Royal Devon and Exeter
NHS Foundation Trust

JOB DESCRIPTION

JOB DETAILS	
Job Title	Agile Research Nurse – Torbay & South Devon
Reports to	Agile Research Team Leader
Band	Band 5
Department/Directorate	NIHR CRN SWP

JOB PURPOSE

The National Institute for Health Research (NIHR) is funded through the Department of Health and Social care to improve the health and wealth of the nation through research. The NIHR is a large, multi-faceted and nationally distributed organisation.

The NIHR plays a key role in the Government's strategy for economic growth, attracting investment by the life-sciences industries through its world-class infrastructure for health research. Together, the NIHR people, programmes, centres of excellence, and systems represent the most integrated health research system in the world.

The NIHR Clinical Research Network is tasked with supporting the rapid set-up and effective conduct of commercial and non-commercial studies, so that researchers can gather the robust evidence needed to improve treatments and provide an evidence base for the health and care system. The NIHR Clinical Research Network is led by a national Coordinating Centre, and operates through 15 Local Clinical Research Networks (LCRNs). These local Networks drive clinical research delivery performance across the locality, and champion the role of research in the health and care system at every level.

This post will work as part of the NIHR Clinical Research Network South West Peninsula's (CRN SWP) expanding Agile Research Delivery Team, supporting research across a variety of clinical specialties and a range of settings including GP practices, acute, community, care homes, local authority and social care settings.

The post-holder will support the safe conduct of research in accordance with the Research Governance Framework and Good Clinical Practice guidelines and provide assurance that the rights, safety and well-being of trial participants are protected. The post-holder will work with the research team to plan, implement, organise and manage concurrent research projects. S/he will develop networks with Multidisciplinary Teams across the Trust and other appropriate regional and national agencies. S/he will coordinate and manage the relevant study portfolio and deliver recruitment accrual in line with performance and monitoring objectives. The post-holder will be responsible for the implementation and monitoring of the clinical requirements associated with research to ensure optimum delivery of clinical trials. S/he will ensure that all research procedures are conducted according to study protocols and will be accountable for the care of research participants with a focus on providing a quality experience. The post-holder is responsible for his/her own workload for the screening, recruitment, consent, data collection and retention of patients into research studies. Workloads will be flexible and at times will involve cross regional support of other research teams and a flexible approach to work. On occasion the post-holder will deputise for the band 6 senior research nurse.

Local Information

The NIHR Clinical Research Network South West Peninsula (NIHR CRN SWP) is formed from partner organisations in Somerset, Devon, Cornwall and the Isles of Scilly covering a population of

approximately 2.2 million. The region includes a range of health and care providers across the South West including acute, mental health, community, primary care, social care and public health.

All the NHS Trusts are currently engaged with and recruiting to NIHR Portfolio research studies and key relationships have been built with other providers of health and care who are also embracing the opportunity to become involved with NIHR research.

For commercial studies the CRN industry team are the single point of contact for life sciences companies wanting to conduct studies, the team work closely with partners to conduct feasibility, site identification and performance manage adopted studies. The NIHR CRN industry team works closely with the post holder and clinical experts to ensure studies are both feasible and eligible to enter the portfolio. CRN will support studies from pharmaceutical companies, biotech and medical device companies, using processes and systems, which are consistent across CRNs.

The region benefits from a 'prime site' relationship with IQVIA, the largest international Contract Research Organisation. The region is also active with many other commercial partners across a breadth of specialty areas.

