University Hospitals of Leicester NHS Trust

Job Description

Job Title:	Senior Clinical Research Practitioner
Band:	NHS Agenda for Change Band 6
Base:	You may be required to work in other designated locations of the Trust as well as your primary base. In particular, flexibility is required across the three main hospital sites (Leicester Royal Infirmary, Leicester General Hospital and Glenfield Hospital). If your initial location is one of these sites, excess travel reimbursement would not apply for a permanent or temporary change of base.
Reports to:	Ophthalmology Specialist Nurses
Accountable to:	Ophthalmology

Find out more about working with us:
https://www.leicestershospitals.nhs.uk/aboutus/work-for-us/

Job Summary	Working as a key member of the Ophthalmology Research team, duties include: • Providing research support to various clinical specialities within Ophthalmology that are conducting research at UHL. • Take responsibility for the management, co-ordination, and facilitation of concurrent research studies. • In addition to clinic/patient based tasks, this role includes document generation and control, project tracking and logistics, data collection, adherence to good clinical practice and research governance and assisting in the continued improvement in the care of research participants and quality of research data. • Provide clinical and laboratory based support and expertise in commercial and non-commercial research projects. • Support the Research lead and wider team in implementing Standard Operating Procedures, local guidance and other procedures based on national operating guidelines and current legislation by effectively communicating the purpose of the procedures and any changes to all staff involved with the Capacity and Capability Assessment processes for studies based in the Trust. • Support the Ophthalmology research lead with ensuring that all research studies are and continue to be properly resourced and conducted according to applicable regulations. • To assist with the retrieval of activity based income as per contract.
Budget	Responsible for assisting when required with study-set up, including the completion of the study costing template / Industry Costing Tool (iCT) system. Assist in the financial management of trials conducted within the department and taking an active role in the tracking, invoicing and recovery of income for both commercial and academic research as stipulated within the financial contract agreements.
Staff	To provide mentorship and supervision for other research professionals and staff within the R&I team and Ophthalmology.
Policy	Follows policy in own role as determined by others; no responsibility for service development, but may be required to comment on policies, procedures or possible developments. Demonstrating a solid understanding of the application of ICH GCP Guidelines, the EU Directive on Clinical Research and Research Governance.

Communications	To have a high degree of interpersonal and communication skills, in order to liaise with a wide range of research personnel, consultants, clinicians, NHS staff within the acute and primary care setting and others in writing or electronically in a professional and courteous manner. Communicates difficult and sometimes challenging information, both orally and in writing, both internally to colleagues and externally to a range of audiences. Maintain efficient and effective communication with the Manager and R&I Leads on issues related to staff conduct within research trials and impact on participant care.

KEY WORKING RELATIONSHIPS

Ophthalmology Research Practitioner
Clinical research delivery staff at UHL and external partners NHS Trusts / organisations (e.g. doctors, nurses, AHP's and other clinicians)
Clinical Service Managers / Departmental Managers and Senior / Lead Nurses at UHL and in NHS Trusts / partner organisations
Clinicians
External sponsors
Research participants / Patients / Carers
Other Clinical / Research Groups

KEY RESULT AREAS

Research Trial Set Up and Initiation

- To support the coordination, preparation, submission of research proposals for approval.
- To coordinate with research Governance officers, NRES administrators, HRA, CRN EM Study Support Service Officers / facilitators / managers as applicable to ensure that new research studies for approval are submitted in a timely and compliant manner.
- To work with departmental managers, service providers and the Trust Research & Innovation team to ensure that local set-up packs are processed, submitted and approved in a timely and compliant manner.
- In conjunction with the finance manager, ensure that all aspects of research are appropriately funded.
- To ensure that all relevant approvals are in place prior to commencing each trial.

Clinical Practice

- To have a solid understanding of the application of ICH GCP Guidelines, the EU Directive on Clinical Research and Research Governance
- To identify patients suitable for entry into research studies. This may include attending clinics and multidisciplinary team meetings, reviewing medical notes and inclusion/exclusion criteria
- To ensure patients / carers are provided with written information relevant to the research study and are given the opportunity to discuss the research study adequately at the outset and during the course of the research in which they are being asked to participate (i.e. informed consent)
- To attend and support patients in the clinical environment for monitoring, assessment and follow up as part of research projects
- Where appropriate, to take consent from patients/participants to enter research studies.
- To retrieve the relevant patient samples for research as per defined protocols.
- To ensure safe and appropriate storage of specimens, in accordance with the trial protocol and in conjunction with specialist teams.

- Maintain accurate patient trial documentation, complete Case Record Forms, including the use of electronic data capture systems and ensure relevant information is recorded in patients' medical notes.
- Ensure safety data is reported to required SOPs and study protocols, and reports are sent in a timely manner
- To record and report any adverse events and serious adverse events according to trial protocol and local procedures.

Professional

- To manage allocated projects, set timescales and resolve problems. Responsibilities within a particular trial must be discussed, agreed and documented within the Study File before conducting any trial related activities
- To provide support for individual trials being conducted within UHL. It is expected that this may involve working on more than one project at any time.
- To ensure that training pertinent to role is up to date e.g. GCP-ICH, informed consent as well as mandatory training as required by individual trusts. Attend training to maintain clinical skills as appropriate
- To be flexible in their approach to work as the role may require flexibility in terms of timing e.g. for specific investigations
- To work with minimal supervision and self-directed in all areas of practice relating to the conduct of clinical trials and research studies
- To assist with the preparation and presentation of abstracts and papers for meetings, conferences and publication
- In accordance with professional codes, maintain own professional development and competence to practice in line with the appraisal process, whilst actively supporting others

Managerial

- Ensure that all activity is based on NHS policies and procedures.
- Accept responsibility for the day to day management of various research studies, ensuring that the service to patients is maintained to a high standard.
- Identify hazards, assess and categorise and report risks using the appropriate systems for Risk Management
- Consults with the R&I Leads on key developments to ensure the efficient and effective management of resources.
- Maintain efficient and effective communication with the R&I Leads on issues related to staff conduct within research trials and impact on participant care
- Provide mentorship and supervision and management of staff within Ophthalmology Research.

Terms and Conditions

NHS Agenda for Change Terms and Conditions apply. Any other particular conditions are listed here:

(Agenda for Change) Working Conditions:

Physical effort:	Desk based, some light lifting (e.g. stationery) and travelling.
Mental effort:	Frequent requirement for concentration, work pattern is unpredictable, and work is likely to be frequently interrupted to deal with queries.
Emotional effort:	The post holder may have to deal with complex research issues involving difficult conversations with researchers, other professionals and R&D staff and will need to do this tactfully and tenaciously.
Working conditions:	Office conditions. Use of a computer for prolonged periods on most days. Frequent travel by car or public transport might be required.

GENERAL

This job description indicates the main functions and responsibilities of the post. It is not intended to be a complete list. You may be required to undertake other duties from time to time as we may reasonably require.

You will be required to maintain compliance with all statutory and mandatory training requirements.

The link to the Trust's policies and procedures is:
https://secure.library.leicestershospitals.nhs.uk/PAGL/SitePages/Home.aspx

University Hospitals of Leicester NHS Trust

PERSON SPECIFICATION

Post: Senior Clinical Research Practitioner
Band: 6
CMG: MSS

Criteria	Essential	Desirable	Stage Measured at A – application I – Interview T – Test
Commitment to Trust Values and Behaviours	Must be able to demonstrate behaviours consistent with the Trust's Values and Behaviours		I
Training & Qualifications	• Educated to degree level or equivalent in related area (e.g. Science, research, healthcare) or equivalent experience.	• Professional knowledge of clinical research • Qualification in accountancy or equivalent • Project management qualification	A
Experience	• Experience in research • Experience of undertaking or planning clinical trials • Experience of working on a portfolio of research studies within the NHS, both commercial and non-commercial • Previous experience of undertaking and an understanding of Ophthalmology research • Fully conversant with financial procedures and can interpret and	• Previous experience at Band 5 • Previous experience of working within a research environment • Experience of the clinical care of patients enrolled in research studies • At least 3 years' experience of managing multiple projects	A/I

	apply financial information • Knowledge of the governance and legislative framework for conducting clinical research studies, including ICH Good Clinical Practice • Knowledge and understanding of accounting processes and financial systems • Knowledge of current national systems and structures for the approval, management and monitoring of clinical research in the NHS	• Previous experience of working in clinical research • Experience in developing, implementing and following standard procedures • Experience of using the IRAS system • Experience of using the EDGE database • NHS (research) finance experience • Knowledge of the clinical trial lifecycle including experience of the set up and performance management of clinical research studies • Experience of staff supervision	
Communication and relationship skills	• Ability to communicate difficult and sometimes challenging information both orally and in writing both internally to colleagues and externally to a range of audiences • Highly motivated, with the ability to influence and inspire others		I

Analytical and Judgement skills	• Ability to prepare and deliver presentations and reports to a high standard • Demonstrate consistent level of attention to detail • Ability to analyse and rationalize financial and research information accurately • Ability to carry out detailed work accurately • Ability to learn new skills and apply them appropriately in the workplace • Prolonged concentration at regular intervals to concentrate on reviewing research proposal and finance reports	• Knowledge of research methodologies and current national systems and structures for the approval of clinical trials	A/I
Planning and organization skills	• Ability to plan, manage and deliver complex projects, involving multiple agencies and individuals and a range of tasks • Ability to manage time effectively, prioritize work and deliver results consistently to tight deadlines		A/I
Physical skills	• Current clinical skills • Good IT skills, particularly in the use of Web applications and MS office • Flexible and responsive to change	• Cannulation and Phlebotomy	A/I

Other requirements specific to the role	• Ability to work both on own initiative and within a team • Flexibility • Ability to travel between sites and out to the alliance is essential • Able to demonstrate attendance in accordance with UHL's policy		A/I
Equality and Diversity	• Able to demonstrate a commitment and understanding of the importance of treating all individuals with dignity and respect appropriate to their individual needs • All staff are expected to engage in compassionate and inclusive leadership		