Guy's and St Thomas' NHS
NHS Foundation Trust

JOB DESCRIPTION

1. General Information

JOB TITLE: Laboratory Coordinator

GRADE: Band 6

DEPARTMENT: R&D Vaccine and Trials Team

HOURS: 37.5

RESPONSIBLE TO: Vaccine and Trials Laboratory Coordinator

Research & Development Department Information

The R&D Department at Guy's & St Thomas' NHS Foundation Trust (GSTFT) is one of the focal points for innovative research in London through its nationally recognised research portfolio and research infrastructure. The broad ranging portfolio includes one of only five National Institute for Health Research (NIHR) comprehensive Biomedical Research Centres awarded in 2007-2012 in partnership with our academic partner King's College London, and one of only 11 NIHR Biomedical Research Centres receiving funding from 2012-2017. The portfolio also includes numerous NIHR Programme Grants for Applied Health, Research for Patient Benefit Project Grants, a wide range of externally funded Research Grants as well as a research scheme for NHS consultants. In addition, the Trust is a stakeholder in the newly accredited Academic Health Sciences Centre, King's Health Partners and the Joint Clinical Trials Office. The R&D Department also supports the recently established Clinical Research Facilities both at St Thomas' Hospital and Guy's Hospital based within the recently opened Experimental Medicine Hub. As well as hosting the South London Comprehensive Local Research Network (CLRN) the Trust is a major player in the South London network both in relation to the NIHR research study portfolio and accruals into studies; the R&D Department also hosts the Primary Care Research Network for Greater London (PCRN-GL) - the South East London Cancer Research Network (SELCRN) is also hosted by the Trust.

Based in refurbished offices within the Tower Wing at Guy's Hospital, this dynamic, lively and diverse department has the breadth of knowledge and skills to ensure that this high level of research activity and associated research processes are managed smoothly, efficiently and collaboratively.

The NIHR Biomedical Research Centre at GSTFT and KCL

The NIHR Biomedical Research Centre (BRC) at GSTFT and KCL has recently been awarded a further £58.7M over the period 2012-2017 as part of the Department of Health's strategy for Research & Development to deliver world class translational research to benefit the health and wealth of the nation. The first GSTFT/KCL BRC award from April 2007-2012 allowed us to establish of state of the art research infrastructure including the development of an Experimental Medicine Hub at Guy's Hospital. The new BRC's research is strategically integrated and managed by five Research Clusters: Experimental Medicine and Therapeutics; Biomarkers, Co-diagnostics and Imaging; Population Sciences; the School of Translational and Experimental Medicine (STEM) and the Operational Infrastructure Cluster. Research within these Clusters are based around eight outstanding research themes encompassing Cancer; Cardiovascular Disease; Cutaneous Medicine; Environmental and Respiratory

Health; Imaging & Bio-Engineering; Infection & Immunity; Translational Genetics; and Transplantation.

The Experimental Medicine Hub houses state of the art facilities for the delivery of translational research and includes the BRC/R&D Department Management offices, CLRN, PCRN, Joint Clinical Trials Offices creating a one stop shop for researchers, as well as the CRF at Guy's, Immune Monitoring Core, Good Manufacturing Practice (GMP) Cell Therapy Suite and Genomics Core, as well as Quintiles Phase I Clinical Trials Unit, GMP Pharmacy, the Assisted Conception Unit with a GMP stem cell suite a GMP Flow Sorting Core and BRC Imaging Core.

