#### **JOB DESCRIPTION**

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| JOB IDENTIFICATION |
| Job Title: R&D Clinical Research Assistant (CRA) Band 3  Responsible to (insert job title): Lead Nurse, Research and Development  Department(s): NHS Fife Research, Innovation & Knowledge  Directorate: Medical Director’s (NHS Fife) Directorate  Operating Division: Corporate Division  Job Reference:  No of Job Holders: 4  Last Update (insert date): 03 August 2023 |

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| 2. JOB PURPOSE | | |
| As part of a multi-disciplinary team the post holder will:   * Provide a comprehensive clinical and administrative support service for the clinical trials team. * Assist research nurses in providing and maximising specialist research and clinical care to research participants and will regularly work unsupervised throughout various locations/sites. * Proficiently perform the necessary aspects of care for this defined patient group and ensure appropriate data and paperwork associated with study recruitment is completed within a reasonable time. * Ensure an effective delivery of nursing care is provided to patients and that an acceptable standard is maintained. * Provide a safe environment for the treatment of patients and protection of staff in accordance with NHS Policies * Participate in Practice Development Programmes as required |

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| **3. DIMENSIONS** |
| 1. All Clinical Research Assistants are required to work within mandatory standards under direction and supervision (direct and indirect) of a Registered Practitioner. 2. As part of a multidisciplinary team the post holder will provide care to patients or healthy volunteers participating in research ranging from epidemiology studies to complex interventional clinical trials and will regularly work unsupervised. 3. Provide a high quality, safe and supportive environment in order to care for patients within NHS Fife and designated clinical areas to meet the identified physical and psycho-social needs of study participants while complying with study protocol requirements. 4. Contribute to the effective management of resources including supplies/equipment in the Clinical Research Facility CRF and hospital sites currently located in VHK and QMH. The post holder may also be required on occasions to support research in other Fife locations. 5. The post holder will provide reports as required to the Lead Nurse, Research and Development, NHS Fife. 6. The post holder will act within the principles of the Division’s Code of Professional Conduct for HCSW. |

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| 4. ORGANISATIONAL POSITION |
| NHS Fife  Director of Nursing – Professional Lead  Research, Innovation & Knowledge Assistant Director  Research & Development  **Lead Research Nurse**  Research & Development  **Research Nurses Band 5**  Research & Development  **Senior Research Nurses Band 6**  Research & Development  **Clinical Research Assistant**  Band 3  Research & Development  **Clinical Research Practitioner**  Band 4 |

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| 5. ROLE OF DEPARTMENT |
| The Research & Development Support Team, part of the Corporate Division and responsible to the NHS Fife Executive Lead for Research, Innovation and Knowledge (RIK) and the RIK Assistant Director. R&D provides a service to facilitate and co-ordinate activities to implement NHS Fife’s Research, Innovation and Knowledge strategy and those required to underpin research governance to deliver high quality, clinically effective services throughout NHS Fife. |
| 6. KEY RESULT AREAS |
| **Clinical, Research & Administrative Responsibilities**Assist patients in activities of daily living throughout the duration of a study visit. Visits in accordance with specific protocol requirements may range in time from 1-2 hour periods.Support the delivery of patient care as defined by the context, purpose and philosophy of the healthcare team to which they contribute.Share responsibility for key aspects of care delivery, demonstrating an awareness of cost efficiency and safety.Provide patient care in support of a registered nurse to ensure delivery of a high quality of patient care.Assist in implementation of clinical trial protocols in accordance with International Conference on Harmonisation/Good Clinical Practice (ICH/GCP). This will include complex commercial trials.Meticulous collection and collation of all clinical trial data using both paper and electronic format e.g. trial specific case report forms, nursing records, processing of study amendments.As part of the multidisciplinary team work in collaboration with investigators and research nursing staff to promote quality patient care and research data.Maintain good relationships and an empathic approach to clients, carers and relatives and refer them to an appropriate member of staff for any questions they may have on the clients condition or for any suggestions or complaints that they wish to raise.Work within departmental and organisational policies and procedures to ensure maintenance of safe working practices for patients and colleagues as outlined by NHS Fife Health and Safety Policies.When deemed competent and in receipt of the necessary skills by Lead Research Nurse (and Principal Investigator), undertake work independently, including consenting participants into appropriate trails/studies.Assist in the development of Standard Operating Procedures (SOPs) for use by all involved in research and/or clinicians using the CRF both within and outside the department and maintain appropriate study documentation, including Site Files, Databases and patient documentation as required.Maintain stock levels of all supplies and carry out housekeeping duties to support the smooth running of the clinical areas across the different NHS sites.Co-ordinate and monitor clinical equipment ensuring maintenance is carried out within necessary timelines reporting to the Lead Research Nurse.Co-ordinate appointment diaries, order patient transport and provide activity reports to RIKmanagement team as required.Perform complex technical duties relating to trial specific protocols for example ECG, venepuncture, processing samples including centrifuging, aliquotting, storage and transport.Maintain patient confidentiality at all times. **6.2 Other**   * Understand and adhere to NHS Fife policies and procedures. * Act in accordance with the Mandatory Induction Standards for HCSWs. * Maintain patient confidentiality at all times.  Ensure that the views of participants are effectively sought, channelled and acted upon, including the efficient actioning of the complaints procedure in accordance with the NHS Fife policy. |

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| 7a. EQUIPMENT AND MACHINERY |
| Post holder is expected to have knowledge and ability to use all equipment used in the area however may not have daily clinical involvement. Equipment will vary according to the requirements of individual research studies.   |  |  |  | | --- | --- | --- | | **Generic** | Specialised | Very Specialised | | Wheelchair | Venepuncture | Blood spinning/processing | | Fridge | Blood Pressure Monitor | Pulse Oximeter | | Temperature Controlled Freezers | Glucose monitoring | Incubator use | | Nurse call system | Urine filtering | Electrocardiograph ECG | | Databases | (others as studies dictate) | Centrifuges | | Fire Equipment |  | Dry and Wet Ice | | Oxygen cylinders |  | (others as studies dictate) | | Pat slides |  |  | | Walking Aids |  |  | | Raised toilet seats |  |  | | Computers/laptops |  |  |   Some studies have new highly specialised electronic equipment and techniques that require training with the development of standard operating procedures, dependant on the study requirements. The post holder will have responsibility for ensuring that adequate training and safety information is in place prior to the use of any new equipment within their team. |
| **7b. SYSTEMS** |
| * Good computer skills are essential for this job, especially demonstrated experience in use of databases for collection, analysis, and reporting of data. * Trakcare SCI Store MS Office software suite EDGE   ▪ Graphics and presentation software  ▪ Data capture and scanning system ▪ PC/Monitor/Mouse  ▪ Photocopier/Scanner/Laminator   * The post holder must be aware of the responsibilities placed upon them under the Health & Safety at Work Act 1974, to ensure that the agreed safety procedures are carried out to maintain a safe working environment for patients, visitors and employees * The post holder must have a working knowledge of multiple research protocols, case report forms, study logs and other documentation relating to research studies and be responsible for in-putting information into electronic patient record where applicable and also into patients written records. They will comply with the Data Protection Act, Caldicott Guidelines and local policies regarding confidentiality and access to medical records * Maintain knowledge and skills in the use of medical and nursing equipment. * Use of complex medical devices and all other patient monitoring equipment used. * Responsible for the safe, efficient and effective use of electro-medical equipment in the delivery of patient care. * Maintenance of study site files and all research records * Electronic CRF’s (on an individual basis) * Ensuring secure back up, storage and archiving of electronic study data  Paper-based Systems: Maintenance, secure storage and archiving of Study Site Files and other/research/patient records |
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| 8. ASSIGNMENT AND REVIEW OF WORK |
| * Although working for several Research Nurses, the post holder is managerially and professionally responsible to the Lead Nurse. * Project progress will be discussed and reviewed within relevant Departmental Team meetings. * The post holder will be expected to work unsupervised and exercise initiative when providing patient care/study support, however, a trained nurse will be available for advice and guidance. * The post holder will be expected to effectively manage unscheduled work activity. * Personal objectives will be agreed, and performance reviewed by the Lead Nurse or Team Lead on an ongoing basis and formally through the NHS Fife appraisal system. |

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| **9. DECISIONS AND JUDGEMENTS** |
| The agreed period of preparation is intended to promote autonomy, within the scope of the profile  contents, to allow the Health Care Support Worker to make:   * Informed decisions and responsible choices * Appropriate contributions to the planning, delivery and evaluation of direct healthcare and the context in which it is provided. * Planning order of work with a broadly defined routine. * Ability to recognise change in patient condition and know when to refer on to Research Nurses /Principal Investigator. * Follow agreed and defined procedures/processes/GCP guidelines. * Record and report serious adverse events to the registered nurse/Lead Nurse/PI and Local Personnel. * Freedom to act is guided by precedent and clearly defined NHS Fife policies, standard operating procedures, protocols and codes of conduct in accordance with NMC regulations, ICH-GCP, guidelines, Research Governance Framework, Medicine for Human Use (Clinical Trials) 2006, Adults with Incapacity Act and GDPR. |
| 10. MOST CHALLENGING/DIFFICULT PARTS OF THE JOB |
| * Managing and prioritising competing demands on time and accurately. * Encouraging study patients to follow treatment plan. * Ensuring patient safety at all times. * Communicating with and supporting distressed/anxious/worried patients/relatives. * Dealing with verbally abusive patients and members of the public. * Working simultaneously across a large number of clinical trials and protocols with very different support requirements from the post holder. * Working across multiple sites and working with a number of different teams. |

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| **11. COMMUNICATIONS AND RELATIONSHIPS** |
| * Promote and develop good relationships with patients, staff and visitors. * Promote good relationships between NHS Fife RIK and other services. * Conduct oneself in such a manner as to uphold and enhance the good standing and reputation of NHS Fife Research, Innovation and Knowledge Department. * Respect confidential information obtained in the course of duty and refrain from disclosing such information without the consent of the patient/client or a person entitled to act on his/her behalf, except where disclosure is required by law or by the order of a Court or is necessary in the public interest. |

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| **12. PHYSICAL, MENTAL, EMOTIONAL AND ENVIRONMENTAL DEMANDS OF THE JOB** |
| **Physical Demands:**  Patient movement with/without use of mechanical aides, manoeuvre patients.  Equipment movement, e.g. ECG machines, BP trolleys, patient trolleys, wheelchairs  Stand/walking for considerable time e.g. collection of patient case-notes from other departments  Exposure to bodily fluids / therapeutic products  Requirement to regularly move and work between sites in Fife  Use of IT equipment, keyboard skills, frequent use of mouse and VDU/Laptop  Requirement to attend meetings across Fife  **Mental Demands:**  Concentration required when checking documents/patient notes, processing samples  Concentration required when completing forms, reading data, entering data into databases, checking data quality.  Basic numeracy and English language skills.  Retention and communication of knowledge and information  Excellent time management skills.  Accuracy and attention to detail.  **Emotional Demands:**  Communicating with distressed/anxious/worried patients/relatives.  Supporting colleagues in emergency situations.  **Working Conditions:**  Exposure to body fluids.  Exposure to verbal aggression – occasionally |

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| 13. KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB |
| Experience, Knowledge and Qualifications   * Previous relevant NHS or other relevant experience. * Possess or be willing to undertake education opportunities at Scottish Credit and Qualifications   Framework (SCQF) level 6.   * Good general education. * Effective written and verbal communication/literacy/numeracy skills. * Evidence of team working skills with an ability to work using own initiative.   Skills   * Possess excellent organisational skills. * Ability to use IT applications proficiently. * Proficient in Venepuncture or a willingness to undertake training to develop skills. * Ability to carry out technical tasks, for example monitoring of vital signs, ECG monitoring and   24 hr blood pressure monitoring, in a busy clinical environment.   * Ability to travel throughout Fife * Mandatory Induction Standards and Code of Conduct for Healthcare Support Workers – NHS Circular CEL(2010)23 * Your performance must comply with the “Mandatory Inductions Standards for Health Care Support Workers in Scotland” 2009; and with the Code of Conduct for Health Care Support Workers, both as amended from time to time, which will be issued with your contract (further copies can be obtained from Human Resources). Failure to adhere to the Standards or to comply with the code may result in poor performance measures or disciplinary action and could lead to dismissal; or if you are self-employed, such failure will be deemed to be a breach of an essential term of your contract, allowing us to terminate with or without notice. |

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| **14. JOB DESCRIPTION AGREEMENT** | |
| A separate job description will need to be signed off by each jobholder to whom the job description applies.  Job Holder’s Signature:  Head of Department Signature: | Date:  Date: |