CAJE REF 2020/0044 / QA477

APPROVED 05/01/2023

JOB TITLE Research Nurse/Practitioner/ Early Phase Team Lead
Band 7

JOB OVERVIEW

1. Provide nurse research management oversite at 2 research delivery sites, Velindre University NHS Trust (VUNHST) and Cardiff & Vale University Health Board (CVUHB)
2. Provide high level clinical oversight and management of the trials within the Multidisciplinary Team
3. Provide clinical supervision, advice and develop the nursing research team.

Main Duties of the Job		
• Clinically steer service to meet clinical and research objectives safely and line with professional NMC standards as part of a multi professional team. • Develop and supervise a portfolio of site specific cancer clinical trials, including taking on the role, when relevant, of Principle Investigator. • Provide an early phase nursing and clinical management focus.		
Responsible to		
Reporting: Senior Research Nurse Manager	**Accountable:** VCC Research Delivery Manager Head of R&D	**Professionally:** VCC Senior Nurse/Appropriate Senior Professional
Main Responsibilities		
Communication and Relationship Skills Communicate competently complex information about specific clinical trials and their consequences, to patients and carers ensuring they have a good understanding of treatment options, thereby ensuring high standards of informed consent. To act as the key worker for patients in your direct care for the duration of active involvement in a clinical trial, ensuring that all patients, carers and appropriate community colleagues are well informed about their disease and its management, providing appropriate and timely information. Work in partnership with clinical investigators with all aspects of a clinical trial, including: trial set up, trial documentation, data collection, administration and patient recruitment and treatment coordination. Actively participate in multi professional meetings acting as a patient advocate and representing the nursing view with expert knowledge of clinical trials available in specific disease site portfolio. To communicate service related reports, information and changes in trials activity directly to MDT and SST To provide support, coaching and advice promoting motivation and reassurance to the research team		

To communicate and co-ordinate with appropriate organisations and personnel about clinical trials as required.
Liaise closely and collaborate with other trials offices in Wales, UK and worldwide trials organisations and appropriate local multidisciplinary teams.

Knowledge, Training and Experience
Registered general nurse / practitioner with evidence of highly developed knowledge in oncology and clinical research to include well developed leadership and managerial skills.
Educated to Masters level or equivalent experience or qualification.
Takes personal responsibility for lifelong learning and personal development through clinical supervision, appraisal and knowledge and skills framework, actively engaging with learning and development opportunities in response to emerging knowledge and techniques.
Demonstrates continuous evaluation of practice and makes changes where appropriate whilst maintaining a unified way of working within the team.
Demonstrates high level of clinical, technical and research skills through their depth and breadth of knowledge.
Adhere to EU legislation – Good Clinical Practice (GCP) on a day to day basis.
Adhere to Research Governance Framework on a day to day basis
Assist in preparation of research reports/audits for local and national meetings and regional management meetings.
Knowledge of Clinical Trial and Research, development and innovation specific databases.
Specific knowledge around early phase and complex clinical trials.
Developed clinical assessment skills, history taking and decision making.
Teaching and presentation skills.
Administer medicines as prescribed with the adherence to Guidelines For Medicine Administration (NMC, 2002) and Velindre Cancer Centre Medicines Management Policy.

Service Management
Work autonomously to manage a large caseload of patients acting as a professional nurse in ensuring a duty of care to the patient and their families.

To be able to provide an expert opinion on the creation and coordination of the disease specific portfolio in collaboration with the MDT.
Judgements on information giving for conflicting studies.
Assessing the feasibility of running a trial in VUNHST and CVUHB.
Patient screening, assessing eligibility, for study entry.
To be able to provide an expert opinion as a patient advocate.
Support the administration of trial drugs.
Clinically assess patients current and medical condition and advise and act accordingly to ensure safe outcomes.
Use of ECG's Blood pressure machines and other equipment required to monitor the patient.

Escalate and record adverse events and suspected unexpected serious adverse events that occur whilst the patient is on study in line with the study protocol and local policies and regulatory requirements.
Ability to prioritise, organise, meet deadlines and make clinical decisions independently ensuring maximum benefit of care is delivered.
To plan and organise treatments, tests and investigations in clinic to ensure that the effectiveness and safety of each patient's treatment can be appropriately managed.
Planning the delivery and content of nurse education programmes in both the formal and informal setting.
Clinical Trial Management- working towards achievement of national KPIs.

Oversee research submissions and amendments as appropriate, Research and Development offices, and other required approvals, as per Good Clinical Practice (GCP) and in accordance with Research Governance and other regulatory requirements.
To develop cancer clinical trials activity in VUNHST and CVUHB.
To supervise, advise and develop the nursing team.
Planning for the impact that a new clinical trial will have on various departmentsin VUNHST and CVUHB.
Attend and represent, Velindre RD&I and/or consultant at appropriate UK and regional meetings.
Review trial protocols and identify risk and resource implications for the site.
Planning the running and co-ordination of new trials in VUNHST and CVUHB as required.
Co-ordinating as part of the management team, the preparation for the audit, monitoring and regulatory inspections of work, by outside research organisations.
Supervise development and implementation of all protocol specific clinical documents adhering to the single way of working process.

Service Improvement
Participate in service reviews in order to instigate and manage change and service improvement within a complex department.
Influence and develop policy and clinical guidelines internally and externally.
Lead on the contribution to the early phase service development, ensuring pursuit of excellence in care for trials patients.
Ability to influence and motivate staff to change practice to fit needs.
Ability to develop nurse led initiatives and evaluate and develop service accordingly.
Adhere to Clinical Trial Unit Standard Operational Procedures (SOP) and Trust policies without supervision
Responsible for allocated SOP update and subsequent training of staff in line with local, national and legislative changes.
Maintain and implement standard operating procedures in your specialist area.
Regularly review policy and procedures relating to the running of clinical trials.

Finance/Resources
Work with the R&D Delivery Manager, and RD& I finance Manager in assessing the financial impact to the Trust and CVUHB of commercial and non-commercial trials.
Financial Initiative – Deal with financial negotiations and contractual agreements with pharmaceutical companies when setting up a clinical trial.
Identify and discuss with individual departments the physical resource implications.
Responsible for reporting defective equipment to relevant department.
Observe personal duty of care when using equipment.
A delegated signatory for CTU budget.

Personal and People Development and People Management
Mentor new research staff and provide training in own discipline and that of other Clinical Trials Unit posts of Band 6 and below as required.
Managing and supervising an early phase team. Implementing annual PADRs
Participate in clinical supervision as both supervisor and supervisee in accordance with the NMC guidelines, and create a climate of psychological safety and active reporting, learning and improvement.
Educate appropriate medical and nursing personnel and departments of portfolio of clinical trials.
Assist in the recruitment and selection of the research staff.
Manage and ensure adherence to trust policies throughout the team.
Maintains a standard of conduct and dress to sustain public confidence in accordance with professional codes of conduct and trust policies.
Abide by uniform policy as set by the VUNHST and CVUHB and localised to research department

Quality
Ensure continued effective registration with the NMC and be aware of NMC Code of Professional Conduct. They must be accountable for their own practice.
Work within the NMC Scope of Professional Practice and ensure competency to undertake duties as allocated.
To be responsible for initiating and coordinating a range of UK, European and World Wide cancer trials for VUNHST and CVUHB as required, in collaboration with the relevant multi-disciplinary research teams.
To contribute in implementing strategies and systems for quality assurance.
To develop a portfolio of cancer clinical trials within VUNHST and CVUHB.
Ensure that Welsh Government national research KPI`s are the focus to prove quality.
Recruit and have continuing responsibility for a patient case load for a large portfolio of cancer clinical trials.
To supervise, advise and develop a team and maintain clinical and research standards for that team.
Be responsible for the collection of complex and accurate data by all team members.
Implement, maintain and review Standard Operational Procedures.
Provide psychological support and ongoing information to the patient and their carer regarding all aspects of their disease and trial information throughout their trial participation.
Responsible for educating Health Care professionals regarding the discipline of Research and Development.
Promote the service and clinical excellence by publishing and presenting innovations audit and research locally and nationally.
Manage a Research Nurse team, refer to Senior Research Nurse manager if an issue occurs that affects the unit as a whole.
Participate as a member of the Operational, Management and Leadership team for the RD&I division.
Ensure team meet responsibilities in respect of Duty of Quality & Duty of Candour.
Ensure all Putting Things Right regulatory requirements are met.

Responsibility for Research and Development
To ensure that as an individual and as a team lead a quality service is delivered maintaining safety of the patient, and working to WG national research KPI`s.
To be responsible for initiating and coordinating a range of UK, European and World Wide cancer trials forVUNHST and CVUHB, in collaboration with the relevant multi-disciplinary research teams.
Recruit and have continuing responsibility for a patient case load for a large portfolio of cancer clinical trials.
Promote clinical trials and create an awareness of Velindre Clinical Trials Unit and Wales Cancer Research Network and the wider Research agenda of VUNHST and CVUHB
To supervise, advise and develop a research nurse team and maintain clinical and research standards for that team.
Be responsible for the collection of complex and accurate data by all team members.
Implementing, maintaining and reviewing Standard Operational Procedures.

Clinical Skills
Request trial related radiological procedures
Clinical assessment of patient.
Use of ECG’s Blood pressure machines and other equipment required to monitor the patient.
Knowledge of trial SACT.
Facilitates, as key worker for clinical workload, whilst patient is receiving active treatment within clinical trials.
Working to co-ordinate nursing care, provision of access for ongoing support for patient and succession planning of care post clinical trial participation.

Establish and participate in MDT clinics to facilitate the coordination of patient care and discuss clinical trial opportunities with MDT as necessary.
To provide information and support to cancer patients and carers on considering entry into a clinical trial and an ongoing basis.
Assess patients' suitability for entry into specific research studies.
Be responsible for the coordination of all clinical trial procedures of patients within the strict protocol requirements eg. Blood tests, ECG's, drug treatment.
Assessing clinical care needs of patients in a clinical trial and relaying pertinent information to the patient's consultants.
Work in close liaison with other research nurses and specialist nurses and promote team working.
Provision of effective clinical Advice and education for patients and carers with respect to their disease process, management of side effects and support services available to them.

Qualifications and Knowledge	Experience
Essential 1st level registered nurse or professional health care equivalent. Masters degree or equivalent experience or qualification. Evidence of continued professional development Working knowledge of G.C.P and its application in the NHS research environment, **Desirable** (for use in shortlisting) Clinical Research Qualification. Teaching qualification E.C.D.L	**Essential** Experience as a specialist nurse. Experience of caring for patients within the research setting. **Desirable** (for use in shortlisting) Experience of caring for patients in the Cancer setting Phase 1 trial experience. Clinical skills in delivering novel early phase therapies.
Skills and Attributes	**Other**
Essential Ability to work on own initiative Excellent communication skills Computing skills Good patient advocate Teaching and presentation skills Counselling skills Knowledge of the research process and regulatory requirements – G.C.P and research governance. Knowledge of MS Office application and E-mail Ability to work autonomously and as part of a Team Enthusiastic and motivated Attention to detail	**Essential** Ability to travel, in the course of duties Flexible approach to working hours according to service needs **Desirable (but not essential):** Welsh Speaker (Level 1) or willingness to work towards