Clinical Research Facility (CRF)

PURPOSE

This procedure aims to describe processes to inform and guide users in the operation of the Clinical Research Facility (CRF) in Metro South Health (MSH).

OUTCOME

The intended outcome of this procedure is to:

- Enable consistency in the application of principles and procedures within the CRF.
- Ensure that all research undertaken in the CRF is conducted in a manner consistent with national frameworks for ethical clearance and Site Specific Assessment authorisation and in compliance with relevant legislation, policies, directives and standards.
- Ensure the CRF is operated in compliance with; relevant agreements (i.e. Clinical Research Facility (R-Wing) Services Agreement, MSH Research Policy Framework, Translational Research Institute (TRI) and Princess Alexandra Hospital (PAH) policies and procedures.
- Uphold principles outlined within Attachment 1: Clinical Research Facility Handbook.

SCOPE

This procedure applies to all persons involved in clinical research conducted at the CRF. It is the responsibility of institutions, facilities, departments, clinicians and researchers to be aware of and apply the principles and processes outlined within this procedure in conjunction with other relevant guidelines, standards, general and specific legal obligations (statutory or otherwise) as in place from time-to-time. Failure to comply with this procedure may constitute professional or research misconduct on the part of the responsible individual.

PROCEDURE

1. GOVERNANCE, OVERSIGHT AND MANAGEMENT

1.1 Clinical Research Facility (R-Wing) Services Agreement

- MSH operates the CRF on behalf of and in collaboration with the TRI in accordance with the Clinical Research Facility (R-Wing) Services Agreement.

1.2 Oversight and management

- Metro South Research provides oversight of and administrative responsibility for the CRF. The CRF Manager is appointed by Metro South Research to provide advanced management and leadership skills in the day-to-day operations and activities of the CRF.
- The CRF Manager ensures compliance with the MSH Research Policy Framework, CRF procedures and work instructions and TRI policies for research projects conducted in the CRF.
- The CRF Manager is accountable to the:

    - Executive Director, Metro South Research, MSH
    - Director, Research Development, Metro South Research, MSH
- For more information see Attachment 1: CRF Handbook.

1.3 CRF Committee and CRF User Committee Structure

- The TRI CRF Committee is responsible for ensuring appropriate administrative and governance mechanisms are in place for the CRF. The TRI CRF Committee is accountable to the TRI Chief Executive Officer (CEO).
- The CRF User Committee includes members/representatives from the greater CRF user base. Their role is to consult, provide guidance and facilitate communication regarding activity in the CRF and relating to the broader clinical research community.

1.4 Compliance

- MSH and PAH policies and procedures relating to the CRF will be developed and maintained as per MSH policy PL2023-92 Research and MSH procedure PR2023-01 Policy document management.
- All PAH policies and procedures relating to patient care and management must be complied with and supersede any other TRI or CRF policies or procedure relating to patient care. TRI policies and procedures relating to the CRF are established and maintained as per TRI processes which are not outlined in this document.
- CRF employee training and management of training records will be maintained MSH Human Resources and the CRF Manager.
- The CRF Manager to ensure that all CRF documentation is stored securely and confidentially.

2. APPLICATION AND USE

- To be eligible to use the CRF, the Principal Investigator must be employed by or credentialled and authorised by a TRI member institute. TRI member institutes include:
    - MSH
    - University of Queensland (UQ)
    - Queensland University of Technology (QUT)
    - Mater Research
- Applications to use the CRF from other research sponsors will also be considered, where appropriate arrangements can be established.
- Refer to MSH work instruction WI2024-335 CRF application and use for more information.

3. PARTICIPANT ADMISSION, SUPERVISION AND CLINICAL MANAGEMENT

- Researchers, CRF users and staff must comply with CRF participant admission, supervision and clinical management processes to ensure research participant safety and compliance with relevant MSH and TRI administrative requirements.

- Refer to MSH work instruction WI2024-336 CRF participant admission, supervision and clinical management for more information.

4. INVESTIGATIONAL PRODUCT MANAGEMENT AND ADMINISTRATION

- Researchers, CRF users and staff must comply with CRF investigational product management and administration processes to ensure the safe conduct of clinical research in compliance with relevant legislation and procedures, sponsor and regulatory requirements, and the principles of Good Clinical Practice (GCP).
- Refer to MSH work instruction WI2024-337 CRF investigational product management and administration for more information.

5. ADVERSE EVENT AND CLINICAL INCIDENT REPORTING

- Researchers, CRF users and staff must comply with CRF safety reporting and clinical incident reporting processes to ensure the research is conducted and reported according to sponsor and regulatory requirements, and to ensure appropriate oversight and analysis of clinical incidents which may occur.
- Refer to MSH work instruction WI2024-338 CRF adverse event and clinical incident reporting for more information.

6. LABORATORY AND ALARM MANAGEMENT

- Researchers, CRF users and staff must comply with CRF laboratory and alarm management processes to ensure safe work practices and equipment compliance, and appropriate processing, storage and monitoring for clinical trial samples and Investigational Product (IP) managed in the CRF.
- Refer to MSH work instruction WI2024-339 CRF laboratory alarm response for more information.

7. ARCHIVING OF CLINICAL TRIAL DOCUMENTS

- It is the responsibility of the Principal Investigator (PI) to ensure appropriate storage of clinical trial records in accordance with GCP and sponsor requirements.
- Clinical trial records (e.g., Investigator Site Files) can be stored in the CRF on application from the Principal Investigator.
- Refer to MSH work instruction WI2024-340 CRF archiving of clinical trial documents for more information.

RESPONSIBILITIES

Position	Responsibility	Audit criteria
MSH Executive Management	• Oversee the operation of the CRF on behalf of and in collaboration with the TRI in accordance with the Clinical Research Facility (R Wing) - Services Agreement.	• Clinical Research Facility (R Wing) - Services Agreement

	• Implement MSH policies and procedures which upholds legislative, NHMRC, GCP, PAH and TRI requirements. • Provide strategic oversight of the CRF, to ensure compliance with PAH and TRI policies and procedures.	
Metro South Research	• Responsible for the day-to-day operation and management of the CRF (in collaboration with TRI). • Develop, disseminate, implement, review and update MSH research policy and procedures.	• N/A
TRI and TRI CRF Committee	• As the lessee of the CRF, the TRI works collaboratively with Metro South Research in the operation and management of the CRF.	• Terms of Reference
CRF Manager	• Responsible for the day-to-day operations of the CRF and ensures compliance with the CRF policy and procedures for research projects conducted in the CRF.	• N/A
Principal investigators/lead researchers	• Principal investigators/lead researchers retain overall responsibility for the conduct of their research at the CRF in accordance with ethical clearance, research governance authorisation and the principles of GCP. • Ensure that the research project complies with appropriate legal, regulatory and guidance requirements applicable to their research project.	• CRF Application Form
Researchers/CRF users	• Share responsibility and accountability for research being conducted according to appropriate regulatory, ethical and scientific standards. • Comply with applicable TRI, MSH and PAH policies and procedures. • Work in accordance with their scope of practice and comply with their relevant professional standards.	• CRF Application Form

DEFINITIONS

Term	Definition
Research	**Clinical research** - A type of scientific research that is conducted with human participants to understand, diagnose, prevent, or treat medical conditions or diseases. It involves the study of human biology, physiology, pharmacology, and psychology, among other disciplines, in order to improve our understanding of health and disease. Clinical research can take many forms, including observational studies, randomised controlled trials, and retrospective analyses of patient data. In some cases, clinical research involves testing new drugs, medical devices, or other interventions in human subjects to evaluate their safety and efficacy. Clinical research is typically conducted in a controlled environment, such as a hospital, and is overseen by a team of researchers, including physicians, nurses, and other healthcare professionals. The goal of clinical research is to generate new knowledge that can improve patient outcomes, inform clinical practice, and advance medical science. **Non-clinical research** - The concept of research is broad and includes the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies, inventions and understandings. This could include synthesis and analysis of previous research to the extent that it is new and creative.
Research Policy Framework	A framework inclusive of policy, procedures, work instructions, guidelines and supporting documents, aligned to MSH research practices.
Policy framework documents	Policy documents include policies, procedures, work instructions and guidelines – PR2013-01 Policy Document Management.

RELATED AND SUPPORTING DOCUMENTS

Legislation and other Authority	**Legislation (as updated and replaced from time to time)** • *Australian Research Council Act 2001* (Cth) • *Hospital and Health Boards Act 2011* (Qld) • *Information Privacy Act 2009* (Qld) • *Financial Accountability Act 2009* (Qld) • *National Health and Medical Research Council Act 1992* (Cth) • *Public Health Act 2005* (Qld) • *Public Sector Act 2022* (Qld) • *Public Sector Ethics Act 1994* (Qld) • *Research Involving Human Embryos Act 2002* (Cth) • *Therapeutic Goods Act 1989* (Cth)

	Regulations • Financial Accountability Regulation 2009 (Qld) • Financial and Performance Management Standard 2009 (Qld) • Hospital and Health Boards Regulation 2012 (Qld) • Public Health Regulation 2018 (Qld) • Therapeutic Goods (Medical Devices) Regulations 2002 (Cth) • Therapeutic Goods Regulations 1990 (Cth) **National Health and Medical Research Council (NHMRC)** • National Statement on Ethical Conduct in Human Research 2023 • Australian Code for the Responsible Conduct of Human Research **Therapeutic Goods Administration** • Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2) **Department of Health** • Health Service Directive: Research Ethics and Governance Directive QH-HSD-035:2023 • Research Management Guideline: external funding and infrastructure support QH-GDL-013-1:2022 • Research Management Policy QH-POL-013:2022 • Research Management Standard QH-IMP-013:1:2022 • Researcher User Guide - Queensland Health • Public Service Code of Conduct

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

Supporting documents	**Metro South Health** • PR2023-411 Research excellence • PR2023-412 Research support and management • PR2023-413 Research administration and compliance • Metro South Health Research Strategy • Finance Management Practice Manual (FMPM) • Contract Management Framework • MSH Risk Management Framework • WI2024-335 CRF application and use • WI2024-336 CRF participant admission, supervision and clinical management

	• WI2024-337 CRF investigational product management and administration • WI2024-338 CRF adverse event and clinical incident reporting • WI2024-339 CRF laboratory alarm response • WI2024-340 CRF archiving of clinical trial documents **Attachment** • Attachment 1: Clinical Research Facility Handbook

HUMAN RIGHTS ACT 2019

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

CONSEQUENCE CATEGORY

Consequence category	Health Service Delivery
Level of consequence	Moderate
What will be monitored	Compliance with CRF procedures
How (method or tool)	• Clinical Research Facility (R Wing) - Services Agreement • Terms of Reference
Frequency	Life cycle of the Services Agreement
Responsible officer	Executive Director, Metro South Research
Reporting to	Metro South Health Research Council and TRI CRF Committee

PROCEDURE DETAILS

Procedure Name	Clinical Research Facility
Procedure Number	PR2024-453
Current Version	1.0
Keywords	Clinical Research Facility, Clinical Trial, research project, Translational Research Institute, Princess Alexandra Hospital
Primary Policy Reference	PL2023-92 Research Policy

Risk Consequence Rating	Moderate
Executive Sponsor	Chief People, Engagement and Research Officer
Endorsing Committee / Authority	Metro South Health Research Council
Document Author	CRF Manager, Metro South Research
Next Review Date	June 2027

REVIEW HISTORY

Version	Approval date	Effective from	Authority	Comment
1.0	28/06/2024	5/07/2024	Chief People, Engagement and Research Officer	New document