible research conduct:

P1 Honesty	P4 Fairness	P7 Accountability
P2 Rigour	P5 Respect	P8 Promotion
P3 Transparency	P6 Recognition	

Critical to achieving research integrity are the ethical leadership and values of MSH and the shared values and expectations of honesty and integrity that characterise our leadership and culture. MSH is obligated to abide by the Code as well as other applicable legislative and policy requirements. The Health Service is responsible for ensuring that research is fostered and underpinned by a strong research culture which encourages and supports responsible research conduct.

Individual researchers also have a responsibility for ensuring their own behaviours and actions are consistent with organisational values, policies and procedures, and with the Code. Researchers must also support and enable the appropriate conduct of others. For more information see MSH work instruction WI2023-287 Research integrity.

# 2.0 Quality

Quality research is research that is conducted in a rigorous, responsible, and reproducible manner that generates new knowledge, as well as stimulates and promotes the use of this knowledge to support change, problem solving and innovation<sup>1</sup>.

An additional feature of quality research is the absence of errors that matter, principally, those errors that impact participants' safety and reliability of data.

The following key principles guide MSH in its research quality management framework and reporting requirements:

- Research quality management frameworks must aim to drive positive research behaviours, encouraging researchers and research organisations to focus on the quality and impact of their research.
- In MSH, research quality management frameworks and subsequent reporting requirements aim to establish greater transparency of the quality of research arising from public investment for MSH, 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 ensure a further deepening of MSH's innovation base.
- In MSH, the core expectations pertaining to research quality and reporting are as follows:
  - Compliance with all applicable legal and regulatory requirements.
  - Trust in the research enterprise.
  - Ensure activities are perceived as reliable, effective, and efficient for all interest groups.
  - Involve, motivate and engage staff in order to seek their participation in the management, development and implementation of research quality management frameworks in MSH.
  - Provide technical, material, and human resources for each research group and innovation centre.
  - Define and implement training requirements to maintain and improve the professional skills of the research group's staff and innovation centres.
- Research quality management frameworks are used to provide a consistent and comprehensive approach to assessing the quality and impact of research projects within the HHS.
- The practice of using research quality management frameworks should apply to all aspects of research. Quality management frameworks and reporting are based on the principles of:
  - transparency
  - o acceptability
  - effectiveness and
  - encouraging positive behaviours.

<sup>&</sup>lt;sup>1</sup> NHMRC's Research Quality Strategy https://www.nhmrc.gov.au/about-us/publications/nhmrcs-research-quality-strategy#toc\_\_1

# 2.1 Transparency

The implementation of a research quality management framework, in its application and measures, enables openness and transparency to government, MSH, 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 MSH's research quality management frameworks and reporting.

# 2.2 Acceptability

A research quality management 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 MSH. Additionally, research quality management frameworks should account for differences across varying research approaches and professional disciplines, while identifying common elements to enable appropriate cross-disciplinary application.

Given the diversity of stakeholders and the range of institutions to which MSH's research quality management frameworks may be applied, it is acknowledged that it may be 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 every metric/measure proposed for a quality management framework, reaching consensus may not be possible. In these circumstances, acceptability will be guided by the other agreed principles.

## 2.3 Cost effectiveness

MSH's research quality management 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 quality management 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 MSH to any additional administrative burden to existing assessment mechanisms and data collection processes.

# 2.4 Research effectiveness

Similarly, a research quality management framework needs to have useful outcomes 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.

# 2.5 Encouraging positive behaviours

Positive behaviours are those overarching practices and actions that target improving the productivity, quality, and impact of research and further develop and support a vibrant research culture in MSH. Some of the activities undertaken to encourage positive behaviours and which may be supported by a research quality management 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;
- Moving from reactive to proactive thinking to prevent important errors that could undermine the ability to obtain meaningful information from the research project;
- enhancing the impact of research on policy and practice;
- improving the internationalisation of MSH research and researchers;
- improving inter-institutional linkages;
- facilitating trans/cross-disciplinary research; and
- encouraging access to high quality research.

## 2.6 Quality Management System (QMS)

A Quality Management System comprises of:

- Processes: procedure manual and Standard Operating Procedures (SOPs).
- Resources, roles and responsibilities: role and job descriptions, training records and CVs.
- Partnering: internal and external partnerships, stakeholder relations and agreements.
- Risk management: managing uncertainty via the prospective use of risk management frameworks setting risk appetite.
- Issue management: identifying, investigating and escalating 'Issues that Matter' documented via a Corrective and Preventative Action (CAPA) report.
- Knowledge management: getting the right information to the right people at the right time, managing staff change over and company knowledge, communicating change and breaking down silos.
- Documentation supporting achievement of quality: ensuring there is a plan in place for managing and retaining quality management in research project documentation.

MSH work instruction WI2023-288 Research quality management systems provides further information.

#### 2.7 Issue management

Given the volume and complexity of issues, a triage process is often required for identifying those issues that could materially impact clinical development outcomes.

A robust Risk Framework and Root Cause Analysis and Corrective and Preventative Action Framework assists in documenting issue management during the research project. It should include both proactive (before the study commences) and reactive (during the study) plan for the assessment of risk and its management.

# 3.0 Data and privacy

## 3.1 Data

Research data is recognised as a valuable product of the research process and are useful to researchers throughout the research cycle. All research data, including primary materials, are MSH records and must be stored, accessed, disposed of, or transferred in accordance with MSH policy and procedure.

Research data should generally be made available, via open access, for use by other researchers unless a specific and valid reason exists for not doing so. MSH is committed to the protection of personal information which may be contained in research data and primary materials.

Data management throughout the research activity must be in accordance with the National Statement, noting in particular Chapter 3.1, Element 4: Collection, Use and Management of Data and Information.

MSH work instruction WI2023-289 Research data and privacy provides guidance on the following aspects of managing research data and should be consulted prior to commencing a research project:

- research data management planning;
- storage and security of research data;
- retention and record keeping;
- access, privacy and confidentiality; and
- disposal.

