Putting patients at the HEART of everything we do

London North West University Healthcare NHS Trust

# JOB DESCRIPTION

**ECF 003**

| | |
|---|---|
| **Job Title:** | Research Nurse / Coordinator |
| **Division/Department:** | Academic Directorate / R&D Department |
| **Responsible to:** | Head of Research Nursing |
| **Accountable to:** | Associate Director of Quality Improvement Innovation & Research |
| **Band:** | Band 6 |
| **Hours:** | 37.5 hours |
| **Location:** | Northwick Park Hospital<br>In order to meet the needs of the Trust's services you may be required from time to time to work at different locations to your normal place of work. |

## Organisational Values

All staff employed by the Trust are expected to embody our 'HEART' values throughout their employment. The values describe how we interact with each other and our patients and underpin everything we do and say to achieve our vision:

**H**onesty - open and honest in everything we do

**E**quality – we value all people equally and treat them fairly whilst recognising their individuality

**A**ccountability – we will provide excellent care and ensure the safety and wellbeing of all patients

**R**espect – we treat everybody the way we would like to be treated

**T**eamwork – we work together to make improvements, delivering consistent, high quality, safe care.

## JOB SUMMARY

The post holder will be responsible for assessing and managing the care pathways for patients and carers participating in clinical studies. This will involve the recruitment, education and monitoring of patients in studies and the collection and documentation of accurate data. You will work collaboratively with different clinical studies team and the wider multi-disciplinary team (MDT) in the management of your own caseload of patients in clinical research studies.

The post holder will participate in the process of supporting the consent process, including the explanation of standard and research treatment, risks, benefits and side effects. She/he will be responsible for randomisation, completion of case report forms (CRFs) and the maintenance of accurate records according to ICH-GCP (Good Clinical Practice). The post holder will also have responsibility for the organisation of investigations, tracking follow-up of patients, entering data and making regular submissions of data to clinical trials centres and the R&D Department. The post holder will be expected to be proactive in educating clinical staff in the specifics of running clinical trials. Willingness to work flexibly is an essential aspect of this post.

Although the post holder will be based at Northwick Park Hospital they will be expected to work flexibly across the Trust.

Honesty Equality Accountability Respect Teamwork

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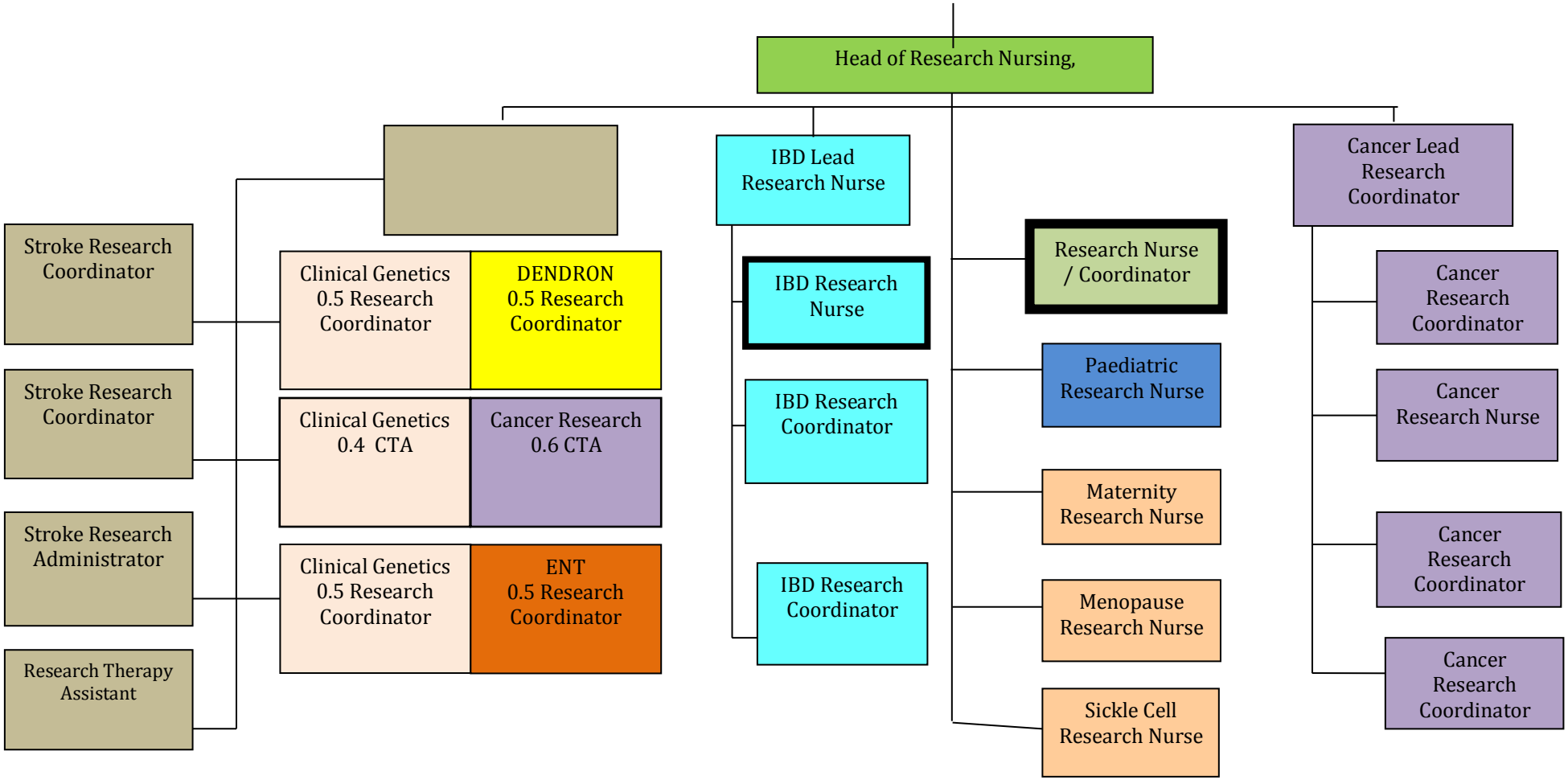

## KEY RESPONSIBILITIES

### Clinical Research Practice

- Function autonomously to manage his/her caseload of patients within a multidisciplinary team
- Identify patients who are suitable for entry into clinical trials
- Plan the care and support of patients according to clinical trial protocols, and to monitor responses throughout the trial
- Be sensitive to the emotional needs of patients and their relatives and to ensure appropriate referral where necessary
- Provide patients with comprehensive information concerning clinical research to facilitate the process of informed consent
- Provides ongoing assessment of patient's clinical condition using expert knowledge and skills, liaising, with relevant clinicians, as appropriate (e.g. if patient condition alters)
- Ensure the safe administration of treatments and drugs that are given within the context of a clinical study
- Coordinate investigations, to collect samples, to ensure safe and appropriate storage of specimens as part of the clinical research study
- Perform venepuncture in conjunction with research projects if required
- Accurately and clearly documents patient information in the patient's health records and relevant case Report Forms and other trial documents, as required
- At all times ensures clear, accurate records are maintained by the research team
- Collect data from patient medical records and complete Case Report Form (CRF's) as required.
- Ensure that all patients entering into clinical trials or their guardians have knowledge of the standard and research treatments, the structure of the trial options, and the risks, benefits and side effects
- Ensure that patients or their guardians are aware of the voluntary nature of participation and the right to withdraw from the study at any time
- Be aware of ethical considerations of research trials
- Arranges and leads follow-up appointments consistent with protocol guidelines
- Ensures the conduct of all trial-related procedures is in accordance with ICH-GCP and trial protocol.
- Provide support and advice to patients, relatives and staff before, during and after treatment
- Function as part of the multi-disciplinary team promoting individual care for patients

