UNIVERSITY OF Hull

Job Description

Job Title:	Clinical Trials Research Assistant
Faculty/Department:	Diabetes and Endocrinology, Hull York Medical
Reporting to:	Prof S Atkin, Chair in Endocrinology
Duration:	Fixed term for 12 months
Job Family:	Clinical/Nursing
Pay Band:	4
Benchmark Profile:	Clinical/Nursing (A4C)
CRB Disclosure requirement:	Enhanced
Vacancy Reference:	HY0078

Details Specific to the Post

Background and Context

The post holder will be a member of HONEI (Humber, Obesity, Nutrition and Education Innovation) and Diabetes/endocrinology research team and responsible for assisting with the delivery of a portfolio of clinical trials including the adherence to regulatory processes including ethics submissions at the Diabetes Centre, Hull Royal Infirmary and the University of Hull sites. In addition to clinic/patient based tasks, this role includes document generation and control, project tracking and logistics, data collection, adherence to Good Clinical Practice and Research Governance and assisting in the continued improvement in the care of research participants and quality of research data. There will be liaison with the management team of HONEI in the Hull York Medical School as directed.

Specific Duties and Responsibilities of the post

The post holder will assist with a variety of clinical research projects and clinical trials, particularly in diabetes and endocrinology. Implement protocol guided care in Research setting; Observe patient condition, record clinical observations, adverse events & reports to PI. To have responsibility for research samples to trial protocols. To work within clinical trial protocols and to ICH/GCP standards.

Ability to work without supervision in some areas, e.g. dealing with telephone and personal enquiries from staff, patients and carers, answering queries where possible and ensuring appropriate personnel informed for further action to be taken.

GENERIC JOB DESCRIPTION

The job duties and responsibilities listed below are intended to describe the general nature of the role. The duties and responsibilities and the balance between the elements in the role may change or vary over time depending on the specific needs at a specific point in time or due to changing needs in the department. Candidates should note that there may not be an immediate requirement to carry out all the activities listed below.

Overall Purpose of the Role

- Roles at this level work within established processes and procedures, with minimum day to day supervision under the guidance of a team leader.
- The role holder will:
    - Provide support to staff, students and more senior colleagues. The role will involve maintaining systems and/or undertaking routine tasks that support the working of teams, processes and/ or projects.
    - Require the relevant knowledge which may be gained through experience and on-the-job training.

Main Work Activities

Communication

- Ensure relevant documents are available for all research patients, adhering to Medical Records tracing systems
- Report untoward incidents to the appropriate Person in Charge and, where related to patient care, complete the Incident Report Form under the supervision of a Registered Nurse/other Professional
- Participate in completing all documentation relating to research patient participation, including hospital records, Case Report Forms (CRF's) and electronic research records
- Ensure relevant documents are available for all research patients, adhering to Medical Records tracing systems
- Deal with telephone enquiries from staff, patients and carers giving responses where this is within the post holder's area of knowledge and ensuring that appropriate personnel are informed if appropriate in order for further actions to be taken.
- Interact with trial participants in relation to the requirements of the clinical trials and be able to work without supervision in some areas.

Teamwork

- Under the guidance of a team leader, where necessary provide day-to-day support to other members of staff and members of staff new to the work area
- Work closely with Clinical Investigators, Research Nurses and other members of research teams to maintain holistic support for all clinical trial participants, thus facilitating a high quality research service.

Service Delivery

- Responsible for the taking, preparation, storage and shipping of research samples, to include:
    - Advance preparation for blood, urine and other bodily fluid and tissue sampling of research patients employing correct sample containers, sample labels and sample dispatch.
    - Taking samples of venous and capillary blood from patients for the purpose of research pathology testing in line with local and central laboratory protocols and the clinical trial protocols. Prepare blood and urine samples to these protocols, including centrifugation and separating samples.
    - Responsible for the preparation and forwarding of correctly, and appropriately, labelled samples to research central laboratories, following mandatory packaging safety requirements.

- Identify eligible patients for recruitment to research from hospital notes, outpatient clinics, patient databases and primary and secondary care screening
- Identify and highlight local activities that might impact on achievement of the Service's aims
- Preparation and observation of patients participating in research, including observation of weight, body measurements, blood pressure, toxicity, quality of life and other appropriate measurements as required. Record and inform team leader of observations.
- Be able to teach patients on the use of insulin and growth hormone pen devices, inhaled insulin devices and similar technologies. Be familiar with and give patients training in the use of home blood glucose monitors. Be aware of normal blood glucose range.

Planning and Organisation

- Plan and prioritise own work activities
- Responsible for facilitation of pharmaceutical company monitoring of the clinical trials being undertaken. Ensuring that visits are co-ordinated with other clinical research staff.

Analysis/Data Inputting

- 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/X-Rays and arranging appropriate appointments as per clinical trial protocols
- Responsible for the tracking of laboratory results and their documentation in patient's research records and hospital care notes
- Responsible for the monitoring and maintenance of clinical stock levels and clerical store levels, ensuring effective and economic use of resources

Work Environment

- Prepare and maintain research and department equipment as directed
- Undertake the safe and competent handling of dry ice for frozen shipments of samples.

Additionally the post holder will be required to:

- Fulfil the employees' duties described in the University's health and safety policies and co-operate with the health and safety arrangements in place within the department. May be required to undertake specific health and safety roles on request e.g. Display screen equipment assessor, departmental safety officer, fire warden
- Show a commitment to diversity, equal opportunities and anti-discriminatory practices This includes undertaking mandatory equality and diversity training
- Comply with University regulations, policies and procedures

- **COMPETENCY SPECIFICATION**
- To fulfil your role, you will need certain knowledge, skills and competencies. The following competency specification provides a framework within which your performance will be assessed. The interview assessment may include, for example, testing on IT skills.
- **The Competencies set out below are essential and are core requirements** needed to perform the role and any candidate who fails the requirement will not be taken forward for further assessment or to interview.

Competency	**Identified by**
Knowledge and Experience Has the ability to communicate directly with patients who may be recently diagnosed with serious illness which requires tact and being sensitive to how the information is communicated, to answer questions about clinical trials within the post holder's area of knowledge, and to refer to more senior team members when appropriate; it may be necessary to deal with complex or sensitive information	**Application/Interview**
Ability to implement local, national and international quality standards for clinical trials and patient care generally, including implementation of ICH-GCP (International Conference on Harmonisation of Good Clinical Practice in Clinical Trials) and associated ethical issues; and to follow all Trust policies and procedures and also make changes to policy within their own area of work	**Application/Interview**
Be familiar with and work to audit, project and clinical trial protocols	**Application/Interview**
Assist Doctors and Registered Nurses in the delivery of direct patient care and management by carrying out assigned tasks including documentation as appropriate	**Application/Interview**
Communication (Oral) Can demonstrate the ability to exchange basic information promptly and in a courteous and effective manner to students, colleagues, line managers and external contacts.	**Application/Interview**
Communication (Written) Can demonstrate the ability to provide information in a suitable format so that the others' needs are met and adjusts the level of content to help others understand.	**Application/Test**
Teamwork and Motivation Can demonstrate the ability to work effectively as part of a team. Is willing to provide cover for colleagues and acts in a supportive manner.	**Application/Interview**
Liaison and Networking Can demonstrate the ability to work with others outside the immediate area to ensure that accurate information is passed on promptly to the most appropriate people to improve working practices.	**Application/Interview**
Service Delivery Has knowledge and understanding of services available to users of this and related areas of work and ensures that the experience of each customer is positive and satisfactory.	**Application/Interview**

Planning and Organisation Can demonstrate the ability to create realistic plans to achieve own deadlines and objectives. Monitors progress of self and/or others and can prioritise tasks/activities effectively. Suggests ways of improving working practices and use of resources.	**Application/Interview**
Initiative and Problem Solving Can demonstrate the ability to solve standard, predictable problems in accordance with procedures and precedent.	**Application/Interview**