

## The Clinical Research Nurse

Clinical Research Nurses (CRN) are highly specialised Registered Nurses (RNs) who combine their clinical nursing expertise with research knowledge and skills, to facilitate the delivery of rigorous, high-quality clinical research to improve health outcomes, the research participant experience and treatment pathways.

## Background

The CRN combines responsibilities of holistic participant care with the integration of specialised research knowledge, skills and humanistic values. CRNs demonstrate advanced communication and care co-ordination competencies to provide nursing care to research participants. CRNs apply problem-solving skills to navigate complex clinical care and integrate research and clinical activities to meet the needs of research participants and their support networks, within the parameters of the research protocol. The CRN empowers translation of research results into clinical practice, facilitating understanding across the research stakeholder network.

Through the application of their knowledge and understanding of current local and international legislative, policy, regulatory and guidance documents, the CRN facilitates research activities within a complex clinical, scientific, methodological, cultural, ethical, legal and regulatory environment. The CRN continually integrates requirements of protocol integrity and data quality with the clinical and safety needs of each participant. By extending the values of caring and advocacy to the participant's families, support networks, and society, and considering the impact of research on each, the CRN builds positive relationships amongst the research team, individual participants and their support networks, and health care consumers.

The CRN promotes a collaborative multi-disciplinary team approach to care within the clinical research environment, with research participants as critical partners. This is achieved through effective communication with internal and external stakeholders to promote the unique contributions and value of clinical research with health care colleagues. The CRN has a pivotal role in the research network, ensuring the inclusion of stakeholders to deliver health and care research.

The CRN contributes to the advancement of the Clinical Research Nursing specialty through involvement in professional activities and development of self and colleagues, including implementation and promotion of evidence-based best practice.

## Scope and Purpose of Standards

These standards have been developed by CRNs for Registered Nurses working in an Australian Clinical Research setting and with reference to the [Nursing and Midwifery Board of Australia Registered Nurse Standards for Practice \(1 June 2016\)](#). They define *minimum* standards of practice for CRNs in Australia, with recognition of the continuum of knowledge and skills development within the CRN role. In some instances, practice extends beyond these standards, however the expert CRN role and specialist CRN career pathway are yet to be formally described within Australia. These standards are not intended to be interpreted as

competency standards but may inform development of specialist Australian CRN competencies and scope of practice guidelines in the future. These standards provide definition of the specialism of Clinical Research Nursing in Australia and highlight the important role of nursing care for clinical research participants and their support networks.

It is important to recognise that these standards directly reflect the role of the CRN as distinct to the unique role of the nurse researcher, which typically involves a nurse leading their own research projects or leading multidisciplinary research teams on systematic enquiry designed to develop and progress knowledge of clinical nursing practice.

## Language and Terminology

In recognition of the evolving nomenclature in clinical research, we seek to provide clarity regarding the language and terminology used within these standards. These standards have been written with the intent of inclusivity and respect. Certain terms act as ‘umbrella’ expressions, to capture homogenous concepts and provide consistency for the reader. For example, the term ‘participants’ recognises all those who choose to take part in health and medical research, which may include healthy volunteers, patients or clinicians. The term ‘support network’ describes the extended families, communities, caregivers or designated Medical Treatment Decision Makers who support patients and participants. The term ‘clinical research’ encompasses interventional clinical trials and observational research conducted across healthcare environments and the community. The terms clinical care and nursing care include health promotion, prevention of illness, support for participant decision making and advocacy.

## Standards Framework

The CRN Standards are described via a framework of ‘Elements’ and associated ‘Performance Indicators’. The ‘Elements’ define the core values and activities of each standard, with ‘Performance Indicators’ providing examples of practical application of the Elements.

## Clinical Research Nurse (CRN): Australian Standards For Practice

<b>Standard 1</b>	Applies <b>critical thinking</b> and <b>research knowledge</b> to nursing practice, clinical care and management of research participants.
<b>Standard 2</b>	Establishes and maintains <b>diverse and collaborative professional relationships</b> .
<b>Standard 3</b>	Maintains <b>proficiency of practice</b> in both <b>clinical</b> and <b>research</b> disciplines.
<b>Standard 4</b>	<b>Plans nursing care</b> for clinical research participants, applying evidence-based clinical skills, as well as validated and standardised research processes.
<b>Standard 5</b>	<b>Delivers safe, appropriate, responsive and cohesive care</b> to clinical research participants.
<b>Standard 6</b>	Applies <b>specialised research and management skills</b> to enable delivery of high-quality clinical and research practice.
<b>Standard 7</b>	Contributes to the <b>advancement of evidence-based healthcare</b> and the <b>Clinical Research Nurse speciality</b> .

## **Standard 1: Applies critical thinking and research knowledge to nursing practice, clinical care and management of research participants**

Clinical Research Nurses use a variety of critical thinking strategies, best available evidence and specialised research knowledge in leading the delivery of research studies, making decisions and providing and coordinating safe and competent care within person-centred, protocol/methodology-driven and evidence-based frameworks.

### **The CRN:**

#### **Element 1.1**

Applies the best available **evidence-based nursing and research knowledge** to assess, analyse and guide practice.

#### **Performance Indicators**

- Demonstrates professionalism and compassion when managing research participants' critical and complex care needs;
- Provides comprehensive, safe and quality nursing care to deliver research-specific study procedures alongside the provision of holistic healthcare to research participants;
- Provides support and education to research participants and their support networks.

#### **Element 1.2**

Uses **ethical decision-making** in delivery of clinical research and clinical care, applying the in-depth knowledge of the principles of current local and international legislative, policy, regulatory and guidance documents.

#### **Performance Indicators**

- Reviews the participant's understanding of information regarding clinical research opportunities and respects the decision-making process;
- Facilitates or leads the informed consent process with participants (or relevant Medical Treatment Decision Maker) in accordance with ICH GCP principles and legal and regulatory processes;
- Continually assesses the care and wellbeing of the participant and the requirements of the research protocol, ensuring the safety and wellbeing of the participant remains the primary consideration.

#### **Element 1.3**

Actively participates in **practice development and continuous improvement** initiatives, in alignment with research, clinical regulations and guidelines.

#### **Performance Indicators**

- Manages risk, through implementation of risk controls, including quality and monitoring activities;
- Identifies opportunities for improvement in the clinical research process;
- Uses reflective practices to review understanding of how evidence-base, knowledge, actions, experience, feelings and beliefs shape practice.

## **Standard 2: Establishes and maintains diverse and collaborative professional relationships.**

CRN practice is underpinned by collaborative and constructive relationships with multidisciplinary colleagues and stakeholders across clinical, and research and service

provision teams, both within and external to the institution.

## The CRN:

### Element 2.1

Respects the **expertise and experience of individuals** who engage in clinical care and research activities.

#### Performance Indicators

- Promotes and utilises effective communication strategies that are inclusive of an individual's dignity, culture, values, beliefs and rights;
- Advocates on behalf of research participants, in a manner that respects the person's autonomy and rights;
- Safeguards a research participants' inherent right to privacy and confidentiality in alignment with policy and best practice guidelines.

### Element 2.2

Promotes **person-centred research** approaches and inclusive study co-design

#### Performance Indicators

- Facilitates and advocates for inclusion of the consumer voice in research design and implementation across the research life-cycle;
- Raises awareness of clinical research within clinical care teams to enhance opportunities for research participation, particularly for under-served and under-represented populations;
- Utilises specialist clinical skills and knowledge to evaluate, promote and advocate for clinical research opportunities for those in their care;

- Collaborates with stakeholders to ensure the views of participants and their support networks are included in research prioritisation, design, conduct and dissemination.

### Element 2.3

Encourages and actively fosters a **research-active culture**, acting as a clinical research champion.