It is also important to note that:

- Data underpinning research conducted at MSH (including electronic data) must be recorded in a protected, durable, and appropriately referenced form.
- Researchers must maintain a catalogue of all research data in an accessible form.
- Research data and other records relating to research must be retained for at least the minimum
  periods required by the Queensland Government General Retention and Disposal Schedule (GRDS),
  funding agency or publisher guidelines, or in accordance with discipline norms, whichever is the
  longer period.
- Research material and data related to publications must be available for discussion with other researchers (unless confidentiality provisions apply).
- Research materials and data remain the property of MSH, unless subject to a third-party agreement.

Use of information and data resulting from a research project must occur in accordance with ethical clearance and authorised site specific assessments. Changes to the utilisation of information, data, confidential information, participant information or personal information must be submitted for ethical approval to MS HREC prior to being implemented.

# 3.2 Privacy

Researchers must be aware of any legal obligations when collecting and handling personal information<sup>2</sup>. Furthermore, adherence to MSH policies and procedures which comply with the *Information Privacy Act* 2009 (Qld) and *Privacy Act* 1988 (Cth) is essential.

Confidential information must only be used for the purpose for which it was made available and in accordance with ethical clearance and research governance authorisation. Researchers must maintain the confidentiality of any information to which they have been given access to on a confidential basis. This includes ensuring secure storage for confidential information.

Confidentiality agreements to protect intellectual property rights may be established between MSH, the researcher and a sponsor of the research. Where such agreements limit free publication and discussion, limitations and restrictions must be agreed explicitly.

# 3.3 Access and use of confidential information for the purpose of research

Health care professionals are generally permitted to access patient information for research purposes provided they have been given approval from the appropriate MSH authority/delegate and have Human Research Ethics Committee (HREC) approval. Access is dependent upon the nature of the information requested, the volume of information requested, and the function to be performed by the researcher as the requestor of the information.

## 3.3.1 Consent to access confidential information

Access to health information for the purposes of research is governed by legislation and is dependent on whether the patient has given specific consent for their records to be accessed or a waiver of consent has been granted by a HREC. Where patient consent is not obtained, researchers may use identifiable (or re-identifiable) patient information for the purpose of research 9s150a *Hospital and Health Boards Act 2011 (Qld)*. Researchers should refer to MSH work instruction WI2023-299 Ethical and scientific review of research and use of confidential health information/data under either the *Public Health Act 2005 (Qld) or Hospital and Health Boards Act 2011 (Qld)*.

## 3.3.2 Access to confidential health information retained by Metro South

When researchers require access and use of confidential information held by MSH for the purposes of research, the provisions of the *Public Health Act 2005 (Qld)* Chapter 6, Part 4, Division 2, s281 must be considered. Confidential Information for the purposes of research under the provisions of the *Public Health Act 2005 (Qld)* refers to information that is identifiable or potentially identifiable and is obtained without participant consent. Researchers must review the Health Information Management Services (HIMS) intranet site with requested access to MSH information.

## 3.3.3 Storage and retention of confidential information

All patient information (whether digital or in hard copy) collected as part of a research project must comply with the Department of Health Retention and Disposal of Clinical Records Standard QH-IMP-280-1:2014, and the National Statement on Ethical Conduct in Human Research (2023) ('National Statement'). Generated data may be stored in databanks. Databanks include any collection of personal information that may be used for the purposes of research. Use of databanks must follow the principles and guidelines for databanks as described in the National Statement.

<sup>&</sup>lt;sup>2</sup> NHMRC Privacy Policy https://www.nhmrc.gov.au/privacy Page 9 of 27

Research material and data, and registers of that material and data, must be kept in a format and time that conforms to the requirements of the *Information Privacy Act 2009 (Qld)* and *Privacy Act 1988 (Cth)*, funding agency or publisher guidelines, or in accordance with discipline norms, whichever is the longer period.

Wherever possible, original data (and other relevant materials or samples) should be retained in the department/division and/or research unit in which they were generated. If required, individual researchers can hold copies of the data for their own use. Retention solely by the individual researcher is not permitted, as it may not protect the researcher or MSH in the event where the veracity of the data is questioned. If the original data are retained by the researcher, the department/divisional delegate must be formally advised of its location and can access the data if required. Where researcher and department/division.

At the end of a research project which has been hosted by MSH, research data and materials remain the property of MSH, unless subject to a third-party agreement. MSH work instruction WI2023-302 Research contracts and study execution provides more information.

Where a researcher moves from MSH, original data must remain at MSH, otherwise a written agreement must be reached with the new organisation covering ownership and storage of research data. When research is carried out at multiple organisations, agreement must be reached in writing, and these must clearly specify the principles of storage and retention of research data within each organisation.

When the data is obtained from limited access databases (or an external database), or via a contractual arrangement, written indication of the location of the original data, or key information regarding the database from which it was collected, must be retained by the researcher or division/department.

#### 3.3.4 Data accessibility

Data related to publications must be available for discussion with other researchers. Where confidentiality provisions apply (for example, where the researchers or the institution have given undertakings to third parties, such as the subjects of the research), it is desirable for data to be kept in a way such that reference to the data by third parties can occur without breaching confidentiality.

## 3.3.5 Disposal of research data and material

When the specified period of retention has finished, researchers have a responsibility to dispose of research data in a secure and safe manner, and in accordance with the Department of Health Retention and Disposal of Clinical Records Standard QH-IMP-280-1:2014

# 4.0 Authorship, publication and peer review

All persons involved in research must adhere to the Code's Principle 4 'fairness in the treatment of others' which requires that the work of others is appropriately referenced and cited by giving credit, including authorship where appropriate, to those who have contributed to the research. In Metro South Health authorship must be based on:

- **Contribution**—to be named as an author, an individual must have made a substantial scholarly contribution to the work and be able to take responsibility for at least that part of the work to which they contributed.
- Active inclusion—all persons designated as authors must qualify for authorship, and all who qualify must be offered authorship. A person who qualifies as an author must not be included or excluded as an author without their written permission.

• **Agreed understanding**—collaborating researchers should agree on authorship of a publication as early as reasonably possible in the research project, and this should be reviewed periodically throughout the project.

## 4.1 Authorship

The following types of work generally would not acknowledge authorship:

- policy, procedure, guidelines and any other document formally endorsed as official departmental information;
- briefs, submissions, media releases, draft letters produced for another's signature; and/or
- official departmental websites.

Where an employee feels that they have created a significant work, and that they have moral rights in the work, this should be discussed with the employee's immediate supervisor or principal investigator.

## 4.1.2 Determining authorship

While authorship conventions vary across disciplines, a significant intellectual or scholarly contribution must include one and should include a combination of two or more of the following (at the minimum):

- conception and design of the project or output
- acquisition of research data where the acquisition has required significant intellectual
- judgement, planning, design, or input
- contribution of knowledge, where justified, including Indigenous knowledge
- analysis or interpretation of research data
- drafting significant parts of the research output or critically revising it so as to contribute to its interpretation.<sup>3</sup>

MSH, universities, institutions, research centres and research units are responsible for encouraging and promoting responsible authorship practices that are considered appropriate within the discipline area. MSH expects that the authorship of research publications will be properly determined in accordance with the following criteria:

- An author's role in a research output must be sufficient for that person to take public responsibility for at least that part of the output in the person's area of expertise.
- Authorship of a research output cannot be claimed where participation is solely in the acquisition of funding or the collection of data. General supervision of the research group does not constitute authorship.
- Authorship of a research output should be discussed between researchers at an early stage in a research project as part of a publication plan and reviewed whenever there are changes in participation.

#### 4.1.3 Recognition of contribution

Due recognition of all participants is part of a proper research process, and the authors must ensure that others who have contributed to the work are recognised in the research output. Authors should ensure that the work of research students/trainees, research assistants and technical officers is properly

<sup>&</sup>lt;sup>3</sup> NHMRC – Authorship - A guide supporting the Australian Code for the Responsible Conduct of Research 2019 https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018 Page 11 of 27

recognised. Courtesy demands that individuals and organisations providing facilities, technical support or research infrastructure should also be acknowledged.

No person who is an author, consistent with the minimum requirement for authorship can be excluded as an author without their prior written permission. Similarly, no person who has contributed to the acquisition of funding, or the collection of research data, can be intentionally excluded from its analysis or interpretation for the purpose of authorship.

Reasonable steps must be taken to respect the right of:

- a creator of intellectual property to be credited as the author of a work and to endeavour to ensure that others respect that right unless the creator chooses not to attribute the work at the time of creation.
- integrity of authorship in respect of works produced in MSH.

MSH is not obliged to take further action if the moral rights of authors are not (asserted) exercised. Researchers must name MSH as one of their affiliations when publishing.

#### 4.1.4 Acknowledgements

Where someone does not meet the criteria for authorship but has contributed to the research, they should be named in the acknowledgements section of a publication with their contribution and role specified. For example, those who have contributed facilities, research materials, technical skills, technical writing assistance or funding under a relevant funding agreement would all qualify for mention in the acknowledgements section.

Individuals and organisations providing access to facilities, samples or reference collections must be fully acknowledged. Written approval must be obtained from the individual to be identified in the acknowledgements. All authors should alert the corresponding author to any author or contributor who may have been inadvertently omitted including contributions from student and junior researchers.

While valuable contributions to research are made through the following roles, they should not be considered in isolation as a basis for authorship:

- a departmental/divisional delegate or other person in a position of leadership
- provision of access to a patient population, research materials, or other technical support to the project without other intellectual input—including enabling access to database material
- provision of routine assistance such as administrative support
- providing data that has already been published or materials obtained from third parties without providing any other intellectual input.

Other types of acknowledgement are:

Acknowledgment of other contributions	Acknowledgment of other contributions of a less substantial nature may be determined by negotiation between authors. These contributions usually include supportive functions such as designing and maintaining apparatus, administrative support and data entry. The usual practice is for these contributions to be cited as acknowledgments or in a footnote.
	For contributors who are recognised as paid consultants (e.g., consumer representatives) to the research output, their inclusion as authors is usually left to the discretion of the research team. According to common practice however,

	consultants who contribute substantially to the intellectual content of the publication are normally included as authors. Those consultants who contribute in a less substantial manner or whose contribution does not add to the intellectual content of the publication are not normally included as authors, but are acknowledged in the work. Under no circumstances should these contributors be excluded from acknowledgment unless they specifically desire exclusion.
	When the consumer is engaged as part of the research team and is likely to be included as a co-author on any resulting publications. By way of example an agreement is required if the consumer is a listed co-investigator, given data to analyse, involved in writing the Participant Information and Consent Form (PICF) or protocol, involved in study design and/or their work is being included. MSH work instruction GL2021-75 Partnering with consumers in research provides further information.
Acknowledgement of funding sources	Where research has been funded by an external agency or individual or by any internal MSH funding scheme, the source of funds should always be acknowledged in a manner consistent with that described under the relevant funding agreement and in accordance with the specific journal requirements. Publications must include information on the sources of financial support for the research. This must include recognition of the support of MSH cases where a by-line is not included.
Acknowledgement of research ethics approvals	As appropriate and as required by the publisher, animal and/or human research ethics approvals, site specific assessment and data access approvals (e.g., the <i>Public Health Act 2005</i> (Qld)), should be recorded in relevant publications arising from that research, with reference to the unique identifiers of the approving committee and authorities.

## 4.1.5 Affiliations

Where authors have university affiliations, they are advised to also refer to their institution for specific policies and procedures. Appropriate author affiliation is important for internal and external analysis of publication data, which may impact receipt of academic or financial recognition. Where an author's primary or secondary affiliation is with a MSH facility or service, it is suggested that, where appropriate, authors cite their institutional affiliation with the relevant department/stream/unit, where there is sufficient space. Authorship protocols should be consistent with the publishing journal requirements or professional body under which the publication is being made.

#### 4.1.6 Ghost authorship

'Ghost authorship'—where an individual such as a research assistant or industry researcher meets the criteria for authorship but is not acknowledged as an author—is not an acceptable practice and is inconsistent with the principles and responsibilities of the Code.

A person who qualifies as an author must not be included or excluded without their written agreement. This written agreement should be provided by each author in a timely fashion. A record of each written agreement must be kept. If an author is deceased, this should be noted in the publication.

## 4.1.7 Custodianship of data

Whilst ownership of a clinical database or custodianship of data does not by itself constitute grounds for authorship, such individuals have a right to be involved in the design and conduct of any research undertaken using this data. In particular, the custodians(s) of clinical databases must be consulted about any planned research that relies on using information in their databases prior to commencement of the research.

Researchers must also abide by other legal rights provided under the *Copyright Act 1968 (Cth)* which gives authors the exclusive right to be attributed as having authored a work, and to publish, reproduce, communicate, adapt or perform their work. It also bars anyone from falsely attributing the work of an author to themselves. Authorship grants these rights for as long as the copyright over the scientific communication lasts, regardless of any other policies, procedures or agreements relating to the communication.

#### 4.1.8 Accuracy and integrity

Authors are also responsible for taking reasonable steps to ensure the accuracy and integrity of the contributions of all other co-authors. This means that authors should, where feasible, be able to identify which co-authors are responsible for specific other parts of the work and that they should raise any concerns about the accuracy and integrity of the research before submission or publication.

If an individual does not agree to be accountable for their contribution, the contribution should not be included in the research output.

Following publication, all authors must also ensure that any concerns about the accuracy or integrity of any part of the output are appropriately responded to. This may mean providing all necessary evidence to demonstrate the accuracy and integrity of their contribution or seeking such evidence from the other co-authors. It may result in correcting the public record by way of erratum, corrigendum, or retraction.

#### 4.1.9 Research students as authors

Research students will normally be primary authors on research publications that arise from their thesis work. If a research student and their supervisor co-author a publication, the research student will normally be listed as the primary author, unless substantial modifications/additions to the manuscript were made following thesis completion. It should be noted however, that this order of authorship may not apply to those academic disciplines which follow a policy of listing authors alphabetically, regardless of the extent of their input.

Publications arising from the work of a research student will not usually be submitted for publication without consultation with a student's supervisor. Supervisors may only be included as a co-author on a research student's publication if they meet the above-mentioned authorship criteria.

#### 4.1.10 Indigenous authorship

MSH is supportive of the Code Principle 6, 'recognition of the right of Aboriginal and Torres Strait Islander Peoples to be engaged in research that affects or is of particular significance to them', which requires researchers to credit the contributions of Indigenous people and knowledge.

Researchers intending to publish Indigenous Australian knowledge obtained through sources including unpublished manuscripts, or audio or video recordings, should seek approval from the Aboriginal and Torres Strait Islander peoples involved in the project or the community from which that knowledge originates, and the individual and collective contributors of the knowledge should be acknowledged, as appropriate.

Generally, researchers should obtain permission from named indigenous contributors before acknowledging them in research outputs, since acknowledgement may imply a contributor's endorsement of the research output.

## 4.1.11 Formalised authorship arrangements

Where there is more than one author, it is good practice to have authorship agreement and publication plan in place before the commencement of writing up a research project. An authorship agreement, Memorandum of Understanding (MOU) and/or publication plan does not need to be a formal legal document. It can be in the form of emails, a transcript of an online discussion or other similar evidence of agreement.

The authorship agreement, MOU and/or publication plan agreement should include:

- identification of those who will be recognised as the authors of the research output.
- a description of the contribution that each author has made (or will make) to the research output.
- an indication of the order in which the authors appear the agreed order of authors should be consistent with any applicable disciplinary norms and publication requirements.
- identification of at least one corresponding author who is responsible for communication with the publisher and managing communication between the co-authors.

It is the responsibility of the executive/corresponding/lead author to maintain records of authorship arrangements. Where the executive/corresponding/lead author is not from the same institution as other listed authors, authors are encouraged to keep their own records.

As a project evolves, it is important to continue to discuss authorship, especially if new people become involved in the research and make a significant intellectual or scholarly contribution. The corresponding author should retain a record of any agreed changes to the authorship of a research output.

#### 4.1.12 Authorship order

The order of authorship is a decision of the combined authorship group and should always comply with publishing journal and professional group requirements. Researchers may seek guidance about the preferred method for listing authors from their university, professional bodies or the journal in which they wish to publish.

Multiple authors are responsible for determining the order in which their names appear on the title page. The order of authorship for MSH publications is determined by the intellectual input from each of the authors. The researcher who makes the largest contribution, in terms of intellectual content, is listed as the executive/corresponding/lead author (which is often listed first or last depending on the discipline). Subsequent authors are listed in order of decreasing contribution. In cases where the order of authorship is not clear, the issue may be resolved by use of a Statement of Authorship or MOU. MSH work instruction WI2023-290 Research authorship, peer review and publication provides further information.

## 4.1.13 Reporting and recording of authorship

No one should be included as an author without his or her explicit agreement. An author of a report may decline to be an author of any subsequent papers because the researcher believes that their current workload makes it impractical for them to make a written or intellectual contribution to the subsequent publications (that is, an assessment that the person could not take public ownership of a subsequent paper).

When there is more than one co-author of a research output, one co-author (by agreement amongst the authors) should be nominated as executive/corresponding/lead author of the whole research output and should take responsibility for record keeping regarding the research output.

All co-authors should acknowledge their authorship in writing. This acknowledgment should be placed on a file to be managed by the executive/corresponding/lead author. Authorship can be confirmed by an exchange of emails between the co-authors, with a copy of those emails stored on the central server in the relevant research project directory. Publication of the research output, including electronic publication, requires all co-authors of the publication to certify that the minimum criteria for authorship have been fulfilled.

Any documentation which records authorship must be retained in research project files and may be subsequently audited. If, for any reason, one or more co-authors are unavailable or otherwise unable to certify and authorship agreement, the delegate may sign on their behalf and must provide a written statement noting the reason for their unavailability.

#### 4.1.14 Declaration of authorship

MSH acknowledges that the criteria for authorship listed above (including the order of authors) of research output vary depending on the currently accepted practice in the research discipline and journal.

All authors of all types of publication (including web-based publication) must certify the authorship agreement (e.g., email correspondence, Statement of Authorship, MOU) prior to its submission. All authors must have final approval of the version to be published. The certified authorship agreement must specify that the signatories are the only valid authors and that there are no other authors.

If an author is deceased (or cannot be contacted after reasonable attempts have been made), all the coauthors must still have confidence in the accuracy and integrity of that author's contribution. This may require consideration of the underlying data and methodology.

If, for any reason, one or more co-authors are unavailable or otherwise unable to certify the authorship agreement, the executive/corresponding/lead author or senior researcher most related to the work may sign on their behalf, noting the reason for their unavailability. Confirmation should be obtained from absentee authors within six months of the publication being submitted.

