UNIVERSITY OF LINCOLN
JOB DESCRIPTION

JOB TITLE	Clinical Trials Coordinator				
DEPARTMENT(S)	Community and Health Research Unit, College of Social Science				
LOCATION	Brayford Campus				
JOB NUMBER	CSS604	**GRADE**	7	**DATE**	December 2021
REPORTS TO	Prof A. Niroshan Siriwardena				

CONTEXT

This post will be based in the new Lincoln Clinical Trials Unit (LinCTU) within the Community and Health Research Unit (CaHRU: http://cahru.org.uk/), which is the research centre for the School of Health and Social care (SHSC) in the College of Social Science.
LinCTU is located at the Lincoln Medical School on the Brayford Campus. The postholder will join a multidisciplinary team with expertise in trials, data management and data analysis, working with Chief Investigators, and national and international collaborators.
The University of Lincoln looks to the future and seeks to serve and develop our local, national and international communities by creating purposeful knowledge and research, confident and creative graduates and a dynamic and engaged workforce. CaHRU's mission is to increase people's health and wellbeing by improving the quality, performance and systems of care across the health, social and third sector care services through world-leading interdisciplinary research with service users, healthcare professionals and organisations. This 3-year full-time fixed term post will contribute to research studies conducted by LinCTU and CaHRU involving clinical trials or related studies. The school H&SC holds an Athena SWAN Bronze award, in recognition of our commitment to advancing gender equality.

JOB PURPOSE

The Clinical Trials Coordinator will be involved in all aspects of clinical trials and related activities, supporting research within the primary, prehospital and acute care quality themes of CaHRU under supervision of its director. The post holder will have a leading role in planning, coordinating and completing designated projects.

They will have excellent communication and presentation skills, together with the ability to organise and motivate others. They will demonstrate flair, enthusiasm, innovation and leadership when faced with challenges and will provide strategic, tactical and operational management skills in the planning and execution of projects. Previous experience in the management and co-ordination of clinical trials is desirable; appropriate academic and/or vocational qualifications are necessary.

They will also work closely with the CaHRU team and other academic collaborators on developing and delivering research studies linked to the aims of the research centre. The post holder will link with team members, partners and stakeholders, to promote the services of the centre, identifying and securing relevant funding opportunities.

KEY RESPONSIBILITIES

Research

The Clinical Trials Coordinator will be required to undertake the following activities:

- Overall efficient day-to-day management of research projects.
- Recruitment, retention, training and supervision of trial team members.
- Establishing procedures to ensure adherence to trial protocols and requirements.
- Ensuring timely recruitment of participants with secure randomisation processes and subsequent efficient and effective data management.
- Monitoring project progress to ensure compliance with and adherence to the project plans, while identifying, evaluating and rectifying problems.
- Management of budget(s) and accounts.
- Act as point of contact for all external and internal agencies.
- Coordinating and contribute to preparation, publication and presentation of data, reports and information, ensuring they meet legislative, contractual and ethical requirements.
- Provision of regular and ad hoc information, both written and verbal, to all the trial participants and sponsor(s), to include reports, updates, guidance, preformed commitments and possibly a newsletter.
- Work with Chief Investigators to ensure that the project or trial is meeting its targets, is producing meaningful outputs and to predict and plan any changes that warrant requests to changes in protocol, funding or time.
- Ensure inclusion of consumer group representatives at the appropriate levels and times.
- Planning and supporting the meetings and work of the various groups and bodies associated with the trial.
- Creation and maintenance of all trial files, including the trial master file, and oversight of site files.
- Assurance that personal and confidential information is restricted to those entitled to know.
- Planning own day-to-day activity within the context of the required research.

Liaison and Networking

- Liaise with internal and external collaborators and colleagues, maintaining positive and effective working relationships, including, sponsors, health professionals and public contributors.
- Understand requirements of the controlling bodies, agencies and frameworks, guiding the project to conform to those requirements, coordinating necessary audit processes.
- Liaise with Trials and Study Steering Committees and Data Monitoring and Ethics Committees ensuring compliance with Research Governance, Good Clinical Practice, Data Protection, Ethical and Regulatory Authority requirements.
- Participate in internal research activities, including seminars, research meetings and continuous professional development activities.

Relationship management

- Work with contacts, partners and stakeholders across sectors of interest to the University, promoting the work of LinCTU and CaHRU, as well as identifying any new opportunities for collaboration.
- Act as a key contact for project delivery, where appropriate establishing working groups / temporary teams to meet the resource needs of each project activity and ensure cohesion of project delivery.

In addition to the above, undertake such duties as may reasonably be requested and that are commensurate with the nature and grade of the post.

ADDITIONAL INFORMATION

Scope and dimensions of the role
The post holder will have the leading role in planning, coordinating and completing projects. They will have excellent communication and presentation skills, together with the ability to organise and motivate others. They will demonstrate flair, enthusiasm, innovation and leadership when faced with challenges and will provide strategic, tactical and operational management skills in the planning and execution of projects. They will also be responsible for supporting preparation of reports, conference abstracts, presentations, and journal papers and contributing more widely to the work of the Community and Health Research Unit.

Key working relationships/networks	
Internal	**External**
• Professor of Primary & Prehospital Health Care; Director of Research Centre and LinCTU • Professor of Medical Statistics and Desputy Director of the LinCTU • Research Centre leads • Head of School • Other academic staff within the Departments involved • LinCTU staff and LinCTU data manager • Research Governance Manager	• Research collaborators • Patients and carers • Health Professionals • Sponsor(s)

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PERSON SPECIFICATION

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JOB TITLE	Clinical Trials Coordinator	**JOB NUMBER**	CSS604

Selection Criteria	**Essential (E) or Desirable (D)**	**Where Evidenced Application (A) Interview (I) Presentation (P) References (R)**
Qualifications:		
Honours degree in relevant subject (1st, 2.1) or equivalent	**E**	**A**
Master's degree in relevant subject	**D**	**A**
PhD	**D**	**A**
Experience:		
Clinical Trial Management experience	**E**	**A/I**
Experience of database design, management and related activities	**E**	**A/I**
Experience of multi-tasking to work on multiple projects at the same time.	**E**	**A/I**
Experience of industry/capital/research liaising	**E**	**A/I**
Skills and Knowledge:		
Excellent project management skills and teamwork	**E**	**A/I**
Excellent communication (written and oral), interpersonal and IT (email, spreadsheets, word processing and databases) skills	**E**	**A/I**
Understanding of clinical protocol development and associated ethics	**E**	**A/I**
Understanding and experience of clinical research ethics and regulatory applications (via IRAS Applications)	**E**	**A/I**
Ability to work without direct supervision; to manage own workload throughout and display good organisational ability	**E**	**A/I**
ICH-GCP, Human Tissue Act and Informed Consent training	**D**	**A/I**
Experience of report/paper writing	**D**	**A/I**
Experience using social media to promote science and/or direct to patient recruitment strategies	**D**	**A/I**
Competencies and Personal Attributes:		
Flexible approach to workload	**E**	**I**
Ability to work on own and as part of a team	**E**	**I**
Enthusiasm and commitment	**E**	**I**
Business Requirements:		
Clinical Trials experience	**D**	**A**

Essential Requirements are those, without which, a candidate would not be able to do the job. **Desirable Requirements** are those which would be useful for the post holder to possess and will be considered when more than one applicant meets the essential requirements.

Author	A N Siriwardena	**HRBA**	SL