SINGLE CORPORATE SERVICES

Research and Development

Job title:	Clinical Trials Assistant	***To be completed by HR*** *Job Reference Number*
Reporting to:	Specialist/Research Nurse	
Accountable to:	Lead Research Nurse	
Pay Band:	B3	

As part of the Single Corporate Service, this role is a designated site-based role however the post holder will be part of the Corporate Service team which provides a service across the Organisation.

As the single corporate service will be delivered across both organisations, individuals may be required to undertake business travel between sites. The frequency and arrangements will be discussed on an individual basis and the staff mobility local agreement will apply.

For our leaders managing staff across multi-site locations, they will need to be visible and provide in person leadership. The arrangements and frequency will be agreed locally.

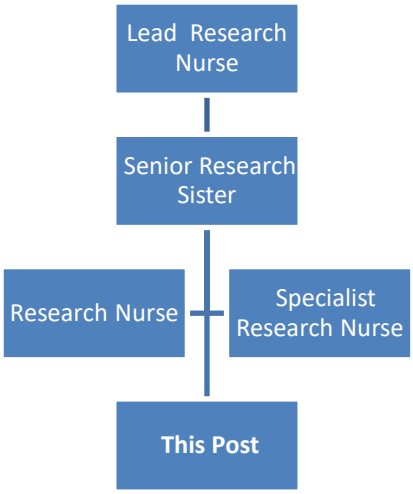
Job purpose

To provide clinical and administrative support to research teams, in order to facilitate recruitment into high quality clinical research.

Job summary To contribute to maintaining a high standard of day-to-day clinical care for all patients eligible for and recruited into Clinical Trials within the departments. To recruit patients into Clinical Trials designated as 'portfolio' studies by the NIHR and/or Commercially sponsored Clinical Trials.

1. To work as part of a team to deliver Clinical Trials within the organisation, providing both clinical and data management support for clinical trial activities undertaken at the Trust.
2. Work alongside the clinical team to co-ordinate and setup new clinical trials, ensuring accurate recording of patient data onto trial case reporting forms and data bases.
3. To provide support to the study Research Team and ultimately the Chief Research Officer in delivering high quality clinical research.
4. Ensure research participant safety is maintained and participant experience is positive by treating all participants, relatives and colleagues with respect, dignity, and courtesy in accordance with Trust Values.
5. Support the Trust culture of collaborative, flexible cross-team working and commitment to delivering quality services and outcomes, which support the Government's policies on public health.
6. The expectations within this job description will be achieved through hands-on clinical practice, education, and training, e.g., Phlebotomy, patient care procedures and specimen collection

Organisational Chart



Specific Core Functions

Research, Patient Experience and Use of Resources

- To contribute to the co-ordination of Clinical Trial activities within the relevant departments.
- To assist with reviewing new Trial protocols and contribute to the assessment of their clinical and practical implications (including feasibility and risk) to local patients and the relevant departments.
- Receive consent from research participants into low-risk research trials with oversight from your line manager and senior colleagues.
- To provide clinical and admin support for a number of clinical trial protocols
- Assist in the identification, screening, and assessment of the suitability of local patients to take part in Clinical Trials, in accordance with specified inclusion/exclusion criteria.
- To provide information to patients about participating in clinical trials, including the risks and benefits of participation and to facilitate the process of gaining their informed consent under the supervision of Research Nurses and Principal Investigators.
- With appropriate training and oversite undertake trial specific sampling as required by the protocol, to support the team to establish the eligibility of patients and to ensure their safe entry into and participation in clinical trials.
- To act as a contact for clinical trial patients within the relevant department and to be a resource for these patients and their families with respect to trial activities.
- Promoting research at ward level, encouraging staff to support research in order to aid recruitment.
- To maintain accurate documentation in an auditable format and accurately record data as required by each trial, including transcribing, and exporting data from medical records and hospital IT systems to clinical trial case report forms (CRFs) as required by trial protocols.
- To ensure the timely submission of accurate and completed CRFs to the trial co-ordinating centre and providing expedited responses to data queries and nonsensical information.
- To use trial internet-based databases and software to organise, report, record and monitor trial activities, including updating details of patients screened and recruited into clinical trials.

- To schedule clinic appointments for trial follow-up visits and refer patients for the relevant investigations as determined by the relevant trial protocol.
- Contribute to the person-centred care of patients in clinical trials; initiating investigations where appropriate and referring to Research Nurses or the Principal Investigator where necessary.
- Provide general administrative support to clinical trials, including filing, typing, fielding telephone calls, ordering patient notes and retrieving patient test results via hospital IT systems.
- Make arrangements for pathological samples, radiological films and electronic data to be sent for central review.
- Support the clinical research teams in preparing trial documentation for monitoring visits from trial sponsors and regulatory agencies.
- To work to Standard Operating Procedures for clinical trials set by the Trust and trial co-ordinators.
- To ensure all activities undertaken meet the standards set out by the Principles of Good Clinical Practice and National Research Governance Framework for Health and Social Care and adhere to all applicable regulatory requirements.
- May be required to work unsocial hours as necessary dependent on the needs of the service.
- May be required to work across more than one location e.g. Research Hubs

Professional Education and Development Role

- Participate fully in the Appraisal and Development Review Process.
- Complete the Competency Framework for the role and achieve the minimum skill set (list of competencies as defined in generic competency framework). Maintaining own learning record of evidence
- Complete the Trust Care Certificate within the assigned 3-month period, and any other training relevant to the post e.g. Good Clinical Practice and Informed Consent training
- Develop a sound knowledge of clinical research and support and contribute to the orientation of new/temporary staff.
- Initiate, develop and strengthen interpersonal relationships with all members of the multidisciplinary team ensuring good team working, collaborative working practices and professionalism throughout the department.
- Deal with interpersonal conflict and escalate to senior nurse to assist with resolution of any adverse situation/incidents. Comply and promote compliance to Trust policies e.g. Harassment and Bullying.

Key Responsibilities

Communication and Working Relationships

- The post holder will be providing and receiving routine information orally, in writing or electronically to inform work colleagues, patients, clients, carers, the public or other external contacts. The communication will include;
  (a) Providing and receiving routine information which requires tact or persuasive skills or where there are barriers to understanding

(b) providing and receiving complex or sensitive information,
(c) providing advice, instruction, or training to groups, where the subject matter is straightforward.

Analytical and Judgement

- Judgements involving straightforward job-related facts or situations.

Planning and organising

- Planning and organisation of straightforward tasks, activities, or programmes, some of which may be ongoing.

Physical Skills

- The post requires physical skills which are normally obtained through practice over a period of time or during practical training e.g. standard driving or keyboard skills, use of some tools and types of equipment.

Patient Client Care

- Provides general non-clinical advice, information, guidance or ancillary services directly to patients, clients, relatives or carers.

Policy and Service Development

- The post holder follows policies in own role which are determined by others; no responsibility for service development, but may be required to comment on policies, procedures, or possible developments.

Financial Management

- The post holder will observe a personal duty of care in relation to equipment and resources used in the course of their work.
- The post holder will handle or process cash, cheques, patients' valuables.
- The post holder will be responsible for the safe use of equipment other than equipment which they personally use.
- The post holder is responsible for maintaining stock control and/or security of stock,
- The post holder will be responsible for the safe use of expensive or highly complex equipment.

Management/Leadership

- The post holder provides advice or demonstrates own activities or workplace routines to new or less experienced employees in own work area.

Information Resources

- The post holder will be responsible for data entry, text processing or storage of data compiled by others, utilising paper, or computer-based data entry systems,

Research and development See specific core functions

Freedom to Act

- Generally, works with supervision close by and within well established procedures and/or practices and has standards and results to be achieved.

Physical effort

- There is an occasional requirement to exert moderate physical effort for several short periods during a shift.

Mental effort

- There is a frequent requirement for concentration where the work pattern is predictable with few competing demands for attention, or there is an occasional requirement for concentration where the work pattern is unpredictable.

Emotional Effort

- Occasional exposure to distressing or emotional circumstances, or frequent indirect exposure to distressing or emotional circumstances, or occasional indirect exposure to highly distressing or highly emotional circumstances.

Working conditions

- Occasional exposure to unpleasant working conditions, or occasional requirement to use road transportation in emergency situations, or frequent requirement to use road transportation, or frequent requirement to work outdoors, or requirement to use Visual Display Unit equipment more or less continuously on most days.

Person Specification

Criteria	Essential	Desirable	*How criteria will be assessed*
Qualifications	- NVQ 3 in Health and Social Care or equivalent relevant experience - Evidence of continuing professional development - Completed Care Certificate or ability to complete within 3-months of appointment - English and Maths qualification GCSE / Functional skills at level 1 or equivalent	- Good Clinical Practice (GCP) training for research	
Experience	- Effective interpersonal skills - Excellent verbal and written communication skills - Ability to gather data, compile information and prepare reports to	- Previous experience of clinical trials or research projects - Experienced in phlebotomy and vital signs observations	

	present to key stakeholders - Skill in organising resources and establishing priorities including time management - Ability to maintain record keeping systems and procedures - Ability to operate a PC with knowledge of word processing, including spreadsheets, database, and presentation software. - Strong customer service skills		
Knowledge	- Can demonstrate understanding of and share the Trust values of Working Together for Patients with Compassion as One Team Always Improving - Desire to deliver compassionate hands-on care in the hospital environment as per study protocol		

Compliance statement to expected organisational standards.

To comply with all Trust Policies and Procedure, with particular regard to

- Risk Management
- Health and Safety
- Confidentiality
- Data Quality
- Freedom of Information
- Equality Diversity and Inclusion
- Promoting Dignity at Work by raising concerns about bullying and harassment
- Information and Security Management and Information Governance
- Counter Fraud and Bribery

The Trust has designated the prevention and control of healthcare associated infection (HCAI) as a core patient safety issue. As part of the duty of care to patients, all staff are expected to:
Understand duty to adhere to policies and protocols applicable to infection prevention and control.

- Comply with key clinical care policies and protocols for prevention and control of infection at all time; this includes compliance with Trust policies for hand hygiene, standards (universal) infection precautions and safe handling and disposal of sharps.
- All staff should be aware of the Trust's Infection Control policies and other key clinical policies relevant to their work and how to access them.
- All staff will be expected to attend prevention and infection control training, teaching and updates (induction and mandatory teacher) as appropriate for their area of work, and be able to provide evidence of this at appraisal.

- To perform your duties to the highest standard with particular regard to effective and efficient use of resources, maintaining quality and contributing to improvements.

- Ensure you work towards the Knowledge and Skills Framework (KSF) requirements of this post. KSF is a competency framework that describes the knowledge and skills necessary for the post in order to deliver a quality service.

- Your behaviour will demonstrate the values and vision of the Trust by showing you care for others, that you act professionally as part of a team and that you will continually seek to innovate and improve. Our vision, values and behaviours have been designed to ensure that everyone is clear about expected behaviours and desired ways of working in addition to the professional and clinical requirements of their roles.

- Ensure you adhere to and work within local and national safeguarding children legislation and policies including the Children Act 1989 & 2004 , Working Together to Safeguard Children 2013, 4LSCB guidance and the IOW Safeguarding Policy.

- Ensure you adhere to and work within the local Multiagency safeguarding vulnerable adults policies and procedures

- Ensure that you comply with the Mental Capacity Act and its Code of Practice when working with adults who may be unable to make decisions for themselves,

- Ensure that you maintain personal and professional development to meet the changing demands of the job, participate in appropriate training activities and encourage and support staff development and training.
- Respect the confidentiality of all matters that they may learn relating to their employment and other members of staff. All staff are expected to respect conform to the requirements of the Data Protection Act 1998, including the responsibility to ensure that personal data is accurate and kept up to date

- If your employment is to a post that requires you to be registered with a professional body, the continuation of your employment is conditional upon you continuing to be registered with the appropriate professional body. The Trust will require evidence of current registration.

- Proactively, meaningfully and consistently demonstrate the Trust Values in your every day practice, decision making and interactions with patients and colleagues.

- Perform any other duties that may be required from time to time.

This job description may be altered, from time to time, to meet changing needs of the service, and will be reviewed in consultation with the post holder.