#### NHS LOTHIAN

##### JOB DESCRIPTION

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| JOB IDENTIFICATION |
| **Job Title:** Research Nurse Manager  **Responsible to**: CRF Deputy Director  **Directorate**: Research and Development  **Operating Division**: NHS Lothian University Hospitals Division  **Job Reference**: 159664  **No of Job Holders**: 1  **Last Update**: July 2021 |

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| 2. JOB PURPOSE | | |
| The post holder has strategic and operational management responsibility for the delivery of the Nursing and Clinical Service (N&C) within Edinburgh Clinical Research Facilities (WGH, RIE, and RHCYP sites). He/she directs the N&C service, ensuring that the staff, environment and facilities provide the highest standard of care and safety for research subjects, and produce quality research data in accordance with, local policy, clinical, professional and Good Clinical Practice Guidelines (GCP). They are a member of the Senior Management Team in Edinburgh CRF.  The post holder has accountability for patient care and the clinical management of up to 100+ active studies annually. Studies involve a broad range of clinical specialities including paediatrics and include first in human trials plus early phase clinical and experimental medicine trials. Studies are undertaken across a variety of hospital and community settings.  The post holder is responsible for managing the delivery and maintenance of Medicines for Healthcare products Regulatory Agency (MHRA) Phase I Accredited Facilities across the CRF N&C adult service at WGH, RIE and RHCYP sites.  The post holder is an expert member of the CRF Phase I Scientific Review Committee (PISRC) will review and contribute to the risk assessment of trial protocols, ensuring safe conduct and mitigation of risk when conducting Phase I and first in human studies within the CRF.  The post holder will contribute to the clinical research agenda locally through active involvement in NHS Lothian’s Research Nurse Forum, and membership of Lothian Research Nurses Operational Management Group. Nationally they will contribute to the United Kingdom Clinical Research Facility (UKCRF) Network and Scottish CRF Managers Group, and participate in their dedicated working groups and the dissemination of outputs through national conferences, education and networking. | | |
| **3. DIMENSIONS** | | |
| The CRF Nursing and Clinical Service operate facilities over three hospital sites located in the WGH, RIE and RHCYP. These facilities provide specialised clinical research services and include a team of research nurses on each site, Lead Nurses who specialise in phase 1 trial delivery and a team of community research nurses based at the RIE site. This necessitates travel across all CRF sites and into the community on a regular basis.  All three Edinburgh CRF sites are Medicines for Healthcare products Regulatory Agency (MHRA) Phase I Accredited Facilities. The post holder is responsible for ensuring operational inspection standards and consistency of practice is maintained across sites, thus ensuring facilities meet, and studies are conducted in compliance with these rigorous standards.  The post holder is a key member of the CRF inspection Team during Phase I MHRA inspection.  The post holder is responsible for developing and maintaining the nursing and clinical workforce establishment and provides professional leadership, specialist nursing and research expertise, to a nursing and clinical team of 65 staff, ensuring that studies are run effectively according to clinical, ethical, governance and financial requirements and meet all targets set and agreed with our local R&D office.  The post holder is responsible for assessing study feasibility and finance costs for access to the CRF nursing and clinical service.  The post holder works within an annual budget of circa £2.5m for the nursing and clinical services. The post holder is an authorised signatory up to £5K.  The post holder will deputise for the CRF Deputy Director as required, including attendance at or hosting local, national and international research meetings. This includes regularly chairing CRF Operational Management Committee (OMC) meetings. | | |
| 4. ORGANISATIONAL POSITION | | |
| *CRF Deputy Director*  Research Nurse  Manager  *(This post)*  Nursing Team  WTCRF  **Organisational Chart**  Lead  Research Nurse  (WGH)  Lead  Research Nurse  (RHCYP)  Lead  Research Nurse x 2  (RIE)  Nursing Team  CCRF  Nursing Team  RIECRF  Biomedical Scientist  (RIE)  Clinical Support & Admin Team  Community Research Nurses x3  Clinical Support & Admin Team  Lead Nurse  x 2  Phase 1 & Education  Clinical Support & Admin Team | | |
| 5. ROLE OF DEPARTMENT | | |
| **Edinburgh Clinical Research Facilities (CRF)**  Edinburgh Clinical Research Facility is a multidisciplinary facility, accessible to all clinical specialities in NHS Lothian and the University of Edinburgh. The role of the facility is to provide a co-ordinated and controlled infrastructure and clinical environment to assist investigators to conduct clinical research safely, efficiently and cost effectively. Edinburgh CRF operates in dedicated clinical research facilities within three NHSL hospitals: the Royal Infirmary of Edinburgh (RIE), the Western General Hospital (WGH) and the Royal Hospital for Children & Young People (RHCYP). In addition, specialist research services are provided within satellite facilities in Edinburgh University’s College of Medicine & Veterinary Medicine (CMVM): the Queen’s Medical Research Institute, Clinical Research Imaging Centre (CRIC) and Brain Research Imaging Centre (BRIC).  The first of five such centres to be established in Scotland, Edinburgh CRF is accessible to multidisciplinary researchers throughout NHS Lothian, the University of Edinburgh and the national / international research community. The CRF provides a high quality clinical environment in which patients and healthy volunteers can participate in research programmes safely and effectively according to robust, ethically approved protocols.  The CRF is composed of over 100 staff (both NHS and University of Edinburgh contracts) and it supports over 400 clinical research studies annually (academic & commercial). Approximately 150-200 of these studies will require Nursing & Clinical Services support, including strictly regulated Phase I/ First in human (FIH) Clinical Trials. 8000 subject visits take place each year (inpatient, outpatient & outreach).The research subject groups cover all clinical specialities and includes adult and paediatric patients and healthy volunteers. Research subjects are managed within a variety of NHS and University settings including primary care.  In July 2011, Edinburgh CRF became a member of the Medicines & Healthcare products Regulatory Agency (MHRA) Phase I Accreditation Scheme. It was the first academic research centre in the UK to achieve this quality standard, having passed rigorous scrutiny during an intense government agency inspection. The CRF is subject to regular compliance checks to maintain this prestigious accreditation status and has established an expert panel of leading clinicians, research managers & statisticians to review early phase and potentially high risk studies on behalf of NHS Lothian (Phase I Scientific Review Committee, PISRC), This post has a key role to play in the PISRC and the postholder is expected to provide expert input in terms of mitigating risks to participants and ensuring regulatory compliance of study conduct.  NHS Lothian has a national and international reputation for its contribution to biomedical research, and NHS R&D activity is viewed as an essential component of its strategic objectives. Working in conjunction with its academic partners, research charities/organisations and clinical specialities, the Board takes a lead in developing research within Scotland. The CRF has a central role in the delivery of the Board’s R&D objectives through the co-ordination of complex studies, management of research data and the delivery of specialist services within a dedicated environment that facilitates compliance with research governance regulations.  The role of the CRF is to facilitate the translation of basic science knowledge into improved methods of patient care by:   * Providing a co-ordinated, controlled infrastructure underpinned by robust Quality Management Systems, to assist investigators to conduct clinical research safely, efficiently and cost effectively. * Providing a team of highly skilled qualified research personnel and associated specialist services to support investigators through every stage of their research (Core areas: Epidemiology & Statistics, Imaging, Genetics, Mass Spectrometry, Education and Information Technology). * Providing an MHRA accredited unit in which to conduct early phase clinical trials & First in Human (FIH) studies. * Leading risk assessment & mitigation processes for Phase I trials on behalf of NHS Lothian Board in order to inform institutional management approval. | | |
| 1. **KEY RESULT AREAS**  |  | | --- | | **Operational management and strategic planning**   1. The post holder is responsible for directing the operational management and development of the nursing and clinical services provided by Edinburgh’s CRF. 2. As a member of the CRF Operational Management Team (OMT) assist in developing and implementing the strategy and organisational goals for clinical research within the CRF, for example, capability and capacity of the expanded Children’s Clinical Research Facility within the RYCYP and the continued expansion of Phase I and advanced therapy capability. 3. As a member of OMT, contribute to Board and national initiatives and goals, for example, direct the nursing and clinical service in supporting and contributing to patient and public engagement/involvement (PPI/PPE). 4. As a member of the CRF Operational Management Committee (OMC), contribute to the approval of all CRF studies across all CRF cores disciplines. 5. Interpret complex research protocols to assess feasibility of study applications for support of CRF nursing and clinical services, including safety, governance and ethics, resources, finance, skills, recruitment and timelines. Present clinical studies to OMC for consideration and approval. 6. Contribute to the ongoing development of CRF IT systems which support study scheduling and project management, providing safety information supporting Phase I and compliance with GCP processes, accurate metrics data for CRF annual reporting, finance information for invoicing and recruitment data for R&D and Scottish Government (Chief Scientist Office-CSO) reports.   **Financial management**   1. Formulate and assess study cost for use of nursing and clinical services and resources for academic and commercial applications. This includes providing prospective costs to researchers and NHS Lothian Research and Development (R&D) Department for research grant submissions. In providing a quality and cost effective service, the CRF contributes to securing research awards within NHS Lothian and University of Edinburgh. 2. Track the nursing and clinical annual recurrent budget of circa £1.0m per year, plus other salary costs (circa £1.5m per year) supported via grant awards to ensure the service operates within the financial allocation and projected income. 3. Liaise with the CRF administration team to ensure appropriate invoicing for nursing and clinical resources, and development of effective tracking of study activity for financial invoicing, 4. Respond to changes in financial instructions and allocations from the Scottish Government’s Chief Scientist Office (CSO).   **Clinical leadership and staff management**   1. The post holder is responsible for directing, developing and maintaining the nursing and clinical workforce establishment across all sites, including providing professional leadership, leading appraisal, personal development planning and performance review for the Lead Nurses and Community Nursing team. 2. Provide clinical leadership and advice to CRF Lead Nurses, clinical staff, researchers and other members of the multidisciplinary team with regard to GCP requirements, project development, implementation, conduct and safety ensuring practice conforms to national and local Research Governance requirements set out to protect the research subject and quality and integrity of each study. 3. Direct the Lead Nurses and research teams in maintaining continuous Phase I Accreditation standards and provide advice on the implementation of the PISRC study risk assessments for early phase clinical studies that involve the administration of new drugs to humans for the first time. | |  | | | |
| 1. Direct, develop, and monitor standards of care for the CRF clinical services and in the defined research protocols, policies, procedures of the organisation to ensure that clinical and research practice is underpinned by current best evidence across all CRF sites. 2. Practice at all times within the Nursing and Midwifery Code of Professional Conduct (updated 2018), using evidence-based practice to continuously improve own and others knowledge and ensure that each research subject’s needs are met. 3. Act as a role model and expert advisor in setting and monitoring standards of care within the CRF by providing high quality, specialist clinical care when conducting assessment, treatment, monitoring and undertaking research interventions with research subjects, for example, when dosing an investigational agent to a trial participant involved in a first in human study. 4. Write, implement and review CRF specific policies and procedures which impact across the CRF organisation.   **Teaching and training**   1. Teach and deliver specialist research specific training in a range of subjects relating to research, locally within NHS Lothian, for example NHS Lothian Research Nurse Forum and UK wide, for example, delivery of study costing tool workshop as part of the UKCRF Network work-stream activity. 2. Support student nurse and MSc in Clinical Research Postgraduate student placements within the CRF, by undertaking mentorship and ensuring systems and resources are in place to support student placement plans and objectives. |

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| 7a. EQUIPMENT AND MACHINERY |
| Volumetric infusion devices and syringe drivers  Specialist research equipment e.g. SphygmoCor Pulse Wave Analysis kit (PWA).  Venepuncture and other clinical supplies  Desktop and laptop computer, network printer  Document Scanner / Document Shredder / Photocopier  Telephone/Teleconferencing Equipment  Videoconferencing Equipment / Power Point Projector / Web cam / Digital Camera  Ultra low temperature freezers (-40oC and -80oC) and associated auto-dialler alarm system. (Post holder is called out in the event of a mechanical failure in order to salvage research samples and ensure their safe transfer under optimal conditions to an alternative freezer. Requires interrogation of auto-dialler to determine location and fault of malfunctioning freezer.)  ADT Security System (CRF Intruder Alarm)  The post holder is expected to have knowledge and ability to operate relevant equipment used in the clinical area however may not have daily clinical involvement. Equipment will vary according to the requirements of individual research studies.  The post holder is responsible for scoping and purchasing new equipment for the CRF and can include advising researchers on the type and specification of equipment required for their studies. The post holder is required to have awareness and working knowledge of a variety of clinical and research equipment. |
| **7b. SYSTEMS** |
| Maintaining electronic spreadsheets and databases that meet the requirements of each study and comply with Data Protection legislation.  Generate reports and run data queries relating to the conduct and status of ongoing research studies allowing analysis of collated information  Use of Share Point electronic document management system and SOP management system  Maintenance of up-to-date information on the progress of research studies  Ensuring secure back up, storage and archiving of electronic study data  Local Patient Administration System: TRAK  Human Resource Administration System: Empowar and SSTS  Manage Incident Reporting System: DATIX Intranet  Apex Laboratory System – Specimen Results  CRF ManagerTM (a bespoke suite of IT applications to record research activity, schedule subject visits and produce activity reports)  Internet and Intranet – Personal and Business Paper-based Systems Maintenance, secure storage and archiving of Study Site Files and other research records  Maintenance of personnel records |

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| 8. ASSIGNMENT AND REVIEW OF WORK |
| The post holder will be responsible to the CRF Deputy Director who will provide professional management.  In conjunction with the CRF Deputy Director the post holder will set broad annual performance objectives and these will be reviewed as part of a formal appraisal process.  The post holder has a significant degree of autonomy in terms of workload management, and is self-directed in organising workload and working within the priorities and responsibilities of the post.  The post holder’s work is generated from management and research activities across the CRF sites and wider research community and any additional organisational and national commitments.  The post holder will oversee the workload of others and delegate/allocate work to the Lead Nurses and research teams as required.  The post holder will be expected to effectively manage and monitor unscheduled work activity, both of self and others.  Workload will be variable dependant on the number and status of research studies, applications and enquiries, operational management and staffing issues across all CRF sites. This requires flexibility of working hours and location to take account of varied workload. |

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| **9. DECISIONS AND JUDGEMENTS** |
| Clinical and professional decisions will be made autonomously on a daily basis, with occasional reference to line manager or Operational Management Team where necessary.  Complex decisions requiring analysis using expert clinical, research and management knowledge to assess suitability of research protocols, address issues of patient safety, of organisational risk, scientific validity, ethics and data Legislation, legal and Governance considerations, resource utilisation, financial arrangements, contractual issues and practical feasibility.  Judgments involving complex facts with multiple stands or situations related to research activity and organizational issues, which require the analysis, interpretation and comparison of a range of options. For example, recruitment, redistribution and allocation of staff and CRF funds to support proposed and projected research activity, purchase of study equipment or allocation of staff for long term training and associated funding.  Decisions and judgments related to resources and creation of CRF financial costs for proposed studies, including discussion and negotiation with NHS R&D and commercial organizations.  Clinical and professional advice and judgements relating to the conduct of clinical research will be provided to the multidisciplinary team. For example, the decision to exclude research participants the research team wish to recruit, this may be as a result of stipulations within the protocol, Research Governance and Statute, GCP requirements, or patient safety standards.  Decisions and judgements will be made that act in the research subject’s best interests to ensure their rights and safety are upheld, when overseeing research activity or when identifying, screening, recruiting, and delivering care in clinical research studies.  Recognising and acting upon staff performance issues that necessitate education, support, counselling. This may require incident investigation or action in accordance with NHS Lothian’s ER policies and include disciplinary and employee capability issues.  Recognising and acting upon breaches of research governance legislation, responding appropriately and escalating action as required. This may involve launching a formal investigation into incidences of suspected fraud or research misconduct that involve senior clinical academic professionals.  Freedom to act is guided by precedent and clearly defined NHS policies, protocol/procedures and codes of conduct in accordance with NMC regulations, GCP Guidelines, UK Policy Framework for Health & Social Care Research, Medicines for Human Use (Clinical Trials) Regulations, Adults with Incapacity Act and Data Protection Legislation. |

