UNIVERSITY OF LEICESTER

Job Summary

Job Title: Clinical Trials Manager
Grade: 7
Salary: £35,326 to £40,927 per annum
Department: Cardiovascular Sciences
Hours/Contract: Part-time (0.75FTE, 28 hours per week), fixed term contract until
Job Family: Management and Administration
Reference: 3716

Role Purpose

Reporting to the Senior Research Manager, you will be responsible for the management of a portfolio of trials. You will be expected to work independently but also as part of the wider team working closely with clinical and academic staff.

Resources Managed

Performance and line management of trial coordinators and trial administrators.

Main Duties and Responsibilities

- To be a leading member of the research team, accountable to the Senior Research Manager, providing leadership and trial management expertise in order to develop, organise and facilitate clinical trials. This includes ensuring trials are conducted in accordance with the appropriate UoL SOP's, regulatory, and ethical approvals.
- Be responsible for the oversight and management of trial co-ordinators and trial administrators with respect to day-to-day supervision, measuring trials performance against project management plans, and taking appropriate action where necessary to ensure timelines are met.
- Providing key input to grant applications, protocols, case report forms design and remote data entry systems and all associated documentation. Assisting Chief Investigators to ensure timely Sponsor, regulatory, ethical, and HRA approvals. Ensure SOPs for the safe conduct of trials are followed, thereby ensuring timely and accurate safety reporting.
- Be a point of communication for the research team, funding bodies, and Sponsor.
- Contributing to data collection and analysis as required, including contact with NHS patients
- Contribute to the reviewing and writing of SOPs, ensuring that practice adheres to relevant UoL policies
- To co-ordinate and support the activities of Trial Management, Trial Steering, and Data Safety Monitoring Committees.
- Contribute to the oversight of the budget for the portfolio of trials; planning expenditure against trial budgets, negotiating with suppliers, and providing finance reports.

Internal and External Relationships

Internal

Daily – research team, including the line management of trial co-ordinators and trial administrators.

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Regular – senior research staff, Sponsor offices, investigators, academics, and clinicians

External

Daily –investigators, trial teams, Sponsors

Regular – funders, Clinical Research Networks, Regulatory Agencies, other NHS Trusts and Institutions, and industries

Planning and Organising

Manage own workload and oversee the management of staff the post holder is responsible for.

Take responsibility for trial management in compliance with regulatory guidelines. Maintain up- to-date knowledge of regulatory, ethical, and governance requirements, and translate this into practical activities.

Effective workload and project planning of own trial activities and those of trial coordinators and trial administrators being managed or mentored: set and ensure that quality control procedures are in place for all aspects of the trial to maintain and improve operational efficiency and quality by development and application of process improvements.

Adjust priorities as needed.

Be able to recognise circumstances that require the involvement of senior staff.

Coordinate and oversee trials through effective communication with research staff and the networks, collaborators, and trial steering committee representing the University in a professional manner.

Qualifications, Knowledge and Experience

Essential

- A higher degree (PhD or MSc) in a relevant biomedical science or associated subject with experience of clinical trials research*
  OR:
- A graduate with extensive experience as a Trial Coordinator*

  AND:

- An in depth understanding of clinical research and trial management methodology, including applicable regulatory requirements, and a proven ability to apply these to the coordination of clinical trials*
- Experience preparing one or more of the following: regulatory and ethics submissions, grant applications, writing and/or amending protocols, patient information sheets, Case Report Forms, reports and other relevant trial management documentation*
- Ability to travel locally and nationally*

Desirable

- Experience preparing publications and submitting grant applications
- Experience of writing SOPs for trials
- Experience of data management

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Skills, Abilities and Competencies

Essential

- Proven project management skills*
- Excellent administrative, clerical and office management skills
- Effective communication, negotiation, presentation and inter-personal skills
- Excellent computing skills including advanced word processing and e-mail
- Able to work on own initiative and problem solve
- Must demonstrate a critical and intelligent attention to detail and high standards of accuracy*

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.

Criminal Declaration and Disclosure and Barring Service (DBS).

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 offence, conviction, caution, bind-over or charges, or warnings.

This post is exempt from the Rehabilitation of Offenders Act 1974 because the appointee will have substantial access to young people and/or vulnerable adults. Therefore, an appointment to this post will be subject to checking through the Disclosure and Barring Service (DBS). The successful applicant for this post will, therefore, be required to give consent for the University to check and obtain appropriate clearance with the DBS for the existence and content of any criminal record in the form of a Standard DBS Check.

Information received from the DBS and the police will be kept in strict confidence and will be destroyed once the University is satisfied in this regard.

NHS Research Governance Requirements

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 indemnity arrangements and the appointee must comply with all such arrangements, including occupational health clearance.

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.

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Equality and Diversity
We believe that equality, 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 equality 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 equality, diversity and inclusion.