St George's School of Health and Medical Sciences

City St George's, University of London

Joint Research and Enterprise Services (JRES)

Clinical Research Associate

269-24-R

JOB DESCRIPTION

Post Title	Clinical Research Associate
Grade	Grade 6
Contract type	Fixed term for 24 months
Responsible to	Research Development and Governance Manager
Accountable to	Head of Research Governance and Delivery
Responsible for	Ensuring that Clinical Trials of Investigational Medicinal Products (CTIMPs) and other high risk studies sponsored by City St George's, University of London or St George's University Hospitals NHS Foundation Trust (SGH) (together: St George's) are conducted in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004, UK Policy Framework for Health and Social Care Research (2017), Good Clinical Practice (GCP) guidelines and other relevant legislation.
Liaises with	Internal: Clinical and academic research staff Administrative staff involved in supporting research External: MHRA and other regulatory bodies St George's University Hospitals NHS Foundation Trust Research funding organisations Other NHS and higher education organisations (research collaborators)

Overall purpose of job

The post holder is responsible for operationally overseeing a portfolio of CTIMPs and other high risk studies sponsored by St George's, ensuring they are set up, managed and conducted in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004, UK Policy Framework for Health and Social Care Research (2017) Good Clinical Practice (GCP) guidelines and other relevant legislation.

The post holder will support a portfolio of trials and will provide advice and support to clinical researchers on clinical trials, sponsorship and regulatory inspections. The post holder will play a key role in developing systems to support clinical trials monitoring work and sponsor oversight systems to ensure CTIMPS are delivered to the highest standard.

The post holder will also support regulatory projects within the JRES.

The post holder will need to be a highly effective and confident communicator, responsible for supporting and advising clinicians and for liaising with colleagues at collaborating institutions and with regulatory agencies, often working to tight deadlines.

1. Main Duties and Responsibilities

Clinical Trials

- Work with other CRAs to support the JRES' portfolio of trials.
- Support the delivery of trials to ensure the trials are run in an efficient way, conforming to their study protocols, SOP's, Operations Manuals, and all applicable regulatory and ethical standards.
- Liaise with regulatory agencies, research collaborators and other external organisations where required to enable the effective development of streamlined, harmonised research governance processes.
- Ensure appropriate MHRA, ethics review, HRA review, peer review and NHS R&D review for all sponsored CTIMPs.
- Work closely with the SGHT Clinical Trials Pharmacy (CTP) team, support and facilitate procurement of Investigational Medicinal Products (IMP) for allocated sponsored CTIMPs and oversee IMP management in compliance with Good Manufacturing Practice for all clinical trials.
- Support and maintain pharmacovigilance systems to ensure appropriate SAE, SUSAR and annual safety reporting to regulatory authorities and ethics committees and ensure procedures for the recording and reporting of AEs/ARs to the sponsor and other relevant parties are followed.
- Support the creation of study-specific monitoring plans with investigators and monitors (whether internal or contracted) and review and approve monitoring reports when required.
- Support the set-up, maintenance, closure and archiving/destruction of Trial Master Files and Investigator Site Files.
- Support the Clinical Trials Archivist in archiving activities by maintaining archiving policies which are compliant with the relevant legislation.
- Identify trial protocol, GCP and SOP deviations; in the event of Serious Breaches of GCP or the trial protocol, to ensure that the MHRA is notified in accordance with legal requirements.

- Support preparations for, and responses to, external regulatory inspections and audits (including in particular those instigated by external sponsors, the MHRA and the US Food and Drug Administration (FDA)), managing risks and identifying changes to policy and processes that may be required.
- Monitor the conduct of assigned CTIMPs and perform source data verification, ensuring that the essential documents and pharmacy records are present, complete, up to date and in line with requirements of the current legislation and SOPs.
- Ensure that technical information relating to any Investigational Medicinal Product (IMP) is verified, in accordance with relevant legislation and that drug accountability is documented to ensure that their receipt, storage, dispensing, administration and disposal is undertaken in accordance with the study protocol and drug safety information.
- Verify that participants meet eligibility criteria; that consent is obtained according to ICH GCP and relevant legislation and signed and dated consent documentation is appropriately filed.
- Ensure that subject withdrawal from a trial and/or non-compliance with the protocol is documented in the site file appropriately, is discussed with the Investigator and is reported to the Sponsor.
- Ensure that all procedures for recording and reporting Adverse Events/ Adverse Reactions to the Sponsor are followed and that Investigator provides the JRES with all the necessary reports and notifications to be submitted to the appropriate regulatory authorities.
- Ensure that the procurement, processing and storage of biological samples is undertaken within the terms of ethical approval and meets the necessary requirements of the research protocol in order to make certain the safe handling, ethical integrity and quality is assured.
- Verify the validity, accuracy and integrity of data collected during the trial.
- Provide written monitoring visit reports on the progress, management and conduct of clinical trials and follow up actions as required.
- Conduct risk-based assessments and be involved in pre-trial planning and protocol development to ensure an appropriate monitoring plan is put in place; perform pre-trial site assessments and on-site initiation visits.
- Assist in preparations for external audit or mandatory inspections.

<u>Developing systems and procedures.</u>

- Develop, improve and maintain the Quality Management System (QMS) for St George's clinical trials, including developing, implementing, disseminating, reviewing and updating Standard Operating Procedures (SOPs) and other quality management tools covering the life cycle of a clinical trial, ensuring all procedures are fit for purpose and effective.
- Work with teams across JRES to develop systems to identify potential sponsored CTIMPs at an early stage and to facilitate their effective support in all aspects.
- Develop and maintain a database of clinical trials monitoring activity in accordance with the local monitoring programme.
- Participate in the development and implementation of Quality Assurance and Quality Control systems for clinical trial monitoring.
- Participate in, and lead on, regulatory projects within the JRES, as assigned.

<u>Liaison with internal staff.</u>

- Liaise closely with key research personnel (PIs, Research Nurses, Trial Coordinators and Data Managers) to provide support and advice during the life cycle of a clinical trial.
- Liaise with divisional research administrators, academic staff and other professional services departments as necessary to support financial administration of research projects.
- Support and provide activity and status reports on sponsored CTIMPs, governance breaches, incidents etc. for committees and other bodies as appropriate.
- Participate in team, JRES, and research support network meetings, taking notes or minutes of meetings on occasion. Represent others on relevant committees/working groups.
- Work with other professional services departments to develop good practice and implement effective services and systems.

Liaison with regulatory agencies and collaborators.

- Perform remote monitoring as deemed necessary and as defined in Sponsor's monitoring procedure, and ensure that monitoring reports for participating sites with delegated monitoring responsibility are reviewed.
- Liaise with regulatory agencies, research collaborators and other external organisations where required to enable the effective development of streamlined, harmonised research governance processes.

General.

- Travel to other hospitals and/or research institutions and be able to work flexible hours in order to meet the demands of the monitoring schedule.
- Undertake training and staff development as appropriate to the grade and nature of the post.
- Undertake other duties as may be requested by the JRES and are consonant with the grade of the post.

It is expected that staff working with St George's School of Health and Medical Sciences, will be involved in our mentoring and tutoring activities, as appropriate, as well as supporting admissions, student recruitment and access and widening participation activities (MMI interviews, Open Days, school visits, clearing etc) where applicable. All academic staff are expected to act as a personal tutor.

You are also expected to undertake other activities appropriate to your grade as directed by your manager. This job description reflects the present requirements of the post. As duties and responsibilities change, the job description will be reviewed and amended in consultation with the post holder from time to time. City St George's, University of London aims to provide opportunities for all its employees to develop the skills required to be successful in their role and to further develop their careers.

St George's School of Health & Medical Sciences, University of London, is committed to the San Francisco Declaration on Research Assessment (DORA) principles.

Person Specification

Criteria	Description	Essential/ Desirable	How it is to be tested
Qualifications	A first degree or equivalent qualification/ experience. (A candidate without a first degree will need to demonstrate in her/his application the equivalence of the experience and qualities that they would bring to the role.)	E	PQ/AF
	Evidence of GCP training	E	PQ/AF
Experience	Experience of managing and auditing/monitoring Clinical Trials of Investigational Medicinal Products (CTIMPs) in an NHS Trust, University, pharmaceutical company or other organisation, including experience of working with clinical researchers and consultants.	E	**SS1**, AF, INT
	Experience of Ethics, MHRA and R&D submission and approval processes	D	AF,INT
	Experience of writing, reviewing and working to standard operating procedures	D	AF,INT
	Experience of developing and implementing new practices and policies within a complex organisation	D	AF,INT
	Experience of developing GCP-compliant systems for managing and overseeing CTIMPs	D	AF,INT
Knowledge/ Skills	Expert knowledge and understanding of Research Governance legislation the UK Clinical Trials Regulations and GCP, and of other elements of legislative and regulatory framework and sponsorship issues relating to clinical research	E	**SS2**, INT, ST

