Royal Devon University Healthcare NHS Foundation Trust

JOB DESCRIPTION

JOB DETAILS	
Job Title	Clinical Research Data Assistant
Reports to	Data Manager/Senior Research Administrator
Band	3 (subject to completion of formal matching)
Department/Directorate	Research and Development

JOB PURPOSE

The post-holder will work with the clinical and administrative research team assisting with data management of NIHR Portfolio studies. They will also support administrative and clerical activities for all aspects of research study delivery.

They will primarily work with the research team working under the supervision of the Data Manager. Their role will involve accessing and entering data from follow up visits for research participants, transcribing and uploading data from participant visits and coordinating data queries using various databases, spreadsheet and paper based systems.

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.

KEY RESULT AREAS/PRINCIPAL DUTIES AND RESPONSIBILITIES

Research and Governance

- Assist the clinical research 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.
- Assist with on-going study data management including:
  - Assist the clinical research team and study coordinators with the acquisition of trial related documentation.
  - Collection of patient data from medical notes and completion of case record forms (CRFs)
  - Liaise with the Clinical Trial coordinators, Research Nurses and clinicians to ensure accurate data collection.
  - Liaise with Clinical Trials Units, Research Networks and Commercial companies regarding data queries, checking and resolving data queries and ensuring that all relevant data has been recorded in a timely and accurate manner.
  - Supporting the clinical research team with data queries and reporting as required.
  - Assist the administrative team with regular site file maintenance to ensure study essential documents are version controlled and are maintained according to regulatory requirements.
  - Assist the administrative team in maintaining study core documents on EDGE and ensuring they are the current version.
  - Maintain effective communication between the study sponsor and the clinical research team.
  - Update quality systems to record study information and enrolled patients' details
  - Assist the Data Manager in producing performance data reports for the Team Lead and Lead Research Nurse, including the tracking of Expressions of Interest and NIHR performance metrics e.g. First Patient First Visit and Time to Target.
  - Coordinate study monitoring visits.
  - Liaise with IT department for firewalls, website issues and data upload issues.
  - Support internal audit and monitoring processes

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.

- Data Manager
- Clinical Research Team
- Administrative Research Team
- Research & Development Team
- IT Team
- Principal Investigators
- Trust Multi-disciplinary Team
- Study Participants and their Families'
- Clinical Trials Pharmacy Team
- Diagnostic Services
- Study Sponsors and monitors
- Clinical Research Associates

ORGANISATIONAL CHART

FREEDOM TO ACT

- Works to achieve agreed objectives and timescales, as prescribed to meet internal and external reporting deadlines, given freedom to organise own workload to meet criteria
- Recognise the importance of and adhere to Standard Operational Procedures and policies without supervision.

COMMUNICATION/RELATIONSHIP SKILLS

- Facilitate and maintain effective communication within the R&D team and across the areas where you have key working relationships (see Key Working Relationships section above).
- Maintain effective communication between the research team and patients tactfully and empathetically.
- 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.
- The ability to view and find clinical data/information that's required to complete a CRF or data request. The post holder will need to communicate with clinical colleagues at times to understand the requests and interpret patient data held on Epic.

ANALYTICAL/JUDGEMENTAL SKILLS

- Support local implementation of study amendments.

- Evaluate and interpret complex data within the context of requests to provide reliable, relevant information
- Supporting the clinical research team with data queries and reporting as required.

PLANNING/ORGANISATIONAL SKILLS

- Set up the local site file and any relevant databases and documents for the study.
- Coordinate and prepare documents for patient visits, including patient documentation packs.
- Coordinate site initiation meetings.
- Book trial specific investigations, procedures and rooms.
- Collecting prescriptions or investigation results.
- Couriering of samples.
- Liaise with the sponsor for final monitoring visit.
- Preparing study documents for archiving.
- Liaise with R&D and following archiving procedures

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.
- Responsible for upholding trust policies in patient interactions, primarily indirect and infrequent, such as handling telephone queries. Additionally, the role includes covering the PRC reception desk and directing research participants to their scheduled appointments.

POLICY/SERVICE DEVELOPMENT

- Support the implementation of new quality systems and processes across the department.
- Contribute to service development by actively participating in admin team meetings.
- Recognise the importance of key performance indicators and support the clinical research team to achieve them.

FINANCIAL/PHYSICAL RESOURCES

-
- Assist with ensuring study and office supplies are sustained by highlighting stock requirements and with ordering suitable goods.
- Support the admin team by liaising with other Trust departments to ensure that equipment is suitably maintained and in good working order.

HUMAN RESOURCES

- Undertake all mandatory training and take part in personal development reviews
- Provide cover during periods of absence for other trial administrators.
- Undertake all mandatory training and take part in personal development reviews.
- Recognise the importance of and contribute to maintaining the health, safety and security of the clinical research team.
- Participate in Good Clinical Practice (GCP) training.

INFORMATION RESOURCES

- Responsible for transcribing clinical data onto the study database
- Responsible for data entry, text processing or storage of data compiled by others, utilising paper or computer-based data entry systems

RESEARCH AND DEVELOPMENT

- Work within the Department of Health's Research Governance Framework for Health & Social Care and the EU Clinical Trials Directive.
-

PHYSICAL SKILLS

- The post holder will be required to use their 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.

PHYSICAL EFFORT

- Requirement to exert moderate physical effort (i.e. walking between offices).
- 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

- Frequent requirement for concentration with complex data and patient information, statistics and ability to manage multiple tasks at once and to prioritise tasks by importance.
- Prioritise a busy workload and manage multiple tasks when frequently interrupted.

EMOTIONAL EFFORT

Exposure to emotional or distressing circumstances is rare.

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.
- The postholder will be a frequent VDU user.

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.

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

Job Title	Clinical Research Data Assistant

Requirements	Essential	Desirable
QUALIFICATION/ SPECIAL TRAINING		
GCSE or equivalent (A-C Grade) in at least 2 subjects – Including Maths and English (Minimum requirement for all posts)	E	
European Computer Driving License (or equivalent computer skills qualification)	E	
NVQ level 3 in Administration (or equivalent qualification/experience)	E	
Good Clinical Practice Training		D
KNOWLEDGE/SKILLS		
Excellent organisation skills	E	
Working knowledge of Microsoft office packages (spreadsheets, databases, word processing and e-mail)	E	
Ability to communicate with staff	E	
Ability to prioritise workload to respond to changing demands	E	
Excellent telephone manner and written communication	E	
Understanding of National Institute for Health Research Clinical Research Network		D
Understanding of the clinical research process including Good Clinical Practice		D
Knowledge of medical terminology		D
EXPERIENCE		
Substantial administrative or clerical experience		D
Previous employment within a healthcare setting		D
Clinical Research experience		D
Data management experience		D
PERSONAL ATTRIBUTES		
Enthusiastic, motivated and committed to developing a professional service A flexible approach to work and the needs of the service Able to prioritise and use own initiative Remain calm in difficult situations Proven ability to work as part of a multi-disciplinary team Excellent communication skills; confidentiality, tact and diplomacy	All E	
OTHER REQUIREMENTS		
Ability and willingness to work across multiple sites	E	
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	

WORKING CONDITIONS/HAZARDS		FREQUENCY (Rare/ Occasional/ Moderate/ Frequent) R	O	M	F
Hazards/ Risks requiring Immunisation Screening					
Laboratory specimens	N				
Contact with patients	N				
Exposure Prone Procedures	N				
Blood/body fluids	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)	Y		x		
Driving	N				
Food handling	N				
Night working	N				
Electrical work	N				
Physical Effort	N				
Mental Effort	Y				x
Emotional Effort	N				
Working in isolation	N				
Challenging behaviour	N				