AfC Reference:

Job Description

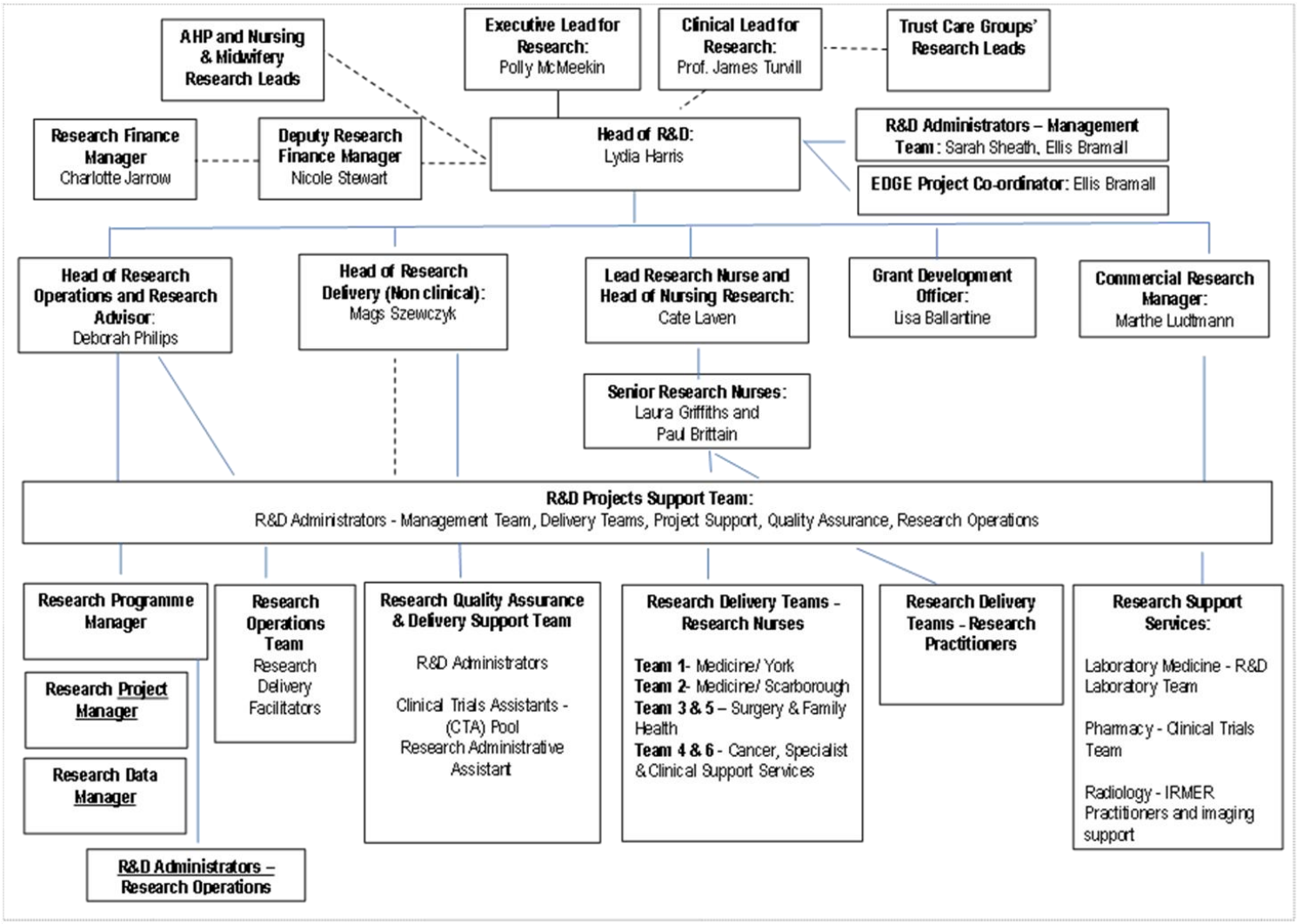
York and Scarborough Teaching Hospitals NHS Foundation Trust

Job Title:	Research Data Manager		
Band:	5		
Department:	Research and Development		
Care Group:	Workforce and Organisational Development		
Reports To:	Research Project Manager		
Accountable To:	Head of Research Operations & Research Advisor		
Professionally Accountable To:	Head of Research and Development Principal Investigators		
Responsible For:			
Main Base/ Site:	York Hospital		
Contract Status:	☒ Permanent	☐ Fixed Term	☐ Other:
AfC Reference Number:			

JOB SUMMARY

As a Research Data Manager, you will be responsible for overseeing data management systems for Trust Sponsored Research studies from the project outset to the end of study. This involves ensuring the high-quality capture of complex clinical and research data from medical records, research documentation and databases through CRF design and building, staff training, and quality control. You will be responsible for ensuring data is submitted in a timely manner in line with contractual obligations. Your role will involve communication with teams within Research & Development and across the Trust, as well as external Trusts and agencies including Clinical Research companies. You will take the data lead on a number of research studies where you will be responsible for data collection, processing, cleaning and generating queries, as well as maintaining EDGE records and running regular reports. You will liaise with the research team and Chief/Principal Investigator(s) running the trial to ensure all data management processes are carried out in an accurate and contemporaneous manner. This role will also provide specialist research advice and support to investigators during the setup and ongoing conduct of research studies within the Trust.

