

## 1. JOB IDENTIFICATION

Job Title: Clinical Trials Assistant – Band 3

Responsible to: Lead Research Nurse

Accountable to: Director, EMERGE

Department(s): EMERGE, Emergency Department, St John's Hospital

Directorate: Acute Medicine

Operating Division: NHS Lothian

No of Job Holders: 1

## 2. JOB PURPOSE

The post holder will assist with the delivery of direct and indirect clinical and research care, sample processing support for research studies. The post holder will assist with the general administrative requirements associated with study set up, running and closing of a clinical trials including data collection, data entry maintenance of essential documents. All work undertaken in the Department, is in accordance with the International Conference on Harmonisation Good Clinical Practice Guidelines (ICH-GCP) to ensure provision of high quality care.

The post holder will carry out assigned clinical duties under direct and indirect supervision of senior nursing staff other relevant professional practitioners to provide, through Divisional policies, a safe environment for the treatment of research subjects, and the protection of staff.

## 3. DIMENSIONS

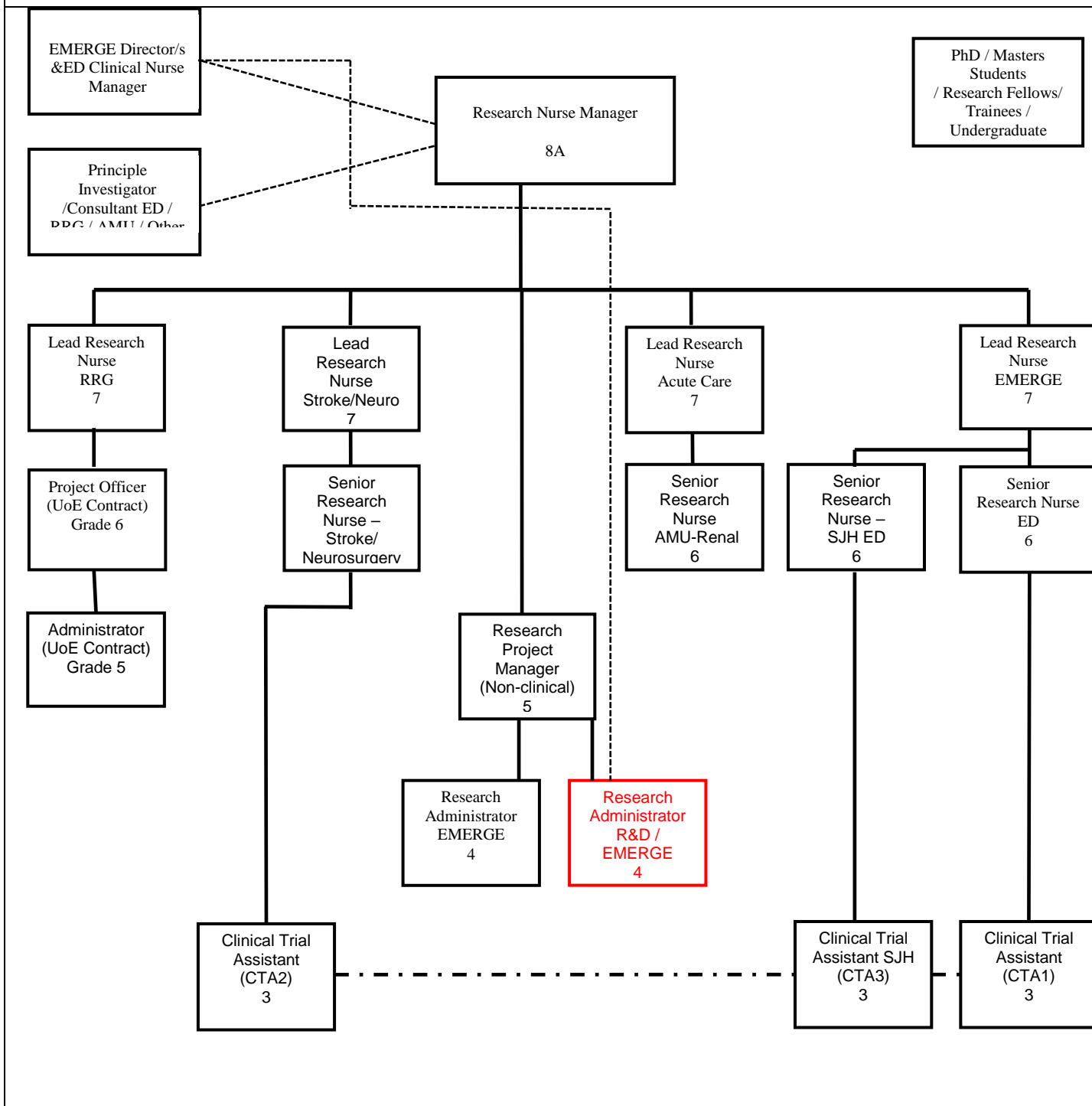
The post holder is employed within NHS Lothian and there may be a requirement to work flexibly across Lothian to meet service demands.

The post holder will work within the Emergency Medicine Research Group Edinburgh (EMERGE) on a range of diverse academic and commercial projects. The research subject groups consist of those patients presenting to the emergency department or pre-hospital care. The emergency department at the St John's Hospital receives ~55,000 patients per annum.

The projects cover all emergency medicine and pre-hospital related conditions and injuries, and change from time to time. The environment is dynamic and changing.

Staffing responsibilities: To work with the senior research nurses on screening, recruiting, following up subjects, maintaining good relationships with subjects, sample processing, data collection and entry, communication with multi-disciplinary teams and external organisations, and working with study monitors.

#### 4. ORGANISATIONAL POSITION



#### 5. ROLE OF DEPARTMENT

##### Role of Department

The Emergency Department at SJH plays a key role in the delivery of emergency care within NHS Lothian. It provides a 24-hour service for approximately 55,000 adult attendances annually across the complete spectrum of emergency medicine. The service aims to assess, treat, discharge or admit all patients within 4-hour targets.

Nationally, research in emergency medicine has remained predominantly on a small-scale and been undertaken in an *ad hoc* manner despite the clinical development of the specialty. Actively coordinated and integrated research needs to underpin clinical development if the specialty is to reach maturity. The Royal Infirmary of Edinburgh has traditionally been at the forefront of the specialties academic output in the UK despite having no formal links with the University of Edinburgh. The Emergency Department at the Royal Infirmary of Edinburgh has a long and distinguished track record of research in Emergency Medicine. For the past 30 years, the department has been renowned as a leading center for innovative research ideas and

their application. This work is recognized by the publication of over a dozen major textbooks and several hundred original research papers have been produced by medical and nursing staff. We would now like to develop research activity at the SJH emergency department following the same model.

The department has a worldwide reputation particularly for research into pre-hospital care, cardiac arrest and cardiopulmonary resuscitation, major trauma and lung injury.

### **Role of EMERGE**

The Emergency Medicine Research Group Edinburgh (EMERGE) has been established with three related aims:

- To support the individual researcher and project, in order to improve the quality of the research or audit
- To co-ordinate the departmental research activity, in order to facilitate the research and minimise disruption to normal clinical practice
- To raise the national profile of Emergency Medicine research

These aims will be achieved by:

- Providing researchers with guidance and information on research processes, from research idea to implementation
- Raising awareness of research amongst clinical staff
- Ensuring training in GCP and other research related procedures
- Regularly reviewing impact of research activity and provision of up-dates on progress (meetings/newsletter)

Maintaining a Register to record & co-ordinate research activity

## **6. KEY RESULT AREAS**

### **Clinical:**

1. Support research studies in accordance with the terms approved by the Research Ethics Committee and the appropriate NHS Research & Development (R&D) Office. This may include assisting in screening and evaluation of patient eligibility and coordinating of study tests and obtaining results. To work within defined standards, protocols, policies and procedures for the clinical area, directorate and NHS to ensure delivery of the highest level of care to research subjects.
2. Carry out a range of clinical duties with minimal / no supervision, adopting a holistic approach including clinical and psychological wellbeing. This may include blood pressure monitoring, oxygen saturation levels, body temperature, pulse rate and respiration rate, glucose monitoring, collection and testing of urine samples / faecal samples / sputum samples and wound swabs ensuring delivery of high quality patient care at all times. Undertake venepuncture procedures and remove cannulae in a safe manner in order to reduce any risk of infection. NB: this list is not exhaustive and will vary depending on area of work.
3. Provide sample processing support in order to ensure the maintenance of a safe and efficient processing, storage and timely shipping of research samples in accordance with local policy and trial protocol.
4. Report any observed changes in the participant's physical / psychological needs or condition and participate in the maintenance of accurate and up-to-date written and verbal communications to ensure participant needs are met and appropriate information is shared and documented
5. Accompany research subjects to other wards / departments / hospitals to ensure they are safe whilst out with the parent ward/research setting.
6. Have an awareness of potential risks within the clinical area, assessing these at all times (including patient behaviours and working environment) to ensure the health and safety of research subjects, visitors and staff and compliance with related legislation and guidelines
7. Maintain good relationships and an empathic approach to research subjects, carers and relatives and refer them to a registered nurse or other members of the research team for any questions, concerns or complaints

**Administrative:**

8. Under guidance of a research nurse gain knowledge of specified research protocols, procedures and documentation to ensure the safe and accurate conduct and recording of the study, including meticulous collection and collation of clinical trial data.
9. Assist with the creation and maintenance of essential trial documentation including Trial Site Files, study documentation and research records, in accordance to ICH GCP and undertake general clerical duties including photocopying and filing in order to support the administrative requirements the research team
10. Maintain confidentiality of patient records and data collection documents at all times, ensuring that Data Protection legislation is observed.
11. Monitor, order and maintain general stock levels and trial specific supplies according to study protocols, procedures and regulations and level of recruitment ensuring that resources are used appropriately and efficiently at all times.
12. Be responsible for ensuring personal ongoing training as required, ensuring skills/competencies are maintained.
13. Participate in clinical audit of services provided to ensure evidence based practice is identified and implemented.
14. To support NHS Lothian's values of quality, teamwork, care and compassion, dignity and respect, and openness, honesty and responsibility through the application of appropriate behaviours and attitudes

**7a. EQUIPMENT AND MACHINERY**

Post holder is expected to have knowledge of equipment used in the area, however appropriate training will be provided. Equipment will vary according to the requirements of individual research studies.

The following are examples of equipment which will be used when undertaking the role.

- Fridges, Freezers, Ultra Low Freezers (-40°C and -80°C)
- Alarm systems linked to fridges and freezers
- Refrigerated and bench top centrifuges
- Personal Computers, laptop, scanners, printers, photocopier, shredder
- Telephony
- Secure entry systems
- Patient handling equipment: wheelchairs
- Medical Equipment: blood glucose monitor, BP and Temperature, blood collection systems

New equipment may be introduced as the organisation and technology develops, however training will be provided

**7b. SYSTEMS**

The following are examples of systems that may be used when undertaking the role.

This list is not exhaustive and may vary depending on the research study:

- Maintaining electronic spreadsheets and databases that meet the requirements of each study and comply with Data Protection legislation
- Maintenance of up-to-date information on the progress of research studies
- Ensuring input, secure back up, storage and archiving of electronic study data
- Local Patient Administration System
- Human Resource Administration System
- Incident Reporting System
- Laboratory System – Specimen Results
- Procurement System
- Internet and Intranet
- eLearning for mandatory training and Continuous Professional Development

**Paper-based Systems:**

- Maintenance, secure storage and archiving of Study Site Files and other research records
- Maintenance of Temperature Records (fridge, freezer, drug cupboards)

**Note:** New systems may be introduced as the organisation and technology develops, however training will be provided.

**8. ASSIGNMENT AND REVIEW OF WORK**

The workload will be variable dependant on the number and status of research studies and is allocated by the appropriate Research Nurse.

The post holder is responsible for planning own workload under the guidance of the Research Nurse.

The post holder will be expected to exercise initiative and work with minimal supervision when providing direct care to research subjects (within scope of practice); however, a research nurse or medic nurse will be available for advice and guidance.

The post holder will be responsible to the Research Nurse who will provide clinical guidance and professional management, work review and formal appraisal of performance.

**9. DECISIONS AND JUDGEMENTS**

The post holder is expected to notice any changes in research subject's condition and report accordingly to a senior colleague.

Follows Standard Operating Procedures, suggesting updates as required.

Plans order of workload according to demands

Uses knowledge of systems and the local environment to make decisions required to carry out duties

**10. MOST CHALLENGING/DIFFICULT PARTS OF THE JOB**

Provision of high quality clinical and research care in a demand led environment, whilst meeting tight deadlines and timescales dictated by strict study protocols.

Working with a large number of research studies and protocols with very different support requirements whilst adhering to Research Governance Guidelines and ensuring accurate information and data collection in a busy and constantly changing environment.

Forward planning and preparing resources, managing time effectively, prioritising work to meet competing demands.

Ongoing maintenance and update of competencies to meet the requirements of the role and new study protocols in a limited timeframe.

**11. COMMUNICATIONS AND RELATIONSHIPS**

The post holder will communicate on a regular basis with the research subject, their relatives, the multidisciplinary team, internal and external agencies involved with the provision of care using effective verbal, non verbal and written communication.

The post holder will be expected to communicate and liaise with the multidisciplinary team and other relevant departments within the division e.g. Facilities, Estates, Pharmacy, Health and Safety, Research &

Development Office.

The post holder will liaise with manufacturers and suppliers of equipment regarding its maintenance and repair.

Will communicate effectively with carers, relatives and research subjects who may be distressed / worried or anxious.

Communicate with the Research Nurse regarding any research subject's care concerns and their personal development needs.

Written communications including meticulous data entry and sample logging

Works as a member of a multidisciplinary team.

Participates in departmental meetings and contributes to effective communication within the Research Team.

## 12. PHYSICAL, MENTAL, EMOTIONAL AND ENVIRONMENTAL DEMANDS OF THE JOB

### **Physical Skills:**

The physical skills required will vary according to study requirements and the post holder is required to acquire new physical skills and knowledge as studies dictate.

- Skills to manoeuvre wheelchairs and other equipment.
- Precision aliquoting of samples.
- 12-lead ECGs.
- Venepuncture.
- Basic life support.

### **Physical Demands:**

- Physical manual handling of research subjects,
- Push wheelchairs and other mobile equipment.
- Stand / walk for the majority of shift.

### **Mental Demands:**

- Working in a busy environment with frequent interruptions.
- Interactions with study investigators, occasionally dealing with complex scheduling requests.
- Concentration required for accurate data collection and input to Case Report Files and processing of clinical samples.
- Retention and communication of information.
- Concentration required when providing research and clinical care to participants e.g. venepuncture, blood pressure, urinalysis and study observations.
- Acknowledging ethical issues related to daily work.

### **Emotional Demands:**

- Communicating with distressed / anxious / worried research subjects and relatives.
- Assisting in the care of research subjects who are participating in studies that offer their only possible treatment hope/option in end of life situations.
- Pressure to ensure that clinical data and specimens are collected and examined correctly and timeously, knowing that inaccurate and delayed results could invalidate research findings and lead to erroneous conclusions.

### **Working Conditions:**

The environmental and working conditions will vary according to study requirements and may be as follows:

- Frequent daily exposure to biological samples of potentially infectious bodily fluids.
- Frequent daily exposure to ultra-low temperatures when archiving freezer samples.

- Temperature/air quality of working environment.
- Ergonomics.
- Requirement to undertake outreach work in a variety of hospital and community settings.
- Frequent exposure to substances classified under COSHH.

### **13. KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB**

SCQF Level 7 education in healthcare related subject E.g. SVQ3 in healthcare

Evidence of continuing development

Effective written and verbal communication, literacy and numeracy skills

Organisational and time management skills with attention to detail

Competent computer skills: familiarity with Microsoft Word, Excel and Outlook

### **14. JOB DESCRIPTION AGREEMENT**

A separate job description will need to be signed off by each job holder to whom the job description applies.

Job Holder's Signature:

Date:

Head of Department Signature:

Date: