Job Description

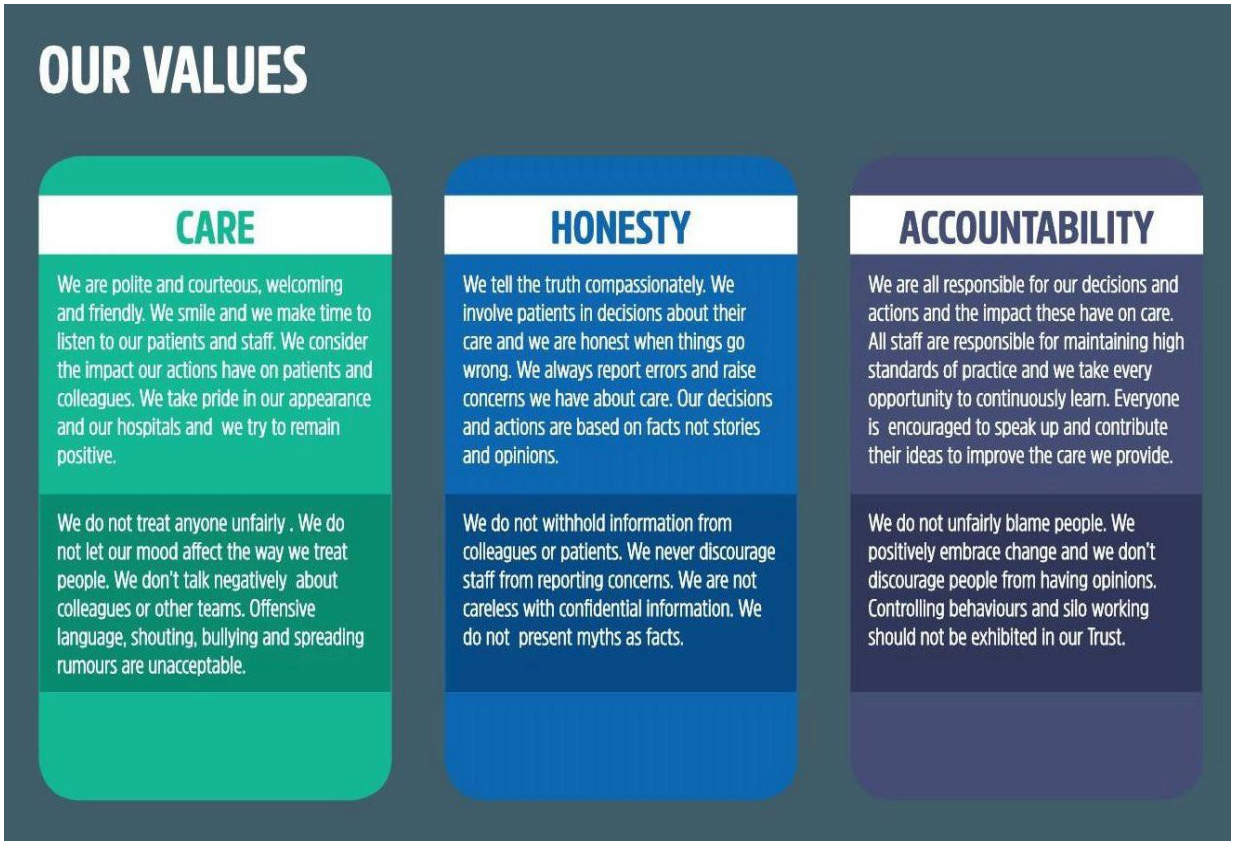
Corporate Services-Research

Job Title: **Clinical Trials Assistant - IBD Research**

Band: **Band 3**

Reports To: **Senior Research Nurse**

Professionally Accountable to: Research, Development & Innovation Matron



JOB STATEMENT:

The focus of this role is to:

- Assist the Research Nurses and the wider team including Principle Investigators and sub Investigators in the identification, recruitment and management of patients enrolled in a portfolio of NIHR commercial and non-commercial clinical trials.

- Undertake procedures under the supervision of registered nurses and the medical team, having been trained, assessed and deemed competent in these activities.
- Perform data-gathering, specified clinical tasks and administrative support for clinical research studies and research team.
- Coordinate and input clinical trials data ensuring data is up to date and ensuring the completeness, accuracy and consistency of trial data in order to meet standards expected of sponsors and regulatory authorities.
- Assist the research team in administrative duties for clinical trial start up, initiation, maintenance and study closure whilst ensuring compliance with regulatory and Good Clinical Practice requirements.
- Accurate entry and timely completion of data either paper or electronic versions in addition to other trial documents as required.
- Assist the research team with the resolution of raised data queries through effective monitoring.
- Establish and maintain site files for trials in accordance with ICH-GCP standards and research governance.
- Arrange monitoring visits for external monitors and assist in the preparation and follow up of these visits.
- Assist the research team in the entry and maintenance of accurate information on data bases such as the patient recruitment data base and EDGE.
- Process amendments, ensuring all the team are aware of changes to protocol and documents.
- Provide administration support for research nurses as required e.g. Send letters and faxes, collecting and returning medical notes, taking and disseminating minutes of meetings**.**
- Manage and respond to any data queries received as directed by the research team.

KNOWLEDGE AND SKILLS

Communication and Relationship skills

- Effective verbal and written communication skills with the ability to communicate with staff at all levels.
- Ensure that all quality of life assessments are completed in line with protocol requests. This may involve undertaking telephone or face to face assessments.
- The post holder should exchange factual information with patients using persuasion, reassurance, tact, empathy and may be required to overcome barriers to understanding, e.g. patient/client has physical impairment, mental health condition or learning disabilities.
- Report adverse events to the research nurse and wider team.
- Manage telephone enquiries from staff, patients and carers ensuring that appropriate people are informed in order for actions to be taken.
- Professional in approach when dealing with patients, their relatives and representatives from both external and internal sources.
- Disseminate information from trial co-ordinators or staff to the local research teams.

- Assist with providing feedback to research nurses and MDT members on issues relating to recruitment, protocol amendments and trial results.
- Maintain good communication to provide the optimum service and quality of care for each patient and family.
- Assist research participants in completing trial related assessments such as paper questionnaires or using electronic data capture devices
- Input research subject alerts and information on relevant hospital systems to ensure all departments are aware that a patient is on a clinical trial/research study thus ensuring patients' safety and well-being and promoting best research practice.
- Participate in regular meetings with the clinical research team and wider research support teams.
- Ensure that all members of the multi-disciplinary team are aware of the current trials portfolio via attendance at meetings, email updates and other research specific forums.

Knowledge, Training and Experience

- Demonstrate effective time management and organisational skills
- The post holder must have knowledge of care and related procedures, clinical observations, relevant research and non-research related legislation;
- Demonstrate the ability to manage own administrative case-load working as part of the multi-disciplinary team
- Communicate factual information accurately using acquired written and oral communication skills.
- Proficient IT skills to include the use of Microsoft word and able to create and use Excel spreadsheets and databases.
- Fine motor skills are required to assist with routine patient care such as venepuncture, ECGs
- Demonstrable experience in IBD or related clinical specialties.
- May be required to undertake short courses to undertake patient and clinical care duties, completion of a competency based workbook or equivalent.

Analytical and Judgemental Skills

- Assess patient/client condition through observations or test results.
- Assess comfort of patient/client, instigate emergency procedures if required.
- Perform data collection and accurate Case Report Form data entry to ICH-GCP standards and research protocols
- Interpret whether data required is recorded correctly/quality check source data ensuring that missing data or corrections are made, referring to clinical staff as required

Planning and Organisational Skills

- Plans own work activities.
- Responsible for the input, collection and collation of accrual and trial data and completion of trial documentation for all patients recruited on to the recruitment database and in accordance with trial protocols.

- Prioritise and manage time effectively to ensure that trial data is submitted to the study sponsor within the specified time constraints.
- Assist in the evaluation of patient eligibility, in liaison with other appropriate health care professionals for clinical trial entry, involving the co-ordination of pre-study tests, obtaining results and arranging appropriate appointments as per clinical trial protocols
- Assist the co-ordination of the patients journey through the clinical trial protocol e.g. requisition and organisation of any necessary investigations, procurement of patient notes.
- Arrange patient clinic appointments with research team and trial participants as required.
- Assist the research team in the preparation and conduct of clinic visits for patients enrolled in clinical trials
- Arrange clinical trial monitoring visits with sponsors and facilitate the running of the visit
- Effectively archive research documentation in line with legal requirements

Physical skills

- The post holder will need to have the dexterity and coordination to use a computer keyboard.
- Physical skills obtained through practice

RESPONSIBILITIES

Responsibility for Patient Care

- Carry out clinical procedures required for clinical trials including but not limited to: Blood pressure recording, heart and respiratory rate, height, weight and BMI assessment, collection of blood and urine samples, blood spinning using a centrifuge and conducting electrocardiograms.
- Report all findings from clinical procedures to the clinical research team and accurately document as advised by the team in the patients case notes, appropriate research files, logs, CRF's and databases.
- Order clinical tests as required by specific research protocols and as directed by research nurses and clinical researchers.

Responsibility for Policy/Service development

- The post holder should follow policies but may be required to comment on proposed changes to procedures as required.
- Assist with implementing local and national quality standards, recommendations and guidelines from national reports.

Responsibilities for Financial and Physical resources

- Responsible for the care and safe use of expensive and/or highly complex equipment

- Correctly provide trial patient schedule information to allow accurate invoicing.
- Order stationary, ensuring this budget is kept in consideration with the support of the Senior Research Nurse.

Responsibilities for Human Resources

- Assist with the training of new clinical trials assistants
- In conjunction with all members of the research team and appropriate healthcare professionals, aim to develop a cohesive and flexible team working environment across the service
- Undertake any training and assessment of competency required for clinical trials assistant role to include Good Clinical Practice Training (GCP) every two years

Responsibilities for Information Resources

- Facilitate collation of patient information required for clinical trials, request collect and return medical notes.
- Ensure all patient identifiable records for clinical trials and otherwise are stored according to information governance policies.

