CAJE REF:	**CYM/2019/0006**
Approved:	**12/09/2019**

Job Description

JOB DETAILS:

Job Title	Senior Clinical Research Officer
Pay Band	Band 6
Hours of Work and Nature of Contract	To be completed on recruitment
Division/Directorate	
Department	Research and Development - Research Delivery
Base	To be completed on recruitment

ORGANISATIONAL ARRANGEMENTS:

Managerially Accountable to:	Research Delivery Manager
Reports to: Name Line Manager	Senior Research Nurse/Team Lead
Professionally Responsible to:	Head of Research Delivery

Background

Health and Care Research Wales is a research infrastructure funded by the Division of Research & Development, Welsh Government. The overarching vision of Health and Care Research Wales is to be internationally recognised for its excellent health and social care research that has a positive impact on the health, well being and prosperity of the people in Wales. A Support and Delivery infrastructure was established in 2015 in order to achieve maximum efficiency and effectiveness and international competiveness in the research environment within Wales. This included a Support Centre to provide centralised functions and services at a National level and local R&D functions via NHS R&D Departments at each organisation. The Health and Care Research Wales Support and Delivery mission is to facilitate health and social care research that will improve the health and well-being of people in Wales by providing and effective and efficient joined up centralised and local service.

The NHS R&D Departments led by a R&D Director provide local services for research support and facilitates the sponsoring and hosting of studies within in each UHB. Part of this service includes a NHS research delivery team consisting of Research Nurses, Research Officers and Administrators, employed by NHS organisations to support the delivery of high quality health and social care studies. The Senior Research Officer will be a part of these NHS research delivery teams.

Job Purpose

- The purpose of this post is to increase the number of patients participating in clinical trials across UHBs.
- The post will contribute to the assessment and management of the care pathways for patients and carers participating in clinical trials. This will include the recruitment, education, monitoring of trial patients, the collection and documentation of accurate data.
- The post holder will be working with Lead Nurses and multidisciplinary teams within the Clinical Boards and Directorates as well as the wider research teams assisting with the management of a caseload of clinical trials patients.
- The post will assess and carry out clinical procedures for patients/participants and will be considered part of the clinical team during the participants' involvement with the study. Implementing a programme of care, providing advice and will maintain records within various settings.
- The post holder will have a specialist knowledge in research and/or clinical practice enabling the post holder to work independently e.g either previous experience as a clinical research nurse or specialist knowledge within a specific disease area meeting the service needs such as diabetes/mental health.
- As part of the Research and Development team the post holder will contribute to the efficient set up and delivery of research within the UHB contributing to the performance metrics set for the UHB.

DUTIES/RESPONSIBILITIES:

Clinical and Professional Responsibilities

- Working autonomously to assist in the management of a caseload of clinical trial patients, whilst working as part of a multi-disciplinary team. Maintain effective communication with patients, carers and professionals to ensure high quality service delivery.
- Manage and oversee a portfolio of research studies in various disease sites.
- Training and assessing research staff as competent in line with the research competencies framework.
- Identifying suitable patients for entry into clinical trials by attending clinics (screening notes) and relevant Multi-disciplinary Team meetings. Use relevant clinical knowledge to identify patients suitable for clinical research using inclusion and exclusion criteria and utilising NHS records, visiting wards and outpatients.
- Act as a resource and role model for all aspects of research clinical practice in order to optimise patient care and clinical practice.
- Carry out physical assessments, taking blood/urine samples and processing according to protocol.
- Ensure the environment is suitable for patient care and research processes, recognising the importance of privacy, dignity and diversity.
- Responsible for the care of research participants within the relevant sphere of practice and use opportunities to provide health promotion and patient education.
- Facilitate recruitment into a number of research studies ensuring all study timelines are met.
- Maintain accurate documentation of patient events in nursing/medical notes and Case Report Forms.
- Demonstrate a comprehensive understanding of treatment options, treatment side effects and disease processes to support patients in making an informed choice.
- Provide ongoing information, education and support to patients (and their significant others) regarding clinical trials and specific trial treatments and procedures.
- Ensure that research specific investigations are undertaken as required by the

protocol and obtain results in order to establish eligibility and safety to enter the research study.

- Assess and manage any adverse and serious adverse events occurring due to ongoing treatment of a participant in a study whilst the participant is in the research study to the Principal Investigator and R&D office in line with the study protocol.
- Ensuring all adverse events and serious adverse events are captured in the appropriate documentation.
- Provide continuity of care to patients and their carers throughout the research study. Provide specific advice and support as appropriate. Refer to other specialists as required to ensure optimum patient care.
- Maintain accurate patient data, complete Case Record Forms, including the use of electronic data capture systems and ensure relevant information is recorded in patients medical notes
- Contribute to the monitoring of clinical standards within the research team.
- Utilise Information Governance guidance for the handling of sensitive patient data.
- Develop additional clinical skills to meet the needs of individual studies.
- Provide line management for band 5 research nurses/research officers within the research team. Monitor leave requests and other absences to ensure agreed manpower and skill mix are available to maintain the safe and effective running of research studies
- Responsible for teaching and delivering core training on competencies within research delivery.

