Royal Devon University Healthcare NHS Foundation Trust

JOB DESCRIPTION

JOB DETAILS	
Job Title	Lead Research Nurse
Reports to	Research and Development Operations Director
Band	Band 8b
Department/Directorate	Research and Development

JOB PURPOSE

The Lead Research Nurse/Practitioner will be responsible for ensuring the delivery of a comprehensive portfolio of clinical trials at the Trust in line with performance and monitoring metric/objectives. The postholder will develop networks with other disciplines across the Trust and other appropriate local and national agencies including the NIHR Clinical Research Network. They will manage the workforce budget of circa £4 million and oversee the various income streams to ensure financial stability. The post holder is a member of the Trust's professional management structure and the South West Peninsula Regional Research Delivery Network (SWP RRDN) Lead Research Nurse Group.

The post holder is the managerial and strategic lead for the clinical research workforce at the Trust which includes all aspects of research activity, including expert practice, education, development and leadership. The post holder will act as line manager for the Research Matrons and act as an expert resource to those involved in clinical trials at all levels. The Lead Research Nurse will ensure that research will be conducted in accordance with the UK Framework for Health and Social Care Research and Good Clinical Practice regulations and guidelines to provide assurance that the rights, safety and well-being of trial participants are protected. The postholder will lead by example and empower staff in their personal and professional development, promoting the undertaking of a broad range of research to modernise and improve patient care

KEY RESULT AREAS/PRINCIPAL DUTIES AND RESPONSIBILITIES

- Support the Director of Research and Development and Research & Development Operations Director to champion the delivery of excellent care of patients in research trials and studies and their families providing compassionate leadership, and retaining a focus on engagement and co-production within the services.
- Provide effective leadership within designated areas of responsibility promoting the highest standards of safe, high quality care and an effective learning environment for all staff.
- Act as line manager for the Research Nurse Matrons and other appropriate research staff and oversee the management of the Clinical Research Delivery Team (circa 110 wte).
- Utilise expert knowledge to continually develop the clinical research service to increase capacity and maximise delivery.
- Strategically develop the clinical research delivery service to increase early to late phase clinical trial capacity and maximise delivery potential

- Provide expert leadership in developing new and innovative ways of working to deliver an expanding portfolio of clinical research trials
- Implement and oversee robust performance management processes to ensure clinical research delivery meets contractual obligations
- Provide specialist knowledge and support to all involved in clinical trials including Chief Investigators, Principal Investigators and Research participants/patients
- As a member of the R&D senior leadership team, support operational and business planning and oversight of delivery
- Act as a key member of the senior R&D Management Team contributing fully to the development delivery and achievement of all R&D objectives
- Support the development of R&D strategy, policies and relevant SOPs for the safe delivery of research.
- The Trust Lead Research Nurse will take the lead on clinical research delivery throughout the Trust, promoting best practice through strong leadership and an effective change management strategy, designed to enhance, develop and improve the nursing care of patients involved in research
- Ensure staff have the appropriate education and training to maintain accurate research patient trial documentation, and completed data sets for study sponsors across all RDUH studies, the quality of data being a key element of research
- Act as a professional lead and work within the relevant professional code of conduct (E.G. NMC scope of Professional Practice and Code of Conduct). Lead by example and act as a positive role model for all staff, taking responsibility for own professional development
- Promote best practice and implement innovations in care within all services

KEY WORKING RELATIONSHIPS

Areas of Responsibility: Clinical trials and research.

No. of Staff reporting to this role: 2 Direct Reports (Circa 1000 wte indirect) across all Royal Devon sites.

The post holder is required to deal effectively with staff of all levels throughout the Trust as and when they encounter on a day to day basis.

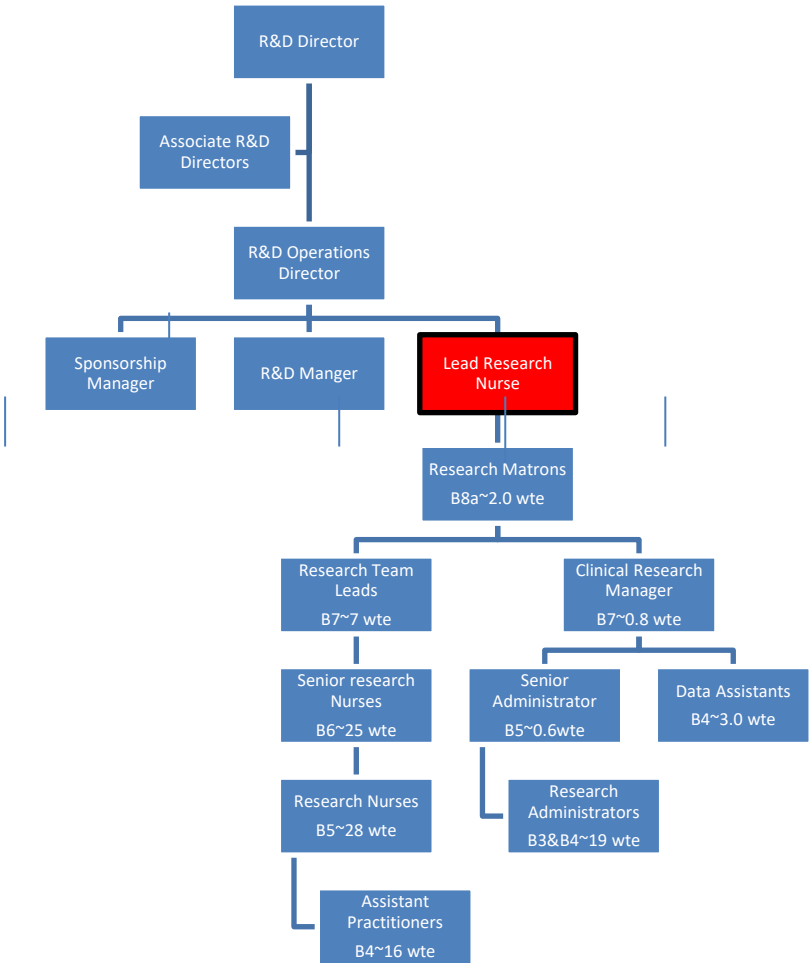
In addition, the post holder will deal with the wider healthcare community, external organisations and the public. This will include verbal, written and electronic media.

Of particular importance are working relationships with:

Internal to the Trust	External to the Trust
• R&D Director and Associate Directors • R&D Operations Director • Research and Commercial Research Matrons	• Sponsor Representatives

	• Senior R&D Professional Services Team and associated teams • Trust Senior Nurses and AHPs • Clinicians and Clinical Teams • Chief/Principal Investigators • Research Team Leads • Clinical Research Delivery Teams • South West Peninsula CRN Chief Operating Officer and associated team	• Regional Lead Nurses • Exeter Clinical Trials Unit • University of Exeter Joint Office Staff	

ORGANISATIONAL CHART



FREEDOM TO ACT

The post holder is accountable to the R&D Director and R&D Operations Director and is the managerial and strategic lead for all research nurses and research delivery staff in the Trust, which includes all aspects of research delivery including expert practice, education & development and leadership.

- Works within codes of practice and guidelines; accountable for their own professional action. They are the lead research practitioner for the Trust.

- Are responsible for proposing & implementing service and departmental policies as well as interpreting wider Trust policy in relation to the clinical trials workforce. They will work closely with the R&D Director and Senior Managers to achieve this.

COMMUNICATION/RELATIONSHIP SKILLS

- On a weekly basis communicate highly complex and commercially sensitive service-related information to senior managers, staff and external collaborators this requiring the use of persuasive, motivational and reassurance skills.

- The Lead Nurse/Practitioner will frequently manage and reconcile conflicting views where there are significant barriers to acceptance or understanding. For example, negotiations with study sponsors and the Trust

- The postholder will give formal presentations where necessary to both internal and external colleagues.

- The Postholder will also regularly converse with patients and their careers as well as health professionals and research staff regarding condition related information and complex research trials and studies.

ANALYTICAL/JUDGEMENTAL SKILLS

- The postholder will be expected to undertake analysis and interpretation of highly complex information including clinical trial protocols

- Provide judgements regarding a range of clinical issues and/or highly complex patient conditions. For example, interpreting the clinical delivery of clinical research protocols

- Weekly/Frequent use of expert knowledge to provide judgements on highly complex facts or situations requiring analysis, interpretation, comparison of a range of options. For example, reviewing of incident reports relating to clinical delivery; carrying out investigations and taking appropriate action where required.

PLANNING/ORGANISATIONAL SKILLS

- The post holder will oversee the delivery of a significant number of clinical trials and studies (circa 400) working with external sponsors to organise complex activities and programmes, requiring formulation and adjustment according to the clinical setting and Trust policies.

- Manage and monitor the research delivery workload across the service and manage team performance to achieve internal and external key performance indicators.

PATIENT/CLIENT CARE

- The post holder will provide direct patient care according to the clinical research protocol

- They will provide ongoing information, education and support to patients (and their significant others) regarding clinical trials and specific trial treatments. When necessary the post holder will facilitate informed consent from patients to participate in a clinical trial or research study.

- The Lead Nurse/Practitioner will oversee the safe delivery of research related care and accurate collection of research data through clinical procedures as required by the protocol. They will also ensure the safe administration of any treatments and drugs given within the context of a clinical trial and act as a specialist clinical resource to the members of the team.

POLICY/SERVICE DEVELOPMENT

- In conjunction with the R&D Director and R&D Operations Director, the post holder is responsible for proposing and implementing service & departmental policies.

- They will lead the development and implementation of relevant clinical and research policies, as well as standard operating procedures (SOPs) and working instructions.

- Responsible for deployment and interpretation of wider Trust policies where they relate to clinical research delivery and ensuring that the clinical research delivery teams adhere to these.

FINANCIAL/PHYSICAL RESOURCES

- The Lead Nurse will work with the R&D Director and Accountant to ensure robust financial management, probity and efficient costing of clinical research trials and studies. In addition, the Lead Nurse will be responsible for the delegated delivery team budget, meeting monthly with the Divisional Accountant to ensure balance is achieved.

- They are authorised signatories for a variety of delegated budgets, including the Trust based Clinical Research Delivery Team, The Clinical Research Facility and the Patient Recruitment Centre.

- The post holder supports the completion of external quarterly finance returns for clinical research delivery staff funded by the NIHR

HUMAN RESOURCES

- The Postholder will act as line manager for the Research Nurse Specialist / Team Leads and oversee the management of the Clinical Research delivery Team (circa 110 members of staff). This consists of the Trust based Delivery Team, Clinical Research Facility and Research Team based in North Devon District Hospital.

- Provide guidance to the Trust on the educational and training needs of research nurses/practitioners and related support staff involved in clinical research

- Oversee and ensure appropriate training and education for the clinical research delivery workforce including supervision and mentorship to members of staff and students

- They will also oversee the delivery of education and training regarding research for the wider multidisciplinary team and encourage the clinical trials team to act as ambassadors for research

INFORMATION RESOURCES

- The Lead Nurse is responsible for ensuring clinical research delivery teams maintain accurate patient trial documentation including the use of electronic data capture systems.

- Use internal and external systems to monitor and manage clinical research delivery regularly reviewing and interpreting complex information and data, for example the postholder produces reports for the monthly Directorate Governance meeting relating to compliance with infection control measures; workforce including retention, recruitment & sickness; performance in relation to clinical research delivery including patient recruitment and retention. They also contribute to the annual Trust report, Quality account and R&D Board report.

- They will work together with the R&D senior management and Team Leads to ensure that the Trust research activity is accurately recorded; this involving regular reviews of complex information and interpreting data. The Lead Nurse will work with the Team Leads and wider NIHR team to make sure their processes capture this effectively and accurately

RESEARCH AND DEVELOPMENT

- Provide specialist advice to Trust researchers on the 'deliverability' of their clinical trial protocols e.g. providing advice about the usual patient pathway and the practicality of protocol activities
- Oversee the management and delivery of the clinical trial portfolio (circa 400 open studies) encompassing a wide breadth of clinical specialties
- Ensure that the delivery of studies meet requirements with regards to the Department of Health's UK Policy Framework for Health & Social Care and the EU Clinical Trials Directive by implementing quality systems
- Oversee the review of new studies in terms of capacity and capability and work to resolve resource issues.
- Use the principles of continuous improvement to support the clinical research team to develop strategies to overcome barriers to recruitment and to solve other problems relating to specific studies.
- Act as Principal Investigator (PI) for suitable studies and promote the non-medic PI role.
- Monitor and plan in advance the research workload across the service and manage team performance. Ensure that study complexity is considered when delegating roles within the team.
- Promote collaborative working across the network and with other clinical researchers, within the CRN and NIHR structure.
- Provide support for external and internal audit, data monitoring and quality assurance by working with R&D, sponsors, study monitors and external bodies.

PHYSICAL SKILLS

- Provide care to clinical trial participants involving developed physical skills; advanced sensory skills and manipulation of objects to administer medications intravenously; Use of clinical equipment, physical skills to assess and diagnose patients
- They will also regularly compile departmental reports for governance groups and the wider CRN team. These reports require the post holder to be proficient n Microsoft Office and analysis of spreadsheets and dashboards. Accuracy is essential.

PHYSICAL EFFORT

- There is the possibility of exposure to episodes of light exertion. For example, whilst moving and handling patients with physical limitations or who are attached to medical devices.
- There may be a requirement to physically manoeuvre (with appropriate aids) heavy pieces of equipment around the research facility/clinical area on an infrequent basis.
- There will be times when you will be required to sit for varying lengths of time in a restricted position inputting data into trial database/writing reports.

MENTAL EFFORT

- On a daily basis the post holder will be responsible for the operational running of the research delivery teams; there will be a frequent requirement for them to support staff and patients when there is a requirement for senior support or escalation.
- Frequent concentration will be required when writing reports including research activity and staff sickness and absence. Analysis of complex data and comparisons is an essential skill needed to complete these.
- The Lead Nurse is required to chair the weekly Team Leads operational meeting as well as being a core member for the R&D Governance and Oversight Group. They will also have membership of other strategic meetings; for example, monthly finance meeting and Quality & Assurance group. Regionally they will sit on the Regional Lead Nurse and R&D Mangers meeting that meet quarterly and chair these according to the ongoing rota.

EMOTIONAL EFFORT

- The post holder will frequently be exposed to circumstances that are distressing or emotional as they will be required to support staff and research participants during discussions and decision-making regarding trial recruitment and management. For example; pregnancy during clinical trials or when patients have exhausted all conventional treatments.
- The postholder is responsible for ensuring clinical research delivery staff compliance with Trust policy and professional standards. They will be responsible for disciplinary and grievance matters if they should need to as well as formally responding to any complaints that should be made against the delivery team. This can be occasionally distressing and will require a large amount of emotional effort.

WORKING CONDITIONS

- Willingness and ability to work across RDUH sites including community settings
- There will be times where the postholder will be required to work in isolation
- There will daily exposure to VDU screens when imputing trial data, report writing, liaising with colleagues and reviewing policies & procedures
- Dependent on the trials there could be exposure to body fluid, for example collection of samples and specimens from patients (stool, blood, saliva)

OTHER RESPONSIBILITIES

Take part in regular performance appraisal.

Undertake any training required in order to maintain competency including mandatory training, e.g. Manual Handling

Contribute to and work within a safe working environment

You are expected to comply with Trust Infection Control Policies and conduct him/herself at all times in such a manner as to minimise the risk of healthcare associated infection

As an employee of the Trust, it is a contractual duty that you abide by any relevant code of professional conduct and/or practice applicable to you. A breach of this requirement may result in action being taken against you (in accordance with the Trust's disciplinary policy) up to and including dismissal.

You must also take responsibility for your workplace health and wellbeing:

- When required, gain support from Occupational Health, Human Resources or other sources.
- Familiarise yourself with the health and wellbeing support available from policies and/or Occupational Health.
- Follow the Trust's health and wellbeing vision of healthy body, healthy mind, healthy you.
- Undertake a Display Screen Equipment assessment (DES) if appropriate to role.

APPLICABLE TO MANAGERS ONLY

Leading the team effectively and supporting their wellbeing by:

- Championing health and wellbeing.
- Encouraging and support staff engagement in delivery of the service.
- Encouraging staff to comment on development and delivery of the service.
- Ensuring during 1:1's / supervision with employees you always check how they are.

DISCLOSURE AND BARRING SERVICE CHECKS

This post has been identified as involving access to vulnerable adults and/or children and in line with Trust policy successful applicants will be required to undertake a Disclosure & Barring Service Disclosure Check.

GENERAL

This is a description of the job as it is now. We periodically examine employees' job descriptions and update them to ensure that they reflect the job as it is then being performed, or to incorporate any changes being proposed. This procedure is conducted by the manager in consultation with the jobholder. You will, therefore, be expected to participate fully in such discussions. We aim to reach agreement on reasonable changes, but if agreement is not possible, we reserve the right to insist on changes to your job description after consultation with you.

Everyone within the Trust has a responsibility for, and is committed to, safeguarding and promoting the welfare of vulnerable adults, children and young people and for ensuring that they are protected from harm, ensuring that the Trusts Child Protection and Safeguarding Adult policies and procedures are promoted and adhered to by all members of staff.

PERSON SPECIFICATION

Job Title	Lead Research Nurse

Requirements	Essential	Desirable
QUALIFICATION/ SPECIAL TRAINING Registered Nurse Relevant Healthcare Degree Research Training (e.g. GCP, degree module, informed consent) Management or Leadership Qualification Master's level qualification or equivalent demonstrable experience	All E	
KNOWLEDGE/SKILLS Knowledge of the Research Governance Framework and the International Conference on Harmonisation Good Clinical Practice Guidelines In-depth knowledge of clinical trials & research methodologies Strong leadership skills and proven managerial ability Knowledge of the NIHR high level objectives and portfolio performance management Knowledge and understanding of NHS R&D systems, processes and legislation Pertinent clinical skills IT skills including ability to work with databases Ability to organise and prioritise own workload and work to tight deadlines Ability to think strategically and make independent decisions Critical appraisal skills Evidence of budgetary control	All E	
EXPERIENCE Extensive experience of clinical research within the NHS setting Broad and recent clinical experience relevant to the post	 E E	

Line Management experience within the NHS Experience of delivering commercial and academic research Experience in delivering continuous improvement projects Proven record of meeting targets	E E E	 D
PERSONAL ATTRIBUTES Ability to work autonomously High level of interpersonal and communication skills Flexible and adaptable Willingness to learn, instigate and develop efficient working systems Ability to work cohesively as a member of a team Willingness to undertake any necessary training and development to enhance work performance Commitment to openness, honesty and integrity in undertaking the role Willingness and ability to work across sites including community	All E	
OTHER REQUIREMENTS Ability to travel between RDUH Sites The post holder must demonstrate a positive commitment to uphold diversity and equality policies approved by the Trust. Committed to further professional development	All E	

WORKING CONDITIONS/HAZARDS		FREQUENCY (Rare/ Occasional/ Moderate/ Frequent) R	O	M	F
Hazards/ Risks requiring Immunisation Screening					
Laboratory specimens	Y	X			
Contact with patients	Y				
Exposure Prone Procedures	N				
Blood/body fluids	Y		X		
Laboratory specimens	Y	X			
Hazard/Risks requiring Respiratory Health Surveillance					
Solvents (e.g. toluene, xylene, white spirit, acetone, formaldehyde and ethyl acetate)	N				
Respiratory sensitisers (e.g isocyanates)	N				
Chlorine based cleaning solutions (e.g. Chlorclean, Actichlor, Tristel)	Y	X			
Animals	N				
Cytotoxic drugs	N				
Risks requiring Other Health Surveillance					
Radiation (>6mSv)	N				
Laser (Class 3R, 3B, 4)	N				
Dusty environment (>4mg/m3)	Y	X			
Noise (over 80dBA)	N				
Hand held vibration tools (=>2.5 m/s2)	N				
Other General Hazards/ Risks					
VDU use (> 1 hour daily)	Y				X
Heavy manual handling (>10kg)	Y	X			
Driving	Y			X	
Food handling	N				
Night working	N				
Electrical work	N				
Physical Effort	Y		X		
Mental Effort	Y				X
Emotional Effort	Y				X
Working in isolation	Y		X		
Challenging behaviour	Y				X