UNIVERSITY OF LEICESTER

Job Summary

Job Title: Clinical Research Project Manager
Grade: 7
Salary: £39,105 to £45,163 per annum, pro-rata if part-time
Department: Respiratory Sciences
Hours/Contract: Full-time or job share, fixed term contract until 30 November 2026, with possible extension subject to funding
Job Family: Management and Administration
Job Reference: 10809

Role Purpose

The post holder will be expected to project manage a portfolio of investigator led single and multi-centre national and international research studies sponsored by the University of Leicester and coordinated by the NIHR-Biomedical Research Centre - Respiratory and Infection theme. Close working with stakeholders including government, charity and industry funders and collaborators, third party service providers, academic partners, in-house researchers and external investigators.

The post-holder will be expected to travel to sites across the UK that are recruiting patients into the studies with some overnight stays. Some overseas travel may be required but is not essential to the role.

The post holder will be responsible for the preparation and submission of applications for Sponsorship, collaborate with the Sponsor to complete risk assessments, develop monitoring plans and mitigate any risks identified.

The post holder will have the responsibility for the resourcing and budget management of the studies and be responsible for ensuring that the studies deliver on time and within budget.

The post holder may be required to provide line management for the research team which will require oversight of training, development and performance.

Resources Managed

- To undertake the day-to-day oversight of NIHR-Biomedical Research Centre - Respiratory theme studies to include facilitating study set up, monitoring, and study delivery.
- Maintain a network of contacts, knowing who to contact to deliver own work as required.

Main Duties and Responsibilities
• To initiate and manage studies on behalf of NIHR-Biomedical Research Centre - Respiratory and Infection theme which involves: Identifying and undertaking feasibility of sites and ensuring all participating sites have received relevant trial specific training. Facilitating approvals in order for sites to open to recruitment. Co-ordinating project activities with other departments internally and with several external collaborating centres. Initiating and co-ordinating the scoping and costing for specific projects and adapting protocols to meet study requirements. This also includes completion of costing templates, ethics documentation and study document preparation for both internal and external collaborating centres. To contribute to, review and amend study documents e.g. protocols, patient information sheets and informed consent documents, site instruction manuals. regulatory documents and the generation of study worksheets and project databases.

- To schedule and drive execution of projects in line with study requirements and have oversight of timelines, quality and deliverables for both internal and external collaborating centres. To establish and monitor communication and report on deliverables including: participant recruitment, drug safety and establishing study costing and adherence to budgets. To support the preparation of regular status reports to the Principal Investigators, the sponsor, ethics committees, funders, and key stakeholders. To organise and conduct team meetings, investigator meetings and regulatory meetings for projects.
- To perform site initiation visits and study closeout visits as required. To prepare and conduct project training both internally and at external collaborating centres.
- To write site initiation and monitoring reports to agreed timelines and to follow up on unresolved issues identified during monitoring visits, maintaining accurate records of monitoring activity. To escalate issues found during monitoring as appropriate.
- To perform or support sponsor to undertake monitoring (onsite and remote) and Source Data Verification (SDV) in accordance with the monitoring plan, ensuring that the sites comply with the protocol and Good Clinical Practice (GCP) regulations and guidance.
- To carry out central and remote monitoring tasks, such as verifying Informed Consent Forms (ICFs) and drug accountability, liaising with site teams where required.
- To maintain oversight of study progress, management and monitoring. Preparing and submitting protocol amendments, annual, statutory and funder report, including regular review of risk assessments and quality assurance processes.
- To stay up-to-date with trial requirements and legislation which affect research conduct.
- To be the main point of contact for all collaborators and coordinate communications among all trial stakeholders including trial research team, funding bodies, sponsor, collaborative groups and participating sites, ensuring a common understanding of trial progress.
- Plan expenditure against trial budgets and monitor the budget for the portfolio of studies the post has responsibility for. Drive the procurement process for suppliers according to UoL policies, where necessary. Prepare trial progress and/or financial reports as required.
- Work closely with both internal and external contract departments to navigate study-related contract negotiations with trial sites (both nationally and internationally), core partners, third party service providers, pharmacies, and local laboratories, where applicable.
- Provide performance and line management to members of the research team, including workload allocation, motivation and support, problem solving, and regular appraisals.

Internal and External Relationships

Other staff within the NIHR BRC-Respiratory and Infection theme, Research Governance team, and the Research and Enterprise Division to ensure good working relationships.

Chief Investigators and the Trial Management teams (e.g., Principal Investigators, Research Nurses/Staff, Pharmacists) across all departments within the University of Leicester and at external collaborating centres.