## 4.2 Peer review

MSH encourages researchers to participate in peer-review to provide public credibility to the reporting of research. MSH recognises that peer-review is an essential component of maintaining research integrity and supports peer-review of its research findings and encourages its researchers to participate as both reviewer and by having their own work reviewed.

#### 4.2.1 Participation

MSH researchers in receipt of public funding have a responsibility to participate in the peer-review process and this may be a requirement of some funding agreements. MSH researchers who are asked to participate in peer-review should do so in an ethical, confidential, and timely manner. Researchers should not agree to peer-review any research for which they have a conflict of interest, or where the research is outside the area of expertise. MSH researchers whose research is being peer-reviewed must not seek to influence the outcomes or process.

#### 4.2.2 Peer review process

Peer review has several important roles in research and research management, including:

- the assessment of research proposals and grant applications
- the assessment and selection of material for publication and dissemination
- the assessment of the research of Higher Degree Research (HDR) candidates
- the assessment of research quality, engagement, and impact by government bodies, and
- other reviews or assessments of research conducted by individual researchers, teams, academic units and institutions.

Peer review provides expert scrutiny of proposed research or research outputs and helps to maintain high standards in research, including by ensuring that accepted disciplinary standards are met. At its best, peer review contributes to accurate, thorough and credible reporting of research.

Peer review may also draw attention to departures from the principles in the Code, including by identifying plagiarism, duplicative publication, errors, and misleading statements.

Participating in peer review also provides benefits for researchers, including keeping abreast of the most recent research, improving critical analysis skills, and understanding of peer review processes, and obtaining recognition for contributions to peer review.

#### 4.2.3 Acting as a peer-reviewer

When acting as a peer reviewer, MSH expects researchers to conduct reviews responsibly in accordance with the Code. This includes:

- complying with the criteria to be applied and meeting specified timeframes
- respecting confidentiality requirements
- acting objectively and professionally
- declaring all conflicts of interest
- only reviewing within their area of expertise.

## 4.3 Publication and dissemination of research

Dissemination of research findings is a core practice that promotes research excellence through the timely sharing of the potential benefits of the research to the wider research, industry, policymaker, funding, and consumer communities. MSH supports publication and dissemination of research findings in a manner consistent with the Code. Numerous avenues for dissemination of research outputs exist.

Research findings are most frequently formally published in peer-reviewed academic journals or books. Journals may use different publishing models such as traditional subscription-based, Open Access, or hybrid (both subscription and open access options). The selection of the publishing model should be informed by discipline requirements or standards.

With changes to scientific communication strategies, Open Access (OA) is a broad international movement that seek to provide content freely and immediately accessible to readers while maintaining the same services common to all scholarly journals, such as management of the peer-review process, filtering, production, and distribution. While articles are free to the reader, the journal must cover their operating expenses, which in many cases involves an article processing fee paid by the authors.

MSH supports equity of the business models by committing to the timely establishment of durable mechanisms for underwriting reasonable publication charges/fees for articles written by its employees and published in fee-based open-access journals and for which other institutions would not be expected

to provide funds. For any publication model, the following general matters must be considered by the authorship team.

## 4.3.1 Prior to publication

Authors must approve the research output before its submission for publication and, in doing so, agree to be accountable for it. Authors must also approve the final version before publication. The final approval process may be coordinated by the publisher, often through the corresponding author. The corresponding author must keep written records that confirm that approval has been obtained from all authors.

If an author is deceased, or after all reasonable efforts that have been made to establish contact have failed and have been documented, publication can proceed, provided that there are no grounds to believe that this person would have objected to being included as an author. In such instances, it may be appropriate for an institution to provide written agreement for the inclusion of an author.

Financial sponsorship that carries an embargo on the naming of the sponsor should be avoided. Furthermore, research findings should not be reported in the public media before they have been reported to a research audience of experts in the field of research - preferably by publication in a peerreviewed journal.

When considering publication researchers must:

- Describe accurately the state of publication (in preparation, submitted, under review, accepted for publication, in press), research funding (applied for, granted, funding period) and awards conferred.
- Not deliberately include inaccurate or misleading information relating to research activity in curriculum vitae, research grant applications, job applications or public statements.
- Ensure that published reports, statistics and public statements about research activities and performance are complete, accurate and unambiguous. If a researcher becomes aware of unintentional misleading or inaccurate statements about their work, they must correct the record as soon as possible.

The publication of research findings must be complete, and where appropriate include any negative findings and results which may be contrary to the hypothesis and/or conclusion. Before disseminating research findings, researchers must consider:

- Any confidentiality requirements of a contractual or funding agreement.
- The protection of any personal information in the research data.
- Intellectual property rights.
- Any contractual restrictions or delays on publication, including any contractual requirements to obtain prior consent from funding bodies.

Publication of multiple full papers drawing the same conclusions from the same set of research findings is not acceptable, except where there is full cross-referencing within the papers (for example, in a series of closely related works, a review article, or where a complete work grew out of a preliminary publication, such as an abstract or conference presentation, and this is fully acknowledged). Publication of the same material translated into different languages is acceptable provided that the original source is fully acknowledged.

Re-publication of control data (rather than performing new control experiments) is not acceptable unless a full justification is provided to and approved by the journal Editor. An author who submits substantially

similar work to more than one publisher must disclose this to the publishers at the time of submission. MSH and sponsors involved in any collaborative research reported must be acknowledged and fully disclosed, unless there are any restrictions on communications which may have been agreed with the sponsor.

## 4.3.2 Delayed publications

Some publications are not produced until sometime after a research project has finished, during which time team members may have changed or the authors of the original work have moved on. In this case, previous team members should be invited to contribute as an author to any subsequent publications if their contribution to the original project was at a level that would entitle them to claim public responsibility for the subsequent publication. This decision is the responsibility of the current team.

## 4.3.3 Publications that incorporate two or more projects

Situations may arise where an individual researcher or a group of researchers want to synthesise the work that has been done across two or more projects. They may or may not themselves have been involved in the original projects.

In doing so, they will generate new knowledge that is quite distinct from the original work on each project. In these situations, authorship would rest with those doing the synthesis, but it is expected that they would advise the researchers involved in the original projects of what they are doing, typically by email.

#### 4.3.4 Phishing and unsolicited email invitations

MSH employees should be cautious of unsolicited email invitations that ask to:

- publish their thesis as an open access book;
- join editorial boards; and/or
- participate in conference or special issues of journals.

These may be from unethical publishers who exploit the open access business model without providing high quality publishing services.

#### 4.3.5 Journal metrics (impact factor)

Journal metrics include a range of measures used to evaluate the quality of a journal. One such metric is the impact factor. The impact factor is a measure of the frequency with which the average article in a journal has been cited in a particular year. It is used to measure the importance or rank of a journal by calculating the times its articles are cited. Researchers should consider the impact factor of a journal in their field of research prior to publishing and can seek guidance from a supervisor in their field.

#### 4.3.6 Ethics approval

For studies involving people, medical records, and human tissues, publication journals will require authors to document that a formally constituted review board—Institutional Review Board or HREC—has granted approval for the research to be done.

If the study is judged exempt from review, a statement from the HREC is required. Informed consent by participants or guardians should always be sought. If this is not possible, a HREC must decide if this is ethically acceptable.

Authorship guidelines of each journal will identify where a statement on ethical approval should be located. For example, this may be in the manuscript submission cover letter, title page, specific section within the manuscript. It should be noted, however, that for most studies involving people, medical

records, and human tissues, reviewers and readers will expect to see a statement about formal ethics approval.

## 4.3.7 Dispute resolution

Disputes over authorship sometimes arise. Attempts should be made to resolve disputes through discussion amongst the authors however consideration should be given to potential power imbalances. If a resolution cannot be reached between the authors, then any affected party may raise the issue for discussion and mediation through their local facility/service.

A dispute between authors does not constitute an allegation of research misconduct, unless it is alleged that there has been a serious and intentional breach of the Code. Researchers must treat fellow researchers and others involved in the research fairly and with respect (see P4 of the Code). The parties to the dispute should maintain records of agreements reached through direct dialogue or mediation.

Where an authorship dispute is raised with the facility/service, an ad hoc mediation group should be established by facility/service, which includes representation from researchers not involved in the publication and should include representation from academic institutions and universities where appropriate.

Individuals should also be aware that universities may have their own mediation policy. In such cases where other parties are involved, consideration should be given to the complexities prior to mediation processes commencing.

The mediation group may require copies of key documentation, including records of authorship, acknowledgements if a scientific communication has been submitted for publication, and summaries of earlier authorship agreements, collaborative research agreements and funding agreements. A report by the Chair of the mediation group should be provided to the relevant departmental/divisional delegate. Cases that are not resolved by the mediation group should be referred to the facility/service Executive Director for final determination.

The principles of procedural fairness will be applied to processes for investigating and managing concerns and complaints about authorship. The departmental/divisional delegate is responsible for the resolution of conflicts arising through disputes about authorship.

# 5.0 Research Complaints and misconduct

As outlined in section 1.0 of this document, MSH's commitment to research excellence means that researchers must observe the highest levels of research integrity and conduct. The Guide to Managing and Investigating Potential Breaches of the Code 2018 ('the Guide') assists MSH in the management, research misconduct investigation and resolution of complaints about potential breaches of the Code.

MSH mandates compliance with the Code. Furthermore, MSH is committed to ensuring systems are in place to promote appropriate conduct, discourage all breaches, and appropriately manage identified serious breaches of the Code or unethical behaviour in its research activities. All allegations of research misconduct will be assessed, and, where necessary, managed in accordance with MSH policies and procedures, whilst ensuring procedural fairness.

All concerns raised regarding failures to comply with regulations, potential research misconduct or allegations of research misconduct, must be made in good faith. Concerns will be investigated in an impartial, timely, fair and transparent manner while maintaining confidentiality.

Consistent with relevant laws, rules, regulations, and practices, MSH is committed to the protection of the privacy and/or confidentiality of respondents, complainants and patients/participants identifiable from research records or evidence.

Concerns and complaints assist MSH and its Human Research Ethics Committee (HREC) to undertake continuous improvement of its research activities and processes, particularly in relation to the ethical conduct of research, research governance and research management.

All persons involved in research—whether patients, research participants, employees, researchers, or Principal Investigators—have a right to report or make complaints and/or raise concerns/allegations in relation to research-related matters directly or through a representative. Complaints and/or allegations may be made to MSH about researchers, the conduct of research or about the conduct of a research-related committee or other review body and may be made by patients, research participants, researchers, staff or other interested persons or bodies.

# 5.1 Breaches of the Code

Complaints and/or allegations about breaches of the Code are addressed under the provisions of the Code and MSH work instruction WI2023-291 Research complaints and misconduct.

The Guide outlines the preferred model for institutions to assess and manage potential breaches, determine any corrective actions to ensure the integrity of the research record and when a finding of research misconduct may be made. MSH has implemented accountability mechanisms and processes to uphold principles outlined within the Code and the Guide. In addition, MSH has established a model for assessing and managing potential breaches of the Code which:

- considers MSH workplace policies, procedures and agreements, other external institutional processes and the law;
- ensures that the processes used to manage and where necessary investigate potential breaches of the Code are procedurally fair and do not hinder the timely implementation of all corrective actions;
- considers relevant funding body/ies expectations regarding institutions in receipt of public research funds;
- as breaches of the Code are likely to be distinct from other forms of misconduct/corrupt conduct in the workplace (such as sexual harassment, bullying and discrimination), the assessment and management of research conduct issues may occur as a discrete process, where applicable;
- considers existing workplace, disciplinary, and student agreements;
- ensures that disciplinary issues, which are outside the scope of this procedure, are managed by MSH Human Relations (HR); and
- ensures that clinical incidents, which are outside the scope of this procedure, are managed in accordance with clinical ethics and incident reporting requirements.

## 5.2 Other MSH processes

When discussing research misconduct, 'other MSH processes' are mentioned and refers to processes including but not limited to: RiskMan/CAMMS/clinical incidents, Australian Health Practitioner Regulation Agency (AHPRA) notification, disciplinary and/or corrupt conduct.

