JOB DESCRIPTION

Royal Devon and Exeter 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 Administrator
Reports to	Senior Research Administrator
Accountable to	Team Lead
Band	3
Department/Directorate	Research and Development

JOB PURPOSE

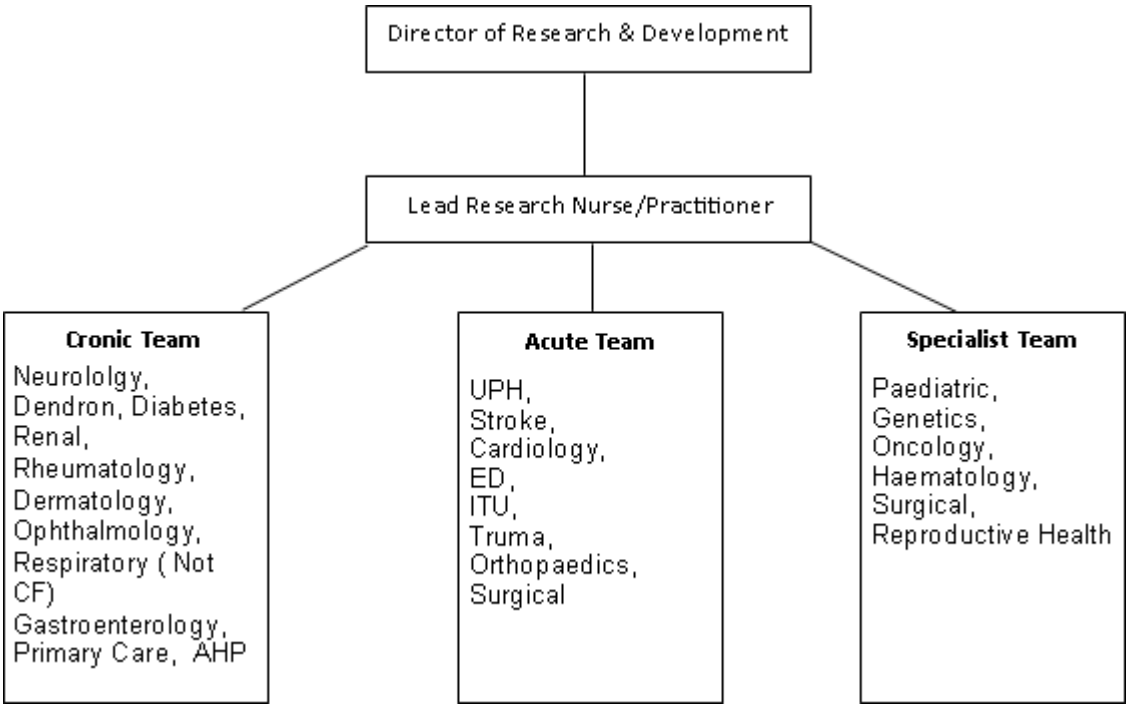
The post holder will work as part of the clinical research team to support the safe conduct of research in accordance with the Research Governance Framework and Good Clinical Practice guidelines and provide assurance that the rights, safety and well-being of trial participants are protected.

The post-holder will work with the research team to provide administrative, clerical and data management support for all aspects of research study delivery across an extensive portfolio of clinical trials.

KEY WORKING RELATIONSHIPS

- Director of Joint Office
- Clinical research teams
- Research and development team Principal Investigators & their clinical teams
- Trust multidisciplinary team
- Study participants & their families' Clinical trials pharmacy team Diagnostic services
- Study sponsors & Clinical Research Associates.

ORGANISATIONAL CHART



KEY RESULT AREAS/PRINCIPAL DUTIES AND RESPONSIBILITIES

Research and Governance

- Assist the clinical research team in coordinating 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 in study set up processes:
  - Expression of interest & study selection documents
  - Liaise with the study sponsor, R&D facilitator team, relevant support and research teams to assist in the successful set up of new studies
  - Prepare submissions for local research and development approval
  - Coordinate site initiation meetings
  - Set up the local site file & collate documents
  - Ensure EDGE is correctly set up & data correctly maintained throughout the study
- Take a leading role in on-going study coordination including:
  - Conduct regular site file maintenance to ensure study essential documents are version controlled and maintained according to regulatory requirements
  - Maintain effective communication between the study sponsor and the clinical research team
  - Support local implementation of study amendments
  - Update quality systems to record study information and enrolled patients details
  - Coordinate and prepare documents for patient visits
  - Respond to patients/carers telephone calls tactfully and professionally
  - Book trial specific investigations and procedures
  - Coordinate study monitoring visits
  - Assist with data queries and AE / SAE reporting
- Take a leading role in study close out procedures including:
  - Liaise with the sponsor for final monitoring visit

- Preparing study documents for archiving
- Liaise with R&D and following archiving SOP & procedures
- Assist with data entry according to study complexity and ensure that data is transcribed accurately where required.
- Support internal audit and monitoring.

Service Delivery and Improvement

- Take a leading role in providing all aspects of general administration and clerical work for the clinical research team including but not exclusively:
  - Document preparation
  - Book couriers & coordinate sample collections
  - Taking phone calls
  - Book Appointments
  - Email and fax correspondence
  - Typing letters
  - Maintaining databases, shared drives, generic email boxes and calendars
  - Filing
  - Patient records requests and collection
  - Gaining signatures
  - Office management (including electronic calendar / diary management)

COMMUNICATION/RELATIONSHIP SKILLS

- Facilitate and maintain effective communication within Research & Development 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.

KNOWLEDGE & TRAINING EXPERIENCE

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

ANALYTICAL/JUDGEMENTAL SKILLS

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

PLANNING/ORGANISATIONAL SKILLS

Resources

- Ensuring study and office supplies are maintained
- Coordinate & manage travel expense claims for patients
- Ensure that equipment is suitably maintained and calibration logs completed and up-to-date

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.

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

- Take a leading role in providing all aspects of general administration and clerical work for the clinical research team including but not exclusively:

HUMAN RESOURCES

- Undertake all mandatory training and take part in personal development reviews.

INFORMATION RESOURCES

- As described in sections Key Result Areas and Planning/Organisational Skills.

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.

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

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/good keyboard skills are required for the inputting and manipulating of data and/or information on computer databases.

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.

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

- 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. It may also be necessary to be flexible in working patterns in order to meet 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 RDE 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 Administrator
BAND	3

PERSON SPECIFICATION

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	E
European Computer Driving License (or equivalent computer skills qualification)	E	E
NVQ in Administration	D	D
Good Clinical Practice Training	D	E
KNOWLEDGE/SKILLS		
Excellent organisational skills	E	
Working knowledge of Microsoft office packages (spreadsheets, databases, word processing and e-mail)	E	
Ability to communicate with staff and patients	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	
EXPERIENCE		
Substantial administrative or clerical experience	E	
Previous employment within a healthcare setting	E	
Clinical Research experience	D	
Data management experience	D	
PERSONAL ATTRIBUTES		
Enthusiastic, motivated and committed to developing a professional service	E	
Flexible approach to work and the needs of the service	E	
Able to prioritise and use own initiative	E	
Remain calm in difficult situations	E	
Proven ability to work as part of a multi-disciplinary team	E	
Excellent communication skills; confidentiality, tact and diplomacy	E	
OTHER REQUIRMENTS		
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				
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)	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				