Research Associate/ Project Coordinator

HRB Clinical Research Facility

School of Medicine, Nursing and Health Sciences

Ref. No. NUIG-039-19

Applications are invited from suitably qualified candidates for a full time fixed term position as a Research Associate/ Project Coordinator with the HRB Clinical Research Facility at the National University of Ireland, Galway and Galway University Hospitals. This post is funded with support from a variety of sources and will be for a period of 1 year initially, with potential to extend subject to project success and funding availability.

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.

Job Description:
We seek a Research Associate/Project Coordinator for NUIG or externally-sponsored clinical trial as part of multi-disciplinary teams. The individual will be a key member of the CRFG Coordination team and may contribute to a number of specific studies comprising part of the CRFG portfolio, while being assigned the role of primary Coordinator for one study in a thematic area.

This is primarily a project management role and the successful candidate will be part of project-specific multi-disciplinary teams having a pivotal role in the co-ordination and project management of a clinical trial or study in the HRB-CRFG. The Research Associate/Project Coordinator will be responsible for overseeing the daily conduct of a trial in a specific therapeutic area. The role will involve the generation of key study documentation, management of resources and budgets, scheduling activities, reporting and training of study personnel associated with a regulated interventional trial in accordance with Good Clinical Practice (GCP). S/He will be the main point of contact for all study stakeholders and provide updates to associated principal investigators, funding bodies and study sponsor, as appropriate. Throughout the project lifecycle, the post holder will manage study outputs and undertake presentations and dissemination exercises related to the study. The post holder will undertake research on and prepare study-specific information for peer-reviewed publication, alongside the research team.

In parallel, the post-holder may be assigned coordination activity for other studies outside their primary thematic research area in the CRFG, contributing to study coordination support, GCP monitoring and data management of clinical research studies in addition to specific tasks as outlined above.

Duties:

- Conduct clinical research work to a high standard in accordance with applicable clinical research regulations and protocols under the direction of the CRFG Programme manager, CRFG Director and the Chief Investigator/Principle Investigator.
- Oversee and ensure key study milestones and objectives are tracking to an agreed timeline and adhere to project management best practices.

- Develop and execute study plans including establishing a project plan, risk assessment and management and planning resources.
- Confirm the necessary processes are in place for study drug and other study supplies.
- Ensure budget agreements and contracts are in place and roles and responsibilities documented prior to commencing study activities.
- Participate in process of protocol development.
- Participate in process of developing other study related documentation such as CRFs, SOPs, information sheets, risk assessments, their amendments and associated quality assurance documents.
- Overall responsibility for management of essential documents and Trial Master File.
- Complete Regulatory and Ethics committee submissions if applicable.
- Evaluate and document investigator and site selection.
- Oversee the process of study initiations, site training, monitoring and close-out.
- 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.
- Ensure compliance with all applicable regulations and guideline, CRFG Sponsor SOPs and/or CRFG site SOPs as required.
- Contribute to preparation for audits and inspections as required.
- Co-ordinate and undertake research study-specific processes according to specific study protocols and regulations.
- Prepare study reports as required.
- Update sponsor, chief investigator, data and safety monitoring committees, regulatory bodies and ethics 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 for participant recruitment for research, utilising the necessary network connections to do so.
- 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 HRB-CRFG whilst keeping up to date with research related methods and techniques.
- Contribution 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.
- Carry out other appropriate and relevant duties under the direction of the CRFG and/or Chief investigator.
- Continue to build personal skills by taking training opportunities as available and required.

Qualifications:
Essential:

- Degree level qualification in a clinical or life sciences related subject.
- Have at least 3 years' experience in clinical research activities or at least 3 years' experience working in a closely related field e.g. Pharma or Medical Device sector.
- Proven track record of project coordination and experience in project managing a cross functional project team.
- Strong organizational skills to ensure timeline for key project milestones are adhered to.
- Strong interpersonal and communication skills with proven leadership and ability to influence.
- Experience in working in a regulated environment.

Desirable:

- A post graduate qualification in a clinical or life sciences related subject (MSc or PhD).
- A Project management qualification.
- Working knowledge of Good Clinical Practice (GCP).
- Experience working within a quality system and adhering to QC and QA control systems and risk management processes.
- Experience with research data collation, management and GCP monitoring.
- Able to work both independently and as part of a team engaging multi-functional stakeholders in the process
- Evidence of on-going professional development.
- Excellent IT skills.
- Self-motivated, high level of initiative and excellent attention to detail.

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.

Salary: €39,530– €45,540 per annum pro rata (public sector pay policy rules pertaining to new entrants will apply)

Start date: Position is available immediately

Further information on research and working at NUI Galway is available on Research at NUI Galway

For information on moving to Ireland please see www.euraxess.ie

Further information about HRB Clinical Research Facility is available at 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-039-19** in subject line of e-mail application.

Closing date for receipt of applications is 5pm on Friday 8th March 2019

A panel of successful applicants may be formed for future posts.

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

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

HRB Health Research Board CRFG HRB Clinical Research Facility, Galway