THE UNIVERSITY OF MANCHESTER

PARTICULARS OF APPOINTMENT

FACULTY OF BIOLOGY, MEDICINE & HEALTH

CHOOSE AN ITEM.

IMAGING FACILITIES

RESEARCH PROJECT MANAGER

Salary:	Grade 6
Hours:	1 FTE
Duration:	Permanant
Responsible to:	Senior Project Manager

Overall Purpose of the Job:

Key Responsibilities, Accountabilities or Duties:

Strategic

- To contribute to the development, implementation, evaluation and monitoring of the School's strategy, policies and procedures
- To provide advice and guidance on key issues concerning activities and other relevant strategies to the successful operation of the School and Imaging Facilities

Operational

- Act as the main liaison point between the Imaging Facilities, Principal Investigators (PIs) and other research collaborators;
- Provide complex and specialist advice to study teams and researchers on the complex regulatory environment surrounding medical imaging research including
    - the use of Ionising Radiation
    - research governance issues
    - adherence to Good Clinical Practice (GCP)
    - the Imaging Facilities' scientific and operational strategies and general capabilities

- Provide specialist advice, guidance and support to researchers on the preparation of regulatory applications and Protocols and on the regulatory application processes (REC, HRA, Trust Capacity and Capability, ARSAC, Sponsor's approval etc.).
- For some internal PET-MR studies, manage the regulatory submissions process and coordinate Protocol amendments on behalf of the study team

- Continual management of ongoing imaging projects, including periodic internal auditing, to ensure continuing adherence to regulatory requirements;
- Take operational decisions where required to enable research and ensure the successful smooth running of the Imaging Facilities, e.g. resolving scheduling conflicts and internal issues
- Manage the internal review process for new PET-MR and MR research studies/Clinical Trials applying to use the Imaging Facilities.
- Review studies and comment on operational feasibility and identification of resource requirements and safety issues.
- Manage the operational and regulatory set-up and launch of new PET-MR and MR research studies / Clinical Trials within the Imaging Facilities and have responsibility for ensuring that all studies using the facilities have the necessary regulatory approvals and operational arrangements in place before launch.
- Chair and lead all PET-MR and MR study -related meetings involving both internal and external researchers and operational staff and act as the liaison between the study team and Imaging Facilities staff.
- Chair and lead PET-MR and MR study review and operational set-up meetings, presenting new studies and leading on study set up to ensure that studies are launched in a time efficient manner and to a high standard.
- Chair and lead the bimonthly Imaging Facilities operations committee
- Represent the Imaging Facilities at external meetings with researchers, funders, Sponsors and commercial stakeholders
- Work with the Senior Project Manager (to be retitled Senior Business Operations Manager) on the project management of new scanner purchases and major upgrades as required, including managing the impact on studies and operational capabilities and communication with users
- Maintain a good working knowledge of the research environment within the Imaging Facilities including the regulatory requirements (GCP,. general data protection etc). This will help ensure research being conducted in the Imaging Facilities continues to be effective and compliant;
- Manage the University's Administration of Radioactive Substances Advisory Committee Employer Licences (ARSAC) for the PET-MR facility.
- In liaison with other colleagues, develop and review internal processes to ensure compliance with the ARSAC Employer Licences (and the Ionising Radiation (Medical Exposure) Regulations 2018 (IR(ME)R))
- Develop and maintain a number of local policies and standard operating procedures for the purpose of improving internal working practices and ensuring the quality of research activities with regard to project management. This will involve working with experts, both internal and

external to the Imaging Facilities, including operational staff (QA, radiographers, physicists, technicians), radiologists, the University Research Office and other clinicians and scientists involved in clinical imaging research;

- Maintain and improve project management systems ensuring that they are populated with accurate information about projects being conducted within the Imaging Facilities (for example, project status including scientific and financial outcomes);
- Maintain and improve the Imaging Facilities project management system for providing centre-wide access to, and robust version control of project information and project-related documents;
- In cases where projects have passed the internal review processes, sign off applications for site-specific approval on behalf of the Site Management Organisation;
- Liaison with QA colleagues to prepare for facility inspections and audits including GCP Sponsor audits and monitoring visits, ensuring follow up actions for external audits and inspections (e.g. GCP) of the Imaging Facilities are completed.
- Manage study monitoring visits from commercial Sponsors for MR and PET-MR scanning sites
- Maintain a solid and up to date understanding of the complex regulatory environment and systems surrounding clinical research
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Managerial

- Line manage junior project management staff and other staff where appropriate, and have systems to ensure that:

    - PDRs are conducted for all PS staff;
    - Cases for regarding, rewarding exceptional performance and distinguished achievement awards are proactively considered;
    - Training needs are identified and met;
    - Workloads are appropriate, requests for flexible working are considered and staffing levels are regularly reviewed;
    - Probationary periods are managed;
    - Performance issues are identified and managed.

- Provide a contribution to the effective and efficient management of the School and Imaging Facilities and the ongoing review of priorities;

General

- Have an understanding of, and commitment to, promote the University's policies and procedures to support and promote equality and diversity;
- To maintain confidentiality and 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.

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Person Specification

Education and Professional Qualifications

Essential

- First degree or equivalent, extensive, demonstrable relevant experience
- Current GCP certification

Desirable

- Accredited to PRINCE2 Foundation level, or experience of working on projects using PRINCE2 methodology

Skills and knowledge

Essential

- Have a solid understanding of the complex regulatory environment and systems surrounding clinical imaging research, particularly ARSAC, IR(ME)R, research governance and GCP
- Demonstrable excellent communication skills (written and oral) with the ability to present information clearly and explain complex issues to a range of audiences
- Sound analytical, creative and pragmatic problem-solving skills
- Excellent IT skills, particularly in the Microsoft Office suite
- Ability to represent the School and Faculty externally
- Have an understanding of the context that the University is operating within and an awareness of current issues facing Higher Education
- Demonstrable commitment to the University's strategy, vision and values

Experience

Essential

- Experience in line management and the development of staff
- Experience of working in a University and/or NHS Trust research environment
- Experience of co-ordinating clinical trials/research projects, specifically involving GCP PET, MR and PET-MR
- Experience of applying for regulatory approvals and demonstrable knowledge of clinical and research governance requirements, specifically involving GCP PET, PET-MRand MR
- Experience in the use of a quality management system
- Demonstrable experience of meeting operational requirements, with excellent planning and organisational skills
- A constructive team player demonstrating an ability to work collaboratively
- Demonstrable experience of policy development and implementation
- Experience of working in a customer-focused environment and delivering exceptional customer service

- Demonstrable significant project management experience

Desirable

- Working knowledge of applying for ARSAC licences

Expectations and success factors

- To be a proactive team member and treat all colleagues and students with respect in accordance with the established PS Behaviours.
- To be willing to work across organisational boundaries.
- To seek new knowledge and share ideas.
- To be open and responsive to change and innovation