Job Profile
Job Description

Queen Mary University of London

Job Details		
Job Title:	**Clinical Trials Coordinator – Maternity cover**	
Institute & Centre:	Institute of Dentistry (IoD), Centre for Oral Clinical Research (COCR) Centre for Immunobiology and Regenerative Medicine	
Reports to:	Accountable to: Clinical Research Facility (CRF) manager. Overall responsibility: Centre Lead	
Grade:	5 Professional Services	**Part Time (**60% FTE) Working days to be confirmed
Appointment period:	12 months	
Current Location:	Dental Hospital, Whitechapel	

Job Context

The Institute of Dentistry (IoD) is one of six Institutes in the School of Medicine and Dentistry (SMD), located primarily on our Whitechapel site. It comprises five academic centres and employs in excess of 170 staff (c77 FTE).

The IoD has been conducting internationally recognised research in oral and dental sciences in Whitechapel for more than a century and is the top rated UK Dental School for quality of dental research, as assessed in the 2014 Research Excellence Framework. It has a long and proud history of providing internationally renowned taught programmes and currently offers 2 undergraduate programmes and 12 Postgraduate taught programmes, with a combined cohort of c500 students. In 2014, we opened the first new dental school and hospital in the UK for 40 years, the stunning £78m Royal London Dental Hospital, incorporating some of the most technologically advanced dental facilities in the country.

Job Purpose

The post holder will play a key role in the set up and ongoing management of new clinical trials in the Centre for Oral Clinical Research (COCR).

To provide trials management advice and support to applicants when preparing the research dossiers towards REC and HRA review and when necessary to MHRA. The trial manager will be conducting due-vigilance review and revision of initial trial documentation and ongoing amendments; including consideration of the sponsorship conditions, sponsor Standard Operating Procedures (SOPs) or the different partners' and collaborators' local Working Practices (WPs) according to which trials can be implemented.

This is a key research governance and support role, which requires understanding and expertise in research management, clinical trials, regulatory and research governance frameworks in the UK, EU or Internationally when applicable. The post holder will:

- Work closely with the Clinical Research Facility Manager to develop a portfolio of clinical trials including the critical review and revision of any documentation and applications needed for the set-up, approvals and active ongoing management of new and existing clinical trials to be established in the COCR or transferred in from other research establishments.

- Be responsible for day-to-day management and co-ordination of the clinical trial(s); in set up or ongoing management phase; including updating the research teams on trials' progress and ensure maximum collaboration from the diverse research teams contributing to the development of the

Job Purpose

research dossiers towards REC and HRA review and when necessary to MHRA. Experienced working with Integrated Research Application System (IRAS) for a portfolio of clinical trials.

- Ensure all research undertaken safeguards the well-being of the participants, is conducted within ICH Good Clinical Practice Guidelines, and complies with the Medicines for Human Use Act (Clinical Trials) Regulations (2004) and the Research Governance Framework for Health and Social Care 2005 as well as Human Tissue Act (HTA).

Main Duties & Responsibilities

- Supporting the development of study protocols and patient information materials. Ensuring the research team contributing to the development of study protocols and patient information materials comply with the highest scientific, regulatory and ethical standards.
- Ensuring appropriate sponsorship arrangements are in place for the conduct of the study.
- Liaising with Queen Mary and Bart's Health NHS Trust Joint Research Management Office (JRMO) contracts managers, sponsor organisations, key collaborators and pharmaceutical partners to ensure appropriate contractual arrangements for trial conduct are in place.
- Negotiating with external collaborators; including academic or NHS collaborators and commercial; pharmaceutical or medical device partners; to ensure effective provision of protocol treatments/supplies.
- Obtaining regulatory, ethical or HRA approval and local NHS capacities and capabilities reviews for trial conduct and ensuring that amendment and annual progress reports are prepared and submitted as necessary.
- Ensuring overall and day-to-day management, monitoring and coordination of all relevant aspects of existing active clinical studies.
- Ensuring successful launch of new trials, including contribution to the development of presentations and training materials at investigator meetings, in conjunction with the Clinical Research Facility manager, the Chief Investigator (CI), the Clinical Project Lead and other research team members.
- Monitoring payment activities to the participating centres.
- Liaise with lead investigators, pharmacists, research nurses, coordinating centre and all other relevant personnel to ensure deadlines for submissions are met.
- Supporting the Clinical Research Facility Manager in developing relevant research governance training and support where required.
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- Contributing to Quality Management (QM) Systems, including:
  - Assisting with the preparation and conduct for any GCP inspection (conducted by MHRA or other regulatory body) or audit (conducted by JRMO on QMUL/Bart's sponsored studies or an external sponsor) or by a third party audit.
  - Contributing to the review of Centre systems and processes to ensure continued compliance with relevant legislation;
  - Contributing to Quality Assurance (QA) or Trials' risk assessment meetings or other working groups.
  - Advising and supporting staff on the ethical principles, research governance and regulatory standards for the conduct of clinical trials;
  - Assisting with the audit of trials activity within the Unit.
- Proactive member of study specific Trials' Management Groups (TMGs), including:
  - Attending and contributing to regular management and clinical trials' operations meetings to provide feedback on the performance of the clinical projects team;
  - Contributing to regular team meetings and providing feedback at those meetings;
- Assist with the production of key documents, including metrics and annual reports.

Main Duties & Responsibilities

- Queries and data entries.
  - Support data entries (directly or whilst training/supervising other team members engaged in data entry).

Other:

- Ensure that all research is undertaken according to GCP, Trust and College protocols.
- Ensure patient confidentiality is maintained at all times and fulfils the requirements of the Data Protection Act.
- The post holder must at all times carry out their responsibilities with due regard to the College's Equal Opportunities policy.
- The post holder must have a good understanding of hospital governance aspects of the clinical trials.

The above list of responsibilities is not exhaustive and the jobholder may be required to undertake other duties commensurate with the level of the role, as reasonable requested by their line manager.

This job description sets out the duties of the post at the time it was drawn up. Such duties may vary from time to time without changing the general character of the duties or level of the responsibility entailed. Such variations are a common occurrence and cannot in themselves justify a reconsideration of the grading of the post.

This table lists the essential and desirable requirements needed in order to perform the job effectively. Candidates will be shortlisted based on the extent to which they meet these requirements.

	Requirements	Essential / Desirable
Qualifications	Undergraduate degree or equivalent in an area of relevance to healthcare research	E
	Relevant postgraduate qualification or equivalent experience	E
Knowledge, Skills and Experience	Thorough working knowledge of research governance requirements, GCP requirements and processes for clinical trial management	E
	Able to provide scientific and logistical input into trial documentation including protocol, CRFs, patient documents and reports	E
	Ability to work with Integrated Research Application System (IRAS) across a portfolio of clinical trials and train other research team members on how to use this system for the completion of regulatory submissions	E
	Knowledge of the EU Clinical Trials Directive, HTA Act UK Clinical Trials Regulations, Principles of Good Clinical Practice (GCP) and research governance framework legislation, together with the ability to disseminate the knowledge and information	E
	Knowledge of laboratory quality systems and procedures	D
	Knowledge of international standards and regulations that apply to clinical trials	E
	Demonstrable IT skills, including: e-mail, word processing and databases (Microsoft Office packages, other database programmes)	E
	Demonstrable medical/technical writing skills	E
	Ability to communicate highly complex, sensitive or contentious information	E
	Ability to plan, manage, adjust and deliver complex projects, involving multiple agencies and individuals to tight deadlines	E
	Friendly, positive and professional disposition	E
	Able to work unsupervised and exercise considerable initiative	E
	Able to work in a multidisciplinary team	E
	Flexible and cooperative, while ensuring compliance to policy	E
	Proven interpersonal skills to work with clinical and management colleagues at all levels across a range of organisations	E
	Significant clinical research experience – including academic, CRO or pharmaceutical company	E
	Experience of directing and supporting staff	E

	Requirements	Essential / Desirable
	Experience of revising Clinical Trial Site Agreements (CTSAs) per trials' specifications and actively monitoring sites' invoices; when applicable costs are to be reimbursed as per CTSAs	E
	Experience of laboratory quality systems and procedures	D
	Proven record in project management / central coordination experience	E
	Significant experience with developing research SOPs	E
	Working experience of the EU Clinical Trials Directive, HTA Act UK Clinical Trials Regulations, Principles of Good Clinical Practice (GCP) and research governance framework legislation, together with the ability to disseminate the knowledge and information.	E
	When applicable be able to support studies incorporating elements of Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP)	E
	Independent clinical trial monitoring experience (internal and external)	E
	Experience of preparing for regulatory/Sponsor inspection	D
	Experience of negotiations with external organisations such as NIHR Comprehensive Local Research Network (CLRN) delegates, Chief Investigators, Sponsors and pharmaceutical companies	E
	Experience of liaising with sponsors' Joint Research Management Offices or sites Research and Development (RD) offices; ideally in NHS academic environment; but also in commercial Regulatory or Clinical Trials Operations environment or Quality Assurance (QA) departments	D
	Willingness to travel as required (within the UK) to participating sites as required to complete duties above	E
	Willingness to work on different QMUL sites	E
	Willingness to work flexibly as project demands	E

E – Essential: Requirements without which the job could not be done.

D – Desirable: Requirements that would enable the candidate to perform the job well.