

Candidate Information

Position:	Clinical Trials Practitioner
School/Department:	School of Medicine, Dentistry and Biomedical Sciences
Reference:	24/112340
Closing Date:	Monday 27 January 2025
Salary:	£33,785-£38,765 per annum
Anticipated Interview Date:	Monday 17 February 2025

JOB PURPOSE:

The post-holder will assist the NI Clinical Research Facility (NICRF), to catalyse our clinical trial growth and high-quality research excellence in clinical trial delivery. The post holder will assist in the planning and delivery of research programmes within the NICRF.

The Clinical Trial Practitioner will become an integral member of the NICRF and will support the general running of the Facility as well as participate in established and new projects. The post duties will include the collation and submission of ethics and regulatory documentation, obtaining HSC permissions and maintaining oversight of trial documentation for the duration of the trial. Project management, quality assurance and preparing for audit/inspection will be an integral part of this job.

The post holder will be required to develop and maintain good working relationships with all staff.

The post is suited to a collaborative team worker that can use own initiative and work within a team.

MAJOR DUTIES:

1. Coordinate the efficient completion of all necessary documentation required for clinical trial approval in accordance with QUB, BHSCT Research Governance as follows:

- Prepare and submit documents to Research Ethics Committee/regulatory applications including ethical applications (full submissions/SSIs), amendments and annual progress reports (on behalf on clinician as required).

- Enter and maintain trial related information on trial database(s).
- 2. Facilitate effective communication and co-ordination of activities between all members of the NICRF, BHSCT and other relevant local, regional and national agencies.
- 3. Undertake basic research activities, critical evaluation and interpretation, computer-based data analysis and evaluation.
- 4. Undergo training in skills and techniques relevant to the post.
- Keep appraised of relevant legal and regulatory guidelines and policies, including the EU Clinical Trial Directive, The Medicines for Human Use (Clinical Trials) Regulations 2004, Research Governance Framework, Human Tissue Act, ICH GCP and other documentations as appropriate.
- 6. Carry out staff supervision/demonstrating/teaching duties under direction.
- 7. Assist in the preparation of reports relating to trial activity, by researching and collating information as directed. To include presentation materials, databases spreadsheets, graphs and PowerPoint as directed.
- 8. Assist in the preparation and maintenance of newsletters/website to publicise the NICRF trial portfolio.
- 9. Assist in audit/inspection activities as required including development and maintenance of Standard Operation Procedures.
- 10. Assist with tracking trial specific invoices, income and expenditure in compliance with Finance Operating Procedure as required.
- 11. Carry out any other duties which are appropriate to the post as may be reasonably requested by line manager and which contribute to the objectives of the NICRF.

ESSENTIAL CRITERIA:

1. * Honours degree in a relevant subject and a minimum of 2 years relevant experience in research or clinical practice OR substantival 5 relevant experience in research or clinical practice.

- 2. *Experience of research governance and regulatory approvals.
- 3. *Experience of analysing and communicating research data effectively across a range of settings.
- 4. Strong analytical and problem-solving skills and ability to use own initiative.
- 5. Relevant computing skills including Microsoft office packages.
- 6. Willingness to contribute to the School and project outreach activities in a professional manner.
- 7. Ability to build contacts and participate in internal and external networks.
- 8. Good team-working skills in multiple team settings as well as leadership qualities. Ability to work independently.
- 9. Willingness to be flexible to meet the deadlines of the post.
- 10. Willingness to handle participant samples.
- 11. Willingness to travel, as required.

DESIRABLE CRITERIA:

- 1. Honours degree in a relevant subject.
- 2. Knowledge of clinical trials and consent.
- 3. Clinical Trial experience and current certificate of Good Clinical Practice.
- 4. Research project management.
- 5. Laboratory experience.

ADDITIONAL INFORMATION:

This post will initially be based in the NICRF but will be relocated to NICRF within iREACH Health building at Belfast City Hospital site.

iREACH Health is an exciting new project for healthcare in Northern Ireland, the outcome of creative collaboration between academia, industry, the NHS, and public sector/government stakeholders to drive UK science and innovation and is focused on modernising our research infrastructure.

iREACH Health will drive continuous improvement in patient care and outcomes through innovation by integrating the activities of clinicians, life scientists and data scientists with industry partners to identify and develop new diagnostic tests, treatments, and health related technologies.

iREACH Health due to be operational in 2026/27 provides the platform to create a patient-centered, pro-innovation and digitally enabled clinical research environment.

Key to the deliverables is clinical trial growth, the NICRF represents a key hub to which we will catalyse our clinical trial growth, setting new benchmarks for when iREACH Health is set to open in 2026.

Informal Enquiries to Kelly Redmond: kelly.redmond@qub.ac.uk