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	Clinical Research Officer/Research Practitioner
Reports to	Team Lead/Research Nurse Specialist
Band	5
National Job Profile used	
Department/Directorate	Research & Development

JOB PURPOSE

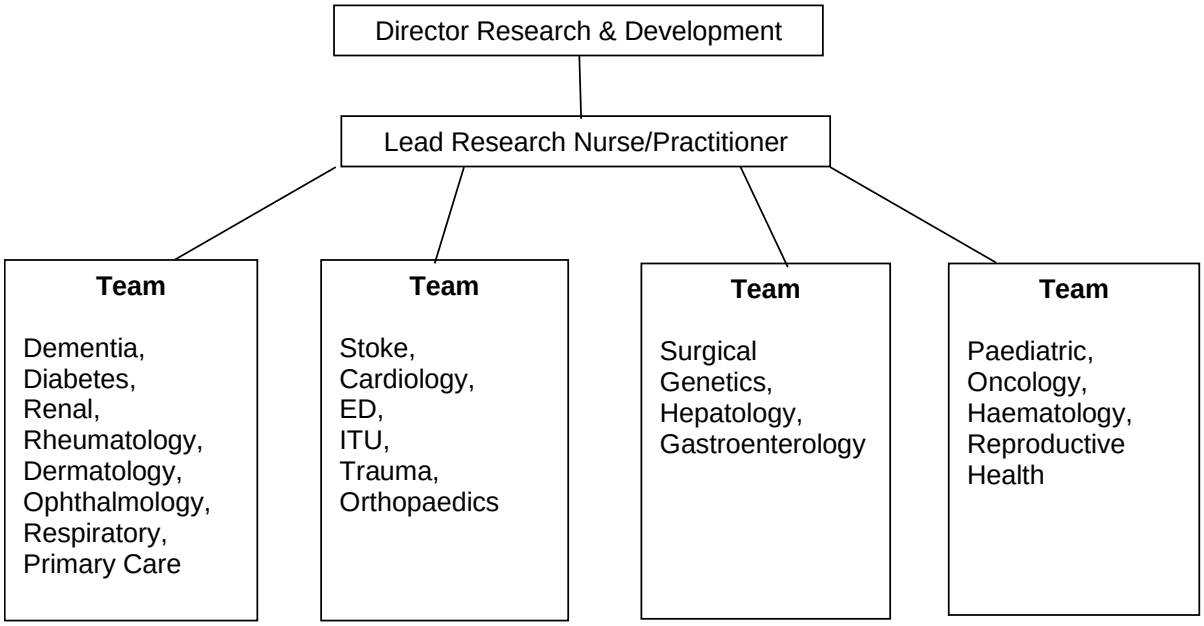
- To use relevant knowledge to perform research procedures according to protocols and extend this experience to support others in the research team and other health care professionals where appropriate.
- The post holder will support the safe conduct of research in accordance with the Research Governance Framework, and in accordance with good standards and guidelines and to provide assurance that the rights, safety and well-being of participants are protected.
- Liaise directly with researchers in the Trust, offering assistance with aspects of local research projects that are identified as being barriers to the progression of successful research.eg. Recruitment, consent, data collection etc.
- To provide admin support and data management for all aspects of research organisation, as an integrated member of the research team working for the Research & Development (R&D) Department, co-ordinating a variety of clinical research.
- To facilitate progression of Trust funded projects and offer assistance where there are difficulties under guidance of Research and Development team.

KEY WORKING RELATIONSHIPS

The Director of Research & Development
Research Governance & Quality Manager
Assistant Research & Development Manager
The Trust Statistical Advisor
Lead Research Nurse
The R&D team
PRC Unit
Trust Consultants engaged in research
Other researchers within the Trust

Medical Staff
Allied Health Professionals
Patients and Relatives/Carers
Diagnostic Services
Admin & Clerical Staff
Research Participants & their Families
GPs & Practice Nurses

ORGANISATIONAL CHART



KEY RESULT AREAS/PRINCIPAL DUTIES AND RESPONSIBILITIES

The post holder will undertake a number of duties and responsibilities as below but not limited to these:

- The post holder will select and recruit participants for specific studies according to inclusion/exclusion criteria.
- The post holder will safeguard the autonomy and integrity of participants by giving sufficient information to assist in the informed consent procedure.
- To conduct assessments, study procedures and documentation in strict compliance with the protocol and Trust policy and interpret these results to assess care needs.
- Refer patients on to health care professionals as appropriate.
- Assess the needs of researchers in the Trust in terms of project support and delivery – to feed back to R&D to action as appropriate.
- Assist researchers in their timely reporting of SAEs, recruitment and study progress to the sponsor, R&D and ethics.
- Undertake accurate data entry using computerised and/or paper-based systems.
- Be responsible for complex data collection on specific studies as per good clinical research practice guidelines (GCP). Transcribe complex information from case report forms with adequate supervision and guidance.
- Distribute and keep updated the research team protocols and pertinent trial information to various departments.

- Be involved in archiving study documentation and contacting various departments once studies are closed down.
- Assist in the preparation of accurate study reports and presentations.
- To work without close supervision and adhere to Clinical Governance initiatives, Code of Professional Conduct and hospital policies.
- Adhere to the ICH guidelines for GCP and R&D/Trust Standard Operating procedures (SOP's) for research.
- Ensure the accuracy, completeness, legibility and timeliness of data recorded in all study related reports.
- To undertake appropriate nursing activities for which training and competency assessment has been completed. This will require assessment and judgement of a patients' personal condition & circumstances.
- Consent adult patients onto a limited range of research studies as deemed appropriate and following specific training. This may require discussion of complex, sensitive information and an awareness that there may be barriers to understanding the nature of research/the interventions patients & or relatives are asked to engage with.
- Perform BPs, height, weight and temperature measurements following appropriate training.
- Record information relating to a patient's previous medical history and current medication regimens following appropriate training.
- Able to receive, handle, analyse and resolve data queries promptly. Direct unresolved queries to appropriate team member.
- Co-ordinate (under supervision) protocol generated assessments, questionnaires and diaries and provide information on trials to medical personnel/multi-disciplinary team.
- Be able to respond to patients/carers telephone calls (who maybe at times distressed) tactfully and empathically to reassure patients/carers regarding arrangements made.
- The postholder will provide technical support in terms of sample processing and management
- To undertake the Spinning, preparing and pipetting samples in preparation for delivering them to local laboratories, storage facilities or prepare for posting to central laboratories, including handling dry ice following training.
- Communicate sensitively with patients to obtain informed consent.
- Deal with enquiries from Health Care professionals, patients and carers.
- Undertake responsibility for data management and ensure that all records and samples are managed according to the human tissue act.
- To handle appropriately any personal, sensitive or confidential information.
- Assist research staff in patient recruitment.
- Keep clear, concise records in terms of subject documentation and data collection.
- Participate in research meetings and ensure accurate information is fed to the R&D.
- Regard effective communication as a key to successful care delivery.
- To contribute to the collection, recording and storage of information in accordance with GCP, research governance and Trust data management policies. Updating patient paper/database records as appropriate.
- Assist with basic data input and accessing Trust databases e.g. EPIC, EDGE, pathology and CDM, along with other trial-based systems as required.
- Assist with the preparation of paperwork for monitor visits.

COMMUNICATION/RELATIONSHIP SKILLS

- Facilitate and maintain effective communication within the research team and between the multidisciplinary clinical team.
- Maintain effective communication between the research team and patients tactfully and empathetically.

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.
- 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

- Support senior staff in recruitment and interviewing processes in line with Trust practices and procedures.
- 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/PRC 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

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.

POST	Research Nurse
BAND	5

PERSON SPECIFICATION

REQUIREMENTS	At Recruitment	At 2nd KSF Gateway
QUALIFICATIONS/SPECIAL TRAINING:		
Degree in Health or Biological Discipline (or educated to Degree level and significant relevant experience)	**E**	**E**
Trained in Good Clinical Practice	**D**	**E**
IT Qualification (e.g. CLAIT)	**D**	**E**
KNOWLEDGE/SKILLS:		
An understanding of the clinical research process including Good Clinical Practice and research governance.	**E**	**E**
Proven project management skills	**E**	**E**
Excellent IT/Internet/MS Office skills	**E**	**E**
Able to work without close supervision	**E**	**E**
Able to prioritise workload to respond to the changing demands of the service	**E**	**E**
Understanding of data collection, entry and validation.	**E**	**E**
Understanding of caring for patients and volunteers	**E**	**E**
EXPERIENCE:		
Previous research co-ordination experience	**E**	**E**
Experience in a clinical role e.g. auxiliary/nurse	**D**	**E**
Experience in handling tissue/blood samples	**D**	**E**
Experience of obtaining informed consent	**D**	**E**
Experience or working with databases and using reporting tools	**D**	**E**
Previous experience of auditing and monitoring research or the management/administration of clinical trials	**D**	**E**
PERSONAL REQUIREMENTS:		
Remain calm in stressful situations	**E**	**E**
Ability to work in multidisciplinary team	**E**	**E**
Ability to work independently without close supervision	**E**	**E**
Willingness to develop clinical skills (e.g. venipuncture and to handle operative tissue)	**E**	**E**
Excellent interpersonal and communication skills	**E**	**E**
Ability to plan prioritise and management deadlines	**E**	**E**
Ability to work calmly and effectively under pressure	**E**	**E**
Accuracy to attention and detail	**E**	**E**
Reliability and flexibility	**E**	**E**
OTHER REQUIREMENTS		
Flexible to the requirements of the role	**E**	**E**
Committed to further professional development	**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				✓
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				