	Excellent communication and presentation skills, both written and oral, and experience of communicating complex issues to a variety of audiences, and the ability to liaise effectively with senior colleagues both within and outside the organisation	E	AF, **SS3**, INT, ST
	Excellent record keeping skills, including the maintenance of confidential records, a high degree of accuracy in your work and the ability to pay close attention to detail.	E	**SS4**, AF, INT
	The ability to read and analyse complex documents and extract salient information to give clear explanations and advice to colleagues at all levels of experience and seniority	E	AF, **SS5**, INT
	Project management skills, experience of planning and managing projects, and the ability to plan, manage and deliver complex projects, involving multiple agencies and individuals and a range of tasks, to tight deadlines	E	AF, **SS6**, INT
	Good practical IT skills (including Word, Excel and a good understanding of databases), and an understanding of the application of IT solutions to information management requirements	E	AF, ST
	Negotiation skills and experience of negotiating with external bodies to achieve organisational objectives	D	AF,INT
	Experience of running training sessions for staff, including developing training materials and delivering presentations	D	AF, INT
Personal Attributes	Flexible and adaptable in your approach to work and the ability to work well in a team	E	INT
	Ability to maintain high standards of confidentiality	E	INT
	Willingness to work longer/flexible hours as necessary to meet deadlines	E	INT

	Committed to embedding practices which embrace diversity and promote equality of opportunity	E	INT

Key:
PQ=Prerequisite Qualification, AF=Application Form, CV=Curriculum Vitae, SS=Selection/Supporting Statements, ST=Selection Test/Presentation, INT=Interview

Updated January 2025.

About City St George's, University of London

City St George's, University of London is the University of business, practice and the professions.

City St George's attracts around 27,000 students from more than 150 countries.

Our academic range is broadly-based with world-leading strengths in business; law; health and medical sciences; mathematics; computer science; engineering; social sciences; and the arts including journalism, dance and music.

In August 2024, City, University of London merged with St George's, University of London creating a powerful multi-faculty institution. The combined university is now one of the largest suppliers of the health workforce in the capital, as well as one of the largest higher education destinations for London students.

City St George's campuses are spread across London in Clerkenwell, Moorgate and Tooting, where we share a clinical environment with a major London teaching hospital.

Our students are at the heart of everything that we do, and we are committed to supporting them to go out and get good jobs.

Our research is impactful, engaged and at the frontier of practice. In the last REF (2021) 86 per cent of City research was rated as 'world-leading' 4* (40%) and 'internationally excellent' 3* (46%). St George's was ranked joint 8th in the country for research impact with 100% of impact cases judged as 'world-leading' or 'internationally excellent'. As City St George's we will seize the opportunity to carry out interdisciplinary research which will have positive impact on the world around us.

Over 175,000 former students in over 170 countries are members of the City St George's Alumni Network.

City St George's is led by Professor Sir Anthony Finkelstein.

St George's School of Health and Medical Sciences currently offers a range of employee benefits:

Salary:	The salary range for **Grade 6** is **£42,632 - £49,250**, inclusive of London Allowance, and appointment is usually made at the minimum point.
Hours:	35 hours per week which can be done flexibly in various ways or part time/job share can also be considered. Staff are expected to work the hours necessary to meet the requirements of the role and this will be dependent on the service area.
Annual leave:	30 days per annum. Plus eight UK public holidays and four days when City St George's, University of London is closed (usually between Christmas and New Year). Part time staff receive a pro rata entitlement.
Pension:	Membership of competitive pension schemes with generous employer contribution and a range of extra benefits. Superannuation Arrangements of the University of London (SAUL) London Pension Fund Authority (LPFA) Universities Superannuation Scheme (USS) National Health Services Pension Scheme (NHSPS) (existing members only)
Flexible working	Flexible working, including part-time or reduced hours of work, opportunities to work from home for many posts, compressed hours and local flexibility in agreeing start and finish times of work.
Travel	City St George's, University of London offers an interest free season ticket loan and participates in the Cycle to Work Scheme.
Gift Aid	If you would like to make a tax-free donation to a charity of your choice, this can be arranged through our Payroll.
Sports and Leisure Facilities	Rob Lowe Sports Centre, situated on the St George's Healthcare NHS Trust site offers exercise facilities that can be utilised by City St George's, University of London staff. Within walking distance from St George's is Tooting Leisure Centre. Facilities include a swimming pool, gym and various exercise classes. The Centre offers staff an all-inclusive corporate membership. For more information please contact Tooting Leisure Centre.

Shops and facilities There are a number of shops and facilities situated on site including ATMs, student bar and shop, Pret a Manger, M&S Simply Food store, library and multi-faith room.

Informal enquiries

Informal enquiries may be made via email to: gbullock@sgul.ac.uk

Making an application

All applicants are encouraged to apply on line at http://jobs.sgul.ac.uk as our system is user friendly and the online application form is simple to complete. Please note that CVs only will not be accepted.

For any accessibility issues please contact hrhelp@sgul.ac.uk

Closing date: 16 January 2025

Interview date is to be confirmed. As shortlisted candidates will be notified by email, it is imperative that you provide an email address that is accessed frequently.

Please quote reference **269-24-R**

We are delighted that you are interested in working at St George's School of Health and Medical Sciences. You will be notified of the outcome of your application by email. We aim to respond to all candidates within 5 weeks of the closing date of the vacancy.