

Job Description

Title: Clinical Trials Research Nurse

Directorate: Queen Square Division

Board/corporate function: Specialist Hospitals

Band: Band 7

Responsible to: Dr ANDREA MALASPINA

Queen Square MND Centre and Centre for Neuromuscular

Diseases, Institute of Neurology

Accountable to: Dr ANDREA MALASPINA

Queen Square MND Centre and Centre for Neuromuscular

Diseases, Institute of Neurology

Hours: 37.5

Location: National Hospital for Neurology and Neurosurgery

University College London Hospitals NHS Foundation Trust

University College London Hospitals NHS Foundation Trust (UCLH) is one of the most complex NHS trusts in the UK, serving a large and diverse population.

We provide academically led acute and specialist services, to people from the local area, from throughout the United Kingdom and overseas.

Our vision is to deliver top-quality patient care, excellent education and world-class research. We provide first-class acute and specialist services across eight sites:

- University College Hospital (incorporating the Elizabeth Garrett Anderson Wing and Grafton Way Building)
- National Hospital for Neurology and Neurosurgery
- Royal National ENT and Eastman Dental Hospitals
- Royal London Hospital for Integrated Medicine
- University College Hospital Macmillan Cancer Centre
- The Hospital for Tropical Diseases

We are dedicated to the diagnosis and treatment of many complex illnesses. UCLH specialises in women's health and the treatment of cancer, infection, neurological, gastrointestinal and oral disease. It has world class support services including critical care, imaging, nuclear medicine and pathology.

We are committed to sustainability and have pledged to become a carbon net zero health service, embedding sustainable practice throughout UCLH. We have set an ambitious target of net zero for our direct emissions by 2031 and indirect emissions by 2040. Clinical Directorates

This post is based at the National Hospital for Neurology and Neurosurgery (NHNN) which is the largest division within the Specialist Hospitals Board of the University College Hospital Foundation NHS Trust

The Specialist Hospitals Board is made up of five divisions, including Queen Square (NHNN and the Royal London Hospital for Integrated Medicine), The Royal National Throat, Nose and Ear Hospital, the Eastman Dental Hospital, Women's Health (the Elizabeth Garrett Anderson and Obstetric Hospitals) and Paediatric and Adolescent Services and is led by Professor Tim Hodgson, Medical Director.

UCLH Vision and Values

At UCLH, we have a real 'One Team' ethos, and our values – safety, kindness, teamwork and improving, are central to the way we work. This is supported by our staff, who voted us as the #1 NHS Acute Trust to work for in the whole of England.

The Trust is committed to delivering top quality patient care, excellent education and world-class research.

We deliver our vision through <u>values</u> to describe how we serve patients, their families and how we are with colleagues in the Trust and beyond.

We put your safety and wellbeing above everything

Deliver the best outcomes	Keep people safe	Reassuringly professional	Take personal responsibility
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We offer you the kindness we would want for a loved one

	Respect individuals	Friendly courteous	and	Attentive helpful	and	Protect dignity	your
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We achieve through teamwork

Listen and hear	Explain involve	and	Work partnership	Respect everyone's time
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We strive to keep improving

Courage to give and	Efficient	and	Develop	through	Innovate	and
receive feedback	simplified		learning		research	

Equality, Diversity, and Inclusion at UCLH

At UCLH, we take equality of opportunity seriously and are committed to being a diverse and inclusive employer, with a culture that creates a real sense of belonging and trust. Respect, inclusion and sensitivity are hallmarks of quality of our care. That is why it is our fundamental aim, to recruit, retain and promote a diverse mix of people from all backgrounds, cultures, and perspectives, who are representative of our local communities to support our world class research, innovation, and creativity. We are proud to have 5 different networks that are owned and led by our staff which give a voice to all our staff to feed up to leadership of the organisation, including the Trust board, thus creating a sense of community and support and help drive cultural change to become a more inclusive organisation.

Our staff networks are:

- Black, Asian and Minority Ethnic (BAME) Network
- Lesbian, Gay, Bisexual Transgender, Queer, Intersex and Asexual (LGBTQIA+)
- Women's
- Disability Network
- Mental Health Network

National Hospital for Neurology and Neurosurgery

This postholder will work alongside the Queen Square MND Centre and neuromuscular clinical research teams at the National Hospital for Neurology and Neurosurgery (NHNN). NHNN is an internationally renowned centre and is the largest division within the Specialist Hospitals Board of University College Hospital Foundation NHS Trust. It is also closely associated with Institute of Neurology (ION), a specialist postgraduate teaching and training institute of UCL. In combination they form a national and international centre at Queen Square for teaching, training and research in neurology and allied clinical and basic neurosciences. The Institute website is at: http://www.ion.ucl.ac.uk/.