Research

- Be responsible for the delivery of allocated research studies. Oversee studies allocated to band 5 research nurses.
- Ensure that the delivery of studies meet requirements with regards to the UK policy framework for health and social care research and the EU Clinical Trials Directive by implementing quality systems.
- Participate in Good Clinical Practice (GCP) training, keeping up to date with any changes in legislation or practice.
- Contribute to the Expression of Interest / Study Selection process
- Contribute to study set up, recruitment planning and study delivery.
- Be responsible for promoting the appropriate referral and recruitment of patients to clinical research studies. Work with research teams and investigators to develop strategies to overcome barriers to recruitment and to solve other problems relating to specific studies.
- Coordinate and run study visits including off site visits whilst adhering to the lone worker policy.
- Work with other departments within the UHB to ensure that research specific investigations and procedures are undertaken as required by the protocol, in order to establish eligibility and safety of patients within research.
- Ensure clear, accurate and concise records are kept for research projects in accordance with all regulatory requirements including the Data Protection Act.
- Ensure that data is transcribed accurately where required and assist with the maintenance of the Trial Master File.
- Respond to data queries generated by the study coordinating team within a timely manner.
- Ensure the recording & reporting of adverse and serious adverse events that occur whilst the participant is in the research study to the study co-coordinator/Principal Investigator (PI) and R&D office in line with the study protocol, local policies and regulatory requirements.
- Assess and evaluate the progress of on-going studies, maintaining accurate records of the status of studies and providing regular updates to the department on the status of the studies. This will involve ensuring that the Local Patient

Management System (LPMS) is updated with key study data and validated efficiently.
- Escalate on-going study performance issues to the Senior Research Nurse/Team Lead.
- Co-operate with external and internal audit, data monitoring and quality assurance by working with R&D, sponsors, study monitors and external bodies.
- Assist with study close down and the preparation of results of research for presentation as posters, abstracts, papers or scientific presentations.

Professional Development and Education
- Attend relevant meetings and provide regular research progress reports. These reports will influence actions and decision on future research. The post holder will contribute to the development of new research proposals as appropriate.
- Required to keep up to date with policy developments especially in Welsh Government and NIHR (UK).
- Mentor new research delivery staff internal and external to R&D and provide clinical supervision to staff and students.
- Whilst the post holder will work within specific research study protocols and guidelines it is essential for the post-holder to work on her/his own initiative, demonstrate a flexible approach to work and to function well as part of the Research Delivery Team within the UHB. The post holder will need to provide professional leadership on research when talking to clinical teams.
- Advocate for research and will provide education and training on research projects to interested parties as required.

Quality
- Support and participate in study audits within research and development actively feeding back on lessons learnt and improving the service provided.
- Participate in task and finish groups developed through the UHB and Health and Care Research Wales, evaluating work to positively introduce change.
- Feedback on pharmaceutical and sponsor monitoring visits in research and distributing any lessons learnt at team meetings.
- Ensure all staff adhere to relevant legislation including the UK policy framework for health and social care research and ICH GCP.

Information, Finances and Physical Resources
- Responsible for reporting defective equipment to relevant department.
- Observe personal duty of care in relation to equipment and resources used in course of work.
- Advise where appropriate on the cost recovery required for commercial trial resource allocation.
- May be required to deliver presentations to clinical teams which will involve standing for periods of time.
- Be able to access and interpret information on the Open Data Platform for Research.
- Requirement to use a keyboard and VDU equipment on a daily basis.

PERSON SPECIFICATION

ATTRIBUTES	ESSENTIAL	DESIRABLE	METHOD OF ASSESSMENT
Qualifications and/or Knowledge	• Allied Healthcare Practioner and/or Health related degree • HCPC Registered • Evidence of continued professional development • Specialist knowledge of research legislation, GCP and National Framework or evidence of post graduate qualification in relevant specialism e.g. Diabetes PgDip. • Knowledge of clinical and Research Terminology or an in-depth knowledge of specific disease site and care pathways • Ability to practice within the sphere of relevant practice e.g. Podiatrist	• Knowledge of clinical and/or research terminology	Application form and pre employment checks
Experience	• Evidence of previous patient/client and Multi Disciplinary Team contact within work environment. • Experience of undertaking clinical research and/or extensive clinical experience in a specific area • Project management • Ability to make independent decisions and advise others on appropriate action.		Application form and interview
Aptitude and Abilities	• Ability to communicate complex information to patients/carers/members of MDT • Team player whilst possessing ability to work independently. • Well organised and able to plan own workload.	• Ability to speak Welsh	Interview
Values	• Positive attitude and respect for others. • Drive enthusiasm and		Application Form Interview

	commitment to the organisation •		References
Other	• Ability to travel within geographical area. • Able to work hours flexibly.		Application form and interview

GENERAL REQUIREMENTS

- **Values:** All employees of the Health Board 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.

- **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 / indirect contact with* patients/service users/ children/vulnerable adults in the course of your normal duties. You will therefore be required to apply for a Criminal Record Bureau *Standard / Enhance Disclosure Check as part of the HB/Trust's pre-employment check procedure. *Delete as appropriate.
  The post holder does not require a DBS Disclosure Check. *Delete as appropriate.