- Works with multi-disciplinary team to conduct feasibility assessments, to ensure all proposed trials are undertaken within the scope of the unit and the available resources.
- Participates in decisions concerning the treatment of patients on trials in accordance with the protocol and clinical need.
- Identifies acts and reports any adverse events and reactions in accordance with the protocol.
- Identifies and evaluates eligibility of potentially suitable patients for trials.
- Randomises patients into clinical trials
- Ensures safe and appropriate storage and processing of samples, in accordance with the trial protocol. GCP guidelines and Trust policy
- Maintenance of all site files in accordance with ICH-GCP and ensure all data clarification issues are resolved quickly
- Ensures all the Case Report Forms are archived according to Trust and Sponsor guidelines
- Ensures all trials and subsequent amendments are registered with Research & Development (R & D) department and that full Trust approval, in addition to ethics approval, has been obtained prior to commencement of the trial /amendment
- Liaises with pharmaceutical sponsors regarding feasibility, implementation and ongoing conduct of clinical trials
- Maintains and prepares reports on patient accruals into clinical trials

**Communication**

- Communicate with other research nurse and co-ordinators within the Trust and develop good working relations to help support them where necessary.
- Encourage a good working relationship with the medical doctors and nurses involved in patient care and facilitate a team approach to patient recruitment/enrolment to trials and safe practice.
- Communicates highly complex, sensitive information to both patients and staff
- Provides ongoing education, advice and information to patients and relatives with regards to their participation in clinical trials, facilitating informed consent, to include discussion of alternative treatments, potential benefits and risks of participation
- Consents patients on to clinical trials where approved, in accordance with GCP and Trust policy and clinical trial delegation.
- Establishes and maintains effective communication with other departments within the Trust, other relevant organisations, non-commercial bodies and pharmaceutical sponsors.

**Management and Leadership**

- Work at all times according to regulations as described in ICH, Good Clinical Practice (GCP), and to the most current guidance relating to research governance and research ethics in each Trust.
- Liaise with Clinical Trial Offices and external investigators and designated staff within supporting departments when necessary to set up and coordinate research studies.
- Support the recruitment of patients into NIHR or Commercial studies. To work with staff across the Research Networks to develop strategies to overcome barriers to patient recruitment.
- Prioritise and manages own workload
- Record and report any serious adverse effects that occur whilst the patient is being treated on a clinical trial.
- Cooperate with all aspects of clinical audit and take part in audit meetings.
- Participates in development of standard operating procedures, in association with Trust Research & Development department, for best research practice.
- Participates in development of departmental policies and procedures
- Participates as a representative of the research team at local and national meetings.

**Service Development**

- Support the research strategy of the Trust.
- Where necessary information and guidance on research should be disseminated to any staff interested in research and to help develop a research culture at the Trusts.
- In association with the multi-disciplinary team, participate in the decision-making process on the suitability of new clinical trials.

**Education**

- Raise the profile of clinical research by educating clinical staff and patients about research.
- Acquire a detailed knowledge of clinical research protocols open to patients at LNWH, and to explain the purpose of the research to clinicians and patients.
- Keep abreast of current developments in research, to present new protocols for consideration by clinical teams in order to develop the local trial portfolio.
- Attend team or Network meetings when required.
- Report Monthly recruitment figures to the R&D Lead Data Manager

- Disseminate research by assisting in the preparation of posters/research papers for meetings, conferences and publications.
- Maintain awareness of current advances in treatments, research and clinical practice and use this knowledge to maintain the highest standard of care for patients
- Participates in the induction, orientation and training of new research team staff
- Provides formal and informal education to the multidisciplinary team about relevant clinical trials and other speciality-associated clinical conditions, treatments and care
- In association with the Lead Research Nurse, maintains personal professional development
- Assumes responsibility for continuing education and development by attending seminars, conferences, investigator meetings and courses, as well as keeping up-to-date on current publications in relation to the clinical trials portfolio

## ADDITIONAL RESPONSIBILITIES

### INFORMATION GOVERNANCE

All NHS workers must abide at all times by the Confidentiality: NHS Code of Practice document issued by the Department of Health, and follow the relevant confidentiality and privacy policies specifically adopted by the Trust. Information relating to patients, employees and business of the Trust must be treated in the strictest confidence and under no circumstances should such information be discussed with any unauthorised person(s) or organisations. All information collected, stored and used must be done so in compliance with the Data Protection Act, the Freedom of Information Act (2000) and all relevant Trust Policy. Breaches of confidentiality or information governance protocol may lead to disciplinary action.

### INFORMATION SECURITY

All staff must adhere to the requirements of the Trust's Information Security Policy, which covers the deployment and use of all of the Trust's electronic information systems (i.e. all computers, peripheral equipment, software and data). In serious cases, failure to comply with the Policy may result in disciplinary action and could also result in a criminal offence.

### HEALTH AND SAFETY AT WORK Act (1974)

You are required to take reasonable care for your health, safety and welfare and that of other people who may be affected by your actions or omissions. These responsibilities apply at all times whilst you are at work or on duty and apply to all Trust premises and also whilst working in the community or on any other Trust business.

### EQUAL OPPORTUNITIES AND EQUALITIES LEGISLATION

It is the policy of London North West Healthcare NHS Trust that no user of service, present or future employee or job applicant receives less favourable treatment on the grounds of their sex, perceived or actual sexual orientation, marital status, race, religion or belief, age, creed, colour, nationality, national origin, ethnic origin, or disability, or on the grounds of their association with someone in one of these groups; nor is disadvantaged by any conditions or requirements which cannot be shown to be justified.

### PATIENT & PUBLIC INVOLVEMENT

Section 11 of the Health & Social Care Act 2001, places a duty on NHS organisations to involve and consult patients, the public and other stakeholders in the planning and ongoing development of services. It is the responsibility of each member of staff, clinical and non-clinical to appropriately involve and consult patients, the public and other stakeholders.

**RISK MANAGEMENT**
You are required to contribute to the control of risk and use the incident reporting system to alert the Trust of incidents or near misses that may compromise the quality of services.

**CORPORATE / CLINICAL GOVERNANCE**
It is the duty of every employee to fulfil their individual clinical governance responsibilities and their expected contribution to ensuring that the Trust complies with benchmarked standards for quality of clinical care.

**INFECTION CONTROL AND HOSPITAL-ACQUIRED INFECTION**
Infection Control is everyone's responsibility. All staff, both clinical and non-clinical, are required to adhere to the Trust's Infection Prevention and Control Policies and make every effort to maintain high standards to infection control at all times thereby reducing the burden of Healthcare Associated Infections including MRSA. In particular all staff have the following key responsibilities:

- Staff must wash their hands or use alcohol hand rub on entry to or exit from all clinical areas and between each patient contact.
- Staff members have a duty to attend infection control training provided for them by the Trust.
- Staff members who develop an infection that may be transmissible to patients have a duty to contact Occupational Health.

**SAFEGUARDING CHILDREN AND VULNERABLE ADULTS**
We all have a personal and a professional responsibility within the Trust to identify and report abuse. The abuse may be known, suspected, witnessed or be limited to raised concerns. Early recognition is vital to ensuring the patient is safeguarded and any other people (children and vulnerable adults) who may be at risk. The Trust's procedures must be implemented, working in partnership with the relevant authorities. The sharing of information no matter how small is of prime importance in safeguarding children, young people and vulnerable adults. As an employee of the Trust you have a responsibility to ensure that:

a) you are familiar with and adhere to the Trusts procedures and guidelines for safeguarding children and vulnerable adults
b) you attend safeguarding awareness training and undertake any additional training in relation to safeguarding relevant to your role.

**STAFF COMMITMENT TO PATIENT CARE**
You are expected to ensure that patients' needs, experience and safety come first and to treat patients, carers, visitors, and colleagues with dignity and respect.

**HEALTH RECORDS**
Clinical staff must keep accurate and clear information which is essential for the proper care of patients. Clinical and non-clinical staff who handle or use, case notes are individually responsible for the confidentiality, tracking, filing and good order of the case note at all times as outlined in the Medical Records Policy and the Information Lifecycle Management Policy. For further information refer to; Department of Health website-*Records Management; NHS Code of Practice- 2006*

**NHS CONSTITUTION AND CODE OF CONDUCT FOR MANAGERS**

Staff are required to act in accordance with the legal duties and expectations relating to their responsibilities to the public, their patients and colleagues set out in section 3b of the NHS Constitution and pages 98-109 of the Handbook to the NHS Constitution. For Managerial staff, including anyone with supervisory responsibility, the core standards of conduct set out in the NHS Code of Conduct for NHS Managers (2002) or any subsequent amendments.

**This list is only an indication of the main tasks required to be performed. It is not an exhaustive list of duties and responsibilities and may be subject to amendments to take account of changing circumstances.**

**The Trust reserve the right that you may be required to undertake such other duties and/or hours of work as may reasonably be required of you commensurate with your grade at your normal place of work or from another location within the Trust.**

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# PERSON SPECIFICATION

**Job Title:** Research Nurse/ Coordinator
**Division/department:** Academic Directorate / R&D Department

| REQUIREMENT | ESSENTIAL | DESIRABLE |
|---|---|---|
| **Education/ Qualifications** | • Registered Nurse or possession of a relevant degree or in the process of obtaining one<br><br>• Current good clinical research practice course (ICH-GCP) or willing to undertake within 1 month of taking up the post | |
| **Knowledge & Experience** | • Must be able to demonstrate they have the ability to work in a clinical environment<br>• Experience of managing complex information or projects<br>• Competent in using Microsoft Office software for storing/retrieving data | • Previous experience in working in clinical research<br>• Participation in consent process for patients entering clinical research<br>• Experience of working independently and as part of a team and working with Databases<br>• Experience of managing and Coordinating patient care<br>• Experience of handling clinical incidents and complaints<br>• Understanding of clinical research methodology<br>• Understanding and or knowledge of research governance and regulations (ICH/GCP and EU Directives ) |
| **Skills, Abilities and Attributes** | • Ability to acquire in-depth knowledge of trial protocols and to communicate this to professionals and lay persons<br>• Ability to communicate well with patients, relatives and members of the multidisciplinary team.<br>• The post holder should be sensitive to the emotional needs of patients and their relatives and be able to work unsupervised as part of team.<br>• They must also be reliable and innovative in their approach to work.<br>• Able to carry out the duties of the post with or without adaptations | • Ability to educate and support nursing and medical staff in clini trials methodology |

| REQUIREMENT | ESSENTIAL | DESIRABLE |
|---|---|---|
| | • Analyse recruitment problems<br>• Attend meetings.<br>• Prioritise own work<br>• Has the willingness to enrol in appropriate continuing professional development programmes.<br>• Keep abreast of technical developments by attending seminars, training courses, reading appropriate journals. All staff should have a personal development plan and in conjunction with their manager, should actively determine and pursue agreed training and development needs and opportunities. | |

*Person specifications should be kept to a maximum of 25 bullet points Paed*

**Job description and person specification drafted / amended by:**

**Name: Mushiya Mpelembue** **Designation: Head of Research Nursing**
**Date:**

## JOB DESCRIPTION AND PERSON SPECIFICATION AGREEMENT

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|---|---|---|---|
| **Job Holder's Signature** | | **Date** | |
| **Line Manager's Signature** | | **Date** | |