

## SHEFFIELD CHILDREN'S NHS FOUNDATION TRUST

### JOB DESCRIPTION

#### 1. JOB IDENTIFICATION

Job Title: Research Sponsorship Officer

Department: Research & Innovation Care Group

Responsible to: Research & Innovation Management Team

Accountable to: Research & Development Manager

Band: 6

#### 2. JOB PURPOSE

The Research Sponsorship Officer will have a responsibility to ensure that all research is conducted in accordance with the Trust's sponsorship requirements, current legislation, national guidelines and Trust policies across all study sites including providing advice and guidance to investigators with administrative planning as appropriate.

The post holder will guide compliance with the Trust policies for Research Governance as well as UK Policy Framework for Health and Social Care Research. With an increasing number of studies being managed by Sheffield Children's NHS Foundation Trust, the post holder will be responsible for the management of a growing portfolio of Trust sponsored trials and be the lead sponsor contact for Trust trials ensuring they are conducted in accordance with current legislation, ensuring all activities are compliant.

#### 3. MAIN DUTIES/RESPONSIBILITIES

##### **Sponsorship and Research Management:**

- To contribute to the development and management of systems and procedures for the co-ordination of clinical research within the Trust with all those working within research
- Communicating effectively with the clinicians and research teams providing clinical trials support and guidance to ensure best practice is achieved.
- Communicating with Ethical Committees and other regulatory authorities such as the HRA and MHRA.
- Liaising with all staff involved in research (Consultants and junior medical staff, project managers, research nurses and other nursing staff, central laboratories, Clinical Trials Unites, Clinical Research Organisations etc). This will involve attendance at project related meetings, investigator meetings (as necessary) to provide guidance and advice on the relevant information to the study team.
- Perform sponsorship reviews of IRAS applications and associated documents for new studies and amendments.
- Providing guidance and support to researchers to determine which approvals are needed

for studies.

- Oversee the maintenance of research management system (EDGE) for the sponsored study portfolio.
- Ensuring compliance with regulatory requirements by implementing appropriate audit and monitoring systems and performing risk assessments for each study.
- Implementation of appropriate pharmacovigilance / adverse event reporting systems in compliance with EU and national regulations.
- Maintaining trial documentation in accordance with the ICH-GCP and the EU Clinical Trials Directive 2004 i.e., protocols, study files, investigator brochure etc.
- Working with the University and other research sponsorship teams, to ensure that research governance regulations are applied consistently across organisational boundaries.
- To identify and refer any major concerns on research governance and sponsorship issues to the Research & Development Manager
- To support the Research & Development Team in the preparations and conduct of any inspection of the Trust's research.
- To manage, in conjunction with other members of the R&D team, a robust file management system for paper-based and electronic files for matters concerning the administration of research projects.
- Ensuring research studies are costed appropriately to ensure that they are being delivered within budget.
- Supporting the collection of clinical research data by designing tools (forms) for data collections and distribution procedures to ensure smooth running of the trial / study.
- Performing miscellaneous job-related duties as assigned, including preparing co-ordinating research / trials related meetings with clinical members of the team i.e Research Nurse teams, Trial Management Groups, Trial Steering Committees, sponsorship meetings, Research Governance and Sponsorship committees and Data Monitoring Committees.
- Co-ordinating the completion of electronic trials documentation for new trials, involving facilitating applications for Ionising Radiation (Medical Physics) Regulations (IRMER) for imaging investigations and for nuclear medicine through the Administration of Radiation Substances Advisory Committee (ARSAC).
- Producing regular trial updates as required.
- Liaising with participating sites, ensuring all work is appropriately contracted and study protocols are complied with.
- Ensuring site initiation, randomisation and site pharmacovigilance are in place where required.
- Provide assurance to the Research Governance & Sponsorship Committee and other committees as required.
- Where required perform monitoring and audit on Trust Sponsored research studies.
- To have a robust knowledge of Information Governance and ensure adherence to applicable legislation and Trust Policies in the conduct of the Trust's Sponsored studies.
- Working with the Research & Development Manager to ensure that all required legal contracts are in place for the effective and robust delivery of Trust Sponsored trials.

## Management

- Day to day management of junior staff.
- Contributing to as required, the development of clinical and research policies / procedures / SOPs.
- Resolving delays and difficulties with activating trials, developing, and managing an escalation process to be followed when trial initiation problems / delays arise.
- Managing workload effectively and in accordance with guidance relating to Research Governance.
- Attending meetings relevant to the nature of the role.
- Providing research governance expertise to team members as and when required.

- Deputise for the R&D Manager where required

## **Training and Professional Development**

- Maintaining professional development whilst evaluating own specialist knowledge and through a process of appraisal and personal development planning.
- Participating in Trust-wide education programmes.
- Participating in research seminars to keep up to date with research.
- Maintaining knowledge on clinical trials including informal learning and attendance at appropriate national training initiatives.
- Networking with local, national, and international colleagues in research.
- Developing and providing training on research within the NHS to other staff, University students, academic supervisors etc.
- Developing and providing training on portfolio adoption and amendments to project managers and trial co-ordinators
- Undertaking any other duties consistent with the responsibilities of the grade and needs of the service

## **4. SCOPE AND RANGE**

### **Internal Relationships**

To work with the following groups:-

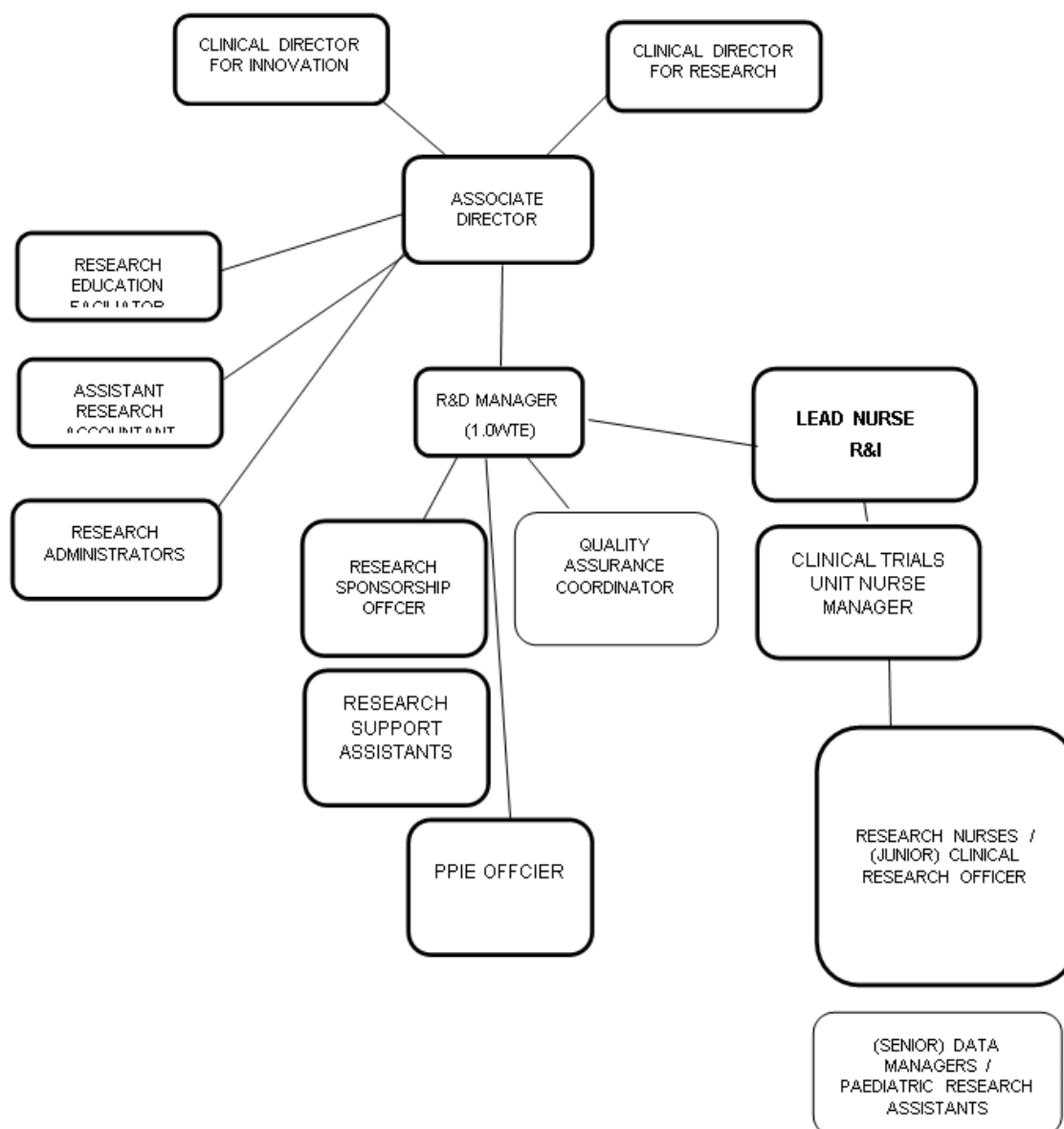
- The team in the Research & Innovation Care Group
- Chief Investigators
- Clinical Staff and Support Department Staff in the Trust
- Information Governance Team within the Trust
- Trust's Legal team
- Senior Management in the Trust

### **External Relationships**

To liaise with the following external organisations:-

- Research Networks
- Academic Institutions
- Other NHS Trusts
- Central laboratories
- Co-sponsors (possibly international)
- CTUs/CROs
- Other external vendors responsible for the delivery of Trust Sponsored trials
- Research funders

## 5. ORGANISATIONAL POSITION



## 6. JOB DESCRIPTION AGREEMENT

Job Holder's Signature:

Manager's Signature:

Date:

Date:

## TRUST VALUES

Our Values express what it is like to work in our organisation and our employees should make these a part of everything we do.

*Keeping children, young people and families at the heart of what we do*

### Compassion

- We are led by kindness for all – for our patients, their families and our colleagues
- We will show empathy and understanding, treating everyone with dignity and courtesy
- We will respect each other and those we care for

### Accountability

- We always strive to do the right thing
- We own responsibility for our successes, failures and understand where we need to improve
- We will create a supportive working environment where everyone takes responsibility for their own actions

### Respect

- We value differences and treat everyone fairly and consistently
- We will actively tackle inequality and will foster a culture of inclusion

### Excellence

- We will seek to improve the way we work and deliver a high quality standard of care
- We will be open to new ideas, through innovation, partnership, research and education locally, nationally and internationally

**Together we care**

**SHEFFIELD CHILDREN'S NHS FOUNDATION TRUST**

**PERSON SPECIFICATION – Research Sponsorship Officer**

Assessment Criteria	Essential	Desirable	How assessed
<b>Qualifications and Training</b>	<p>First degree in biomedical / scientific discipline or equivalent experience</p> <p>Management qualification, or equivalent Experience</p> <p>ICH-GCP qualification</p>	<p>Postgraduate qualification</p> <p>Project Management Qualification</p>	AF
<b>Experience</b>	<p>Previous experience of working in a research support environment and/or understanding of NHS R&amp;D environment, Sponsorship, research funding systems, managing clinical trials and clinical trial methodology and logistics.</p> <p>Managerial experience in an administration environment</p> <p>Experience in a governance or a research role</p> <p>Excellent knowledge of Microsoft Office (Word, Excel, PowerPoint) and using them to produce written formal reports with quality presentation skills</p> <p>Experience of managing multiple projects / assignments independently and as a team</p> <p>Advanced decision making skills and ability to resolve complex work-related issues.</p>	<p>Project Management</p> <p>Experience of working in the NHS</p> <p>Experience in a customer facing role</p> <p>Experience of managing a team</p>	AF/In
<b>Knowledge and Skills</b>	<p>Proven knowledge and understanding of (clinical) research issues such as research governance, ethical review, Medicines for Human Use Regulations, Human Tissue Act etc Working knowledge of UK Policy Framework for Health and Social Care Research and ICH Good Clinical Practice</p>		AF/In/P

	<p>Excellent understanding of people management, ability to supervise, inspire and promote confidence in a team.</p> <p>Able to autonomously prioritise and plan workload to meet deadlines, often in a pressurised environment.</p>		
<b>Personal Attributes</b>	<p>Proven record of planning, organisational, change management and administration skills</p> <p>Excellent level of verbal and written communication with the ability to persuade, negotiate and influence others.</p> <p>Able to use judgement and initiative to provide information and support.</p> <p>Excellent numerical and analytical skills with excellent attention to detail and accuracy</p> <p>Empathetic approach to managing and resolving enquiries.</p> <p>Able to manage difficult and distressing situations effectively.</p> <p>Able to collaborate with others.</p> <p>Positive and flexible approach to work</p> <p>Understands limits of own responsibilities</p>		AF/In/P
<b>Demonstrates Trust Values</b>	<p>Must be able to demonstrate behaviours consistent with the Trust's values:</p> <p>Compassion, Accountability, Respect and Excellence.</p>		In/REF

**Key for How Assessed: AF = Application form, In = Interview, P = Presentation, T = Test, REF= Reference**