PROCEDURE

Research Management - Compliance Framework

PR2017/112
Version No. 1.0

PURPOSE

To achieve Metro South Health's research values as outlined in the Research Management Policy and to align with the principles of the Australian Code for the Responsible Conduct of Research (the Code), the Metro South Health Research Management Compliance Framework sets out the arrangements by which research in Metro South Health is administered.

In order to promote the responsible conduct of research in Metro South Health research management compliance documents have been established which promote awareness and encourage responsible conduct by researchers. These governance documents promote quality in research, enhance Metro South Health's reputation and minimise the risk of harm for all involved.

OUTCOME

Adherence to this Procedure will ensure all research conducted within Metro South Health or in collaboration with external entities, is of the highest ethical and scientific standard and is compliant with relevant legislation, standards and guidelines.

This Procedure applies to:

- All Metro South Health employees who conduct human research within or in association with Metro South Health facilities, or through access to Metro South Health participants; and
- All personnel (including researchers, students and visitors) involved in all aspects of human research in or in association with Metro South Health.

Failure to comply with this Procedure may amount to research misconduct on the part of the responsible individual. This Procedure must be read in conjunction with other Metro South Health Research Management Procedures.

KEY PRINCIPLES

The following key principles guide Metro South Health in utilising the Metro South Health Research Management Compliance Framework.

- The Metro South Health Research Management Compliance Framework specifies the roles, responsibilities and accountability of all involved and provides principles in which research is assessed for ethical acceptability, quality, safety, privacy, risk management and financial management.
- The Metro South Health Research Management Compliance Framework has three (3) fundamental principles of; compliance/governance, funding/grants and integrity/quality.

Queensland Government

- Metro South Health is committed to the ongoing review and continuous improvement of its research governance and management processes.
- The Metro South Health Research Management Compliance Framework:
    - adopts the governance practices outlined in Metro South Health corporate governance processes;
    - sets out governance and compliance principles and standards that apply to all research disciplines;
    - clarifies roles and responsibilities of people and organisational structures involved in research management in Metro South Health;
    - supports and promotes research quality and good research practices; and
    - aims to prevent; adverse incidents, breaches of guidelines and codes, and research misconduct.
- Good institutional governance, compliance and management practices encourage responsible research practices. These practices promote quality in research, enhance the reputation of the institution and its researchers, and minimise the risk of harm to humans, animals and the environment.

LEGISLATION OR OTHER AUTHORITY

Legislation

- *Defence Trade Controls Act 2012 (Cth)*
- *Gene Technology (Queensland) Act 2016 (Qld)*
- *Gene Technology Act 2000 (Cth)*
- *Hospital and Health Boards Act 2011 (Qld)*
- *Information Privacy Act 2009 (Qld)*
- *Privacy Act 1988 (Cth)*
- *Public Health Act 2005 (Qld)*
- *Therapeutic Goods Act 1989 (Cth)*

Regulations and Standards

- Gene Technology Regulations 2001 (Cth)
- Information Privacy Regulation 2009 (Qld)
- Therapeutic Good (Medical Devices) Regulations 2002 (Cth)
- Therapeutic Goods Regulations 1990 (Cth)

Statements, Papers and Guidelines

- National Health and Medical Research Council (NHMRC):
    - Australian Code for the Care and Use of Animals for Scientific Purposes 8th Edition 2013
    - Australian Code for the Responsible Conduct of Research 2007
    - Guidelines to Promote the Wellbeing of Animals Used for Scientific Purposes 2008
    - National Statement on Ethical Conduct in Human Research (2007) - Updated May 2015
    - Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research 2003
- Office of the Gene Technology Regulator, National Framework of Ethical Principles in Gene Technology 2012

- Singapore Statement on Research Integrity
- Therapeutic Goods Administration:
    - Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) 2000 - Annotated with TGA Comments
    - The Australian Clinical Trial Handbook 2006

Metro South Health Policies, Procedures, Manuals, Frameworks etc.

- Finance Management Practice Manual (FMPM)
- Integrated Risk Management Framework
- Management of Conflict of Interest – All Staff Procedure (PR2016-66)
- Management of Conflict of Interest Policy (PL 2014/0038)
- Research Biorepositories Policy (PL2017/53)
- Risk Assessment Guide (V12 6-11-2013)
- Risk Management Policy (PL2013-06)

RESPONSIBILITIES

Metro South Health Research Committee

Responsible for Metro South Health Policy relating to research and innovation (including research conduct), commercialisation and research higher degree training (including issues of quality) and reports to Metro South Health Executive on these matters at least annually.