The Clinical Research Facilities

The Clinical Research Facilities (CRFs) at GSTFT and KCL are established platforms for translational research, experimental medicine and early clinical trials. They will support the accelerated discovery of novel approaches to the prevention, diagnosis and therapy of major diseases relevant to the NHS and will ultimately contribute to the improvement of patient outcomes. The CRF is an integral part of the NIHR Biomedical Research Centre at GSTFT and KCL and will support the BRC to deliver on its translational agenda. The CRF includes two adult facilities; one based at Guy's Hospital within the experimental medicine hub and one at St Thomas' Hospital; along with a paediatric CRF within the Evelina Children's Hospital and an Imaging CRF based within the Imaging Centre at St Thomas' Hospital. These facilities have differentiated functions based on the clinical setting within the campuses. The Trust were awarded £5.6m through the NIHR funding for CRFs for Experimental Medicine to support these facilities for the period September 2012-March 2017. Clinical research activities within these differentiated facilities include asthma & allergy, atherosclerosis, cutaneous medicine/dermatology, cancer, immunity and infection, transplantation, cardiovascular disease, nutrition, women's' health, clinical pharmacology, paediatrics and imaging research.

Organisational Values:

The post holder will:

- **Put patients first** - consider the patient's needs and wishes in all that they do
- **Take pride in what they do** – strive for highest standards on own work and challenge colleagues to do the same
- **Strive to be the best** – in terms of patient care & teamwork
- **Act with integrity** - maintain the privacy & dignity of patients, work with integrity and be trustworthy, be accountable for own work
- **Respect others** – patients, visitors and colleagues. Actively give and receive feedback.

2. Job Summary

This unique post offers and exciting opportunity to work as the Laboratory Coordinator for the Vaccine and Trials Research team at Guy's and St. Thomas' NHS Foundation Trust.

The team manages a broad portfolio of Vaccine and Trials research studies, requiring a comprehensive and high-quality laboratory service including sample reception, preparation, processing, storage and shipment for samples collected as part of a complete portfolio of clinical trials of all phases and including in-patient, out-patient and healthy volunteer studies.

The post holder will have knowledge of a range of pre-analytical processing procedures and will be responsible for overseeing the processing and storage of clinical trial samples to the highest standard. This includes:

- receiving, sorting, labelling and processing samples;
- resolving issues such as mislabelled or missing specimens;
- maintaining study data documentation;
- overseeing laboratory checks;
- facilitating scheduled internal audits;
- performing quality control checks on routine equipment;
- completing feasibility assessments and laboratory costings;
- contributing to COSHH and Risk Assessments (as required and appropriate);
- dealing with enquiries;
- preparing weekly laboratory work schedules.

The post holder will oversee equipment maintenance, repair and calibration. They will work with the CRF laboratory co-ordinator and ensure adherence to Temperature monitoring systems and processes related to fridge/freezer alarms and out-of-hours laboratory storage and back-up solutions.

It is expected that the post holder will lead by example and spend a significant portion of their time in the laboratory preparing and processing samples. It is expected that the post holder will maintain relevant competencies and will be able to develop these competencies in others. You will be responsible for ensuring all staff working in the Laboratory have up to date laboratory training and provide training to all users of the laboratory as required. You will provide expert guidance to colleagues working in, or setting up research laboratories within the trust.
GSTT is a dynamic organisation and research activity is dependent on continued funding from external sources, therefore changes in the core duties and responsibilities of this role may be required from time to time to meet the requirements of funders or the needs of the Vaccine and Trials team or the Research and Development department. This job description is intended as an outline of the areas of activity. The activities required of the post holder and the working locations may be amended. Any changes will be reviewed as necessary in conjunction with the post-holder.

Key working relationships

Internal

- Vaccine and Trials Team colleagues – Medical and clinical staff, quality team, operational and administrative staff
- Study Teams
- Clinical Research Facility Team
- Principal Investigators and Sub/Co Investigators
- King's Health Partners Clinical Trials Office (KHP CTO) staff
- Trust porters
- Trust maintenance and engineering staff
- Research and academic staff from Kings College London

3. Duties and Responsibilities

Management

1. Manage the flow and organisation of work coming through the lab, ensuring that work is carried out in a timely and efficient manner, in accordance with the laboratory manual and to the appropriate standards and regulations for research and the use of human tissue.

2. Using the departmental database (CRF Manager®), oversee the weekly laboratory schedule and coordinate the work of laboratory staff and service users to ensure the most economical use of resources, space and equipment.
3. Liaise with colleagues to ensure standardised lab checks are completed.
4. Oversee the booking of couriers and dry ice
5. Plan and prioritise own workload adjusting plans according to unforeseen circumstances.
7. Appropriately and fairly delegate duties, tasks and responsibilities to Medical Lab Assistant(s) (MLA) and other members of the team.
8. Ensure the efficient use of laboratory consumables, chemicals and reagents by monitoring stock levels (being aware of rotation, storage requirements, batch numbers and expiry dates) and being responsible for the ordering and preparation of consumables and reagents required for the laboratory. This will include the management of generic laboratory supplies and study specific laboratory/sample kits etc.
9. Purchase generic laboratory consumables using the standard stock order procedure.
10. Ensure all sample records are adequately stored and accessible by members of the research teams.
11. Ensure personal and laboratory compliance with national and local guidance regarding commercial confidentiality.
12. Ensure the laboratories are clean and tidy at all times and maintained to the required standard.

Technical

1. Ensure that specimens and forms are adequately labelled before being accepted into the laboratory and to resolve problems arising from incorrectly or inadequately labelled specimens and forms.
2. Ensure personal, staff and laboratory users appropriate handling, use and disposal of patient/participant tissue in accordance with the Human Tissue Authority (HTA) guidelines.
3. Carry out sample receiving, preparation, processing, coding, logging and shipping, as set out in the study protocol and laboratory manual, adhering to current ICH Good Clinical Practice (ICH GCP) guidelines and the Human Tissue Act.
4. Maintain concentration when performing complex sample processing, including multiple aliquot requirements to ensure the right sample is pipetted into the right numbered tubes and processing is completed within the sponsor specified time limits.
5. Be responsible for the appropriate and safe transport of research samples as dictated by each study.
6. Take responsibility for sample preparation accuracy for all samples processed in the laboratory.
7. Work with the Vaccine and Trials Management Team to develop new laboratory services and expand the type of samples that can be processed in the Laboratory.

Study/trial feasibility and set up

1. Understand all new research protocols and lab manuals, identifying any aspects that may require additional feasibility testing or additional training for laboratory and research staff.
2. Provide advice regarding sample management pathways and internal/inter-departmental transport requirements.
3. Create study-specific SOPs and Work Instructions where required.
4. Consult sponsor and Quality Assurance team prior to implementation of locally created study documents.
5. Document the review of laboratory activities within the established on-boarding and study set up processes.
6. Contribute to the costing of studies.
8. Ensure laboratory staff attendance at all Site Initiation Visits (SIV) for studies using the laboratories.

Health and Safety

1. Be responsible for providing new Laboratory users an Induction Programme, providing advice on safe waste disposal and decontamination, enhanced personal protection, and contamination management.
2. Work in a safe manner with regard to the safety of self and others, complying with appropriate Codes of Conduct and local safety rules.
3. Ensure safe handling and storage of hazardous materials in accordance with COSHH regulations.
4. Complete risk assessments of activity carried out in the sample laboratory adhering to Trust procedures and, where necessary, seek guidance from Trust Biological Safety Office (BSO)/Health and Safety team
5. Oversee the safe and compliant handling of human biological samples (including relevant material) using appropriate containment procedures. This may include working with limited risk Hazard Group 3 material such as samples positive for COVID-19, HIV or Hepatitis B.
6. Disseminate and ensure compliance with study-specific risk management plans.
7. Be responsible for maintaining and updating the laboratory Health and Safety policies as required.
8. Be responsible for ensuring all staff using the laboratory have read and signed the appropriate policies and SOPs and completed the relevant lab training.
9. Be responsible for ensuring sufficient provision of PPE for all laboratory users.
10. Report any accidents/incidents or ill health and failings in premises, equipment or personal protective equipment.
11. Work in accordance with good clinical laboratory practices and local safety and quality initiatives.
12. Oversee the removal of clinical waste.
13. Notify management team of any changes required to waste management processes.
14. Deal with spillage of samples/chemicals in a safe and appropriate manner when necessary.

