

## Senior Clinical Research Nurse Consultant

### 1 JOB IDENTIFICATION DETAILS

Job title:	Senior Clinical Research Nurse Consultant
Responsible to:	Principal Investigator and/or Department Head
Department:	Add local specifications
Division/directorate:	
Job reference no.:	
No. of CRMs:	
Last update:	

### 2 JOB PURPOSE

As a senior member of a research team, the SCRNC 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 SCRNC will ensure the highest standard of care is delivered to research participants and, where relevant, their families, in partnership with all members of the multidisciplinary and research teams. The SCRNC has responsibility and accountability for maintaining clinical, staff and research governance. The SCRNC will have the capacity to be a PI or associate PI on appropriate studies. The SCRNC has responsibility over protocol budgets within the framework of the research unit overall budget. In collaboration with the Department Head and the PI/s, the SCRNC will have control over which type of clinical protocols are undertaken within the unit resources.

### 3 DIMENSIONS OF THE POSITION

The SCRNC will work within the department of (insert Dept name) and within specified research networks. The research network groups consist of (insert group names). The SCRNC is responsible and accountable for the management of staff and resources within the department. Additionally, in smaller units, the SCRNC may oversee individual research studies to ensure their effective operation and completion. Key staff interactions include – nursing staff, clinicians, management, local research office as appropriate, pharmaceutical companies, support services, health & safety and risk management. The SCRNC will act as a consultant to other clinical staff and research staff, and to the wider community where appropriate. The SCRNC is responsible for managing the budget within resources available and budget parameters. The SCRNC will oversee the running of the research unit rather than be responsible for individual studies.

### 4 ORGANISATIONAL STRUCTURE

Insert organisational structure flow chart relevant to the position here.

### 5 ROLE OF THE DEPARTMENT

Insert department description and role here.

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### 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.
- 6.1.3 Ensure the conduct clinical research in accordance with TGA ICH GCP and the NHMRC National Statement on Ethical Conduct in Research Involving Humans and any other statutory and regulatory requirements (eg Privacy laws), in order to protect the research participant and quality of each study.
- 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 Ensure that staff are practising at their level of competence/ experience and that workload is evenly distributed.
- 6.1.7 Ensure that all staff within the unit are given the professional development they need to gain the expertise needed to co-ordinate clinical trials.
- 6.1.8 Make decisions on the use of research resources.
- 6.1.9 Recognise staff performance issues and appraise accordingly.

#### 6.2 Research Leadership/Management

- 6.2.1 In conjunction with Principal Investigator/Department Head, develop and update a strategy for clinical research in order to direct the departmental research programme.
- 6.2.2 Direct the development, implementation and monitoring of new research protocols in order to ensure that the effective management, resource implications, care requirements of the participants and training implications of each study are fully considered.
- 6.2.3 Co-ordinate the research set up processes (ethical, management, financial and resources) in the department and, if appropriate, act as a consultant in other study centres, to ensure that planned research studies are commenced with all required approvals and without undue delay.
- 6.2.4 Raise the profile of the clinical research programme among health professionals, patients and the public in order to promote and maximise recruitment to the research studies.
- 6.2.5 Be responsible for the control and monitoring of the research budget in order to ensure the provision of a quality and cost effective service.

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### 6.2 Research Leadership/Management (cont)

- 6.2.6 Provide advice and support to other members of the multidisciplinary team with regard to TGA ICH GCP and research governance requirements, project development, implementation and completion for each study, to ensure the safe and accurate conduct of the research.
- 6.2.7 Identify the training and education implications of each protocol and develop appropriate strategies to meet these needs to ensure the safe and accurate implementation of the study by self and others.
- 6.2.8 Recognise the importance of resolving complaints in a timely and effective manner and escalate as appropriate. Be aware of any/all complaints made within the unit and act accordingly.
- 6.2.9 In conjunction with the research team, write, publish, present and if appropriate, disseminate the research findings from studies to the wider medical community and the public.
- 6.2.10 Direct the multidisciplinary team, to the development, implementation and maintenance of policies, procedures, standards and protocols of the Ward, Directorate and Division to ensure adherence to, and delivery of the highest possible level of patient care within available resources at all times.
- 6.2.11 Ensure that all nursing staff are aware of, and work within, local, Directorate and Division policies and procedures to ensure that safe working practices are maintained for both patients and staff.

### 6.3 Education

- 6.3.1 Lead, motivate, support, develop and retain the research nursing team, utilising mentorship, objective setting and appraisal, enabling education needs of nursing staff to be met.
- 6.3.2 Ensure that the on going personal development needs and professional education and research are identified and met.
- 6.3.3 Undertake teaching of registered and non-registered nursing staff, including pre and post registration students, and participate in the implementation of staff personal development plans to facilitate ongoing development.

### 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.

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### 6.5 Research

- 6.5.1 Coordinate and participate in internal and external clinical trial monitoring/auditing activities as required to ensure professional standards and improvement, as well as regulatory and scientific requirements of each study are met.

NB. In smaller units, the SCRNC may also be actively involved in participant recruitment in which case items 6.5.2, 6.5.3 and 6.5.4 will apply.

- 6.5.2 Screen/register only appropriate patients onto clinical trials as per clinical trial protocol inclusion/exclusion criteria. Follow patients as per protocol and be involved with patient withdrawal from clinical trials as appropriate.
- 6.5.3 Provide ongoing advice and information to patients, be present at the signing of the patient information and consent form (PICF) and be actively involved in the ongoing informed consent process.
- 6.5.4 Liaise with all involved groups/departments to ensure all biological samples are collected, stored and processed as per clinical trial protocol requirements.

## 7 POLICY AND PROCEDURES

The SCRNC will have knowledge of local institutional/hospital policies and procedures. The SCRNC is responsible for ensuring all staff are familiar with policies and procedures to include -

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

The SCRNC will have knowledge of the unit standard operating procedures and ensure these are up to date and implemented appropriately by all staff within the unit.

## 8 DATA COLLECTION SYSTEMS

The SCRNC will be able to source or develop, use and maintain all forms of data collection systems used for current clinical trials including both paper and electronic. The SCRNC will also have the knowledge to utilise databases to collect ongoing unit activity/statistics.

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

## 9 ASSIGNMENT AND REVIEW OF WORK

The SCRNC's work is generated from the research activities within the department. The SCRNC will be responsible to the appropriate line manager as determined by the relevant employing organisation who will provide clinical guidance and professional management, work review and formal appraisal of performance. The post is self-directed in terms of time and workload management and duties are performed without direct supervision. The SCRNC will delegate/allocate work to the research team. The SCRNC will have a professional personal development plan and be reviewed. Workload may be variable dependent on the number and status of research studies.

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### **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 the Principal Investigator regarding patients condition and ongoing clinical trial participation.
- 10.1.3 Communicate with the Principal Investigator on a regular basis – regarding participant and study issues.
- 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 Maintain an awareness of current divisional issues and imparting information to colleagues.
- 10.1.6 Where relevant and in consultation with staff, discuss complex personal performance development and appraisal matters in a constructive manner.
- 10.1.7 Liaise with clinical and non-clinical support departments (eg pharmacy, medical records, imaging, procurement) to ensure all requirements for an individual study have been negotiated and approved during the development of the research protocol, and are in place for its implementation.
- 10.1.8 Participate in department/institutional research nurse forums and meetings.
- 10.1.9 Communicate with other relevant departments such as the Directorate/Operations Manager, finance, procurement, support services, human resources, health and safety, and risk management regarding clinical research studies and personal development.

#### **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 Where relevant, liaise with external research support organisations such as statistics and randomisation services.
- 10.2.3 Participate in, and where appropriate, present at external professional meetings/conferences related to research studies.
- 10.2.4 Liaise with collaborators and sponsor organisations.
- 10.2.5 Liaise with external Human Research Ethics Committees.

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

- 11.1 Registered nurse with a minimum of 2 years experience as a Level 2 Senior Research Nurse, or relevant experience demonstrating the appropriate competencies and skills for the job and clinical setting.
- 11.2 Degree level education or other relevant further education.