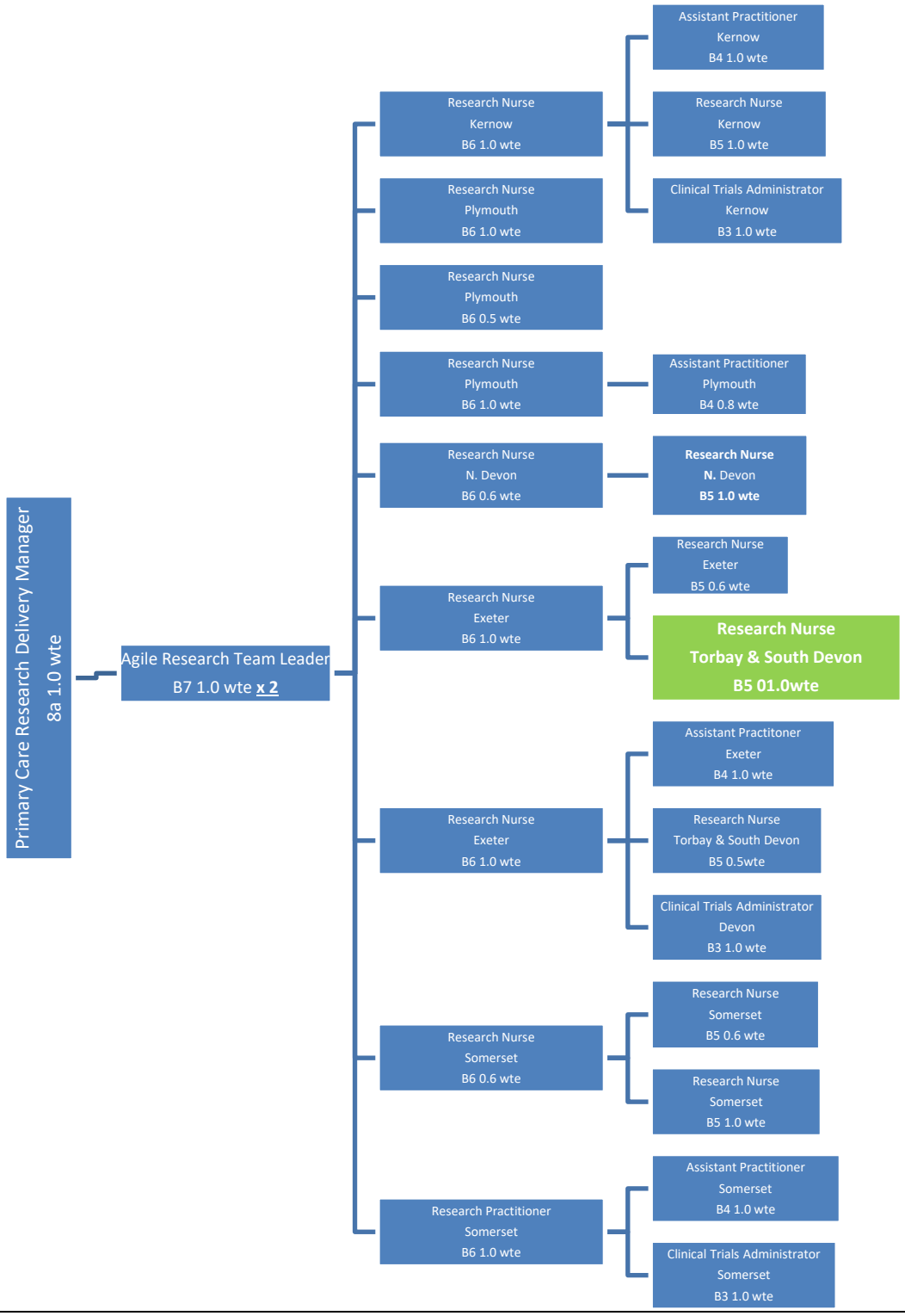
KEY RESULT AREAS/PRINCIPAL DUTIES AND RESPONSIBILITIES

- Responsible for the operational delivery of the clinical research team work-plan within the relevant specialties.
- Manage research performance within the relevant specialty in relation to team activities and study timelines.
- Collaborate across the healthcare community within the region to improve research delivery.
- Keep up to date with research management issues through liaison with other Research Specialists /Team leaders and link with national networks.
- Act as line manager for junior members of the research staff as applicable (e.g. Research Assistant Practitioner, Research HCA, and Research Administrator). This will include clinical supervision and mentorship to members of staff and students.
- Ensure all staff within sphere of responsibility have access to essential training and achieve 100% compliance.
- Be responsible for the deployment of HR policies including proactively managing sickness and performance in line with the Trust policy.
- Ensure the health, safety and security of the clinical research team within sphere of responsibility.
- Assist the Team Lead with the training and development of clinical research practitioners and administrators to ensure retention of staff and workforce development where possible.
- Lead in the delivery of education and training regarding research for the wider Multidisciplinary Team and act as an ambassador for research.
- Contribute to the development and implementation of clinical and research policies, procedures and SOPs.
- Facilitate and maintain effective communication within the research team and between the multidisciplinary clinical team.
- Promote a blame free culture in reporting incidents and where appropriate support local investigation of incidents.
- Attend and actively participate in Trust Appraisal. Appraise other staff where appropriate.
- Manage, coordinate, implement and undertake delegated research/clinical trials and provide supervision to other research staff and students.

KEY WORKING RELATIONSHIPS

Internal to the Trust	External to the Trust
• SWP CRN Chief Operating Officer • Deputy Chief Operating Officer • Clinical Leads • Clinical Research Speciality Leads • Research Delivery Managers • Agile Research Team Leader • Agile Research Nurses/Practitioners • Senior Research Associates	• Lead Research Nurses / Practitioners • Principal Investigators • General Practices • Community Pharmacists • Study Participants and their families • Study Sponsors and Clinical Research Associates • Partner Organisations

ORGANISATIONAL CHART



FREEDOM TO ACT

- Be responsible for the care of research participants within the relevant sphere of practice and use opportunities to provide health promotion and patient education.
- To provide information and support to patients and their families involved in research / clinical trials.
- Provide clear information and support to patients and carers relating to the research protocol, procedures treatment and follow-up.
- Adhere to Standard Operating procedures
- Escalate on-going study performance issues to the Senior Research Nurse or Team Lead.

COMMUNICATION/RELATIONSHIP SKILLS

Recognise the value of skilled open communication in the development of professional-patient relationships and with other members of the multi-disciplinary team.

Facilitate and maintain effective communication within the research team and between the multidisciplinary clinical team.

To communicate with a variety of members of the multidisciplinary team on a daily basis communicating complex trial information in a clear and effective manner.

Communicate with the Clinical Research partners and their representatives on a daily basis attending meetings where required.

Obtain informed consent where delegated to do so by the Principle Investigator.

Deal with enquiries from other Health Care Professionals, patients and carers.

ANALYTICAL/JUDGEMENTAL SKILLS

- Clinical knowledge within a relevant sphere of practice is required to enable screening against specified inclusion / exclusion criteria for recruitment.
- Post-holders will need to have relevant clinical knowledge and the ability to critically evaluate participants' progression through research pathways in order to respond and refer appropriately.
- Critical research evaluation and the ability to conduct feasibility will be key requirements when working on research protocols.
- Engage in early evaluation of Expressions of Interests (EOI) received with Principal Investigator and team lead to ensure feasibility of study at site is properly assessed.
- Work with the lead clinician and senior research nurse/team lead to review complex clinical trial protocols and to develop a balanced portfolio of studies for each speciality that the post holder works across.

PLANNING/ORGANISATIONAL SKILLS

- Be responsible for managing & organising own day-today activities and workload, liaising with the senior research nurse and working within the team to ensure the portfolio remain covered at times of leave.
- Deputises for the senior research nurse on an ad hoc basis.
- Supports the planning of both short-term and long-term research projects.
- Work with the Team Lead to understand and plan the portfolio of studies that may be open, in follow up or in setup at any one time.

PATIENT/CLIENT CARE

- Assess, plan, deliver an implement the individual research care requirements according to the research protocol being mindful of any clinical care requirements.
- Undertake the care and management of the unwell or deteriorating patient.
- Use relevant clinical knowledge to screen and identify patients suitable for clinical research using inclusion and exclusion criteria and utilising IT systems & databases, screening clinics, visiting wards and Outpatients.
- Carry out physical assessments, sample retrieval and processing, providing or coordinating interventions and treatments, clinical monitoring.
- Ensure the environment is suitable for patient care and research processes, recognising the importance of privacy, dignity and diversity.
- Provide on-going advice, information and health education to patients and their carers/families with regard to their participation in clinical research in order to facilitate effective informed consent.
- Where appropriate receive and document written informed consent from research subjects.
- Be responsible for the safe and accurate collection of research data through clinical procedures such as venepuncture, history taking, standard observations (height, weight, BP, RR, HR, SpO2 temperature) and other assessments such as ECG, physical examinations, disease specific outcome measures, questionnaires, rated scales, qualitative interviewing as required by the protocol.
- Centrifuge, process track and ship samples in line with protocol requirements.
- Manage the accountability of Clinical Trial Investigational Medicinal Products (CTIMP)
- Ensure the safe administration of any treatments and drugs given within the context of a clinical trial.

- Monitor treatment toxicity/side effects and initiate changes to treatment as required by the protocol. Escalate any concerns to the Principle Investigator or relevant physician.
- Undertake accurate recording of serious adverse events according to the protocol and sponsor requirements.
- Ensure accurate patient trial documentation, including the use of electronic data capture systems and ensure relevant information is recorded in patients' medical notes and case report form in a timely manner.
- Refer to other specialists as required in order to provide optimal care of the participant.
- Contribute to the monitoring of clinical standards within the research team.
- Contact with patients, participants, families, carers happens directly within Primary Care sites, in patient homes, and public spaces.
- Contact can also happen remotely via phone, email, and social media. Contact is agreed in the protocol that has been ethically approved and given capacity and capability at this site for the research to go ahead.

POLICY/SERVICE DEVELOPMENT

- Assess and evaluate the progress of on-going clinical trials for which the post holder has responsibility, 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 EDGE (Local Patient Management System) is updated with key trial data and validated efficiently. Ensure NIHR metrics are adhered to and recorded accurately on EDGE.
-

FINANCIAL/PHYSICAL RESOURCES

- Contribute to the accurate costing for clinical trials and appropriate negotiation of required financial support to deliver clinical trials.
- Ensure that participants can claim appropriate travel and other expenses and completing invoices in a timely and accurately.

HUMAN RESOURCES

- Supervise band 4 Assistant Research Practitioners and a range of junior staff.
- Support senior staff in recruitment and interviewing processes in line with Trust practices and procedures.
- Take an active role in the mentoring and supervision of student nurses and junior staff.
- Provides teaching in practice to other staff and students through clinical supervision and facilitation.
- Assist in the delivery of education and training regarding research for the wider Multidisciplinary Team and act as an ambassador for research.

INFORMATION RESOURCES

- 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 entry is accurate.
- Respond to data queries generated by the study coordinating team within a timely manner.
- Demonstrate awareness of the Ethics Committee Procedures through prompt reporting of Serious Adverse Events, submission of Trust application, protocols, advertisements and amendments.

RESEARCH AND DEVELOPMENT

- Be responsible for the delivery of a clinical trial portfolio relevant to the specialty.
- Ensure that the delivery of studies meet requirements with regards to the Department of Health's Research Governance Framework for Health & Social Care and the EU Clinical Trials Directive by implementing quality systems.
- Contribute to the Expression of Interest / Study Selection process for the relevant specialty.
- 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 the clinical trials team 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 Trust to ensure that trial specific investigations and procedures are undertaken as required by the trial protocol, in order to establish eligibility and safety of patients within clinical trials.

- Ensure the recording & reporting of adverse and serious adverse events that occur whilst the participant is in the clinical trial to the trial co-coordinator/Principal Investigator (PI) and R&D office in line with the study protocol, local policies and regulatory requirements.
- Cooperate with internal audit requests from Research and Development teams.
- Liaise with clinical trial monitors and external auditors.
- Comply with National and Internal audit agencies such as the Medicines & Healthcare Products Regulatory Agency (MHRA).
- Contribute to the monitoring of clinical standards within the research team.

PHYSICAL SKILLS

The role requires flexibility as the research offices are not necessarily based where the patients are recruited or seen for their clinical research appointments.
Covering a multi Trust site portfolio or performing home visits will mean the post-holder is required to ensure they can commit to this requirement.

PHYSICAL EFFORT

Frequent requirement to exert moderate physical effort. Research offices are not based where patients are seen or recruited and the research team members are required to work across multiple sites in Primary Care and the Community in Devon and on occasion working, meeting in Somerset and Cornwall.
Frequent car journeys – on occasions - some of which may be longer than 1 hour.

MENTAL EFFORT

Data accuracy and IT skills are essential to this role and combining clinical skills with these demands can be mentally difficult. Undertaking data entry is a requirement for this role and can often require long periods of concentration.
There can be occasional requirements for intense concentration when performing IT training for a new study requiring mastering a series of IT programmes.

EMOTIONAL EFFORT

Rare exposure or occasional indirect exposure to distressing/emotional circumstances.
On occasion the post holder maybe required to undertake discussions about research with participants and their families during times of emotional distress.

WORKING CONDITIONS

Attending Investigator Meetings can mean traveling around the country or even abroad. Travel arrangements are made and costs covered by the sponsors and commercial companies but flexibility is required in order to accommodate attending these meetings.
The post-holder maybe required respond to an incidence driven recruitment strategy and this may be achieved through use of a bleep, group WhatsApp, text, and phone call.

OTHER RESPONSIBILITIES

- To take part in regular performance appraisal.
- To undertake any training required in order to maintain competency including mandatory training, i.e. Fire, Manual Handling.
- To contribute to and work within a safe working environment.
- The post holder is expected to comply with Trust Infection Control Policies and conduct him/herself at all times in such a manner as to minimise the risk of healthcare associated infection.
- As an employee of the Trust, it is a contractual duty that you abide by any relevant code of professional conduct and/or practice applicable to you. A breach of this requirement may result in action being taken against you (in accordance with the Trust's disciplinary policy) up to and including dismissal.

You must also take responsibility for your workplace health and wellbeing:

- When required, gain support from Occupational Health, Human Resources or other sources.
- Familiarise yourself with the health and wellbeing support available from policies and/or Occupational Health.
- Follow the Trust's health and wellbeing vision of healthy body, healthy mind, healthy you.
- Undertake a Display Screen Equipment assessment (DES) if appropriate to role.

APPLICABLE TO MANAGERS ONLY

Leading the team effectively and supporting their wellbeing by:

- Contribute to the accurate costing for clinical trials and appropriate negotiation of required financial support to deliver clinical trials.
- Ensure that participants can claim appropriate travel and other expenses and completing invoices in a timely and accurately.

DISCLOSURE AND BARRING SERVICE CHECKS

This post has been identified as involving access to vulnerable adults and/or children and in line with Trust policy successful applicants will be required to undertake a Disclosure & Barring Service Disclosure Check.

GENERAL

This is a description of the job as it is now. We periodically examine employees' job descriptions and update them to ensure that they reflect the job as it is then being performed, or to incorporate any changes being proposed. This procedure is conducted by the manager in consultation with the jobholder. You will, therefore, be expected to participate fully in such discussions. We aim to reach agreement on reasonable changes, but if agreement is not possible, we reserve the right to insist on changes to your job description after consultation with you.

Everyone within the Trust has a responsibility for, and is committed to, safeguarding and promoting the welfare of vulnerable adults, children and young people and for ensuring that they are protected from harm, ensuring that the Trusts Child Protection and Safeguarding Adult policies and procedures are promoted and adhered to by all members of staff.

Northern Devon Healthcare NHS Trust and the Royal Devon and Exeter NHS Foundation Trust continue to develop our long standing partnership with a view to becoming a single integrated organisation across Eastern and Northern Devon. Working together gives us the opportunity to offer unique and varied careers across our services combining the RD&E's track record of excellence in research, teaching and links to the university with NDHT's innovation and adaptability.

PERSON SPECIFICATION

Job Title	Community Research Nurse – Band 5

Requirements	Essential	Desirable
QUALIFICATION/ SPECIAL TRAINING		
Registered Nurse	**E**	
Research Training (e.g. GCP, degree module, informed consent)		**D**
Up to date professional portfolio	**E**	
KNOWLEDGE/SKILLS		
Good understanding of nursing care methods and models	**E**	
Understanding of data collection and data entry for clinical trials		**D**
Pertinent clinical skills	**E**	
IV Drug Administration		**D**
Computer literacy including ability to work with databases	**E**	
Ability to organise and prioritise own workload and work to tight deadlines	**E**	
Ability to make independent decisions	**E**	
Understand the significance of research and use of validated results to improve practice	**E**	
Skilled at clinical observations and venepuncture		**D**
Knowledge of the Research Governance Framework and		**D**
Good Clinical Practice Guidelines		**D**
Knowledge of clinical trials & research methodologies		**D**
EXPERIENCE		
Experience with dealing with confidential patient information	**E**	
Ability to communicate complex information to patients/carers/members of MDT	**E**	
Broad and recent clinical experience relevant to the post		**D**
Proven record of meeting targets		**D**
Experience of clinical research within the NHS setting		**D**
PERSONAL ATTRIBUTES		
Ability to work autonomously	**E**	
Ability to work cohesively as a member of a multidisciplinary team	**E**	
High level of interpersonal and communication skills	**E**	
Flexible and adaptable	**E**	
Willingness to learn, instigate and develop efficient working systems	**E**	
Willingness to undertake any necessary training and development to enhance work performance	**E**	
Commitment to openness, honesty and integrity in undertaking the role	**E**	
Willingness and ability to work across sites including community	**E**	
OTHER REQUIREMENTS		
The post holder must demonstrate a positive commitment to uphold diversity and equality policies approved by the Trust.	**E**	
Ability to travel to other locations as required.	**E**	

WORKING CONDITIONS/HAZARDS		FREQUENCY (Rare/ Occasional/ Moderate/ Frequent) R	O	M	F
Hazards/ Risks requiring Immunisation Screening					
Laboratory specimens	Y/N				F
Contact with patients	Y/N				
Exposure Prone Procedures	Y/N				F
Blood/body fluids	Y/N				F
Laboratory specimens	Y/N				
Hazard/Risks requiring Respiratory Health Surveillance					
Solvents (e.g. toluene, xylene, white spirit, acetone, formaldehyde and ethyl acetate)	N				
Respiratory sensitisers (e.g isocyanates)	N				
Chlorine based cleaning solutions (e.g. Chlorclean, Actichlor, Tristel)	N				
Animals	N				
Cytotoxic drugs	Y				
Risks requiring Other Health Surveillance					
Radiation (>6mSv)	N				
Laser (Class 3R, 3B, 4)	N				
Dusty environment (>4mg/m3)	N				
Noise (over 80dBA)	N				
Hand held vibration tools (=>2.5 m/s2)	N				
Other General Hazards/ Risks					
VDU use (> 1 hour daily)	Y				F
Heavy manual handling (>10kg)	N				
Driving	Y				F
Food handling	N				
Night working	N				
Electrical work	N				
Physical Effort	Y				F
Mental Effort	Y				F
Emotional Effort	Y				F
Working in isolation	Y				F
Challenging behaviour	Y				