THE UNIVERSITY OF MANCHESTER

PARTICULARS OF APPOINTMENT

FACULTY OF BIOLOGY, MEDICINE & HEALTH

SCHOOL OF BIOLOGICAL SCIENCES

RESEARCH PROJECT MANAGER (CYSTIC FIBROSIS RESEARCH HUB COORDINATOR)

VACANCY REF: BMH-026979

Salary: Grade 6 £36,924 to £45,163 per annum, depending on relevant experience

Hours: 1 FTE

Duration: January 2025 for 5 years

Location: Wythenshawe Hospital

Reports to: Julie Teague

Enquiries about the vacancy, shortlisting and interviews:
Name: Professor Alex Horsley
Email: alexander.horsley@manchester.ac.uk

BACKGROUND

PULSE-CF Innovation Hub
The role is that of a Project Manager for a new Cystic Fibrosis (CF) Innovation Hub. This is led by Professor Alex Horsley and funded with a new award from the CF Trust and LifeArc charities. The Hub is a multi-centre initiative that will deliver two large clinical studies, and a package of translational science across 3 academic centres (with a Hub workforce of 10 PhD students). A lay summary of the Hub is provided in the further particulars.

PURPOSE OF THE ROLE
This post is for an experienced Research Project Manager to coordinate and provide administrative oversight for the new Cystic Fibrosis (CF) Research Innovation Hub. They will support the Principal Investigator and be responsible for the day-to-day delivery of the project, ensuring key milestones are achieved and coordinating successful delivery to project stakeholders. As a key member of the project team, the Research Project Manager must demonstrate excellent organisational, planning and communication skills with the ability to work with minimal supervision.

KEY RESPONSIBILITIES, ACCOUNTABILITIES OR DUTIES

Project management

- Support the Principal Investigator by facilitating the day-to-day running of two large clinical studies and contributing to the development of strategy.
- Maintain clear working practices for management of the project amongst the Management Team, and stakeholders, including financial and administrative reporting mechanisms, quality assurance measures and GDPR requirements.
- Implement chosen study designs and ensure effective delivery of all aspects of the study outcomes with regards to patient recruitment targets and follow-up.
- Identify and have a pro-active approach to solving problems with study recruitment / management of patient and biological sample recruitment, both in Manchester Adult CF Centre and supporting these activities at collaborating sites.
- Monitor compliance with the funder grant conditions, and agreements with partners, ensuring that all contractual obligations are met.
- Contribute to the development of project plans, key performance indicators, timelines and reporting structures to ensure all stakeholders are up to date with project progress and the effective delivery of high-quality work packages.
- Identify and monitor risks to delivery, coordinate and implement changes to the project plans as required.
- Contribute to recruitment campaigns and induction of new staff.
- Ensure all relevant publications, activities and impacts are captured and recorded.
- Be innovative in finding creative solutions when unforeseen challenges arise.

Communication and networking

- Facilitate communication between the management team, other University departments, external colleagues at NHS hospital and university sites and funders.
- Plan and organise regular meetings for the Core Management Group, project stakeholders and partners and contribute to drafting of terms of references and agendas and monitor delivery of actions.
- Present project management / progress updates on administrative, contractual and financial aspects of the project to the management team and consortium members at meetings, and on request.
- Update and maintain outward facing websites pertaining to studies, recruitment and publications.
- Communicate complex information about the research in a way that is appropriate to the audience.
- Liaise with colleagues via internal and/or external networks to ensure effective management and project delivery.
- To support delivery of PPIE and communication strategies
- To actively engage with CF Trust initiatives to promote the Hub and it's outputs.

Finances

- Manage the project budget, including production of budget summary and expenditure reports in liaison with Research Finance colleagues.
- Produce budget forecasting reports and work with Research Finance to manage revisions.
- Ensure optimum value is obtained from available budget resource.

Research governance

- Collect and manage clinical data and patient information in accordance with GDPR, data protection, confidentiality, ethical guidelines and research governance.
- Help coordinate the construction of research databases, data entry, quality control, error reporting and cleaning of data according to study priorities.
- Ensure that appropriate applications for ethical and other regulatory approvals are made as required. Liaise with the Clinical Research Network, Clinical Research Facilities, CF Clinical Trials Accelerator Programme, and all relevant University and NHS Colleagues throughout this process.
- Establish procedures to ensure adherence to relevant protocols and administrative requirements.
- Understand requirements of various controlling bodies, agencies and frameworks, ensuring that these meet legislative and contractual requirements.

General Requirements

- Undertake the above duties in accordance with the requirements of the University's equality, diversity and inclusion policy, information governance policy, health & safety policy, and its financial regulations.
- Engage actively with the need for diversity and inclusion in all that we do, for example when collaborating with individuals who identify with a protected characteristic under the Equality Act.
- Be aware of and support compliance with statutory obligations and external requirements.
- Maintain confidentiality of information in line with data protection requirements and University policy.
- Engage in continuous personal and professional development in line with the demands of the role, including undertaking relevant training and development activities.
- Contribute to the University's agenda for social responsibility, including sustainability.

PERSON SPECIFICATION

Essential knowledge, skills and experience

- Degree (or equivalent qualification), and/or significant experience in project management/administration
- Experience of management of multidisciplinary research programmes and/or networks.
- Experience of budget management including tracking, forecasting and the ability to interpret financial information.
- Experience of preparing project reports, work plans and milestone setting.
- Experience of contributing to strategy, implementation and contingency planning for projects.
- High level of written and oral communication skills with experience of writing and presenting clearly to varied audiences.
- Demonstrable understanding of good research governance, including data protection, etc.
- Excellent time-management and organisational skills with the ability to prioritise competing demands.
- Excellent communication skills with the ability to present information clearly and explain complex issues to a range of audiences with varying levels of understanding.
- Proven IT Skills, including MS Office packages and electronic databases particularly Microsoft Access, and social media/web content
- Understanding of the context that the University is operating within and an awareness of current issues facing Higher Education, particularly with respect to research and innovation.

- Knowledge of the University's organisation, governance and strategic objectives.
- Understanding of the interface between Higher Education and the NHS.
- Demonstrable commitment to the University's strategy, vision and values.
- Willingness to learn new skills and undertake further training as necessary.

Desirable knowledge, skills and experience

- Experience of working in a research environment
- A formal project management qualification such as PRINCE2, MSP Practitioner, APMP, or industry equivalent
- Data Management - Proven excellence in handling and entering data including an understanding of data protection and confidentiality guidelines within data management.

Appendix: PULSE-CF Innovation Hub summary

Pulmonary exacerbations are one of the cardinal features of CF, carrying huge clinical burdens and causing disruption to patients' lives. They are associated with poorer quality of life, poorer lung function and shorter life expectancy. Exacerbation treatments may also cause harm. Despite this, little is known about what actually causes exacerbations nor why patient responses to similar triggers vary so widely. Understanding what makes someone susceptible (from clinical, immunological and microbial perspectives) as well as knowing the impact of different triggers (e.g. viral infections, allergic responses, environmental pollution) are key to developing a mechanistic understanding of exacerbations and delivering evidence-based interventions. To do this requires a multi-dimensional multi-centre collaborative approach to deliver longitudinal studies at scale and depth, and is only possible with a transformational Innovation Hub.

To address these challenges, we will deliver two linked clinical studies. **TRACKER** is a community-based longitudinal surveillance study of people with CF (pwCF) to identify the triggers of pulmonary exacerbations and underlying predisposing factors. We will follow 300 pwCF for 12months. Baseline assessments will include sputum, blood, saliva, sweat chloride, symptoms and lung function. For most participants, this will be the only in-person assessment. Participants will post back viral swabs, saliva and finger-prick CRP samples, and complete home spirometry and symptom scores (CFRSD-CRISS, via a custom-built app) fortnightly for 6months. Additional samples will be returned if starting antibiotics at home, and clinical outcomes will be followed to 12months. For 100 participants at four core Hub centres, there will be additional sampling at baseline, repeated at 1 and 6months. These participants will also be invited for in-clinic sampling of blood and sputum if starting home antibiotics. A subset (n=50) will undergo home pollution and airborne mould monitoring to document environmental exposures. We will also recruit up to 25 children within a paediatric feasibility study, and up to 40 healthy adult volunteers.

The **RESOLVE** study will run concurrently and will detail the response to IV antibiotics in 100 pwCF admitted for treatment of pulmonary exacerbations at the four core centres. We will conduct multi-modal phenotyping of host immunity and airway microbiome at start (pre-treatment) and repeated timepoints during IV antibiotics. Shotgun and culture-enriched metagenomic sequencing and deep phenotyping of key CF pathogens will deliver new understanding of the evolution of the CF microbiome during and after IV antibiotics. This will be linked to stable and triggered immune response, exacerbation triggers and clinical

response to treatment. We will also investigate adverse effects of antibiotics and social/economic burdens of treatment.

Both studies will be supported by a fully integrated bioinformatics group, and cross-cutting workstreams investigating inflammatory response, immunological phenotypes, microbiome and metagenomics, and novel environmental sampling.

The ultimate aim of the Hub is to **establish a trial platform** of exacerbation prevention therapies. Preparation will begin in parallel with the clinical studies, but final design, patient population, intervention and endpoints will be based on the evidence generated by TRACKER and RESOLVE. We will work with academic and industry colleagues to identify target therapeutics, and will generate the evidence and infrastructure to support this.