



Job Title: Head of Trial Management
Grade: 8
Salary: £47,047 to £52,841 per annum
Department: Clinical Trials Unit
Hours/Contract: Full-time, fixed term for two years
Job Family: Management and Administration
Reference: 7299

Role Purpose

You will co-lead the Trial Management function for LCTU, overseeing development and delivery of a large portfolio of clinical trials, including CTIMPs, ensuring international quality standards in trial management are met. You will be responsible for trial management staff working across the portfolio and be expected to ensure the delivery of trials against key performance milestones. You will manage projects independently, including those in Grant application work-up, but in close collaboration with colleagues in other functional areas, highlighting issues and solutions for discussion within the Unit’s Leadership Team.

Main Duties and Responsibilities

- Managing delivery of a portfolio of projects to time and target, and within budget. This includes: supporting CTU staff and external research project teams to anticipate and address issues affecting trial delivery; managing resources for existing projects; and planning the resources required for new projects.
- Working in partnership with Chief Investigators, co-applicants and CTU colleagues to develop funding applications. This includes providing a careful and realistic assessment of resource requirements for the project, and advising on the practicalities of trial delivery in relation to all aspects of the study protocol, such as design, timelines, feasibility and regulatory and governance requirements.
- Leading, managing, motivating and developing a team of trial management staff, including Senior Trial Managers, Trial Managers, Trial Coordinators and Administrators, ensuring: ongoing assessment of performance; identification and addressing of training needs; provision of in-house training; and development of a culture of learning and excellent customer service.
- Review of Standard Operating Procedures (SOPs), leading Working Groups and supporting Quality and data management staff in development of associated documentation and training
- You will be responsible for highlighting trial-specific and standard contractual requirements to colleagues in the University Research & Enterprise Division, and ensuring that all necessary contractual paperwork is correct and in place within expected timeframes.
- Maintaining comprehensive and up-to-date knowledge and understanding of legislation, guidance and local and national initiatives relating to clinical research, providing expert advice to colleagues and collaborators, and ensuring that CTU working practices are updated as required.
- Contributing to high-quality publications in peer-reviewed clinical and methodological journals, and presenting research and/or issues in trial design and conduct at local, national and





international meetings and conferences

- Representing LCTU on local and national committees
- Deputising for the Operations Director as required

Internal and External Relationships

Internal relationships: All CTU staff, College of Life Sciences, Research Support Office, Research and Enterprise Division, Human Resources, IT Services, UHL/UoL Joint Research and Innovation Office, Information Assurance Services

External relationships: research funding bodies, NHS Trusts, HEIs, NIHR CRN, NIHR RDS, UKCRC CTU Network, MHRA, other regulatory agencies, Chief Investigators, commercial companies

Planning and Organising

Contribute to planning the strategic direction of the LCTU

Lead the planning and organisation of an efficient and effective trial management function

Ensure that all trials run through the CTU are conducted in accordance with CTU guidelines and procedures

Effectively organise and prioritise a heavy and complex workload to meet short-, medium- and long-term deadlines

Establish clear roles and responsibilities for self and others

Adapt work plans in response changing circumstances

Set priorities in conjunction with team and area objectives

Meticulous document, data and financial management

Qualifications, Knowledge and Experience

Essential

- Undergraduate degree (or equivalent professional experience) in a relevant discipline*
- Substantial experience of developing and delivering multi-centre interventional trials in a quality-assured clinical trials environment, including CTIMPs*
- Experience of supervising or line managing multiple people across multiple projects, and of developing and leading a collaborative, facilitative and skilled team*
- Experience of working independently, assuming responsibility for the development and delivery for a substantial area of work, whilst collaborating with others*
- Knowledge of UK regulatory and governance requirements for clinical research, and experience of successfully applying these at both project-specific and organisation-wide levels





through the development of SOPs and associated documents and guidance*

- Experience of developing/contributing towards successful research funding applications, including realistic and accurate costings*
- Experience of managing substantial (>£1m) research project budgets
- Experience of successful contract negotiations for complex research projects

Skills, Abilities and Competencies

Essential

- A high level of organisational, planning and self-management skills, including the ability to manage competing deadlines, deliver multiple projects across multiple organisational boundaries, and resolve problems efficiently and effectively on your own initiative
- The ability to lead complex multi-disciplinary meetings effectively and efficiently, resulting in clear outcomes and progress
- The ability to assimilate complex, detailed information and to reproduce it in a clear, consistent, accurate and appropriate format, dependent on purpose and audience
- The ability to build productive working relationships with internal and external staff at all levels of seniority, using effective negotiation, diplomacy and influencing skills*
- The ability to coach and develop staff, advancing their skills, confidence and knowledge*
- Evidence of developing robust processes and procedures
- Strong team player who will support the wider endeavour and can demonstrate the ability to deliver positive cultural change*

****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.

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.

