



ROLE PROFILE

Job Title:	Trial Coordinator (Fixed Term)
School/Department:	School of Medicine – Nottingham Clinical Trials Unit (NCTU)
Job Family and Level:	APM Level 3
Contract Status:	This post will be offered on a fixed-term contract for a period of one year
Hours of Work:	Preferably this will be a full time position (36.25 hours); however applications are welcome from candidates wishing to work part-time to a minimum of 0.8 fte, 29 hours per week. Please indicate on your application the hours you wish to work
Location:	Nottingham Clinical Trials Unit, Queen’s Medical Centre, South Block
Reporting to:	Trial Manager

Purpose of the New Role:

To provide management and operational support for the Trial Manager in day-to-day running of the trial in order to ensure effective and efficient trial conduct. They will work closely with the Trial Manager, Chief Investigator, local Investigators, and the NCTU Senior Trial Manager to ensure successful completion of studies. The candidate may work on more than one trial over time. This job description may be subject to revision following discussion with the person appointed and forms part of the contract of employment.

	Main Responsibilities	% time per year
1.	<p>General Research-related Duties</p> <p>To provide management and operational support to the Trial Manager in effective and efficient trial conduct, by:</p> <ul style="list-style-type: none"> • Supporting the CI and Trial Manager to write and prepare applications for submissions to the Health Research Authority (HRA), Research Ethics Committee (REC) and Regulatory Authorities (Medicines and Healthcare products Regulatory Agency – MHRA). • Co-ordinating the implementation of all necessary trial approvals. • Assisting with development and writing of study related documents, reports and processes (e.g. protocol, participant information sheets, informed consent forms, case report forms etc.) in accordance with relevant Standard Operating Procedures (SOPs). • Working with the Trial Manager to deliver trial-related training. • Working with the Trial Manager to monitor centre recruitment, data completeness and quality, and retention of participants in follow up; and to identify problems, and implement strategies to overcome any identified problems. • Assisting the Trial Manager in performing site monitoring according to the monitoring plan. • Preparing trial correspondence and communications e.g. newsletters, flyers, posters and other updates for centres. 	40

	<ul style="list-style-type: none"> • Providing support to the Trial Manager for preparing documentation and contributing to Investigator, Trial Steering Committee, Data Monitoring Committee, and Trial Management Group meetings. • Working in accordance with Good Clinical Practice and undertaking regular training to keep up to date with all relevant research regulations and research methodology. • Contributing to unit-wide activities and process improvements, for example sitting on working groups, reviewing SOPs and sharing best practice. • Adherence to appropriate trial regulations and procedures to ensure conduct of the whole life-cycle of the trial. 	
2.	<p>To provide operational support to the Trial Manager to help ensure the smooth running of the trial. This will include:</p> <ul style="list-style-type: none"> • Printing, sending and tracking of trial materials to trial sites and / or participants. • Preparation and maintenance of trial files and documentation. • Arranging and coordinating trial-related meetings and documentation including taking and writing of meeting minutes. • Liaising with third party providers. • Assisting with monitoring of trial budgets and performing financial reconciliation activities. 	20
3.	<p>To provide research specific data entry / data validation support:</p> <ul style="list-style-type: none"> • Working in accordance to the trial data management plan and associated documents. • Ensuring timely entry and management of trial data. • Ensure quality of trial data. • Working collaboratively with other members of the trial team to identify and resolve data issues in a timely manner in accordance with trial documents. 	20
4.	<p>Project Management.</p> <ul style="list-style-type: none"> • Contributing to the development of a project plan as appropriate for the project. • Adherence to project timelines. • Tracking/monitoring of project progress in accordance to project plan and needs of the trial escalating issues to the Trial Manager as appropriate. 	15
5.	Any other duties appropriate to the grade and role of the post holder.	5

Knowledge, Skills, Qualifications & Experience

	Essential	Desirable
Qualifications/ Education	<ul style="list-style-type: none"> • HNC or HND in a relevant subject, or equivalent qualifications/certification, plus considerable experience in a relevant role(s) in a research environment. 	<ul style="list-style-type: none"> • Degree (or equivalent qualification) in a relevant subject or significant experience as a Clinical Trial Administrator.
Skills/Training	<ul style="list-style-type: none"> • Excellent Computer literacy skills particularly in using Microsoft applications (Word, Excel and Outlook). • Excellent organisational skills. • Able to prioritise and manage own workload and work with minimal supervision. • Capable of flexibly managing own workload. • Ability to use own initiative. • Knowledge of databases. • Understanding of research approvals (Ethics and Trust approval). • Excellent communication skills both written and oral. 	<ul style="list-style-type: none"> • Excellent presentation skills. • Self-motivated and able to motivate and influence others within a multi-disciplinary team from a range of professional backgrounds and levels of seniority. • Demonstrate initiative to deal with challenges. • Working knowledge of Clinical Trial Regulations. • People management skills.
Experience	<ul style="list-style-type: none"> • Experience of working in a clinical trial research environment. • Clinical trial data entry. 	<ul style="list-style-type: none"> • Experience in clinical trial coordination/ management and track record of successfully completed trials.

