

Clinical Research Facility (CRF)



History of the CRF

- Took approximately 2 years to build, and a further 12 months to rectify design mistakes and for policies and SOPs to be developed and agreed upon
- Officially opened in December 2014, first participants were seen in January 2015
- Occupies Level 4 and 5 of R-Wing which are connected directly to Building 1 of the Princess Alexandra Hospital (PAH)
- One staff member (CRF Nurse Manager) during development phase
- Office Coordinator commenced in January 2015 which coincided with first participants being seen
- Support Registered Nurse commenced in February 2016
- Unique as a research facility that is managed by a health service

What the CRF Offers

To enhance the conduct of high quality, clinically relevant research by:

- Providing adequate space and infrastructure for researchers
- Providing a safe and controlled environment for volunteers to participate
- Assisting researchers to establish high quality clinical research studies
- Helping to improve the translation of research into clinical practice

CRF Services

- 2 short stay rooms equipped with 4 recliner chairs
- 4 bed bay (not able to do overnight stays at this stage)
- 2 single rooms that can be used for clinical or examination purposes
- 3 examination rooms
- 2 interview rooms
- 1 bariatric room
- Gym
- Laboratory
- Monitored freezer room for sample storage (-30 and -70)
- Monitored refrigerators for IP storage
- Nutritional suite
- Desk space

CRF Services

- Clinical spaces are 'shared space' and bookable - first come, first served
- Desk spaces are bookable for short term periods or the life of a project
- The CRF nursing staff provide clinical back up coverage and emergency situation support for researchers
- Standard operating hours are 8:00am to 4:30pm, weekdays
- Nursing support can be provided from 7am to 7pm, weekdays (if pre-arranged)
- Resources necessary for safe conduct of the study are to be provided by the researcher
- Researcher requiring nursing assistance can book nursing time (e.g. venepuncture, IV cannulation, study visits)

General Information

- Use of the clinical facilities is available to TRI partners (Queensland Health (QH), Queensland University of Technology (QUT), University of Queensland (UQ) and Mater Research Institute (MRI) and their associate researchers
- Applications will be considered from external researchers not directed affiliated with TRI
- Use of the CRF is subject to the terms of the lease between Metro South Hospital and Health Service (MSHHS) and TRI
- The Principal Investigator is accountable for all aspects of the conduct of a study
- Studies must be ethically approved and have a MSHHS SSA approval or waiver
- Employing institutions are required to sign a User Agreement for their researchers to use the clinical facilities

Operational Governance of the CRF

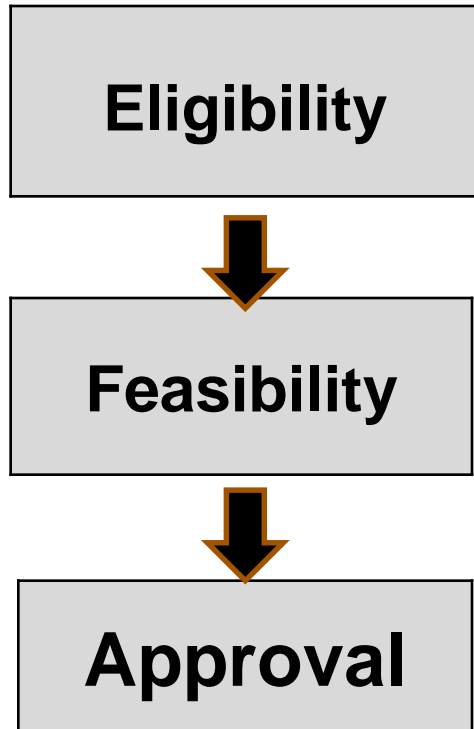
- Managed by the Centres for Health Research (CHR)
- TRI's Clinical Research Facilities Committee oversees the operations of the CRF and reports to TRI's Innovation and Translation Committee. This includes the Translational Research Institute, Children's (TRIC)

The committee is tasked with:

- Building relationships with clinical service groups to enable translational research activities
- Monitoring the facility's operational structure, policies and procedures and undertaking risk management assessments

Cost Recovery Model

- The CRF operate under a cost recovery model i.e. charges apply for use and occupancy of space
- Basic Infrastructure costs are paid for by the partners (water, electricity, standard cleaning etc.)
- Use of the clinical spaces and additional consumables (e.g. linen, parking vouchers, meals) charged to researcher
- User charges are subsidised for TRI members and partially subsidised for Associate researchers.
- Sponsored pharmaceutical or device trials are not subsidised



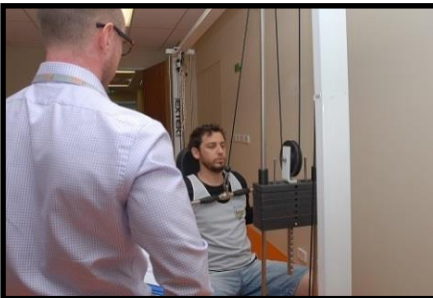
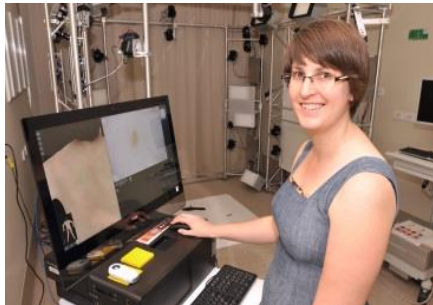
Eligibility	<p>Investigators: TRI Members and External Members and their research associates</p> <p>Research participants: with differing level of health risk</p> <p>Procedures: 'research studies that involve either 'low risk' and/or 'non low-risk' procedures are now eligible to apply to use the CRF (<i>refer to the 'CRF Research Risk Stratification Assessment Tool' for guidance</i>)</p>	
Feasibility	<p>Applicant must discuss project feasibility with CRF Nurse Manager</p> <ul style="list-style-type: none"> • Discussion to include: CRF Application process, terms of use, User Agreements, User charges, hours of operation, space and storage requirements, booking procedures, consumables, equipment and laboratory process, research staff qualifications and training etc. • CRF Application documents reviewed and if project meets eligibility it will be recommended by the Nurse Manager to CRF Director for approval. 	
Approval	Existing Studies	New Studies
	<ol style="list-style-type: none"> 1. Study already approved by an NHMRC-certified HREC 2. SSA already authorised by Metro South Health 3. CRF Application to be approved 	<ol style="list-style-type: none"> 1. CRF Application approved 2. Study approved by an NHMRC-certified HREC 3. SSA authorised by Metro South Health

CRF Application Process

CRF Project vs. Participant Risk Stratification Tool

Procedural Risk	Health Status					
	Minimal Health Risk		Low Health Risk	Intermediate Health Risk	High Health Risk	Extremely High Health Risk
	Healthy	Single Disease Well Controlled	2 - 3 Comorbid Diseases Well Controlled	Compromised Health Multiple Comorbid Diseases All Well Controlled	Unhealthy Multiple Comorbid Conditions Partially Controlled	Unhealthy Multiple Comorbid Conditions Not Well Controlled
No Known Disease No Medications (except contraceptives) Non Smoker	Single Disease Well Controlled Minimal Medications No Abnormalities on Examination Average Fitness and Mobility	2 - 3 Comorbidities (e.g. skin diseases, GIT Disorders, hypertension, diabetes, BMI 30 - 40) Controlled disease No Recent Known Adverse Medical or Surgical History No Significant Abnormality on Examination Average Fitness and Mobility	Active Disease or Disorders responding to Treatments (e.g. Rheumatoid Arthritis, Cancer, Lung, Kidney or Liver disease) Comorbidities Well controlled with Medications Reduced Fitness and Mobility	Active Disease or Disorders not responding to standard Treatments (e.g. Solid Organ or Blood Cancers, Unstable CVD, End stage Kidney Disease) One serious and active comorbidity partially controlled Abnormality on Examination Strong Family History of illness Low Fitness and Mobility Potential for health incidents requiring hospital admission	Active Disease or Disorders not responding to standard Treatments (e.g. Solid Organ or Blood Cancers, Unstable CVD, End stage Kidney Disease) More than one serious and active comorbidity Abnormality on Examination Strong Family History of illness Limited Fitness and Mobility Frequent health incidents requiring hospital admission	
Minimal Risk						
Focus Groups, Information Collection, Interviews, Imaging, Psychometric testing, Clinical Examination, Vital Sign Measurements, ECG, EEG, Biometric Training, Spirometry testing, indirect calorimetry, Body Composition Scans, Pulse Wave Velocity, Strain Gauge Plethysmography.	Minimal	Minimal	Minimal	Minimal	Minimal	Minimal
Low Risk Minor Invasive Procedures including Routine Diagnostic Tests						
Phlebotomy, Skin biopsy, Fine needle biopsies, Procedures involving motion and exercise e.g. 6 minute Walk Tests, Moderate Ergometry testing, Phase 2B, 3 and 4 Clinical Drug Trials (Self Administration Medications)	Minimal or Low	Minimal or Low	Minimal or Low	Intermediate	Intermediate	Intermediate
Diagnostic Tests e.g. Glucose Tolerance, Short Synacthen, Metirapone Stimulation, Dexamethasone challenge, Sputum Induction, Skin Prick Allergy Tests, Methacholine Challenge, Allergen Challenge, Lipid Metabolism						
Intermediate Risk Invasive or Experimental Procedures						
Phase 1 and 2A Drug Trials (Oral, IM, SC or IV), Medical Device Trials	Minimal or Low	Minimal or Low	Minimal or Low	Intermediate	Intermediate	High
Higher Risk Invasive or Experimental Procedure						
Cardio-pulmonary Stress Testing	Minimal or Low	Minimal or Low	Intermediate	Intermediate	High	Extremely High
Extremely High Risk						
Surgical procedures, Anaesthetic procedures	Extremely High	Extremely High	Extremely High	Extremely High	Extremely High	Extremely High
Risk Stratification Colour Codes	Blue = Minimal Health Risk: Projects Suitable for CRF	Green = Minimal or Low Risk: Projects Suitable for CRF	Yellow = Intermediate Risk: Projects Suitable for CRF	Red = High Risk: Project only suitable for CRF if low - intermediate risk procedures conducted in CRF.	Black = Extreme High Risk - Not Suitable for CRF, Use PAH	

Questions???



Contact Details:

Nicolla Lewin

3443 7545 / 3176 8708

CRF@health.qld.gov.au