Job Description

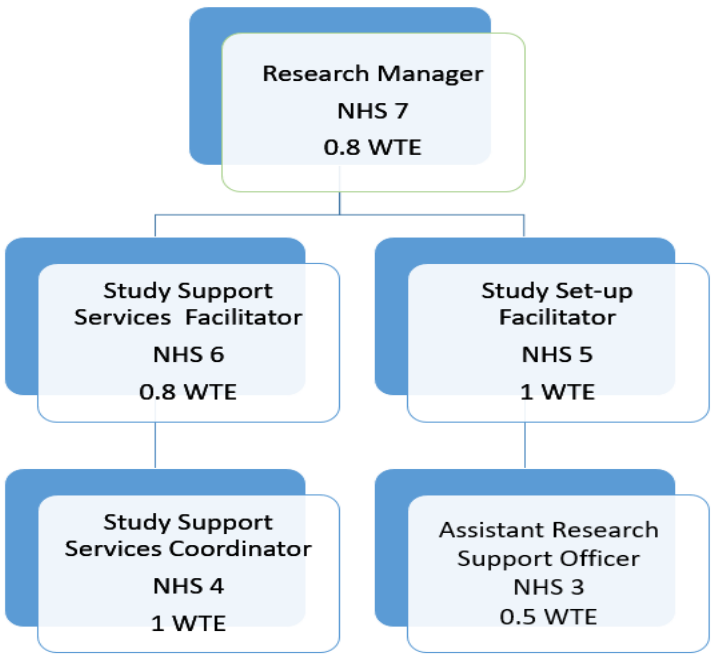
1. Job Details	
Job title:	Study Set-up Facilitator
Current Job grade:	Band 5
Reports to (Title):	Research Manager
CMT:	
Department/Ward:	Research & Innovation
Location/Site:	Trust-wide

2. Job Purpose

The Study Set-up Facilitator works closely with the R&I management team, Trust Principal Investigators, R&I Delivery team, R&I Support Office, the wider Trust and external research teams, Clinical Trials Units and study sponsors to establish and deliver the systems and processes required to support the efficient and timely set up and delivery of clinical trials.

The post holder will be required to support the develop Trust policies and Standard Operating Procedures in response to local, national and regulatory changes.

3. Organisation Chart



4. Duties

1. Study Delivery and Support Service

- Support Principal Investigators and local research teams to undertake feasibility review as part of the HRA Confirmation of Capacity and Capability process to ensure that studies can be opened at site level and delivered to time and target.
- Identify and resolve potential challenges to study start-up/delivery.
- Work with the R&I Management Team to support the development of early career researchers (medical and other clinicians/AHPs).
- Link with the relevant East Midlands Clinical Research Network Study Support Team regarding study feasibility and set-up.
- In collaboration with the R&I Delivery Team, co-ordinate responses to NIHR Site ID/Site Intelligence requests (includes EOIs for non-commercial studies), including provision of feedback/intelligence on why the site has declined to take part.
- Abide by HRA guidance/directives, including the terms set out for study set-up under HRA Approval.
- Support the R&I Management Team with the development of the commercial research portfolio to increase income to the Trust.
- In collaboration with Research Delivery Team, facilitate robust feasibility of research proposed in the Trust.
- Work with local research teams to ensure that NIHR study start-up and delivery timelines are achieved. Communicate reasons for delays/issues to the CRN via Edge notes (see below).
- Engage with appropriate NIHR/HRA training and development opportunities.

2. Information management

- Disseminate and interpret information in relation to updates on regulations. This will mean having the freedom to act on handling and making decisions on complex information that will require analysis, interpretation and comparison of a range of options in the effective running of clinical trials.
- Development and maintenance of in house database to record patients entered onto Clinical Trials. Collate such information on an ad hoc basis to reflect centre activity.
- Ensure the requirements for the Central Portfolio Management System reports accurate and timely information to the CRN to support the Trust's financial allocation.
- Maintain a spread sheet and ensure compliance for mandatory training for all research staff.
- To be responsible for ensuring that security and confidentiality of information is maintained at all times e.g. that data stored in the database is regularly backed up and that data is anonymised and encrypted to ensure patient confidentiality is maintained.
- Analyse and make definite judgement on complex research projects to determine if the projects remain compliant with current legislation