Responsibilities for Research & Development

- Contribute to the ongoing development of research systems and processes and their implementation in the department through participation in discussion with the wider team
- Required to participate in audits, surveys and R&D activities as directed.

Freedom to Act

- Manage and organise own work load and meet deadlines as required, using own initiative
- Work without direct supervision and within well established procedures and/or practices, with outcomes assessed at agreed intervals.

EFFORT & ENVIRONMENT

Physical effort

The post requires a combination of sitting, standing and walking with occasional requirement for intense physical effort when manoeuvring and transferring patients safely or when transporting heavy clinical research equipment or files.

Mental effort

- Frequent sustained levels of concentration required when undertaking clinical procedures.
- Work to tight deadlines and demanding timescales.

Emotional effort

- Frequent exposure to distressing or emotional circumstances with patients

Working Conditions

- Occasional exposure to highly unpleasant working conditions that arise through the taking of blood and other bodily fluid samples

Health and Safety

In addition to the Trust's overall responsibility for your health and safety you have a personal responsibility for your own health and safety. As such you are required to inform your line manager of any safety issues that you identify, that could affect you or others in the workplace. You must co-operate with management and colleagues at all times in achieving safer work processes and work places, particularly where it can impact on others.

As a Trust employee you will be trained in the correct use of any equipment provided to improve safety and health within the Trust. You are required to use the equipment when necessary and as instructed which will include checking the equipment is safe to use, prior to its use and must report any defects immediately to your line manager.

You are responsible for the implementation and adherence to Trust safety policies and procedures for areas within your remit.

You are required to ensure suitable and sufficient risk assessments are completed for all areas within your remit. The controls identified must be evaluated and implemented where necessary.

You are required to review all risk assessments periodically and particularly when staffing and/or equipment changes, monitoring the effectiveness of any control measure implemented.

You are to ensure suitable and sufficient equipment is provided to sustain the health and safety of staff, patients and visitors to areas within your remit.

Infection Control

In addition to the Trust's overall responsibilities under The Health and Social Care Act 2008 Code of Practice for healthcare, including primary and adult social care on the prevention and control of infections (revised December 2010) for your safety, you have a personal responsibility to ensure your work adheres to this Code in the delivery of safe patient care within the organisation. This code relates to ALL Trust staff and contractors working within the organisation who are employed to ensure this level of care is provided.

As an employee you will be trained to ensure adherence and compliance to the various

Infection Control policies within the Trust.

Sustainability

To actively support the Trust's goals for sustainability by encouraging and adopting sustainable ideas and practices.

Safeguarding

The Trust has a duty and is committed to safeguarding all service users and provide additional measures for adults and children who are less able to protect themselves from harm or abuse**.** As an employee* you have an individual responsibility to contribute to the detection, reporting and prevention of abuse to safeguard those in our care (Section 11 Children Act, 2004, Human rights Act 1998, Equality Act 2010 Mental Capacity Act 2005 Care Act 2014) and are accountable to ensure that you know how to respond when you are concerned for the safety of a child, young person or adult at risk. The Trust will assist you in this process by providing training, guidance and advice. There are corporate safeguarding teams who can be contacted for advice, support and safeguarding supervision. All concerns must be reported as per Trust Safeguarding Policies which are available on the Trust Intranet. Every member of staff must undertake regular mandatory safeguarding training at a level relevant to the role

This job description is not meant to be exhaustive. It describes the main duties and responsibilities of the current post. It may be subject to change in the light of developing organisational and service needs, and wherever possible change will follow consultation with the post holder.

Person Specification

Corporate Services (Research & Development)

Job Title: Clinical Trials Assistant-IBD Research

Band: Band 3

Reports To: Research Nurse

Professionally Accountable to: Research, Development & Innovation Matron

AREAS	ESSENTIAL	DESIRABLE
Qualifications	Good level of general education to GCSE level including English. NVQ level 3 in Health Care/Care Certificate or willingness to undertake. Good Clinical Practice Course (or willingness to undertake)	Familiar with paper and electronic hospital records (or willingness to be trained).
Experience	Experience of working with the patients in a health care environment-preferably an NHS setting. Proficient in Microsoft Office software Proven experience of dealing with clinical situations.	Familiarity with medical terminology relevant to the clinical area e.g. ophthalmology/paediatrics. Knowledge of clinical trials and Good Clinical Practice Guidelines.
Skills, Knowledge and Ability	Effective time management and organisational skills. Effective written and oral communication skills. Ability to communicate factual information	

	accurately. **Ability to use Excel spreadsheets and databases.** **Ability to undertake additional skills as required- venepuncture, ECGs.**	
Personal Attributes	**Professional aptitude to work, diplomatic and calm under pressure.** **Team player.** **Effective communicator.** **Responsive and flexible attitude and approach.** **A willingness to undergo personal development and training and learn new skills.** **Strong interpersonal and administration skills.** **Has the ability to act and ensure delivery.**	
Other Requirements	**Flexibility in working hours to meet the service needs.** **Ability to work independently and as part of a team. Flexible approach to working and a desire to develop knowledge.** **Assertive and confident.** **Professional manner.**	

Organisational Chart

Corporate Services (Research & Development)

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