Other university employed personnel such as the business development managers, departmental secretaries, and finance advisors.

Stakeholders: sponsors, both internal and external investigators, study team.

Communication with the ethics committee and R&D staff both internally and externally.

Suppliers, company representatives and service engineers to obtain quotes, negotiate prices and discounts on goods, chase orders discuss invoices arrange equipment services etc.

Trial oversight committees.

External organisations within both the private and public sectors including commercial companies and regulatory authorities

Planning and Organising

The post holder will be required to organise the set up and delivery of research projects across collaborating research sites, manage the day-to-day monitoring of studies in accordance with the trial risk assessment, monitoring plan, the highest scientific and regulatory standards, and Sponsor policies and SOPs.

Take into account costs, deadlines and current workload of staff and collaborators and be prepared to alter and amend timeframes and plans to meet changing needs of the project.

Planning and organisation will be required to undertake the initiation, monitoring and close out of participating sites. This will require close liaison with Trial Management teams, participating site study teams and the Research Governance Team. The post holder must have the ability to plan and manage their own workload and maintain oversight of the workload of clinical staff within the team, prioritising tasks and working within deadlines, and to effectively communicate and build relationships with others.

This role will require the post holder to travel throughout the UK and occasionally internationally which may require overnight stays.

Qualifications, Knowledge and Experience

Essential

- Educated to degree level (minimum 2.1) and/or extensive experience acquired in relevant roles and job-related training (i.e., Study Manager or Coordinator)*
- Understanding of Sponsor responsibilities and issues relating to Studies, in particular an understanding of non-commercial Sponsorship
- Experience and knowledge of research governance and/or the regulatory guidelines that govern clinical research*
- Full understanding of the ethics application process and evidence of managing ethical submission for clinical research*
- Experience in working with commercial companies for studies, assisting in project set up
- Able to make effective use of standard office computer systems including word-processing and spreadsheets
- Excellent communication in written and spoken English*
- Experience of multi-centre trials (i.e., set-up, management and/or monitoring of)*

- Proven/demonstratable experience of project management and line management*

Desirable

- Experience of external/quality assurance audits
- Up to date ICH-GCP training
- Knowledge of medical or medical research terminology
- Experience and knowledge of monitoring studies

Skills, Abilities and Competencies

Essential

- Self-motivated with ability to manage and prioritise own workload*
- Able to identify and solve problems by applying judgement and initiative to tackle some situations in new ways and by developing improved work methods and/or sharing best practice*
- Attention to detail, accuracy and the ability to assimilate information quickly and within a busy environment*
- Able to positively influence the way a team works together*
- Able to proactively work with colleagues in other work areas to achieve outcomes
- Able to offer proactive advice and guidance with tact and diplomacy*
- Able to deal with sensitive information in a confidential manner
- Able to collate and compile complex information into written reports
- Attention to detail, accuracy and the ability to assimilate information quickly and within a busy environment*

Criteria to be used in shortlisting candidates for interview

Reason for Fixed Term Contract

The reason for the fixed term contract is stated in section 1.9 in the summary of contractual terms in your contract of employment.

NHS Research Governance

Where it is determined that the duties of this post for the purposes of research involve work with the NHS, it is necessary to ensure that the performance of the duties attached to the post are covered by NHS research governance arrangements and the appointee must comply with all such arrangements, which may include occupational health clearance and DBS clearance.

Criminal Declaration

If you become an employee, you must inform your manager immediately, in writing, if you are the subject of any current or future police investigations/legal proceedings, which could result in a criminal office, conviction, caution, bind-over or charges, or warnings.

Supporting University Activities

As a University of Leicester citizen, you are expected to support key university activities such as clearing, graduation ceremonies, student registration and recruitment open days. We expect all staff as citizens to work flexibly across the University if required.

University Values

Inclusive - We are diverse in our makeup and united in ambition. Our diversity is our strength and makes our community stronger.

Inspiring - We are passionate about inspiring individuals to succeed and realise their ambitions. We challenge our community to think differently, to get involved, and to constantly embrace new ideas.

Impactful - As Citizens of Change we will generate new ideas which deliver impact and empower our community

Equity and Diversity

We believe that equity, diversity and inclusion is integral to a successful modern workplace. By developing and implementing policies and systems that challenge stereotypes across all aspects of our work, we have a culture that recognises and values the diverse contributions of our staff which benefits everyone. Our strong values of inclusivity and equity support our efforts to attract a diverse range of high quality staff and students, and identify our University as a progressive and innovative workplace that mainstreams equity, diversity and inclusion.