UNIVERSITY OF LEICESTER

Job Summary

Job Title: Project Support Manager
Grade: 6
Salary: £32,296 to £36,924 per annum, pro rata if part-time
Department: Cardiovascular Sciences
Hours/Contract: Full-time, or job share considered, fixed term contract for 24 months
Job Family: Management and Administration
Reference: 11163

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 support, 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 support 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 team player and excellent communicator.

Main Duties and Responsibilities

Management of Research Projects

- Be a proactive member of the multi-disciplinary team accountable to the Cardiovascular Research Manager, providing support and trial management expertise in order to develop, organise and facilitate a variety of studies within the research portfolio.
- Provide input on study design and set up, study documentation including protocols and patient information. Collate study documentation ready for Sponsorship review, and regulatory and ethical approvals.
- Assist 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.
- To be the key contact for specific trials and coordinate and support the activities of the Project Support Group, Study teams, Trial Steering and Data Monitoring Committees. To undertake site initiation visits throughout the UK, produce trial specific guidance notes, and provide training. Provide support to research staff on the practical implementation of GCP and on trial-related activities, taking appropriate action to enable staff to carry out their respective trial duties and tasks. This requires regular liaison with clinicians, database developers, statisticians, research nurses and other personnel, across the UK and sometimes overseas.

- To inform and motivate trials staff by writing newsletters, updating web pages, organising investigator or trial management meetings and holding training sessions.
- Reporting on performance and progress of each trial site and take appropriate action to ensure good recruitment, compliance with the protocol, the quality and timeliness of the data collection. Use initiative to tackle any practical difficulties reported by clinical sites, i.e. which affect recruitment, protocol adherence or patient safety. Conduct problem solving/ quality assurance monitoring visits as required.
- Take responsibility for ensuring that trial research data is complete and accurate. To write Data Management and Validation plans for the trials, ensuring they are followed and all data validation/checks are undertaken, either by themselves or other staff members. Decide what steps need to be taken to correct any missing, contradictory or incorrect data and ensure this is resolved within a reasonable timescale. In consultation with relevant study team members.

Governance

- To help provide guidance on governance queries relating to studies running within the department and facilitate discussions with Sponsors when necessary.
- Support 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 that 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 and 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.

People

- Support, 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.
- NHS staff & patients

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.
- Coordinate and oversee trial through effective communication with research staff in trial sites and the networks, collaborators, the trial steering committee, and other members of the trial team, representing the CTU in a professional manner
- Support the day-to-day running of the Project Support 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 degree (BSc/FdSci) or equivalent experience 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 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 preparing one or more of the following: regulatory and ethics submissions, grant applications, writing and/or amending protocols, patient information sheets, case report form.

- Knowledge of HRA and MHRA application process and requirements*
- Proven project management and line management skills*

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
- Experience preparing publications and submitting grant applications
- Previous experience of running research within the NHS
- Experience of writing SOPs

Skills, Abilities and Competencies

Essential

- Ability to demonstrate behaviours that are in accordance with the University values of inclusive, inspiring and impactful.
- Excellent administrative, clerical and office management skills
- Effective communication, negotiation, presentation and inter-personal skills, including leadership and motivation*
- 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.
- Ability to demonstrate a critical and intelligent attention to detail and high standards of accuracy*

Desirable

- Understand, interpret and critically analyse data and information and prepare progress reports

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

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.

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.