CAJE REF 2020/0133
QA 444

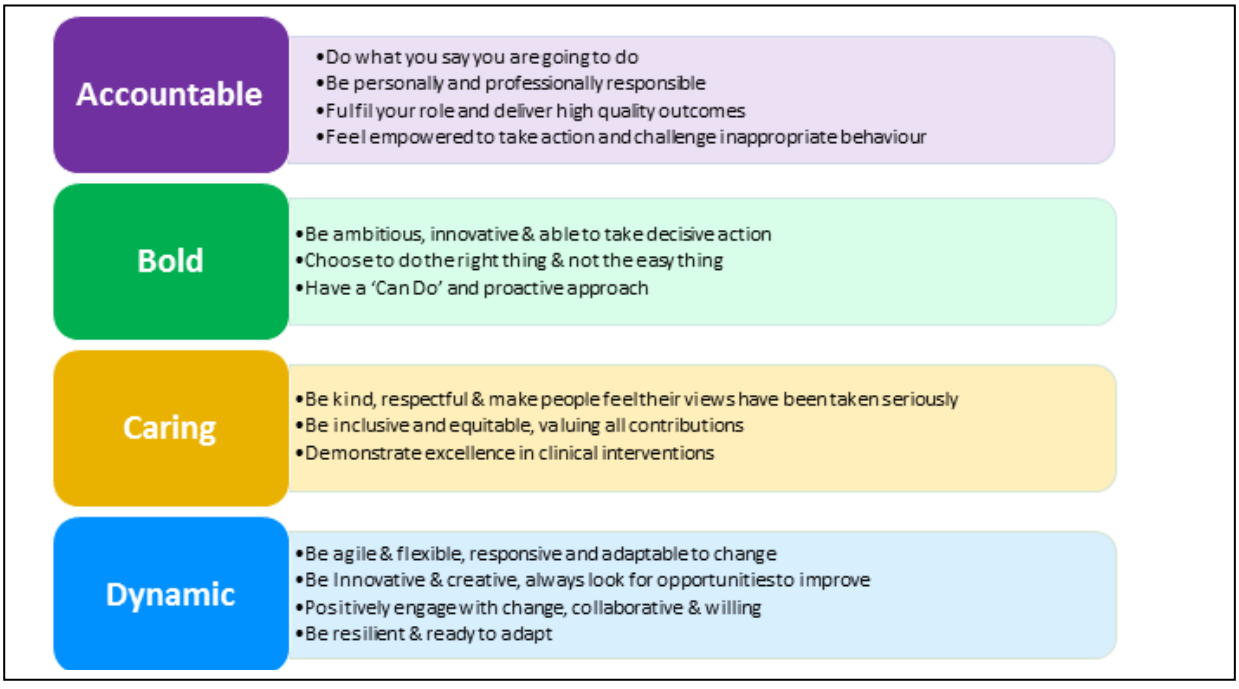
VELINDRE JOB DESCRIPTION TEMPLATE

JOB DETAILS:

Job Title	Early Phase Oncology Research Nurse
Pay Band	6
Hours of Work and Nature of Contract	To be completed on recruitment
Division/Directorate	Cancer Services
Department	Clinical Trials Department
Base	To be completed on recruitment

ORGANISATIONAL ARRANGEMENTS:

Managerially Accountable to:	Clinical Trials Unit Manager/SE Wales Network Manger
Reports to: Name Line Manager	Clinical Trial Unit Manager/Team Lead
Professionally Responsible to:	Director of Nursing and Quality Velindre NHS Trust



Job Summary/Job Purpose:

To assist the Early Phase Trial Team in entering patients into trials and subsequent co-ordination and administration of treatment at 2 research delivery sites, Velindre University NHS Trust (VUNHST) and Cardiff & Vale University Health Board (CVUHB).

