Royal Devon University Healthcare NHS Foundation Trust

JOB DETAILS	
Job Title	Research Nurse Specialist/Team Lead
Reports to	Lead Research Nurse/Practitioner
Accountable to	Director Joint Research Officer
Band	7
Department/Directorate	Research and Development

JOB PURPOSE

The Clinical Trials Team is made up of around 70 members of staff who support the delivery of National Institute for Health Research (NIHR) studies at the Royal Devon and Exeter NHS Foundation Trust. The team structure reflects the national NIHR configuration and is divided into Divisions and subdivided into Specialties and also infrastructure such as the patient recruitment centre and the clinical research facility. The Research Nurse Specialist/Team Lead will be part of this Team and responsible for coordinating and managing the performance of the Cancer portfolio of clinical trials and the management of a team of Clinical Research Staff within the relevant Division/s/Infrastructure.

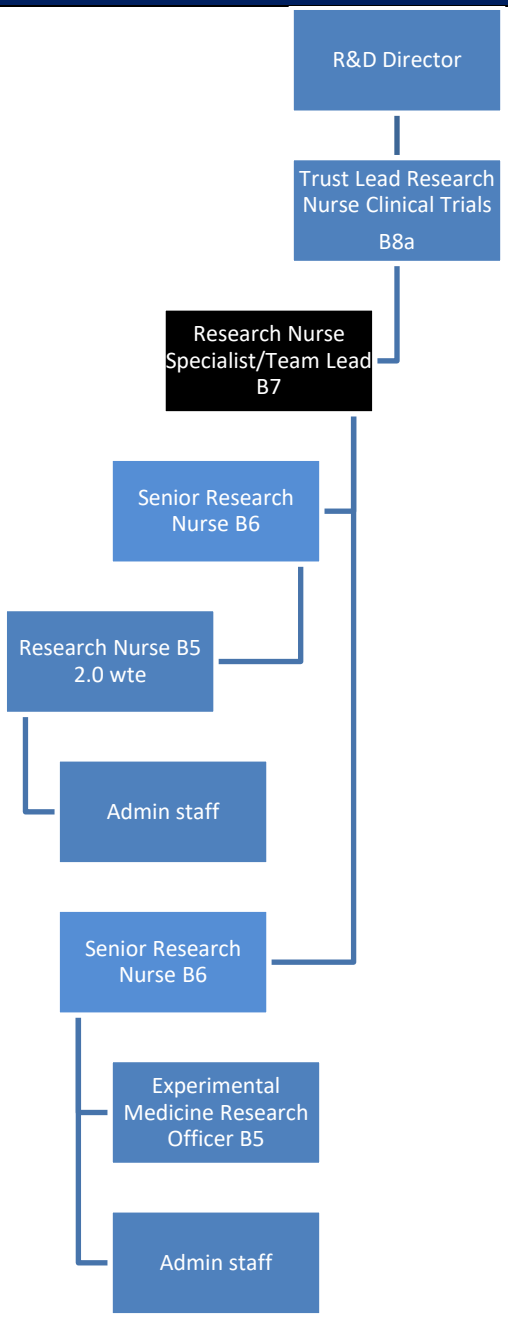
The post holder will provide expert knowledge, skill and experience in this specialist field, and act as an expert resource to advise and support those involved in clinical trials at all levels. The post-holder will be able to autonomously plan, implement, organise and manage concurrent research projects. S/he may source and manage funding for clinical trials and will develop networks with other disciplines across the Trust and other appropriate local and national agencies. S/he will coordinate and manage the study portfolio and recruitment accrual in line with performance and monitoring metrics.

As a Research Nurse Specialist / Team Lead s/he 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 therefore be required to adopt a highly visible clinical profile and accessible approach towards both research participants and staff. It will mean that s/he leads by example and empowers staff in their personal and professional development, promoting the undertaking of a broad range of research to modernise and improve patient care. S/he will ensure that research will be conducted in accordance with the Research Governance Framework and Good Clinical Practice guidelines to provide assurance that the rights, safety and well-being of trial participants are protected.

KEY WORKING RELATIONSHIPS

- Director of Joint Office
- Lead Research Nurse / Practitioner Clinical Research Team
- SWP CRN Chief Operating Officer and Research Delivery Managers Research and Development Manager and associated team
- Principal Investigators/Chief investigators and their research teams
- Trust Senior Nurses and AHPs
- Study participants and their families
- Clinical Trials Pharmacy Manager & staff Diagnostic services
- Study Sponsors and Clinical Research Associates.
- University clinical research infrastructure eg Mireille Gillings Neuroimaging Centre and the Clinical Trials Unit, Governance unit, CRF Team and Joint Office Team

ORGANISATIONAL CHART



KEY RESULT AREAS/PRINCIPAL DUTIES AND RESPONSIBILITIES

Leadership

- To assist the Lead Research Nurse / Practitioner to ensure the operational delivery of the clinical research team work plan, particularly with respect to achieving NIHR targets.
- Manage research performance in relation to team activities and study timelines and targets set by R&D and the SWP CRN.
- Collaborate with other Trusts and organisations 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.
- Assist the Lead Research Nurse/Practitioner with the training and development of clinical research practitioners and administrators to ensure retention of staff and workforce development where possible.

- Oversee 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, and Standard Operating Procedures (SOPs).
- Facilitate and maintain effective communication within the research team and between the clinical team.
- Represent the Clinical Research Team and Royal Devon University Healthcare NHS Foundation Trust at a regional and national level.
- Work as part of the clinical trials core operational team and contribute to the on-going development of the R&D department.
- Deputise for the Lead Research Nurse / Practitioner and provide cover for other Team Leads when required.
- Promote a blame free culture in reporting incidents and where appropriate initiating a local investigation in a timely manner.

Research

- Lead the management and delivery of a large clinical trial portfolio relevant to the Division/s/ infrastructure and ensure a balanced portfolio of studies.
- 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.
- Lead the Expression of Interest / Study Selection process for the Division. Review and assess trial protocols, consider all potential trials in terms of capacity and capability and viable recruitment period. Identify and work with the Principal Investigator (PI), RM&G Manager and Lead Nurse/Practitioner to resolve resource implications in delivering and facilitating clinical research.
- Act as an expert resource and provide complex advice, regarding study set up, recruitment planning and study delivery including hands on delivery of specialist investigations.
- Be responsible for promoting and overseeing the appropriate referral and recruitment of patients to clinical research studies. Work with investigators and support the clinical research team to develop strategies to overcome barriers to recruitment and to solve other problems relating to specific studies.
- Act as PI for suitable studies and promote the non-medic PI role.
- Decide and delegate roles for the clinical research team in terms of study delivery, using the right skill mix for the study complexity.
- Oversee the coordination of study visits including off site visits and ensure the team adhere 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, ensure and safety of patients within clinical trials.
- Ensure both accurate costing for clinical trials and appropriate negotiation of required financial support to deliver clinical trials.
- Ensure clear, accurate and concise records are kept for research projects in accordance with all regulatory requirements including the Data Protection Act.
- Oversee the maintenance of Trial Master Files and essential documents.
- Ensure that the team respond to data queries generated by the study coordinating team within a timely manner and review monitoring visit reports within the team.
- Ensure that the team record and report adverse and serious adverse events that occur whilst the participant is in the clinical trial to the trial co-coordinator/ PI and R&D office in line with the study protocol, local policies and regulatory requirements.
- 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.

- Promote collaborative working across the network and with other clinical researchers, within R&D and NIHR structure.
- Ensure high quality publicity about clinical research is visible in the department including easy access to information about current trials for patients and the public.
- Co-operate with external and internal audit, data monitoring and quality assurance by working with R&D, sponsors, study monitors and external bodies.
- Oversee study close down and the preparation of results of research for presentation as posters, abstracts, papers or scientific presentations.

CLINICAL AND PROFESSIONAL SKILLS

- Be highly visible in the clinical area, working alongside and supporting staff in a managerial and clinical capacity.
- Act as a specialist resource and role model for all aspects of research clinical practice in order to optimise patient care.
- Undertake all mandatory training and ensure that the clinical workforce is up to date with mandatory training.
- Ensure the environment is suitable for patient care and research processes, recognising the importance of privacy, dignity and diversity.
- Review incident reports related to the relevant area, carrying out investigations and taking appropriate action where required.
- Demonstrate professional development and an in-depth knowledge of current clinical and research practice and encourage and ensure the development of others.
- Provide on-going specialised advice and information to patients and their carers/families with regard to participation in clinical research.
- Actively participate with patient, public, involvement and engagement outreach and other activities recognising the importance of such activities in the development, delivery and dissemination of clinical research and ensure the engagement of others in this area.
- Where appropriate receive and document written informed consent from research subjects and act as an expert resource in informed consent.
- Ensure the safe and accurate collection of clinical research data such as venepuncture, infusions, biopsies, history taking, standard observations (height weight, BP, temperature, heart rate) and other assessments such as ECG, physical examinations, disease specific outcome measures, questionnaires, rated scales, qualitative interviewing and specialist experimental medicine techniques as required by the protocol through clinical supervision of the research team.
- Ensure staff competency to centrifuge, process, track and ship samples in line with protocol requirements.
- Ensure the safe administration of any treatments and drugs given within the context of a clinical trial and act as a specialist clinical resource to the members of the team.
- Support the research team to monitor treatment toxicity/side effects and initiate changes to care as required by the protocol, escalating issues to the Principle Investigator where required.
- Ensure accurate patient trial documentation, including the use of electronic data capture systems and ensure relevant information is recorded in patients' medical notes.
- Refer to other specialists as required in order to provide optimal care of the participant.
- Monitor clinical standards within the research team and identify action plans to address any areas of concerns. Work with the Trust Lead Nurse for Patient Safety and Risk where there are persistent problems.
- Treat all persons encountered during the course of duties with respect and courtesy
- Act as a professional lead and work within the relevant professional code of conduct. (e.g. NMC Scope of Professional Practice and Code of Conduct) demonstrating accountability for own actions and awareness of own limitations.
- Ensure the on-going registration of clinical staff with relevant professional bodies.

