

Job Description

Title: Research Facilitator

Band: 6

Staff Group: Administration and Clerical

Reports to: Research Manager

Job Summary:

- To work with clinical researchers and Research Management staff to ensure effective, efficient and speedy set-up and on-going management of clinical research studies in PHU.
- To provide a specialist role, giving expert support to Chief and Principal Investigators and delivery staff in NIHR research studies.
- To assist in the facilitation the entire life cycle of NIHR portfolio research study undertaken within the Trust. This will include clinical researcher support, study co-ordination, data management and research portfolio database training.
- Act as a Project/Trial Manager for research studies within the Trust.
- To oversee the performance of portfolio research studies and work with NIHR regional/national colleagues regarding study set-up, initiation and delivery performance management.
- Ensure that research projects are approved and conducted in compliance with PHU policies for research governance, quality assurance and national regulatory requirements.
- To actively contribute to quality management of research studies e.g. monitoring, reviewing standard operating procedures and undertake continuous improvement projects.
- Oversee the entire portfolio for assigned research speciality including; performance, pipeline planning (including grant applications) and delivery as well as acting as an advocate for their specialities.
- To deputise for the Research Manager as required.

Key Responsibilities:

Study Development

- Act in an advisory capacity to assist researchers in the preparation and development of competitive funding proposals in support of their research activities.
- Provide detailed assistance in all aspects of research grant applications.
- In liaison with the R&I Office, ensure that any costing elements of application and project budget development are in place in a timely manner. To ensure that all recoverable costs are identified within the specified criteria for the grant application.
- Contribute to accuracy and completeness of central grants tracking database.
- Maintain comprehensive knowledge of resources available to assist researchers in the development, funding and delivery of high quality clinical research.
- Act as a central reference point for researchers, guiding them to the appropriate resources at the appropriate time. Assisting researchers in using resources available.

Project identification, feasibility and facilitation

- Identify NIHR Portfolio studies for potential Trust involvement.
- Work with clinicians to establish interest and scope for participation in research studies, working to address their support needs and barriers to involvement.
- Identify staff to act as Principal Investigators for NIHR Portfolio studies.

- Lead site feasibility assessments within the Trust as required by external project teams, research networks or commercial partners.
- Ascertain resource and staffing needs for study participation. Work with the R&I team and across the Trust to address these needs.
- Plan, organise, prepare, submit and effectively manage research applications for approval by the NHS and other regulatory bodies via the Integrated Research Application Service (IRAS) on behalf of the Trust employed Chief or Principal Investigators.
- Determine key process issues for the governance and approval of NIHR research studies within the Trust.
- Provide advice to Trust staff on issues such research funding, training opportunities, portfolio adoption, research approval processes, and use of programmes such as IRAS and EDGE portfolio management.

Study Set-up

- To assist CIs, PIs and research teams with study set-up to ensure efficiency, accuracy and timeliness.
- Plan, organise, prepare, submit and effectively manage research applications for site specific assessments to the appropriate regulators on behalf of the Chief or Principal Investigator (for example, supporting IRAS applications for HRA submission).
- To monitor the progress of each study during the approvals process including details of approved document versions etc.
- To plan, organise, prepare and effectively set-up research studies to support research nurses/staff to begin to recruit patients into studies on behalf of the Chief or Principal Investigator.
- To work with the Research staff and managers to co-ordinate other approvals and/or agreements from third parties (eg Service Support Leads and Sponsors) that are required for the study.
- To identify and rectify “blocks” to the successful approval and initiation of research studies.
- Analyse and make definitive judgements on complex research study issues.
- Ensure a consistent approach to local study documentation taking account of regulations and external requirements e.g. Trial Master Files.

Study Support

- Preparation and project management of plans and programmes for research study development.
- With the CI, PI and research staff, assist in the prioritisation and management of the workload to ensure timelines are maintained.
- Manage and monitor the progress of each study including details of approved document versions etc.
- Develop methods within clinical departments to promote study recruitment.
- Set up and maintain systems for the regular collection of data on Portfolio study accrual figures.
- Provide reports on accrual information for use by the R&I team and external partners.
- Provide ongoing assistance to study teams on the issues on reporting and governance issues.
- Provide ongoing project/performance management within given specialities for entire study lifecycle (including set-up, monitoring, amendments, governance, study meetings, closure, publications etc.).
- Support the set-up and management of external sites acting as delivery sites for PHU sponsored research.
- Maintain systems for the reporting of serious adverse events, ensuring that researchers meet their responsibilities in line with PHU SOPs. Provide reports of serious adverse events to the relevant authorities and follow-up as required.
- Lead specialty meetings where required.
- Provide support to Research Coordinators in complex matters (e.g. contract negotiations, performance management, study finance reviews etc.).
- Develop research management plans and schedules to ensure efficient organisation and delivery of studies, adapting and updating plans to reflect changing priorities, resources and new studies as needed.

Communication

- Maintain strong relationships and develop regular communication and reporting channels between the study teams, R&I teams and the NIHR.
- Liaise with researchers, clinicians, research nurses, other clinical staff and the NIHR to set-up and manage studies in a timely manner and keep them informed of the progress.

- Contribute to R&I Team and CRN meetings, discussing issues such updates of study set-up, identifying and resolving any barriers to successful set-up
- Ensure all communication is evidenced and documented as required by governance standards.

Research Governance

- To conduct all activities in accordance with the Research Governance Framework 2005, ICH Good Clinical Practice (ICH GCP) guidelines, Data Protection Act 1998 and all other appropriate local and national policies and procedures.
- Contribute to ongoing quality management and governance oversight of research at PHU (including quality management system development, SOP development, governance committee attendance, QA and QC activities etc.).
- Liaise and collaborate with external agencies during external reviews or inspections.

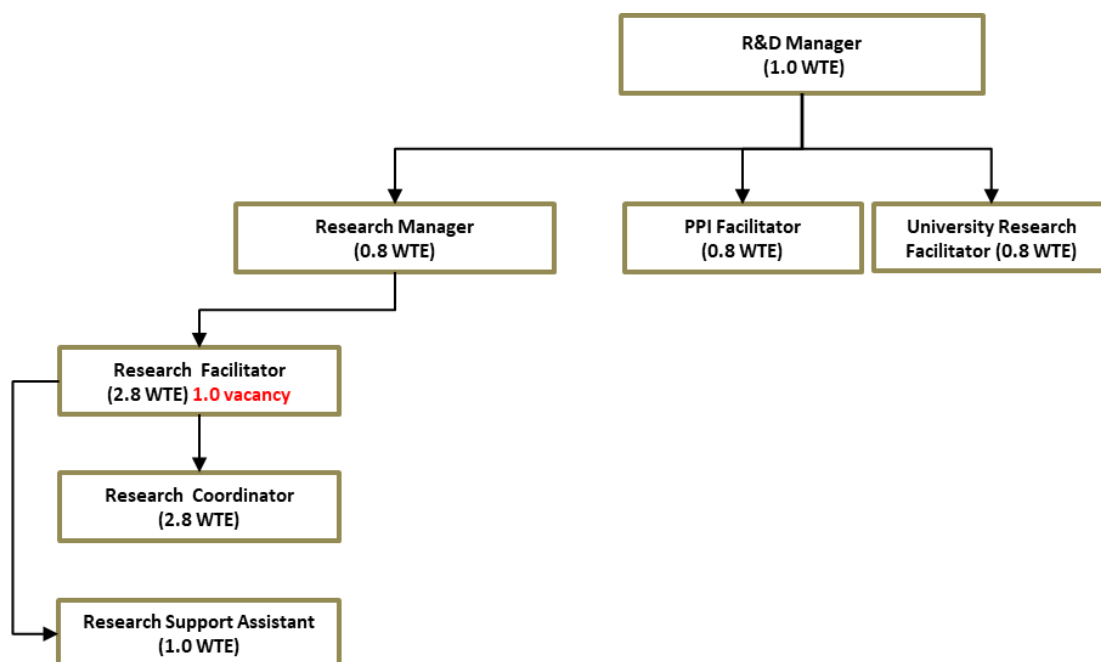
Education & Training

- Support University Research Facilitator in the navigation of external collaborators with local research processes and collaboration building.
- Assist academics and NHS staff to make connections with one another to enable the development of cohesive and viable research bids.
- To maintain excellent and specialist knowledge of changes in NIHR Portfolio management, research governance requirements, use of specific databases, etc
- To develop and maintain links with other study facilitators, coordinators, data managers, research nurses across this and neighboring Trusts and the CRN.
- Nationally, develop and share knowledge and to provide mutual support.
- To continue professional development as set out in the AfC Personal Development Review.

Management

- To manage staff within the research office team as required i.e. research coordinator and/or administration and clerical staff.

Organisational Chart



Person Specification

Qualifications

Essential

- Degree in health, clinical, science discipline or equivalent experience

Desirable

- Evidence of significant NHS experience **or** research management experience within a health related organisation.
- Recent Good Clinical Practice (GCP) in research training

Experience

Essential

- Previous experience of using IRAS for R&D applications
- Experience of working in a research environment requiring critical appraisal of clinical research evidence

Desirable

- Experience of working within NHS R&D Management
- Experience of supporting a grant application to a national body
- Experience of working on research prioritisation with a variety of stakeholders
- Experience of supporting/facilitating research in a clinical setting

Skills and Knowledge

Essential

- Strong Interpersonal skills
- Excellent written and verbal communication skills including presentation and report writing skills
- Ability to work to deadlines and manage a diverse workload with cross functional teams
- Excellent project management skills
- Ability to deliver feedback in a positive, constructive manner, skills in motivating
- Well-developed influencing skills across hierarchies and disciplines
- Confidence in making decisions when dealing with competing priorities
- Ability to work independently with minimal supervision
- Responsive and flexible attitude and approach
- Excellent working knowledge of using Microsoft Office suite (Word, Excel & Powerpoint) comparable computer packages
- Excellent working knowledge of using the internet
- Demonstrates leadership qualities

Desirable

- Knowledge of Good Clinical Practice Guidelines and current Trials' Regulations (EU Directive Clinical Trials)
- Knowledge of EDGE (Local Performance Management System)
- Critical appraisal and analytical skills for interpreting qualitative and quantitative information
- A high level of numeracy with the ability to interpret statistical and epidemiological data
- Formal project management qualification

Working Together For Patients with Compassion as One Team Always Improving

Strategic approach (clarity on objectives, clear on expectations)

Relationship building (communicate effectively, be open and willing to help, courtesy, nurtures partnerships)

Personal credibility (visibility, approachable, back bone, courage, resilience, confidence, role model, challenge bad behaviour, manage poor performance, act with honesty and integrity)

Passion to succeed (patient centred, positive attitude, take action, take pride, take responsibility, aspire for excellence)

Harness performance through teams (champion positive change, develop staff, create a culture without fear of retribution, actively listen and value contribution, feedback and empower staff , respect diversity)

Job holders are required to act in such a way that at all times the health and well being of children and vulnerable adults is safeguarded. Familiarisation with and adherence to the Safeguarding Policies of the Trust is an essential requirement for all employees. In addition all staff are expected to complete essential/mandatory training in this area.

Print Name:

Date:

Signature: