UNIVERSITY OF LEEDS

CANDIDATE BRIEF

Trauma & Orthopaedics Trial Coordinator

Faculty of Medicine and Health

Salary: Grade 6 (£27,511 to £32,817 p.a.)

Reference: MHLRM1137

Closing date: 30 August 2020

Part time: 64% of full time equivalent (24 hours a week)

Fixed-term for up to one year to cover maternity leave.

Trauma & Orthopaedics Trial Coordinator (Maternity Leave Cover)
School of Medicine
Leeds Institute of Rheumatic & Musculoskeletal Medicine

Do you have experience in setting up, managing and coordinating clinical trials? Would you like to work in a clinical academic environment? Do you have an understanding of trials using medical devices as well as medicinal products?

We are looking for someone with a strong background in managing projects, and working within a clinical trials setting to become a key member of our research team. You will be responsible for coordinating specific Trauma & Orthopaedics (T&O) research projects and clinical trials from set-up and recruitment through to trial closure and analysis.

You will provide a wide range of support for the T&O Research Group's clinical research activities and the senior academic staff. You will also have responsibility for coordinating the Section studies, monitoring and managing a variety of aspects of the project to ensure it progresses well and to time.

You will possess strong problem solving and analytical skills with experience of establishing and implementing systems and processes to support reliable delivery of projects. You will be educated to degree level or equivalent relevant qualification/experience. Effective communication, organisational and prioritising skills with an ability to meet tight deadlines, along with well-developed computer skills and excellent attention to detail are essential.

This post is based in the Section of Orthopaedics and Trauma Surgery, based at Worsley Building and the Leeds General Infirmary and also at Chapel Allerton Hospital and is available immediately.

This large clinical Institute now represents one of the largest clinical academic groups for rheumatology and musculoskeletal medicine in the world. The Section of Orthopaedics is strategically focussed on increasing its portfolio of high quality research, particularly via Clinical Trials.



The T&O Trial Coordinator is a key member of the research team and will be responsible for the co-ordination of one or more trials/studies within the T&O research portfolio. Duties of the post will include study set up, collection, computerisation and validation of data in accordance with Good Clinical Practice, the Medicines for Human Use act (2004) and the Research Governance Framework as appropriate. You will advise the project team and investigators on the progress of the study from a trial co-ordination, regulatory and logistics perspective and work with the Chief Investigator (CI) to resolve problems. You will develop specialist musculoskeletal knowledge relevant to the post.

What does the role entail?

As a Trauma & Orthopaedics Trial Coordinator, your main duties will include:

- With CI delegation, day-to-day management and coordination of all clinical research administration for the T&O research portfolio;
- Offer advice, guidance and management to CIs, Fellows, Researchers and Research Nurses in all stages of each clinical trial;
- Draft and co-ordinate ethics and R&D applications and approvals;
- Provide administrative support to PIs in the preparation of grant applications for new research studies;
- Implement on-going quality assurance and audit programmes. Raise awareness of quality control within the department, according to Good Clinical Practice guidelines;
- Ensure adherence to statutory requirements of the legislation regarding clinical trials of investigational medicinal products and devices;
- Ensure that essential documents for all studies are well maintained;
- Work with the Researchers and CI in order to optimise patient recruitment to each trial, by making available all trial details, including patient information sheets, consent forms, GP letters and clear inclusion and exclusion criteria, to all clinicians and nursing staff during clinical sessions;
- Work closely with the Institute's (MSK) Portfolio manager to ensure accurate and timely accrual of trial data;
- Identify amendments needed as the trial progresses and ensuring all members of the project team are aware of amendments;
- Contribute to the development of best practice systems through the ability to review existing processes, making recommendations for improvement and implementing agreed changes;



