UNIVERSITY OF LEICESTER

Job Summary

Job Title: Project Support Officer
Grade: 7
Salary: £35,326 to £40,927 per annum
Department: Cardiovascular Sciences
Hours/Contract: Full-time (job share considered) fixed term contract until 30th November 2022
Job Family: Management and Administration
Reference: 3555

Role Purpose

Reporting to the Cardiovascular Research Manager, the post-holder will be responsible for supporting staff and students in Cardiovascular Sciences to complete grant applications and to set up and run research projects. In particular the post-holder will be expected to provide governance oversight, working pro-actively as part of a wider team of NHS clinical and academic staff to ensure the highest standards of research governance. You will provide oversight and clinical trial management expertise to ensure the smooth and effective set-up and running of studies operating within the department, in accordance with the trial protocols, ethical and regulatory approvals, SOPs, the principles of GCP, applicable EU directives and UK legislation.

The post holder must be able to use their own initiative, be an effective leader, team player and excellent communicator.

Main Duties and Responsibilities

Management of Research Projects

Be a proactive, leading member of the multi-disciplinary team accountable to the Cardiovascular BRC theme Research Manager, providing leadership and trial management expertise in order to develop, organise and facilitate a variety of studies within the research portfolio.

Utilise regulatory and ethical knowledge to work closely with Chief Investigators and study teams to inform on grant applications, study design and set up, provide input into study protocols, patient information documents and any associated research documentation.

Assisting Chief Investigators to ensure timely regulatory and ethical approvals for projects, including study sponsorship and HRA authorisations (including REC and MHRA approvals). Ensure Standard Operating Procedures for safe trial conduct are followed, and that study teams employ and comply with current legislation.

Be proactive in identifying potential obstacles to the progress of projects and providing solutions, or making strategic changes in order to progress the projects.

Governance

To be the key contact for any governance queries relating to studies running within the department.

Manage and oversee the confirmation of capacity and capability process for new studies within the cardiovascular team. This includes ensuring that EDGE is updated and completed with relevant and up to date study information, and workflows are completed in a timely manner.

Lead on the development, implementation and maintenance of efficient research management processes to support efficient study set up, management and reporting.

Ensure that Trial Master Files and Site Investigators Files are created and maintained in line with local requirements, and participating external sites have current trial information.

Provide quality management for research undertaken by the department and BRC cardiovascular theme. Reviewing and writing SOPs and developing procedural documentation as applicable. Undertake quality checks and assurance audits to maintain trial quality, highlighting any deviations for further action.

Reporting, Resources and Finance

Prepare general, trial and finance progress reports as required by the BRC management team, departmental or College senior management teams, funding bodies, regulatory authorities, ethics committees, Investigators, trial Steering and Data Monitoring Committees, and external collaborators. Provide timely and accurate reporting of the cardiovascular research portfolio, including study status and progress for meetings and relevant reports.

Plan expenditure against own trial budgets and negotiate with suppliers; and oversee and monitor the budget for trials if required.

People

Manage, train and develop the Governance Administrator.

Provide relevant training relating to study management and governance requirements to study teams and project delivery personnel as required.

Internal and External Relationships

The post-holder is expected to deal effectively with a wide range of individuals including:

Internal

- Cardiovascular Research Manager, Governance Administrator and the Cardiovascular Biomedical Research Centre team.
- Chief/Principal Investigators, Academics, Research Fellows, Research Nurses, department IT and Finance teams.
- University sponsors office, UHL sponsors office and R&I department.
- Governance and management teams within the other themes of the Leicester Biomedical Research Centre.

External

- External investigators, academics and trial teams and external sponsors.
- Funders, Clinical Research Networks, Regulatory agencies, other NHR Trusts and Institutions, and Industry.

Planning and Organising

Maintain up-to-date knowledge of regulatory, ethical and governance requirements and translate this in to practical activities.

Effective workload and project planning without reference to others: set and ensure that quality assurance procedures are followed for every aspect of studies to maintain and improve operational

efficiency and quality by development and application of process improvements. Plan own work activities against the agreed quality standard and team objectives, to ensure operational quality and efficiency. Adjust priorities as needed. Be able to recognise circumstances that require the involvement of the Research Manager or Chief Investigators.

Support the day-to-day running of the Project Delivery team by establishing standardised procedures that ensure compliance with regulatory standards, and taking on decisions as required. This requires a high level of organisation with good attention to detail including high standards of accuracy and an ability to forward plan with prioritisation of tasks and workload to ensure studies are delivered to time and target.

Qualifications, Knowledge and Experience

Essential

- A higher degree (PhD or MSc) in a relevant biomedical science of associated subject with experience of clinical trials research OR a graduate with experience as a Trial Manager/Coordinator OR extensive experience as a Trial Manager/Coordinator*
- An in depth understanding of clinical research and trial management methodology, including applicable regulatory requirements, and a proved ability to apply these to research projects.*
- Sound knowledge of the principles of research governance and ICH-GCP*
- Experience of creating research ethics applications including all supporting documentation and knowledge of HRA and MHRA application process and requirements*
- Experience of writing and/or amending protocols, patient information sheets and other associated study documentation*

Desirable

- Significant experience within the research field
- Knowledge and understanding of EU and UK legislation and guidance relating to the conduct of research
- Detailed knowledge and understanding of the Research Governance Framework for Health and Social Care and its application
- Experience of monitoring research in a commercial and non-commercial environment
- Knowledge and understanding of research costs and funding streams
- Experience preparing publications and submitting grant applications
- Previous experience of running research within the NHS
- Experience of writing SOPs

Skills, Abilities and Competencies

Essential

- Proven project management and line management skills*
- Excellent administrative, clerical and office management skills
- Effective communication, negotiation, presentation and inter-personal skills, including leadership and motivation*
- Understand, interpret and critically analyse data and information and prepare progress reports
- Excellent computing skills including advanced word processing, spreadsheets, databases, email and a working knowledge of MS office suite
- Able to work on own initiative and problem solve, as well as collaboratively as part of a team.

- 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

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.

VITAL

The University encourages all staff to live our VITAL values which are:

Valuing People, Innovators, Together, Accountable, Leaders.

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.