KNOWLEDGE & TRAINING EXPERIENCE

- Knowledge of the Research Governance Framework and the International Conference on Harmonisation Good Clinical Practice Guidelines
- In depth knowledge of clinical trials & research methodologies
- High level of interpersonal and communication skills
- In-depth knowledge of data collection and data entry for clinical trials
- Extensive experience of clinical research including exposure to early phase and experimental medicine research within the NHS setting
- Broad and recent clinical experience relevant to the post
- Ensure that all relevant staff participate in Good Clinical Practice (GCP) training.

ANALYTICAL/JUDGEMENTAL SKILLS

- Appraise research findings that inform and influence practice, policy and service provision and demonstrate the ability to make research and clinical judgments based on this appraisal.

PLANNING/ORGANISATIONAL SKILLS

- Monitor and plan in advance the research workload within the department and manage team performance.
- Ensure accurate patient trial documentation, including the use of electronic data capture systems and ensure relevant information is recorded in patients' medical notes.

PHYSICAL SKILLS

- Highly developed skills with high degree of precision appropriate for a Registered Nurse

PATIENT/CLIENT CARE

- Proactively seek feedback from participants and their families during their research involvement.
- Resolve relevant complaints and issues at a local level in partnership with patients, carers and their family and other healthcare professionals.

POLICY/SERVICE DEVELOPMENT

- Adheres to Professional Body Code and Scope of professional conduct / practice and policies which govern clinical practice at local and national level including Trust policies.
- Works within the range of research guidelines, ethical principles and protocols, whilst adhering to organisational policies and procedures.
- Observes the confidentiality of patient information at all times, in accordance with the data protection act and Caldicott regulations.
- Contributes to the development of nursing practice within their area of work through the application of nursing research.
- Contributes to the ongoing development of the department, is instrumental in the development of policies and SOPs which may impact on other personnel within the department.
- Ensures that nursing team members are aware of, and implement local, regional and national policies governing research and nursing practice.

FINANCIAL/PHYSICAL RESOURCES

- Have an awareness of the clinical trials workforce budget and understand the various income streams including Core Network Funding, Research Capability Funding and study income.
- Assist the Lead Research Nurse / Practitioner to ensure financial stability or the clinical trials workforce budget.
- Have responsibility for the non–pay budget within own team including managing clinical trial equipment costs and training and travel costs.

- Ensure the clinical research team are aware of, and work within financial and budgetary guidelines.
- Ensure accurate costings for clinical research workforce activity during study set up. Oversee all commercial costing meetings relevant to the Division and utilise planning tools such as the intensity toolkit.
- Identify resource implications for individual studies and the portfolio of studies within the Division.
- Ensure research equipment is maintained in an effective working and good clinical order

HUMAN RESOURCES

- Oversee the recruitment of new personnel, ensure that an appropriate and safe skill mix is maintained and act strategically to enable retention of staff.
- Act as line manager for the Senior Research Nurses/ Practitioners within the team and oversee the management of other members of the research staff within the team (Research Nurse/Practitioner, 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.
- Lead in the recruitment of Senior Research Nurses/Practitioners within the relevant team.

INFORMATION RESOURCES

- Responsible for collecting, recording, verifying and entering study data into the trial database with a high degree of accuracy.
- Competent in and uses on a daily basis Microsoft Word, spreadsheet and database programs, patient administration systems

RESEARCH AND DEVELOPMENT

- Research is a major component of the post.

FREEDOM TO ACT

- Works to achieve agreed objectives and timescales, as prescribed to meet internal and external reporting deadlines, given freedom to organise own workload to meet criteria.

PHYSICAL EFFORT

- There is the possibility of exposure to episodes of light exertion. For example whilst moving and handling patients with physical limitations or who are attached to medical devices.
- There may be a requirement to physically manoeuvre (with appropriate aids) heavy pieces of equipment around the research facility/clinical area on an infrequent basis.
- There will be times when you will be required to sit for varying lengths of time in a restricted position inputting data into trial database/writing reports.

