Royal Devon University Healthcare NHS Foundation Trust

JOB DESCRIPTION

1. JOB DETAILS

Job Title: Senior Research Nurse / Practitioner

Band: 6

Reports to: Research Specialist Nurse / Team Lead

Department / Directorate: Research & Development

2. JOB PURPOSE

The Senior Research Nurse / Practitioner will be responsible for coordinating and managing the delivery of a portfolio of clinical trials and the management of clinical research staff within the relevant specialties.

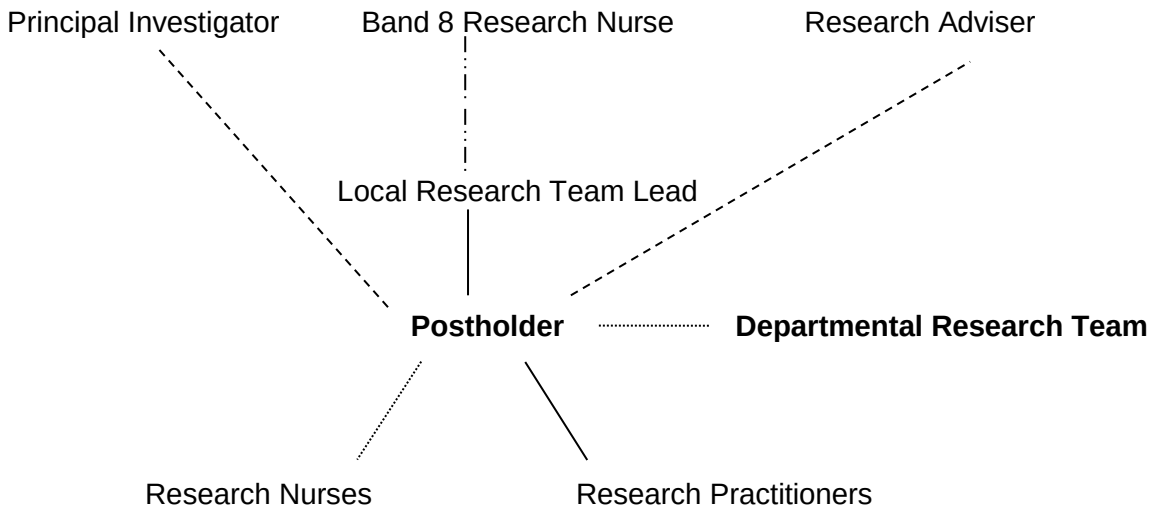
The post holder will provide specialist knowledge, skills and experience within clinical research, and act as a resource to advise and support those involved in clinical trials at all levels. The post-holder will be able to autonomously plan, implement, organise and manage concurrent research projects. S/he will develop networks with Multidisciplinary Teams across the Trust and other appropriate local and national agencies. S/he will coordinate and manage the relevant study portfolio and deliver recruitment accrual in line with performance and monitoring objectives.

As a Senior Research Nurse/Practitioner s/he will be responsible for the implementation and monitoring of the clinical requirements associated with research to ensure optimum delivery of clinical trials. S/he will ensure that research will be conducted in accordance with the Research Governance Framework and Good Clinical Practice guidelines to provide assurance that the rights, safety and well-being of trial participants are protected. S/he will ensure that all research procedures are conducted according to study protocols and will be accountable for the recruitment, data collection and care of research participants with a focus on providing a quality experience.

3. KEY WORKING RELATIONS

Lead Research Nurse / Practitioner
Research Nurse Specialist /Team Lead
Clinical research team
South West Peninsula Clinical Research Network
Research and development team
Principal Investigators
Trust multidisciplinary team
Study participants and their families
Clinical trials pharmacy team
Diagnostic services
Study sponsors and Clinical Research Associates.

4. ORGANISATIONAL CHART:



Line management ——————
Reporting Relationship - - - - - - -
Professional accountability —··—··—
Working Relationship .....

5. KEY RESULT AREAS/PRINCIPAL DUTIES AND RESPONSIBILITIES:

Leadership

- Responsible for the operational delivery of the clinical research team work-plan within the relevant specialties.
- Manage research performance within the relevant specialty in relation to team activities and study timelines.
- Collaborate with other Trusts and organisations within the region to improve research delivery.
- Keep up to date with research management issues through liaison with other Research Specialists /Team leaders and link with national networks.
- Act as line manager for junior members of the research staff as applicable (e.g. Research Nurse/Practitioner, Research Assistant Practitioner, Research HCA, and Research Administrator). This will include clinical supervision and mentorship to members of staff and students.
- Ensure all staff within sphere of responsibility have access to essential training and achieve 100% compliance.
- Be responsible for the deployment of HR policies including proactively managing sickness and performance in line with the Trust policy.
- Ensure the health, safety and security of the clinical research team within sphere of responsibility.
- Lead in the recruitment of Research Nurses/Practitioners within the relevant team.

- Assist the Team Lead with the training and development of clinical research practitioners and administrators to ensure retention of staff and workforce development where possible.
- Lead in the delivery of education and training regarding research for the wider Multidisciplinary Team and act as an ambassador for research.
- Contribute to the development and implementation of clinical and research policies, procedures and SOPs.
- Facilitate and maintain effective communication within the research team and between the multidisciplinary clinical team.
- Promote a blame free culture in reporting incidents and where appropriate support local investigation of incidents.

Research

- Take a leading role in the delivery of a clinical trial portfolio relevant to the specialty and ensure a balanced portfolio of studies.
- Ensure that the delivery of studies meet requirements with regards to the Department of Health's Research Governance Framework for Health & Social Care and the EU Clinical Trials Directive by implementing quality systems.
- Ensure that staff participate in Good Clinical Practice (GCP) training.
- Be responsible for the Expression of Interest / Study Selection process for the relevant specialty. Review and assess trial protocols, consider all potential trials in terms of capacity and capability and viable recruitment period. Identify and work with the Team Lead to resolve resource implications in delivering and facilitating clinical research.
- Monitor and plan in advance the research workload within the specialty and manage team performance. Ensure that study complexity is considered when delegating roles within the team.
- Act as an expert resource and provide complex advice regarding study set up, recruitment planning and study delivery.
- Be responsible for promoting and overseeing the appropriate referral and recruitment of patients to clinical research studies. Work with investigators and 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.
- Coordinate and run study visits including off site whilst adhering to the lone worker policy.
- Work with other departments within the Trust to ensure that trial specific investigations and procedures are undertaken as required by the trial protocol, in order to establish eligibility and safety of patients within clinical trials.
- Work with the team lead and research facilitators to ensure accurate costing for clinical trials and appropriate negotiation of required financial support to deliver clinical trials.
- Ensure clear, accurate and concise records are kept for research projects in accordance with all regulatory requirements including the Data Protection Act.
- Ensure that data is transcribed accurately where required and assist with the maintenance of the Trial Master File.
- Respond to data queries generated by the study coordinating team within a timely manner.
- Ensure the recording & reporting of adverse and serious adverse events that occur whilst the participant is in the clinical trial to the trial co-coordinator/Principal Investigator (PI) and R&D office in line with the study protocol, local policies and regulatory requirements.
- Assess and evaluate the progress of on-going clinical trials for which the post holder has responsibility, maintaining accurate records of the status of studies and providing regular updates to the department on the status of the studies. This will involve ensuring that EDGE (Local Patient Management System) is updated with key trial data and validated efficiently.

- Identify and resolve study performance issues, escalating on-going issues to the Team Lead where required.
- Promote collaborative working across the network and with other clinical researchers, within the CRN and NIHR structure.
- Appraise research findings that inform and influence practice, policy and service provision and demonstrate the ability to make research and clinical judgments based on this appraisal.
- Co-operate with external and internal audit, data monitoring and quality assurance by working with R&D, sponsors, study monitors and external bodies.
- Assist in study close down and the preparation of results of research for presentation as posters, abstracts, papers or scientific presentations.

Clinical & Professional

- Take a leading role in the care of research participants within sphere of competence and provide relevant health promotion and education.
- Use relevant clinical knowledge to screen and identify patients for clinical research using inclusion and exclusion criteria and utilising NHS records, screening clinics, visiting wards and outpatients and using Trust IT systems and databases.
- Act as a specialist resource and role model for all aspects of Research Clinical Practice in order to optimise patient care and clinical practice this may include carrying out physical assessments, conducting sample retrieval and processing, providing or coordinating
  interventions and treatments, clinical monitoring.
- Undertake all mandatory training and ensure that the clinical workforce is up to date with mandatory training.
- Ensure the environment is suitable for patient care and research processes, recognising the importance of privacy, dignity and diversity.
- Demonstrate professional development and an in-depth knowledge of current clinical and research practice.
- Provide on-going specialised advice and information to patients and their carers/families with regard to their participation in clinical research in order to facilitate effective informed consent.
- Where appropriate receive and document written informed consent from research subjects, for their participation in research studies and support other members of the team with best practice.
- Be responsible for the safe and accurate collection of research data through clinical procedures such as venipuncture, history taking, standard observations (height, weight, BP, RR, HR, SpO2 temperature) and other assessments such as ECG, physical examinations, disease specific outcome measures, questionnaires, rated scales, qualitative interviewing as required by the protocol.
- Monitor treatment toxicity/side effects and initiate changes to treatment as required by the protocol. Escalate any concerns to the Principle Investigator or relevant physician and act as a support to other members of the team.
- Centrifuge, process, track and ship samples in line with protocol requirements.
- 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.
- Ensure accurate patient trial documentation, including the use of electronic data capture systems and ensure relevant information is recorded in patients' medical notes in a timely manner.
- Refer to other specialists as required in order to provide optimal care of the participant.
- Monitor clinical standards within the research team and escalate any persistent issues to the Team Lead.

- Treat all persons encountered during the course of duties with respect and courtesy and maintain a standard of conduct which best represents the clinical trials team and the Trust.
- Work within the relevant professional code of conduct, demonstrating accountability for own actions and awareness of own limitations.
- Provide cover for other Research Nurses/ Practitioners as required, within sphere of competency.
- Proactively seek feedback from participants and their families during their research involvement on the standard of information and care that they have received including participating in the clinical trials patient feedback survey.

Resources

- Lead the recruitment of new junior personnel and ensure that an appropriate and safe skill mix is maintained. Work with the Team Lead to promote retention of staff.
- Have an awareness of the income stream relevant to Clinical Trials and work within, local and Trust wide financial and budgetary guidelines.
- Ensure accurate costings for clinical research activity during study set up. Utilise planning tools such as the intensity toolkit.
- Identify resource implications for individual studies and the portfolio of studies within the specialty.
- Ensure research equipment is maintained in an effective working and good clinical order.

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.

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.

At the Royal Devon, we are committed to reducing our carbon emissions and minimising the impact of healthcare on the environment, as outlined in our Green Plan available on our website. We actively promote sustainable practices and encourage colleagues to explore and implement greener ways of working within their roles.

PERSON SPECIFICATION

POST: Senior Research Nurse / Practitioner

BAND: 6

REQUIREMENTS	At Recruitment	At 2nd KSF Gateway
QUALIFICATIONS/SPECIAL TRAINING:		
Registered Nurse or Healthcare Professional	**E**	**E**
Relevant Healthcare Degree	**E**	**E**
Research Training (e.g. GCP, degree module, informed consent)	**E**	**E**
Management or Leadership Qualification	**D**	**E**
KNOWLEDGE/SKILLS:		
Knowledge of the Research Governance Framework and Good Clinical Practice Guidelines	**E**	**E**
In depth knowledge of clinical trials & research methodologies	**E**	**E**
In-depth knowledge of data collection and data entry for clinical trials	**E**	**E**
Pertinent clinical skills including venipuncture	**E**	**E**
IT skills including ability to work with databases	**E**	**E**
Ability to organise and prioritise own workload and work to tight deadlines	**E**	**E**
Ability to make independent decisions	**E**	**E**
Critical appraisal skills	**E**	**E**
Good leadership skills and proven managerial ability	**D**	**E**
EXPERIENCE:		
Experience of clinical research within the NHS setting	**E**	**E**
Broad and recent clinical experience relevant to the post	**E**	**E**
Proven record of meeting participant recruitment targets	**E**	**E**
Line Management experience within the NHS	**D**	**E**
Experience of delivering commercial and academic research	**D**	**E**
PERSONAL REQUIREMENTS:		
Ability to work autonomously	**E**	**E**
High level of interpersonal and communication skills	**E**	**E**
Flexible and adaptable	**E**	**E**
Willingness to learn, instigate and develop efficient working systems	**E**	**E**
Ability to work cohesively as a member of a team	**E**	**E**
Willingness to undertake any necessary training and development to enhance work performance	**E**	**E**
Commitment to openness, honesty and integrity in undertaking the role	**E**	**E**
Willingness and ability to work across sites including community	**E**	**E**

* Essential/Desirable

HAZARDS:- Updated 12th Aug 2014					
Laboratory Specimens	✓	Clinical contact with Patients	✓	Dealing with violence & aggression of patients/relatives	
Blood / Body Fluids	✓	Dusty Environment		VDU Use	✓
Radiation / Lasers		Challenging Behaviour		Manual Handling	✓
Solvents		Driving		Noise / Vibration	
Respiratory Sensitisers		Food Handling		Working in isolation	✓
Cytotoxic Drugs		Electrical work		Night Working	