Job Description

Job Title	Clinical Trials Manager
School/Service	Lancashire Clinical Trials Unit (CTU)
Grade	H
Responsible to	Principal Clinical Trials Manager and Lancashire CTU Directors
Responsible for	Clinical Trial(s) Management

Job Purpose:

The post holder will be expected to have a leading role in planning, coordinating and completing projects; providing strategic, tactical and operational management skills in the set-up and implementation of such projects. Trial responsibility for ensuring effective trial management (under the leadership of Principal Clinical Trials Manager) and good clinical practice; working within current legislative and governance frameworks. Trial managers are required to organise and motivate others demonstrating flair, enthusiasm, innovation and leadership when faced with challenges and targets. Knowledge and experience of the conduct of trials involving complex and non-drug interventions will be an advantage.

Main Duties and Responsibilities

1. Work with Principal Clinical Trials Manager, Principal Investigators and relevant Stakeholders to identify resource implications prior to involvement with trials, this will include such items as staffing, time management, finance, travel and project timeline.
2. Manage the initiation, day to day running and closure of trial centres. Ensuring all staff have the relevant training, skills and knowledge for their role. Monitor quality and completeness of CRF`s. Provide effective advice to sites on trial related matters including AE, SAE, IME incidence reporting, data queries, organisation of source files, monitoring procedures and schedules, reporting on such matters to Principal Clinical Trials Manager. This may involve multiple complex trials.
3. Monitor and report recruitment of participants into trials, identifying barriers and implementing strategies to improve recruitment.
4. Play a leading role in developing, implementing and maintaining (trial specific as needed) administrative systems ensuring that all key responsibilities are met. Responsible for producing and maintaining trial master file and all site specific files, ensuring that all documents and approvals are current.
5. Play a leading role in the monitoring and implementation of Standard Operating Procedures, and where required (in conjunction with Principal Clinical Trials Manager), auditing such procedures to ensure that they are fit for purpose and accurately detail all trial processes.
6. Liaise with Trial Steering Committees, Data Monitoring and Ethics Committees. Provision of regular and ad-hoc information to include reports, updates as needed.
7. Plan and support the meetings and work of the various groups and bodies associated with trials.
8. Ensure the inclusion of all stakeholders and consumer group representatives at the appropriate level and time within the scope of the project.
9. Ensure compliance with Research and Clinical Governance standards: ethics, R&D and ICH Good Clinical Practice Guidelines for Research.

10. Liaise with Principal Clinical Trials Manager to ensure that trials are meeting targets, are producing meaningful output and to predict and plan any changes that warrant requests to changes in protocol, funding or time.
11. Undertake other duties and research-related activities relevant to the role and commensurate with the level of the post as directed by the appraiser, Principal Clinical Trials Manager and Directors of Lancashire Clinical Trials Unit where appropriate.

Person Specification

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Attributes	Essential	Desirable	Measured By
Work Experience	Significant experience in clinical trial activities for IMP and/or Device studies and understanding of current issues in delivery of clinical trials research Experience of making applications to ethical committees and regulatory bodies including HRA and MHRA Experience of working independently and as part of a team with project management and research responsibilities Competent in computer and report generating skills Experience of working within the NHS or in a clinical academic research setting	Hands on experience of central and/or site-based trial monitoring Experience in managing complex information or projects	Application Form and Interview
Education/ Qualifications	1st degree (or equivalent professional qualification) in a relevant discipline Formal training in Good Clinical Practice Detailed knowledge of the provisions of the Research Governance Framework and the EU clinical Trials Directive	Higher degree in a relevant discipline and/or extensive research/trial management experience	Application Form and Interview

Skills/Abilities	Ability to acquire in-depth knowledge of trial protocols and to communicate this to professionals and lay persons Ability to communicate highly complex information effectively at all levels and overcome barriers to understanding Self-motivated and able to motivate and influence others within a multi-disciplinary team from a range of professional backgrounds and levels of seniority Ability to work in a methodical manner showing accuracy and attention to detail when needed but has ability to innovate and respond to change Ability to write reports and present data at meetings and conferences To be able to contribute to collaborative links nationally and internationally Good IT skills particularly MS Office software and use of databases (Word, Excel, Access, Project) Able to work flexibly as required by the project	Advanced IT skills Enthusiastic	Application Form and Interview
Other	Effective time management and prioritisation of work Willing to travel (perhaps extensively) as required by projects		Application Form and Interview

	Full driving licence Act with Integrity, maintaining the privacy and dignity of participants Respect colleagues and actively give and receive feedback An understanding of and demonstrable commitment to the University's Values of Common Sense, Compassion, Teamwork, Attention to Detail, and Trust as a framework for decisions, actions and behaviours		