MENTAL AND EMOTIONAL EFFORT

- The post holder will be frequently exposed to circumstances that are distressing or emotional as they will be required to support participants during the discussion and decision making process regarding trial entry with patients who have exhausted all conventional treatments.
- The post holder will be required to assess and evaluate potential side effects of trial drugs which were not predictable at the time of study entry.

- The post holder will also be responsible for Disciplinary and Grievance matters in relation to staff and staff welfare.
- Frequent requirement for concentration when undertaking research activities, for example: collecting, recording, verifying and entering study data with a high degree of accuracy, report writing and associated tasks.

WORKING CONDITIONS

- Willingness and ability to work across sites including community
- There will be times when you would be required to work in isolation
- There will be exposure to VDU screens whilst inputting trial related data.
- Dependant on the trials there could be exposure to body fluids, for example collection of samples and specimens from patients (stools, blood, saliva).

OTHER RESPONSIBILITIES

To take part in regular performance appraisal.

To undertake any training required in order to maintain competency including mandatory training, e.g. 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.

APPLICABLE TO MANAGERS ONLY

THE TRUST- VISION AND VALUES

Our vision is to provide safe, high quality seamless services delivered with courtesy and respect. To achieve our vision we expect all our staff to uphold our Trust values. Our Trust values are:

Honesty, Openness & Integrity
Fairness,
Inclusion & Collaboration
Respect & Dignity

We recruit competent staff that we support in maintaining and extending their skills in accordance with the needs of the people we serve. We will pay staff fairly and recognise the whole staff's commitment to meeting the needs of our patients.

We are committed to equal opportunity for all and encourage flexible working arrangements including job sharing.

We are committed to recruiting and supporting a diverse workforce and welcome applications from all sections of the community, regardless of age, disability, gender, race, religion, sexual orientation, maternity/pregnancy, marriage/civil partnership or transgender status. We expect all staff to behave in a way which recognises and respects this diversity, in line with the appropriate standards.

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.

The RDE is a totally smoke-free Trust. Smoking is not permitted anywhere on Trust property, including all buildings, grounds and car parks. For help to quit call: 01392 207462.

POST	Research Nurse Specialist/Team Lead
BAND	7

PERSON SPECIFICATION

Job Title	Research Nurse Specialist/Team Lead

Requirements	Essential	Desirable
QUALIFICATION/ SPECIAL TRAINING		
Registered Nurse	E	E
Relevant Healthcare Degree	E	E
Research Training (e.g. GCP, degree module, informed consent)	E	E
Post graduate /Master's level qualification or willing to work towards	D	E
Management or Leadership Qualification	D	E
KNOWLEDGE/SKILLS		
Knowledge of the Research Governance Framework and the International Conference on Harmonisation Good Clinical Practice Guidelines	E	E
In depth knowledge of clinical trials & research methodologies	E	E
High level of interpersonal and communication skills	E	E
In-depth knowledge of data collection and data entry for clinical trials	E	E
Good leadership skills and proven managerial ability	E	E
Pertinent clinical skills	E	E
IT skills including ability to work with databases	E	E
Ability to organise and prioritise own workload and work to tight deadlines	E	E
Ability to think strategically and make independent decisions	E	E
Critical appraisal skills	E	E
Evidence of budgetary control	D	E
EXPERIENCE		
Extensive experience of clinical research within the NHS setting	All E	
Broad and recent clinical experience relevant to the post		
Line Management experience within the NHS		
Proven record of meeting participant recruitment targets		
Experience of delivering commercial and academic research		
PERSONAL ATTRIBUTES		
Ability to work autonomously	All E	
High level of interpersonal and communication skills		
Flexible and adaptable		
Willingness to learn, instigate and develop efficient working systems		
Ability to work cohesively as a member of a team		
Willingness to undertake any necessary training and development to enhance work performance		
Commitment to openness, honesty and integrity in undertaking the role		
Willingness and ability to work across sites including community		
OTHER REQUIRMENTS		
The post holder must demonstrate a positive commitment to uphold diversity and equality policies approved by the Trust.	E	
Committed to further professional development	E	

WORKING CONDITIONS/HAZARDS		FREQUENCY (Rare/ Occasional/ Moderate/ Frequent) R	O	M	F
Hazards/ Risks requiring Immunisation Screening					
Laboratory specimens	Y			✓	
Contact with patients	Y			✓	
Exposure Prone Procedures	N				
Blood/body fluids	Y			✓	
Laboratory specimens	Y			✓	
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	N				
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			✓	
Heavy manual handling (>10kg)	N				
Driving	Y		✓		
Food handling	N				
Night working	N				
Electrical work	N				
Physical Effort	Y		✓		
Mental Effort	Y				✓
Emotional Effort	Y			✓	
Working in isolation	Y			✓	
Challenging behaviour	Y		✓		