Data Management

- Prepare and submit trial documentation to various committees and regulatory agencies for review and approval (Sponsor, ethics and R&I etc.).
- Lead in the set-up of commercial and non-commercial trials i.e. liaise with trial centre / Commercial Clinical Research Organisations (CROs) and other relevant staff within host NHS Trust to organise trial set-up.
- Plan, prepare and participate in monitoring visits and respond to trial data queries.
- To undertake formal internal monitoring of research studies in accordance with Trust policy.
- To monitor the progress of research trials within the Trust to ensure compliance with Good Clinical Practice, regulatory approvals and internal Trust policy. This is a requirement for patient safety and Trust indemnity.
- To be responsible for preparing and disseminating the monitoring report and negotiating with researchers any follow up action necessary. Negotiation skills will be the key to dealing with contentious viewpoints and unclear / conflicting information and discussing poor or unacceptable performance.
- To contribute to the revision of local policies and procedures in addition to their implementation. This will include contributing to the development of Standard Operating Procedures (SOPs).
- Responsible for the over-sight of spread sheets/databases on participant recruitment into clinical trials.
- Oversee the production of accurate and timely reports on participant recruitment as required, to the National Institute of Health Research.
- Oversee Edge records to ensure minimum data set compliance is achieved and maintained.

4. Financial Management

- To support the clinical team in compiling research related costs for the UKCRN industry costing template and work with R&I team to facilitate sign off as part of study set-up.
- To develop and maintain activity and financial information data relating to all elements of research studies
- To interpret and implement financial guidance from the clinical research network
- To work with R&I Management Team in preparing and completing infrastructure funding bids
- To work with key study personnel including the Principal investigator, Research Delivery staff and other members of the research team to ensure that relevant activity data is captured.
- To develop systems to ensure that prompt reimbursement of support departments within United Lincolnshire Hospitals NHS Trust is established and maintained

5. Human Resources

- Keep up to date with health and safety developments throughout the department and Trust.
- Attend all mandatory training as required by the role.

- Identify through PDP and own needs on-going training in any areas relevant to the post.
- To deputise for the Study Support Service Facilitator/ Research Manager in their absence.
- To take line management responsibility, providing managerial leadership, managing sickness absence, appraisals and leading performance issues.
- To work with the National Institute of Health Research to facilitate mandatory training such as Good Clinical Practice.
- Oversee the training of staff on the Local Portfolio Management System
- Ensure awareness of developments relating to the Local Portfolio Management System, attending external training sessions as required.

6. Working Relationships

- Senior Managers and staff
- Research sponsors
- Chief Investigators, Principal Investigators and Research Staff
- Service Support Departments
- Human Resources Department
- Finance Department
- Local Clinical Research Network (LCRN)
- Health Research Authority / NHS Research Ethics Committees
- Commercial companies including contract Clinical Research Organisations
- Non-commercial research organisations including DoH and charities
- External researchers
- Academia
- Partner agencies including local voluntary organisations, community groups, local authorities and specific projects or programmes
- Voluntary & Private Sector Managers
- Patients, Carers & the Public

OTHER INFORMATION

- The postholder may be required to carry out other relevant duties as required.
- The postholder will adhere to the duties specified under the Staff Responsibilities of the NHS Constitution in their day to day work and behaviours.
- The postholder will be expected to aspire to the Values of the Trust in their day to day work and behaviours in order to support the Trust in achieving its Vision.
- The postholder will adhere to, at all times, any relevant Professional or NHS Code of Conducts, legislation and Assurance Frameworks.
- The postholder will make themselves familiar with, and adhere to, at all times, the policies and procedures of the Trust, and their area of work.
- The postholder will be expected to work to any personal, Corporate Directorate and Departmental objectives and standards in order to provide an acceptable level of service.
- The postholder will be expected to undertake training, including mandatory and role specific training, relevant to their role and ensure it is renewed as required.

This job description reflects the present requirements of the post and it does not form

part of the contract of employment. If the duties of the post change and develop the job description will be reviewed and will be subject to amendment, in consultation with the postholder. It is the Trust's aim to reach agreement on reasonable changes, but if agreement is not possible the Trust reserves the right to effect changes to the postholder's job description after consultation with them. Appropriate notice of such changes will be given.

5. Physical and Mental Skills

- **Physical skills**
  - Ability to travel across the Trust
- **Knowledge, Training & experience**
  - Knowledge of local, national and international Research Governance and legislation
- **Communication and relationship skills**
  - To employ excellent communication skills
  - Communicate with Medical/nursing and allied health professional staff
  - Influence people and events, formally and informally, at all levels through successful communication and interpersonal skills
  - To demonstrate motivating and influencing skills to promote and support clinical trials
- **Analytical and Judgmental skills**
  - To demonstrate an ability to analyse complex documents
  - To interpret local and national Research based policies and their implementation across the Trust
- **Planning and organisational skills**
  - Implements formulated plans within time scales, monitoring progress regularly to ensure that deadlines and targets are met in line with local policies and procedures.
  - Considers resources available and how they can be most effectively deployed to achieve objectives.

6. Responsibilities of the Post Holder

United Lincolnshire Hospitals Trust is committed to providing consistently excellent and safe patient-centred care for the people of Lincolnshire, through highly skilled, committed and compassionate staff working together. We do this by putting our patients at the centre of all that we do and providing the best quality care with passion and pride. We have a set of values that inform every action we take and every decision we make. They are the foundation of what United Lincolnshire Hospitals NHS Trust stands for, and encompass a desire in all of us to provide the highest quality of care to patients and each other.

All staff are required to advocate, champion and demonstrate the below values and behaviours

Patient centred	I am fully committed to providing the very highest standards of care to our patients
Safety	I do everything I can to keep my patients and my colleagues safe
	I keep my environment clean and tidy
	I recognise when something is going wrong and I have the courage to do something about it

Compassion	I show a genuine concern for my patients and my colleagues
	I communicate well with others, listening and showing an interest in what they have to say
	I am positive, approachable and friendly
Respect	I treat my patients and my colleagues with dignity and respect
	I work openly and honestly as part of an effective team
	I keep my promises and do what I say I will, when I said I will, or I will provide an explanation if I can't
Excellence	I will always go the extra mile and improve things for my patients and my colleagues
	I am competent to carry out my role and committed to my personal and professional development
	I will share good ideas and best practice and encourage my team members to do so too

7. Freedom to Act

Accountable for own actions, supported by the appropriate line management and in line with trust and departmental values and behaviours.

8. Physical, Mental and Emotional Effort Required

Physical effort: Desk based, some light lifting (e.g. stationery) and travelling. Occasional heavy lifting (e.g. full lever arch files and archive boxes).

Mental effort: Frequent requirement for concentration, work pattern is unpredictable, and work is likely to be frequently interrupted to deal with queries.

Emotional effort: The post holder may have to deal with complex research issues involving challenging conversations with researchers, other Study Support staff and R&I staff and will need to do this tactfully and tenaciously.

9. Outline of Working Conditions

Office conditions. Use of a computer for prolonged periods on most days. Some travelling by car or public transport required

United Lincolnshire Hospitals NHS Trust

OUTSTANDING CARE personally DELIVERED

United Lincolnshire Hospitals NHS Trust

Person Specification

Post of ……

Job Related Criteria	Essential	How Identified	Desirable	How Identified
Qualifications (Academic, Professional & Vocational)	• Degree or equivalent experience • Maths & English at GSCE level or higher • Up to date knowledge and experience of Microsoft Office suite of programmes	Application Form	• ICH GCP Training	Application Form
Previous Experience (Nature & Level)	• Able to demonstrate clinical research experience	Application Form and Interview	• Experience in NHS R&I office • Understanding of Trust standing financial instructions	Application Form and Interview
Evidence of Particular: **- Knowledge** **- Skills** **- Aptitudes**	Ability to evidence/demonstrate key values and behaviours in line with the Trust framework: • Patient Centred • Safety • Compassion • Respect and • Excellence	Application Form and Interview		

	• Knowledge of medical terminology • Working knowledge of patient confidentiality / Caldicott guidelines • Understanding and application of Clinical Trials Regulations and guidelines including the Medicines for Human Use Regulations (2004) and the Research Governance Framework. • Understanding and application of Regulations and guidance which may impact on research, such as the Human Tissue Act; Mental Capacity Act; Data Protection Act, etc. • Well-developed IT skills including use of Microsoft Office (Word and Excel) software and email. • Experienced user of databases and reporting tools and ability to update skills as necessary. • Accurate and attentive to detail. • Motivated and able and willing to learn. • Excellent numerical and written skills. • Able to produce reports and graphs for internal and external purposes as required. • Well-developed communication skills. • Ability to seek out information when not readily available • Minute-taking skills			

Specific Requirements	• Ability to work under own initiative and to prioritise and manage own workload. • Ability to work to deadlines and under pressure. • Able to work independently and as part of a team. • To have a flexible approach to work with the conflicting demands of this post	Application Form and Interview		

Job Description Agreement

I declare that I have read the Job Description and Person Specification and confir
is an accurate and fair description of the role.

Signature **Date**

Job Holder:

Line Manager: