UPMC Beacon Hospital

Job Description

Job Title	**RN - Clinical Research**
Department	**Radiotherapy**
Reports to	**Clinical Research Coordinator**
Date	**February 2013**

Overall Purpose of Job

To assist in the coordination and facilitation of clinical research projects with UPMC Beacon Hospital. This position includes patient care/assessment, ensuring compliance with; the research protocols, relevant hospital policies, regulatory/legislative/data protection requirements whilst demonstrating our mission to provide exceptional patient care in an environment where quality, respect, caring and compassion are at the centre of all we do.

Key Responsibilities and Deliverables

Protocol Co-ordination and Development

- To collaborate in the development of clinical research programmes in the Hospital.
- Establish relationship with team members and Hospital disciplines and other research institutions involved in Clinical Research.
- To collaborate with external agencies attending research meetings where necessary
- To ensure compliance with ethical and regulatory requirements for each protocol.
- Maintenance of essential documents, site files and research records.
- Assist with co-ordination of study start up, documentation development, initiation, research operations, and study close-out
- Ensure that all serious adverse events (SAE) are documented and reported to the relevant authorities.
- Assist in preparation of reports of serious adverse events as required by the protocol, sponsor, Ethics Committee, Irish Medicine Board (IMB) according to hospital protocol and sponsor/regulatory requirements.
- Assist in the collection of data and specimens where appropriate.
- Assist with monitoring visits, audits and inspections both internal and external.

Patient Management

- Educate patients and their families on study participation.
- Keep patients informed of procedures and changes in studies in which they are participating.

- Assist in the informed consent process and ensure adherence to policies and standard operating procedures to ensure the protection of patient's rights, interests and well being through efforts to comply with national and institutional guidelines.
- Scheduling of patients and tests in accordance with protocol requirements and department standard operating procedures. Follow-up to ensure that all required tests, procedures or treatments were completed as ordered.
- Perform and document study related procedures/treatments within their scope of practice and in accordance with research protocol and hospital policy.
- Monitor through various forms of communication (phone, patient diary, and visits), patients for side effects of treatment.
- Assist in screening/determining patient eligibility for clinical research studies.
- Ensure that all baseline tests required by protocol are performed within specified timeframe and all eligibility requirements are met.
- Assisting and arranging ongoing follow up of participants in trials.
- Ensure that protocol deviations are documented.

Data Management

- Ensure all study-related data is collected and recorded in the patient note thereby accurately maintaining the source documents.
- Complete or assist with completion of outstanding queries and case report forms as needed.
- Review records with all site visit teams, Irish Medicine Board or other agents designated by sponsors (especially as related to appropriate consent, proper record keeping and quality assurance) when requested.
- Perform consistency checks; edit for errors and monitor timeliness of data submission.
- Evaluate completed protocol study forms for completeness, accuracy and compliance to protocol in accordance to Good Clinical Practice and department standard operating procedures.
- Verify that all data are transferred from original source documents accurately.
- Ensure compliance with the obligations required by the Data Protection Act.

Training and Education

- Participate in continuing education activities to improve knowledge for job performance, including GCP training, sponsor training, protocol training and any other required training.
- Instruct other healthcare professionals in clinical research procedures and assist with protocol training.
- Educate appropriate personnel on study-related matters.
- Alert investigators and appropriate personnel of communications regarding adverse drug reaction update reports received from the sponsor for the duration of the study.

General

- This is a new position and the job description will be subject change as the role and Clinical Trials develop.
- The extent and speed of change in the delivery of health care is such that adaptability is essential at this level of management. The incumbent will be required to maintain, enhance and develop their professional knowledge, skills and aptitudes necessary to respond to a changing situation. The Job Description must be regarded as an outline of the major areas of accountability at the present time, which will be reviewed and assessed on an on-going basis.

Person Specification

Qualifications	▪ Current (and in good standing) licence to practice as an RN by An Bord Altranais (ABA). ▪ Preferably post graduate qualification. ▪ Have good communication and interpersonal skills.
Experience	▪ Have not less than 1 year's experience in Clinical Trials. ▪ Excel and database skills.
Job Specific Competencies and Knowledge	▪ Good organisational and time management skills ▪ Ability to work independently and initiatively ▪ Must have excellent attention to detail µ ▪ Data analysis skills.
Personal Competencies	▪ All posts in UPMC Beacon Hospital require a high level of flexibility to ensure the delivery of an effective and efficient service. Therefore, the post holder will be required to demonstrate flexibility as and when required by their manager or hospital management.

This job description is intended to be an outline of the areas of responsibility and deliverables at the time of its writing. As the Hospital and the post holder develop, this job description may be subject to review in light of the changing needs of the Hospital.

Job Description received by employee: _____ _____
Signature Date