ORGANISATIONAL CHART



KEY RELATIONSHIPS

- Research & Development (R&D)
- Researchers
- Clinicians, health professionals and clerical staff within NHS Trusts
- Care Groups Research Delivery Teams
- Patients and Carers
- Yorkshire and Humber (Y&H) Research Network staff
- Support Services
- NIHR

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KNOWLEDGE AND SKILLS

1. Communication and Relationship Skills

- Communicate effectively to internal collaborators as well as a variety of external organisations. Acting on routine and ad-hoc information requests in a timely manner, advising others on process, collecting and inputting data, undertaking detailed analysis, and ensuring accurate and user-friendly reports are produced.
- Build and maintain effective working relationships with staff members both within Research and Development, in other departments in the Trust, and with external agencies e.g. Participating research sites, Study Funders, External Sponsors & Clinical Research Organisations.
- Liaise with the Research team and Chief / Principal Investigators in order to clarify source data which may be unclear, helping to facilitate a reduced number of data queries generated.
- Liaise and work effectively with the R&D department and all members of the multidisciplinary team in order to assist with the conduct of research studies with particular emphasis on setting up and maintaining appropriate databases.
- Collaborate with other members of data staff within the Trust or externally to maintain effective working relationships.
- Responsible for accessing and disseminating complex data within data governance procedures and guidelines and according to Trust policies.
- Participate in regular internal audits and to produce reports in an accurate and user-friendly format, helping to maintain data quality standards and assisting the senior management team to identify compliance with research governance standards.
- Assist Investigators and Clinical staff in collating, reporting, analysing and disseminating data which will be used to inform service improvement initiatives.
- Provide information, advice and practical support to clinical investigators on study feasibility, ethical approval procedures and research governance with particular emphasis on data collection and reporting procedures.
- Contribute to the provision of support for all aspects of Trust-sponsored research studies including, but not limited to, completion of study documentation for regulatory submissions or amendments, preparing documentation for study files and project delivery, and ordering supplies.
- Support the Programme Manager and Project Manager with all aspects of site set up, including distributing and reviewing Expressions of Interest (EOIs), completing Organisation Information Documents (OIDs). Working collaboratively with sites, support departments and investigators to provide training as necessary and to confirm that arrangements are in place to deliver the study to time and target.
- Liaise and work with the admin and clinical teams on any study amendments, updating and superseding CRFs accordingly.
- Represent the Project Management Team at appropriate meetings.

2. Knowledge, Training and Experience

- Knowledge of Good Clinical Practice requirements for management of clinical study information.
- Knowledge of General Data Protection Regulation (GDPR) with particular emphasis on the use of PID in research.

- Experience using a range of analytical and reporting tools including Microsoft Excel, EDGE and Power BI.
- Experience working with electronic case report forms or survey instruments e.g. REDCap.
- Undertaking training and development that is required to stay up to date with local and national research guidelines and data management processes.
- Thorough working knowledge of medical terminology and clinical language.
- Contribute to the development and maintenance of REDCap.
- Responsible for identifying your own learning needs and maintaining your own personal development including knowledge and skills relating to ICH GCP and research governance legislation.

3. Analytical Skills

- Participate in the preparation and organisation of audits and monitor performance against targets where necessary.
- Undertake audits and monitoring visits of sponsored studies as required. Audits and monitoring would require the ability to cross-check actual documentation with that which is reported to us and highlight and report on discrepancies.
- Uphold data quality and ensure issues are reported and dealt with appropriately.
- Liaise with clinical staff in the Trust as appropriate to collect information/data necessary for research studies.
- Responsible for responding to data queries generated by Sponsors within their set timeframe, liaising with the research team in order to analyse the reason for the discrepancy in the data, in order that this can be rectified/action taken.
- Work with the Research and Development Unit to update and analyse the monthly activity and performance metrics presented. To assess the quality of the data collected and report any anomalies identified during this analysis.
- Retrieve data from the Trusts Electronic Patient Record system (EPR), in compliance with GDPR.
- Interrogate data systems in order to support Investigators in analysing and presenting data in the required format, enabling performance to be monitored against set standards.
- Read and interpret protocol information and translate into a simplified CRF for use by the clinical teams particularly the safety data capture and reporting.