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| 10. MOST CHALLENGING/DIFFICULT PARTS OF THE JOB |
| Directing, leading developing, managing and motivating the nursing and clinical teams across three sites and across several specialist clinical areas.  Ensuring the delivery of the highest quality patient care, clinical and research standards within the existing resources, whilst ensuring consistency and co-ordination of work practices and processes across all CRF clinical teams,  Ensuring the CRF MHRA Phase I Accredited sites operate at the required standard to ensure subject safety in early phase and First in Human studies and adhere to the Scheme requirements.  As a key member of the inspection personnel undergo inspection interviews and manage information gathering to facilitate a positive inspection outcome.  The use of specialist research knowledge to promote and encourage best practice across the nursing and clinical team and provide guidance to other multidisciplinary teams accessing the CRF services.  Identifying and dealing appropriately with contentious performance, personnel, recruitment or other issues with staff, or complaints from research subjects or relatives.  Dealing with difficult situations involving senior researchers that require a great deal of tact, diplomacy and assertiveness e.g. communication of unfavourable findings during facilities inspection, issues of study conduct or patient participation.  Promoting the CRF clinical service both locally and nationally, across all disciplines, ensuring current best practice and attracting and supporting the highest quality clinical research.  Contributing to the development and delivery of the CRF’s long term strategic goals within the context of dynamic healthcare and research policy. |

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| **11. COMMUNICATIONS AND RELATIONSHIPS** |
| The post holder is required to possess a high level of communication skills adaptable across a wide range of communication abilities from MHRA Inspectors, Principal Investigators, CRF staff, and other research personnel across all disciplines and departments within NHS Lothian and the University of Edinburgh, to potentially distressed or upset patients or relatives, or those with communication difficulties. This includes communication with external organisations on a national level.    The post holder will require specific communication skills at a level and ability to:   * Chair meetings effectively * Manage and address contentious personnel issues informally and formally in line with NHS Lothian’s Employee Relations policies e.g. addressing conflict or capability issues within the clinical team * Persuade, influence and negotiate in order to reach consensus, and secure involvement of colleagues, researchers, other departments and external agencies e.g. negotiating CRF charges with commercial organisations, stopping study recruitment of patient participation in a given trial, or communicating and managing change within the organisation and across departments. * Write reports, articles and papers to publication standard * Present complex/specialist information at meetings e.g. prepare and present nursing and clinical studies to Operational Management Committee (OMC) for approval, collate and report serious adverse events (SAE’s) for trend reporting * communicate clearly and effectively on CRF practice during critical Phase I Accreditation or GCP inspection interviews * Provide patients with complex information regarding study participation and undertake the informed consent process effectively * Communicate clear and concise decisions regarding daily work practice and ongoing management within the clinical facilities to all levels of staff. * Communicate in a manner appropriate to the situation at any given time, considering the appropriate level of communication required for the group or individuals involved. This will involve frequent alteration of approach due to the number of interruptions and operational nature of the post. |

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| * 1. **PHYSICAL, MENTAL, EMOTIONAL AND ENVIRONMENTAL DEMANDS OF THE JOB** |
| **Physical Skills:**  There is a requirement for speed and accuracy in dealing with research subjects, equipment and data management with narrow margins for error. The physical skills required will vary according to study requirements and the post holder may be required to acquire new physical skills and knowledge as studies dictate.  Administer intravenous injections and or intra-muscular injections,  12-lead ECGs.  Intravenous cannulae / venepuncture  Intravenous additives  Blood Glucose monitoring  Intermediate life support  **Physical Demands/Effort:**  Frequent periods of VDU exposure  Occasional requirement to manoeuvre patients using trolleys, wheelchairs.  Occasional requirement to lift and manoeuvre research equipment and study supplies.  Positional work related to specific study procedures and techniques e.g. Pulse Wave Analysis  **Mental demands of the job**  Managing and balancing the multiple and competing demands associated with responsibility for, staff, resources, facilities, data, research subjects, maintaining quality and inspection standards across 3 sites and with in the community. This involves an unpredictable work pattern and often requires working late or adjustment of work hours or location at short notice.  Motivating the clinical teams and directing change management to meet strategic targets.  Working with constant interruptions whilst reading / writing reports including frequent enquiries from internal and external departments requiring information and or specialist advice with no prior warning and within tight time constraints.  Frequent requirement for long periods of intense concentration e.g. when preparing data and information, writing reports, calculating study finances and resources for complex commercial protocols, interpreting and implementing complex protocols, observing subjects receiving non-routine, novel investigational medicinal product (IMP) or research interventions.  Recognising and responding to ethical issues in the review of protocols, or that may arise during the conduct of a study and acting as a source of advice in these situations.  Managing highly stressful meetings requiring high levels of tact, diplomacy, assertiveness and negotiation skills, requiring difficult decisions to be made, for example staff management, first line disciplinary or and capability issues, addressing patient safety concerns or complaints, study finance, facilities and resource management.  **Emotional effort**  Frequently dealing with complex and sensitive staff performance and personnel issues that may include conflict resolution and or negotiation skills.  Dealing with and resolving complaints where individuals/patients may be upset or angry, investigating incidents addressing issues raised.  Occasional exposure to distressing or emotional circumstances e.g. emotional effects before and during MHRA and other regulatory agency GCP inspections and interviews.  Supporting staff conducting, and patients who are participating in studies that may offer the only possible treatment hope/option in end of life situations.  Working daily to maintain inspection standards and undertaking business critical regulatory inspections that have implications for the CRF’s future compliance and sustainability.  **Environmental and working conditions:**  Exposure to body fluids whilst conducting patient care and processing samples  Frequent requirement to travel between hospital and university sites within Lothian.  Occasional requirement to travel throughout the UK for meetings that involve an overnight stay.  Occasionally called out in unsocial hours in event of triggered security alarm or freezer failure.  Rare exposure to verbal aggression |

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| 13. KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB |
| Registered nurse with evidence of extensive clinical and research experience in a management and leadership role  Educated to masters degree level in a clinical or life sciences related subject or with equivalent highly developed specialist knowledge and practical experience, demonstrating the ability to interpret, analyse and write technical documents and reports at an academic and theoretical level and able to deliver Masters level training e.g. for MSc in Clinical Trials  Postgraduate certification/ diploma/ Continuous Professional Development in clinical leadership and management up to date Good Clinical Practice Certification  Experience of working at a senior level in a Clinical Research Facility or large Research Team  Extensive clinical and research experience in a management and leadership role  Specialist knowledge and experience of clinical research delivery across a broad range of clinical specialities and study types  Experience of managing and leading on complex regulated clinical trials  Experience of participating in, preparing and directing a team on regulatory compliance  Proven leadership qualities and ability to work effectively as part of a team  Highly developed working knowledge of regulatory frameworks and legislation governing the conduct of clinical research e.g. UK Policy Framework for Health and Community Care Research, Medicines for Human Use (Clinical Trials) Regulations, Adults with Incapacity (Scotland) Act, Data Protection Act, Governance Arrangements for Research Ethics Committees and Human Tissue Act.  Detailed understanding of local and national prioritisation for research activity and the ability to convey that knowledge across multiple stakeholders  Excellent communication skills (oral, written & presentation) including effective listening and interpersonal skills.  Ability to interpret complex information and disseminate that clearly to all grades of staff  Self-motivated and able to work independently and as part of team  Demonstrates a strict attention to detail  Highly efficient time management and organisational skills with the ability to prioritise workload, delegate and direct others  Advanced IT Skills with a proven ability to maintain and interrogate complex information sources and databases |

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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: |