

JOB DESCRIPTION

JOB DETAILS	
Job Title	Research Sponsorship Manager
Reports to	Senior Research & Development Manager
Band	Band 8a
Department/Directorate	Research & Development

JOB PURPOSE
<p>The post holder will ensure the Trust carries out its responsibilities as sponsor for all Trust sponsored research studies and clinical trials.</p> <p>The post holder will provide regulatory support to researchers from grant application, through sponsorship and regulatory approval, initiation at sites, study conduct and close-down; ensuring studies meet regulatory requirements and other obligations as Sponsor.</p> <p>The study portfolio will include (but is not restricted to) Clinical Trials of Investigational Medicinal Products (CTIMPS) and Medicines and Healthcare Regulatory Agency (MHRA) regulated Clinical Investigations of Medical devices as well as interventional trials, basic science studies involving procedures with human participants, observational studies, qualitative research and studies working with tissue or data.</p> <p>The post holder will support the Research & Development (R&D) Senior Team for Trust sponsored studies, ensuring research studies are of a consistently high standard. Ensuring that all research carried out in the Trust complies with the UK Policy Framework for Health & Social Care Research, ICH GCP standards and best practice, including MHRA guidance.</p> <p>The post holder will be required to work autonomously, managing their day-to-day workload and prioritising as needed.</p>

KEY RESULT AREAS/PRINCIPAL DUTIES AND RESPONSIBILITIES
<ul style="list-style-type: none"> • Ensure that the Trust has an effective, responsive and high-quality research sponsorship function. • Provide expertise regarding research regulatory requirements, e.g. NHS Research Ethics Committee, HRA, MHRA, Research Governance Framework, ICH-GCP, General Data Protection Regulation (GDPR), Medicines for Human Use Regulations, and advise accordingly. • Provide Trust researchers with early engagement support. Ensuring they are directed to the most appropriate resource to develop research idea. • Support Trust researchers with identifying appropriate funding streams. • Support clinical teams in developing grant applications, including coordinating early engagement meetings, statistic signposting, regulatory considerations, costs, feasibility of delivery, assessment of risks and protocol development. • Coordinate and oversee contracting with funder and service providers. • Promote the Patient and Public Involvement and Engagement (PPIE) and Equality, Diversity and inclusion (EDI) aspects of study design. Signposting to relevant support and resources. • Oversee R&D support offered to researchers with trial registration and NIHR portfolio adoption (if relevant). • Work with Trust researchers and finance team to accurately cost research grants, monitor expenditure and ensure accurate invoicing. • Support and collaborate with researchers developing study specific documentation and Integrated Research Application System (IRAS) application. • Oversee lifetime of Trust sponsored studies, including monitoring recruitment, safety and breach oversight, amendment review, Trial Management Meetings (TMG). Coordinate and manage end of

study activities. Including closeout, archiving, final funder reporting, dissemination and oversight of publications and impact.

- Responsible for providing assurance of Sponsor compliance to the wider R&D governance group. For example, grant activity, national and local key performance indicators (KPIs), recruitment numbers, safety and monitoring oversight and identification of key risks.

KEY WORKING RELATIONSHIPS

No. of Staff reporting to this role: 2

The post holder is required to deal effectively with staff of all levels throughout the Trust as and when they encounter on a day to day basis

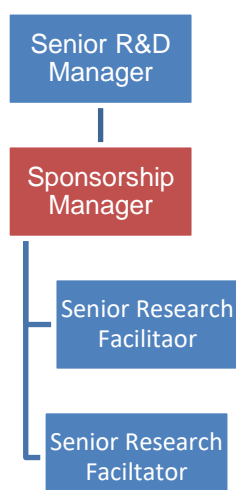
In addition, the post holder will deal with the wider healthcare community, external organisations and the public.

This will include verbal, written and electronic media.

Of particular importance are working relationships with:

Internal to the Trust	External to the Trust
<ul style="list-style-type: none"> • Trust Researchers & clinical teams • R&D Director • Senior R&D Managers • Research Delivery Teams • R&D Finance Teams • Lead Research Nurse • Sponsorship Facilitators • Pharmacy Teams • Information & Digital Analysts • Clinical Research Facility (CRF) • Health Tech Research Centre (HRC) • Quality Assurance R&D team 	<ul style="list-style-type: none"> • University of Exeter • Other Academic Institutions • Clinical Trials Units • Research Support Service • Research Ethics Committees/HRA • Biomedical Research Centre (BRC) • Commercial Partners • Regional Research Delivery Network (RRDN)

ORGANISATIONAL CHART



FREEDOM TO ACT

The post holder will support the Research & Development (R&D) Senior Team for Trust sponsored studies, ensuring research studies are of a consistently high standard. Ensuring that all research carried out in the Trust complies with the UK Policy Framework for Health & Social Care Research, ICH GCP standards and best practice, including MHRA guidance.

Provide expertise regarding research regulatory requirements, e.g. NHS Research Ethics Committee, HRA, MHRA, Research Governance Framework, General Data Protection Regulation (GDPR), Medicines for Human Use Regulations, and advise Trust researchers accordingly with reference to each research study protocol.

The Sponsorship manager will work independently from the senior R&D manager, they are an expert in their field. They will ensure that all sponsored research adheres to the regulatory requirements listed above as well as Trust R&D policy and standard Operating Procedure (SOP's). They will work independently with researchers to guide them in their protocol development and applications for approval.

COMMUNICATION/RELATIONSHIP SKILLS

Frequently engaging with numerous investigators, academic collaborators, clinical research fellows, nurses, support departments, academic departments and external organisations to ensure they receive appropriate and tailored support. Working closely with collaborators throughout the lifetime of a trial.

Ensures there is good internal communication, with members of Research infrastructure staff, regarding decision making and complex sponsorship pathway process.

Tact and sensitivity will need to be used when delivering negative news to recipients. For example, explaining feedback from grant applications and ethic committee submissions to researchers.

Lead on early engagement meetings with researchers, which can involve collaborating with a diverse group of highly skilled individuals. This requires the ability to negotiate, co-operate and an understand a range of specialist knowledge (e.g. Statistics, research design and methodology).

ANALYTICAL/JUDGEMENTAL SKILLS

Regularly reviews sponsorship applications to ensure the quality and regulatory compliance of the research. This requires interpretation of national regulations and guidance, which can be complex and can involve a comparison of a range of options.

Evaluate the Trust Sponsorship service against a range of internal and external performance metrics. Reporting into the R&D governance group and presenting complex metric data on a monthly basis.

Acts as an expert on sponsorship governance. Advising research teams and collaborators on sponsor requirements and ensuring research meet this. They will be required to be a key member of Study Trial Management Groups (TMG), acting as Sponsor representative. Ensuring that the study meets all requirements and that protocols are adhered too. As part of the TMG they will be required to investigate and lead on any root cause analysis when reviewing any deviation to protocol or process. They will also be required to develop and own any corrective action preventative action plans (CAPA) that are required within the Sponsored service.

PLANNING/ORGANISATIONAL SKILLS

Responsible for organising and coordinating early engagement meetings with Trust researchers. These can be complex and involve a range of colleagues from across institutions.

Work with the senior R&D Manager & R&D Director in long term strategic planning for the Sponsorship service. This will involve improving and growing the service offer and collaborating with different institutions.

Strategically planning within the Trust, for example, raising the profile of research sponsorship within the wider Trust as well as engaging in new speciality areas and new research active staff. This can involve training and working in partnership with the communication team to celebrate successes.

Work with the researchers and other institutions e.g. University of Exeter to plan and prioritise resource according to need and study pipeline – working towards a tight deadline with grant applications.

PATIENT/CLIENT CARE

Patient contact is incidental but to provide assistance to patients and/or clients as required.

POLICY/SERVICE DEVELOPMENT

The post holder will support the Research & Development (R&D) Senior Team for Trust sponsored studies, ensuring research studies are of a consistently high standard. Ensuring that all research carried out in the Trust complies with the UK Policy Framework for Health & Social Care Research, ICH GCP standards and best practice, including MHRA guidance.

Responsible for writing and reviewing R&D policy relating to Sponsorship oversight. Therefore, responsible to revise these accordingly. Also oversight the wider R&D policy relating to all sponsored research activity within the Trust. Ensuring that all Trust sponsored research is compliant with R&D policy. This may entail a review of study protocols and patient facing information, or interpretation a grant application to ensure it is compliant.

