The Newcastle upon Tyne Hospitals NHS Foundation Trust

Job Description

1. Job Details

Job Title: Clinical Trials Assistant

Band: 4

Directorate: Clinical Research

Base: Trust wide

Essential Requirements

- Experience of caring for patients in a professional setting
- NVQ level 4 or equivalent qualification or NVQ level 3 and an ability to demonstrate significant experience relevant to role
- Ability to coordinate collection of data to agreed timescales
- Excellent interpersonal skills
- Ability to communicate well (written and verbally)
- Understanding of the Trust's confidentiality procedures (Data Protection Act, Caldicott guidelines)
- Strong IT skills, specifically in database management and Microsoft excel
- Knowledge of medical terminology

Desirable Requirements

- Venepuncture skills
- Evidence of any education related training programs pertaining to clinical trials
- Knowledge regarding the mandatory standard regarding conduction/construction of clinical trials (to include ICH GCP, UK Policy Framework for Health and Social Care Research etc.)
- Experience of using NHS patient management systems

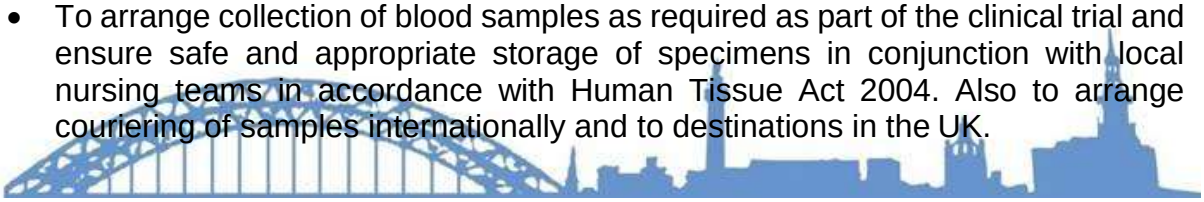
2. Job Purpose

- Coordinate and improve trial communication throughout Multi-Disciplinary Teams throughout the Trust
- Maintain effective communication with patients, carers and professional to ensure service delivery
- Communicates effectively with research team and study participants and their family members. Is able to provide patients with information, which may be complex or sensitive, regarding their participation in the clinical trial and the care that they will receive as a consequence of that
- Facilitate the recruitment of research participants in to low risk research studies, which is likely to include quality of life and tissue sample collection studies
- Support the research delivery team to successfully deliver a broad ranging portfolio of clinical trials

- Coordinate and supervise housekeeping duties and ordering of all clinical trial supplies
- Co-ordinate the collection transfer and storage of blood / tissue samples in accordance with the Human Tissue Act 2004 as required by trial protocol

3. Dimensions

- The Clinical Trials Associate is responsible for implementing guidelines pertaining to GCP this includes communicating information to patients and their families and ensuring adequate documentation of events
- Ensuring all trials within the post holders remit run within the unit have received full ethical and Trust approval before being opened to recruitment
- Overseeing and partaking in the timely completion of Case Report Forms (CRFs) to reflect ongoing status of patients on trials.
- Responsible for reporting of any Serious Adverse Event (SAE) affecting patients enrolled into a clinical trial within required timeframe (usually 24 hours)
- Receipt and dissemination of new protocols and amendments within the centre (following approval) to relevant clinical areas. Maintenance of appropriate records to reflect this.
- Development and maintenance of trial site files.
- Updating and maintaining centralised patient database.
- Providing timely information on trial recruitment figures for reporting purposes.
- To arrange collection of blood samples as required as part of the clinical trial and ensure safe and appropriate storage of specimens in conjunction with local nursing teams in accordance with Human Tissue Act 2004. Also to arrange couriering of samples internationally and to destinations in the UK.



4. Organisational Arrangements

Reports to: Team Lead/Senior Research Sister

Accountable to: Research Matron

5. Knowledge, Training and Experience

- Please see Essential Requirements.

6. Skills

Communication and Relationships

- Communicates on a regular basis with senior medical staff, nursing, pharmacy, radiology, pathology and laboratory staff.
- Communicates trial related information effectively with research team and study participants and their family members. Is able to provide patients with information, which may be complex or sensitive, regarding their participation in the clinical trial and the care that they will receive as a consequence of that whilst being mindful that there may be barriers to understanding.

- Liaises with external co-ordinators of trials, nationally and internationally
- Attends both national and international trial specific meeting and disseminates information to members of the multi-disciplinary team
- Requires ability to cascade clear, concise information in a timely manner
- Responsibility to ensure that all information relating to updates in trial protocols and guidelines are disseminated to key areas.

Analytical and Judgmental

- Ability to analyse and propose recommendations for improvements in the conduction of clinical trials.
- Analyse medical case notes and extract relevant data to assist in reporting of trial patients

Planning and Organisational

- A high degree of organisational skills required to ensure that correct procedures are followed in terms of a number of trial protocols
- Post holder will be responsible for the co-ordination of numerous research studies these studies will be related to quality of life/epidemiology studies
- Post holder will be able to identify strategies for recruiting patients into clinical trials

Physical Dexterity

- Venepuncture skills/ECG competent
- Good computer skills

7. Key Result Areas

Patient / Client care

- Ensure that proposed patients for clinical trials are enrolled in accordance with unit standard operating procedures
- Organise any trial specific tests and trial related care for a group of low risk patients
- To provide ongoing support to the patient and carer whilst participating in the clinical trial
- Report any adverse events which occur whilst the patient is participating in the trial to the appropriate principle or co-investigator.
- Ensure the risk of infection to yourself, colleagues, patients, relatives and visitors is minimised by:
    - being familiar with and adhering to Trust policies and guidance on infection prevention and control
    - attending Trust Induction Programme(s) and statutory education programmes in infection prevention and control
    - Including infection prevention and control as an integral part of your continuous personal/professional development
    - taking personal responsibility so far as is reasonably practicable, in helping ensure that effective prevention and control of health care acquired infections is embedded into everyday practice and applied consistently by you and your colleagues

Policy and Service Development

- All policies and updates relating to the administration of trial conduct (GCP/Research Governance Framework / EU Directive) should be implemented

within the department – the trials assistant will play a key role in carrying this out
- Requirement to keep up to date with policy developments pertaining to data collection and implement where necessary.
- To be aware of, and comply with, all Trust policies and procedures.

Financial and Physical Resources
- Regularly completes stock and non-stock requisitions
- Regular stock take of clinical trials supplies

Human Resources
- Attend regular updates (both within the Trust and externally) in clinical trial protocols and regulatory guidelines pertaining to the safe running of said trials in the Unit

Information Resources
- Accurate collection of clinical research data relating to patients on clinical trial protocols
- Maintain and update a record of open clinical trials for MDT reference
- Maintenance of central attendance files/database to reflect any training carried out pertaining to the post
- Updates patient records to reflect plan of care

Research and Development
- As a member of the multi-disciplinary team, there will be involvement in the entire process of recruiting an individual patient to a clinical trial which will include:- ensuring informed consent has been obtained, registration, randomisation, monitoring progress throughout treatment, relapse or treatment failure, treatment sequelae and follow up.
- Some responsibility to assist in the submission of trial documentation for Trust Research and Development approval and local ethical approval.

8. Freedom to Act

- Objectives are agreed with Senior Research Team Lead but expected to prioritise and work on own initiative to achieve these.
- Set objectives must be achieved within the boundaries of Good Clinical Practice, Research Governance Framework and European Union Directive on Clinical Trials.

9. Effort and Environment

Physical Effort
- Daily requirement to manually carry cumbersome /protocols to and from clinical areas (usually not exceeding 5kg). This occasionally includes retrieval of deceased case notes from secondary storage areas, which are housed away from working environment.
- Daily use of keyboard/VDU.

Mental Effort
- High level of concentration and accuracy will be required for prolonged periods on

a daily basis. Interruptions are frequent but predictable.
- Requirement for prolonged periods of concentration when cross-referencing medical case notes

Emotional Effort
- Regular direct exposure to distressing or emotional circumstances with patients and carers
- There are specific standards to be met in the management of clinical trials and specifically around data quality. Work can be time consuming and intricate.

Working Conditions
- Ability to work in both clinical and clerical areas which will change a session basis
- Open plan office
- Frequent use of VDU/keyboard
- Regular exposure to tissue/blood samples

Signed: ……..…….. **Date:** …….
(Post holder)

Signed: ……..…….. **Date:** …….
(Directorate Manager or equivalent)

Job Evaluation Reference: CAN/NAM/NCCT/NGH/085h

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Person Specification

JOB TITLE: Clinical Trials Assistant **BAND:** 4 **DIRECTORATE:** Clinical Research

REQUIREMENT	ESSENTIAL Requirements necessary for safe and effective performance of the job	DESIRABLE Where available, elements that contribute to improved/immediate performance in the job	ASSESSMENT
Qualifications & Education	• NVQ level 4 or equivalent qualification or NVQ level 3 and an ability to demonstrate significant experience relevant to role		
Knowledge & Experience	• Experience of caring for patients in a professional setting • Knowledge of medical terminology • Understanding of the Trust's confidentiality procedures (Data Protection Act, Caldicott guidelines)	• Evidence of any education related training programs pertaining to clinical trials • Experience of using NHS patient management systems • Knowledge regarding the mandatory standard regarding conduction/construction of clinical trials (to include ICH GCP, UK Policy Framework for Health and Social Care Research etc.)	
Skills & Abilities	• Ability to coordinate collection of data to agreed timescales • Excellent interpersonal skills • Ability to communicate well (written and verbally) • Strong IT skills, specifically in database management and microsoft excel	• Venepuncture skills	
Values / Behavioural / Attitudes			

Core Behaviours	• Alignment to Trust Values and Core Behaviours
	• Take personal responsibility to:
	  ○ engage with the Trust's Climate Emergency Strategy and Sustainable Healthcare in Newcastle (SHINE) initiatives;
	  ○ assist in embedding our sustainability values into everyday practice; and
	  ○ help ensure such practice is applied consistently by you and your colleagues		

CANDIDATE: **REFERENCE NO:**

SIGNED BY: **DATE:**

DESIGNATION:

Job Evaluation Reference: CAN/NAM/NCCT/NGH/085h