- Monitor the progress of the project/s including current and planned project timelines, data collection and data quality. Flagging problems to the PI or raising them at project team meetings, working with the PI to identify and implement appropriate solutions, and taking appropriate action to ensure that documentation and study procedures are updated to reflect any changes;
- Maintain a thorough and up-to-date understanding and working knowledge of the EU Directive on Clinical Trials, GCP guidelines and the Research Governance Framework, and experience of applying this knowledge through working practices on the projects you co-ordinate, development of trial specific Work Instructions and liaising with the CTRU QA manager;
- Develop specialist knowledge relevant to projects;
- Communicate and give support to all members of the research team as point of contact for expert knowledge in clinical research;
- Support the delivery of the clinical research portfolio;
- Aid in education and research staff development;
- Facilitate effective communication between all levels of research staff;
- Manage your own time effectively, taking into account other members of the research team;
- Attend relevant investigator meetings and trial update meetings;
- This post requires the post holder to visit participating sites across the UK;
- You may be required to conduct some work across trust sites or in neighbouring hospitals.

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 Trauma & Orthopaedics Trial Coordinator you will have:

- A degree or equivalent qualification / experience in health research;
- Previous experience working in Clinical Trials setting and knowledge of GCP, the Medicines for Human Use Act (2004) and the Research Governance Framework;
- Previous experience in drafting, co-ordinating and submitting HRA, ethics and R&D applications and approvals;

- Effective organisational skills demonstrated by a proven ability to support a range of different projects simultaneously with an ability to retain a clear focus on outcomes along with delivering good results;
- Ability to review situations using strong problem solving and analytical skills to identify, gather and assess relevant information;
- Experience of establishing and implementing systems and processes to support reliable delivery of projects along with an ability to write clearly and concisely;
- Ability to develop effective working relationships, interact and collaborate with a wide range of professionals, including senior staff, across a range of organisations;
- Relevant working experience of the Microsoft Office suite, especially Word, Excel, PowerPoint, and Outlook;
- Ability to use initiative and apply knowledge to practical situations, prioritise own workload along with the ability to participate constructively in meetings, working effectively both independently and in a team;
- Motivation to maintain up-to-date knowledge of clinical research environment ;
- Enthusiastic, proactive and flexible approach to working in a dynamic and diverse academic organisation;
- Demonstration of willingness to support team members, share experience and develop good practice.

You may also have:

- Experience of co-ordinating device clinical trials in a quality assured clinical trials environment;
- Experience of producing reliable and complete reports using effective communication and presentation skills along with evidence of attention to detail;
- Experience of setting up a multi-centre clinical trial in a quality assured clinical trials environment;
- Experience of co-ordinating phase III multi-centre clinical trials in a quality assured clinical trials environment;
- Understanding of clinical trial design and feasibility issues;
- A science degree or postgraduate research degree.

How to apply

You can apply for this role online; more guidance can be found on our How to Apply information. 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:

Professor Peter Giannoudis,
Tel: +44(0)113 206 7068
Email: P.Giannoudis@leeds.ac.uk

Professor Hemant Pandit
Email: H.Pandit@leeds.ac.uk

Additional information

You will be expected to work closely with other members of the Institute, in particular James Goulding, Trial Management Lead. In addition, you will be expected to develop good external working links with staff in Clinical Trials Team, the wider research community, the NHS Research Networks, the NIHR CRN Coordinating Centre, Clinical Trials Units, other researchers (professors, clinicians, research nurses etc.) national funding bodies and relevant professional bodies and organisations.

Find out more about the Faculty of Medicine and Health.

Find out more about Athena Swan in the Faculty of Medicine and Health.

Find out more about our Institute.

Find out more about our Research and associated facilities.

You will report to Prof Peter Giannoudis (Head of Section) and Prof Hemant Pandit.

Working at Leeds
You can find out more about our generous benefits package and more about what it is like to work at the University and live in the Leeds area in our Working at Leeds information.

Candidates with disabilities
Information for candidates with disabilities, impairments or health conditions, including requesting alternative formats, can be found in our Accessibility information 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 subject to the University being satisfied with the outcome of these checks, in accordance with our Criminal Records policy. You can find out more about required checks and declarations in our Criminal Records information.