

## Clinical Research Nurse Consultant

### 1 JOB IDENTIFICATION DETAILS

Job title:	Clinical Research Nurse Consultant (CRNC)
Responsible to:	Senior Clinical Research Nurse Consultant/ Department Head / Principal Investigator
Department:	Add local specifications
Division/directorate:	
Job reference no.:	
No. of SCRNs:	
Last update:	

### 2 JOB PURPOSE

As a member of a research team, the CRNC will have responsibility for the delivery of direct and indirect care and associated data collection for concurrent research studies undertaken in the department, in accordance with the Therapeutic Goods Administration (TGA) Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Research Involving Humans. The CRNC will ensure the highest standard of care is delivered to all patients involved in clinical trials and, where relevant, their families, in partnership with all members of the multidisciplinary and research teams. The CRNC has responsibility and accountability for maintaining clinical, staff and research governance.

### 3 DIMENSIONS OF THE POSITION

The CRNC will work within the department of (insert Dept name). In the absence of the Senior Clinical Research Nurse Consultant /Principal Investigator, will take charge of individual clinical trials to ensure their effective operation. Key staff interactions include – nursing staff, clinicians, management, local research office as appropriate, pharmaceutical companies, support services, health & safety and risk management. The CRNC will act as a consultant to junior research staff and to clinical staff as appropriate. The CRNC is not responsible for managing the budget but needs to be aware of the resources available and the need to remain within budget parameters.

### 4 ORGANISATIONAL STRUCTURE

Insert organisational structure flow chart relevant to this position here.

### 5 ROLE OF THE DEPARTMENT

Insert department description and role here.

### 6 KEY PERFORMANCE INDICATORS

#### 6.1 Professional

- 6.1.1 Practice at all times within current appropriate state regulations (eg Victorian Nursing Board) to ensure that each patients nursing needs are met.

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- 6.1.2 Develop the role by using evidence based practice and continuously improving knowledge following training and education guidelines.

### **6.1 Professional (cont)**

- 6.1.3 Conduct clinical research in accordance with TGA ICH GCP and the NHMRC National Statement on Ethical Conduct in Research Involving Humans.
- 6.1.4 Make clinical and professional autonomous decisions on a daily basis.
- 6.1.5 Provide clinical and professional advice relating to the conduct of clinical research to the multidisciplinary team.
- 6.1.6 Analyse and assess each patients condition to establish the continuing care plan, appropriate action and future participation in the study in consultation with the treating doctor and/or the trial investigator.
- 6.1.7 Act as a patient advocate at all times.
- 6.1.8 In the absence of the Research Manager/Principal Investigator, make decisions on the use of research resources.

### **6.2 Research Leadership/Management**

- 6.2.1 Contribute to the development of new research protocols and ensure the effective management of the study and care requirements of the patients are fully considered.
- 6.2.2 Ensure clinical trials are undertaken in accordance with the terms approved by local Human Research Ethics Committees (HRECs) and the Therapeutic Goods Administration (TGA).
- 6.2.3 Consider the training and education implications of each protocol and work with the Principal Investigator/Senior Clinical Research Nurse Consultant to develop appropriate strategies to meet these needs in order to ensure the safe and accurate implementation of the study.
- 6.2.4 Effectively and efficiently manage and forward plan the use of the nursing research resource to ensure that an appropriate skill mix is maintained at all times.
- 6.2.5 Act as a consultant to Level 1 Research Nurses and research assistants to ensure development needs are identified.
- 6.2.6 Understand and function within the guidelines of the Hospital Policies and Procedures manual.
- 6.2.7 Responsible for reporting adverse events and serious adverse events in a timely and effective manner at a local level and escalate as appropriate.
- 6.2.8 Recognise the importance of resolving complaints in a timely and effective manner at a local level and seek assistance as necessary. All complaints involving patient care to be reported to the Senior Clinical Research Nurse Consultant/Principal Investigator according to departmental guidelines.

### **6.3 Education**

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- 6.3.1 Plan and undertake teaching of registered nursing staff and non-nursing staff, including students, and participate in the implementation of staff personal development plans to facilitate ongoing professional development.

### **6.3 Education (cont)**

- 6.3.2 Demonstrate a commitment to personal continuing professional development and actively participate in performance review/appraisal.
- 6.3.3 Maintain up-to-date clinical skills and knowledge delivering care to allocated study clinical trial patients.  
  
Identify the educational needs of junior research staff and initiate appropriate training programs.

### **6.4 Clinical**

- 6.4.1 Organise personal workload to ensure that the interests of the research participants are met.
- 6.4.2 Ensure effective communication processes are in place to meet the needs of patients, relatives, investigators and other members of the multidisciplinary/research team.
- 6.4.3 Work within and monitor standards of care in allocated research protocols and ward, department and institutional standards, policies and procedures to ensure adherence to, and delivery of, a high quality service.
- 6.4.4 Propose and develop working practices/innovative processes within clinical research areas and assist in their implementation.

### **6.5 Research**

- 6.5.1 Ensure that studies are undertaken in accordance with the terms approved by the institutional ethics committee and TGA.
- 6.5.2 Gain knowledge of each research protocol including procedures and documentation to ensure the safe and accurate conduct and recording of the study.  
  
Advertise clinical trials to external hospitals, GPs and the community as appropriate.
- 6.5.3 Screen/register only appropriate patients for clinical trials as per clinical trial inclusion/exclusion criteria. Follow patients as per protocol and, where necessary, facilitate a participants withdrawal from a study in order to ensure the patients best care and the effective achievement of the study aims.
- 6.5.4 Provide ongoing advice and information to patients and be present at the signing of the informed consent (PICF) and be actively involved in the ongoing informed consent process.
- 6.5.5 Liaise with all involved groups/departments to ensure all biological samples are collected, processed, stored as per the clinical trial protocol requirements.

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- 6.5.6 Participate in clinical trial monitoring/auditing internally and externally as required in order to meet the regulatory and scientific requirements of each study. Work and cooperate with pharmaceutical company representatives (CRAs) when they come to monitor ongoing clinical trial data, internal company audits and external reviews.

### **7 POLICY AND PROCEDURES**

The Clinical Research Nurse Consultant will be actively involved in the setting up and maintaining unit standard operating procedures and be involved in implementation and updates.

The CRNC is expected to have knowledge of the local institutional/hospital policy and procedure manual to include -

- Local human resources department procedures
- All relevant equipment
- Intranet, internet responsibilities
- Database systems
- Medical record management.

### **8 DATA COLLECTION SYSTEMS**

The CRNC will be able to use and maintain all forms of data collection systems used for clinical trials including paper and electronic. The CRNC will be able to instruct Research Nurses in the use of this equipment.

All data systems to be used in compliance with state and national data protection and privacy legislation.

### **9 ASSIGNMENT AND REVIEW OF WORK**

The CRNC's work is generated from the research activities within the department. The CRNC will be responsible to the Senior Clinical Research Nurse Consultant/Principal Investigator who will provide clinical guidance and professional management, work review and formal appraisal of performance. Workload will be assigned by the Senior Clinical Research Nurse Consultant/Principal Investigator however the CRNC will have responsibility for self-managing a defined workload within professional guidelines. Workload will be variable dependent on the number and status of research studies. Where the CRNC is a sole practitioner, they will control their own workload.

### **10 COMMUNICATIONS AND RELATIONSHIPS**

#### **10.1 Internal**

- 10.1.1 Communicate and liaise with research participants, their relatives and multidisciplinary team.
- 10.1.2 Communicate with Principal Investigator regarding patients condition and ongoing trial participation.
- 10.1.3 Communicate with the Senior Clinical Research Nurse Consultant/Principal Investigator in regard to workload issues and professional development.

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- 10.1.4 Communicate with the local ethics committee and other relevant departments regarding the approval of, management and monitoring of clinical research studies.
- 10.1.5 Communicate with other relevant departments, such as pharmacy, human resources, fire officer, infection control, education departments, health and safety and risk management regarding clinical research studies and personal development.
- 10.1.6 Report adverse events in a timely and effective manner at local level and escalate as appropriate.

### **10.1 Internal (cont)**

- 10.1.7 Participate in department/institutional research nurse forums and all other departmental meetings as appropriate or deemed by the Senior Clinical Research Nurse Consultant/Principal Investigator.

### **10.2 External**

- 10.2.1 Liaise with other research centres and multidisciplinary research teams on the day-to-day running of research studies and participant queries.
- 10.2.2 Participate in, and where appropriate, present at external professional meetings/conferences related to research studies.
- 10.2.3 Liaise with collaborators and sponsor organisations.
- 10.2.4 Liaise with external regulatory and statutory research bodies as required.

## **11 KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED**

- 11.1 Registered Nurse with a minimum 5 years post graduate nurse experience demonstrating the appropriate competencies and skills for the job and clinical setting.
- 11.2 Degree level education.
- 11.3 Research experience including awareness of TGA ICH-GCP Guidelines and relevant regulatory/statutory guidelines.
- 11.4 Evidence of further education including post-graduate certification / diploma / continuous professional development in a relevant area.
- 11.5 Demonstrated excellent team working skills with ability to work using own initiative.
- 11.6 Effective listening and interpersonal skills.
- 11.7 Time management skills/ability to prioritise workload.
- 11.8 IT skills.

## **12 JOB DESCRIPTION AGREEMENT**

Clinical Research Nurse Consultant signature:

Date:

Department Head signature:

Date:

[Salary - 4B year 1, then year 2]