



UNIVERSITY OF LEEDS

CANDIDATE BRIEF

Head of Clinical Trial Management, Complex Interventions Division
Faculty of Medicine and Health



Salary: Grade 8 (£40,792 – £48,677 per annum)

Reference: MHCTR1155

Closing date: 16 June 2019

Open Ended Fixed Funding for 36 months

Head of Trial Management, Complex Interventions Division School of Medicine, Clinical Trials Research Unit (CTRU)

Following several years of success and growth, we are looking to appoint an enthusiastic and motivated candidate to the position of Head of Trial Management within the Complex Interventions Division.

- **Are you interested in evaluations of complex interventions?**
- **Can you lead a clinical trials team to overcome the challenges in research conduct to deliver gold standard clinical trials research?**
- **Do you have excellent organisational and communication skills and an in-depth knowledge of clinical trial conduct and the regulatory and governance environment?**
- **Do you want to be part of a leading Unit that has a national and international reputation for excellence in conducting complex, multi-centre clinical trials of complex interventions?**

We are particularly keen to hear from candidates with experience in any of the following: evaluation of complex interventions, delivering research across different organisations or within a wider programme, or specialist knowledge in a relevant area (for example, elderly care, stroke, mental health, physical activity, supportive care, use of patient reported outcomes).

You will join our Complex Interventions Divisions and lead the trial and data management team for a large portfolio of projects by acting as Trial Delivery Lead on projects, ensuring international quality standards in trial conduct are met. You will be responsible for trial and data management staff working on your portfolio trials and be expected to deliver trials to key performance milestones. You will use your problem solving skills to identify and resolve issues affecting the successful delivery of your portfolio trials, including recruitment, intervention delivery and follow-up. You will also manage projects with a high degree of autonomy but will be expected to highlight any critical issues for further discussion with the Divisional Director, Operations Director and other members of the CTRU Senior Management Group.



You will have substantial experience of managing multi-centre clinical trials / research projects, preferably evaluating complex interventions. You will also have up-to-date knowledge of legislation, regulatory and governance environment relating to clinical trials. As you will work closely with multiple stakeholders you will need excellent communication and interpersonal skills, along with the ability to lead a team and meet project deadlines.

What does the role entail?

As a Head of Trial Management – Complex Interventions, your main duties will include:

- Managing a portfolio of projects to 'time and target', to high methodological rigour and within budget. This includes supporting the project team in identifying and resolving critical issues and managing resources for new and existing projects;
- Working in partnership with the Divisional Director and Principal Statisticians to develop grant applications. You will advise on the practicalities of trial delivery in relation to study design and regulatory and governance requirements whilst developing the resource requirements for the project;
- Identifying the contractual requirements for each study and leading on contractual negotiations. You will be responsible for highlighting trial specific and standard contractual requirements with the contracts team;
- Maintaining a thorough and up-to-date understanding and working knowledge of legislation, guidance and local and national initiatives relating to clinical research and applying this knowledge through working practices on the projects in your portfolio and sharing knowledge and practice across Divisions;
- 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;
- Leading, managing, motivating and developing a team of Trial Managers, Data Managers and associated clerical staff responsible for the project management and day to day conduct of complex, high profile, national and international clinical trials;
- Authorship of Standard Operating Procedures (SOPs), leading Working Groups and supporting trial and data management staff in development of associated documentation and training;
- Delivering relevant training sessions, both internally and externally



- Establishing and maintaining professional relationships with collaborators including funders, staff from other trials units, clinicians, professors, relevant laboratory and research staff at both national and international centres;
- Portfolio development through grant applications and training and developing trials staff.
- Representing CTRU on local and national committees.

These duties provide a framework for the role and should not be regarded as a definitive list. Other reasonable duties may be required consistent with the grade of the post.

What will you bring to the role?

As a Head of Trial Management you will have:

- Substantial experience in the management of multi-centre interventional trials in accordance with ethical and regulatory standards;
- Previous experience supervising or line managing multiple people across multiple projects, with the ability to lead a team, assume responsibility and make decisions impacting the course of a project;
- Knowledge of the UK regulatory and governance environment and other relevant guidance, for example Consolidated Standards of Reporting Trials (CONSORT), and experience of implementing these within projects and at an organisational level through development of SOPs or associated documents;
- A high level of organisational, planning and self-management skills, including the ability to manage and meet multiple deadlines and deliver projects across several organisational boundaries and handle problems, efficiently and effectively, using your own initiative;
- Confidence, experience and the ability to lead complex multi-disciplinary meetings and decision making processes with strategic thinking and an inquisitive mind;
- The ability to assimilate information and reproduce it in a clear, consistent, accurate and relevant manner according to purpose and audience;
- The ability to build professional working relationships with internal and external staff, using effective negotiation, diplomacy and influencing skills;
- The ability to coach and develop staff and advance their skills and knowledge;
- A commitment to upholding University values and taking ownership for personal development.



You may also have:

- Experience in trial management in a quality assured clinical trials environment.
- Experience of trial management within a relevant area; trials with complex intervention, complex patient flows from multiple organisations, delivering trials as part of a wider programme or specialist knowledge in a relevant clinical area (for example, elderly care, stroke, mental health, physical activity, supportive care, use of patient reported outcomes).
- Knowledge of methodological issues related to the conduct of complex intervention evaluations, including measuring and reporting intervention fidelity.
- Experience of budget management and workforce planning;

How to apply

You can apply for this role online; more guidance can be found on our [How to Apply](#) information page. Applications should be submitted by 23.59 (UK time) on the advertised closing date.

Contact information

To explore the post further or for any queries you may have, please contact:

Vicky Napp, Operations Director

Tel: +44 (0)113 343 4681; Email: V.Napp@leeds.ac.uk

Gill Booth, Operations Director

Tel: +44 (0)113 343 1496; Email: G.Eddison@leeds.ac.uk, or

Additional information

The [Clinical Trials Research Unit](#) (CTRU) within the Leeds Institute of Clinical Trials Research (LICTR) is an international leader in the field of clinical trials. The Unit is one of the largest in the UK and conducts national and international randomised and early phase clinical trials in a variety of clinical fields.



Our main aim is to support the challenge of changing clinical practice for the better and our [past results](#) and current work have already helped to do this. Our results inform the academic development of this specialised field of clinical research on a national and international level. Particularly, we specialise in complex phase III trials, efficient phase I/II trials, biomarker driven designs, seamless phase II/III designs, adaptive designs and the development and evaluation of complex interventions.

Find out more about our Institute [Leeds Institute of Clinical Trials Research](#).

Find out more about the [Faculty of Medicine and Health](#).

Find out more about [Athena Swan](#) in the Faculty of Medicine and Health.

Working at Leeds

Find out more about the benefits of working at the University and what it's like to live and work in the Leeds area on our [Working at Leeds](#) information page.

Candidates with disabilities

Information for candidates with disabilities, impairments or health conditions, including requesting alternative formats, can be found on our [Accessibility](#) information page or by getting in touch with us at disclosure@leeds.ac.uk.

Criminal record information

Rehabilitation of Offenders Act 1974

A criminal record check is not required for this position. However, all applicants will be required to declare if they have any 'unspent' criminal offences, including those pending.

Any offer of appointment will be in accordance with our Criminal Records policy. You can find out more about required checks and declarations in our [Criminal Records](#) information page.