- **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.

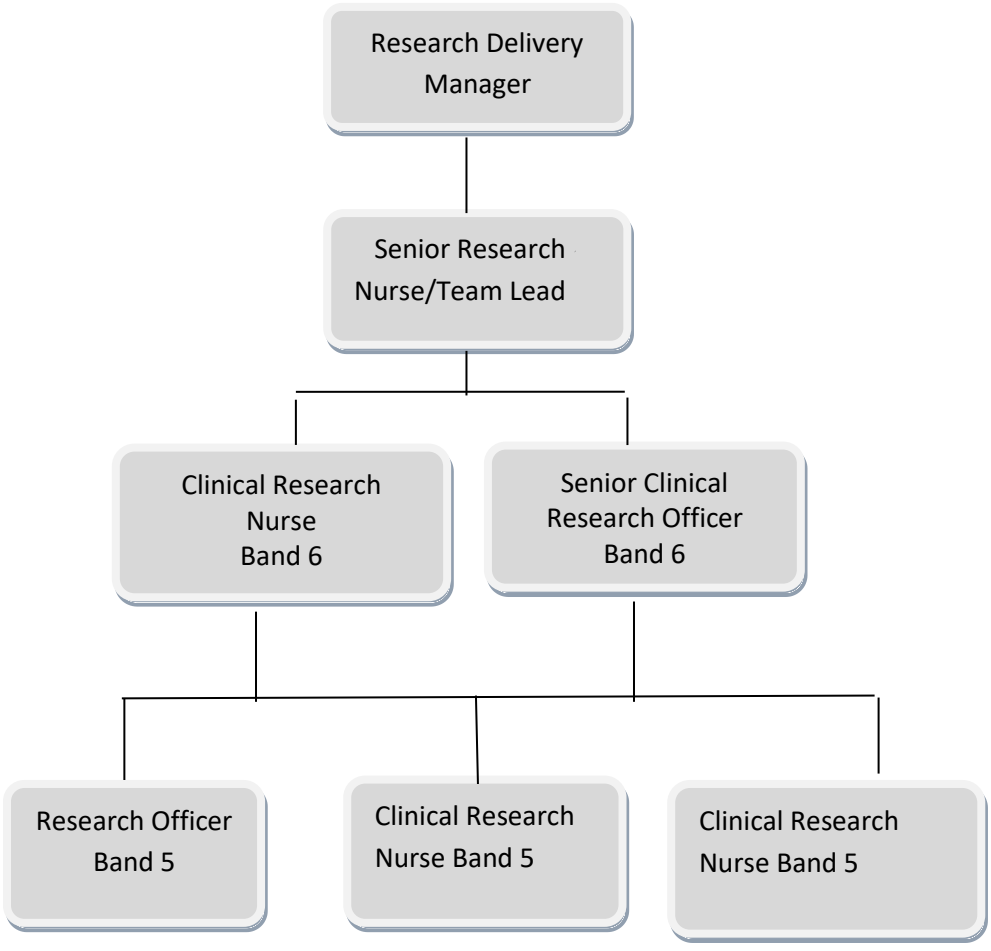
APPENDIX 1

Job Title: Clinical Research Nurse

Organisational Chart

The Organisational Chart must highlight the post to which this job description applies showing relationship to positions on the same level and, if appropriate, two levels above and below.

Complete, add or delete as appropriate the text boxes below showing the organisational relationships.



APPENDIX 2

Job Title: Clinical 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, such as:

'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 / month	For how long?	Additional Comments
The post-holder is frequently exposed to unpredictable episodes of moderate exertion. For example whilst moving and handling patients with physical limitations from bed to chair or who are attached to medical devices.	Variable	Variable	
The post-holder maybe required to physically manoeuvre (with appropriate aids) heavy pieces of equipment. The post holder will frequently be required to bend, lift, stretch and kneel whilst undertaking clinical duties	Weekly	Variable	
The post-holder maybe required to sit for varying lengths of time in a restricted position using computer.	Variable	Variable	

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, e.g. :

'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
Check documents, undertake clinical interventions- e.g.: venepuncture, Enter data onto databases, record adverse events all on an ongoing basis.	Variable	Variable	
Collecting, recording, verifying and entering clinical activity data from external and internal sources with a high degree of accuracy and ensuring all data are validated	Daily	Variable	
Resolve data queries for a wide portfolio of studies	Daily	Variable	

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
Occasional dealings with complaints, incidents (clinical and non-clinical)	Variable	Variable	
Act as an advocate for patients, occasional requirement to intervene on behalf of patients. Dealing with distressed patients and or relatives	Variable	Variable	
In contact with patients at differing points of their care pathway. Dealing with patients from a newly diagnosed disease to patients with an end of life scenario and palliative care.	Variable	Variable	

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
Use of VDU.	Daily	1 – 3hrs	
Requirement to work across the regional infrastructure of local services and to travel on a regular basis	Weekly	Variable	
Exposure to body fluids, for example collection of samples and specimens from patients (stools, blood, saliva, sputum, urine).	Weekly	Variable	