Clinical Research Facility participant admission, supervision and clinical management

PURPOSE

This work instruction describes processes for participant admission, supervision, and clinical management in the Clinical Research Facility (CRF), located at the Princess Alexandra Hospital (PAH) and operated by Metro South Health (MSH) on behalf of the Translational Research Institute (TRI).

OUTCOME

This work instruction aims to:

- Ensure a consistent approach is applied for the admission, supervision and clinical management of CRF participants to ensure participant safety and compliance with relevant PAH, CRF, MSH and TRI requirements.
- Maintain the highest standards and practices in the operation of the CRF by ensuring that responsible personnel abide by; legislative requirements, principles of Good Clinical Practice (GCP) and PAH, TRI and MSH policies and procedures.

This work instruction outlines processes described in MSH procedure PR2024-453 Clinical Research Facility (CRF) and upholds principles outlined within the Clinical Research Facility Handbook.

SCOPE

This work instruction applies to all eligible users of the CRF, and all MSH & TRI employees involved in clinical research conducted at the CRF.

WORK INSTRUCTION

1. STEP 1: PARTICIPANT ADMISSION

1.1 Application and research protocol review

- All applications to the CRF will be assessed to determine if research participants require registration as MSH patients to attend the CRF for visits.
    - Clinical trials involving MSH patients will require admission using an outpatient encounter on the integrated electronic Medical Record (ieMR) or an in-patient encounter (if applicable) to the relevant PAH Division/Department (e.g., Division of Cancer Services).
    - Research projects suitable for a Site-Specific Assessment (SSA) waiver (research involving non-MSH patients with minimal MSH resource impact) and/or healthy volunteer studies may not require admission on ieMR however participants will be required to check-in for the duration of the study visit using the TRI electronic log-in system.

    - Refer to MSH work instruction WI2023-301 Site specific assessment for more information.
- CRF admission procedures will depend on the nature of the research project or clinical trial. The CRF Manager can advise the Principal Investigator/lead researcher if this is required and what the appropriate process is.
- Refer to MSH work instruction WI2024-335 CRF application and use for more information regarding the application process.

1.2 Presentation at the CRF

- The participant is advised by the research team of their appointment details and presents to the CRF Reception Desk.
- The CRF Administration Officer must confirm the participant's identity in compliance with the PAH procedure Patient Identification and Procedure Matching (01538).
- If the participant does not require admission using ieMR the participant will be asked to confirm their identity to match against the details provided by the Principal Investigator/lead researcher when booking the appointment.

1.3 Admission

- The CRF Administration Officer will admit the participant as determined during trial feasibility or request that the patient login using the TRI electronic log-in system.
- The CRF Administration Officer will then contact the principal investigator/lead researcher (or delegate) to notify of the participant's arrival to the CRF.

1.4 Participant identification

- Participants receiving an investigational product or having a procedure performed as part of their clinical visit will require a PAH arm band and identification checks as per PAH Procedure: Patient Identification and Procedure Matching (01538).
- Refer to MSH work instruction WI2024-337 CRF investigational product management and administration for more information.

1.5 Supervision

- The Principal Investigator/lead researcher (or delegate) is responsible for supervision of the participant while in the CRF.
- A minimum of two clinical staff competent in PAH emergency response procedures must be available in the CRF when a participant is present.
- CRF staff can assist with participant visits and supervision as required.

1.6 Completion

- On completion of the visit, the participant is required to notify the CRF Administration Officer who will discharge the patient or request that the participant check-out using the TRI electronic log-in system.

2. STEP 2: CLINICAL MANAGEMENT OF UNWELL PARTICIPANTS IN THE CRF

- If a research participant becomes clinically unwell with non-life-threatening symptoms - which do not meet the criteria for a medical emergency as per PAH Procedure PAH01346, whilst visiting the CRF, the following process must be followed.

2.1 Perform all immediate tasks

- Clinical staff caring for the participant are to perform all immediate tasks required to ensure the safety of the participant within their scope of practice.
- The CRF Manager and CRF staff must be notified to assist as required.

2.2 Clinical review

- The designated medical officer from the research team must be contacted by the researcher/CRF staff member and asked to review the participant in the CRF as soon as possible.
- If the designated medical officer is available to review the subject, appropriate care will be provided under the direction of the designated medical officer.
- If the designated medical officer is unavailable to review the participant in a timely manner (or a designated medical officer is not assigned to the research project) and the participant is deemed significantly unwell, they will be referred to the Emergency Department (ED) for assessment and management.

2.3 Transfer

- The Computer Assisted Radio Personnel System (CARPS) should be used for requesting a wards person and wheelchair/trolley to transfer the participant to the ED.
- CRF staff can assist researchers with this task if required.
- Participants must be escorted to the ED by the designated medical officer, CRF Nurse or researcher.
- A clinical handover must be provided to ED staff.

2.4 Documentation

- Staff involved in the management of the unwell participant are required to ensure comprehensive documentation is completed to document the event in the participant’s medical record and as required to comply with sponsor and regulatory requirements for Adverse Event (AE) reporting.

2.5 Adverse Events (AE) and clinical incidents

- AEs and clinical incidents must be reported as per MSH work instruction WI2024-338 CRF adverse event and clinical incident reporting.

3. STEP 3: MEDICAL EMERGENCY

- In the event of a medical emergency the PAH Procedure: Code Blue - Medical Emergency (Emergency Response System: Medical Emergency Team and Code Blue Team calls) - (01346) must be followed.

- ‘Staff assist’ buttons are present in all clinical areas of the CRF which can be used by staff to request immediate assistance when required.
- Staff and users of the CRF will be made aware of the staff assist buttons during induction to the CRF.
    - Refer to MSH work instruction WI2024-335 CRF application and use for more information.
- CRF staff will respond immediately to assist in a medical emergency.
- Direct access for the Medical Emergency and Code Blue teams is via the double doors at the end of the clinical corridor on Level 4.
- Medical Emergency and Code Blue teams have swipe access to the CRF through this entrance, but an emergency door release is also present on Level 4 which when activated will release the door lock for 20 minutes to ensure unobstructed access to the facility.
- For medical emergencies on Level 5 the Medical Emergency and Code Blue teams will use the service lifts on Level 4 to access Level 5.
- The staff assist buttons located on level 5 will alert staff on Level 4 that assistance is required when activated.

RESPONSIBILITIES

Position	Responsibility	Audit criteria
TRI and TRI CRF Committee	As the lessee the CRF, the TRI works collaboratively with Metro South Research in implementing the CRF participant management procedures.	• N/A
CRF Manager	Responsible for the day-to-day operations of the CRF and ensures compliance with the CRF procedures and work instructions for research projects conducted in the CRF.	• N/A
Principal Investigators (PIs)/lead researchers	Retains overall responsibility for the conduct of their research at the CRF in accordance with the principles of GCP. Ensures that the research project complies with appropriate legal, regulatory and guidance requirements applicable to their research project. Ensures the safety and rights of participants is paramount in all research activities.	• N/A

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.	• N/A

DEFINITIONS

Term	Definition
Clinical incident	• Any event or circumstance which has actually or could potentially lead to unintended and/or unnecessary mental or physical harm to a patient/participant.
Good Clinical Practice (GCP)	• A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected.
ieMR	• Integrated Electronic Medical Record (PAH Patient electronic Medical Record)
RiskMan	• Electronic information system to collect, integrate, manage and report clinical incidents, workplace incidents, consumer feedback and risk.
Scope of clinical practice (SoCP)	• The extent of an individual health professional's approved clinical practice within an organisation based on the individual's credentials, competence, performance and professional suitability and the needs and capability of the organisation to support the health professional's SoCP.

RELATED AND SUPPORTING DOCUMENTS

Legislation and other Authority	**Legislation (as updated and replaced from time to time)** • *Hospital and Health Boards Act 2011 (Qld)* • *Human Rights Act 2019 (Qld)* • *Public Health Act 2005 (Qld)* • *Therapeutic Goods Act 1989 (Cth)* **Regulations**

	• Therapeutic Good (Medical Devices) Regulations 2002 (Cth) • Therapeutic Goods Regulations 1990 (Cth) **Other authority** • National Statement on Ethical Conduct in Human Research 2023 • Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2)

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	**Policy** • PL2015-41 Clinical governance • PL2014-10 Credentialing and Scope of Clinical Practice for medical and dental practitioners, allied Health professionals, advanced practice nurses & Midwives • PL2018- 62 Risk management **Procedures** • PR2014-13 Credentialing and Scope of Clinical Practice for medical and dental practitioners • PR2018-97 Risk management • PR2023-411 Research excellence • PR2023-412 Research support and management • PR2023-413 Research administration and compliance • PAH 01538 Patient identification and procedure matching **Work instructions** • WI2024-335 CRF application and use • 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

HUMAN RIGHTS ACT 2019

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

WORK INSTRUCTION DETAILS

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V1.0	28/06/2024	3/07/2024	Executive Director, Metro South Research	• New MSH work instruction adapted from rescinded PR2021-240.