

# Work Instruction

## Clinical Research Facility

### Requesting Nursing Support, CRF Nurse Training and Delegation Requirements

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<b>Primary Document</b>	CHQ-PROC-90040 Clinical Research Facility - Application and Use				
<b>Risk</b>	Medium				
<b>Applicable to</b>	Applies to all researchers, study coordinators and clinical staff involved in the conduct of human research studies requiring nursing support within the CRF.				

### HUMAN RIGHTS

This governance document has been human rights compatibility assessed. No limitations were identified indicating reasonable confidence that, when adhered to, there are no implications arising under the *Human Rights Act 2019*.

### PURPOSE

This work instruction describes the processes for requesting nursing support for clinical trial activities in the Level 4 and level 5 Clinical Research Facility (CRF) at the Centre for Children's Health Research (CCHR). It ensures CRF nursing support staff are appropriately trained and delegated clinical research activities to support safe and ethical research in accordance with institutional and regulatory standards.

### SCOPE

This work instruction applies to all researchers, study coordinators and clinical staff involved in the conduct of human research studies requiring nursing support within the CRF.

### OUTCOME

This work instruction outlines the standardised process for requesting nursing support within the CRF to ensure safe, efficient, and compliant delivery of clinical research activities. It defines the responsibilities of the Principal/Clinical Investigator and researchers in initiating and managing nursing support requests and specifies the mandatory training requirements to uphold patient safety, clinical governance and research integrity in the CRF.



## WORK INSTRUCTION

### 1. CCHR CRF CLINICAL RESEARCH SUPPORT NURSE(S)

- The CRF clinical research nurse(s) provide assistance and support to CCHR partner organisation researchers and clinician investigators.
- Clinical research nurse(s) are clinically trained and competent in both general patient care and research-specific responsibilities, including the management of clinical trial participants, investigational products, and medical emergencies.
- The clinical research nurse(s) specialised expertise supports both the care of clinical trials participants and the delivery of targeted clinical trial education within the CRF.
- The Clinical Research Nurse Manager (CRNM) is responsible for ensuring the CRF clinical research nurse(s) is compliant with CHQ nursing training requisites; [CHQ-PROC-34050 Requisite Training Requirements - Nursing](#), [CHQ-PROC-20005 Corporate Mandatory and Required Training](#), [CHQ-FACT-20301 Corporate mandatory training matrix](#) and research certification guidelines (e.g. Good Clinical Practice - GCP).

#### 1.1 Training and Delegation Requirements for CRF Clinical Research Nurse(s) Support

- Each clinical trial comes with its own specific training and qualification requirements in addition to research certification guidelines (e.g. GCP training).
- The CRF clinical research nurse(s) can provide support for study activities within routine scope of clinical practice (SoCP) (e.g. vital signs, electrocardiography (ECG), urinalysis) without the requirement to complete study specific training and delegation.
- The CRNM is responsible for confirming the clinical research nurse(s) is qualified to perform SoCP research activities, based on their prior education, training and experience.
- The Principal investigator (PI)/Clinical investigator (CI) requesting SoCP support remains responsible for the conduct of the trial activity and interpreting the results.

#### 1.2 SoCP Nursing Requests

- Requests for clinical research nurse(s) support with routine SoCP during study visits must be made in writing via an outlook calendar invitation to [CRF.CCHR@health.qld.gov.au](mailto:CRF.CCHR@health.qld.gov.au).
- The CRF clinical research nurse(s) will accept or decline requests for nursing support based on individual SoCP, schedule availability and rostered workdays.
- The researcher/study team must notify the clinical research nurse(s) of appointment cancellations or rescheduling as early as possible by:
  1. Cancellation of outlook calendar invitation
  2. Email to [CRF.CCHR@health.qld.gov.au](mailto:CRF.CCHR@health.qld.gov.au)

#### 1.3 Study Specific Nursing Support

- When the research nurse(s) requires specific training to complete a study delegated task or access to study databases, the PI/CI (or delegate) must submit a request for nursing support to the CRNM

via email to [TRICInquiry@tri.edu.au](mailto:TRICInquiry@tri.edu.au) (level 4) or [CRF.CCHR@health.qld.gov.au](mailto:CRF.CCHR@health.qld.gov.au) (level 5). Refer to the steps below:

### Step 1: Identify Nursing Requirements

- Review the study protocol to identify procedures requiring nursing support (e.g., IV cannulation, ECGs, blood draws).
- Determine the time and scheduling requirements for nursing support.