To co-ordinate a portfolio of early phase trials under the supervision of Early Phase Team Lead

Deputise for Band 7 Team Lead in their absence

DUTIES/RESPONSIBILITIES:

Communication

To provide information and support to cancer patients considering entry into an early phase clinical trial.
Describe and explain complex trials information in both written and oral forms to both patients and their carers.
Describe and explain complex information to medical staff, health professionals and allied health professionals.
Negotiating the logistics of conducting a clinical trial with other departments, including across 2 research sites, under the supervision of team lead.
Diplomacy when dealing with pharmaceutical companies over the use of their resources when discussing new trial feasibility.
Give formal and informal presentation to patients, carers, health professionals and research organisations, raising awareness of clinical trials.
To communicate with other trials offices and outside organisations locally nationally and worldwide trials.

Clinical Skills

1st level registered nurse or healthcare equivalent.
Numerate and literate.
Health professional with experience at Band 5 in oncology and research.
Excellent knowledge of cancer terminology acquired through experience.
Adhere to EU legislation – Good Clinical Practice (GCP) on a day to day basis.
Adhere to research governance on a day to day basis.
Evidence of post basic education.
Computing skills, knowledge of MS Office application and E-mail.
Venepuncture and cannulation skills.
Emergency treatment skills including treatment of anaphylaxis and other medical emergencies or willingness to gain these skills.
Judgement on information giving for conflicting studies.
Screen patients to assess eligibility for study entry.
Help to assess feasibility of conducting complicated trials.
Able to receive, handle, analyse and resolve data queries promptly.
Ability to work on own initiative.
Use of ECG's, B.P. machines and other equipment and to monitor patients, including invasive monitoring.
Able to provide expert opinion as patient advocate.
Administration of novel therapy trial drugs.
Ability to recognise potential adverse events.

Service Management
Co-ordinating visits for audit and monitoring of work by outside research organisations and auditors.
Knowledge of how to submit studies and amendments for required approvals in accordance with GCP, Research Governance and other regulatory requirements.
Prioritise work load when frequently interrupted.
Day to day organising within the department.
Arrange meetings to initiate new studies.
Planning, approaching and discussions with patients/ carers.
Liaise with trial monitors from research organisations to assist with monitoring functions.
Ability to be flexible and provide cover for other team members as required, including cross site cover at VUNHST and CVUHB.
Planning for the impact that a new clinical trial will have on various departments in VUNHST and CVUHB.
Planning the delivery and content, with Band 7 support, of educational programmes.
The ability to assess protocols for resource issues at both VUNHST and CVUHB.
Perform registration of patient to clinical trial. Ensure accurate documentation maintained in patient records.
Liaise with research assistant and in his absence process samples in PK/PD laboratory, using techniques for serum, plasma and peripheral blood lymphocyte isolation.
Prepare all samples for storage or shipping and ensure appropriate risk assessment, compliance with COSHH guidelines and safe maintenance of appropriate laboratory equipment, supplies and specimens.

Effort and Environmental (physical, mental emotional and work conditions)
Use of ECG's and other patient monitoring equipment.
Use of computers daily and for extended periods
Administration of trial drugs

Quality
Advice and education given to patients and carers with respect to their disease process, management of side effects and support services available to them.
Ensure case notes are tracked on entry and leaving the unit.
Involvement in the provision of clinical advice to patients and carers.
Responsible for coordination of all clinical trial procedures of patients.
Assess patient suitability for entry into research studies.
Assess clinical care needs of patients relaying pertinent information to Consultants.
Work in close liaison with other research nurses across 2 research sites to promote team work.
Administer diaries and quality of life questionnaires to patients, provide instruction and subsequent collection.
Play a key role in informed consent process including:
Provision of the current approved Patient Information sheet.
Explanation of study procedures, treatment and research terminology, in lay terms where possible.
Explanation of the risks and benefits associated with participation in the clinical trial, including the treatment, procedures, time and any inconveniences involved.
Involvement of the patient's family/carers as appropriate.
Explanation of the patients' rights in a research setting.
Providing contact information to allow patients to ask questions and discuss options.
Assessing patient understanding and capability to consent. Liaise with investigator and at all times act as patient advocate.
Supporting patients through news of their condition and treatment side-effects.