Work closely with the R&D Quality Assurance team (QA), to ensure sponsored specific standard operating procedures and work instructions are up -to date and still relevant to the service.

FINANCIAL/PHYSICAL RESOURCES

Oversight of financial management including study costings, research budget and effective management of individual study budgets.

Act as an authorising signatory for the research budgets, within limits agreed.

HUMAN RESOURCES

Act as manager for the sponsorship team, supervising senior research facilitators. Take the lead for performance and conduct issues within the Sponsorship team. Identify training and development needs of staff and ensure all new staff receive adequate training and induction.

Managing a team of staff that may have include performance issues, instigating Trust policies and procedures.

Work with researchers to ensure they have the right research training, sign posting them to the relevant resources. Also support wider sponsorship team to develop research specific training, for example, site file maintenance and EDGE training.

INFORMATION RESOURCES

Oversees the data inputted into EDGE for all Trust sponsored studies, including number of participants recruited and whether we are delivering time to target. Also, cross referencing this data against the wider NIHR data platform to ensure accuracy of activity. This feeds into our Trust R&D key performance indicators. This data can be complex and attention to detail is essential.

RESEARCH AND DEVELOPMENT

Research is a key dimension to this role. The sponsorship manager will act as the first point of contact for any Trust researcher aiming to create their own research study.

They will oversee lifetime of Trust sponsored studies, including monitoring recruitment, safety and breach oversight, amendment review, Trial Management Meetings (TMG). Coordinate and manage end of study activities. Including closeout, archiving, final funder reporting, dissemination and oversight of publications and impact.

The post holder will work in collaboration with QA R&D team. Supporting the QA facilitators to undertake regular monitoring audits of Trust sponsored studies. Reviewing all research activity against the protocol and regulatory approved activity. As sponsor manager, the postholder will be in receipt of these reports and must action any requirements with the research teams. Highly developed research governance knowledge is essential.

The postholder will be a member of the Joint Research Office in collaboration with the University of Exeter.

PHYSICAL SKILLS

Advanced keyboard skills essential for creating reports, presentations and spreadsheets. Accuracy of data inputting essential for data quality and accurate reporting.

There may be a need to travel between research sites and universities, depending on the need of the researcher.

PHYSICAL EFFORT

Light physical effort. Computer and VDU use for majority of work time.

MENTAL EFFORT

Frequently required to concentrate for long periods of time when analysing reports, preparing policy and strategy documents, interpreting policy and reviewing grant proposals and protocols.

As the postholder is the first point of contact for Trust researchers, the ability to prioritise workload is essential. Due to the nature of the timing of research grant applications throughout the year, being able to manage competing demands will be vital.

EMOTIONAL EFFORT

Occasional exposure to emotional circumstances. For example, discussing with researchers unsuccessful grant applications or unfavourable ethics opinions.

WORKING CONDITIONS

Office conditions, requiring VDU use most of the time. Driving to meetings on other sites is occasionally required.

OTHER RESPONSIBILITIES

Take part in regular performance appraisal.

Undertake any training required in order to maintain competency including mandatory training, e.g. Manual Handling

Contribute to and work within a safe working environment

You are expected to comply with Trust Infection Control Policies and conduct him/herself at all times in such a manner as to minimise the risk of healthcare associated infection

As an employee of the Trust, it is a contractual duty that you abide by any relevant code of professional conduct and/or practice applicable to you. A breach of this requirement may result in action being taken against you (in accordance with the Trust's disciplinary policy) up to and including dismissal.

You must also take responsibility for your workplace health and wellbeing:

- When required, gain support from Occupational Health, Human Resources or other sources.
- Familiarise yourself with the health and wellbeing support available from policies and/or Occupational Health.
- Follow the Trust's health and wellbeing vision of healthy body, healthy mind, healthy you.
- Undertake a Display Screen Equipment assessment (DES) if appropriate to role.

APPLICABLE TO MANAGERS ONLY

Leading the team effectively and supporting their wellbeing by:

- Championing health and wellbeing.
- Encouraging and support staff engagement in delivery of the service.
- Encouraging staff to comment on development and delivery of the service.
- Ensuring during 1:1's / supervision with employees you always check how they are.

GENERAL

This is a description of the job as it is now. We periodically examine employees' job descriptions and update them to ensure that they reflect the job as it is then being performed, or to incorporate any changes being proposed. This procedure is conducted by the manager in consultation with the jobholder. You will, therefore, be expected to participate fully in such discussions. We aim to reach agreement on reasonable changes, but if agreement is not possible, we reserve the right to insist on changes to your job description after consultation with you.

Everyone within the Trust has a responsibility for, and is committed to, safeguarding and promoting the welfare of vulnerable adults, children and young people and for ensuring that they are protected from harm, ensuring that the Trusts Child Protection and Safeguarding Adult policies and procedures are promoted and adhered to by all members of staff.

At the Royal Devon, we are committed to reducing our carbon emissions and minimising the impact of healthcare on the environment, as outlined in our Green Plan available on our website. We actively promote sustainable practices and encourage colleagues to explore and implement greener ways of working within their roles.

PERSON SPECIFICATION

Job Title	Research Sponsorship Manager
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Requirements	Essential	Desirable
QUALIFICATION/ SPECIAL TRAINING		
Post graduate diploma or equivalent experience or training in a field relevant to healthcare and/or clinical research.	E	
Research Training e.g. Good Clinical Practice (GCP).	E	
Management or leadership qualification or relevant experience to masters level or equivalent.	E	
KNOWLEDGE/SKILLS		
In depth knowledge of the Research Governance Framework and the International Conference on Harmonisation Good Clinical Practice Guidelines.	E	
In depth understanding of the research process within the NHS.	E	
Experience working with researchers developing their own studies including protocol development, risk assessment and IRAS applications.	E	
Sponsorship process experience.	E	
Knowledge of the NIHR high level objectives and portfolio performance management.	E	
IT skills including the ability to work with databases and systems.	E	
Ability to organise and prioritise own workload whilst working to rigorous timelines.	E	
Proven ability of strategic thinking and ability to make independent decisions.	E	
Critical appraisal skills.	E	
Evidence of budgetary control.		D
Able to use research software to analyse data, extract information, produce presentations and reports.	E	
EXPERIENCE		
Established management track record.	E	
Worked within the NHS/University in a research governance capacity.	E	
Proven record of the ability to meet targets.	E	

Ability to work with range of staff, disciplines, and seniority in a healthcare environment.	E	
Ability to take and exercise responsibility and initiative when dealing with issues within own specialist area of competence.	E	
PERSONAL ATTRIBUTES		
High level of interpersonal and communication skills.	E	
Attention to detail.	E	
Honesty, integrity, reliability, and respect for confidentiality. Self-motivation.	E	
Good interpersonal and negotiation skills.	E	
Able to work effectively within clinical and research multidisciplinary teams.	E	
Able to work as a team member.	E	
OTHER REQUIREMENTS		
The post holder must demonstrate a positive commitment to uphold diversity and equality policies approved by the Trust.	E	
Ability to travel to other locations as required.	E	

WORKING CONDITIONS/HAZARDS		FREQUENCY (Rare/ Occasional/ Moderate/ Frequent)			
		R	O	M	F
Hazards/ Risks requiring Immunisation Screening					
Laboratory specimens	N				
Contact with patients	N				
Exposure Prone Procedures	N				
Blood/body fluids	N				
Laboratory specimens	N				
Hazard/Risks requiring Respiratory Health Surveillance					
Solvents (e.g. toluene, xylene, white spirit, acetone, formaldehyde and ethyl acetate)	N				
Respiratory sensitisers (e.g isocyanates)	N				
Chlorine based cleaning solutions (e.g. Chlorclean, Actichlor, Tristel)	N				
Animals	N				
Cytotoxic drugs	N				
Risks requiring Other Health Surveillance					
Radiation (>6mSv)	N				
Laser (Class 3R, 3B, 4)	N				
Dusty environment (>4mg/m3)	N				
Noise (over 80dBA)	N				
Hand held vibration tools (=>2.5 m/s2)	N				
Other General Hazards/ Risks					
VDU use (> 1 hour daily)	Y				X
Heavy manual handling (>10kg)	N				
Driving	Y		X		
Food handling	N				
Night working	N				
Electrical work	N				
Physical Effort	Y		X		
Mental Effort	Y				X
Emotional Effort	Y				X
Working in isolation	N				
Challenging behaviour	Y		X		