### Step 2: Submit Request

- Complete the Nursing Support Request Form.
  - Email the form with CRF Feasibility document(s) submission or at least two (2) weeks prior to the planned activity requiring nursing support to [CRF.CCHR@health.qld.gov.au](mailto:CRF.CCHR@health.qld.gov.au)

### Step 3: Provide Supporting Documentation

- Attach relevant documents including:
  - Study protocol
  - Participant schedule
  - Patient Information and Consent Form (PICF)
  - Investigator brochure (if applicable)

### Step 4: Review and Outcome Notification

- The CRNM and clinical research nurse(s) will review the request.
  - Where additional information is required, the CRNM or clinical research nurse(s) may request a meeting with the PI/CI/research group.
- The CRNM and clinical research nurse(s) will review the SoCP to assess the appropriateness of the delegated nursing task(s).
- Confirmation of outcome is communicated to the PI/CI via email from the CRNM.
- A copy of the clinical research nurse(s) qualifications (e.g. AHPRA & CV) and certificates (e.g. GCP) will be emailed to the researcher for monitoring and compliance.

### Step 5: Training and Delegation

- The clinical research nurse(s) must complete training on and receive information about the trial relevant to their role in the study.
- The PI/CI (or delegate) conducting research in the CRF are responsible for ensuring that documentation for protocol specific training and delegation of clinical research nurse(s) duties is contemporaneous and compliant with sponsor requirements.
- The PI/CI (or delegate) is responsible for ensuring adequate training and information is provided for the tasks delegated to the clinical research nurse(s) prior to commencing trial activities.
- The PI/CI (or delegate) is responsible for providing study specific training (e.g. study devices) to the clinical research nurse(s) and determining clinical competence in application prior to commencement of any research activities.
- Evidence of protocol specific training and delegation logs for the clinical research nurse(s) will be documented by the PI/CI (or delegate) coordinating the relevant study.

- The PI/CI requesting nursing support is responsible for overseeing the delegated activity and interpreting the results.

### Step 6: Ongoing Communication

- All requests for clinical research nurse(s) support must be made via outlook calendar invitation to [CRF.CCHR@health.qld.gov.au](mailto:CRF.CCHR@health.qld.gov.au).
- The CRF clinical research nurse(s) will accept or decline the request for nursing support based on availability and scheduled days of work.
- The PI/CI must maintain open communication regarding changes to participant visits, changes to study procedures (including protocols), or adverse events.
- The PI/CI must notify the CRNM and clinical research nurse(s) of cancellations or rescheduling as early as possible:
  1. Cancel outlook calendar invitation
  2. Email to [CRF.CCHR@health.qld.gov.au](mailto:CRF.CCHR@health.qld.gov.au).
- The PI/CI conducting research in the CRF is responsible for ensuring updated information including protocol amendments and other documents relevant to clinical research nurse(s) delegated activities (e.g. laboratory manuals/flow charts) are provided to the CRNM and clinical research nurse(s) in a timely manner.

### 2.0 Principal Investigator and Nursing Support Responsibilities

- The PI/CI retains overall responsibility for the conduct of their research at the CRF in accordance with the principles of GCP and regulatory and institutional standards.
- The PI/CI may delegate study tasks to the clinical research nurse(s) based on individual skill level, qualifications and the task requirements with consultation and approval from the CRNM.
- The CRNM and clinical research nurse(s) will contact the PI/CI, sub-investigator, or research team directly to clarify any concerns or uncertainties regarding clinical trial training or conduct (e.g. protocol deviations).
- The PI/CI is responsible for ensuring adequate training and information is provided for the research nurse(s) prior to commencing trial activities and determining clinical competence in application prior to commencement of any research activities.

## ROLES AND RESPONSIBILITIES

Role	Responsibility
Clinical Research Nurse Manager	Reviewing all protocol specific information. Coordinates CRF study activities, supports clinical research nurse(s) training and facilitates patient safety.
Principal investigator (PI)/Clinical investigator (CI)	Retains overall responsibility for the conduct, oversight and integrity of the research project at the CRF. The PI ensures compliance with the requirements of appropriate legal, regulatory, ethical and guidance documents applicable to the research

	project and is accountable for participant safety, data accuracy and study outcomes.
Clinical Research Nurse(s)	<p>Shares responsibility and accountability for research being conducted according to appropriate regulatory, ethical and scientific standards.</p> <p>Comply with applicable, CHQ HHS and TRI (level 4 CRF only) policy and procedures.</p> <p>Works in accordance with their scope of clinical practice (SoCP), complies with relevant professional standards and facilitates patient safety.</p>

## SUPPORTING DOCUMENTS

### Legislation and other Authority:

- Hospital and Health Boards Act 2011 (QLD)
- Human Rights Act 2019 (QLD)
- Public Health Act 2005 (QLD)
- Therapeutic Goods Act 1989 (Cth)
- Therapeutic Goods (Medical Devices) Regulations 2002 (Cth)
- Therapeutic Goods Regulations 1990 (Cth)
- National Statement on Ethical Conduct in Human Research 2023
- Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R3)
- Australian Clinical Trial Handbook

### Standards:

- [National Clinical Trials Governance Framework](#)
- [National Safety and Quality Health Service \(NSQHS\) Standards](#)

### Supporting documents:

- [CHQ-PROC-90040 Clinical Research Facility: Application and Use](#)
- [CHQ-PROC-34050 Requisite Training Requirements - Nursing](#)
- [CHQ-PROC-20005 Corporate Mandatory and Required Training](#)
- [CHQ-FACT-20301 Corporate mandatory training matrix](#)
- [CHQ-WI-80167 Clinical Research Facility: Participant admission, supervision and clinical management](#)
- [CHQ-FW-90038 Research Governance Framework](#)
- [CHQ-GDL-02232 Clinical Trials](#)

## CONSULTATION

Key stakeholders who reviewed this version:

- Clinical Research Nurse (CRF)
- Research Monitoring and Compliance
- Senior Manager Research Services and Partnerships
- Director of Research
- Translational Research Institute (TRI)

## DEFINITIONS

Term	Definition
Nursing support	Clinical services provided by the CRF Registered Nurse(s) including but not limited to participant assessment, sample collection, medication administration and data capture.
Principal Investigator (PI)/Clinical Investigator (CI)	The lead researcher responsible for the conduct, oversight and integrity of the study/research.
Good Clinical Practice (GCP)	An international ethical and scientific standard for designating, conducting and reporting clinical trials.
Clinical Research Facility (CRF)	A purpose-built setting where clinical trials and research studies involving human participants is conducted. This specialised unit is designed to support investigations into the safety, efficacy and effectiveness of new medicines, treatments and devices. The CRF at CCHR are located on level 4 (Translational Research Institute @Children's – TRIC) and level 5.
Scope of clinical practice (SoCP)	The range of activities, procedures, and responsibilities that a healthcare professional is educated, trained, and credentialed to perform within their professional role. It is defined by regulatory standards, institutional policies, individual competence and the needs capability of the organisation to support the health professional to ensure safe and effective patient care.

## AUDIT/EVALUATION STRATEGY

<b>Strategy</b>	All clinical trials in the CRF are reviewed and approved by the CRNM prior to commencement. Observe practice, review documentation/requests for assistance.
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Audit/review tools	Audit/review tools frequency
Review requests for clinical research nurse(s) support	Study feasibility/every study; ongoing
Review clinical research nurse(s) mandatory training completion.	TeachQ/iLearn; Ongoing

## WORK INSTRUCTION REVISION AND APPROVAL HISTORY

Version No.	Modified by	Amendments authorised by	Approved by	Comments
1.0 18/09/2025	Clinical Research Nurse Manager (CCHR)	Director of Research	N/A	New document

<b>Key words</b>	Clinical Research Nurse, Nursing Support, Training, Delegation, Good Clinical Practice (GCP), Clinical Research Facility (CRF), Education, Clinical Trial, 90052
<b>Accreditation references</b>	The National Safety and Quality Health Service (NSQHS) Standards (1-8) and The National Clinical Trials Governance Framework: <ul style="list-style-type: none"> <li>• Standard 1 Clinical Governance</li> <li>• Standard 2 Partnering with Consumers</li> </ul>