Research and Development

Job Description

Job Title: Clinical Research Coordinator

Band: 5

Hours of Work (p/w): 37.5

Service Centre/Directorate: Vaccine Institute / Paediatric Research

Base: St George's Hospital but the post holder may be required to work at any of the Trust's sites.

Accountable to: Head of Research Nursing /research Lead

Reports to: Senior Clinical Research Nurse/ Research Matron

Key working relationships: Vaccine Institute, CRF, Joint Research and Enterprise Service (JRES), study sponsors, clinical multi-discplinary teams as appropriate to the care of patients and Principal Investigators.

Role of the Department: Support the Trust and University clinical research agenda assisting in the clinical research studies undertaken in or associated with the relevant department

Job Summary: To support the research team in all aspects of administration and governance related to relevant research studies Carry out responsibilities that are related to the day to day running of clinical trials to ensure quality is maintained. The post holder will work across clinical research studies within the Paediatric Research portfolio. The post holder must also be willing to move to different clinical specialties where the need to do so is identified.

Trust Vision & Values:

The postholder is expected to have a clear understanding of how this post contributes to the achievement of the trust vision of:

We are a thriving Foundation Trust at the heart of an integrated healthcare system. One that delivers improved patient care at a community, hospital and specialist setting, supported by a unique and nationally recognised programme of research, education and employee engagement.

We expect all our staff to share the values that are important to the Trust, being Excellent, Kind, Responsible & Respectful, and behave in a way that reflects these.

St George's University Hospitals NHS Foundation Trust is committed to safeguarding children and vulnerable adults and expects that all staff will share in this commitment. The Trust is clear that all staff have a responsibility to be aware of children and adult safeguarding policies and procedures and that each member of staff, clinical and non-clinical, will attend child or adult safeguarding training that is provided at an appropriate level to suit their role. The Trust has the additional expectation that all staff will be able to identify concerns and know what action to take.

Main Duties/Key Results Areas:

Administraion:

- Initiate and manage the day to day running of allocated trials in accordance with Good Clinical Practice (GCP) and Standard Operating Procedures (SOPs)

- To complete applications to the Health Research Authority (HRA) , Research Ethics Committees (REC), Medicines and Healthcare products Regulatory Agency (MHRA) and the Joint Research & Enterprise Serivce (JRES) for new research proposals. This will include:
    - Assisting the Principal Investigator (PI) and the Research Nurses and Practitioners with feasibility and expressions of interest within the department
    - Liaising with pharmacy, finance, radiology and laboratories in the set up of new trials
    - Ensuring that trials do not commence until all regulatory, sponsor and local JRES/R&D requirements are satisfied

- Ensure trial specific responsibilities delegated by the Sponsor to the PI are carried out in accordance with the specific contract. Ensure that this correlates to the information recorded on the delegation log and is accordance with protocol guidance.

- Responsible for correct version control of all documentation. Prepare and submit amendments, as required and update trial documentation as necessary e.g. protocols, investigator brochures, case report forms. Ensure all allocated Site Files are ready to be reviewed by study teams and regulatory bodies. Ensure that electronic and paper documents are stored appropriately and are easily accessible by the team.

- Work closely with clinical teams to aid liaisons between research and clinical teams for effective communications. This will include:

    - Attending relevant/allocated multi-disciplinary team (MDT) meetings, to ensure recruitment of patients to trials are carried out appropriately
    - Attending relevant meetings, highlighting eligible patients, completing and processing relevant screening logs.
    - Tracking patients (this may include screening clinics) and ensure informed consent procedures are followed by the clinical staff, file consent forms appropriately and document on recruitment log.
    - Inform Trials office and complete randomisation as required.
    - Working In collaboration (or independently) with the research Midwives to ensure all schedule requirements are organised and completed as per protocol requirements.

- Responsible for ensuring CRFs (Case Report Forms) both paper and electronic, are accurately completed in a timely manner. Ensure that confidentiality is maintained and adhere to the Data Protection Act. Within the allocated portfolio the post holder will work independently on several studies.

- Ensure that high quality is maintained, by demonstrating minimum data query requests. Take action to complete missing data as required and ensure efficient procedures are in place to improve data capture. Able to discuss concerns with the CRF Senior Research Nurse/Research Matron and implement changes to improve quality.

- Responsible in collaboration with the nursing and clinical team for ensuring that Serious Adverse Events (SAEs) are identified, recorded and reported by clinical staff in accordance to GCP and Trust SOPs. Ensure that SUSARs are reviewed by the Principal Investigator and filed appropriately

- Be the main point of contact with JRES (sponsor), ensure that communication is cascaded to the team and the Principal Investigator, and facilitate any actions required. Including updating the MDT on trial activity to ensure that invoices are raised and relevant departments are cross charged. Draft progress reports to REC, R&D, funders, sponsors and regulatory bodies as appropriate.

- Facilitate monitoring visits to ensure a positive monitoring report by ensuring that all necessary documentation is readily available to be reviewed by Trials office representative.

- Ensure trial closure is correctly communicated and processed with internal departments (pharmacy, pathology, radiology etc), JRES, Sponsor, HRA, REC, and MHRA as appropriate. Ensure that trial is archived according to Sponsor and local requirements.

- Organise and prepare in-house meetings by ensuring that all necessary attendees are notified in advance of meeting and agenda items are sent out to all relevant parties, take notes at meeting.

- Regular update meetings with Principal Investigator to ensure the smooth running of all study trials and that all administrations are up to date.

Research practice:

- To deal sensitively and in a professional manner with patients in person and on the telephone when dealing with queries and booking appointments.

- To perform observations e.g. temperature, pulse, blood pressure, respiration, urine testing, height & weight and to record these correctly in the patient's records, reporting any abnormality or change in these to the research nurse.

- Once fully trained and competent to take consent, perform venepucture and process (centrifuging and sending to internal and external labs) clinical specimens, including blood and urine as per protocol requirements.

- Ensure the collection, processing, storage and use of human tissue is carried out according to protocol requirements and in accordance with local SOPs and the Human Tissue Act

- To adhere to the recommendations for the Control of Substances Hazardous to Health (COSHH) and risk assessments appropriate to the clinical area.

General:

- To have responsibility for the Health, Safety and Welfare of self and others and to comply at all times with the requirement of the Health and Safety Regulations.

- To ensure confidentiality at all times, only releasing confidential information obtained during the course of employment to those acting in an official capacity in accordance with the provisions of the Data Protection Act and its amendments.

- To work in accordance with the Trust's Equality and Diversity policy to eliminate unlawful discrimination in relation to employment and service delivery.

- To promote at all times equal opportunities for staff and patients in accordance with the Trust's policies to ensure that no person receives less favourable treatment than another on the grounds of: age; disability; marriage and civil partnership; pregnancy and maternity; race (ethnicity); religion or belief; sex (gender); gender reassignment or sexual orientation.

- To ensure skills are up-to-date and relevant to the role, to follow relevant Trust policies and professional codes and to maintain registration where this is a requirement of the role.

- To comply with the Trust's No Smoking Policies.

- To undertake such duties as may be required from time to time as are consistent with the responsibilities of the grade and the needs of the service.

This job description is not an exhaustive document but is a reflection of the current position. Details and emphasis may change in line with service needs after consultation with the postholder.

Person Specification

Job Title: Clinical Trials Coordinator **Band: 5**

Factor	Essential	Desirable	Method of Assessment
Education	Life sciences degree, or equivalent experience	Recent GCP training or qualification in research/clinical trials	Application form
Experience	Minimum 1 year working in a clinical Trial setting or equivalent experience 1 year experience of data entry and data management in clinical trials or equivalent experience Experience dealing with the general public. Experience working in a team on joint projects.	Experience in the NHS Teaching or training experience	Interview and application form
Skills and Abilities	Excellent organisation skills. Excellent oral and written communication skills. Excellent attention to detail. Excellent IT skills including access excel and power point. Ability to communicate with patients in a sympathetic and efficient manner. Good time management. Able to work under pressure.	Phlebotomy Experiences in project management Experience of Clinical Laboratory work (i.e. Spinning and aliquoting blood samples) Experience of working with Research Governance policies and issues Experience in undertaking medical /Clinical Research	Interview and application form
Knowledge	Understanding of clinical trials and regulation governing clinical research. Medical terminology Smart appearance. Polite Flexible and Dynamic		Interview and application form