4. Planning and Organisational Skills

- Responsible for the timely capture of complex clinical data from source documentation i.e. from medical notes in the Trusts EPR, paper based case record forms, ensuring the data is accurately entered into the appropriate electronic data base.
- Ensure where required participants who have consented to take part in a clinical trial/research study, have the trial/study R&D number recorded on their EPR record, ensuring the maintenance of accurate Trust accrual data.
- Attend Site Initiation meetings to alert the team of any data issues that may be foreseen prior to a new study.
- Work with the clinical research delivery team to develop a schedule for clinical data capture for each clinical trial and to identify the time frames within which this work must be completed, ensuring the data is submitted in a timely manner and that contractual obligations are met.
- Responsible for creating and maintaining Data Management and Statistical Analysis plans.

- Carry out general administrative duties such as photocopying, scanning and opening and distribution of post and sending out of correspondence where necessary.
- Assist in the maintenance of study files, by ensuring these are kept tidy and updated.
- Organise and coordinate meetings and training events on behalf of the Project Management Team, organising facilities, circulating the agenda and other information in advance and writing and disseminating minutes.
- Undertake clerical/secretarial tasks where necessary and provide cross cover for the other administrative posts.
- Organise and book travel and accommodation if required by the Project Management Team.
- Maintain Trial Master Files, Site Files and support admin team members to ensure that site files are managed according to Good Clinical Practice (GCP).

5. Physical Skills

- Computer literacy and keyboard skills, experienced in the use of Microsoft office packages, able to interrogate databases.

RESPONSIBILITIES

6. Responsibilities for Patient/ Client Care

- Maintain confidentiality at all times.
- Respond to patient telephone queries as required regarding Trust Sponsored research, directing to appropriate staff/departments as required.

7. Responsibilities for Policy and Service Development

- Understand and adhere to Trust policies and procedures.
- Develop and maintain Standard Operating Procedures and associated documentation to ensure consistent and robust processes are in place for all regular reporting.
- Participate in regular review of R&D department SOPs suggesting changes or updates that may be required.
- Develop and review study Standard Operating Procedures and Guidance for researchers.
- Undertake that all work is consistent with departmental guidelines and is appropriately documented.

8. Responsibilities for Financial and Physical Resources

- Ensure maintenance of confidentiality for all personally-identifiable data.
- Stock management and ordering of study supplies.

9. Responsibilities for Staff/ HR/ Leadership/ Training

- Assist in ensuring that all staff are aware of the principles of data protection and GDPR legislation is adhered to at all times within the unit.
- Provide training and support for other users (clinical and non-clinical) on databases and systems.

- Provide any specific training required on the accurate completion of fields within the systems, when internal audit/interrogation demonstrates that data input is affecting data quality within the systems.
- Participate in the induction of new staff, providing mentoring re: data capture/entry as required.
- Provide and support training to clinical research team members on IRAS, research governance, site file maintenance.

10. Responsibilities for Information Resources

- Support the R&D team in compiling data reports using a range of IT applications for tracking research activity, ensuring data quality checks are undertaken prior to submission and assisting in identifying and rectifying areas of incomplete data.
- Responsible for data security and integrity and ensuring the timely back-up of data, systems configuration and other software files as necessary to support business continuity and disaster recovery.
- Perform periodic validation of these systems (daily/weekly/monthly as required).
- Ensure the correct operation of the software packages, correct back-up of the data, configuration and software files and to report any defects in functionality in a timely manner.
- Ensure confidentiality, integrity, and availability of data across a range of formats.
- Ensure all patient identifiable information is communicated according to Trust policy.
- Manage data management systems and databases.
- Manage storage and retrieval of information and records.
- Ensure secure storage and retrieval of data for clinical trials/research studies in accordance with the requirements of ICH GCP and GDPR.
- Responsible for the preparation of accurate trial/study reports and presentations.

11. Responsibilities for Research and Development

- Provide ongoing support and advice for the project to research teams
- Represent the R&D Unit and/or Trust as required.
- Contribute to the Unit's annual report and other Unit communications
- Work to Unit Standard Operating Procedures.
- Carry out any other duties that may be required and that are consistent with the responsibility of the band and this post.

12. Freedom to Act

- Take ownership of issues raised, ensuring they are logged, investigated, and resolved/escalated as appropriate.
- Able to work on own initiative and unsupervised.

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EFFORT AND ENVIRONMENT

13. Physical Effort

- Light physical effort, lifting heavy files and filing.

