Royal Papworth Hospital NHS Foundation Trust

Band 5 Clinical Research Nurse/ Clinical Trials Co-ordinator

Job Description

Directorate	Research & Development	**Reporting to**	Senior Clinical Research Nurse/ Senior Clinical Trial Co-ordinator OR Clinical Research Team Leader
Department	Research & Development	**Appraised by**	Senior Clinical Research Nurse/ Senior Clinical Trial Co-ordinator
Band	**5**	**Working hours**	

Job Summary

The post holder will provide a high standard of safe individualised, holistic and evidence-based patient care whilst participating in a research study, in consultation with the patient, their relatives and the multi-disciplinary team.

The post holder will be responsible for supporting the set up and coordination of multiple clinical trials. Their duties include recruiting and consenting (where applicable) suitable patients, coordinating data collection, arranging, and conducting assessments, follow up appointments, tests and investigations which are specified by the trial protocol. They will also be involved in liaising with investigators, R&D staff, internal departments, and other staff at RPH in respect of the clinical trial as well as contacting external sponsors when appropriate.

The post holder, with the support of senior research colleagues will aim to achieve specified milestones in a timely manner and ensure high quality data is collected and that the trial is being conducted according to the ethically approved protocol and ICH-GCP standards.

The post holder will be responsible for a portfolio of commercial and academic clinical trials supported by senior research colleagues if applicable including randomised, controlled trials and observational studies and conducting trial specific delegated tasks as per the trial protocol.

Where the post holder is a registered nurse or a clinical trials co-ordinator, there is an expectation that the postholder will complete all required training to be able to undertake complex interventions for example: venepuncture, ECG, vital signs, centrifugation etc. Where the postholder is a registered nurse, they will also be required to administer trial medications and maintain study blind as per protocol.

Research & Development

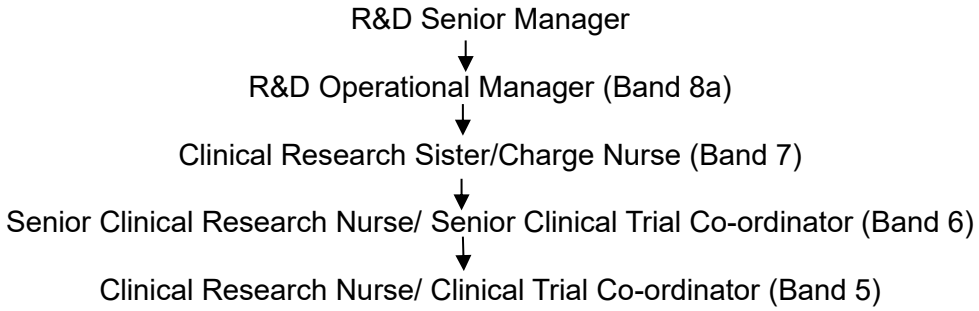
The Research and Development (R&D) department at Royal Papworth NHS Foundation Trust is dedicated to advancing the field of Heart and Lung research conducting high quality, innovative clinical trials that aim to improve the health and wellbeing of patients and communities. Our department consists of a Trials Unit collaboration between the MRC Biostatistics Unit, University of Cambridge and Kings College London.

Our department also consists of a research delivery team of experienced and dedicated professionals collaborating with our talented multi-disciplinary clinical teams to deliver a wide range of innovative high quality research trials to inform the future care of our patients. The research & development team support a large and growing portfolio of studies across multiple specialities at Royal Papworth NHS Foundation Trust.

The research delivery team coordinates and delivers many complex commercial and non-commercial and the Trust's own sponsored studies, ranging from early phase CTIMPs and device studies to high recruiting observational registries and novel device sensor studies. Our research delivery team are enthusiastic, motivated, autonomous and proactive. They enjoy the challenge of study feasibility, set up and delivering high quality research through all stages of a trial protocol.

As a specialist tertiary centre, we also treat patients with specific rare diseases. Complex interventional and observational studies are delivered here giving our patients access to cutting edge research opportunities where we often achieve global and UK first recruits.

Structure Chart



Band 5 Clinical Research Nurse/Clinical Trials Co-ordinator Person Specification

Requirements	Essential criteria
Qualifications and Professional Registration	Professional adult nursing or equivalent level science qualification; and clinical knowledge acquired through training to degree level **OR** diploma level qualification or above. Registered with Nursing and Midwifery Council or other regulatory body as applicable and / or NIHR CRP accreditation.
Knowledge, Skills, and Experience	To support the collection of clinical trial information and research samples in line with research legislation, adhering to procedures to ensure that confidentiality, accuracy, and security is maintained at all times and ensuring data collected meets required criteria. To conduct clinical assessments as per protocol within scope of practice and actively support the conduct of research trial(s) according to agreed research governance standards and legislation. To liaise with investigators, research delivery staff, research and development department, clinical departments and staff across RPH in respect of the study feasibility, set up and delivery and monitors the progress of that research study. To be able to demonstrate use of a range of judgement and assessment skills in planning, delivering and evaluating complex patient care plans as per trial protocol whilst communicating with patients, families and the multi-disciplinary team. The post holder will be expected to manage routine studies but will be supported by their senior colleagues. To support complex patients with their potentially unpredictable care/treatment needs whilst participating in a clinical trial; ensuring care delivered is evidence based. The post holder will provide clinical services by undertaking diagnostic and research tests on patients for research purposes. The post holder will provide, implement and evaluate clinical knowledge and expert advice to the patient on the research study including any research treatment that needs to be considered alongside their substantive care plan. To be able to prioritise care based upon patient safety trial information need in a busy clinical environment and effectively prioritise own workload in line with local and regional targets and clinical trial visits in accordance with protocol-mandated timelines and existing clinical appointments, escalating as necessary To be able to undertake occasional moving and handling tasks relating to patient care utilising mechanical aids with some tasks requiring moderate effort. The post holder will have occasional exposure to some emotional / distressing incidents and frequent exposure to bodily fluids including from research sample collections, processing and shipping.

To be able to effectively communicate complex, confidential, and/or sensitive condition related information through a range of interpersonal skills to colleagues, patients/visitors and external organisations (eg trial sponsors) (such as providing educational support, complex research planning); and to support patients to be able to make informed choices about health and treatment options related to clinical research trials.

To act as a patient advocate when necessary, safeguarding and promoting the interests of patients and carers. This may involve explaining research procedures and the nature of the patient's medical condition, in conjunction with the specialist clinical team, to ensure full understanding.

To provides accurate and appropriate support for patients in conjunction with clinical nurse specialists and senior research colleagues.

To work effectively within the research and development and clinical teams, maintaining professional relationships and good communication by participating in multi-disciplinary research team meetings.

To act in a professional manner and as a role model to other staff members, providing day to day clinical supervision of junior staff as well as patients and their families/carers.

To understand the process of escalation within the trust ensuring this is done promptly to ensure patient and staff safety and recognising and raising any safeguarding concerns; including escalation to senior colleagues/investigator/ sponsors (as appropriate) under ICH GCP guidelines regarding adverse event documentation and reporting.

To uphold Trust policies and procedures, knowing when to appropriately escalate and to act independently within own regulatory body Code of Conduct as appropriate.

To be responsible for the day-to-day supervision of trial back up staff within their teams including allocating patient research activities.

To support with the orientation of new staff, mentor new junior staff as appropriate (including research interns and student nurse placements); and support on-going staff development.

The postholder will take responsibility for own continuing professional development and ensure own knowledge remains current and is evidence based; and keeps abreast of current research and government issues relating to research and disseminate information as appropriate.

To participate in reviewing policies and procedures to improve outcomes and the quality of service provided and actively participate in the implementation of any changes in practice within the clinical area, in line with statutory and NHS guidelines; and ensure timely dissemination of any agreed changes in practice.

To support senior research colleagues with regular verbal and comprehensive written reports to the study investigators/study sponsors.

	To support senior research staff/line manager with monitoring/assessing and reporting in relation to both clinical and non-clinical risks and incidents. To maintain accurate database entry/record keeping that is consistent with all legislation, policies, and procedures and , with the support of senior research colleagues, to anticipate, problems and issues on available data and identify and implement solutions.
Values and Behaviours	As well as being able to demonstrate examples of how they work in a way that is consistent with our values of compassion, excellence and collaboration the post holder will be able to clearly demonstrate a commitment to driving culture change through **equality, diversity and inclusion**.

General compliance and standards

1.	It is expected that you will role model the Trust's values of Compassion Excellence Collaboration and will perform your duties inclusively ensuring that equality and diversity sits at the core of your everyday practice.
2.	You must perform your duties to the highest standard, with particular regard to effective and efficient use of resources, maintaining quality and contributing to improvements
3.	You must comply with all Trust Policies and Procedures (and subsequent updates thereof) and with particular regard to Risk Management — Health & Safety — Information Governance Confidentiality — Data Quality — Freedom of Information Dignity at Work — Safeguarding Vulnerable People — Smoke-free Equal opportunities — Being open: a duty to be candid
4.	You will be responsible for compliance with infection prevention and control policies, procedures and standards and associated mandatory training. You must practice and encourage appropriate hand hygiene and act professionally to ensure the hospital environment, and other Trust premises, are clean, safe and tidy.
5.	You must follow all Trust security policies and procedures and be vigilant to ensure a safe and secure environment for care
6.	The Trust is committed to carefully screening all staff working with vulnerable people. If this applies to this post, the appointment will be subject to a satisfactory Disclosure and Barring Service disclosure of the appropriate level
7.	You will be required to participate in the Trust's Appraisal process and associated development review. If your role includes line management, you must ensure your direct reports participate in an annual appraisal and development review.
8.	You must remain compliant with mandatory training requirements applicable to the post. If your role includes line management, you must ensure your direct reports remain compliant as applicable to their roles.
9.	You will be responsible for data quality and complying with the policies, procedures and accountability arrangements relating to maintaining accuracy and probity in the recording of the Trust's activities.
10.	You will be required to perform any other duties that may reasonably be required from time to time