



UNIVERSITY OF LEEDS

CANDIDATE BRIEF

Senior Clinical Trial Manager – Complex Interventions (2 x posts)
Faculty of Medicine and Health



Salary: Grade 7 (£33,199 – £39,609 per annum)

Reference: MHCTR1149

Closing date: 6 May 2019

Open Ended Fixed Funding for three years

Senior Clinical Trial Manager – Complex Interventions School of Medicine, Clinical Trials Research Unit (CTRU)

Are you interested in evaluations of complex interventions? Do you have experience of study coordination or trial management? Do you want to be part of a leading team that has a national and international reputation for excellence in conducting complex, multi-centre clinical trials of complex interventions?

This is an exciting opportunity for enthusiastic and motivated individuals to join the Complex Intervention Division to lead on the implementation, delivery and monitoring of newly funded projects in Mental Health (1 post) and in Cancer (1 post).

You will be based at the [Clinical Trials Research Unit](#) (CTRU) within the Leeds Institute of Clinical Trials Research (LICTR). The CTRU 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**.

You will join our Complex Intervention Division and take responsibility for coordinating a large complex intervention trial from set-up and recruitment, intervention delivery, follow-up, through to trial closure and analysis. You will use your problem solving skills to identify and resolve issues affecting the successful delivery of your trials.

You will directly co-ordinate large multi-centre trials in either the Mental Health or the Cancer portfolios. You will lead a CTRU portfolio trial management team, ensuring international quality standards in trial management for the portfolio projects by supervising complex trials and associated trial co-ordination staff across the portfolio. You will contribute to research portfolio development through grant applications and training and developing trials staff. You will also support the dissemination of research results by contributing to high quality publications and presenting at meetings and conferences.



You will have experience of trial coordination and/or trial management gained working on clinical trials, 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, interactively and collaboratively with multiple stakeholders you will need excellent communication and interpersonal skills, along with the ability to manage and meet deadlines.

What does the role entail?

As a Senior Clinical Trial Manager – Complex interventions your main duties will include:

- Leading the set-up, conduct and closure of multi-centre randomised controlled trials and actively contribute to the design, from a trial co-ordination, regulatory and logistics perspective;
- Managing projects, making day-to-day decisions and highlighting critical issues to the senior team, adhering to milestones and resources outlined in the grant application and supervising and managing trial co-ordination staff;
- 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 you manage;
- Working in partnership with the Divisional Director, Principal Statistician and Head of Trial Management to develop grant applications and implement high quality randomised controlled trials;
- 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;
- Actively contributing to the development of systems and processes through involvement in Working Groups and development or amendment of associated documentation;
- 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;
- Delivering relevant training sessions, both internally and externally and ensuring continuing professional development for portfolio trials staff.



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 Senior Clinical Trial Manager you will have:

- Substantial experience in Trial Management of interventional trials in a quality assured clinical trials environment or substantial experience of leading and implementing research across several organisations;
- Knowledge of the regulatory and governance environment in the UK and other relevant guidance, for example Consolidated Standards of Reporting Trials CONSORT, and experience of implementing within projects;
- Confidence, experience and the ability to lead and participate constructively in 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;
- Previous experience supervising or line managing people, with the ability to work effectively in a team assuming responsibility, leading projects and making decisions within the sphere of the role;
- The ability to build professional working relationships with internal and external staff, using with effective negotiation, diplomacy and influencing skills;
- 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 own initiative;
- A commitment to upholding University values and taking ownership for personal development.

You may also have:

- Experience of trial management within a relevant area; Clinical Trials of Complex interventions, particularly those in mental health or cancer.
- Knowledge of methodological issues related to the conduct of complex intervention evaluations, including measuring and reporting intervention fidelity.



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:

Suzanne Hartley, Head of Trial Management

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Email: S.Hartley@leeds.ac.uk

Additional information

Find out more about the [Clinical Trials Research Unit](#).

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.