If it is determined that the matter; does not involve a MSH employee or participant; is <u>unrelated</u> to the conduct of research and/or is not a potential breach of the Code (with supporting evidence), it may be referred to:

- Hospital Patient Safety and Quality Unit (PSQU)
- MSH/Facility/Service HR
- MSH Ethical Standards Unit (ESU)
- hospital Patient Liaison Officer (PLO)
- delegate/line manager
- University or external institution's Research Integrity Office (RIO).5.3 Consideration and management of complaints and allegations

A complaint or allegation about a potential breach of the Code occurs when a concern is raised or identified that one or more researchers have conducted research that is not in accordance with the principles and responsibilities of the Code.

Well-defined processes for receiving and managing concerns, allegations and complaints (hereafter only referred to as complaints) and communicating with the complainant are essential. These processes are readily accessible on the Metro South Research website and the key considerations for these processes are described below. Complaints may be dismissed at any stage for a variety of reasons, including if the complaint appears to have been made in bad faith or is vexatious.

Alternatively, a complaint may trigger other processes or require immediate action if corrupt or criminal behaviour is potentially involved or if it relates to an activity that could harm humans, or the environment.

It is important to document all decisions and reasons for those decisions. These decisions include, but are not limited to, whether to proceed to a preliminary assessment, whether to investigate a complaint or whether to cease investigating a complaint. Records and documentation must be retained in accordance with MSH processes.

# 5.4 Participant Information and Consent Form (PICF)

Researchers are responsible for including relevant contact details for the for the research project in the Participant Information and Consent Form (PICF). All PICFs for research projects being conducted in MSH must include the following paragraph:

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if the participant has any medical problems which may be related to their involvement in the project (for example, any side effects), you can contact the principal study doctor on [Contact phone number] or any of the following people:

Reviewing HREC name	[Name of HREC]	
HREC Executive Officer	[Name]	
Telephone	[HREC Executive Officer Phone number]	
Email	[ HREC Executive Officer Email address]	
Local HREC Office contact	(Single Site -Research Governance Officer)	
Local HREC Office contact	(Single Site -Research Governance Officer) [Name]	
Local HREC Office contact Name Position	(Single Site -Research Governance Officer) [Name] [Position]	

#### Reviewing HREC approving this research and HREC Executive Officer details

[Email address

Email

Participants may utilise the listed contact details on a PICF to submit a complaint either verbally (in person or by telephone), or in writing to the research project team and/or the reviewing HREC. Alternatively, complainants can lodge a concern, allegation, or complaint with the MSH:

- Research Integrity Advisor (RIA) or Designated Officer (DO)
- HREC Chair or Coordinator
- ESU/HR
- PLO/PSQU
- department/division contact
- relevant delegate.

## 5.5 Initial receipt of complaints

Complaints may arise from a range of sources. MSH processes for submitting, receiving, and documenting a complaint about a potential breach of the Code is MSH work instruction WI2023-291 Research complaints and misconduct.

## 5.6 Corrupt conduct and/or criminal behaviour

Some matters may involve potentially corrupt conduct and/or potential criminal behaviour. These matters require referral to an appropriate agency, for example, a crime commission and/or the police. They may also trigger other MSH responsibilities and processes.

MSH must have processes that encourage early identification of these matters. Where an external agency chooses to investigate, MSH must seek advice on whether internal processing of the complaint as a potential breach of the Code can continue and, if so, with what authority and parameters, if any.

Following completion of an external investigation, MSH may need to consider if there are outstanding matters, relevant to the Code, to be addressed internally, and may decide to initiate further internal processing.

It is important to note that this procedure only pertains to the conduct of research. Any other matters of misconduct must be referred to an appropriate area such as MSH HR and/or ESU, hospital PLO and/or delegate. The matter may also be referred to a university or external institution's HR area.

Whilst the Code introduces additional processes that are to be applied when allegations involve the conduct of research, all MSH employees (including Principal Investigators, researchers and research student supervisors) have an obligation to disclose corrupt conduct, including fraud, misconduct and maladministration.

The processes in the Code are not for the assessment, management or investigation of other forms of misconduct, although sometimes the conduct of research and research misconduct may be associated with other forms of misconduct and/or corrupt conduct. Therefore, it is vital that all complaints which may result in an allegation of misconduct and/or corrupt conduct are handled by appropriate MSH personnel and in conjunction with HR policies and procedures if/when required.

The RIA and DO/r will be able to advise if the matter it is be referred for resolution. Where the research participant is a MSH patient, the relevant hospital PLO will be notified of the complaint. Records of allegations and related documents must be retained and stored appropriately, including recommendations and actions taken.

# 5.7 Other considerations

There are some other considerations when a complaint is received about research:

Safety issues	If at any time it becomes apparent that the complaint relates to an activity that could harm humans, animals or the environment, immediate action must be taken to minimise the risk of harm. This action is at the discretion of MSH and is independent of assessment against the Code. These matters may require referral or notification to an appropriate agency (e.g., regulatory agencies, WorkSafe, AHPRA). They may also trigger other MSH responsibilities and processes.
Public Interest Disclosure (PID)	Nothing in this procedure prevents a person from making allegations under the <i>Public Interest Disclosure Act 2010</i> (Qld). The MSH ESU is the responsible officer for receiving and acting on public interest disclosures in MSH. Please see Public Interest Disclosure (PID) Procedure (WS.E.PR.1.2) for more information.
Misconduct or unsatisfactory performance unrelated to research	If at any stage it is considered that misconduct or unsatisfactory performance may have occurred which is not related to research activities, the relevant allegations may be referred to an appropriate officer for management in accordance with relevant MSH processes.
Participation in research misconduct processes	MSH may issue reasonable and lawful directions to staff members in relation to their participation in any preliminary assessment, or research misconduct inquiry.
Restoration of Reputation	If allegations of research misconduct or breaches of the Code are shown to be unsubstantiated, MSH will take reasonable steps to reinstate the reputation of the respondent where this may have been damaged.
External Obligations	When allegations are made, MSH may have an obligation to make statutory reports to other external organisations about matters that arise.

## 5.8 Frivolous and vexatious complaints

Individuals are expected to make complaints in good faith and complaints must not be vexatious, frivolous, misconceived or completely without substance. This procedure is not to be used as a forum for revenge, retribution or mischief. Examples of frivolous, vexatious and bad faith complaints include (but are not limited to):

- fabricating a complaint to get another person into trouble.
- making trivial or petty complaints.
- making repeated, unsubstantiated complaints.
- seeking to re-agitate issues that have already been addressed or determined.

At any stage where such behaviour is suspected, this matter maybe referred to HR who may make an assessment that the complaint is vexatious, frivolous, misconceived without substance or that an alternative MSH process is applicable to the subject matter of the complaint and, therefore, the matter

will not be progressed through these procedures. Persons making frivolous or vexatious complaints may be subject to disciplinary action.

## 5.9 Collaborative research

Research is increasingly an inter-disciplinary, multi-institutional and a multi-national endeavour. This involves all aspects of research, including the initial collaboration, peer review, data management and dissemination of research output. Consideration should be given to how potential breaches of the Code will be investigated at the outset for collaborative research projects that reach across multiple institutions and jurisdictions.

Institutions should consider how preliminary assessments and investigations into potential breaches of the Code are to be conducted for multi-institutional collaborations on a case-by-case basis, taking into consideration issues such as the lead institution, where the complaint was lodged, contractual arrangements or where the events occurred. Institutions should cooperate if there is a potential breach of the Code to ensure that only one research misconduct investigation is conducted. There should be clear communication between all parties throughout the research misconduct investigation. Special consideration needs to be given to international collaborations since research practices and guidelines about the conduct of investigations differ between countries.

# 6.0 Risk assessment and management

Risk assessment and management are essential in research, especially following updates to the National Statement and the implementation of the National Clinical Trials Governance Framework (NCTGF) to ensure ethical, safe, and compliant practices, protect participants, maintain research quality, and uphold the integrity of research outcomes. MSH work instruction WI2023-292 Assessing and managing risk in research provides more information.

MSH supports risk assessment and management in research for several reasons:

- Risk assessment helps identify potential ethical and safety issues within research projects, ensuring that these concerns are addressed appropriately.
- By conducting risk assessments, researchers can align their projects with the updated standards and demonstrate their commitment to ethical and safe research practices.
- Effective risk management ensures the quality and integrity of research. It helps prevent deviations from planned research protocols and minimises the likelihood of errors, inaccuracies, or misconduct that could compromise the validity of research outcomes.
- Research often involves human participants who must be protected from harm. Risk assessment allows researchers to identify and mitigate potential risks to participants' physical, psychological, or social well-being.
- In an era of increasing data collection and sharing, it is essential to protect research data from breaches and unauthorised access. Risk assessment helps identify data security vulnerabilities and develop strategies to safeguard sensitive information.
- Failure to conduct risk assessment and management can lead to legal issues if research-related problems arise. Adhering to these processes can help protect researchers and institutions from potential legal liabilities.

- Efficient risk management can prevent cost overruns and delays in research projects. By identifying and mitigating risks, researchers can allocate resources more effectively and reduce the financial impact of unexpected issues.
- Following best practices in risk assessment and management enhances the trust of stakeholders, including research participants, funding agencies, and the general public. Transparent risk management processes demonstrate a commitment to responsible research.
- Regular risk assessment and management promote a culture of continual improvement in research practices. Researchers can learn from past experiences and apply lessons to future projects.
- Research environments and conditions can change over time. Ongoing risk assessment allows researchers to adapt to evolving circumstances, such as emerging ethical concerns or new regulatory requirements.
- Risk assessment often involves input from multiple stakeholders, including researchers, ethics committees, and regulatory bodies. This collaborative approach encourages interdisciplinary communication and alignment.
- Research involving clinical trials may have specific ethical and compliance risks that need to be addressed. The NCTGF places a greater emphasis on effective governance and risk management in clinical trials, making risk assessment and management even more critical.

# 7.0 Guidelines

MSH guidelines have been developed to assist MSH researchers in undertaking research in MSH and translating findings into practice. For more information please see the following MSH guidelines:

- GL2021-75 Partnering with consumers in research
- GL2023-97 Aboriginal and Torres Strait Islander health research
- GL2023-98 Research translation and impact

# Glossary

Acceptability	Acceptability in research refers to the degree to which research methods, interventions, or findings are deemed suitable, appropriate, and agreeable by relevant stakeholders, such as participants, the research community, or the broader society. It assesses whether the research is well-received and considered ethical, culturally sensitive, and practical.
Agreement	An agreement used in a research setting is a formal and documented understanding or contract between parties involved in research. It outlines the terms, conditions, rights, and responsibilities related to the research project, such as collaboration, data sharing, confidentiality, funding, or any other relevant aspects. These agreements ensure clarity and compliance among involved stakeholders.
Breach	A breach of the Code refers to a violation or failure to adhere to the ethical and integrity standards outlined in the code. This can include actions such as plagiarism, data fabrication, falsification, research misconduct, or any other unethical behaviours that undermine the principles of responsible research conduct. Breaches can have serious consequences, including damage to research integrity and professional reputation.
Effectiveness	Effectiveness in research refers to the ability of an intervention, method, or approach to achieve its intended objectives and produce the desired outcomes in a real-world setting. It assesses the practical impact and success of the research in addressing a specific problem or research question.
Peer review	Peer review is a process in which experts or peers in a particular field critically assess and evaluate the quality, validity, and significance of a research study, manuscript, or proposal before it is accepted for publication or funding. It helps ensure the accuracy and credibility of research by subjecting it to scrutiny and feedback from knowledgeable individuals in the same field.
Research material	Research material refers to the physical or digital resources, such as documents, data, samples, equipment, or any information sources, that researchers use to gather, analyse, and support their investigations and studies. These materials are essential for conducting research and generating insights.
Research misconduct	Research misconduct, as defined in accordance with the Code, refers to serious violations of research integrity and ethics. It includes actions such as fabrication, falsification, or plagiarism in proposing, conducting, or reporting research. Research misconduct compromises the validity and trustworthiness of research and may lead to significant consequences, including damage to one's reputation and professional consequences.
Transparency	Transparency in research refers to the practice of openly and honestly disclosing all relevant information and details about the research process, methodology, data, findings, and any potential conflicts of interest. It promotes accountability, trust, and the ability for others to scrutinise and verify the research, enhancing the credibility and reproducibility of the work.