UNIVERSITY OF MEDICINE AND HEALTH SCIENCES

RCSI

Job Title:	Assistant Good Clinical Practice Monitor
Department:	Sponsorship Office
Reporting to:	Quality and Regulatory Affairs Manager
Location:	RCSI affiliated Hospitals (as applicable)
Contract/Duration	Specified Purpose Contract initially to aligned with maternity leave with the potential of the role being made permanent following the maternity leave period
Closing Date:	14-Dec-2023

RCSI is a community of academic, research, clinical and professional staff working collaboratively to lead the world to better health. Here, you will thrive in an innovative and inclusive atmosphere and your personal development and wellbeing will be supported. We invite you to join us to help deliver on our exciting mission "To educate, nurture and discover for the benefit of human health". We seek candidates whose experience to date has prepared them to contribute to our commitment to the "Race Equality Action Plan 2021-2024" at RCSI. Our students come from all walks of life and so do we. We hire great people from a wide variety of backgrounds. This makes our university stronger and ensures we hire the best talent.

For each of the last six years, RCSI has been positioned in the Top 300 of universities worldwide in the Times Higher World university Rankings. We are proud to announce that RCSI has ranked first in the world for "Good Health and Well-being" in the Times Higher Education #SDG Impact Rankings 2023. This reflects our commitment to supporting people of all ages to live healthy lives and our work to promote the concepts of well-being and positive health. Our values of Respect, Collaboration, Scholarship and Innovation continue to unite and direct our purpose.

About Our Research

RCSI recognises that excellence in research is critical to the quality of its educational activities, its credibility, and, overall, to its mission to enhance human health. RCSI's research strategy aims to build upon its strength in translational biomedical and clinical research to deliver transformational, high impact changes in health care. Targeting both Irish national and EU funding, along with increased collaboration with industry, is a major part of the RCSI research strategy. Forging increased collaboration between RCSI PIs and industry is of critical importance to achieving success in this area. RCSI is also committed to provide its researchers with the supports and developmental opportunities to enable them to continuously grow and support their overall career development.

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Summary of Post

This position will involve monitoring RCSI sponsored clinical trials for compliance with the International Council on Harmonisation of Good Clinical Practice guidelines (ICH GCP) and applicable regulatory guidelines. In addition, this role will include pharmacovigilance duties on behalf of the RCSI Sponsorship Office.

Specifically, the duties of the post are:

Pharmacovigilance responsibilities will include:

- Review of standard operating procedures to support RCSI pharmacovigilance processes
- Collection, processing, and tracking of serious adverse event reports from hospital sites
- Quality Control (QC) checking of collection, processing, and tracking of serious adverse event reports
- Assist the QRAM with safety-related regulatory reporting to competent authority and ethics committee(s)
- Assist the Principal Investigator and the Quality and Regulatory Affairs Manager (QRAM) in the training of clinical site staff on safety reporting requirements and processes

GCP monitoring responsibilities:

Be responsible for the monitoring of RCSI sponsored studies or external studies as assigned to you, to include but not limited to;

- Check that reported study data are accurate, complete and verifiable from source documents;
- Check for compliance with approved version of protocol, standard operating procedures, GCP and applicable regulatory requirements;
- Check for the proper storage, dispensation, and accountability of all Investigational Product(s) and trial-related materials;
- Regularly review the status of the contents of the site file;
- Issue, investigate and resolve data discrepancies.
- Monitor and maintain site personnel list, qualification and training records.
- Ensure that all reportable events are identified, clearly documented and reported per protocol and as per applicable regulations.
- Ensure any identified non-compliance issues are addressed in a timely manner, clearly communicated, documented and escalated as required through monitoring visits.
- Support regulatory inspection activities as required.
- Act as direct line of communication between the site team personnel and the RCSI Sponsorship Office

- Support the site team personnel with clinical research activities (e.g. SOP development, protocol amendments as needed).
- Assist the QRAM in delivering Good Clinical Practice certification training when required;
- Devise a monitoring plan for each sponsored study you are assigned to
- Assist the QRAM in preparing the Monitoring and Auditing section of clinical trial protocols
- Assist in the delivery of site initiation meetings on behalf of RCSI Sponsorship office prior to study start up in association with the PI and his/her team;
- Be responsible for writing and distributing time sensitive site visit reports, tracking resolutions of outstanding issues, and ensuring compliance with regulatory requirements, ICH guidelines, Standard Operating Procedures (SOPs), the study protocol and overall research objectives;
- Provide support to the PI and QRAM in the start-up, enrolment, follow up and closure of clinical trial activities.
- Provide clear written communication to clinical sites and project team members through monitoring reports, follow-up letters, study memos, and general correspondence.

Professional development opportunities and requirements

- Undertake further education as appropriate to keep updated with changes within the field of Clinical Research or your assigned research project.
- Take responsibility for own professional development and skills updating including maintaining a record of training, continuing education and continuing professional development.
- Attend and participate in:
    - In service and staff education.
    - Sponsor Management meetings.
    - Appropriate outside conferences and/or other professional development activities.

Qualifications – (Essential):

- Degree level qualification (or equivalent e.g. nursing qualification) in a clinical or life sciences related subject.

Knowledge & Experience – (Essential):

- Significant recent experience in a clinical research setting.
- Excellent knowledge of the ICH GCP Guidelines.
- Willingness and flexibility to travel between work sites if required.
- Excellent IT skills including Microsoft Office (particularly Word, Excel and PowerPoint) and internet and email systems.

- Good decision making, critical thinking and problem resolution based skills.
- Ability to build strong working relationships and demonstrates good leadership skills.
- Strong organisational skills and the ability to manage and co-ordinate diverse projects.
- Highly effective oral and written communication skills, particularly report writing.
- Effective negotiating, influencing and persuasion skills.
- Attention to detail and the ability to work effectively in an environment characterised by tight timelines and changing priorities.
- Self-motivated, able to work independently, as well as in multi-disciplinary teams, and with the intellectual flexibility to continually develop and learn new skills to compliment the position.

Knowledge & Experience – (Desirable):

- Relevant experience in any of the following areas: clinical trial monitoring, project management, drug safety, or clinical research nursing.
- Knowledge of HPRA clinical trial and safety regulations, ICH GCP Guidelines, global safety regulations and other applicable regulatory guidance documents.
- Previous experience of clinical research document development and contribution to protocol development.
- Experience of standard operating procedure development or organisational policy development.
- Previous experience in the development and maintenance of safety databases.

- Proven leadership and management skills.

We are all too aware that imposter syndrome and the confidence gap can sometimes stop fantastic candidates putting themselves forward, so please do submit an application — we'd love to hear from you.

Application Process

Please apply online through the RCSI careers portal on the closing date with your CV and cover letter.

Informal Enquiries can be directed to Mandy Jackson (mandyjackson@rcsi.com). Please note we do not accept CVs directly.

Click here to read our Recruitment and Selection Policy for Researcher.

Employee Benefits

RCSI make sure you have the resources you need to thrive by offering a wide range of benefits in areas including time away, finance, community, health, and well-being and insuring your financial future. Below are some additional benefits available to you as an RCSI employee:

- 20 days annual leave for full time employees, plus an additional 6.5 Privilege days
- Flexible/hybrid working options for colleagues across many roles
- Additional leave options incl. paid maternity leave, paternity/parental leave, study leave
- 7% Employer pension contribution
- Onsite gym €10 per/mth incl. classes and PT sessions
- Childcare support 20% discount at Giraffe
- Free eye test and annual flu vaccination
- TaxSaver commuter tickets and Bike to Work schemes
- A site sustainability team focusing on the environmental initiatives; *Green Campus Initiative* '
- Competitively priced café and restaurant
- Equality, Diversity & Inclusion forums, and network groups
- Employee assistance programme with Spectrum Life
- Learning and Development training programmes incl. LinkedIn Learning for career progression
- Discounted services incl. GP visits, 10% off dental, staff parking, mobile tariffs, Group Scheme discount on numerous brands
- Sports and social club incl. yoga, Pilates, fitness classes, Zumba, running club, social evenings, Summer BBQ
- Ticket Draws for events including; Rugby, Taste of Dublin, Dublin Horse Show, theatre, music & comedy events

Note: This job description may be subject to change to reflect the evolving requirements of the Department and RCSI. Similar vacancies that arise in the next 6 months may be filled from the pool of applicants that apply for this position. RCSI is proud to be an equal opportunity employer and welcome applications from all suitably qualified persons regardless of their gender, civil status, family status, sexual orientation, religion, age, disability or race. RCSI is committed to embedding equality, diversity and inclusion (EDI) across everything we do. This ensures we can all work and learn in an environment defined by dignity and respect. Eligibility to work in Ireland is a requirement of this role, Proof of eligibility documentation will be required at a later date. Under limited and specific circumstances

(research/ specialist roles) RCSI may be in a position to seek a hosting agreement and/or work permits. Employees are required to undertake 6 months service in their current role before applying for other internal opportunities, unless agreed in advance by the SMT representative