In 2001 the Institute of Neurology was awarded a Grade 5*A rating (the highest possible rating), and this record of exceptional achievement was repeated in the 2008 Research Assessment (RAE). Overall 70% of research was deemed to be internationally competitive or world leading, and there are a number of important research centres based at the Institute. These include:

- Wellcome Centre for Neuroimaging http://www.fil.ion.ucl.ac.uk/
- MRC Prion Unit
- Centre for Neuromuscular Diseases https://www.ucl.ac.uk/centre-for-neuromuscular-diseaseshttp://www.ucl.ac.uk/neuromuscular/
- Dementia Research Centre http://www.dementia.ion.ucl.ac.uk/
- Department of Health Dementias and Neurodegenerative Diseases Research Network (DENDRON) http://www.dendron.org.uk/
- QS MND Centre (https://www.ucl.ac.uk/ion/research/research-centres/motor-neuron-disease-centre)

The QS MND Centre is part of a national network of Universities and NHS Institutes at the forefront of research and treatment of motor neuro disease (MND; Directors: Professor Linda Greensmith and Prof Andrea Malaspina). It is at the nexus of recent developments towards the creation of a UK MND Research Institute and it is one of the 5 Universities and NHS Trusts in the UK that are part of the united to end MND (U2EM) effort to establish a translational platform, where research in the lab is expected to feed into clinical trials and vice versa. MND clinics within the Centre cover a large catchment population for referrals of over 5 million people and from the whole of the UK. The Centre has adopted and it is in the process of starting early and late phase clinical trials, taking part in platform studies (SMART) and partnering in international consortia including the largest European research initiative to find a cure for ALS to date (TRICALS). The Centre works closely with Leonard Wolfson Experimental Centre (LWEC), a dedicated neuroscience experimental medicine facility at the National Hospital for Neurology and Neurosurgery (NHNN) at QS, to conduct phase one and phase two clinical trial including first in human investigations. The Centre for Neuromuscular Diseases (CNMD) (Directors: Professor Michael Hanna and Professor Mary Reilly) is the largest clinical and research centre in the UK for patients with muscle wasting disease such as muscular dystrophy and peripheral neuropathy. The development of clinical trials is one of the 5 key priorities in this centre.

The post holder will have overall responsibility for one or more multi-disciplinary clinical studies in the QS MND Centre. The appointee will be expected to play a major role in overseeing and be responsible for the day-to-day management of conducting clinical drug trials as part of the MND Centre, work closely with our senior clinical trial research coordinator, existing research Nursing staff, Principal Investigators, research support staff and the research team at the CNMD and LWENC to ensure compliance with Trust Policy, Good Clinical Practice (GCP), Human Tissue Act (HTA), and trial specific protocols.

This varied and challenging post, will involve, among other tasks: acting as a first point of contact for potential and recruited patients, entering patients into the database, ensuring that

all necessary study procedures and assessments are performed, take responsibility for supporting the monitoring of safety of the study participants and reporting events as required by protocol, and liaise with multidisciplinary colleagues to ensure the smooth operation of the trials, and in compliance with the protocols and relevant legislation. The post-holder would also be expected to support where necessary the preparation of regulatory submissions in conjunction with the trial coordinators attached to the QS MND Centres and CNMD.

Job Purpose

The Research Nurse is an autonomous practitioner working within the multi-disciplinary team. The post holder will be required to work according to the NMC Code of Professional Conduct and relevant professional guidelines, taking responsibility for the coordination and support of clinical trials within the QS MND Centre and CNMD. Responsibilities include coordination of care of patients on trials, collection and preparation of biological samples, administration of experimental agents and monitoring of expected and unexpected side effects of drugs and other treatment modalities, and patient/carer education. The post holder will be expected to develop specialized skills and knowledge relating to the conduct of clinical trials in MND, the therapies and relevant disease types. The post holder will be expected to have sufficient skills to enable the patients to make informed choices concerning their involvement in clinical trials by providing advice and information and acting as the patient's advocate.

The post holder will also be responsible for liaising with drug companies if required and other study sponsors and ensuring the accurate collection and submission of data, in line with the study protocols and research regulations, as well as to deputise for the Senior Research Nurses in their absence.

The post holder will function as part of a dynamic team and have an active involvement in the wider NHNN and neuromuscular and research teams and UCLH research nurses group activity.

The Successful applicant will:

- The post holder will be working within a team of research nurses, study co-ordinators, clinicians and scientists within the QS MND Centre and the CNMD.
- Play a major role in overseeing and conducting clinical trials as part of the NHNN and UCL QS MND Centre clinical and research teams.
- Conduct assessments and monitoring of patients entering and participating in research
- Liaise with multidisciplinary teams to ensure the smooth conduct of the study in accordance with the protocols and relevant legislation and guidelines.
- Maintain and update clinical study database(s) of patients for research.
- Provide an expert information source for patients, carers and health care professionals.
- Take responsibility for other duties relevant to the effective running of the trials.

Key Results Areas

Research and development

- Assist with or lead (as appropriate) the assessment, development, implementation and evaluation of clinical research studies, and the setting of standards of practice.
- Assist with or lead (as appropriate) patient recruitment and day to day management/ organisation of clinical trials and studies, to include: patient assessment, data collection and database management, blood sample collection, monitoring of adverse reactions and compliance.
- Assist with data entry on to clinical trial database.
- Have an up to date working knowledge of governing research legislation.
- Ensure the specific study protocols and procedures are adhered to in accordance with local practice and Good Clinical Practice Guidelines (GCP).
- Participate in audit programmes and identify areas of potential research relating to the speciality.
- Identify own developmental needs and establish objectives for personal development
- Take part in reflection and appropriate learning from practice, to maintain and develop competence and performance.
- To maintain an effective working relationship with the CRN by maintaining regular contact
 with the regional network manager to facilitate patient recruitment and retention for clinical
 trials and help in the collection and feeding of accrural data for studies in the national
 portfolio.

Clinical

- Assume responsibility for the nursing care of research participants.
- To collect clinical data and to administer functional rating scales and questionnaires to evaluate patients in accordance with study protocols.
- Assist clinicians in the assessment of the neurological and respiratory functional state in the progression of the clinical trial.
- Assist or lead (as appropriate) and supervise the scheduled remote collection of patients reported functional measure as specified in the research Protocols.
- Adhere to Trust-wide clinical trial protocols. e.g. manual handling, infection control.
- To act as contact point (for trial issues) for the participant.
- Maintain health, safety and security of self and others in own work area through ensuring own and others' knowledge of relevant local / national policies and procedures, and that these are adhered to.

- Work according to the QS MND Centre and the CNMD Code of Professional Conduct and relevant professional standards and guidelines.
- Promote peoples' equity, diversity and rights, through ensuring that own and others' practice is in the best interests of patients
- Develop own knowledge and expertise within the MND speciality / research field.
- To collect clinical data and use the appropriate scales to evaluate patients in accordance with trial protocols
- To collect blood samples when required from patients, their relatives and volunteers;
- To work in co-operation with other members of the neurological/neuromuscular disease clinical service and clinical research team
- Maintain knowledge and up-to-date competency with regards to emergency treatment measures and trust protocols, e.g. anaphylaxis.
- Refer to other health professionals when this will improve health outcomes or when risks and needs are beyond own competence and scope of practice
- Support patients in the delivery of care and meeting their health and wellbeing needs by providing advice and information, promoting their wishes and beliefs and addressing their concerns

Management/Education /Leadership

- Develop effective planning, organising, problem-solving and prioritisation skills.
- Manage own workload effectively through developing project and time management skills.
- Negotiate and agree with individuals, groups and other practitioners, outcomes, roles and responsibilities and action to be taken to develop resources, services and facilities.
- Maintain appropriate channels and styles of communication to meet the needs of patients, relatives and carers, managers, peers and other professions / agencies.
- Develop and use effective decision-making skills and evaluate the process and results.
- Responsible and accountable for resource issues directly related to the research studies as delegated.
- Liaise with Divisional and related departments (i.e. pharmacy and laboratories) as appropriate.
- Ensure adequate study supplies are maintained; order further stocks/supplies as required.
- Contribute to local, national and international research nurse networks to exchange and enhance knowledge and expertise.

- Participate in a peer network of support, information and learning with other research nurses at UCLH.
- To help the research team in the preparation and submission of research protocols to the relevant ethics committees and R&D committees for approval.

Communication/administration

- Provide nursing advice and support to patients participating in research studies and be identifiable as point of contact.
- Provide advice and support to the multidisciplinary team both internally and externally regarding patients and research studies.
- Contribute to effective communication between trial centres, sponsors and investigator sites nationally and internationally as required.
- Promote effective communication with study participants regarding study protocol, patient information sheets and consenting procedures and abide by ICH/GCP research practice.
- Ensure that appropriate information is disseminated within the speciality, the organisation and within external agencies and forums.
- Disseminate study data, research outcomes and specialist knowledge via poster presentations, written publication and other media as appropriate at local, national and international conferences.

Miscellaneous

- To carry out any other duties as are within the scope, spirit and purpose of the job, the title of the post and its grading as requested by the line manager or Head of Department/Division.
- To understand and adhere to Trust policies and procedures.
- To ensure that trust wide standards are maintained and monitored to improve the quality of care to all those who come in contact with the service provided by the Trusts.
- Facilitate change to meet the needs of the service
- Act in manner consistent with the QS MND Centre and the CNMD carrying out role in accordance with locally agreed policies and procedures.
- Ensure all documentation relating to participant care is clear, concise and legible and in accordance with NMC 'Standards for Records and Record Keeping'.
- Ensure familiarity with risk issues pertaining to confidentiality of participant and research related documentation (Data protection act, Caldicott 1999).

General

 To adhere to the UCLH Service Commitment "Putting Patients First" and adopt a professional approach to customer care at all times.

- To comply with the Trust's Equal Opportunities Policy and treat staff, patients, colleagues and potential employees with dignity and respect at all times
- To take personal responsibility for promoting a safe environment and safe patient care by identifying areas of risk and following the Incident, Serious Incidents and Near Misses reporting policy and procedure
- To take personal responsibility for ensuring that UCLH resources are used efficiently and with minimum wastage and to comply with the Trust's Standing Financial Instructions (SFIs).
- To comply with Trust policies for personal and patient safety and for prevention of healthcare-associated infection (HCAI); this includes a requirement for rigorous and consistent compliance with Trust policies for hand hygiene, use of personal protective equipment and safe disposal of sharps
- In accordance with the Trust's responsibilities under the Civil Contingencies Act 2004 to undertake work and alternative duties as reasonably directed at variable locations in the event of and for the duration of a significant internal incident, major incident or pandemic.
- To be aware of and adhere to all Trust policies and procedures, the Health and Safety at Work Act and the Data Protection Act
- To act at all times in accordance with the QS MND Centre and the CNMD Code of Conduct and ensure that the highest standards are maintained in the delivery of all aspects of patient care.
- To maintain confidentiality at all times.

Other

These guidelines are provided to assist in the performance of the contract but are not a condition of the contract. The job description is not intended to be exhaustive and it is likely that duties may be altered from time to time in the light of changing circumstances and after consultation with the postholder.

All staff will be regularly assessed on their knowledge, skills and behaviour, and application of all aspects of the job description, in line with the Trust's Personal Development Review (PDR) process.

Staff will also be expected to abide by the relevant code of professional practice relating to their discipline.

Key Working Relationships

Identify the reporting arrangements and job titles of the posts directly reporting to the post holder; indicate whether there is a full line management, or supervisory responsibility.

Specify other major working relationships and liaison with any other departments or external agencies.

For example:

Directors of Nursing, Divisional Managers, Consultant Medical Staff, Workforce, Finance

Insert an organisational chart to demonstrate how the job fits into the rest of the organisation. It must be clear to whom the job holder is responsible for and whether they have any other key lines of accountability, e.g. to a professional head. It should show:

- The manager's position;
- Job titles of colleagues reporting to the same manager/peers (not their names);
- Jobs reporting directly to the job holder.

It is usually best to draw the organisation chart with the manager in the centre at the top, the job in question immediately below with peers on either side. Jobs which report to the job holder should then be shown below

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Key Results Areas

The primary responsibilities of the post holder. The focus should be on results rather than activities. There should be between 3 and 6 key result areas or perhaps more if the job is very senior.

Main Duties and Responsibilities

There is no definitive way of recording main duties and responsibilities. The following are the top 5 tips for completing this section.

- 1. Be readily understandable to potential applicants for the post avoid jargon and unexplained acronyms and abbreviations.
- 2. Use active verbs not passive verbs. For example explain further "Support the implementation of the National Standards Framework" with "by developing policies for the service, ensuring staff are aware of the standards and by monitoring outcomes".
- 3. Avoid ambiguity about responsibilities and be clear about the post holder's accountability for resources, staff etc.

For example:

- Responsible for the day to day management of a group of staff including work allocation, performance/attendance issues, participating in recruitment, appraisal and development; or
- Supervision of reception staff, including work allocation and checking.
- 4. To help structure the main tasks and responsibility section further the key areas of the job should be broken into smaller sections such as:
- Professional / Clinical responsibilities
- Management and Leadership
- Financial responsibilities
- Information management
- Education & Professional Development
- Operational Delivery
- Project Management
- Risk & Governance Management
- Service Development

Agenda for Change job factor plan terminology should be avoided where possible and avoid the use of factor names as your subheadings unless they are relevant to your role.

N.B.Some roles require additional levels of checks as a part of the employment process i.e. roles which come into contact with children, vulnerable adults or their families should have the responsibility towards their welfare, explicitly stated in the job description.

Other

The job description is not intended to be exhaustive and it is likely that duties may be altered from time to time in the light of changing circumstances and after consultation with the post holder.

You will be expected to actively participate in annual appraisals and seek to implement our Equality, Diversity and Inclusion Policy and the objective to promote

equality of opportunity in relation to the duties of the post. Objectives will be set, that your performance will be monitored against in conjunction with your manager.

Sustainability at UCLH

You will be required to demonstrate a personal commitment to the Trust's Net Zero Strategy and to take personal responsibility for carrying-out your work duties in a way which is compliant with this strategy.

Person Specification

Band 6 Clinical Research

Post:: Nurse Dept/Ward: Neuromuscular

Diseases

MRC Centre for

REQUIREMENTS	*E/D	How assessed	Met	Not Met	EVIDENCE TO SUPPORT ASSESSMENT
Qualifications/Experience a. Registered Nurse b. Relevant post-registration programme c. Teaching/Assessment programme d. Minimum 2 years' relevant post registration experience at senior band 6 level	E E E D	A A A			
e. Completed/completing Honours Degree in	Е	Α			
Nursing, midwifery, research or ethics f. Completed/completing Masters/Degree g. Leadership development programme h. Management development programme i Clinical knowledge of neuromuscular diseases	D D D	A A A			
2. Clinical Practice a. Demonstrates up to date knowledge and expertise in the specialty	Е	A/I			
b. Evidence of ability to work collaboratively	E	A/I			
c. Knowledge of key professional issues and NMC guidelines relating to professional practice	E	_			
3. Education / Researcha. Evidence of continuing professional	E	А			
development b. Previous experience of formal &	Е	A/I			
informal teaching of patients & staff. c. Knowledge of research design and	D	A/I			
methods d. Knowledge of good clinical practice	D	A/I			
guidelines (GCP) e. Knowledge of trust research governance	Е	A/I			
issues f. Skills in critical analysis and application	D	A/I			
of research to practice g. Experience of developing standards,	D	A/I			
guidelines and policies f. Experience in audit and evaluation of	D	Α			
practice / services	D				

g. Published articles / poster presentations		Α		
4. Communication/administration a. Demonstrates commitment to multidisciplinary working b. Able to work across organisational and	E	I		
professional boundaries c. Able to negotiate effectively with different disciplines	Е	I		
d. Understanding of relevant national strategy / policy and how this relates to	Е	I		
research governance	D	I		
5. Leadership a. Demonstrates a clear vision of the role and service.	E	ı		
b. Decision making skillsc. Able to work autonomouslyd. Able to resolve complex problems	E E E			
e. Able to initiate, sustain and evaluate change. f. Effective communicator, in writing,	Е	A/I		
verbally & electronically g Presentation skills h. Keyboard and word processing skills	E E E	 		
6. Other Requirements a. Awareness of budgetary management b. Commitment to maintaining own fitness for practice through maintaining a personal portfolio of competencies c. Understanding of appropriate health and	D E	A/I I		
safety legislation d. Understanding of equal opportunities e. Ability to manage change f. Responsiveness and flexibility as service requires	E E E			

Shortlist:	Yes / No	Reason:

Signatures:

Offer Post: Yes / No Reason:

Signatures: