JOB DESCRIPTION

Royal Devon University Healthcare NHS Foundation Trust

***"Our vision is to provide safe, high quality seamless service delivered with courtesy and respect. To achieve our vision we expect all our staff to uphold our Trust Values"***

| JOB DETAILS | |
|---|---|
| **Job Title** | Research Nurse/Practitioner |
| **Reports to** | Team Lead/Research Nurse Specialist |
| **Band** | 5 |
| **National Job Profile used** | |
| **Department/Directorate** | Research & Development |

## JOB PURPOSE

We are seeking an experienced registered research nurse who has recent relevant clinical experience to be part of the Clinical Research team. You will support the safe conduct of research in accordance with the Research Governance Framework and Good Clinical Practice guidelines and provide assurance that the rights, safety and well-being of trial participants are protected.

The post-holder will work with the research team to 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.

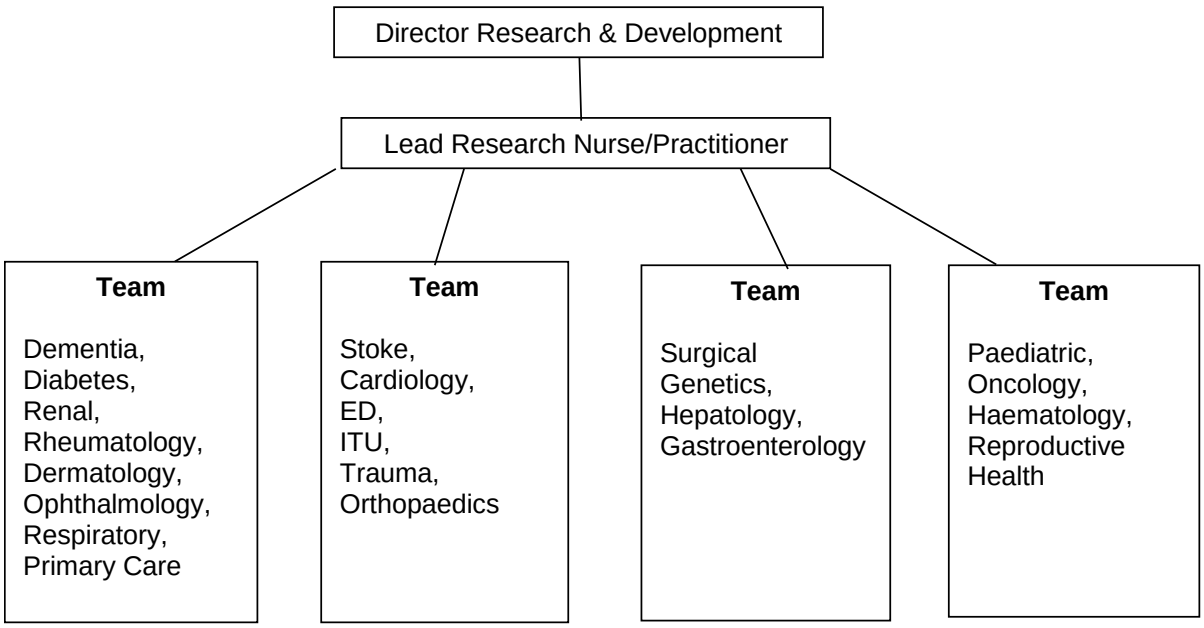
The post holder will be responsible for the implementation and monitoring of the clinical requirements associated with research to ensure optimum delivery of clinical trials. S/he will ensure that all research procedures are conducted according to study protocols and will be accountable for the recruitment, data collection and care of research participants with a focus on providing a quality experience.

## KEY WORKING RELATIONSHIPS

Trust Lead Research Nurses
Trust Research Team Leads
Trust Pharmacy Trials Team
Trust Diagnostic Services
Trust Finance Team
Research and Development Department
Principal Investigators
Study participants and their families
Study sponsors and Clinical Research Associates

South West Peninsula Clinical Research Network

## ORGANISATIONAL CHART




## KEY RESULT AREAS/PRINCIPAL DUTIES AND RESPONSIBILITIES

**Leadership**

- Manage research performance and study timelines of relevant studies.
- 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.
- Provide relevant supervision and mentorship to members of staff and students.
- Take responsibility for own health, safety and security and promote the health, safety and security of the wider team.
- Contribute to the development and implementation of clinical and research policies, procedures and SOPs.
- Assist in the delivery of education and training regarding research for the wider Multidisciplinary Team and act as an ambassador for research.
- Promote a blame free culture in reporting incidents and where appropriate support local investigation of incidents.

**Research**

- Be responsible for the delivery of the clinical trial portfolio.
- 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.
- Participate in Good Clinical Practice (GCP) training.
- Contribute to the Expression of Interest / Study Selection process for the relevant specialty.
- Contribute to study set up, recruitment planning and study delivery.
- Be responsible for promoting the appropriate referral and recruitment of patients to clinical research studies. Work with the clinical trials team and investigators to develop strategies to overcome barriers to recruitment and to solve other problems relating to specific studies.

- Coordinate and run study visits including off site visits 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.
- Contribute to the 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.
- Escalate on-going study performance issues to the Senior Research Nurse or Team Lead.
- 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**

- Be responsible for the care of research participants within the relevant sphere of practice and use opportunities to provide health promotion and patient education.
- Use relevant clinical knowledge to screen and identify patients suitable 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 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 take part in personal development reviews.
- 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 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.
- Training and support for informed consent will be given. Be responsible for the safe and accurate collection of research data through clinical procedures such as venepuncture, 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.

- 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.
- 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.
- Ensure accurate patient trial documentation, including the use of electronic data capture systems and ensure relevant information is recorded in patients' medical notes and case report form in a timely manner.
- Refer to other specialists as required in order to provide optimal care of the participant.
- Contribute to the monitoring of clinical standards within the research team.
- 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 (if applicable) demonstrating accountability for own actions and awareness of own limitations.
- Supervise the work of junior members of staff and delegate work where appropriate.
- Provide cover for other research nurses/ practitioners as required.
- Proactively seek feedback from participants and their families during their research involvement.

**Resources**

- Have an awareness of the income stream relevant to Clinical Trials and work within, local and Trust wide financial and budgetary guidelines.
- Assist in accurate costings for clinical research activity during study set up. Utilise planning tools such as the intensity toolkit.
- Assist in identifying resource implications for individual studies.
- Ensure research equipment is maintained in an effective working and good clinical order.

## COMMUNICATION/RELATIONSHIP SKILLS

- Facilitate and maintain effective communication within the research team and between the multidisciplinary clinical team.

## ANALYTICAL/JUDGEMENTAL SKILLS

- Clinical knowledge within a relevant sphere of practice is required to enable screening against specified inclusion/exclusion criteria for recruitment.
- Post-holder will need to have relevant clinical knowledge and the ability to critically evaluate participant' progression through research pathways in order to respond and refer appropriately.
- Critical research evaluation and the ability to conduct feasibility will be key requirements when working on research protocols.
- Engage in early evaluation of Expressions of Interest (EOI) received with Principal Investigator and team lead to ensure feasibility of study at site is properly assessed.
- Work with the lead clinician and senior research nurse/team lead to review complex clinical trial protocols and to develop a balanced portfolio of studies for each speciality that the post holder works across.

## PLANNING/ORGANISATIONAL SKILLS

- Be responsible for managing and organising own day-to-day activities and workload,

liaising with the senior research nurse and working within the team to ensure the portfolio remains covered at times of leave.

- Deputises for senior research nurse on an ad hoc basis.
- Supports the planning of both short-term and long-term research projects.
- Works with the Team Lead to understand and plan the portfolio of studies that may be open, in follow up or in set up at any one time.
- The post–holder will be able to work autonomously whilst ensuring that all research procedures are conducted according to study protocols and Standard Operating Procedures (SOP), both Trust and study specific.
- If working alone the post-holder will adhere to the Trust's Lone Worker SOP and the speciality's Working Instructions.

## PHYSICAL SKILLS

- The post holder will be required to use their excellent IT skills including MS Office, Google docs, internet, databases etc. in order to monitor activity, systems and processes and to produce reports including in time-bound circumstances.
- Standard keyboard skills are required for the inputting and manipulating of data and/or information on computer databases.

## PATIENT/CLIENT CARE

- The post holder will contribute to ensuring the patient experience is excellent ensuring patients are at the heart of service design and delivery.
- Ensure Trust policies are applied in the Clinical Team support reporting of complaints and concerns by research participants that may be related to their participation in research and to ensure these complaints are appropriately managed and acted upon in accordance with requirements of the UK Policy Framework for Health and Social Care Research.

## POLICY/SERVICE DEVELOPMENT

- Promote a culture of continuous improvement and transformation, enabling all change management activity, providing expertise, advice and guidance to staff and working with staff groups and change champions as required.

## FINANCIAL/PHYSICAL RESOURCES

- Frequent requirement to exert moderate physical effort. Research offices are not based where patients are seen or recruited and the research team members are required to work across multiple sites at the RDE Wonford and where necessary Heavitree.
- Contribute to the accurate costing for clinical trials and appropriate negotiation of required financial support to deliver clinical trials.
- Ensure that participants can claim appropriate travel and other expenses and completing invoices in a timely and accurately.

## HUMAN RESOURCES

- Supervise band 4 Assistant Research Practitioners and a range of junior staff.
- Support senior staff in recruitment and interviewing processes in line with Trust practices and procedures.
- Take an active role in the mentoring and supervision of student nurses and junior staff
- Provides teaching in practice to other staff and students through clinical supervision and facilitation.
- Assist in the delivery of education and training regarding research for the wider Multidisciplinary Team and act as an ambassador for research

## INFORMATION RESOURCES

- 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 entry is accurate.
- Respond to data queries generated by the study coordinating team within a timely manner.
- Demonstrate awareness of the Ethics Committee Procedures through prompt reporting of Serious Adverse Events, submission of Trust application, protocols, advertisements and amendments.

## RESEARCH AND DEVELOPMENT

- Demonstrate awareness of R&D/CRF facilities within the Trust and their working relationships
- Demonstrate awareness of the Ethics Committee Procedures through prompt reporting of Serious Adverse Events, submission of Trust application, protocols, advertisements and amendments.

## MENTAL EFFORT

- Data accuracy and IT skills are essential to this role and combining clinical skills with these demands can be mentally difficult. Undertaking data entry is a requirement for this role and can often require long periods of concentration.
- There can be occasional requirements for intense concentration when performing IT training for a new study requiring mastering a series of IT programmes.

## EMOTIONAL EFFORT

- Rare exposure or occasional indirect exposure to distressing/emotional circumstances.
- On occasion the post holder maybe required to undertake discussions about research with participants and their families during times of emotional distress

## WORKING CONDITIONS

- The role requires flexibility as the research offices are not necessarily based where the patients are recruited or seen for their clinical research appointments.
- Attending Investigator Meetings can mean traveling around the country or even abroad. Travel arrangements are made and costs covered by the sponsors and commercial companies but flexibility is required in order to accommodate attending these meetings.
- The post-holder maybe required respond to an incidence driven recruitment strategy and this may be achieved through use of a bleep, group WhatsApp, text, and phone call.
- Covering a multi Trust site portfolio or performing home visits will mean the post-holder is required to ensure they can commit to this requirement.

## FREEDOM TO ACT

- The post holder will work autonomously within general policies and procedures guided by national policy and regulations and the Trust's own policies.

## OTHER RESPONSIBILITIES

- To take part in regular performance appraisal.
- To undertake any training required in order to maintain competency including mandatory training, e.g. Manual Handling
- To contribute to and work within a safe working environment
- The post holder is 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.

## APPLICABLE TO MANAGERS ONLY

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## THE TRUST- VISION AND VALUES

Our vision is to provide safe, high quality seamless services delivered with courtesy and respect. To achieve our vision we expect all our staff to uphold our Trust values. Our Trust values are:

Honesty, Openness & Integrity
Fairness,
Inclusion & Collaboration
Respect & Dignity

We recruit competent staff that we support in maintaining and extending their skills in accordance with the needs of the people we serve. We will pay staff fairly and recognise the whole staff's commitment to meeting the needs of our patients.

We are committed to equal opportunity for all and encourage flexible working arrangements including job sharing.

We are committed to recruiting and supporting a diverse workforce and welcome applications from all sections of the community, regardless of age, disability, gender, race, religion, sexual orientation, maternity/pregnancy, marriage/civil partnership or transgender status. We expect all staff to behave in a way which recognises and respects this diversity, in line with the appropriate standards.

## GENERAL

The nature of clinical research is such that flexibility is required from the workforce. Periodically it may be necessary to move staff within the different specialties in order to meet the needs of the portfolio and maintain the required skill mix. The Patient Recruitment Centre provides a flexible service to research participants including the opportunity for evening and weekend appointments, the post holder will need to be flexible with working patterns in order to meet participant and study requirements.

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.

The RD&E is a totally smoke-free Trust. Smoking is not permitted anywhere on Trust property, including all buildings, grounds and car parks. For help to quit call: 01392 207462.

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|---|---|
| **POST** | Research Nurse |
| **BAND** | 5 |

PERSON SPECIFICATION

| REQUIREMENTS | At Recruitment | At 2nd KSF Gateway |
|---|---|---|
| **QUALIFICATIONS/SPECIAL TRAINING:** | | |
| Registered Nurse | **E** | **E** |
| Research Training (e.g. GCP, degree module, informed consent) | **D** | **E** |
| Up to date professional portfolio | **E** | **E** |
| **KNOWLEDGE/SKILLS:** | | |
| Good understanding of nursing care methods and models | **E** | **E** |
| Understanding of data collection and data entry for clinical trials | **D** | **E** |
| Pertinent clinical skills | **D** | **E** |
| IV Drug Administration | **D** | **E** |
| Computer literacy 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** |
| Understand the significance of research and use of validated results to improve practice | **E** | **E** |
| Skilled at clinical observations and venepuncture | **D** | **E** |
| Knowledge of Research Governance Framework and Good Clinical Practice Guidelines | **D** | **E** |
| Knowledge of clinical trials and research methodologies | **D** | **E** |
| **EXPERIENCE:** | | |
| Experience with dealing with confidential patient information | **E** | **E** |
| Ability to communicate complex information to patients/carers/ members of MDT | **E** | **E** |
| Broad and recent clinical experience relevant to the post | **E** | **E** |
| Proven record of meeting targets | **D** | **E** |
| Experience of clinical research within the NHS setting | **D** | **E** |
| **PERSONAL REQUIREMENTS:** | | |
| Ability to work autonomously | **E** | **E** |
| Ability to work cohesively as a member of a multidisciplinary team | **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** |
| 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** |

| WORKING CONDITIONS/HAZARDS | | FREQUENCY (Rare/ Occasional/ Moderate/ Frequent) R | O | M | F |
|---|---|---|---|---|---|
| | | | | | |
| **Hazards/ Risks requiring Immunisation Screening** | | | | | |
| Laboratory specimens | Y | | | | ✓ |
| Contact with patients | Y | | | | ✓ |
| Exposure Prone Procedures | Y | | | | ✓ |
| Blood/body fluids | Y | | | | ✓ |
| Laboratory specimens | Y | | | | ✓ |
| | | | | | |
| **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) | N | | | | |
| Animals | N | | | | |
| Cytotoxic drugs | N | | | | |
| | | | | | |
| **Risks requiring Other Health Surveillance** | | | | | |
| Radiation (>6mSv) | N | | | | |
| Laser (Class 3R, 3B, 4) | N | | | | |
| Dusty environment (>4mg/m3) | N | | | | |
| Noise (over 80dBA) | N | | | | |
| Hand held vibration tools (=>2.5 m/s2) | N | | | | |
| | | | | | |
| **Other General Hazards/ Risks** | | | | | |
| VDU use ( > 1 hour daily) | **Y** | | | | ✓ |
| Heavy manual handling (>10kg) | N | | | | |
| Driving | **Y** | | ✓ | | |
| Food handling | N | | | | |
| Night working | N | | | | |
| Electrical work | N | | | | |
| Physical Effort | N | | | | |
| Mental Effort | **Y** | | | | ✓ |
| Emotional Effort | Y | | ✓ | | |
| Working in isolation | N | | | | |
| Challenging behaviour | N | | | | |