JOB DESCRIPTION TEMPLATE

1. JOB IDENTIFICATION

Job Title:	**Lead Research Nurse (Band 7)**
Responsible to:	Clinical Research Nurse Manager
Department(s):	Respiratory, Cystic Fibrosis Research
Directorate:	Medicine Services
Operating Division:	NHS Lothian
Job Reference:	**033009**
No of Job Holders:	1

2. JOB PURPOSE

Lead responsibility for clinical research projects 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 to ensure that each study is run effectively according to clinical, ethical and financial requirements and meets all targets.

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

3. DIMENSIONS

The post holder will work within the Cystic Fibrosis Respiratory Research Team to Co-ordinate both adult and paediatric Early Phase Trials in close association with the Clinical Trials Accelerator Platform.

The Clinical Trials Accelerator Platform (CTAP) is a Cystic Fibrosis Trust coordinated programme which aims to support sponsors and CF centres with set-up and delivery of cystic fibrosis (CF) clinical trials. The CTAP network is made up of 20 adult and paediatric CTAP Centres, including NHS Lothian. Through the programme, CTAP has created and fostered a team of 20 CF Trial Coordinators to facilitate the set-up and delivery of CF trials at the 20 CTAP Centres, improving access to these trials for the regional CF population (adults and children with CF).

It is currently expected that there will be a greater requirement for early phase CF clinical trials in the UK over the coming years. To enable the UK to be at the forefront of early phase CF research, CTAP is expanding to create a specialist sub-network of CTAP centres with expert knowledge and facilities to lead in the UK delivery of CF Early Phase Clinical Trials.

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 the coordination of or participation in international multi-centre studies. This will necessitate extensive external networking with sponsors, collaborative study sites, non-commercial bodies and pharmaceutical companies. The post holder will work closely with members of the local Cystic Fibrosis clinical and research team including both the Adult and Paediatric Clinical Research Facilities. In addition to the Head of CTAP at the Cystic Fibrosis Trust and the Trial Co-ordinators at other Trials Accelerator centres.

The recruitment of patients to the CTAP programme will be from across Scotland and will require close working with CF teams from other Scottish Health Boards.

Staffing responsibilities

Line management responsibility for: Research Nurses and Administrative staff (ad hoc) working in the team

Financial responsibilities

The post holder will be responsible for monitoring trial/study budgets, ordering & purchasing, and ensuring the team budget is adhered to under the supervision of the line manager.

Authorised signatory up to £500 for booking of bank staff and equipment purchase

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

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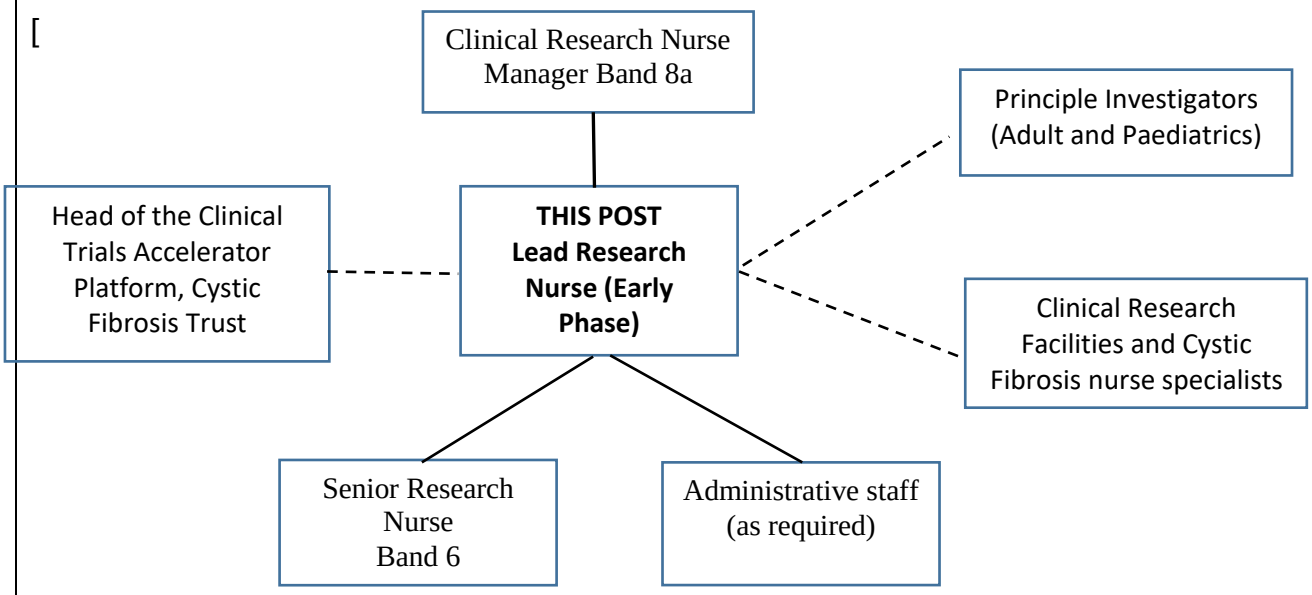

