 

**Senior Clinical Trial Coordinator**

**HRB Clinical Research Facility, Galway**

**NUI Galway.**

**Ref. No. NUIG 002-20**

Applications are invited from suitably qualified candidates for a fixed-term contract position as a Senior Clinical Trial Coordinator within the HRB Clinical Research Facility at the National University of Ireland, Galway (CRFG). The position is available immediately for a period of two years, with potential to extend subject to project success and funding acquisition.

The HRB Clinical Research Facility, Galway’s (CRFG) remit is to contribute to the development, coordination and service delivery of clinical research in Ireland and the support of emerging academic investigators. Multidisciplinary teams work in a coordinated fashion to improve our understanding of a variety of diseases and to develop new strategies to help tackle these challenges. The Centre provides patients with the latest advances in areas such as psychiatry, cancer, obstetrics and gynaecology, diabetes, inflammatory diseases, critical illness, cystic fibrosis and cardiovascular disease amongst others. We provide supporting services in quality and regulatory oversight, data management, study design and roles associated with the legal sponsorship of regulated clinical trials.

Please see [www.crfg.ie](http://www.crfg.ie/) for more information on the facility.

**Job Description:**

The Senior Clinical Trial Coordinator works under the direction of the CRFG Director/Clinical Trials Programme Manager and/or the Chief Investigator to co-ordinate studies for regulated (academic or commercially sponsored) clinical trial(s) and/or clinical investigation(s) and/or for non-regulated studies in the CRFG. The role is part of a multi-disciplinary team within the CRFG co-ordination unit.

This is a lead project coordination and management role within the coordination unit of the CRFG and the post holder has a senior level coordination role leading research studies, clinical trial(s) or clinical investigation(s) throughout the study lifecycle of set-up, execution, close-out and reporting in addition to mentoring coordination personnel in the unit.

The Senior Clinical Trial Coordinator supports the Clinical Trials Programme manager and the clinical trial coordinators to ensure that the studies coordinated in the CRFG coordination team are in line with Good Clinical Practice (GCP) and/or ISO 14155, internal SOPs and policies and relevant legislation and regulatory requirements. The role acts at a senior level and involves mentorship of clinical trial coordination team(s), involving tutoring and training of more junior or less experienced coordinator team colleagues. Where appropriate the role will act as project leader and as a line manager of research teams as required.

The role leads the development and setup of appropriate clinical trial coordination processes, documents, SOPs and associated templates to guide the successful and standardised execution and delivery of clinical trials in the CRFG co-ordination unit. The role involves hands on execution of operational trial duties including the generation of key study documentation, management of resources, scheduling activities, reporting and training of study personnel in accordance with GCP. The Senior Clinical Trial Coordinator undertakes periodic research landscape review to ensure adherence to applicable legislation. The role demonstrates leadership on complex and high risk processes within the operational team, possesses and disseminates specialist knowledge and demonstrates a level of autonomy and decision making, in collaboration with the CRFG Director/CT Programme Manager and/or the Chief Investigator.

The role contributes to and support the development of research grant funding applications and supports chief investigator and research teams as required to develop funding applications. The role has strong regulatory knowledge for the delivery of clinical trials and investigations in line with applicable regulations and all data protection and confidentiality data protection requirements.

In parallel, the post-holder may undertake clinical trial monitoring risk assessment, planning and operational activities, contributing to the delivery of the GCP-required monitoring function in the CRFG. The post holder may also be required to participate in coordination activities at the site or within the coordination team for non-regulated trials (e.g. recruitment) as required to support the activities underway in the CRFG.

**Duties:**

* Conduct clinical research work to a high standard in accordance with applicable clinical research regulations and protocols under the direction of the CRFG Director/Clinical Trials Programme Manager and/or the Chief Investigator.
* Undertake periodic landscape review for legislative requirements and implement processes to incorporate changes into existing systems or introduce new processes to ensure regulatory compliance.
* Leadership in the development and setup of appropriate clinical trial co-ordination processes, SOPs and associated templates to guide the successful and standardised execution and delivery of clinical trials in the CRFG co-ordination unit.
* Oversee and ensure key study milestones and objectives are tracking to an agreed timeline and adhere to project management best practices, promoting a best practice culture and leading on project management techniques within the facility.
* Lead the development and execution of study plans including leading the establishment of project plans, risk assessments and management and planning resources.
* Confirm the necessary processes are in place for management of the investigational product, as applicable and other study supplies.
* Take the lead on budget agreements and contract negotiation as appropriate and when delegated.
* Lead the process of protocol development, where applicable and design and support quality by design.
* Lead on the development of study monitoring strategies taking into account risk based approaches where applicable.
* Provide an advisory role and participate in the process of developing study related documentation such as CRFs, SOPs, information sheets, risk assessments, their amendments and associated quality assurance processes and documents as required for applicable studies.
* Lead the process, when required, to identify and procure vendors/suppliers or service providers, vendor/service provider assessment, and undertake any associated computer system validation requirements.
* Overall responsibility for distribution and management of essential documents and the Trial Master File(s).
* Complete host institution(s), Regulatory and Ethics Committee approvals submissions, as applicable.
* Lead on investigator and site evaluation and selection processes.
* Oversee the process of study initiations, site training, monitoring and close-out as required.
* Liaise directly with clinical sites as required to aid resolution of queries that arise and provide direction on implementation and management of the study protocol and procedures, and provide direction to coordination unit colleagues as applicable.
* Manage the study deviation process and liaise with sites and sponsor where required on the documentation, tracking and resolution of study deviations and associated corrective/preventive actions as required for the studies assigned.
* Implement, manage and oversee the study risk assessment/risk management processes for studies as required.
* Manage monitoring report/letter review and responses on behalf of sponsor for any queries/issues that arise during monitoring as required for the studies assigned.
* Implement systems to ensure compliance with all applicable regulations and guidelines, CRFG coordination level SOPs and/or CRFG site SOPs as required.
* Contribute to preparation for audits and inspections as required and present work as required during audits and inspections.
* Co-ordinate and undertake research study-specific processes according to specific study protocols and regulations.
* Prepare study and coordination unit summary reports as required.
* Provide training as appropriate on study-related activities and processes for site personnel.
* Provide training as required for new personnel undertaking co-ordination tasks.
* Update sponsor, Chief Investigator, data and safety monitoring committees, regulatory bodies, ethics committees, and other governing bodies on the status of all clinical trial activities.
* Provide support and backup as necessary for colleagues in coordination activities for other clinical studies forming part of the CRFG research portfolio.
* Implement strategies, support and lead as required, initiatives for participant recruitment for research studies as required.
* Undertake clinical data compilation and literature reviews for the research area and participate in dissemination of same at international meetings.
* Undertake research on, and analysis of, study outputs and measures with the aim of providing information for future funding proposals and applications.
* Determine appropriate methodologies and activities for relevant research studies in the CRFG whilst keeping up to date with research related methods and techniques.
* Contribute to manuscripts for publication to peer reviewed internationally recognised journals.
* Contribute to the dissemination of knowledge in the CRFG and facilitate research activities such as workshops and screening events.
* In parallel, additional duties for this role may be to undertake monitoring activities. This will be as assigned for a select number of studies in the CRFG to ensure patient safety, data integrity and GCP compliance.
* Continue to build personal skills by taking training opportunities as available and required.
* Carry out other appropriate and relevant duties under the direction of the CRFG Director/Clinical Trials Programme Manager and/or Chief investigator.

**Qualifications/Skills required:**

**Essential Requirements:**

* Degree level qualification in a clinical or life sciences related subject.
* Five years’ experience gained working in clinical research or a closely related field e.g. Pharma or Medical Device sector.
* Previous experience gained in a clinical trial co-ordination role working on the co-ordination of regulated clinical trials/investigations or non-regulated clinical studies.
* Experience working within a Quality Management adhering to QC and QA control systems and risk management processes.
* Experienced in leading and establishing new processes.
* Working knowledge of Good Clinical Practice as outlined per ICH GCP and ISO14155.
* Strong project management skills and ability to take the lead on the delivery of key project milestones.
* Leadership and mentoring skills.
* Excellent verbal and written communication/presentation skills.

**Desirable Requirements:**

* Post graduate level qualification in a clinical or life sciences related subject (MSc or PhD).
* A Project management qualification.
* Experience adhering to applicable regulations, guidelines and legislation for Clinical Trials.
* Previous experience gained project managing a cross functional project team.
* Experience in the identification, assessment and management of risk.
* Experience with research data collation, management and GCP monitoring.
* Self-motivated, high level of initiative and excellent attention to detail.
* Able to work both independently and as part of a team.

**Salary**: €54,717 - €71,430 per annum.

**Start date**: Position is available immediately.

**NB**: Gárda clearance is a requirement for this post

**Continuing Professional Development/Training**:

Researchers at NUI Galway are encouraged to avail of a range of training and development opportunities designed to support their personal career development plans.

Further information on research and working at NUI Galway is available on [Research at NUI Galway](http://www.nuigalway.ie/our-research/)

For information on moving to Ireland please see [www.euraxess.ie](http://www.euraxess.ie)

Further information about our centre is available at [www.crfg.ie](http://www.crfg.ie)

**To Apply:**

Applications to include a covering letter, CV, and the contact details of three referees should be sent, via e-mail (in word or PDF only) to grainne.macnamara@nuigalway.ie

Please put reference number **NUIG 002-20** in subject line of e-mail application.

**Closing date for receipt of applications is 5.00 pm Friday, 31st January 2020.**

**A panel may be formed for future similar posts.**

All positions are recruited in line with Open, Transparent, Merit (OTM) and Competency based recruitment

National University of Ireland, Galway is an equal opportunities employer.