Executive Management Team

Responsible for implementation of the research compliance framework and for fostering good research governance practices.

Centres for Health Research

Responsible for:

- The implementation of the Metro South Health Research Management Compliance Framework and for fostering good research governance practices;
- Provision of information resources and services pertaining to research to Metro South Health;
- Strategic oversight of research development in Metro South Health;
- Leadership and for embedding a culture of responsible research conduct;
- Ensuring the administrative processes for ethical approval and governance of all human, animal and biological related research are in place and promotes research integrity;
- Assisting researchers with applications for funding and finances and in developing, costing and negotiating consultancies and commercial contract research; and
- Assessing the adequacy and effectiveness of Metro South Health's internal controls, including the risk management and compliance frameworks.

Employees and Researchers

Share responsibility and accountability for Metro South Health's research being conducted according to appropriate regulatory, ethical and scientific standards.

SUPPORTING DOCUMENTS

Attachment 1 – Application (see page 6)

Attachment 2 - Metro South Health Research Management Compliance Framework

Attachment 3 - Metro South Health Research Management Governance/Committee Structure

Attachment 4 - Metro South Health Research Council Terms of Reference

Attachment 5 - Metro South Health Research Committee Terms of Reference

DEFINITIONS

See the Metro South Health Research Management Glossary

PROCEDURE - COMPLIANCE FRAMEWORK

STEP 1: Compliance

Researchers must comply with legislation and other mandatory requirements outlined within the Metro South Health Research Management Compliance Framework. Researchers must develop applicable documents and governance arrangements which are in compliance with the Metro South Health Research Management Compliance Framework. Applicable documents and internal governance arrangements include but are not limited to; Research Protocol and Standard Operating Procedures (SOPs).

STEP 2: Oversight

The Centres for Health Research provides oversight of and administrative responsibility for the Metro South Health Research Management Compliance Framework.

STEP 3: Governance/Committee Structure

A robust and detailed Metro South Health Research Management Governance/Committee Structure is outlined in Attachment 3.

STEP 4: Risk Management

Metro South Health risk management, finance, budgeting, contracts and intellectual property must be embedded and regularly reviewed throughout the lifecycle of a research project/activity. Metro South Health has an internal auditing process to examine and evaluate the adequacy, economy, effectiveness and efficiency of risk management, systems of internal control and the quality of management. Incidents of non-compliance must be reported to the Centres for Health Research. Ad hoc reports may be made to the Metro South Health Audit and Risk Management Committee as required. Health, safety and environmental considerations must be embedded and regularly reviewed throughout the lifecycle of research projects.

PROCEDURE DETAILS

Procedure Number
PR2017/112

Procedure Name
Metro South Health Research Management - Compliance Framework Procedure

Policy Reference
PL2017/55
Metro South Health Research Management Policy

Supersedes
Nil

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ATTACHMENT 1 - APPLICATION

1.0 International, National and State Regulation, Accountability and Best Practice Principles

Metro South Health's research practices must operate within applicable laws, regulations, guidelines and codes of practice, as well as Hospital and Health Service Policies, Procedures and Guidelines. The ethical, legal and scientific review of human research is regulated by a number of international, national and state laws, legislation, regulations, ethical guidelines, instruments, codes, guidelines institutional requirements and standards.

Metro South Health has a statutory obligation to ensure all human research is managed scientifically and is conducted in a legally and ethically appropriately manner. Common law obligations may arise from the relationships between institutions, researchers and participants, while contractual arrangements may impose further obligations.

1.1 Legislated Requirements

Research management compliance practices must be consistent with state legislation, including but not limited to:

- The *Public Health Act 2005 (Qld)* aims to protect and promote the health of the Queensland public by preventing, controlling and reducing risks to public health and collecting and managing particular health information, and establishing mechanisms for health information held by a health agency to be accessed for appropriate research.
- The *Information Privacy Act 2009 (Qld)* regulates how Queensland government agencies, including Metro South Health, must manage personal information and provides a right for individuals to apply for access and amendment of their personal information. Metro South Health is required to comply with Privacy Principles outlined in the *Information Privacy Act 2009 (Qld),* in particular, the National Privacy Principles. These privacy principles include rules about the collection, use, quality, security and disclosure of personal information. They also provide conditions under which personal information may be transferred outside of Australia and rules regarding contracted service providers.
- The *Hospital and Health Boards Act 2011 (Qld)* gives effect to the principles and objectives of the national health system and hospital and health services. It applies to the collection of confidential information (including public and private hospital data) regarding users of the health system (Part 7 Confidentiality).
- The *Transplantation and Anatomy Act 1979 (Qld)* regulates the removal and use of tissue in certain circumstances including for the purpose of transplantation. The Transplantation and Anatomy Regulation 2004 (Qld) and Transplantation and Anatomy Act 1979 (Qld) - Explanatory Notes provides additional information relevant to the removal and use of tissue.

Metro South Health is also required to comply with Federal laws, codes and institutional requirements that exist in Australia:

- The *Privacy Act 1988 (Cth)* promotes the protection of the privacy of individuals and the handling of personal information. The Ten National Privacy Principles (NPPs) contained in Schedule 3 of the *Privacy Act 1988 (Cth)* regulates how large businesses, all health service providers and some small businesses and non-government organisations handle individuals' personal information. Additionally Guidelines have been approved under Section 95 and 95A of the *Privacy Act 1988 (Cth).*
- The *Therapeutic Goods Act 1989 (Cth)* details the legal requirements for the import, export, manufacture and supply of therapeutic goods in Australia. The meaning of a 'biological' is also included under Section 32A *Therapeutic Goods Act 1989 (Cth)*. This is particularly relevant when reviewing sections of the *Transplantation and Anatomy Act 1979 (Qld)* which pertains to research biorepositories.
- The *Gene Technology Act 2000 (Cth)* the Gene Technology Regulations 2001 (Cth) protects the health and safety of people and the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with Genetically Modified Organisms (GMO).
- The *Defence Trade Controls Act 2012 (Cth)* regulates dealings in certain goods, services and technologies.

1.2 Other Mandatory Requirements

Additionally, national guidelines exist to assist with implementing best practice principles including but not limited to:

- The National Health and Medical Research Council (NHMRC), 'National Statement on Ethical Conduct in Human Research' (2015) sets out specific guidelines regarding ethical review of proposed access to and use of biospecimens and associated personal information including pathways for low and high risk review.
- The National Health and Medical Research Council (NHMRC), 'Australian Code of the Responsible Conduct of Research' (2007) provides a framework for managing breaches of the Code and allegations of research misconduct, managing research data and materials, publishing and disseminating research findings, including proper attribution of authorship, conducting effective peer review and managing conflicts of interest. It also explains the responsibilities and rights of researchers if they witness research misconduct.
- The National Health and Medical Research Council (NHMRC), 'Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research' (2003) provides guidance to researchers and Human Research Ethics Committees (HRECs) on the complex considerations necessary in the conception, design and conduct of appropriate research in Aboriginal and Torres Strait Islander communities.
- The National Health and Medical Research Council (NHMRC), 'Australian code for the care and use of animals for scientific purposes 8th edition' (2013) promotes the ethical, humane and responsible care and use of animals used for scientific purposes.

- The National Health and Medical Research Council (NHMRC), 'Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals' (2008) promotes the wellbeing of animals used for scientific purposes and aims to minimise their experience of pain and distress.
- 'National Framework of Ethical Principles in Gene Technology' (2012) Gene Technology Ethics and Community Consultative Committee, is a set of principles which Australian scientists and researchers are expected to abide by when dealing with gene technology and Genetically Modified Organisms (GMOs) at all times. It is a means to encourage ethical conduct in gene technology – in particular where it relates to human health, the environment, genetically modified organisms and products.

Queensland professional codes of conduct also apply to the governance of research including but not limited to:

- The Queensland Biotechnology Code of Ethics, 'Update of the Code of Ethical Practice of Biotechnology in Queensland' (2006) outlines general principles pertaining to integrity, benefice and non-maleficence, respect for persons, respect for the law and system of government, justice and care and protection of animals.