14. Mental Effort

- The job will be demanding and very busy at times with many conflicting demands.
- Concentration required to collect, enter, check, analyse and interpret complex information and data.
- The job will require a lot of mental effort.

15. Emotional Effort

- The job will involve tight deadlines for multiple stakeholders and juggling work across different teams which could have challenges.

16. Working Conditions

- The post is housed within R&D – mainly on-site (60%) but there is potential for a mixed model with some work-from-home days once established in the role.

KEY VALUES

The Trust would expect all employees to demonstrate our values as part of their day to day working lives:

- We are **kind**
- We are **open**
- We pursue **excellence**

These values are underpinned by behaviours:

We are **kind**, this means we:
- **Respect** and value each other;
- Treat each other **fairly**;
- Are **helpful**, and seek help when we need it.

We are **open**, this means we:
- **Listen**, making sure we truly understand the point of view of others;
- Work **collaboratively**, to deliver the best possible outcomes;
- Are **inclusive**, demonstrating everyone's voice matters.

We pursue **excellence**, this means we:
- Are **professional** and take pride in our work, always seeking to do our best;
- Demonstrate high **integrity**, always seeking to do the right thing;
- Are **ambitious**, we suggest new ideas and find ways to take them forward, and we support others to do the same.

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STANDARD GENERIC ITEMS:

The post holder will uphold and support these values in accordance with the Behavioural Framework. To this end, in our goal to promote and embed equality and diversity throughout the organisation, the post holder will ensure that everyone is treated as an individual, with dignity and respect.

In addition to observing the departmental rules and procedures, which all staff are required to observe and follow, the post holder is also required to follow the Trust's general policies and procedures that apply to the employment relationship. Whilst the Trust recognises specific responsibilities fall upon management, it is also the duty of the post holder to accept personal responsibility for the practical application of these policies, procedure and standards. The post holder should familiarise themselves with these, and ensure they have an understanding of them, and adhere to them.

The Trust has a No Smoking Policy. All its premises are considered as non-smoking zones.

In order to ensure the Trust's ability to respond to changes in the needs of the service, the Trust may make changes on a temporary or permanent basis, that are deemed reasonable in the circumstances, to the duties and responsibilities outlined in the job description. Any changes will be made with reasonable notice, taking into account the circumstances of the Trust and the post-holder.

This job description is not meant to be exhaustive. It describes the main duties and responsibilities of the post. It may be subject to change as the organisation and services develop and wherever possible change will follow a consultation with the post holder.

JOB AGREEMENT:

Job Holder *(PRINT NAME)*	
Job Holder *(SIGNATURE)*	
Date	

Recruiting Manager *(PRINT NAME)*	
Recruiting Manager *(SIGNATURE)*	
Date	

Person Specification

York and Scarborough Teaching Hospitals NHS Foundation Trust

Insert Job Title

Criteria	Essential	Desirable
Education, Qualifications and Training	• Degree level qualification or equivalent knowledge and experience • Willing to undergo training as necessary to undertake role	• Good Clinical Practice training • Electronic Health Record System training
Experience and Knowledge Required	• Previous Data Management or Administrative experience, or equivalent • Knowledge of health information management or equivalent experience of information handling and analysis gained in a work environment • Experience of working on multiple parallel tasks to strict and often tight deadlines. • Experience of managing information systems and developing databases and spreadsheets • Experience of analysing large quantities of complex information from databases and generating reports • Knowledge of GDPR • Experience of working within a hospital setting and be familiar with understanding and interpreting information from patient notes. • Thorough knowledge of medical terminology • Experience working in a research environment • Knowledge of research methodologies and current national systems and structures for the approval, management and monitoring of clinical research in the NHS	• Experience working in a clinical environment • Experience using MS Power BI or other BI software.

	• Experience using specialist research data capture software e.g. REDCap	
Skills and Attributes	• Numerate with advanced IT skills (MS Office - Excel and PowerPoint) • Advanced in the use of spreadsheets, including the manipulation, analysis, and interpretation of large volumes of complex data • Good verbal and written communication skills, with the ability to interact effectively with staff at all levels • Able to handle sensitive and/or confidential information • Able to transcribe data in a timely and consistently accurate manner with excellent attention to detail • Able to work calmly under pressure and manage and prioritise own and others workloads whilst performing to tight deadlines • Ability to compile, interrogate and analyse data to produce meaningful and accessible management reports	
Aptitude and Personal Qualities	• Able to make sound judgements, use own initiative and work with minimal day-to-day supervision	
Values & Behaviours	Ability to demonstrate our organisational values and behaviours: • We are **Kind.** • We are **Open.** • We pursue **Excellence.**	