Clinical Research Facility application and use

PURPOSE

This work instruction describes the processes relating to use of the Translational Research Institute (TRI) Clinical Research Facility (CRF) including the application process, booking CRF facilities, CRF induction requirements and equipment and storage procedures.

OUTCOME

The work instruction outlines the responsibilities of facilities, departments, clinicians, and researchers when requesting to utilise the CRF as part of their research. 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 employees involved in clinical research conducted at the CRF.

WORK INSTRUCTION

1. STEP 1: CRF APPLICATION PROCESS

1.1 Submit the CRF application form

- Researchers are encouraged to contact the CRF Manager via email CRF@health.qld.gov.au or telephone (07) 3176 8708 to discuss an application prior to submission, to ensure that the research project is suitable for the CRF and all required facilities are available.
- The Principal Investigator/lead researcher submits a completed Attachment 1: CRF application form to the CRF Manager by emailing the application form and all required supporting documents to CRF@health.qld.gov.au
    - Failure to provide all requested documents will result in the application being delayed or declined.
- Applications and approval to use the CRF must be reflected in the Site Specific Assessment (SSA) authorisation for research projects in accordance with MSH work instruction WI2023-301 Site specific assessment.
- The Principal Investigator/lead researcher is required to agree with the TRI CRF schedules as listed within Attachment 1: CRF application form.
- Applications from external (non-TRI member) applicants to use the CRF will be considered by the CRF Manager and escalated to the TRI CRF Committee for further action if required.

1.2 Quote for use

- Charges apply for the use of the CRF. The CRF Manager can provide Principal Investigators/lead researchers with a quote for use of the CRF on application.
- The CRF Manager will advise the researcher of user charges and invoicing processes prior to processing the application and use of the CRF.
- Please refer to the ‘User Charges and invoicing’ outlined below for further information.

1.3 Credentialing

- CRF users with a current MSH employment contract do not require further credentialing by the CRF.
- Medical practitioners who are not MSH employees must apply for credentialing and scope of clinical practice as per MSH policy PL2014-10 Credentialing and defining the scope of clinical practice.
- A medical researcher who is being directly supervised during the conduct of a research procedure by an appropriate MSH employee or clinical researcher with credentialing approval from the Princess Alexandra Hospital (PAH) does not require independent credentialing approval.
- The credentialing of non-medical research staff is the responsibility of the TRI member organisation that has employed the non-medical research staff. The CRF is not responsible for the credentialing of these staff. The CRF Manager may however request evidence of qualifications and professional registrations relevant to their application.
- If a non-TRI member researcher or company applies to use the CRF, the research staff would be required to provide the CRF Manager with evidence of qualifications and professional registrations relevant to their application and appropriate credentialing arrangements established.

1.4 Feasibility

- The CRF Manager will review the application and complete a feasibility assessment to ensure that the application meets CRF eligibility criteria and that adequate resources are available to facilitate the research project.
- The CRF Manager will ensure that all requirements, as per the CRF feasibility review, are completed to ensure the safe conduct of research in the CRF.

1.5 Risk assessment

- The CRF Manager will perform a risk assessment for all CRF applications as part of the feasibility process using Attachment 2: CRF Risk Assessment Matrix.
- Minimal, low and intermediate risk trials have been approved to proceed in the CRF by the TRI CRF Committee, therefore the CRF Manager can approve research projects which meet these approved risk categories.
- High risk projects require individual approval by the TRI CRF Committee and Executive Director, Metro South Research with additional criteria as outlined in the CRF Risk Matrix.
- Extremely high-risk projects as per the CRF Risk Assessment Matrix are not suitable for the CRF.

1.6 Application outcome

- The CRF Manager will notify the Principal Investigator/lead researcher of the outcome of the application.
- Successful applications can commence research project activity in the CRF only when notified by the CRF Manager.

1.7 Updated Documents

- The Principal Investigator/lead researcher is responsible for providing all new and amended documents pertaining to the safe conduct of their research project to the CRF Manager in a timely manner throughout the life of the project (e.g. approved protocol amendments).

2. STEP 2: CRF USE PROCESS

2.1 CRF induction and swipe card access

- Following approval, all researchers who use the CRF for approved research projects are required to complete a CRF induction and will be granted swipe card access restricted to appropriate areas of the CRF. Persons requiring access to the CRF can apply to the CRF Manager via email CRF@health.qld.gov.au or telephone 3176 8708.
    - An online induction may also be suitable for certain applicants requiring limited access to the CRF (e.g. short visits during business hours without primary care responsibilities for participants).
    - Further information is available from the CRF manager as required.
- The CRF Manager (or delegate) and the applicant will arrange a mutually convenient time to complete the CRF induction.
    - The CRF conducts a routine CRF induction once per week and inductees are encouraged to attend this induction time in the first instance.
- Once the CRF induction is complete the inductee and CRF Manager will complete the TRI CRF Access Request Form.
- The CRF Administration Officer will submit the application to TRI Security.
- When TRI Security has confirmed that access has been granted the CRF Administration Officer will notify the applicant via email.
- Applicants who use a PAH or UQ ID badge are required to present to the TRI Security office to activate their ID access.
- Existing TRI ID badges are updated without further action required by the applicant.
- Completed TRI CRF Access Request Forms are filed by the CRF Administration Officer with the CRF induction training records.
- The CRF induction manual is provided to all inductees.

2.2 CRF bookings

- Requests to book CRF participant visits, use of storage space, meeting rooms and office space must be emailed to the CRF Administration Officer via CRF@health.qld.gov.au who will confirm once the booking has been completed.
- The researcher must provide the following information when booking:
    - study name
    - date
    - commencement time
    - visit identifier (e.g., Cycle 1 Day 1, as described in the quote)
    - total time required for booking (including set-up and clean-up time)
    - CRF facilities required (e.g., CRF Nurse, investigation room, recliner chair).
- The CRF Administration Officer will complete the booking using the centralised TRI CRF booking system: PPMS. The reservation is confirmed by return email to the researcher.
- CRF users are responsible for ensuring the facility is cleaned following use and any equipment is properly stored.
- Any changes or cancellations to a booking must be notified to the CRF Administration Officer at CRF@health.qld.gov.au with reasonable notice.
- CRF meeting rooms and office/desk space may also be booked by CRF users, please contact CRF Administration Officer at CRF@health.qld.gov.au for more information.

2.3 Out-of-hours access

- To apply for out-of-hours access for participant visits without CRF nursing support the following must occur:
    - The Principal Investigator/lead researcher must discuss any requirements to perform participant visits outside of hours with the CRF Manager.
    - If adequate staff and resources can be provided by the investigating research team to safely conduct participant visits, the Principal Investigator/lead researcher and identified research staff must complete Attachment 3: CRF request for out-of-hours access for participant visits form and submit it to the CRF Manager for review.
    - The CRF Manager will request evidence of relevant qualifications and competency in Basic Life Support (BLS).
    - Non-MSH staff that require training to be competent in PAH emergency response procedures must complete the relevant training on MSHLearn, MSH's learning management system.
        - Access to MSHLearn can be facilitated by the CRF Manager on request.
    - Individuals with external BLS training will be required to undergo a practical assessment by a MSH BLS Assessor. This can be arranged via the CRF Manager.

- The CRF Manager and the nominated research staff will complete an Out-of-hours induction to ensure that the research staff are aware of all policies, procedures and requirements for out-of-hours participant visits.
- The CRF Manager will notify the Principal Investigator/lead researcher and research staff of approval if granted. The completed Attachment 3: CRF request for out-of-hours access for participant visits form, evidence of qualifications and induction paperwork will be filed in the applicable research project folder on the CRF electronic drive.

2.4 CRF and investigator owned equipment

- The CRF can provide Principal Investigators/lead researchers with shared equipment to conduct clinical research in the CRF which is appropriately maintained in accordance with PAH and TRI policies and procedures.
- The use and storage of investigator owned equipment is available on application to the CRF Manager and must comply with PAH standards.
- Principal Investigators/lead researchers are responsible for the maintenance of investigator owned equipment.

2.5 CRF storage

- The CRF can provide dedicated storage spaces (lockable cupboards, lockable cabinets, secure document room with compactus shelving and equipment storage rooms) for files and equipment that is the property of researchers who are conducting research within the CRF.
- A user storage charge may apply to use these storage spaces and a list of the charges can be obtained from the CRF Manager or the CRF Administration Officer.

3. STEP 3: COMPLETION OF A RESEARCH PROJECT

- Principal Investigators/lead researchers are required to notify the CRF Manager when a research project completes recruiting.
- Archiving remains the responsibility of the Principal Investigator/lead researcher.

RESPONSIBILITIES

Position	Responsibility	Audit criteria
TRI and TRI CRF Committee	• As the lessee of the CRF, the TRI works collaboratively with Metro South Research in the management, application and use of the CRF. • The TRI CRF Committee is responsible for determining criteria for CRF application approval (feasibility and risk	• N/A

	assessment) as applied by the CRF Manager.	
CRF Manager	• Responsible for consideration and approval of all applications to use the CRF in accordance with the criteria agreed by the TRI CRF Committee. • Responsible for completing a feasibility and risk assessment on all applications and to ensure adequate resources are available to provide safe, high-quality research 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 Good Clinical Practice (GCP). • It is the responsibility of the Principal Investigator/lead researcher to ensure compliance with requirements of appropriate legal, regulatory, ethical and guidance documents applicable to the research project.	• 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 Trial (National Clinical Trials Governance Framework definition)	A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials include but are not limited to:

	• Surgical and medical treatments and procedures • Experimental drugs • Biological products • Medical devices • Health-related service changes • Health-related preventative strategies • Health-related educational interventions
Credentialing	• The formal process used to verify and review the qualifications, experience, professional standing and other relevant professional attributes of health professionals for the purpose of forming a view about their competence, performance and professional suitability to provide a safe, high quality healthcare service within specific environments.
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.
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)* • *Information Privacy Act 2009 (Qld)* • *Public Health Act 2005 (Qld)* • *Therapeutic Goods Act 1989 (Cth)* **Regulations** • Gene Technology Regulations 2001 (Cth) • 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 **Work instructions** • 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 **Attachments** • Attachment 1: CRF application form • Attachment 2: CRF risk assessment matrix • Attachment 3: CRF request for out-of-hours access for participant visits form

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

Work Instruction Name	Clinical Research Facility application and use
Work Instruction Number	WI2024-335
Current Version	1.0
Keywords	Clinical Research Facility, application, use, credentialing, CRF
Primary MSH or Directorate Procedure Reference	PR2024-453 Clinical Research Facility (CRF)
Executive Sponsor	Executive Director, Metro South Research
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	3/07/2024	Executive Director, Metro South Research	• New MSH work instruction adapted from rescinded PR2021-239.