Deputy/Acting CCRU Programme Manager

Background:

The National Children's Research Centre (NCRC) is the primary paediatric research institute in Ireland. Based at Our Lady's Children's Hospital, Crumlin, it funds and provides infrastructure to conduct research into childhood disease and has a national and international reputation for high quality research.

The NCRC is funded by the CMRF Crumlin.

Clinical research is essential to provide an evidence base for improved medicines and treatment of sick children. The Children's Clinical Research Unit (CCRU) was established in 2010 by the NCRC to provide key infrastructure to support clinical teams in the conduct of clinical research at OLCHC and other paediatric centres. The CCRU is made up of a team of research staff with the specialist expertise required to conduct clinical trials in children and young adults. The unit is organised into functional sub-units of Clinical Operations, Quality & Regulatory Affairs, Data Management, Trial Pharmacy and Laboratory, each with a designated lead.

The CCRU Programme Manager's role is to provide overall leadership and strategic direction for the CCRU and be responsible for coordinating and managing the unit under the direction of the CCRU Oversight Committee. A Deputy Programme Manager is now being recruited to provide additional support and maternity leave cover for a one year fixed term period.

Job Description:

Title: Deputy/Acting CCRU Programme Manager
Location: National Children's Research Centre, Our Lady's Children's Hospital Crumlin
Reporting to: CCRU Programme Manager / Director of Research

The Deputy/Acting CCRU Programme Manager will provide support to the CCRU Programme Manager in leading and coordinating the delivery of support services across the CCRU, and act as their backup during leave. In conjunction with the CCRU Programme Manager, they will undertake the following:

Key Duties and Responsibilities:

Oversight & Management

- Manage the overall portfolio of clinical research studies supported by the CCRU, ensuring they are conducted in line with the CCRU quality management system and according to study timelines
- Work closely with the CCRU Team, Clinical Study Teams and other stakeholders to ensure the smooth conduct of studies from set-up through to study closedown, providing direction and guidance as required
- Lead the CCRU Management Team and provide oversight and direction to the functional sub-units as required
- Coordinate the implementation of the CCRU annual workplan
- Represent the CCRU on the CCRU Oversight Committee and provide regular progress reports and updates
- Review and advise on new applications for CCRU support and coordinate their review by the CCRU Oversight Committee
- Support the CCRU Management Team to carry out internal feasibility assessments to feed into resource planning, budget development and applications for CCRU support

- Ensure that study and staff activity is tracked in a timely manner and generate metric and activity reports as required
- Resource planning and allocation of staff across research studies and ongoing monitoring of workload across groups to ensure best use of resources and to identify capacity limitations
- Act as the main point of contact for study costings and budget negotiations
- Coordinate and input to the development and review of Investigator sub-agreements and clinical study agreements
- Work closely with the CCRU Team and NCRC Finance to ensure timely study invoicing and pass through cost management
- Support the NCRC Financial Controller with financial planning and management of CCRU activity
- Attend sponsor and clinical study team meetings as required
- Coordinate team meetings as required and ensure good communication within the team
- Direct and indirect line management of functional group leads and as required, seconded staff
- General management and mentoring of staff, encouraging and fostering an environment of team work and continuous development
- Liaise with hospital staff as required to support CCRU staff development and research activities
- Develop and maintain positive working relationships with hospital departments involved in the provision of services to support clinical research activity
- Provide key support in the planning towards the New Children's Hospital and the integration of clinical research activities in the interim period

Communication

- Represent the CCRU and NCRC at events, meetings and networking opportunities
- Participate in internal and external networks and working groups as required
- Contribute to Public & Patient Involvement initiatives
- Prepare materials for external communications including the NCRC annual highlights and website

Quality

- Maintain systems to ensure that studies are conducted in accordance with ICH GCP guidelines and all relevant legislation and quality standards
- Support the ongoing development and implementation of the Quality Management System across the CCRU, contributing to process, and document development and review as required
- Support the Quality & Regulatory Affairs Manager and study teams in the implementation of corrective and preventative action plans
- Provide support in the preparation for and conduct of audits and inspections

Training & Development

- Promote sharing of knowledge and experience across the team and assist with the development of training material where necessary
- Organise or provide training to staff as required
- Complete all assigned training and facilitate ongoing personal development and learning
- Perform other duties as required to ensure the delivery of CCRU services

All duties will be carried out in accordance with ICH-GCP guidelines, CCRU and any relevant hospital policies and all applicable laws and regulations for the conduct of clinical research.

Requirements:

Essential:

- BSc or relevant third level qualification.
- Significant relevant experience, including at least 5 years of relevant clinical trial experience
- Strong knowledge of data management, regulatory affairs and ethics
- Understanding of current Irish medical, academic and health services research environment and knowledge of GCP requirements relating to the conduct of clinical research
- Experience of managing and leading a team
- Direct line management experience
- Initiative and good judgement, capable of problem solving and working independently
- Possess the highest degree of integrity and confidentiality at all times
- Strong leadership and interpersonal skills with the ability to motivate people and promote a positive team environment
- Ability to lead and communicate effectively and in a professional manner
- Versatility and capable of coping with ambiguity and change
- Ability to manage competing priorities and maintain high level of professionalism when working under pressure
- Excellent attention to detail
- Strong planning and organising abilities
- Readiness to work to deadlines and flexibility with regard to working hours
- Excellent IT skillsAbility to build and maintain effective internal and external relationships at a senior level
- Proven track record in effective project management
- Proven track record of developing and maintaining effective internal and external relationships at a senior level

Desirable:

- Prior experience in paediatric research
- Knowledge of the paediatric regulatory landscape
- Previous experience working in a Clinical Research Facility or pharmaceutical industry
- Demonstrated ability to build close working relationships with internal and external stakeholders and influence decision making
- Demonstrated leadership ability, proactive staff development, motivation and engagement skills