Royal Devon University Healthcare NHS Foundation Trust

JOB DESCRIPTION

JOB DETAILS	
Job Title	Assistant Research Practitioner
Reports to	Team Lead
Band	4
Department/Directorate	Research & Development

JOB PURPOSE

The post holder will work as part of the clinical research team to 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 provide technical, practical and clinical assistance for research projects. As a member of the Clinical Trials Team they will provide core support within this multidisciplinary setting. S/he will support 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 responsible for the recruitment, data collection and care of research participants with a focus on providing a quality experience.

KEY RESULT AREAS/PRINCIPAL DUTIES AND RESPONSIBILITIES

Research

- Assist the clinical trials team in the delivery of a large clinical trial portfolio.
- Support the clinical trials team to 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.
- 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 and study delivery planning.
- Assist in promoting the appropriate referral and recruitment of patients to clinical research studies. Work with the clinical trials team and investigators to implement strategies to overcome barriers to recruitment and to solve other problems relating to specific studies.
- Coordinate and run appropriate study visits with oversight from the clinical trials team in order to collect study data.
- Work with other departments within the Trust to ensure that trial specific investigations and procedures are undertaken as required by the trial protocol.
- 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 relevant data queries generated by the study coordinating team within a timely manner and escalate any issues to a senior member of the team where required.
- With support, contribute to the recording & reporting of adverse and serious adverse events that occur whilst the participant is in the research study.
- Contribute to the evaluation of study performance, maintaining accurate records of the status of studies. This will involve ensuring that EDGE (Local Patient Management System) is updated with key trial data.
- Co-operate with external and internal audit, data monitoring and quality assurance by working with R&D, sponsors, study monitors and external bodies.
- Collect and handle clinical trial prescriptions and medicinal products.
- Assist in study close down.

Clinical

- Assist in the clinical care of research participants within the relevant specialty in accordance with the specifications of each research study.
- With training and support, 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.
- 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, oxygen saturations, temperature) and other assessments such as ECG, physical examinations, disease specific outcome measures, questionnaires, rated scales, qualitative interviewing as required by the protocol.
- With regard to the above clinical duties, assist in the monitoring of treatment toxicity/side effects by reporting any abnormal values to a senior member of the team.
- Centrifuge, process track and ship samples in line with protocol requirements including handling dry ice following training.
- Record information relating to a patient's previous medical history and current medication regimens following appropriate training, escalating any changes for review by a senior colleague.
- Follow the process for receiving informed consent on a limited range of research studies as deemed appropriate and following specific training. This may require discussion of complex, sensitive information and awareness that there may be barriers to understanding the nature of research and the interventions that patients and/or relatives are asked to engage with.
- 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 members of the MDT 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.
- Demonstrate responsibility for own actions and awareness of own limitations by working within the non-registered practitioners competency framework.
- Proactively seek feedback from participants and their families during their research involvement.
- 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 personal development and knowledge of relevant current clinical and research practice.

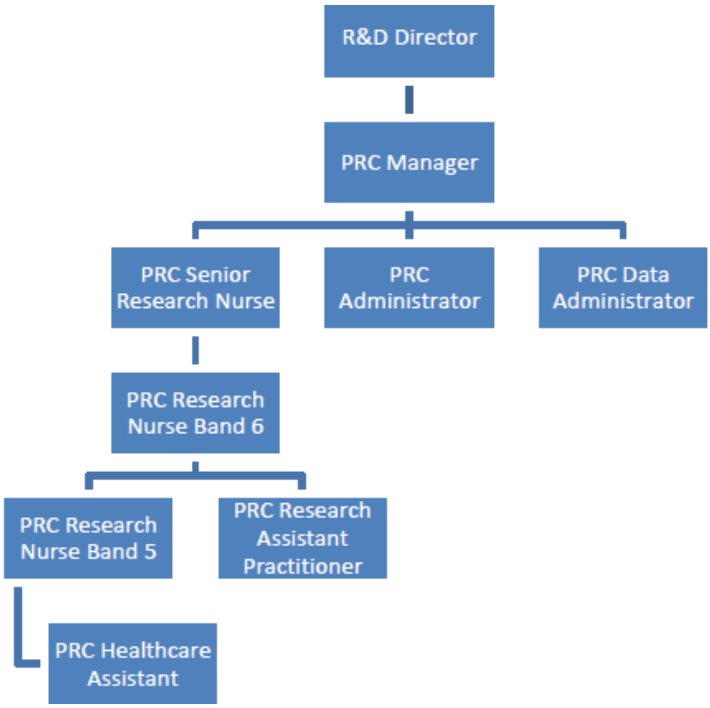
KEY WORKING RELATIONSHIPS

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. Facilitate and maintain effective communication within Research & Development and across the areas where you have key working relationships. Maintain effective communication between the research team and patients tactfully and empathetically.

Of particular importance are working relationships with:

- Director of Research & Development
- Clinical research team
- 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.

ORGANISATIONAL CHART



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

COMMUNICATION/RELATIONSHIP SKILLS

- Have an understanding of the clinical research team work-plan and contribute to its achievement.
- Contribute to research performance of relevant studies.
- Take responsibility for own health, safety and security.
- Contribute to the development and implementation of clinical and research policies, procedures and SOPs.
- Adhere to Standard Operating Procedures without direct supervision. Maintain effective communication within the research team and between the multidisciplinary clinical team.
- To be able to prioritise workload even when frequently interrupted and under pressure.
- 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.

ANALYTICAL/JUDGEMENTAL SKILLS

- Support local implementation of study amendments.
- Supporting the clinical research team with data queries and reporting as required

PLANNING/ORGANISATIONAL SKILLS

- To be able to prioritise workload even when frequently interrupted and under pressure.
- Assist in promoting the appropriate referral and recruitment of patients to clinical research studies. Work with the clinical trials team and investigators to implement strategies to overcome barriers to recruitment and to solve other problems relating to specific studies.
- Coordinate and run appropriate study visits with oversight from the clinical trials team in order to collect study data.
- Respond to relevant data queries generated by the study coordinating team within a timely manner and escalate any issues to a senior member of the team where required.

PATIENT/CLIENT CARE

- The post holder will contribute to ensuring the patient experience in the relevant trails is excellent ensuring patients are at the heart of service design and delivery.
- Ensure Trust policies are applied to 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

- Ensure the environment is suitable for patient care and research processes, recognising the importance of privacy, dignity and diversity.
- Demonstrate personal development and knowledge of relevant current clinical and research practice.

HUMAN RESOURCES

- Participate in Good Clinical Practice (GCP) training and ensures GCP compliance of self and team.

INFORMATION RESOURCES

- Ensure the relevant research facilities are adequately stocked and maintained in order to ensure a safe environment for patients and staff. For example: order and top up supplies e.g. blood and urine bottles, gloves, sharps, other consumables and patient information leaflets, ensure refreshments are ordered and appropriately stored, prepare patient couches and top up linen supplies, perform safety checks e.g. resus and blood sugar monitoring equipment following appropriate training, manage waste and dirty linen, ensure research equipment is maintained and calibrated, manage and maintain cleanliness of the patient areas, liaising with housekeeping services to ensure high standards of cleanliness.
- Maintain calibration logs for research equipment e.g. centrifuges, freezers and weighing scales.

RESEARCH AND DEVELOPMENT

- Assist the clinical research delivery team in co-ordinating a portfolio of National Institute Health Research (NIHR) studies.
- Participate in Good Clinical Practice (GCP) training and ensures GCP compliance of self and team.

PHYSICAL SKILLS

- 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, oxygen saturations, temperature) and other assessments such as ECG, physical examinations, disease specific outcome measures, questionnaires, rated scales, qualitative interviewing as required by the protocol.
- Any other physical skills as listed within this job description.

PHYSICAL EFFORT

- Requirement to exert moderate physical effort. Research offices and teams may not be based where patients are seen or recruited, research team members are required to work across multiple sites at the RDE Wonford and where necessary Heavitree.

MENTAL EFFORT

- Prolonged concentration with complex research information, statistics and preparing reports and figures.
- Ability to manage multiple tasks at once and to prioritise tasks by importance.

EMOTIONAL EFFORT

- Rare exposure or occasional indirect exposure to distressing/emotional circumstances.

WORKING CONDITIONS

- 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. Research 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.

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.

PERSON SPECIFICATION

Job Title	Assistant Research Practitioner

Requirements	Essential	Desirable
QUALIFICATION/ SPECIAL TRAINING		
GCSEs including English, Maths and Science at grade A-C (or demonstrable equivalent)	E	E
NVQ level 3 / 4 in Healthcare or equivalent	E	
Diploma in Health or willingness to undertake	E	
Research Training (e.g. GCP, degree module, informed consent)	D	
KNOWLEDGE/SKILLS		
Understanding of data collection and data entry for clinical trials	E	
Pertinent clinical skills including venepuncture or willingness to undertake	E	
Computer literacy including ability to work with databases	E	
Ability to collect accurate clinical measures including standard observations (BP,HR,RR, SPO2 Temp, height, weight, blood sugar)	E	
Ability to organise and prioritise own workload and work to tight deadlines	E	
Understand the significance of research and use of validated results to improve practice	E E	
Knowledge of the Research Governance Framework and the International Conference on Harmonisation Good Clinical Practice Guidelines	D	
EXPERIENCE		
Experience in dealing with confidential patient information	E	
Ability to communicate information to patients/carers/ members of MDT	E	
Broad and recent clinical experience relevant to the post	E	
Proven record of meeting targets	D	
Experience of clinical research within the NHS setting	D	
PERSONAL ATTRIBUTES		
Ability to work cohesively as a member of a multidisciplinary team	E	
High level of interpersonal and communication skills	E	
Flexible and adaptable	E	
Willingness to learn, instigate and develop efficient working systems	E	
Willingness to undertake any necessary training and development to enhance work performance	E	
Commitment to openness, honesty and integrity in undertaking the role	E	
Willingness and ability to work across sites including community	E	
OTHER REQUIREMENTS		
The post holder must demonstrate a positive commitment to uphold diversity and equality policies approved by the Trust.	E	
Committed to further professional development	E	
Ability and willingness to work across multiple sites	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
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				X
Heavy manual handling (>10kg)	Y		X		
Driving	N				
Food handling	N				
Night working	N				
Electrical work	N				
Physical Effort	N				
Mental Effort	Y				X
Emotional Effort	Y		X		
Working in isolation	Y		X		
Challenging behaviour	N				