Provide first line of contact for patients and relatives with concerns or questions when at home. Acts as an on-going primary contact and resource throughout the duration of study intervention and follow-up. Provide support, information and easy contact through bleep, phone and regular communication. Provide referral as appropriate, liaising with primary care and other settings as required.
Co-ordination and drug administration, as appropriate, of early phase therapies including therapy not previously administered to humans.
Maximise patient safety through facilitating protocol compliance, monitoring of Adverse Events and Serious Adverse Events, timely reporting to Principal Investigator and study sponsor as appropriate.
Assist in clinical tests where these are protocol specific.
Advice and education given to patients and carers with respect to their disease process, management of side effects and support services available to them.
Care for the acutely unwell patient, in the event of a serious adverse event requiring escalation of care to HDU/ ITU.

Service Improvement
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.
Adhere to policy and procedures of any Local Health Board's in South East Wales where an honorary contract may be held.

Finance and Resources
Under Team Lead supervision assess the cost implication of a study and be able to commence financial negotiations and contractual agreements with pharmaceutical companies.
Assessing the cost implications of commercial and non-commercial early phase studies under the supervision of Team Lead.
Identify with Team Lead supervision, the physical resource implications within the departments that a trial impacts upon.

Information Processing
Responsible for completion, maintenance and storage of hard copies and electronic CRF's containing all clinical trial data in accordance with GCP legislation.

Responsibility for Research and Development
Assist team lead to initiating and coordinating a range of UK, European and World Wide early phase cancer trials for Velindre Cancer Centre, in collaboration with the relevant multi-disciplinary research teams.
Responsible for co-ordinating and implementing research protocols.
Assist and supervise in the preparation of submissions to appropriate committees, research and development and other bodies for approval, working in partnership with the Team Lead and trial administrator.
Promote clinical trials and create an awareness of Velindre Clinical Trials Unit and Wales Cancer Research Network amongst the NHS, and promote awareness of S E Wales early phase portfolio and activity.
Responsible for collection of complex accurate data.

PERSON SPECIFICATION

ATTRIBUTES	ESSENTIAL	DESIRABLE	METHOD OF ASSESSMENT
Qualifications and/or Knowledge	1st Level Registered Nurse with evidence of continued professional development. Post basic qualification in cancer care/ research or willingness to work towards Graduate or willingness to work towards Knowledge of the research process and regulatory requirements e.g. ICH-GCP	Clinical Research Qualification Teaching qualification ECDL	Application Form Certificate / Registration Check
Experience	Experience at Band 5, with experience in Oncology Previous clinical trial experience	Phase I/II trial experience ITU / HDU experience	Application Form Interview References
Aptitude and Abilities	Venepuncture/cannulation skills Ability to work on own initiative Organisational skills Excellent communication skills Good patient advocate IT Skills – able to use WORD, Internet and Email	Counselling skills Teaching and Presentation skills Chemotherapy administration.	Application Form Interview References
Values	Motivated Able to work flexibly Works well as part of a team but also able to work independently as required Enthusiastic Good attention to detail Reliable Supportive	Diplomatic Proven attendance record	Application Form Interview References
Other		Welsh Language – Level 0	

GENERAL REQUIREMENTS

Include those relevant to the post requirements

- **Values:** All employees of the Trust are required to demonstrate and embed the Values and Behaviour Statements in order for them to become an integral part of the post holder's working life and to embed the principles into the culture of the organisation.

- **Registered Health Professional:** All employees who are required to register with a professional body, to enable them to practice within their profession, are required to comply with their code of conduct and requirements of their professional registration.

- **Healthcare Support Workers:** Healthcare Support Workers make a valuable and important contribution to the delivery of high quality healthcare. The national Code of Conduct for NHS Wales describes the standards of conduct, behaviour and attitude required of all Healthcare Support Workers employed within NHS Wales. Health Care Support Workers are responsible, and have a duty of care, to ensure their conduct does not fall below the standards detailed in the Code and that no act or omission on their part harms the safety and wellbeing of service users and the public, whilst in their care.

- **Competence:** At no time should the post holder work outside their defined level of competence. If there are concerns regarding this, the post holder should immediately discuss them with their Manager/Supervisor. Employees have a responsibility to inform their Manager/Supervisor if they doubt their own competence to perform a duty.

- **Learning and Development:** All staff must undertake induction/orientation programmes at Corporate and Departmental level and must ensure that any statutory/mandatory training requirements are current and up to date. Where considered appropriate, staff are required to demonstrate evidence of continuing professional development.

- **Performance Appraisal:** We are committed to developing our staff and you are responsible for participating in an Annual Performance Development Review of the post.

- **Health & Safety:** All employees of the organisation have a statutory duty of care for their own personal safety and that of others who may be affected by their acts or omissions. The post holder is required to co-operate with management to enable the organisation to meet its own legal duties and to report any hazardous situations or defective equipment. The post holder must adhere to the organisation's Risk Management, Health and Safety and associate policies.

- **Risk Management:** It is a standard element of the role and responsibility of all staff of the organisation that they fulfil a proactive role towards the management of risk in all of their actions. This entails the risk assessment of all situations, the taking of appropriate actions and reporting of all incidents, near misses and hazards.

- **Welsh Language:** All employees must perform their duties in strict compliance with the requirements of their organization's Welsh Language Scheme and take every opportunity to promote the Welsh language in their dealings with the public.

- **Information Governance:** The post holder must at all times be aware of the importance of maintaining confidentiality and security of information gained during the course of their duties. This will in many cases include access to personal information relating to service users.

- **Data Protection Act 1998:** The post holder must treat all information, whether corporate, staff or patient information, in a discreet and confidential manner in accordance with the provisions of the Data Protection Act 1998 and Organisational Policy. Any breach of such confidentiality is considered a serious disciplinary

offence, which is liable to dismissal and / or prosecution under current statutory legislation (Data Protection Act) and the HB Disciplinary Policy.

- **Records Management:** As an employee of this organisation, the post holder is legally responsible for all records that they gather, create or use as part of their work within the organisation (including patient health, staff health or injury, financial, personal and administrative), whether paper based or on computer. All such records are considered public records and the post holder has a legal duty of confidence to service users (even after an employee has left the organisation). The post holder should consult their manager if they have any doubt as to the correct management of records with which they work.

- **Equality and Human Rights:** The Public Sector Equality Duty in Wales places a positive duty on the HB to promote equality for people with protected characteristics, both as an employer and as a provider of public services. There are nine protected characteristics: age; disability; gender reassignment; marriage and civil partnership; pregnancy and maternity; race; religion or belief; sex and sexual orientation. The HB is committed to ensuring that no job applicant or employee receives less favour-able treatment of any of the above grounds. To this end, the organisation has an Equality Policy and it is for each employee to contribute to its success.

- **Dignity at Work:** The organisation condemns all forms of bullying and harassment and is actively seeking to promote a workplace where employees are treated fairly and with dignity and respect. All staff are requested to report and form of bullying and harassment to their Line Manager or to any Director of the organisation. Any inappropriate behaviour inside the workplace will not be tolerated and will be treated as a serious matter under the HB/Trust Disciplinary Policy.

- **DBS Disclosure Check:** In this role you will have direct contact with patients /service users/ children/vulnerable adults in the course of your normal duties. You will therefore be required to apply for a Disclosure Barring Scheme Enhance Disclosure Check as part of the HB/Trust's pre-employment check procedure.

- **Safeguarding Children and Adults at Risk:** The organisation is committed to safeguarding children and adults at risk. All staff must therefore attend Safeguarding Children & Adult training and be aware of their responsibilities under the All Wales Procedures.