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5. ROLE OF DEPARTMENT

Research and Development is integral to health care delivery in NHS Lothian through the close collaboration of clinical specialities with academic partners, research organisations and industry. The Research and Development Office has a central role to play in the facilitation, co-ordination and management of clinical research and does so in line with the strategic direction of the organisation, NHS Scotland and statutory legislation.

There are Cystic Fibrosis respiratory services for adult and children in NHS Lothian.
Adult Services: The respiratory/cardiology directorate offers a comprehensive specialist service to respiratory patients with acute and chronic respiratory and cardiology conditions for Lothian and the East of Scotland. Ward 54 is a regional centre for adult cystic fibrosis patients.

The children's service is based at the Royal Hospital for Sick Children (RHSC) and will be moving to the Royal Infirmary site (RHCYP) and provides care for approximately 150 children across SE Scotland. The service has contributions from five consultants, one staff specialist, 3 nurse specialists, dieticians, physiotherapists and physiologists. There is an active research programme across the age ranges in cystic fibrosis. RHSC is an MHRA Phase I accredited research facility and we have performed early phase clinical trials in young children to MHRA and EMA inspected standards. There is a dedicated clinical research facility.

Both Adults and children accessing our early phase cystic fibrosis trials are from across Scotland and NE England.

6. KEY RESULT AREAS

1. Responsible for leading, co-ordinating, and implementing research projects within area of work, including planning and co-ordinating multidisciplinary activities associated with the management of the research study(ies) to ensure effective and smooth running of the research project.

2. To develop and implement policies, procedures, standards and protocols of the clinical area to ensure that clinical, research and working practice is underpinned by current best evidence. Adhere to national and local Research Governance Framework and legislative requirements, to ensure delivery of the highest level of care to research subjects and to protect the research subject and quality of each study at all times; this will include using specialist knowledge and skill in assessing, planning, implementing and evaluating programmes of care.

3. Where relevant to study, contribute to the development of new research protocols in conjunction with Principal Investigator(s) in order to ensure that the feasibility, effective management, resource implications, and care requirements of the subjects are fully considered in each study.

4. Identify the training and education implications of each study and develop appropriate strategies to meet these in order to ensure the safe and accurate implementation of the study by self and others. 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. Using specialist skills, identify, screen and recruit subjects into research studies according to inclusion and exclusion criteria, and where necessary withdraw a subject from a study.

6. Provide advice and information to subjects in order to facilitate initial and ongoing informed consent including where indicated in the protocol, obtain informed consent on behalf of the Principal Investigator ensuring that the patients rights are upheld throughout the study.

7. Communicate effectively and provide specialist advice to research subjects, relatives and other members of the multidisciplinary/research team to ensure that accurate and appropriate information is shared to facilitate decision making and the research subjects receive quality care.

8. Responsible for reporting adverse events and serious adverse events in a timely and effective manner at local level, investigating and responding to the Principal Investigator, study sponsor and R&D office as required.

9. Take responsibility for setting and monitoring standards of care within research setting and undertake risk assessment (including patient behaviours and working environment) and incident management within clinical area including implementation of action plans and associated learning to ensure ongoing compliance with related legislation and guidelines, including Health and Safety at Work Act and NHS Lothian Health and Safety policy and reporting systems, to safeguard patients, visitors and staff.

10. Where relevant, responsible for ensuring that the processing and storage of biological samples by members of the team meets the necessary requirements of the research protocol in order to make certain that safe handling and quality is assured.

11. Work with the Principal Investigators to develop and implement the departmental research strategy including identifying areas for service development, workforce planning and skills profiling.

12. Responsible for the day to day management of research staff including recruitment, induction, personal development planning and appraisal, performance management issues.

13. Responsible for teaching and delivery of core training in a range of subjects relating to research and clinical speciality.

14. Responsible for managing the delegated project budget(s), maintaining trial specific supplies according to study protocols, procedures and regulations and level of recruitment ensuring economic use of all resources, and where appropriate act as authorised signatory.

15. To facilitate resolution of complaints in line with NHS Lothian policy and escalate as appropriate. Understand and share the learning points emerging from the investigation of complaints to enhance the delivery of the research study and improve the subjects / carers experience.

16. Responsible for accurate and secure data collection, entry and storage, including secure back up of study data. Where appropriate, arrange proper archiving of research data, in accordance with statutory requirements for medical record keeping and the specific requirements of the research study. Where appropriate, create and maintain electronic databases in order to meet the data requirements of each study, generating reports and running data queries relating to the conduct and status of ongoing research studies.

17. In conjunction with the research team write up, publish, present and disseminate the research findings to large groups in order to promote the study and contribute to the evidence-base of the subject and to lead implementation of changes by integrating research findings into existing clinical practice.

18. Deputise for the Principal Investigator in their absence, including attendance at national meetings and liaison with local and national research bodies, in order to maintain communication and continuity of the research programme.

19. 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.

7a. EQUIPMENT AND MACHINERY

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

The post holder will be expected to be responsible and knowledgeable in the safe use of all clinical and non clinical equipment used within the area ensuring this is checked 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
Incident Reporting System
Laboratory System – Specimen Results
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

Post holder works independently within research protocols and professional guidelines. Workload is generated from the research activities within the Department and wider research community.

The post holder will be responsible for organising their own workload and that of others working within the planned research programme and external responsibilities and to effectively manage and monitor unscheduled work activity.

The post holder will be responsible to the Line Manager who will provide clinical guidance and professional management, work review and formal appraisal of performance.

9. DECISIONS AND JUDGEMENTS

Clinical and professional decisions will be made autonomously on a daily basis, with occasional reference to line manager and/or Principal Investigator where necessary.

Decisions relating to the management of the clinical research portfolio including allocation and re-allocation of resources to ensure that needs of each study are met e.g increased focus on recruitment to a specific study where it has been identified that numbers have not been achieved or where there is a risk to funding of the study.

Judgements will be made regarding a range of clinical issues or complex patient conditions. For example; each research subject's condition will be assessed to establish the continuing care plan, appropriate action and future participation in the study. All decisions will be made that act in the research subject's best interests to ensure their rights are upheld, when identifying, screening and recruiting them into clinical research studies

Decisions and judgments regarding protocol development and implementation including consideration of resource requirements may be made in conjunction with the research team.

Decisions relating to the management of staff including skill mix, performance management, matters of discipline and grievance, application of appropriate Employment Policies.

10. MOST CHALLENGING/DIFFICULT PARTS OF THE JOB

Manage the research team including a fluctuating human resource whilst meeting the demands of direct patient care and maintaining a quality research service.

Meeting the unpredictable demands of the research study e.g. recruitment schedules which require responses within short timescales and/or out of hours where a suitable patient is identified and balancing the pressure of meeting recruitment targets with the patient's ultimate right to make an informed decision.

Address identified/escalated sensitive situations e.g non-compliance with regulatory requirements within the research team or obtaining informed consent for example patients under the Adults with Incapacity Act, reconciling ethical issues in a complex working environment.

Ensuring new clinical skills and knowledge are developed for self and relevant teams (as applicable) within a limited timeframe in order to ensure that study deadlines are met.

11. COMMUNICATIONS AND RELATIONSHIPS

Communicate verbally and in writing to members of the research team and multi-professional, team regarding subject's clinical care, participation in research and study progress.

In addition to the above other contact falls into the following main categories in relation to healthcare, staffing and service issues:

The research subject eg communicating complex clinical and research information and informed consent where skills need to be balanced with respect for the subject's autonomy, their relatives and the multidisciplinary team involved in the provision of care. Other relevant departments within the division e.g. Facilities, Estates, Pharmacy, Health and Safety, Research & Development Office and ACCORD regarding the approval, management and monitoring of clinical research studies.

To external collaborators and sponsor organisations with the ability to express professional views within group settings and support client advocacy. Where relevant, communication with other study centres and external multidisciplinary research teams on the day-to-day running of studies.

Participate in and present at external professional meetings/conferences related to the research studies.

Ongoing liaison with external research organisations e.g. National Research Ethics Service (NRES) and Medicines and Healthcare products Regulatory Agency (MHRA)

Participate and present in the Divisional Research Nurse Forum.

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

Due to the diversity of research studies it is acknowledged that the frequency of demands may vary.

Physical Skills:
The physical skills required will vary according to study requirements and the post holder is required to acquire new physical skills and knowledge as studies dictate. Physical skills may be required to undertake clinical activities e.g. Administer intravenous injections and or intra-muscular injections, syringe pumps and infusions; insertion of urinary catheters; 12-lead ECGs; intravenous cannulae / venepuncture; intravenous additives; blood glucose monitoring; basic life support, semi-automatic defibrillator.

Physical Effort:
The physical demands required will vary according to study requirements and may be as follows:
Requirement to manoeuvre patients using trolleys, wheelchairs.
Frequent requirement to lift and manoeuvre speciality research equipment and study supplies.
Stand/walking for several long periods each shift.
Frequent VDU use.
Positional work related to specific study procedures

Mental Effort:
The mental demands required will vary according to study requirements and may be as follows:

Frequent requirement for concentration when undertaking clinical and managerial components of the role e.g. interpreting and implementing complex protocols, observing subjects receiving non-routine, novel investigational medicinal product (IMP) or research interventions, operational management of studies, staff/budget management.
Precision entry of study data and maintaining research records.
Concentration required when checking documents/patient notes and calculating drug dosages, whilst subject to frequent interruptions from patient/relatives/team members.
Overcoming communication difficulties (multidisciplinary, multicultural, deaf, blind)

Emotional Effort:
The emotional effort required will vary according to study requirements and may be as follows:

Dealing with performance and staffing issues that may require application of diplomacy and negotiation skills.
Exposure to distressing or emotional circumstances e.g. supporting patients who are participating in studies that offer their only possible treatment hope/option in end of life situations, challenging identified non-compliance with regulatory requirements.
Requesting participation in a research study during a critical point in the subject's care or the relative's experience of that care.

Environmental and working conditions:
The environmental and working conditions will vary according to study requirements and may be as follows:

Frequent exposure to body fluids/unpleasant working conditions
Potential for exposure to verbal aggression
Where relevant, requirements to travel or undertake home visits.

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

Registered Nurse

Evidence of specialist knowledge and relevant experience demonstrating the appropriate competencies and skills for the research portfolio and clinical setting e.g. - postgraduate courses in clinical specialty and previous research experience demonstrating knowledge of ICH GCP Guidelines, EU Clinical Trials Directive, Research Governance Framework and Adults with Incapacity Act. Experience of financial management Experience of staff management, education and training Effective listening and interpersonal skills. Competent in standard IT packages e.g. Microsoft Word & Excel

14. JOB DESCRIPTION AGREEMENT	
A separate job description will need to be signed off by each jobholder to whom the job description applies. Job Holder's Signature: Head of Department Signature:	 Date: Date: