

Clinical Research Nurse

1 JOB IDENTIFICATION

Job title:	Clinical Research Nurse (CRN)
Responsible to:	Senior Research Nurse Consultant/ Unit Manager /PI
Department:	Add local specifications
Division/directorate:	
Job reference no.:	
No. of CRNs:	
Last update:	

2 JOB PURPOSE

As a member of a research team, the Clinical Research Nurse will, under supervision, 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 CRN will deliver 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 CRN will maintain clinical and research governance.

3 DIMENSIONS OF THE POSITION

The Clinical Research Nurse will work within the department of (insert Dept name). In the absence of the Senior Research Nurse Consultant/Principal Investigator, the CRN may charge of individual clinical trials to ensure their effective operation. Key staff interactions include – nursing staff, clinicians, management, local research office as appropriate, support services, health & safety and risk management. The CRN is not responsible for managing the budget but needs to be aware of the resources available and the need to remain within budget parameters. The exact dimensions of the numbers and types of studies may vary in accordance with the dynamic nature of the clinical research unit.

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

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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 Senior Research Nurse Consultant/Principal Investigator, make decisions on the use of research resources.
- 6.1.9 Maintain a flexible approach to working hours in order to meet the requirements of the research protocols and subject recruitment.

6.2 Research Leadership/Management

- 6.2.1 In the absence of senior staff, assume responsibility for daily operational issues in regard to clinical trial protocols.
- 6.2.2 Recognise the importance of resolving complaints in a timely manner and effectively at local level and seek assistance as necessary. All complaints involving patient care to be reported to the unit manager as a matter of course.

6.3 Education

- 6.3.1 Where appropriate participate in the teaching of registered and non-registered nursing staff, including pre and post registration students.
- 6.3.2 Demonstrate a commitment to a personal continuing professional development and participate in performance review/appraisal.
- 6.3.3 Undertake additional training in order to acquire the knowledge and skills needed to implement new study protocols from a variety of clinical specialities.

6.4 Clinical

- 6.4.1 Organise own workload to ensure that the interests of the patients on the clinical trial are met
- 6.4.2 Maintain effective communication processes with patients and relatives, investigators, and other members of the multidisciplinary team to ensure information is appropriately shared.
- 6.4.3 Work within and monitor standards of care in the defined clinical trial protocols and the policies, procedures, standards and protocols of the research unit and local institution (hospital) to ensure adherence to, and delivery of, a high quality service.

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6.4 Clinical (cont)

- 6.4.4 Contribute to the development of policies and procedures within the research unit and/or research network conducting clinical research to ensure that clinical practice is underpinned by current best evidence.

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 clinical trial protocol including procedures and documentation to ensure the safe and accurate conduct and recording of the study.
- 6.5.3 Under the supervision of the Research Nurse Consultant, and in collaboration with investigators, develop and utilise study specific documentation to ensure that data is recorded accurately and in accordance with regulatory requirements.
- 6.5.4 Screen/register only appropriate patients for clinical trials as per clinical trial eligibility criteria. Follow patients as per protocol and, where necessary, facilitate participant withdrawal from a study in order to ensure the patients best care and the effective achievement of the study aims.
- 6.5.5 Provide ongoing advice and information to patients, be present at the signing of the patient/information consent form (PICF) and be actively involved in the ongoing informed consent process.
- 6.5.6 Liaise with all involved groups/departments to ensure all biological samples are collected, stored and processed as per the clinical trial protocol requirements.
- 6.5.7 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 CRN 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.

The CRN is expected to have knowledge of the research unit standard operating procedures and work within these guidelines.

8 DATA COLLECTION SYSTEMS

The CRN needs to be able to use and maintain all forms of data collection systems used for current clinical trials including both paper and electronic. Both to be used in compliance with state and national data protection and privacy legislation.

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8 ASSIGNMENT AND REVIEW OF WORK

The Clinical Research Nurse's work is generated from the research activities within the department/unit. The CRN will be responsible to the Senior Research Nurse Consultant / Unit Manager who will provide clinical guidance and professional management, work review and formal appraisal of performance. Workload will be assigned by the Senior Research Nurse Consultant / Unit Manager however the Clinical Research Nurse will have responsibility for managing defined workload within professional guidelines. Workload will be variable dependent on the number and status of clinical trial protocols being undertaken by the unit.

9 COMMUNICATIONS AND RELATIONSHIPS

9.1 Internal

- 9.1.1 Communicate and liaise with research participants, their relatives and multidisciplinary team.
- 9.1.2 Communicate with the Principal Investigator regarding patients condition and ongoing clinical trial participation.
- 9.1.3 Communicate with the Senior Research Nurse Consultant/Unit Manager regarding participants condition, workload issues and personal development.
- 9.1.4 Communicate with the local ethics committee and other relevant departments regarding the approval of, management and monitoring of clinical research studies.
- 9.1.5 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.
- 9.1.6 Report adverse events in a timely and effective manner at local level and escalate as appropriate.
- 9.1.7 Participate in the divisional Clinical Research Nurse forum and all other departmental meetings as appropriate or deemed by research manager.

9.2 External

- 9.2.1 Liaise with other research centres and multidisciplinary research teams on the day-to-day running of research studies and participant queries.
- 9.2.2 Liaise with collaborators and sponsor organisations.
- 9.2.3 Liaise with external regulatory and statutory research bodies as required.

10 KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED

- 10.1 Registered nurse with a minimum of 3 years post graduate nursing demonstrating the appropriate competencies and skills for the job and clinical setting.
- 10.2 Evidence of further education/continuous professional development.

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10 KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED (cont)

- 10.3 Demonstrated excellent team working skills with ability to work using own initiative.
- 10.4 Effective listening and interpersonal skills.
- 10.5 Time management skills/ability to prioritise workload.
- 10.6 IT skills.

11 JOB DESCRIPTION AGREEMENT

Clinical Research Nurse signature:

Date:

Department Head signature:

Date:

[Salary – Grade 3B Year 1, then year 2]