- **Infection Control:** The organisation is committed to meet its obligations to minimise infections.
  All staff are responsible for protecting and safeguarding patients, service users, visitors and employees against the risk of acquiring healthcare associated infections. This responsibility includes being aware of the content of and consistently observing Health Board Infection Prevention & Control Policies and Procedures.

- **No Smoking:** To give all patients, visitors and staff the best chance to be healthy, all Health Board sites, including buildings and grounds, are smoke free.

- **Flexibility Statement:** The duties of the post are outlined in this Job Description and Person Specification and may be changed by mutual agreement from time to time.

Job Title: B6 Early Phase Research Nurse

Organisational Chart

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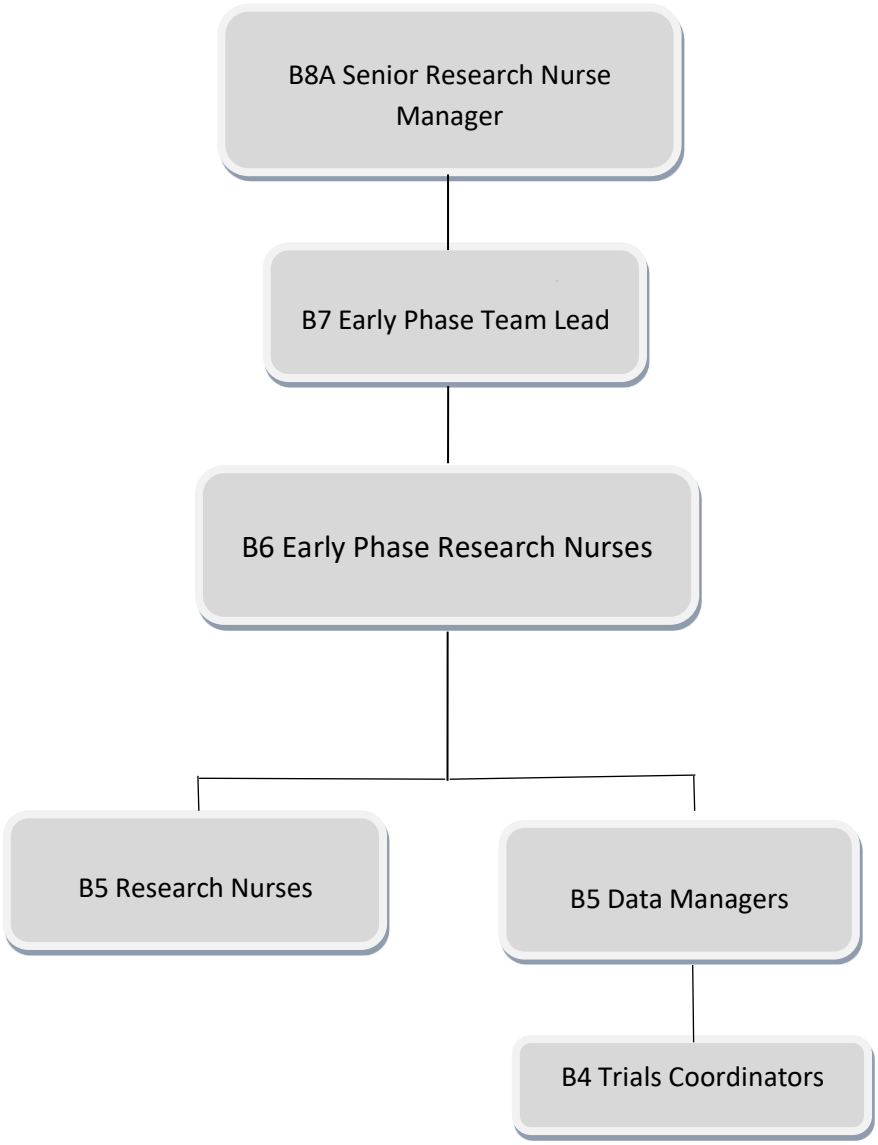

Job Title: B6 Early Phase Research Nurse

Supplementary Job Description Information

Please complete information on Physical Effort, Mental Effort, Emotional Effort and Working Conditions in order to assist the Job Matching process.

Physical Effort

This factor measures the nature, frequency and duration of physical effort (sustained effort at a similar level or sudden explosive effort) required for the job. Please ensure any circumstances that may affect the degree of effort required, such as working in an awkward position; lifting heavy weights etc. are detailed, for example, 'Working in uncomfortable/unpleasant physical conditions; sitting in restricted positions; repetitive movements; lifting heavy weights; manipulating objects; kneeling, crouching, twisting; heavy duty cleaning; working at heights; using controlled restraint; driving as part of daily job - **N.B. Walking /driving to work is not included'**

Examples of Typical effort(s)	How often per day / week /	For how long?	Additional Comments
Long periods sitting using VDU	Daily	As required	
Lifting of Bulky case report forms and trial site files	Daily	As required	
Assisting patients can involve physical effort	Daily	As required	
Travel to other hospitals in South Wales	If required		

Mental Effort

This factor measures the nature, level, frequency and duration of mental effort required for the job, for example, concentration, responding to unpredictable work patterns, interruptions and the need to meet deadlines. Please identify the normal requirement to concentrate in the post and determine, how often and for how long it is required to concentrate during a shift / working day. For example. 'Carrying out formal student assessments; carrying out clinical/social care interventions; checking documents; taking detailed minutes at meetings; operating machinery/equipment; carrying out screening tests/microscope work; carrying out complex calculations; carrying out non-clinical fault finding; responding to emergency bleep; driving a vehicle; examining or assessing patients/clients.

Examples of Typical effort(s)	How often per day / week / month?	For how long?	Additional Comments
The work entails concentration with frequent unpredictable interruptions	Daily	As required	
Transcribe complex data from the case notes into case report forms	Daily	As required	
Resolve data queries for portfolio of studies.	As requested		
Finance calculations to assess the cost of running a study	As required		

Emotional Effort

This factor measures the nature, frequency and duration demands of the emotional effort required to undertake clinical or non clinical duties that are generally considered to be distressing and/or emotionally demanding. Please identify how often the post holder has exposure to direct and/or indirect distressing and/or emotional circumstances and the type of situations they are required to deal with. For example,' processing (e.g. typing/transmitting) news of highly distressing events; giving unwelcome news to patients/clients/carers/staff; caring for the terminally ill; dealing with difficult situations/circumstances; designated to provide emotional support to front line staff; communicating life changing events; dealing with people with challenging behaviour; arriving at the scene of an accident.' **N.B. Fear of Violence is measured under Working Conditions**

Examples of Typical effort(s)	How often per week / month?	For how long?	Additional Comments
Breaking distressing news to patients and relatives including progression of disease.	As required		
Informing patient of treatment cessation due to disease progression /intolerable toxicities	As required		
Supporting patients and relatives through the emotions of a cancer diagnosis.	As required		

Working Conditions

This factor measures the nature, frequency and duration of demands on staff arising from inevitably adverse environmental conditions (such as inclement weather, extreme heat/cold, smells, noise and fumes) and hazards, which are unavoidable **(even with the strictest health and safety controls),** such as road traffic accidents, spills of harmful chemicals, aggressive behaviour of patients, clients, relatives, carers. Please identify unpleasant working conditions or hazards which are encountered in the post holder's working environment and establish how often and for how long they are exposed to them during a working day / week / month. Examples are – use of VDU more or less continuously; unpleasant substances/non-household waste; infectious material/foul linen; body fluids, faeces, vomit; dust/dirt; fleas/lice; humidity; contaminated equipment or work areas; driving/being driven in normal or emergency situations - ***Driving to and from work is not included**

Examples of Typical Conditions	How often per week / month?	For how long?	Additional Comments
Frequent use of VDU	Daily	Long periods	
Occasional use of transport for work purposes	When required		
Occasionally distressed relatives and patients can lead to verbal aggression	Rarely		
Shift work and out of hours working as and when service requires	When required		