THE UNIVERSITY OF MANCHESTER

PARTICULARS OF APPOINTMENT

FACULTY OF BIOLOGY, MEDICINE & HEALTH

SCHOOL OF BIOLOGICAL SCIENCES

DIVISION OF CELL MATRIX BIOLOGY AND REGENERATIVE MEDICINE

PROJECT MANAGER

VACANCY REF: BM&H-015961

Salary:	£32,816 to £35,845 per annum, depending on relevant experience
Hours:	Full Time
Duration:	Fixed Term, starting as soon as possible until 31 October 2023
Location:	Oxford Road, Manchester

Enquiries about the vacancy, shortlisting and interviews:
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Faculty of Biology, Medicine and Health

The University of Manchester is the largest single-site university in the UK with around 38,000 students and more than 11,000 staff. We aim to become one of the top 25 research universities in the world by 2020 and are committed to delivering an outstanding teaching and learning experience; contributing to the social and economic success of local, national and international communities; producing the highest calibre graduates; and developing our staff to be amongst the very best of their peers.

To achieve our ambitious goals we aim to attract and retain the very best people to work across a range of academic disciplines and support functions.

The Faculty of Biology, Medicine and Health (FBMH)

The Faculty of Biology, Medicine and Health was created on 1 August 2016 when the Faculty of Life Sciences and the Faculty of Medical and Human Sciences were brought together in a new, integrated structure to deliver a truly translational approach to the life sciences, ensuring smooth research pathways - from pure discovery science through to clinical application and patient care.

With a total annual income of over £300 million, and over 3,000 members of staff, the new Faculty is comparable in size to a medium-sized UK university. Thirty undergraduate and 90 postgraduate programmes will offer our 11,000 students opportunities to develop the skills and knowledge they need for a successful career.

The Faculty's matrix structure facilitates interdisciplinary working and enables us to learn from each other and share best practice; and our eight, strategic Research Domains help to articulate our research strengths, drive large-scale, collaborative research activities and strengthen relationships with our research and healthcare partners.

The integration of discovery biology, clinical application and patient care within a single Faculty, particularly in a region with notable health inequality, provides us with a real opportunity to have a very significant and positive impact on people's lives.

Our strategic partnerships

The new Faculty inherits a number of key strategic partnerships that underpin its ambitions to develop ground-breaking research.

Working alongside six local NHS Trusts, the Faculty is a key member of the Manchester Academic Health Science Centre (MAHSC) - a federation of equal partners that unites leading healthcare providers with world-class academics and researchers. It aims to be a global centre for the delivery of applied health research and education and provide leadership for our local and regional health systems.

It also plays a leading role in Health Innovation Manchester (HInM), which was launched in September 2015, as part of the UK Government's decision to devolve health and social care responsibilities to Greater Manchester. HInM offers a unique opportunity to bring together health and social care, academic and life science related business resources across the region to deliver an innovative health ecosystem that can help accelerate innovation into our local health and social care systems, enhance our global scientific standing and act as a magnet for inward investment.

Key partnerships in the charitable sector include Cancer Research UK; Diabetes UK; and the Wellcome Trust; and the Faculty will also has research and funding links to a number of commercial organisations including Unilever, AstraZeneca, GlaxoSmithKline and Boots, who will help us to bring new drugs and products to the market.

Working for the University of Manchester

The University of Manchester strives to make our community a welcoming, caring and enthusiastic one, fuelling ambition with opportunities and support to help us all achieve our personal and professional goals.

Our diverse job opportunities include an attractive benefits package with family-friendly policies that provide for flexible working. We care deeply about career and personal development, offering a structured induction programme for new staff, an annual performance and development review, staff training for all career stages and mentoring opportunities to support your career development.

We have a genuine commitment to equality of opportunity for our staff and students, and are proud to employ a workforce that reflects the diverse community we serve.

As a global institution, situated at the heart of a lively, culturally diverse city, we welcome applicants of all nationalities. To help international job applicants plan for life in the UK, we have put together some useful information on passports and visas, travel to the UK, accommodation and a number of other practical considerations.

The Stem Cell & Neurotherapies Laboratory

The Stem Cell & Neurotherapies (SCN) laboratory, uses a multidisciplinary approach to investigate the pathology of neurological diseases and to develop novel stem cell and gene therapies for these diseases. Working together with the Willink Biochemical Genetics Unit and the Bone Marrow Transplant Unit at the Central Manchester University Hospitals NHS Foundation Trust, we have made significant contributions to the diagnosis, pathology and treatment of lysosomal storage diseases. We also have close links with industry, charities and patient organisations in the diseases that we work on.

Overall purpose of the role

Work over the last six years in the SCN group has led to the development of a stem cell gene therapy for mucopolysaccharidosis type II (MPSII) or Hunter syndrome and this therapy is now ready to be used in a clinical trial in humans. You will manage an academic gene therapy clinical trial in MPSII patients. The role will involve working between the clinical trial academic lead Professor Brian Bigger and the University of Manchester trial Sponsors office. You will provide operational co-ordination for the assurance and development of good research practice, research ethics and compliance with legislation and regulations governing research. As a member of the Sponsors Team, you will support and promote good research practice and integrity across the University. You will have specific responsibility for developing and managing systems for the assurance of compliance with the requirements of the Medicines and Healthcare products Regulatory Agency (MHRA) in relation to clinical trials of investigational medical products (CTIMPs). The role will involve meeting with key stake holders including the funder of the trial, the contracted CRO providing medical and clinical monitoring of the trial, the clinical site and other third party vendors.

This post is funded by a grant from AvroBio, a company that specialises in gene therapy treatments for rare diseases.

Key Responsibilities, Accountabilities or Duties:

- To maintain a general understanding of issues relating to the Medicines for Human Use (Clinical Trials) Regulations 2004, subsequent amendments, and all associated legislation and guidance relating to CTIMPs.

- Provide oversight and ensure adherence to GCP working practice, clinical trial policies and management plans.

- To prepare and maintain all necessary documentation in relation to MHRA compliance, including: SOPs, policies and procedures, audit records, training, communication, meetings, etc.

- Develop effective working relationships across complex research organisations both internally and externally (University, NHS, industry and third party CROs) to deliver the trial and facilitate research.

- Manage communication activities with various stake-holders (academics, health professionals, funding bodies, patients and the public). Ensure communication is appropriate, timely and effective.

- Prepare and submit ethics and regulatory applications to the relevant bodies, and assist in the review of study documentation namely research protocols, investigational product dossier, patient information sheets, consent, questionnaires, and CRFs.

- Produce reports on the trial together with all supporting documentation as required for University, funding bodies, ethics, R&D, NCRI etc.

- Demonstrate a strong personal presence with negotiation and diplomacy skills in the management of projects, in partnership with the Principal Investigator and Chief investigator.

- To work with the Contracts team to ensure all contracts are in place in relation to funding, CROs, site and other third parties required for the trial, monitoring compliance and ensuring processing of amendments as required.

- Ensure completion of up to date vendor assessments and audits of third party contractors.

- Regularly review vendor management and negotiate changes to contracts etc as required.

- Manage and review trial objectives on a regular basis to identify potential risks to progress and liaise and collaborate with others to decide upon appropriate actions.

- Review and input into clinical, medical, data and safety management plans and ensure all members of the team adhere to these.

- Liaise with the trial management group, trial steering committee and data monitoring committee, ensuring meetings are timely, all relevant information is provided in advance and arising issues are actioned.

- Ensure the project keeps to specific timelines and can deliver on objectives by overseeing the work of the project manager and project officer assigned to the trial.

- Attend and oversee regular meetings with all contracted third parties. Ensure action points from meetings are achieved.

- Provide regular updates to the Principal Investigator and project partners with regards to overall progress and in particular milestones, key deliverables and reporting.

- Present trial results on a national and international scale and oversee publication of trial results in line with funder requirements.

- Maintain clinical trials registration.

- To maintain confidentiality of information in line with data protection requirements and University policy.

- To comply with Health and Safety requirements, including having an awareness of personal responsibilities to maintain a safe working environment.

- To contribute to the University's agenda for social responsibility, including sustainability.

- Undertaking internal and external networking practices with the aim of continually enhancing and developing professional awareness, knowledge, skills and other abilities.

- To undertake such other duties as may be reasonably requested and that are commensurate with the nature and grade of the post.

PERSON SPECIFICATION

Essential Knowledge, Skills and Experience

Education:

- A first degree and PhD (or equivalent) in a relevant discipline e.g. medical or biological sciences or extensive equivalent experience

Experience:

- Relevant experience in a similar or related role, ideally in an ATMP, gene therapy or MPS disease trial.

- Knowledge of the academic research environment and of the expectations of good conduct that are associated with research activity.

- Extensive project management experience.

- Experience of working across the interface between academia, clinical and industrial boundaries demonstrating the skills and ability necessary to contribute effectively to team-working in a highly devolved structure.

- Experience of giving presentations/providing training.

- Experience of budget preparation and management.

- Experience of contract review and negotiation.

- Knowledge of and experience of writing clinical trial documents including the protocol, investigators brochure, IMPD and patient facing material.

Skills:

- Experience of drafting and reviewing clinical trial management plans.
- Excellent organisational, administrative and communication skills (oral and written).
- Evidence of an ability to write reports, design presentations and create training materials.
- Strongly developed interpersonal skills.
- Evidenced ability to prioritise workloads and meet deadlines.
- The ability to analyse and interpret data or information and to communicate its meaning effectively to staff at all levels.
- Highly developed IT skills (MS Office, email, database and website maintenance).

Aptitude:

- Ability to develop and maintain personal relations at all levels across disciplines.
- Decisive and diplomatic.
- Self-confident, self-motivated and articulate.
- Conscientious and hardworking.
- Evidence of commitment to developing personal and professional skills.

Desirable Knowledge, Skills, Experience and Qualifications

- Demonstrable leadership skills, particularly the ability to lead project teams.
- A detailed knowledge of organisational and administrative functions, including research grants and contracts processes, within HEIs and NHS Trusts.
- Detailed knowledge of legislation and regulations associated with biomedicine, particularly those associated with the management and governance of CTIMPs, most notably the Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments.
- Experience of auditing and monitoring of trials.
- Experience of writing and management of SOPs.