Job Profile
Person Specification

Job Details		
Job Title:	**Research Portfolio Officer**	
School/Dept/Institute & Centre:	School of Medicine and Dentistry, Barts Cancer Institute, Centre for Experimental Cancer Medicine	
Reports to:	Centre Operations Manager	
Grade:	4	Full Time
Appointment period:	12 months	
Current Location:	Currently based at Charterhouse Square, although the post-holder may be required to move to another of the School's sites should the need arise.	

Job Context

Barts Cancer Institute (BCI) is one of six institutes within The School of Medicine and Dentistry (SMD). The Institutes are complementary and follow the same strategic plan for SMD, and also have Institute-specific objectives and requirements. The Institutes vary in scale, ranging in personnel from 150-400; financial turnover of £8 – £23 million per annum; and research income of £7 - £17 million per annum (for research active institutes).

In addition to the usual academic staff of a university, BCI also employs a significant number of clinical academic staff, who are intrinsic to the delivery of clinical practice primarily within Barts and The London NHS Trust.

The Centre for Experimental Cancer Medicine (CECM) is comprised of a Clinical Trials Unit (CTU) which oversees the set up and coordination of all early phase investigator led clinical trials sponsored by Barts Health or QMUL and the Cancer Research Delivery Group (CRDG) which is responsible for recruiting patients into all hosted trials, regardless of phase, at Barts Health, coordinating trials from a site perspective and collecting data. The post is based with the CECM CRDG.

Job Purpose

- To work with the CRDG Team to ensure the successful set-up of hosted clinical trials by co-ordinating with the Sponsor, Principle Investigator, NIHR CRN: North Thames and other departments / suppliers to provide accurate documentation and information for study set-up and managed to the highest standards, in a timely manner and to agreed levels of patient recruitment
- Proactively building and establishing excellent working relationships with Life Sciences Industry partners to provide a single point of contact service for the CRDG, liaising with the Life Sciences Industry to address and remove barriers to timely study site set up and acting as a point of contact for issue escalation.
- To manage CRDG portfolio reviews, with the clinical leads, to ensure studies are assessed for feasibility and appropriate recruitment targets are agreed
- To assist with the maintenance and development of the of the EDGE Research Management System including data input and managing reporting requirements for the CRDG

Main Duties & Responsibilities

Working closely with the CRDG and with both commercial and non-commercial sponsors to set-up clinical trials which are hosted by Barts Health NHS Trust. This will include maintenance of the Research Management System (currently EDGE) for trials in set-up, managing reporting requirements for the Centre from EDGE as required, and ensuring that appropriate information is collated at the beginning of the study to enable timely invoicing to an agreed schedule.

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Main Duties & Responsibilities

Main duties include:

1. **Ensuring that all research governance and regulatory requirements are met:**

- Be familiar with the regulatory and ethics requirements for the conduct of clinical research, especially the Research Governance Framework, ICH-GCP, and the processes of HRA, in order to ensure delivery of authoritative NHS Permission advice to investigators, academic collaborators, clinical research fellows, nurses and support staff as well as the sponsor where necessary.
- Responsible for obtaining NHS Permissions and local approvals with relevant departments within Bart's Health NHS Trust (BHT) (including pathology, radiology, pharmacy and others) for non-commercial CECM hosted study portfolio in accordance with BHT/QM Joint Research Management Office (JRMO) requirements.
- Co-ordination and submission of documentation to Research Governance Committee for trials approved for submission within the CECM hosted study portfolio.
- Co-ordination of local approvals for trials being processed through the University College London Partners (UCLP) Harmonisation Project.

2. **Ensuring effective set-up of studies hosted by Barts Health NHS Trust:**

- Liaise with investigators at Barts Health to ensure they have sufficient capacity and resource to carry out new research projects.
- Take lead on the timely completion of Feasibility and Expression of Interest questionnaires on behalf of the CRDG.
- Co-ordination and tracking of all Feasibilities or Expressions of Interests submitted to sponsors on behalf of Barts Health NHS Trust.
- Co-ordinating set-up meetings and Site Initiation Visits (SIVs) for CECM hosted study portfolio trials.
- Responsible for the creation of (or requesting from sponsor) Investigator Site File (ISF) and set-up of trials on the EDGE Research Management System for CECM hosted study portfolio trials ensuring correct version control is maintained at the set-up stage.
- Using knowledge of trial regulations, determining realistic timelines for study to set-up which can be used by the investigator and study team to facilitate appropriate planning of resources and determining milestones.
- Responsible for the creation of Patient Trackers for the study to be used by the CRDG and Finance Officer to ensure timely invoicing to agreed study schedule.
- On completion of site activation, provide accurate and concise handover to the CRDG, identifying and follow-up actions required.
- Continual review of resources and analysing protocol requirements to ensure accurate assessment of required resources for studies, then reporting back and advising CECM Management.
- Offering expert advice in ways to improve systems and processes in order to combat barriers to setting up sties and providing a better level of service to study sponsors.

3. **Maintaining efficient communication with relevant stakeholders at all times:**

- Primary point of contact for sponsors for collection, collation of all documentation required for study set-up and acting as a point of contact for issue escalation.
- Provide interface between the department and investigator for information such as imaging forms, costing reviews etc.
- Inform Principle Investigator of any issues / hold-up of trial set-up in a timely manner.
- Answer queries from research staff promptly and efficiently in relation to the requirements of legislation impacting on the conduct of clinical research, acknowledging all communication, and ensuring efficient flow of information.

Main Duties & Responsibilities

- Responsible for scheduling and co-ordinating documentation for the CRDG portfolio review meetings, with the clinical leads, including co-ordinating spreadsheet preparation, minute taking and action monitoring.
- Escalation of process issues to relevant departments to facilitate discussion and resolution.

4. **Ensuring appropriate measures are in place to facilitate accurate management of data once the study is open:**
   - Participate in the maintenance of the EDGE Research Management System.
   - Responsible for report generation from the EDGE Research Management System to support CRDG internal and external reporting requirement and for maintenance of trial based spreadsheets to facilitate collation of data for the CECM Annual Report, monthly reviews of accrual data and other reporting requirements as necessary.
   - Provide specialist advice and training to the CRDG to assist data capture on EDGE and the Patient trackers, this is a crucial aspect of the role as many of the reporting element and income of the CECM is dependent on accurate data capture.

The post-holder must at all times carry out their responsibilities with due regard to the College's Equal Opportunities policy.

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	Degree in biological sciences or an equivalent level of qualification or extensive relevant experience in a similar role	E
	A Levels or equivalent Grade A-C. (including a science subject)	E
Knowledge, Skills and Experience	Significant experience of working in a clinical research management environment	E
	Demonstrable experience of using a Clinical Trial Research Management database/software (e.g. EDGE)	E
	Proficient user of Integrated Research Application System (IRAS)	E
	Evidence of awareness of Good Clinical Practice and the regulatory environment that surrounds clinical research	E
	Experience of working on clinical trials in oncology	D
	Proven record in project management / central coordination experience	D
	Thorough understanding of Good Clinical Practice guidelines	E
	Comprehensive knowledge of local and national clinical trial regulations	E

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	Requirements	Essential / Desirable
	Detailed knowledge of the clinical trial development process	E
	Excellent IT skills, including email, word processing, spreadsheets and databases (Microsoft Office)	E
	Effective written and verbal communication skills	E
	Excellent organisational skills and ability to prioritise own workload	E
	Must demonstrate a critical and intelligent attention to detail and high standards of accuracy	E
	Ability to work on own initiative and problem solve	E
	Proven analytical skills	E
	Ability to plan, manage, adjust and deliver complex projects, involving multiple agencies and individuals to tight deadlines	E
	Ability to work autonomously with multiple deliverables and sponsors	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.