UNIVERSITY OF LEICESTER

# Job Summary

**Job Title:** Project Support Manager (Vascular)
**Grade:** 7
**Salary:** £39,906 to £46,049 per annum
**Department:** Cardiovascular Sciences
**Hours/Contract:** Full-time (job share considered) fixed term contract to 30 September 2030
**Job Family:** Management and Administration
**Reference:** 12419

## Role Purpose

Reporting to the Senior Clinical Research Manager (Vascular), the post-holder will be responsible for supporting the set up, management, and closedown of research projects within the Vascular Research Team, directly supporting the NIHR Professor of Vascular Surgery, Athanasios Thanos Saratzis on their portfolio, with a focus on their NIHR funded Professorship.

You will provide line management of a small team of trial managers/coordinators/administrators and be expected to work independently but also part of the wider team, working closely with the Senior Clinical Research Manager, other research managers, and collaborating with NHS clinical and academic staff. You will provide oversight and clinical trial management expertise to ensure the smooth and effective set-up and running of studies operating within Vascular Surgery, 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

- Accountable to the Senior Clinical Research Manager, providing trial management expertise in order to develop, organise and facilitate a portfolio of clinical research projects. This includes ensuring trials/research projects are conducted in accordance with the appropriate SOPs, regulations and ethical approvals.
- Be responsible for the oversight, management and delivery of a trial/research project management team, including trial managers, co-ordinators and trial administrators (as appropriate). Motivate your team and provide day-to-day supervision, coaching and operational direction. Monitoring performance against project management plans, using various online tools and proactively solve problems, taking appropriate action where necessary to ensure timelines are met.
- Providing key input to grant applications, protocols, case report forms design, site agreements, and remote data entry systems and all associated documentation. Assisting Chief Investigators to ensure timely sponsor, regulatory, ethical and HRA approvals. Responsible for the creation and maintenance of Trial Master Files and Investigator Site Files ensuring all participating sites have current trial information.
- Set up participating sites by undertaking site initiation visits, remotely and/or in person as necessary. Identify and undertake feasibility of sites, ensuring all participating sites have received relevant trial specific training. Facilitating approvals in order for sites to open to

recruitment. Monitoring performance and progress of each trial site and take appropriate action.

- Working with the database, statistics, and quality teams (where appropriate) contribute to and implement data management and trial monitoring plans, incorporating appropriate risk assessments and appropriate mitigations in the running of all trial/research activity. To coordinate and support the activities of the Study Management Group, Study Steering and Data Safety Monitoring Committees. To coordinate communications among all trial stakeholders including trial research team, funding bodies, sponsor, collaborative groups and participating sites, ensuring a common understanding of trial progress.
- Plan expenditure against trial budgets and monitor the budget for the portfolio of trials the post has responsibility for. Drive the procurement process for suppliers according to UoL policies, where necessary. Prepare trial progress and/or financial reports as required by the Senior Clinical Research Manager and College senior management teams, funding bodies, regulatory authorities, ethics committees, Investigators, trial Steering and Data Monitoring Committees, funding bodies and external collaborators.

Miscellaneous

- As an when needed, prepare standard operating procedures/procedural documentation for the running of individual clinical trials/research projects to ensure research complies with current guidance and legislation. Ensure that practice adheres to relevant University policies and procedures.
- As part of the wider Vascular Research Team, drive and support necessary change in order to optimise the operations of Leicester Vascular Research Team and proactively contribute to its continued growth and sustainability.
- To represent Leicester Vascular Research at external conferences/meetings and undertake any other relevant duties as required by the Senior Clinical Research Manager.

## Internal and External Relationships

**Internal**

- Daily – trial/research project management (with key focus on the deliverable of the NIHR Professorship), and monitoring personnel, IT and data management staff, administration and finance staff, and statisticians across the University (including the Leicester Clinical Trials Unit).
- Regular – NIHR Professor of Vascular Surgery, BHF Chair of Vascular Surgery, Senior Clinical Research Manager, other research managers (within Cardiovascular) internal sponsor offices, internal senior investigators, academics and clinicians.

**External**

- Daily – external investigators, academics and trial teams, external sponsors.
- Regular – funders, Research Delivery Networks, Regulatory Agencies, other NHS Trusts and Institutions, and Industry.

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## Planning and Organising

- Manage own workload and oversee the management of trial teams the post holder is responsible for.
- Take overall responsibility for trial management in compliance with regulatory guidelines. Maintain up-to-date knowledge of regulatorym, ethical and governance requirements and translate this into practical activities.
- Effective workload and project planning of own trial activities and those of direct reports: set and ensure that quality control procedures are in place for all aspects of the trial, to maintain and improve operational efficiency and quality by development and application of process improvements. Plan 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 Senior Clinical Research Manager.
- Coordinate and oversee the multicentre trial(s) 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 Leicester Vascular Research in a professional manner.
- Manage the day-to-day running of the trial(s) by establishing standardised procedures that ensure compliance with the protocol and regulatory standards, monitoring compliance, and taking decisions on actions required.

## Qualifications, Knowledge and Experience

**Essential**

- A higher degree (PhD or MSc) in a relevant biomedical science or associated subject with experience of clinical applied research* **OR**
  A graduate with experience in a Trial Management environment* **OR** An in depth understanding of clinical research and trial management methodology, including applicable regulatory requirements, and a proven ability to apply these to the coordination of clinical trials*
- Experience preparing the following: regulatory and ethics submissions, grant applications, writing and/or amending protocols, patient information sheets, site agreements, Case Report Forms, reports and other relevant trial management documentation
- 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 preparing the following: regulatory and ethics submissions, grant applications, writing and/or amending protocols, patient informatin sheets, site agreements, case report forms, reports or other relevant trial documentation.*

**Desirable**

- Experience of using Canva
- Knowledge and understanding of research and NHS costs with experience of generating SoECATs to the point of approval
- Experience of writing SOPs either for trials or within a CTU

- Experience of data management
- Experience of project management tools
- Experience of running research within the NHS

## Skills, Abilities and Competencies

**Essential**

- Proven project management and line management skills*
- Effective communication, negotiation, presentation and interpersonal skills, including team leadership and motivation*
- Must demonstrate a critical and intelligent attention to detail and high standards of accuracy*
- Excellent computing skills including email, spreadsheets, word processing, databases, internet and working knowledge of MS office suite
- Able to work on own initiative and problem solve as well as collaboratively as part of a team

**Desirable**

- Contract management
- Experience in both quantitative and qualitative applied research
- Experience working in diverse research teams.

***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 warningsInformation 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.

## Supporting University Activities

As a University of Leicester citizen, you are encouraged to support key university activities such as clearing, graduation ceremonies, student registration and recruitment open days. We encourage all staff as citizens to work flexibly across the University if required. If supporting these activities is likely to affect your workload, please speak to your line manager in the first instance

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# Job Summary

## 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

## Freedom of Speech

The University is committed to upholding freedom of speech and academic freedom within the law throughout our recruitment processes. We ensure that all candidates are considered based on merit and suitability for the role, without regard to their lawful viewpoints or the expression of challenging or controversial ideas. Our recruitment policies and practices are designed to protect applicants from discrimination or adverse treatment on the basis of their opinions, and to foster an environment where open debate and diverse perspectives are valued as essential to our academic mission.

## 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 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.