1.3 Guidelines and Standards

Additionally, international guidelines exist to assist with implementing best practice principles including but not limited to:

- 'Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants' (2011), World Health Organisation (WHO), intends to provide guidance to the Human Research Ethics Committees (HRECs) on which organisations rely to review and oversee the ethical aspects of research, as well as to the researchers who design and carry out health research studies.
- 'International Ethical Guidelines for Biomedical Research Involving Human Subjects' (2002), prepared by the Council for International Organisations of Medical Sciences (CIOMS) in collaboration with the World Health Organisation (WHO) is designed to be of use in defining national policies on the ethics of biomedical research, applying ethical standards in local circumstances, and establishing or redefining adequate mechanisms for ethical review of research involving human subjects.
- 'International Ethical Guidelines for Epidemiological Studies' (2008), prepared by the Council for International Organisations of Medical Sciences (CIOMS) in collaboration with the World Health Organisation (WHO) addresses observational studies by noting the ways in which it may be appropriate to treat such research differently than interventional studies (for example, regarding informed consent).
- 'Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects ' (2001), World Medical Association, Bulletin of the World Health Organisation, is a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. Medical research involving human subjects includes research on identifiable human material or identifiable data.

- ‘Statement on Clinical Trials’ (2013), ‘Statement on Research Integrity’ (2015) and ‘Statement on Gene Editing’ (2016), the European Group on Ethics in Science and New Technologies (EGE) is an independent, multi-disciplinary body appointed by the President of the European Commission which advises on all aspects of Commission policies where ethical, societal and fundamental rights issues intersect with the development of science and new technologies. The EGE develops statements on the formulation of a code of conduct for gene editing, research integrity and clinical trials for projects funded by the European Commission.
- ‘Directive 2001/20/ec of the European Parliament and of the Council’ (2001) Official Journal of the European Communities, discusses the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.
- ‘Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research’ (2007) Council of Europe, builds on the principles embodied in the Oviedo Convention, with a view to protecting human rights and dignity in the specific field of biomedical research. Its purpose is to define and safeguard fundamental rights in biomedical research, in particular of those participating in research.
- ‘The ethics of research related to healthcare in developing countries’ (2000), Nuffield Council on Bioethics examines the ethical issues raised when research related to healthcare is carried out in developing countries and funded by sponsors from developed countries.
- ‘Singapore Statement on Research Integrity’ (2010) is intended to challenge governments, organisations and researchers to develop more comprehensive standards, codes and policies to promote research integrity both locally and on a global basis.
- The Australian Stock Exchange (ASX) Corporate Governance Council, ‘Principles of Good Corporate Governance and Best Practice Recommendations’ (2003) develops and delivers an industry-wide, supportable and supported framework for corporate governance.
- The Organisation for Economic Co-operation and Development (OECD), ‘G20/OECD Principles of Corporate Governance’ (2015) outlines principles to assist in evaluating and improving legal, regulatory and institutional frameworks for corporate governance.
- The Therapeutic Goods Administration (TGA) has adopted the ‘Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)’ which is internationally accepted standard for the designing, conducting, recording and reporting of clinical trials. The ‘Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - Annotated with TGA comments’ replaces the Guidelines for Good Clinical Research Practice (GCRP) in Australia, but at the same time has recognised that some elements are, by necessity, overridden by the National Statement (and therefore not adopted) and that others require explanation in terms of 'local regulatory requirements'.

2.0 Metro South Health Research Management Compliance Framework

The Metro South Health Research Management Compliance Framework (Attachment 2) illustrates a quality system by which research in Metro South Health is directed and managed. It also illustrates effective governance and tools for addressing governance risk, oversight and management responsibilities. The Compliance Framework provides structure to research Policies, Procedures, Research Protocols and Standard Operating Procedures (SOPs) and also assists in clarifying roles and responsibilities in fulfilling Metro South Health objectives from a corporate governance perspective.

Metro South Health employees must all abide by operational governance and quality assurance Procedures contained within the Metro South Health Research Management Compliance Framework.

The Compliance Framework influences how the objectives of Metro South Health are set and achieved, how risk is monitored and assessed and how performance is optimised.

The following documents are included as part of the Metro South Health Research Management Compliance Framework:

- Policy: The Metro South Health Research Management Policy has been issued to influence and reflect Metro South Health's strategic direction pertaining to research conducted in Metro South Health.
- Procedure: A series of Procedures have been developed which describe the process for a particular research practices. Metro South Health Procedures also include guiding principles to assist in establishing the direction and application for each required process.
- Participant Information and Consent Form (PICF): The Metro South Health Participant Information Consent Form provides information such as what the process involves, what to expect before and after the procedure, the risks and benefits and any alternative options that maybe available to the participant. The Metro South Health Participant Information Consent Form is attached to the Biospecimen Ethics and Participant Information and Consent Form Procedure (PR2017/115).

The Centres for Health Research is responsible for providing oversight and maintaining the Metro South Health Research Management Compliance Framework. Principles outlining Metro South Health's expectations relating to the conduct of research are provided in the Ethical and Scientific Review of Human Research Procedure (PR2017/113) and Research Complaints and Misconduct Procedure (PR2017/124).

3.0 Metro South Health Research Management Governance/Committee Structure

The Metro South Health Research Management Governance/Committee Structure and the Metro South Health Research Management Compliance Framework are administered in the spirit of:

- the Ten Essential Principles outlined in the 'Principles of Good Corporate Governance and Best Practice' published by Australian Stock Exchange (ASX) Corporate Governance Council; and
- the Six Essential Principles of the 'OECD Principles of Corporate Governance'.

Metro South Health considers management as dealing with the day-to-day activities of research activities and projects, while corporate governance involves the provision of strategic advisory and oversight of matters relating to research in Metro South Health and within partner institutions. Please see Attachment 3 - Metro South Health Research Management Governance/Committee Structure for a description of this structure.

3.1 Metro South Health Research Council

Metro South Health's Vision is to be renowned worldwide for excellence in healthcare, teaching and research. The Metro South Health Research Council is the peak advisory body to enable and facilitate the achievement of Metro South Health's Vision in relation to research and Research Management Values

The Executive Director, PAH-QEII Health Network, Metro South Health has been delegated the portfolio for 'Research' in Metro South Health and has responsibility for making Health Service-wide decisions which effect research activities and partnerships throughout Metro South Health.

The Metro South Health Research Council:

- Provides strategic advice and makes recommendations to the Metro South Health Research Portfolio Leader (Executive Director, PAH-QEII Health Network), to enable and facilitate the achievement of Metro South Health's Vision in relation to research;
- Identifies and prioritises Metro South Health's research goals and strategies;
- Drives the development of strategies that place research as an integral part of health care planning and delivery;
- Advocates for, and facilitates the implementation of research strategies that bring excellence in health care for Metro South Health;
- Influences and informs Metro South Health executive in relation to opportunities, issues and risks that are relevant to research; and
- Ensures congruence between clinical, corporate and research governance.

The scope includes:

- Funding and business administration of research;
- Assessment and determination of research priorities;
- Requirements that build research capacity, improve standards and increase productivity;
- Embedding of research as core business in clinical service departments;
- Commercialisation of research discoveries;
- Strengthening collaboration and partnerships with Metro South Health affiliated universities; and
- Oversight of the Metro South Health Research Committee.

Membership is drawn from Metro South Health, the Translational Research Institute (TRI), Princess Alexandra (PA) Research Foundation, affiliated university's and appropriate external advisors(s). Please see Attachment 4 for the Metro South Health Research Council Terms of Reference.

3.2 Metro South Health Research Committee

The Metro South Health Research Committee provides advice to the Centres for Health Research management, to enable and facilitate the achievement of Metro South Health's Vision in relation to research and Research Management Values.

The Metro South Health Research Committee aims to foster research (clinical and management) and to promote and facilitate excellence in research within Metro South Health. The Metro South Health Research Committee functions to oversee the provision of research support, including administration of peer-review grant support.

The Metro South Health Research Committee provides advice to assist the Centres for Health Research, in the:

- Provision of operational support to research and researchers within Metro South Health;
- Oversight and administration of the Metro South Health Research Support Scheme;
- Development of procedures for the appropriate management of research activities and research infrastructure across Metro South Health;
- Promotion of specific initiatives to facilitate research in Metro South Health;
- Implementation of research strategies to ensure all research personnel use fair, equitable and transparent mechanisms, and protect the interests of patients/participants and the community;
- Monitoring of, and maintenance of compliance with the Metro South Health Research Management Compliance Framework;
- Management of research-related opportunities, conflicts of interest, issues, risks, and disputes.

Membership is drawn from Metro South Health, the Translational Research Institute (TRI), PA Research Foundation, affiliated university's and appropriate external advisors(s).

Please see Attachment 5 for the Metro South Health Research Committee Terms of Reference.

3.3 Biosafety

Within Metro South Health laboratory work health and safety, general biosafety and biosecurity issues are discussed at relevant work health and safety committees. Specific concerns or matters pertaining to the storage, processing or use of specific biospecimens may be raised with the Metro South Health biosafety representative on the relevant work health and safety committee. Work health and safety committees may discuss specific Metro South Health biosafety or biosecurity Standard Operating Procedures (SOPs) and assist in the development and amendment of procedural documents.

Examples of relevant work health and safety committees include:

- Princess Alexandra Hospital Work Health and Safety Committee discusses matters which pertain specifically Princess Alexandra Hospital biosafety matters; and
- Translational Research Institute Work Health and Safety Committee discusses matters which pertain specifically to laboratory biosafety matters within the Translational Research Institute facilities safety@TRI.edu.au.

Metro South Health employees also have access to the University of Queensland Institutional Biosafety Committee (UQ IBC) which is able to assess and approve Genetically Modified Organisms (GMOs) research proposals. Please see Specific Human and Animal Ethical and Scientific Review Requirements Procedure (PR2017/114) for more information.

3.0 Risk Management

Metro South Health is committed to the management of its compliance obligations as an integral and embedded part of all its activities. Effective management of Metro South Health's compliance obligations, through a risk-based approach, ensures that the Health Service's strategic direction and corporate objectives are pursued in a lawful and sustainable manner.

Consistent with principles of good governance, Metro South Health has a responsibility to identify and comply with all relevant laws, regulations and other externally imposed requirements, e.g. codes of relevant industry or regulatory bodies. Metro South Health achieves this through the implementation of Metro South Health's Risk Management Policy and Integrated Risk Management Framework (Metro South Health staff access only) which sets out process for risk management.

The Metro South Health Risk Management Policy and Integrated Risk Management Framework applies to all Metro South Health research activities to which external compliance obligations are relevant.

At the time of occurrence, all incidents of non-compliance must be assessed. Where a non-compliance incident is assessed as having moderate or major consequences (as described in the Integrated Risk Management Framework) the issue must be reported to the Centres for Health Research. The Centres for Health Research will determine if adjustments to research management compliance Procedures and risk treatments are required, and whether an ad hoc report should be made to the Metro South Health Audit and Risk Management Committee.

The Centres for Health Research is also required to oversee and monitor any remedial action or adjustments to compliance risk management activities (including Policies, Procedures and processes) which may be required in light of the non-compliance incident.

A summary of all incidents of non-compliance must be included in annual reporting.

Risk assessment and monitoring for industry sponsored and investigator initiated research will include review by the Human Research Ethics Committee (HREC) of local Serious Adverse Event (SAE)/Suspected Unexpected Serious Adverse Reaction (SUSAR) Reports and Data Safety and Monitoring Board (DSMB) reports. The Principal Investigator (single site research) or Coordinating Principal Investigator (multi-centre research) will coordinate the processing of these documents to the approving HREC.

If a DSMB has not been formed for the submitted research project, the Principal Investigator must stipulate in their HREC application whether an interim safety analysis is required for the research project. If it is not required, then the Principal Investigator must provide a rationale.

In the absence of a DSMB the Principal Investigator must outline to the HREC the process for ensuring adequate independent monitoring of efficacy and safety for the duration of their research project.

For investigator initiated research projects, a risk assessment by the Principal Investigator must be undertaken and comply with the Metro South Health Risk Management Policy.

In the instance whereby, Metro South Health is requested to act as a sponsor for an investigator initiated clinical trial, the Principal Investigator must submit a risk benefit letter to the Metro South Health Research Governance Office/r for Metro South Health Executive review and sign-off.

Risk assessment and monitoring for industry sponsored research may include periodical sponsor monitoring, inspections by regulatory bodies (both national and international) as well as sponsor initiated internal audits. Please see Research Governance (Site Specific Assessment) Procedure (PR2017/116) for more information.

All relevant Metro South Health employees must comply with the requests of an appointed monitoring body. Risk assessment and monitoring risk assessment for investigator initiated research projects may include inspections by the designated Metro South Health Research Monitoring Office/r. All relevant Metro South Health employees must comply with requests from the Metro South Health Research Monitoring Office/r. Please see Research Governance (Monitoring) Procedure (PR2017/117) for more information.