JOB DESCRIPTION

Job Details:

Job Title:	Clinical Research Nurse/Practitioner
Band:	Band 6
Location:	Based at NNUH (with possibility of occasionally working at other sites across the research network if required)
Department:	Emergency Department
Managerially Accountable to:	EM-ACP lead for research
Professionally Accountable to:	EM Nurse consultant

Job Purpose:

As a clinical research nurse practitioner they will be responsible for managing a speciality portfolio of research studies, including the assessment & management of care pathways for clinical trial participants. This will involve the recruitment, education and monitoring of trial participants and the collection and documentation of accurate data. They will work collaboratively with the clinical trials team and the wider multi-disciplinary team in the management of a caseload of clinical trial participants. They will provide relevant clinical skills/competencies relevant to the role and consummate with professional registration, including phlebotomy, cannulation, administration of IV infusions, vital sign assessment and ECG. This list is not exhaustive and as according to trial protocol requirements, relevant training will be provided.

The role involves using an in-depth knowledge of trial protocols and their application in practice, alongside a working knowledge and compliance with the local, national and international research regulations.

To support the delivery of a high quality, safe and compassionate healthcare service, all staff are expected to act as a role model to others in all aspects of their work and consistently demonstrate NNUH's 'PRIDE' values of People focused, Respect, Integrity, Dedication and Excellence and demonstrate behaviours that support and encourage an inclusive culture.

Overview of Essential Responsibilities:

1. To work according to ICH Good Clinical Practice (GCP) guidelines and research governance standards for clinical trials and current Standard Operating Procedures (SOPs)

2. To demonstrate in-depth knowledge of trial protocols and their application in practice alongside a working knowledge of how to comply with local, national and international research regulations.

3. To manage a caseload of concurrent clinical studies following a range of complex clinical trial protocols and to contribute to the management of the local portfolio of clinical trials.

4. To identify, screen and recruit participants into research studies according to the inclusion and exclusion criteria to ensure the effective achievement of study aims and monitoring of their condition throughout participation.

5. To ensure that trial specific investigations are undertaken as required by the research protocol in order to establish eligibility and safety to enter the trial for its total duration.

6. To attend multi-disciplinary team meetings (MDT), and appropriate clinics, to screen and recruit new participants, and to act as a resource to the members of the MDT.

7. To register/randomise participants into trials and to ensure that all clinical trial records, Case Report Forms (CRFs) and participant records are completed contemporaneously and maintained with a high degree of accuracy. These records may be in paper, optical or electronic form. To maintain accurate documentation of participant events in nursing/medical notes.

8. To identify barriers to recruitment to trials and ensure that the Network and R&D is aware of them. To support/action plans as required.

9. To act as a primary contact point for the clinical trial participant..

10. To provide ongoing information, education and support to participants (and their significant others) regarding clinical trials.

11. To act in the best interest of the research participants to ensure that their rights are upheld.

12. To facilitate the informed consent process ensuring the following is accounted for: -
    - The participant (and significant others) fully understands the nature of the clinical trial.
    - They are aware that entry into the trial is voluntary and they can withdraw at any point without prejudice.
    - They are aware of any extra procedures required by the trial.

- The consent form is completed accurately and filed as required

13. To provide ongoing follow up care whilst participant is in the clinical trial.

14. To co-ordinate the visit schedules of research participants and ensure the most appropriate venue is offered subject to local guidelines.

15. To maintain and further develop a range of clinical skills necessary to facilitate research as determined by the research protocol i.e. phlebotomy, administration of intravenous treatments, cannulation, vital sign assessment and ECG recording.

16. To ensure blood is collected for pharmacokinetic studies, and as required by the trial protocol, processed and stored appropriately and shipped according to international and national regulatory requirements

17. To ensure the safe ordering and storage of study medication prior to dispensing to participants as stipulated in the trial protocol/pharmacy manual/laboratory manual.

18. To ensure the safe administration of treatments and drugs given within the context of clinical trials adhering to local and national guidelines.

19. To adhere to all safe systems of work applicable to the work area and to take appropriate action in the event of unexpected results/equipment failure.

20. To be competent in taking the lead role in managing emergency situations such as cardiac arrest, major incident and fire procedures as they relate to the work area and providing support for other members of the team.

21. To participate in clinical trials monitoring internally and externally as required to meet the governance requirements of each study.

22. To monitor treatment toxicity/side effects and initiate changes to treatment as required by the protocol.

23. To record and report adverse events/serious adverse events which occur whilst the participant is in the clinical trial to the relevant personnel and act as required. This may include the trial co-coordinator/Principal Investigator and relevant local personnel/regulatory authorities in the event of serious adverse events.

24. To promote effective communication with the Project Co-ordinator, Sponsor, medical staff and other departments and agencies involved, to ensure optimal safety of trial participants.

25. To be responsible for forwarding trial data in a timely manner to the trial co-ordinating centre. Liaise with clinical trial personnel outside the hospital as necessary.

26. To ensure that clinical trials are effectively archived as required.

27. To supply data as required to the Information Manager/R&D regarding progress of clinical trials.

28. Under the direction of and reporting back to the Senior Research Nurse provide advice to clinicians and Clinical Research Associates regarding the feasibility of potential new studies to be added to the current research portfolio.

29. To assist, where necessary, in the process of gaining local regulatory committee approvals (ethics and R&D approval).

Line Management/Financial Management Responsibilities:

People Management

1. Being responsible for the recruitment and retention of staff in collaboration with the Senior Research Team, coordinating and liaising with the NNUH Recruitment Team to maximise interest in clinical research roles and to ensure a timely and smooth recruitment process to current vacancies. To include preparing relevant documentation for finance approvals processes, preparing advertisement of vacancies for Recruitment Advertising team, organising and coordinating interviews and all processes involved in appointing to post

2. Ensuring that the Direct Reports are managed in accordance with all relevant Trust policies such as the Attendance, Misconduct, Appraisal, Cyber Code of Conduct policies.

3. Ensuring the appropriate teaching and supervision of junior staff, participants, students, carers, and new staff members.

4. Helping create a suitable educational environment so staff are given appropriate learning opportunities and encouraged to apply theory to practice.

5. Identifying performance issues and initiate action in accordance with the Trust's Capability and Misconduct policies procedure including referral as appropriate to the line manager.

6. To gain awareness of resource management and departmental budgets utilising allocated resources appropriately and in collaboration with the Senior Management Team, manage financial budgets to ensure maximum provision of staff within budgetary restraints.

7. To liaise with the R&D finance team to ensure maximum renumeration for clinical trial activity as appropriate and as per clinical trial agreement/costings template.

Other Management responsibilities

1. To attend departmental meetings relevant to the post and represent the Senior/Lead Nurse in their absence at other Senior Management meetings as required, reporting back appropriately and undertaking any actions required.

2. To liaise with members of the multi-disciplinary team i.e., Pharmacists, Radiologists, Pathologists, to establish procedures for the caseload of trials held.

3. To develop managerial skills within sphere of responsibility.

4. To propose changes to working practices and SOPs and to work with others on the development of new SOPs.

5. To use leadership skills to create an environment that is safe and supportive to ensure effective teamwork and a motivated, efficient workforce.

6. To act as a role model and demonstrate expertise within their sphere of practice.

7. To act as an ambassador for the Trust and Network in professional and public settings.

Specific Additional Responsibilities:

Functional Requirements			
Direct face to face patient contact	Yes	Blood/body fluid exposure	Yes
Managing a team who hold professional registrations	Yes	Prevention and management of aggression	No
Exposure prone procedures (EPP)	No	Crouching/stooping or kneeling	Yes
Manual handling	Yes	Frequent hand washing/wearing gloves	Yes
Night working/shift work	No	Chemical sensitisers	Yes
VDU user	Yes	Noise	Yes
Driving patients	No	Other (please state)	Choose an item.

Job Specification:

		Means of Assessment
	Essential/ Desirable	Application Form/ Interview/Test
Qualifications/training and professional development		
Registered Nurse/Midwife on the appropriate part of the NMC register **or** in possession of Health Related Degree	D	A/I
Have, or be working towards, a health/research related degree or equivalent demonstrable knowledge/experience.	E	A/I
Post Graduate diploma or equivalent professional qualification in Health Sciences field .	D	A/I
ICH Good Clinical Practice training	D	A/I

Experience		
Significant experience at Band 5 or above, working in an NHS environment some of which should have been working in a research role	E	A/I
Evidence of research activity and a good understanding of research and clinical trials	D	A/I
Knowledge of sample preparation and transportation	D	A/I
Experience of collaborating with other agencies	D	A/I

Skills, abilities and knowledge		
Advanced clinical skills relevant to the role e.g.; phlebotomy, cannulation, ECG recording or willingness to undertake training to achieve required competencies	E	A/I
Awareness of research governance issues	E	A/I
Competence in standard PC packages (including Excel, Access)	E	A/I
Excellent communication and inter-personal skills with an ability to deal with the public and colleagues in a pleasant and polite manner at all times	E	A/I
High level of organisational and time management skills	E	A/I
Highly motivated	E	A/I
Leadership qualities and possession of supervisory skills to develop junior staff	E	A/I

Attitude, aptitude		
Ability to travel independently and attend training and meetings outside the employing organisation.	E	A/I
Evidence of Continuing Professional Development and maintenance of a Personal, Professional Profile	E	A/I
Willingness to further develop knowledge and skills	E	A/I
Effective role model, demonstrating NNUH's PRIDE values of People focussed, Respect, Integrity, Dedication and Excellence	E	A/I
Demonstrates understanding and commitment to Equality, Diversity and Inclusion	E	A/I

Reasonable adjustments can be considered to support disabled candidates in respect of the requirements of this role.

For information regarding general terms and conditions of employment please ask your line manager or Human Resources.

This job description indicates currently the main responsibilities of the post. It is not a complete list and may be amended and developed as necessary in consultation with the manager and post holder. We would aim to reach agreement on any changes, but if agreement is not possible, the Trust reserves the right to make changes to this job description.