

## RESEARCH AND DEVELOPMENT

### JOB DESCRIPTION

<b>Job Title:</b>	Clinical Research Nurse Paediatrics
<b>Band:</b>	6
<b>Hours of Work (p/w):</b>	37.5
<b>Department:</b>	Paediatric infectious diseases research group
<b>Base:</b>	St George's Hospital but the post holder may be required to work at any of the Trust's sites.
<b>Accountable to:</b>	Head of Research Nursing
<b>Reports to:</b>	Senior Clinical Research Nurse/Clinical Research Matron
<b>Responsible for:</b>	Clinical research studies within the Vaccine Institute / Paediatric Infectious Diseases Research Group
<b>Key working relationships:</b>	All groups of Trust staff and external stakeholders to provide a safe and effective clinical research service
<b>Role of the Department:</b>	Support the Trust and University clinical research agenda assisting in the clinical research studies undertaken in or associated with the PIDRG

**Job Summary:** The post holder will be responsible for the co-ordination and management of an agreed clinical research portfolio at St George's Hospital. The post holder will work collaboratively with the research teams and wider multidisciplinary team in the management of their own caseload of clinical trials patients and be accountable for the achievement of local and national targets in relation to the service.

Responsibilities include: facilitating study set-up; identifying suitable patients through the process of MDT's/screening notes; collecting data; interviewing; supporting and monitoring patients and data entry. The post holder will also be expected to have sufficient skills to enable patients to make informed choices concerning their involvement in clinical trials by providing advice and information and acting as the patients advocate. The post holder must also be willing to move to different clinical specialties within the remit of their qualifications and where the need to do so is identified.

#### Trust Vision and Values:

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

*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:**

### **1. Clinical and Research.**

- Act as a role model for excellence in clinical research
- Work autonomously to manage his/her caseload of patients, whilst working as part of a multidisciplinary team. Maintain effective communication with patients, carers and professionals to ensure service delivery.
- Identify suitable patients for entry into clinical trials by attending out-patient clinics (screening notes/clinician referral) and Multidisciplinary Team (MDT) meetings.
- Ensure patients are fully informed prior to entry in to any clinical trial programme, acting as a guide and advocate to the patient throughout the complex decision making process.
- Participate in the informed consent process ensuring adherence to the UK Policy Framework for Health and Social Care Research.
- Evaluate patient eligibility and safe entry to clinical trials, co-ordinating investigations, obtaining results and arranging appropriate appointments according to trial protocol requirements.
- Register/ randomise patients into clinical trial protocol
- Act as an on-going resource and support to patients and their carers, regarding practical aspects of clinical trial participation.
- Recognise the complex emotional/psychological needs of patients entering a clinical trial and provide an appropriate level of support.
- Collect any blood samples as required, strictly adhering to the clinical trial protocol and ensuring safe handling and appropriate storage of specimens.
- Be aware of and report any unusual side-effects and interactions of study drugs/devices to Principal Investigator/Research Nurse.
- Maintain comprehensive and accurate documentation of patient events in patient's medical notes.

- Responsible for timely, accurate and complete documentation in the patients case report form (CRF) in accordance to several regulations including the Medicines for Human Use (Clinical Trials Regulations) Regulations 2004 and Amended Regulations 2006 Incorporating International Conference on Harmonisation of Good Clinical Practice (ICH GCP) and the UK Policy Framework for Health and Social Care Research.
- Report treatment toxicity/side effects and initiate changes to treatment as required by the protocol and Principal Investigator
- Record and report adverse events, serious adverse events and suspected, unexpected, serious adverse reactions (SUSARS) that occur whilst the patient is participating in the clinical trial to relevant personnel and act as defined in trial protocol and according to Trust policy.
- Implement and adhere to the European Directive (Regulation if this supersedes the Directive) for clinical trials incorporating the principles of GCP (Good Clinical Practice).
- Co-ordinate end of trial activities including archiving.
- Prepare for and participate in internal and external audit inspections, evaluations and benchmarking exercises and suggest any change to improve standards

## **2. Organisational / management**

- Work closely with the Senior Research Nurse and Lead Clinicians in the provision of a comprehensive clinical trial service.
- Be aware of and work within Local Trust's policies and procedures.
- Deputise for Senior Research Nurse where appropriate.
- Be responsible for the induction, line management and development of assigned junior team members ensuring that they recruit effectively to clinical trials where appropriate.
- Assist in the review of trial protocols and identify resource implications for the site. Provide guidance on appropriate recruitment strategies and calculating study resource needs, particularly with regard to proposed service support activities.
- Liaise with the medical team and sponsor organisation in:
  - on-study treatment and follow-up of patient
  - ensuring the collection of accurate data
- Implement the set-up of clinical trials on site, involving liaison with Joint Research and Enterprise Service, Sponsor Organisations, Clinical Trials Units Health Research Authority (HRA) and other relevant staff to facilitate trial set-up visits.
- Ensure that timely and accurate screening and accrual data is recorded and reported as required.

- Liaise with other departments and wards at the site/s, including attendance at relevant Multidisciplinary meetings in order to promote collaborative working, integration of research and maintenance of open and effective communication.
- Participate in the maintenance of a high profile for the work of the Vaccine Institute / Paediatric Infectious Diseases Research Group Team within St Georges Healthcare NHS Foundation Trust, SGUL and with outside agencies as appropriate.
- Be able to provide information to allow for invoices to be raised for payments where appropriate.
- Identify barriers to recruitment to trials and plan and implement strategies to overcome them.
- Innovate and contribute to the development of clinical research policies/procedures/Standard Operating Procedures within the department.
- Keep up to date on research management issues through liaising with Senior Research Nurse and attending national meetings.

### 3. Education and Training

- Act as a resource for colleagues in relation to clinical trials.
- Continue and provide evidence of own professional development.
- Maintain links with other clinical trials professionals across local and national networks to share knowledge, skills and provide mutual support.
- Maintain up to date knowledge of research related advances in clinical trials supported by the .PIDRG
- Attend national meetings in relation to clinical trials as appropriate and agreed with line manager.
- Participate in provision of education and study days Trust wide to all levels of clinical staff to promote clinical trial awareness.
- Attend trial Investigator meetings and conferences as appropriate when required.
- Disseminate research by assisting in the preparation of poster/research papers for meetings, conferences and publications.
- Contribute to the induction and orientation of new research nurses/practitioners to the Team.

### 4. 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 be trained in and demonstrate fair employment practices, in line with trust policies.
- 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 post holder.**