Royal Devon University Healthcare NHS Foundation Trust

JOB DESCRIPTION

JOB DETAILS	
Job Title	Clinical Research Coordinator
Reports to	Lead Nurse Clinical Trials and Sponsorship
Band	Band 6
Department/Directorate	Research and Development

JOB PURPOSE

The post holder will deliver high quality clinical, administrative and study management support to the development and implementation of clinical trials and other research studies within Royal Devon University Healthcare NHS Foundation Trust.

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. They will develop networks with Multidisciplinary Teams across the Trust and other appropriate local and national agencies. They will coordinate and manage clinical trials/research and deliver recruitment accrual in line with performance and monitoring objectives.

The post holder will work in compliance with the International Conference on Harmonisation Good Clinical Practice Guidelines (ICH-GCP), the NHS Research Governance Framework for Health & Social Care and, in the case of a Clinical Trial of an Investigational Medicinal Product (CTIMP), in compliance with the Medicines for Human Use (Clinical Trials) Regulations 2004.

KEY RESULT AREAS/PRINCIPAL DUTIES AND RESPONSIBILITIES

Trial Coordination, Implementation and Delivery

- Coordinate all aspects of the set up and day to day conduct of clinical trials/studies from set-up to close down.
- Organising and liaising with patients regarding visits in collaboration with the study nurse
- Leading site initiation visits to ensure research teams are fully informed regarding the set up and delivery of the trial / study.
- Prepare and liaise with appropriate staff for monitoring visits, audits or statutory GCP inspection by the Medicines & Healthcare products Regulatory Agency (MHRA) or any other body
- Develop and maintain systems for tracking trial conduct, recruitment and data capture.
- Liaise with members of the research and clinical teams and provide on-going advice and support to ensure the smooth conduct of clinical research ensuring compliance with study protocol, and all relevant guidelines regulations and legislation
- Maintain site file and recruitment, screening logs ensuring all documentation is managed within GCP guidelines as well as developing and maintaining systems for tracking trial conduct, recruitment and data capture.
- Ensuring safety reporting is carried out within Trust guidelines and reports are followed up in a timely manner

Research Trial Development

- Develop and/or review essential clinical research documents including patient information sheets/letters, informed consent forms as well as regulatory paperwork ensuring compliance with relevant SOPs, legislative requirements and GCP guidelines.
- Prepare and submit applications and required amendments for Health Research Authority (HRA), Research Ethics Committee (REC), MHRA and R&D approvals.

Trial Management Group (TMG) and Trial Steering Committee (TSC)

- Provide regular reports and updates to the TMG and TSC as well as disseminating findings to the clinical teams
- Organise, coordinate and run regular TMG/TSC meetings as applicable

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.

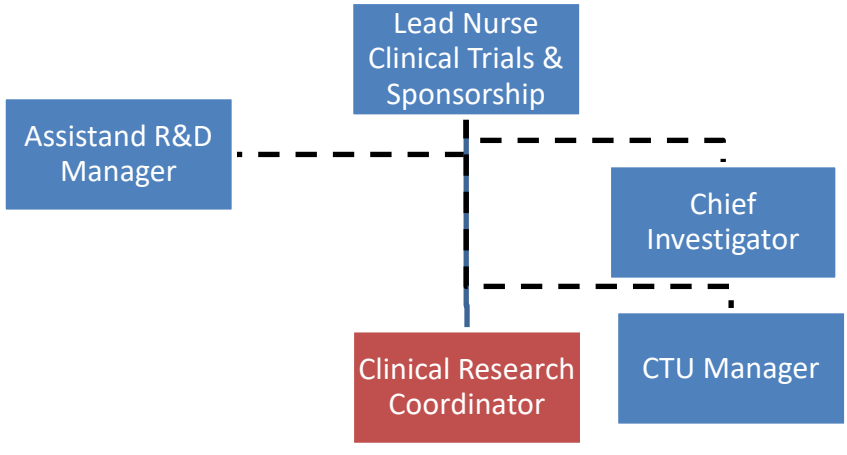
In addition, the post holder will deal with the wider healthcare community, external organisations and the public.

This will include verbal, written and electronic media.

Of particular importance are working relationships with:

Internal to the Trust	External to the Trust
• Research and Development Director • Assistant Research and Development manager • Lead Nurse Clinical Trials and Sponsorship • Clinical trials delivery teams • Chief and Principal Investigators • Clinical hospital-based teams • Trust Finance Team	• Study participants and their families • Colleagues in the Clinical Trials Unit (CTU) • University Researchers

ORGANISATIONAL CHART



FREEDOM TO ACT

The postholder is guided by GCP requirements, research governance principles and framework. Study specific activities are clearly defined by the study protocol and supporting documents, as well as departmental SOPs.

The postholder is expected to manage their workload independently. Achievement of their responsibilities will be demonstrated by efficient study delivery and achieved targets.

Guidance can be sought from the Chief Investigator, Lead Nurse, CTU or the larger Research and Development team if needed.

COMMUNICATION/RELATIONSHIP SKILLS

The post holder is expected to regularly liaise with patients regarding participation in clinical trials and any issues they may have. This including consent to participation and discussions around commitment and expectations of outcome. This can sometimes be of a sensitive nature, for example contraception use during clinical trials or potential drug side effects. The post holder will also need to communicate effectively to enable to optimise participant understanding of the trial and potential barriers to participation.

Regular effective communication will be needed when liaising between clinical and research delivery teams, to ensure safe delivery of the trial. The postholder will be responsible for delivering complex information to the Trial Management Group, for example patient recruitment and retention rates as well as an overview of trial safety reporting activity and outcomes.

ANALYTICAL/JUDGEMENTAL SKILLS

Regular review of study performance is essential for efficient study delivery and to monitor progress. Regular analysis and interpretation of complex study data is essential for achieving this. The post holder will be expected to constantly have oversight of study procedures and data using their analytical skills to ascertain when the study is underperforming or identify issues with patient recruitment and management. Examples of complex data may be recruitment numbers for each research site, forecasting projected recruitment time to target as well as assessing barriers to recruitment. They may be involved in writing amendments to study protocols to enable more efficient study delivery.

Analytical skills will also be needed when identifying and investigating safety reporting events and follow-ups – ensuring that all information and reporting to the study Sponsor is correct and within Medicines and Healthcare products Regulatory Agency (MHRA) guidelines.

PLANNING/ORGANISATIONAL SKILLS

The post holder will be expected to plan and organise straightforward research activities in accordance with the study protocol. For example, booking patients into clinics and making sure they have attended appropriate scans within the study visit window.

PATIENT/CLIENT CARE

Due to the nature of clinical trials, the postholder will have regular direct contact with participants. They will be expected to identify potential trial recruits and introduce the study to them. This will utilise their specialist knowledge of the study and clinical trial governance to support the informed consent procedure and subsequent queries.

They will work in conjunction with the research nurse to manage patient visits and ensure that trial procedures are carried out as per the protocol.

The postholder will be expected to deliver trial specific clinical advice to participants as directed by the trial protocol and study procedures. For example, explaining rehabilitation schedules for an orthopaedic trial participant or training diabetic trial participants in reporting blood glucose levels to a study app.

The postholder will also be responsible for the safe and accurate collection of research data through clinical procedures such as venepuncture, history taking, disease specific outcome measures, questionnaires, rated scales and qualitative interviewing as required by the protocol.

The post holder will also be expected to centrifuge, process, track and ship samples in line with protocol requirements including handling of dry ice following training.

POLICY/SERVICE DEVELOPMENT

The postholder will work within the Research and Development SOP's and Trust based policies. In order for the trials to run effectively they may be required to change working procedures or adjust the protocol to fit in around the clinical care pathways. These amendments will be subject to HRA & R&D approval.

FINANCIAL/PHYSICAL RESOURCES

The postholder will be an authorised signatory for patient expenses and trials supplies / equipment. It is their responsibility that there is enough supplies and equipment to run the trial effectively.

They will also be responsible for ensuring all patients visits are recorded in the EDGE research management system so that the correct invoicing for activity can be undertaken.

HUMAN RESOURCES

Responsibility for the day to day oversight of trial delivery will be with the post holder. The delivery team may consist of health care staff at many levels, included trained nurses and consultants dependant on the trial/study. The postholder will be responsible for the teaching and delivery of all specialist training related to trial procedures and protocols.

INFORMATION RESOURCES

The postholder will be responsible for ensuring that data collected as part of the trial is inputted accurately to the trial electronic data capture software in a timely manner.

There will be a requirement to compile reports for review by the trial management team and independent trial steering committee, for example recruitment rate, safety reporting activity, data query incidence and training activity. The post holder will need to be able to record their own data accurately and will be confident in using computer software to be able to do this.

RESEARCH AND DEVELOPMENT

The research coordinator is responsible for the safe and effect conduct of clinical trials within their remit. Therefore, they will regularly undertake R&D activities including, patient screening, consent, site file management, data inputting, and training on study specific procedure.

They will also be responsible for disseminating results to participants and the wider clinical team.

PHYSICAL SKILLS

This post requires highly developed physical skills where recording of data is essential. Data collecting during clinical visits E.G surgical theatre visits or gait measurement may require data recording in a timely manner.

Clinical assessment for trials may involve patient manipulation and manual assessments depending on the protocol. The post holder must be able to measure outcomes accurately which may involve high levels of hand, eye and sensory co-ordination. This is also required for large amounts of data entry. As trials report outcomes, it is essential that all data collected is accurate and of a high standard.

PHYSICAL EFFORT

Frequent light effort for short periods of time will be required for this post. For example, movement of patient files and protocols.

Depending on the trial there is the requirement for equipment to be used and brought to clinical areas which would may result in an occasional requirement to exert moderate physical effort for several short periods during a working day.

There will also be a requirement to stand for long periods of time, for example collecting data in surgical theatres.

MENTAL EFFORT

Frequent concentration is required however this will be predictable. For example, inputting data into the study database or compiling documents for a report.

EMOTIONAL EFFORT

Due to the nature of clinical trials in treating an illness or condition there will be the occasional exposure to distressing or emotional circumstances. For example, discussing a difficult diagnosis with a patient and explaining treatment arms available in the trial. The postholder will be supported by the clinical team and chief investigator in this instance.

There may also be the occasion of acting on an abnormal clinical result that the trial assessments may pick up – again there will be support from the clinical team and chief investigator if this occurs.

WORKING CONDITIONS

The post holder may be occasionally exposed to unpleasant odours or bodily fluids whilst carrying out study procedures in a clinical area.

There will also be a requirement to use Visual Display Unit equipment regularly on most days.

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.

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.

Northern Devon Healthcare NHS Trust and the Royal Devon and Exeter NHS Foundation Trust continue to develop our long standing partnership with a view to becoming a single integrated organisation across Eastern and Northern Devon. Working together gives us the opportunity to offer unique and varied careers across our services combining the RD&E's track record of excellence in research, teaching and links to the university with NDHT's innovation and adaptability.

PERSON SPECIFICATION

Job Title	Clinical Research Coordinator

Requirements	Essential	Desirable
QUALIFICATION/ SPECIAL TRAINING		
University graduate in a relevant subject area or equivalent level of professional experience	E	
Research Training (e.g. GCP, degree module, informed consent)	E	
Management or leadership qualification		D
Evidence of post graduate training in a relevant field, and/or continuous professional development in relevant fields	E	
KNOWLEDGE/SKILLS		
Knowledge of the Research Governance Framework and Good Clinical Practice Guidelines	E	
In depth knowledge of clinical trials & research methodologies	E	
Ability to use Microsoft Office to an advanced level	E	
Ability to organise and prioritise own workload and work to tight deadlines	E	
Ability to make independent decisions	E	
Critical appraisal skills	E	
Ability to present data in a clear, simple format	E	
EXPERIENCE		
Experience of clinical research within an NHS setting	E	
Experience with databases	E	
Previous direct clinical trials and/or project management experience	E	
Proven record of meeting participant recruitment targets		D
PERSONAL ATTRIBUTES		
Ability to work autonomously	E	
High level of interpersonal skills ad communication skills	E	
Flexible and adaptable	E	
Willingness to learn, investigate and develop efficient working systems	E	
Ability to work cohesively as a member of a team	E	
Willingness to undertake necessary training and development to enhance work performance	E	
Commitment to openness, honesty and integrity in undertaking the role	E	

OTHER REQUIREMENTS The post holder must demonstrate a positive commitment to uphold diversity and equality policies approved by the Trust. Ability to travel to other locations as required.	E 	 D

WORKING CONDITIONS/HAZARDS		FREQUENCY (Rare/ Occasional/ Moderate/ Frequent) R	O	M	F
Hazards/ Risks requiring Immunisation Screening					
Laboratory specimens	N				
Contact with patients	Y				
Exposure Prone Procedures	N				
Blood/body fluids	Y		X		
Laboratory specimens	N				
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)	N				
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			