Equipment

1. Be responsible for the safe and effective use of laboratory equipment
2. Ensure fitness-for-purpose checks are performed on a regular basis on existing and newly purchased equipment.
3. Ensure Laboratory equipment, freezers and fridges are organised according to local policy and that they are maintained according to daily/weekly/monthly checks.
4. Proactively identify and manage issues relating to breakdown/unavailability of laboratory equipment, carry out corrective actions independently as appropriate and develop contingency plans as necessary.
5. Liaise with the Trust Estates and Facilities and Biomedical Engineering department regarding acceptance, installation and testing of laboratory equipment.
6. Take responsibility for ensuring Laboratory equipment repair, servicing and calibration occur within the set timeframe and documentary evidence of these visits is supplied and filed.
7. Be responsible for ensuring maintenance contracts and warranties are in place for laboratory equipment.
8. Participate in the evaluation of new equipment and service contracts.
9. Following approval from the management team, oversee the procurement process of all new laboratory equipment and minor works as required

Temperature controlled storage and monitoring

1. Ensure IMP, stock drugs, reagents, lab kits and samples are stored and/or shipped at appropriate temperatures as directed by manufacturer or sponsor.
2. Track storage of all temperature-controlled items and report any out-of-range temperatures according to local SOPs and sponsor requirements.
3. Manage the Vaccine and Trials continuous temperature monitoring system for all temperature-controlled storage including drug preparation rooms and fridges and freezers for samples and medicinal products.

Quality

1. Maintaining oversight of the chain of custody and ensuring there is an audit trail showing the collection, transfer, receipt, storage, and disposal of samples.
2. Quality Check (QC) completed lab checklists on a monthly basis.
3. Oversee the day-to-day implementation of all the quality systems and monitoring schemes in the laboratories.
4. Identify and escalate any areas of concern where there is potential non-compliance in the processing, storage, handling or shipping of samples.
5. Submit incident reports via the Trust reporting system (Radar) for any incidents occurring in the Laboratory and contribute to the incident investigations as appropriate.
6. Report and discuss any quality issues/concerns pertaining to the laboratory with the Quality Assurance Team and Vaccine and Trials Research Management team in a timely manner.
7. Provide expert advice to the Quality Assurance team when quality systems, SOPs, policies and work instructions are being reviewed if they apply to the laboratories.
8. Notify the Quality Assurance team of any changes in laboratory practice which would require the SOPs, policies or work instructions to be updated
9. Proactively identify areas for improvement within the service and collaborate with colleagues to deliver agreed service improvement projects.
10. Ensure records are kept up to date and stored safely to ensure compliance with good working practices outlined in the guidelines and regulations for clinical trials and the use of human tissue
11. Compile and action Corrective Action Preventative Action (CAPA) plans in response to incidents, audits and inspections of the laboratories.
12. Oversee regular stock checks of laboratory consumables and reagents ensuring out-of-date stock is not used without prior approval from study sponsor.
13. Participate fully in quality assurance and audit programmes.
14. Be jointly responsible for validating and managing software used for logging and tracking samples and monitoring the temperatures of temperature controlled storage equipment/areas and reporting any problems with these systems to the Quality Assurance team.

Education and Training

1. Ensure all users of the Laboratory are competent to undertake sample processing for their research studies, providing regular training and signing off on competency documents.
2. Ensure an adequate number of staff are trained in laboratory techniques to fully utilise staffing resources across team.
3. Appropriately document all training provided to staff and laboratory users.

