UNIVERSITY OF LEICESTER

Job Summary

Job Title: Research Quality Assurance Officer
Grade: 7
Salary: £34,804 - £40,322 per annum
Department: Research and Enterprise Division
Hours/Contract: Full Time, Fixed Term for 3 years
Reference: 2058

Role Purpose

To work within the University of Leicester research governance team, ensuring best practice for studies Sponsored by the University of Leicester and that studies are conducted to appropriate regulatory, ethical and quality assurance standards required under the International Conference on Harmonisation Good Clinical Practice (ICH-GCP), the UK Policy Framework for Health and Social Care Research (2017) and the Medicines for Human Use (Clinical Trials) Regulations (2012), ensuring adherence to University research governance policies and procedures.

To assist in the monitoring programme for studies , including multi-centre, sponsored by the University of Leicester. To conduct Sponsor reviews for new studies, including where necessary the completion of a risk assessment, development of a monitoring plan and to mitigate any risks identified.

Resources Managed

- To assist in the monitoring of studies, including multi-centre studies, sponsored by the University of Leicester.
- Maintain a network of contacts, knowing who to contact to deliver own work as required.

Main Duties and Responsibilities	% Time
• Maintain a monitoring system for University sponsored studies in line with the International Conference on Harmonisation Good Clinical Practice (ICH-GCP), the UK Policy Framework for Health and Social Care Research (2017) and the Medicines for Human Use (Clinical Trials) Regulations (2012) and any subsequent amendments. o Carry out risk based assessment and pre-study planning to develop an appropriate monitoring plan, undertaking site initiation visits (both on-site and remote, as necessary) and study close-out visits in line with Research Governance Office Standard Operating Procedures (SOPs). o Monitor studies in accordance with the monitoring plan and all applicable laws affecting research, including but not limited to the Human Tissue Act, the Mental Capacity Act and the Data Protection Act. o Responsibility for the monitoring, conduct, documentation and progress of studies by performing Source Data Verification (SDV), and ensuring that essential file documents and pharmacy records are up to date in accordance with ICH-GCP. o Provide written reports on the progress, management and conduct of studies including the production of corrective and preventative action	70

plans, and to follow-up corrective actions until satisfactory resolution. ○ Performing "remote" monitoring and drug accountability when required. ○ Maintain a database of research monitoring activity. For multi-centre trials, ensure that monitoring arrangements for participating sites are reviewed and approved prior to the delegation of monitoring responsibilities to third parties.	
• To conduct Sponsor reviews for new studies including where necessary the completion of a risk assessment, development of a monitoring plan and to mitigate any risks identified.	10
• Participate in the development and implementation of Quality Assurance and Quality Control systems for monitoring studies. In the event of any statutory inspection to assist with the preparation, the conduct of the inspection and any corrective action required within specified timeframes.	5
• Assist in the reporting and review of pharmacovigilance reports ensuring that all information is available for onward reporting to third parties, the competent authority(ies) and Research Ethics Committee, and for clinical review within the University.	5
• To deliver training on research governance matters as required.	5
• To assist in the maintenance of a quality management system and management of all SOPS within the Research Governance Office.	5
• To represent and promote the services offered by the Research Governance Office to colleagues, academics and senior professional staff across the University and externally as appropriate.	
• To undertake additional duties as reasonable required by the Research Governance Manager.	

Internal and External Relationships

- Research Governance team at the University and the Research and Development/Innovation teams at host NHS organisations as necessary.
- Research Ethics, Governance and Integrity team at the University.
- Clinical and academic research staff, at all levels, within the University of Leicester and host NHS organisations.
- External organisations within both the private and public sectors including commercial companies and regulatory authorities.
- Internal departments within host NHS organisations, such as pharmacy, pathology and imaging departments.
- University of Leicester Research Sponsorship Management and Operations Group.
- University of Leicester Human Tissue Act Committee.

- University Research & Enterprise Division.

Planning and Organising

An essential part of this role will be planning and organising the monitoring of a wide range of studies sponsored by the University of Leicester, including multi-centre Clinical Trials of Investigational Medicinal Products (CTIMPs).

For all CTIMPs there will be the requirement for a detailed Sponsor review, development of a risk assessment and the formation of a monitoring plan. This will also be applicable on a case-by-case basis for other non-clinical trial studies which require detailed oversight.

Planning and organisation will be required for the successful set-up, conduct and close out of studies, and will require close liaison with the study teams to achieve best practice and the provision of deliverables within timelines as determined by the Research Governance Office Standard Operating Procedures (SOPs) and statutory regulations.

This role will require the post holder to travel throughout the UK, the ability to plan own workload, whilst working within a team environment, and to be able to prioritise tasks in order to carry out monitoring visits, attend meetings and assist with audits where required. Travel to sites will be essential and this may require an overnight stay.

Qualifications, Knowledge and Experience

Essential

- Educated to degree level or extensive relevant experience in a similar role (e.g., Trial Management/Co-ordinator)*
- Previous experience working in the field of clinical research (e.g., Trial Management/Co-ordinator)*
- A sound working knowledge of monitoring and audit procedures for research studies*
- Excellent working knowledge of regulatory guidelines which govern research*
- Up to date ICH-GCP training*
- Evidence of monitoring course attendance
- Experience of monitoring Clinical Trials of Investigational Medicinal Products (CTiMPs)

Desirable

- Experience of study set-up and governance
- Experience of multi-centre studies (set-up, management or monitoring of)
- Understanding of Sponsor issues relating to research studies
- Experience of statutory audit and inspections such as Competent Authority Inspection Human Tissue Act audits
- Experience of writing and reviewing SOPs

Skills, Abilities and Competencies

UNIVERSITY OF LEICESTER

Job Summary

Essential

- Attention to detail, accuracy and the ability to assimilate information quickly and within a busy environment*
- Problem solving and decision making skills
- Excellent communication skills, both written* and verbal
- Ability to demonstrate tact and diplomacy with others to achieve necessary objectives whilst promoting a good image for the Research Governance Office and the University
- Ability to communicate firmly and effectively with others to establishing best practice and maintain good working relationships
- Demonstrate an understanding of the importance of maintaining security and confidentiality of information*
- Ability to collate and compile complex information into written reports
- Sound working knowledge of IT applications, particularly Microsoft Word, Excel, Access, PowerPoint and the Internet*
- Self-motivated with ability to manage own workload
- Self-confidence and ability to cope under pressure
- Ability to travel between sites as necessary

Desirable

- Effective networker

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.

Research Passport 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.

VITAL

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

UNIVERSITY OF LEICESTER

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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.