#### Performance Indicators

- Establishes and maintains effective relationships with multidisciplinary team colleagues, clinical care teams, consumers, clinical and academic stakeholders and commercial partners;
- Acts as a specialist resource for research staff and non-research colleagues to promote safe and ethical conduct of research activities;
- Shares research knowledge and practical skills to support embedding research alongside evidence-based and person-centred care;
- Promotes a cross-disciplinary culture of innovation and learning through leadership (and mentorship) of staff directly or indirectly involved in clinical research.

### Standard 3: Maintains proficiency of practice in both clinical and research disciplines.

CRNs are responsible for ensuring that they maintain their professional nursing registration, and work safely and competently within their scope of practice. CRNs must demonstrate ongoing professional development and currency of practice in their clinical specialty as well as demonstrating proficiency in specialist clinical research skills and knowledge.

## The CRN:

### Element 3.1

Applies knowledge of relevant **nursing** legislation and ethical frameworks, professional standards, policies and procedures for clinical and research practice.

#### Performance Indicators

- Maintains current nursing registration and ensures currency and competency of clinical nursing skills;
- Practices within the scope of the Nursing and Midwifery Board of Australia Registered Nurse Standards for Practice and their own scope of practice;
- Contributes to the establishment and maintenance of a clinical and research environment that is conducive to safe, quality care that maintains fidelity to clinical research methodologies and practice.

### Element 3.2

Understands, navigates and complies with legislative and regulatory policy and guidelines relevant to **clinical research**.

#### Performance Indicators

- Contributes to, and coordinates the applications processes for ethical, regulatory and governance approvals associated with clinical research activity and ensures adherence to ongoing reporting requirements;
- Provides support and advice regarding ethical and regulatory authorisations to colleagues establishing clinical research activities, including those who are new to research;

- Identifies and addresses gaps in study design or processes that may impact safe, and high-quality conduct of research.

### Element 3.3

Accepts **accountability** for decisions, actions, behaviours and responsibilities inherent in their role, and delegated responsibilities.

#### Performance Indicators

- Undertakes training for specialist tasks within the CRN role, including (but not limited to) compliance, data governance, project management, informed consent processes, and safety event reporting;
- Establishes and maintains accurate, comprehensive and timely documentation of planning, decision-making, actions, evaluations and clinical and research activities;
- Assesses, maintains and monitors safe and effective functioning of clinical trial related equipment and consumables;
- Coordinates, contributes, or leads in the effective management of study interventions.

### Element 3.4

Demonstrates an **attitude of enquiry** regarding best practice evidence and opportunities for professional development.

#### Performance Indicators

- Develops and implements appropriate education programs to disseminate the findings of completed research studies amongst multidisciplinary colleagues, study participants and consumers;
- Supports translation of research results into clinical practice and facilitates understanding of research impact within the research stakeholder network.

## **Standard 4: Plans nursing care for clinical research participants, applying evidence-based clinical skills, as well as validated and standardised research processes.**

CRNs are responsible for the development, implementation, coordination, documentation and evaluation of individual research participant plans of care, in accordance with the approved research protocol/methodology and regulatory requirements.

### **The CRN:**

#### **Element 4.1**

**Plans safe and effective nursing care** with consideration of the clinical research protocol/methodology and the CRN's scope of practice.

#### **Performance Indicators**

- Performs focused health assessments and undertakes appropriate nursing interventions as necessary;
- Contributes a nursing perspective to implementation of clinical research projects to ensure appropriate workflows and prioritisation of clinical needs;
- Effectively plans and coordinates clinical research participation and clinical follow up, prioritising treatment and care according to research requirements and participants' needs.

#### **Element 4.2**

**Plans care and research engagement with respect for all cultures and experiences**, which includes responding to the role of family and community that underpin the health of Aboriginal and Torres Strait Islander peoples and people of culturally and linguistically diverse backgrounds.

#### **Performance Indicators**

- Actively seeks to understand the cultures and experiences of participants, applying this awareness and knowledge to clinical care and research interactions;
- Advocates for participant-centered approaches to research participation;
- Uses knowledge of research processes and methodology to enhance accessibility to research for all populations, including consideration of how to address practical barriers that may limit participation.

#### **Element 4.3**

**Supports participants in informed decision-making and promotes autonomy** regarding participation in clinical research, including emphasis on the voluntary nature of participation, ongoing consent process and options for withdrawal.

#### **Performance Indicators**

- Applies nursing and research communication skills and training to ensure participants receive, understand and can act upon provided clinical research information prior to giving informed consent;
- Works with participants to continually assess the individual's risk/benefit assessment of research participation, supporting participants to re-evaluate consent decisions, if required;
- Ensures continuity of care for participants who complete or withdraw (or are withdrawn) from clinical research.

#### **Element 4.4**

**Enhances the participant's understanding and management of their clinical condition** through application of clinical and research knowledge and skills.

## Performance Indicators

- Demonstrates a thorough understanding of the clinical or health topic of research and the research objectives;
- Accurately and transparently communicates the risks and benefits of research participation within scope of practice and with consideration and awareness of individuals' experiences, values and beliefs;
- Within scope of practice, provides information and education regarding alternatives to research participation, including standard clinical care pathways;
- Uses research interactions as opportunities to provide holistic education and support to participants.

## Standard 5: Delivers safe, appropriate, responsive and cohesive care to clinical research participants.

CRNs draw on clinical and organisational skills to plan and implement care for research participants, with a focus on balancing the requirements of the research methodology with the clinical care requirements of the participant.

### The CRN:

#### Element 5.1

Prioritises **safety and wellbeing in the delivery of care** for research participants.

#### Performance Indicators

- Ensures that research requirements are complimentary to clinical needs, effectively evaluating, prioritising and triaging care;
- As relevant and within the scope of practice, safely administers and monitors investigational therapies based on

accurate knowledge of the product (including investigational devices) and potential interactions with concurrent therapies that the research participant is receiving.

#### Element 5.2

Identifies and appropriately responds to **clinical concerns**, liaising with clinical colleagues and the multidisciplinary team to ensure **timely referral or review** of research participants' clinical and research care.

#### Performance Indicators

- Uses nursing knowledge and assessments to identify and communicate changes in the participant's condition that require assessment or intervention, with an holistic approach to care;
- Assesses and implements appropriate nursing care pathways related to adverse events experienced during a clinical trial, regardless of causality;
- Continuously monitors research participants for adverse events, working to mitigate harm, and expedites reports of adverse events to appropriate authorities in keeping with the protocol, relevant guidelines and regulatory and organisational requirements.

#### Element 5.3

Provides a **continuum of care**, focused on supporting participants to retain autonomy over research and clinical care decisions.

#### Performance Indicators

- Establishes participant priorities and communicates participant needs, barriers, opportunities and logistics of participation to the clinical and research teams (and other stakeholders), advocating for an individualised approach;



- Led by the participant, engages and involves the participant's support network in decisions relating to delivery of care and research involvement, especially where existing care pathways are impacted;
- Builds rapport and maintains effective communication with participants and their support networks.

## Element 5.4

Adheres to established local, national and international clinical research and trial policy, guidelines and best practice standards when making **complex and informed independent decisions** related to the delivery of research and clinical care.

### Performance Indicators

- As relevant, ensures informed consent has been received prior to implementation of any research related procedures and advocates effectively for vulnerable populations;
- Considers the existence of real or perceived conflicts or duality of interests for stakeholders, in particular those of the research participant;
- Exercises knowledge of research regulatory processes to facilitate and maintain high-quality data integrity and care delivery practice;
- Recognises when qualified input is required from clinical or research colleagues, consciously working within scope of research and clinical practice.

**Standard 6: Applies specialised research and management skills to enable delivery of high-quality clinical and research practice.**

CRNs are required to apply traditional and innovative project management methods, skills and knowledge to support the design and conduct of clinical trials and research projects, ensuring care of the participant in unison with the delivery of research objectives.

### The CRN:

#### Element 6.1

Provides specialised clinical and research expertise to guide discussions on **key feasibility factors**, including study suitability, adequacy of organisational resources, competencies, capabilities, and access to target population.

### Performance Indicators

- Undertakes research training in project and data management within the clinical research setting;
- Co-ordinates and manages clinical research project across the entire study lifecycle to ensure resources and risk are effectively and efficiently managed;
- Applies and implements project management skills and methodologies in the clinical research setting;
- Participates in decision-making for proposed clinical research studies within their area of practice, considering resources and skills available to support the proposed research;
- Ensures appropriate clinical oversight and access to clinical safety processes and procedures.

#### Element 6.2

Advocates for **participant-centred approaches to project management**, particularly during the planning stages.

### Performance Indicators

- Demonstrates an in-depth understanding of the application of nursing principles to clinical research project management and care planning for research participants;
- Demonstrates an in-depth understanding of the application of ICH GCP to project management of clinical research;
- Optimises strategies to promote inclusive care and research opportunities for under-served and under-represented populations;
- Minimises waste and promotes sustainable research practice to foster a culture of responsible environmental decisions in research related healthcare.

### Element 6.3

Collaborates with multidisciplinary colleagues and project stakeholders to understand **clinical and project workflow**, creating and communicating a plan of care for the safe and effective delivery of nursing care that is aligned to the project deliverables and scope.

### Performance Indicators

- Ensures clear delegation of research project activities and responsibilities;
- Communicates effectively with research and clinical colleagues to facilitate, where appropriate, the integration of approved research activities into routine care;
- Facilitates effective monitoring processes for each project to ensure project risk and quality are proactively managed across the lifecycle and the rights and welfare of research participants are protected;
- Utilises reflective practice to facilitate safety, quality and risk identification and management.

## **Standard 7: Contributes to the advancement of evidence-based healthcare and the Clinical Research Nurse speciality.**

CRNs contribute to building evidence-based health care and to the advancement of the CRN specialty through coordination and delivery of high-quality research. With their specialised research skill set, CRNs are optimally positioned to enable a research-active workplace culture and lead professional research development opportunities.

### The CRN:

#### Element 7.1

Provides specialised clinical and research coordination skills and expertise to deliver research **that addresses important clinical questions and gaps in healthcare knowledge.**

#### Performance Indicators

- Practices in accordance with all applicable local, national and international regulatory, policy and guideline requirements to ensure high-quality, reliable, replicable and valid research data is collected;
- Acts as a critical reviewer, to inform the design, and delivery pathway of quality clinical research studies with translatable impact;
- Fosters links with Nurse Researchers to support research capabilities within the Nursing Profession.

#### Element 7.2

Contributes to the **development and implementation** of safe, effective, inclusive and participant-cantered **clinical research practices.**

#### Performance Indicators

- Supports implementation and evaluation of consumer feedback on the clinical research process;
- Contributes to the development of clinical research Standard Operating Procedures (or similar) to ensure standardised, reliable research practice and data generation, aligned with the study protocol/methodologies;
- Aligns practice with relevant [National Safety and Quality Health Service](#) (NSQHS) standards relating to health and care research in Australia.
- Participates in peer-support activities, networks or relationships, to ensure own well-being, as well as personal and professional development.

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### Element 7.3

Fosters **best practice and knowledge sharing** across CRN speciality, advocates for growth and recognition of the role.

#### Performance Indicators

- Provides positive role-modelling, leadership and mentorship for the CRN role;
- Supports advocacy and advancement of the role of the CRN, including for education and training opportunities, in public and professional forums;
- Contributes to local professional networks and support frameworks for CRNs.

### Element 7.4

Pursues **personal and professional development for self.**

#### Performance Indicators

- Demonstrates professional development and education in clinical and research domains;
- Maintains clinical competencies and mandatory training related to nursing registration;