Job Summary

Job Title: Trial Coordinator
Grade: 5
Salary: £22,847 to £27,116 per annum
Department: Clinical Trials Unit
Contract: Full-time fixed term contract for one year
Job Family: Management and Administration
Job Reference: 2835

Role Purpose:
To carry out the initiation, organisation and administration of one or more clinical trials supported by the Leicester Clinical Trials Unit (LCTU), working under the direction of a trial manager, the CTU senior managers and the trial Chief/Principal Investigator. You will work proactively as part of a wider team working closely with NHS clinical and academic staff to ensure the highest standards of research governance, and to deliver the trials on time and to budget. You will have trial management knowledge to maintain the smooth and effective running of the clinical trials and research studies in accordance with the study protocols, ethics and regulatory approvals, SOPs, the principles of GCP, applicable EU Directives and UK legislation.

Main Duties and Responsibilities

To be a proactive contributing member of the multi-disciplinary team accountable to the Chief/Principal Investigator, running clinical trials and other research studies. This includes ensuring that the trial is conducted in accordance with ethical and regulatory approvals of the protocol, with trial sponsor and CTU quality standards, ensuring all relevant records and audit trails are maintained.

To organise and administer the trial(s). To assist with production of the final or amended protocol and all associated documentation, assisting the Chief/Principal Investigator to obtain ethics and regulatory approvals, and ensuring that collaborating sites have the required and approved documentation in order for site opening.

To be responsible for maintaining the essential documents in the Trial Master File (paper and electronic), ensure secure storage of the documentation and have an integral role in adverse event/SAE reporting.

To be the key contact in the trial for study conduct, communicating with the study team often across different sites, support the activities of the trial management group, steering and data monitoring committees, including arrangement, agenda preparation and production of minutes.

To inform and motivate trials staff by writing newsletters, updating web pages, organising investigator or trial management meetings which may require visiting trial sites. To assist writing and reviewing trial quality, checking plans and reports, undertaking quality checks where applicable to maintain trial quality, highlighting any critical issues for further review.

To contribute to the LCTU quality management system and assist in developing procedural documentation as applicable, ensuring that practice adheres to relevant University policies and procedures. To carry out any other relevant duties as required by the CTU management staff.

Job Summary

Internal and External Relationships

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

Internal

Daily - trial management, IT and data management staff, administration and finance staff, and statisticians in the CTU.

Regular – senior trial manager(s) for support, monitoring personnel

External

Daily – principal investigators and administrative, nursing, medical, academic and other support staff in the trial team, CRN and hospital Trusts, patients and study participants.

Regular –administrative and senior members of organisations sponsoring and/or funding the trials including research charities and NHS organisations

Planning and Organising

Assist with the 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 in conjunction with others: to ensure that the quality control procedures in place are followed for all aspects of the trial. Plan own work activities with supervision from senior staff, ensuring operational quality and efficiency, adjusting priorities as appropriate. Identify circumstances requiring escalation to senior trial managers.

Co-ordinate the 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 LCTU in a professional manner.

Manage the day-to-day running of the trial, following established standardised procedures that ensure compliance with the protocol and regulatory standards, monitoring compliance, and escalating issues/decisions as appropriate. A high degree of organisation with good attention to detail is required including high standards of accuracy and an ability to forward plan with prioritisation of tasks and workload to ensure trial deadlines are met. If required, monitor the trial budget, advising the LCTU senior trial manager of any cause for concern.

Qualifications, Knowledge and Experience

Essential

Either

- Academic and vocational qualifications (science related degree, nursing or allied health professional qualification) plus relevant formal training or professional qualification in related role(s)*

Or

- Experience in trial co-ordinating, data management or monitoring of clinical trials in an academic or health-related role*

Plus

- Experience in clinical research*
- Thorough working knowledge of the relevant ethical, legislative and research governance requirements relevant to clinical trials*
- An understanding of clinical research and trial methodology
- Experience of working with Standard Operating Procedures and a Quality Management System*
- Experience of planning and progressing work activities with minimal supervision or recourse to seniors*

Desirable

- Experience of working in a clinical or research environment*
- Experience of maintaining patient confidentiality when appropriate*
- Willingness to travel to trial sites and to meetings

Skills, Abilities and Competencies

Essential

- Good communication skills (oral and written), confident and able to work across professional team and organisational boundaries to deliver training and work well with staff at all levels
- Ability to demonstrate good organisational and problem-solving skills i.e. able to plan and prioritise, to work to deadlines with an enthusiastic approach to challenges*
- High attention to detail
- Ability to communicate confidently, clearly and appropriately orally and in writing to ensure effective contact handling and maintain good interpersonal relationships*

Desirable

- Willingness to travel to trial sites and to meetings.

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.

VITAL

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

Valuing People, Innovators, Together, Accountable, Leaders.

Equality and Diversity

Job Summary

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.