



JOB DESCRIPTION

1. JOB IDENTIFICATION

Job Title: Lead Research Project Manager

Responsible to: Clinical Research Nurse Manager

Department(s): EMERGE

Directorate: Acute Medicine

Operating Division:

Job Reference: 236377

No of Job Holders: 1

2. JOB PURPOSE

Lead responsibility for ensuring research projects are managed, coordinated and documented in accordance with the International Conference on Harmonisation Good Clinical Practice Guidelines (ICH-GCP), including development, design and implementation. This involves liaison with all Principal Investigators, commercial companies and clinical research staff to ensure that each study is run effectively according to governance, ethical and financial requirements and meets all targets.

The post holder will provide professional, operational and leadership and management of research staff and members of the multi-disciplinary team acting as a role model, providing specialist research advice with responsibility for staff and research governance issues.

3. DIMENSIONS

The post holder will work within EMERGE and will be responsible for aspects of research project management, in-house monitoring and quality control for the EMERGE research portfolio.

The EMERGE research group has grown considerably in the last 17 years and is now nationally important in terms of the quality of research and its direct influence on patient outcomes. The group continues to develop NHS emergency medicine research activity and capacity and become internationally recognised in clinical emergency medicine research.

The post holder will work on a variety of studies and trials including Clinical Trials of Investigational Medicinal Products (CTIMPs) and non-CTIMPs, with a focus on commercial studies in a governance and delivery capacity, and project work as required by EMERGE, this could include organising study days and events.

The exact dimensions of the post will vary according to the dynamic nature of the department's research portfolio. The research programme encompasses both commercial and non-commercial studies, single and multi-site studies and participation in international multi-centre studies. These will include other research and clinical teams, and central coordinating and governance structures such as the Edinburgh Clinical Trials Unit (ECTU) for study management and NHS Lothian's Academic and Clinical Central Office for Research and Development (ACCORD) for monitoring and regulatory and governance advice and support. Ensuring governance, monitoring and data quality checks are completed regularly, is an essential component of this post to ensure the quality, consistency and adherence to research governance and regulatory body requirements and delegating this as necessary.

Financial Responsibilities

Authorised signatory of up to £1000, the post holder requires to have an awareness of the resources available and the need to remain within budget. Maintaining spreadsheets and records of purchases and finance will be achieved under senior supervision. The number and value of the budgets will vary depending on the number of projects.

Responsible for monitoring project budgets for multiple research studies, the total amount can vary. This will be under the supervision of the Clinical Research Nurse Manager.

Staffing responsibilities

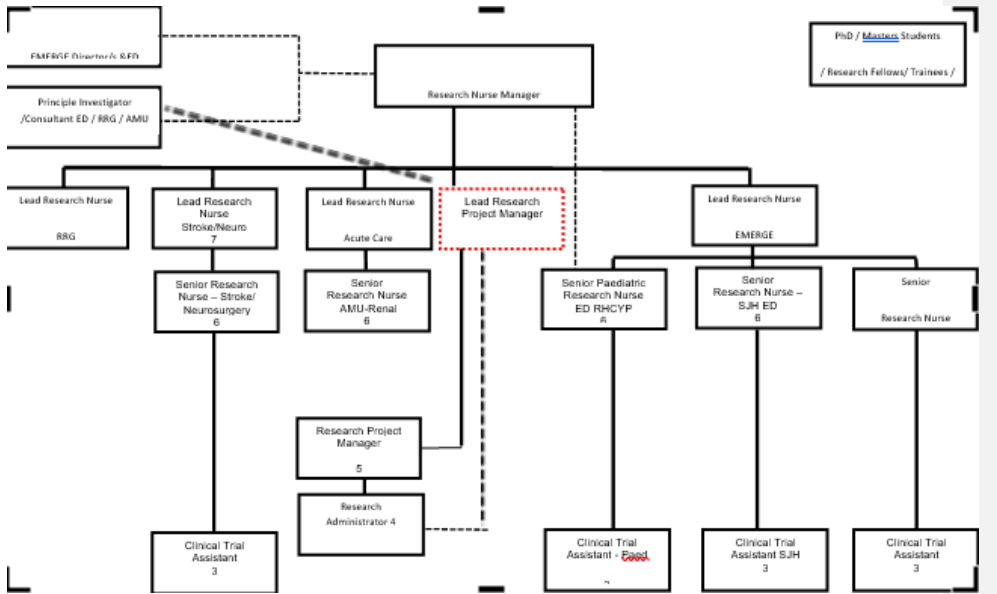
The post holder will have day to day management responsibility for the clinical trials assistant, for the Research Project Manager and Research Administrator. The post holder will also provide non-clinical research advice to PIs and the clinical research delivery team.

