

# Senior Clinical Research Coordinator

## 1 JOB IDENTIFICATION DETAILS

Job title:	Senior Clinical Research Coordinator (SCRC)
Responsible to:	Clinical Research Manager (CRM) or Department Head or Principal Investigator (PI) (insert appropriate role name)
Department:	Add local specifications
Division/directorate:	
Job reference no.:	
Direct reports:	
No. of SCRCs:	
Last update:	

## 2 JOB PURPOSE

As a member of a research team, the Senior Clinical Research Coordinator (SCRC) will, in conjunction with medical staff, contribute to or ensure (if appropriate for unit managers) the delivery of direct and indirect clinical trial related care of patients 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 Human Research and applicable state/federal privacy laws. The SCRC has responsibility and accountability for maintaining clinical and research governance.

## 3 DIMENSIONS OF THE POSITION

The Principal Investigator/Unit Head is responsible for delegating authority to suitably qualified staff. Within this authority, the Senior Clinical Research Coordinator will perform the role, using the required qualifications and experience, within the department of (insert Dept name). In the absence of senior clinical research staff, the SCRC will manage, and possibly oversee, individual clinical trials to ensure their effective and timely operation. Key staff interactions include – administrative staff, nursing staff, clinicians, management, local research office as appropriate, support services, health & safety and risk management. The SCRC will act as a consultant to junior research staff and to clinical staff as appropriate. The SCRC may also be responsible for staff supervision. The SCRC is not responsible for managing the budget but needs to be aware of the resources available and the need to remain within any specifically allocated 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 or bullet list relevant to this 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 Develop the role by using evidence based practice and continuously improving knowledge following training and education guidelines.
- 6.1.2 Conduct clinical research in accordance with TGA ICH GCP and the NHMRC National Statement on Ethical Conduct in Human Research and relevant state/federal privacy laws.
- 6.1.3 Make professional decisions relating to clinical trial management on a daily basis.
- 6.1.4 Provide professional advice relating to the conduct of clinical research to the multidisciplinary team.
- 6.1.5 In conjunction with medical staff, analyse and assess each patient's condition according to the trial protocol and determine appropriate action to ensure the patient's future care and participation in the study.
- 6.1.6 Act as a patient advocate at all times to ensure the patient's privacy and safety.
- 6.1.7 Within the guidelines of the employment contract, maintain a flexible approach to working hours in order to meet the requirements of the research protocols and patient recruitment.

### 6.2 Research Leadership/Management

- 6.2.1 In the absence of senior clinical research staff, assume responsibility for daily operational issues in regard to the management of clinical trials.
- 6.2.2 Contribute to the development of new research protocols and ensure the effective management of the study and patient requirements are fully considered.
- 6.2.3 Consider the training and education implications of each protocol and work with senior clinical research staff 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 research staff resources to ensure that an appropriate skill mix is maintained at all times.
- 6.2.5 Act as a consultant to Level 1 Clinical Research Coordinator/s and research/trial assistants to ensure development needs are identified.
- 6.2.6 Understand and function within the guidelines of hospital/departmental policies, guidelines and procedures.
- 6.2.7 Follow, develop, implement and maintain research standard operating procedures and guidelines as required.
- 6.2.8 Recognise the importance of resolving complaints in a timely and effective manner at a local level and seek assistance as necessary. Report all complaints involving patient care to senior clinical research staff according to departmental guidelines.

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### 6.3 Education

- 6.3.1 Plan and undertake teaching of clinical research staff, including students, and participate in the implementation of staff personal development plans to facilitate ongoing professional development.
- 6.3.2 Demonstrate a commitment to continuing professional development and actively participate in performance review/appraisal.
- 6.3.3 Maintain up-to-date clinical research skills and knowledge.
- 6.3.4 Identify the educational needs of junior research staff and initiate appropriate training programs.

### 6.4 Clinical

- 6.4.1 Organise workload to ensure that the interests of the research participants are met while still achieving study milestones (eg start-up, data locks, close-out).
- 6.4.2 Maintain and/or 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 within research protocols and research unit standards, policies and procedures to ensure adherence to, and delivery of, a high quality service.
- 6.4.4 Propose and develop working practices and 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.
- 6.5.3 In collaboration with senior clinical research staff, 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 protocol eligibility criteria. Follow participants as per protocol and, where necessary, act as a patient advocate to facilitate withdrawal from a study in order to ensure the patient's best care.
- 6.5.5 Ensure patients receive a copy of the Participant Information and Consent form and, if applicable, 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 and applicable storage and handling regulations.
- 6.5.7 Report serious adverse events and adverse events according to TGA ICH GCP guidelines and the trial protocol to ensure patient safety.

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- 6.5.8 Participate in clinical trial monitoring/auditing internally and externally as required in order to meet the regulatory and scientific requirements of each study in the prescribed timeframe. Collaborate effectively with relevant personnel to facilitate monitoring of clinical trial data, internal company audits and external reviews.

### 7 POLICY AND PROCEDURES

The Senior Clinical Research Coordinator will be actively involved in developing and maintaining unit standard operating procedures and be involved in implementation and updates.

The SCRC 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 SCRC will be able to use and maintain all forms of data collection systems used for clinical trials including paper and electronic. The SCRC will be able to instruct Clinical Research Coordinators in the use of these systems.

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

### 9 ASSIGNMENT AND REVIEW OF WORK

The Senior Clinical Research Coordinator's work is generated from the research activities within the department. The SCRC will be responsible to the [insert role name] who will provide clinical guidance and professional management, work review and formal appraisal of performance. Workload will be assigned by the Research Manager, Department Head or Principal Investigator however the SCRC 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 SCRC is a sole practitioner, they will be responsible for 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 each patient's condition and ongoing trial participation.
- 10.1.3 Communicate with the Research Manager/Unit Head in regard to workload issues and professional development.
- 10.1.4 Communicate with the local ethics committee and other relevant departments regarding the approval of, management and monitoring of clinical research studies.

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- 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/serious adverse events and resulting queries in a timely and effective manner according to the protocol, local ethics requirements and TGA ICH GCP guidelines.
- 10.1.7 Participate in departmental/hospital meetings and forums as appropriate or deemed by the Research Manager/Department Head or Principal Investigator.

### 10.2 External

- 10.2.1 Liaise with external research organisations and other health providers to obtain relevant clinical trial related data and/or pathology samples.
- 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 Degree qualified graduate with a minimum 5 years relevant work experience demonstrating the appropriate competencies and skills for the job and clinical setting.
- 11.2 Appropriate research experience including working knowledge of TGA ICH GCP Guidelines and relevant privacy legislation.
- 11.3 Evidence of further education including post-graduate certification / diploma / continuous professional development in a relevant area.
- 11.4 Demonstrated, excellent team working skills with ability to work using own initiative.
- 11.5 Effective communication and interpersonal skills.
- 11.6 Time management skills/ability to prioritise workload.
- 11.7 IT skills.

## 12 JOB DESCRIPTION AGREEMENT

SCRC signature: \_\_\_\_\_ Date: \_\_\_/\_\_\_/\_\_\_

Department Head signature: \_\_\_\_\_ Date: \_\_\_/\_\_\_/\_\_\_

Recommended minimum remuneration scales

- Health Information Manager Grade 3, Year 2
- Scientist Grade 2, Year 4
- Senior Research Officer 3

or other relevant equivalent award