People management

1. Motivate, encourage and mentor Laboratory staff
2. Provide professional leadership for staff working within the Laboratories.
3. Provide the day-to-day supervision of Medical Laboratory Assistant(s) (MLA).

4. Provide appropriate induction, mentoring, supervision and input into the ongoing professional and personal development for team members.
5. Review and sign off on leave requests from direct reports always ensuring sufficient service provision during times of personal and staff leave.
6. Cover for staff shortages as far as is reasonable, in order to maintain the service.
7. Contribute to the recruitment of staff as required.
8. Oversee the training and development needs of Laboratory staff.
9. Ensure regulatory and Trust mandatory training is up to date for all direct reports.
10. Manage and undertake objective setting and annual performance development reviews (PDR) for direct reports.
11. Contribute to a working environment which encourages staff to identify concerns and speak up.

Compliance with Trust Policies

The post holder is required to follow Trust policies and procedures which are regularly updated including:

Confidentiality / Data Protection / Freedom of Information

Post holders must maintain the confidentiality of information about patients, staff and other health service business in accordance with the Data Protection Act of 1998. Post holders must not, without prior permission, disclose any information regarding patients or staff. If any member of staff has communicated any such information to an unauthorised person those staff will be liable to dismissal. Moreover, the Data Protection Act 1998 also renders an individual liable for prosecution in the event of unauthorised disclosure of information.

Following the Freedom of Information Act (FOI) 2005, post holders must apply the Trust's FOI procedure if they receive a written request for information.

Information Governance

All staff must comply with information governance requirements. These includes statutory responsibilities (such as compliance with the Data Protection Act), following national guidance (such as the NHS Confidentiality Code of Practice) and compliance with local policies and procedures (such as the Trust's Confidentiality policy). Staff are responsible for any personal information (belonging to staff or patients) that they access and must ensure it is stored, processed and forwarded in a secure and appropriate manner.

Equal Opportunities

Post holders must at all times fulfil their responsibilities with regard to the Trust's Equal Opportunities Policy and equality laws.

Health and Safety

All post holders have a responsibility, under the Health and Safety at Work Act (1974) and subsequently published regulations, to ensure that the Trust's health and safety policies and procedures are complied with to maintain a safe working environment for patients, visitors and employees.

Infection Control

All post holders have a personal obligation to act to reduce healthcare-associated infections (HCAIs). They must attend mandatory training in Infection Control and be compliant with all measures required by the Trust to reduce HCAIs. All post holders must comply with Trust

infection screening and immunisation policies as well as be familiar with the Trust's Infection Control Policies, including those that apply to their duties, such as Hand Decontamination Policy, Personal Protective Equipment Policy, safe procedures for using aseptic techniques and safe disposal of sharps.

Risk Management

All post holders have a responsibility to report risks such as clinical and non-clinical accidents or incidents promptly. They are expected to be familiar with the Trust's use of risk assessments to predict and control risk, as well as the incident reporting system for learning from mistakes and near misses in order to improve services. Post holders must also attend training identified by their manager, or stated by the Trust to be mandatory.

Flexible Working

As an organisation we are committed to developing our services in ways that best suit the needs of our patients. This means that some staff groups will increasingly be asked to work a more flexible shift pattern so that we can offer services in the evenings or at weekends.

Safeguarding children and vulnerable adults

Post holders have a general responsibility for safeguarding children and vulnerable adults in the course of their daily duties and for ensuring that they are aware of the specific duties relating to their role.

Sustainability

It is the responsibility of all staff to minimise the Trust's environmental impact by recycling wherever possible, switching off lights, computers monitors and equipment when not in use, minimising water usage and reporting faults promptly.

Smoking Policy

It is the Trust's policy to promote health. Smoking, therefore, is actively discouraged. It is illegal within Trust buildings and vehicles.

Review of this Job Description

This job description is intended as an outline of the general areas of activity and will be amended in the light of the changing needs of the organisation. To be reviewed in conjunction with the post holder.

17/04/2024