The post holder is employed within NHS Lothian and there may be a requirement to work flexibly across Lothian to meet service demands.

4. ORGANISATIONAL POSITION

----- represents professional accountability

_____ represents line management



5. ROLE OF DEPARTMENT

The NHS Lothian Emergency Departments (EDs) play a key role in the delivery of emergency care within NHS Lothian. They provide a 24-hour service for approximately 180,000 adult and paediatric attendances annually across the complete spectrum of emergency medicine. The service aims to assess, treat, discharge or admit all patients within 4-hour targets.

Nationally, research in emergency medicine has remained predominantly on a small-scale and has been undertaken in an *ad hoc* manner despite the clinical development of the specialty but this is now changing. Actively coordinated and integrated research needs to underpin clinical development if the specialty is to reach maturity. NHS Lothian has traditionally been at the forefront of the specialties academic output in the UK. The Eds have 17 years of distinguished track record of research in Emergency Medicine. For the past 40 years, the department has been renowned as a leading centre for innovative research ideas and their application. The work is recognised by the publication of over a dozen major textbooks and several hundred original research papers have been produced by the medical and nursing staff.

The department has a worldwide reputation particularly for research into pre-hospital care, cardiac arrest and cardiopulmonary resuscitation and major trauma and more recently randomized controlled trials such as 3CPO, 3MG, SNAP, TRIGGER, HALT-IT, POP and RAPID-CTCA. This work continues to require a significant amount of research project management and governance as well as internal monitoring.

Role of EMERGE

The Emergency Medicine Research Group Edinburgh (EMERGE) has been established with three related aims;

To improve the quality of the research and audit by supporting the individual researchers and projects.

To facilitate the research alongside excellent clinical practice by co-ordinating and governing departmental research activity.

To raise the national profile of Emergency Medicine research.

These aims will be achieved by;

Guiding and informing researchers with input to development of research processes, from research idea to implementation.

Building a culture and expectation of clinical research amongst all ED staff.

Ensuring training in GCP and other research related procedures.

Regularly reviewing impact of research activity and provision of updates on progress through meetings/newsletters and annual reporting.

Maintaining a register to record & coordinate research activity.

6. KEY RESULT AREAS

1. Responsible for the coordination and management of multidisciplinary research projects within the clinical area with a focus on commercial activity. This includes planning, organising, and monitoring all study activities to ensure smooth, timely delivery while maintaining high-quality standards in line with study protocols, research governance, and legislative requirements.
2. Develop, implement, and maintain policies, procedures, protocols, and standards that ensure clinical practice and research activities adhere to current best evidence, national and local Research Governance Frameworks, and legislative requirements, working with clinical staff to safeguarding research subjects and maintaining study integrity.
3. Collaborate with Principal Investigators (PIs) to develop and review research protocols, ensuring feasibility, resource allocation and risk management considerations are fully addressed to support safe and effective study delivery.
4. Identify training needs related to research protocols and governance. This may include provision of advice and support to other members of the multidisciplinary team with regard to ICH GCP and research governance requirements, project development, implementation and completion for each study in order to ensure the safe and accurate conduct of the research.
5. Oversee timely reporting and management of adverse events (AEs) and serious adverse events (SAEs), in conjunction with clinical research staff, PIs, sponsors, and regulatory bodies to ensure patient safety and study compliance. Support risk assessments and incident management in the research environment to uphold health and safety standards.
6. Develop tools and documents to ensure the clinical research team are aware of the proper handling, processing, storage, and archiving of biological samples and research data according to protocol requirements and statutory regulations, maintaining data integrity, confidentiality, and security at all times.
7. Work with PIs and senior stakeholders to develop and implement departmental research strategies, including identifying service development opportunities, workforce planning, and skills profiling to support sustainable research capacity.

8. Monitor budgets responsibly, including cost control, resource allocation, and maintaining trial supplies according to study protocols. Act as authorised signatory where appropriate and ensure the economic use of all resources.
9. Day to day management of the research project team including recruitment, induction, development, appraisal, and performance management. Provide mentorship, coaching, and support to ensure team members meet their project responsibilities effectively.
10. Provide clear, regular progress reports and updates to project boards, steering groups, and other stakeholders, highlighting risks and mitigation strategies. Develop and implement communication strategies to raise awareness, share learning, and promote research findings through presentations, publications, and networking.
11. Deputise for the Principal Investigator when required, including attending local and national meetings and liaising with research bodies to maintain continuity and profile of the research programme, disseminating information and updates.
12. To support NHS Lothian's values of quality, teamwork, care and compassion, dignity and respect, and openness, honesty and responsibility through the application of appropriate behaviours and attitudes.

Commented [RO1]: Both the nursing team and this role could perform this task

7a. EQUIPMENT AND MACHINERY

The following are examples of equipment which will be used when undertaking the role:

Personal Computer – for audio/visual presentations during meetings.

Laptop and projector– for audio/visual presentations during meetings.

Telephone.

The post holder will be expected to be responsible and knowledgeable in the safe use of all equipment used within the area ensuring this is checked, calibrated and maintained and where problem are identified these resolved so that all equipment is fit for purpose.

Note: New equipment may be introduced as the organisation and technology develops, however training will be provided.

7b. SYSTEMS

The following are examples of systems which will be used when undertaking the role. This list is not exhaustive and may vary depending on the research study:

Maintaining electronic spreadsheets and databases that meet the requirements of each study and comply with Data Protection legislation.

Maintenance of up-to-date information on the progress of research studies.

Ensuring input, secure back up, storage and archiving of electronic study data.

Local Patient Administration System.

Human Resource Administration Systems.

Occupational Health Systems.

Incident Reporting System.

Laboratory Systems.

Internet and Intranet.

eLearning for mandatory training and Continuous Professional Development.

Paper-based Systems

Maintenance, secure storage and archiving of Study Site Files and other research records.

Note: New systems may be introduced as the organisation and technology develops, however training will be provided.

8. ASSIGNMENT AND REVIEW OF WORK

The post holder will operate autonomously within established research protocols and professional standards, with a primary focus on managing commercial research studies within the Department and the broader research community. They will be accountable for independently organising and prioritising their own workload, as well as coordinating and overseeing the activities of the wider research team to ensure seamless delivery of planned research programmes and external commitments.

While overall strategic direction and governance will be provided by the senior management team, research Sponsor or Steering Group, the post holder is expected to exercise sound professional judgment and make independent decisions within the scope of their role. They will proactively manage and monitor both scheduled and unscheduled work, adapting resources and priorities as required to maintain progress and meet project objectives.

Reporting to the Line Manager, the post holder will receive guidance and professional oversight, with regular performance reviews and formal appraisals to support ongoing development and accountability.

9. DECISIONS AND JUDGEMENTS

The post holder will be responsible for developing and maintaining a comprehensive project plan that establishes clear, achievable, and sustainable objectives within defined timeframes, ensuring the successful delivery of the project to the required standards. They will exercise autonomous, informed decision-making to proactively identify and mitigate any risks or issues that could potentially impact project timelines, implementing effective solutions to maintain progress and quality.

Operational responsibility for overseeing management of research projects within the team's portfolio which vary over time, including oversight of staff, financial resources, and skill requirements whilst working with the PI and clinical research team who are delivering the clinical aspects of studies. This includes implementing robust project controls, budgets, and schedules, and advising stakeholders and the Project Board/Steering Group accordingly. The post holder will play a key role in decisions when to start projects, assessing project readiness and ensuring all criteria are met prior to implementation.

The role demands coordination and prioritisation of multidisciplinary teams operating across various organisational levels and contexts, as well as external commercial partners. The post-holder will navigate complex challenges requiring innovative problem-solving skills to reconcile competing interests, priorities, and project specifications of diverse stakeholders, for example, aligning the timelines and resource needs of clinical staff, and external sponsors when unexpected regulatory changes impact project delivery.

Professional decisions will be made independently daily, with escalation to the line manager or Principal Investigator, especially for clinical decision making. The post holder will manage the research portfolio from a governance and administrative aspect, making strategic decisions around resource allocation and reallocation to address study-specific needs, for example, increasing recruitment efforts for studies at risk of underperformance or funding challenges.

Decisions regarding protocol development and implementation, including consideration of resource implications, will be made collaboratively with the research team.

In addition, the post holder will oversee staff management responsibilities, including skill mix optimisation, performance management, disciplinary and grievance processes, and adherence to employment policies to ensure a high-performing and compliant workforce.

10. MOST CHALLENGING/DIFFICULT PARTS OF THE JOB

This role requires balancing the competing demands of supporting a research team with fluctuating staffing levels to deliver research studies on time and target, and maintaining a consistently high-quality research service, especially with commercial partners.

The unpredictable nature of research recruitment adds significant pressure, with schedules often requiring rapid responses, whilst still ensuring the clinical team are safeguarding patients' rights to make fully informed decisions. Sensitive and complex issues frequently arise, such as addressing non-compliance with regulatory requirements, obtaining informed consent in challenging contexts (including under the Adults with Incapacity Act), and navigating ethical dilemmas in a demanding clinical research environment within the restraints of a research protocol.

The post also demands rapid development of new skills and knowledge, both personally and within the team, to ensure tight study deadlines are met. A further challenge lies in influencing service redesign, communicating complex technical information, and driving cultural and organisational change across stakeholders without direct management authority.

The role requires constant reassessment of priorities across a wide-ranging portfolio, alongside the monitoring of complex budgets with contributions and reporting requirements from multiple strategic partners. Finally, success depends on skilfully managing the expectations of diverse stakeholders, including individuals, communities, organisations, and partners while ensuring that project goals are achieved, and that responsibilities and boundaries are clearly defined and understood.

11. COMMUNICATIONS AND RELATIONSHIPS

The postholder will be expected to communicate with a wide range of stakeholders across projects, including senior personnel, both internally and externally. The post holder must have excellent presentation skills with the ability to express coherent and convincing views, verbally and in writing.

To undertake the role will require developed communication skills to enable key messages to be cascaded effectively to stakeholders. Skills of negotiation, tact and diplomacy will be required when communicating on behalf of the team.

The post-holder will be expected to demonstrate sensitivity and awareness when handling confidential or emotionally charged issues, such as discussing adverse trial outcomes with staff, and adapt communication style to suit different cultural and professional contexts.

There will be a regular requirement for advanced communication and negotiation skills in challenging situations, for example, resolving conflicts between research priorities and clinical service demands or negotiating timelines with external sponsors under political and organisational pressures.

Internal

Medical - the post holder will need to communicate effectively with medical staff specific to the projects undertaken regarding specific research projects and their involvement.

Research and Development (R&D) Office - the post holder will be responsible for liaising with ACCORD for updated SOPs, and pertinent research governance.

Procurement- the post holder will liaise with procurement if required and/or in collaboration with the EMERGE Research Project Manager and Administrator.

Support Services- communication will be required as per research project requirement.

Education Facilitators- as required through training & education of team.

Health and Safety and Risk Management – where required to ensure safety of the research processes and equipment used.

External

Research Ethics Committees - typically about submission of study documents and addressing ethical queries or amendments as well as submitting annual progress reports.

Project Steering Committees and Data Monitoring Committees – focused on study progress updates, recruitment status and safety reporting.

Commercial stakeholders – communication often relating to contractual obligations, timelines, consumables and finances.

Edinburgh Clinical Trials Unit – communication about trial management, data integrity, monitoring schedules and compliance with governance.

Research Sponsors, both academic and commercial - reporting milestones, budget updates, regulatory compliance, and addressing sponsor queries.

University of Edinburgh Usher Institute – communication on collaborative research opportunities, governance advice, and academic reporting requirements.

External Chief investigators – communication about study design clarifications, operational updates, and resolving site-specific issues.

Post holder may be required to communicate/present through formal presentation to the wider public e.g. national research Investigator meetings, internal research forum, at trial steering committees of experts and patient representatives.

12. PHYSICAL, MENTAL, EMOTIONAL AND ENVIRONMENTAL DEMANDS OF THE JOB

Physical

Standard keyboard skills for producing reports and project plans.

Transferring equipment required for presentations/training sessions across sites.

Mental

The role requires sustained periods of concentration for decision-making and report writing, but these are often disrupted by frequent interruptions, such as urgent queries from clinical teams or immediate governance issues. Frequent requirement for concentration when undertaking clinical and managerial components of the role e.g. interpreting and implementing complex protocols, operational management of studies, staff/budget management.

Requirement for extended periods of concentration required when analysing data, preparing findings and presenting in report format.

Workload may be unpredictable due to changing priorities of the project.

Emotional

Communicating sensitive issues or unwelcome information to stakeholders of the project.

Liaising between groups of colleagues in different organisations who may have conflicting agendas, and ways of working.

Environmental

Regular VDU use.

Requirement to occasionally travel between sites to attend project meetings.

13. KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB

Educated to degree level or equivalent in a business or scientific discipline.

Postgraduate diploma/qualification in project management or equivalent experience.

PRINCE 2 accreditation.

Research experience including awareness of ICH-GCP guidelines, UK Policy Framework for Health and Social Care Research.

Knowledge and application of research methodologies.

Experience of working within the NHS or similar large and complex organisation.

Excellent verbal and written communication skills with an ability to communicate well with staff at all levels.

Strong leadership and team working skills, with good team management and motivational skills.

Advanced level use of MS Word, Excel and PowerPoint.

Competent in the use of web-based IT systems to support clinical research, including MS Office and patient administration systems.

A good grounding in data presentation.

Budget/financial management experience.

Experience of working in an environment with competing and conflicting priorities, deadlines and workloads.

14. JOB DESCRIPTION AGREEMENT

A separate job description will need to be signed off by each job holder to whom the job description applies.

Job Holder's Signature:

Date:

Head of Department Signature:

Date:

(I confirm that the Job Description accurately reflects the duties and responsibilities of the postholder and does not impact upon any other postholders role)