		<ul style="list-style-type: none"> • Experience of writing proposals and study related documents within teams.
Personal Attributes	<ul style="list-style-type: none"> • Ability to work alone, as well as part of a team. • Ability to work under pressure and to deadlines. • Adaptable and flexible to hours and work. • Excellent attention to detail. • Excellent team player. 	
Other	<ul style="list-style-type: none"> • Travel to UK sites will be required for training, support and monitoring as applicable. • Willingness to adopt the Ethos and Principles of the School of Medicine to improve the student experience. 	

Additional Information

<p>Working Environment: Nottingham Clinical Trials Unit (NCTU) is a UK Clinical Research Collaboration registered Clinical Trials Unit (http://www.ukcrc-ctu.org.uk) based in the School of Medicine at the University of Nottingham. The unit's mission is to conduct high quality, high impact multicentre trials to improve health and well-being. The unit has close links with local NHS Trusts (Nottingham University Hospital NHS Trust, Nottinghamshire Healthcare NHS Foundation Trust, and Derby Teaching Hospitals NHS Foundation Trust), the Institute of Mental Health and the School of Health Sciences.</p> <p>NCTU has a broad portfolio of trials including studies evaluating medical devices, CTIMPs and complex interventions. Particular strengths and clinical areas with potential for further development are trials of skin conditions and wound healing, perinatal trials, gastroenterology, respiratory, stroke, mental health, hand surgery and genitourinary medicine. The unit currently has around 50 staff, and with the recent investment of strategic development funding from the University this is anticipated to expand to 100 staff over the next 3-5 years.</p> <p>For further information see: www.nottingham.ac.uk/ctu</p> <p>Scope of Role The position will be within the Nottingham Clinical Trials Unit. The role holder will primarily support the project trial manager, but will also be expected to support other ongoing trials in the department, as required.</p> <p>This will enable the most efficient use of our trial managers, whose responsibility it will be to ensure that the study is being run to the highest possible standard, and within the time frame allowed by funders. This will facilitate the high quality research output of the department / school.</p>



The University of Nottingham strongly endorses Athena SWAN principles, with commitment from all levels of the organisation in furthering women's careers. It is our mission to ensure equal opportunity, best working practices and fair policies for all.

Appendix 1

The University of Nottingham

Described by the Times Good University Guide 2017 as "the nearest Britain has to a truly global university" The University of Nottingham has award-winning campuses in the UK, China and Malaysia and hosts a global academic community in all three countries. The University has an institution-wide commitment to embedding an international dimension across all of our activities enabling us to produce graduates who are empowered to excel in a challenging global environment and deliver genuinely world-changing research.

Our reputation for world-class research has yielded major scientific breakthroughs such as Nobel-winning MRI techniques, drug discovery, food technologies and engineering solutions for future economic, social and cultural progress.

Already ranked among the UK's elite universities and global polls for research excellence, our reputation for world-class research has been further enhanced with the 2014 results of the Research Excellence Framework (REF).

In addition to scoring highly in quality rankings covering major disciplines in science, engineering, the social sciences, medicine, business and the arts, it is Nottingham's research power rankings which demonstrate the impressive volume of excellent research which is carried out. We are now ranked 8th in the UK on a measure of 'research power' which takes into account both the quality of research and the number of research-active staff who made REF returns, confirming Nottingham's place in the top tier of the world's elite higher education institutions.

The main University campus is set beside a lake, in an extensive belt of woodland, parks and playing fields. The 330 acre University Park Campus is the focus of life for more than 32,000 students and houses the majority of the University's academic schools and many of the central Services. The Jubilee campus is situated 2 miles away from the University Park, and provides extra capacity. The University Medical School is situated next to the University Park. Together with the University Hospital, it forms the Queen's Medical Centre (QMC).

University of Nottingham Medical School

Nottingham has a strong reputation for both clinical medicine and teaching. As one of the most popular medical schools in the country, it is able to select excellent students and produce and attract good junior doctors.

The School of Medicine comprises the Divisions of Cancer and Stem Cell Sciences, Child Health, Obstetrics and Gynaecology; Clinical Neuroscience; Epidemiology and Public Health; Primary Care; Psychiatry and Applied Psychology; Rehabilitation and Ageing; Medical Sciences and Graduate Entry Medicine; Respiratory Medicine; Rheumatology, Orthopaedics and Dermatology and the Nottingham Digestive Diseases Centre. The School also hosts the Education Centre, the Centre for Interprofessional Education and Learning, the Clinical Research Facility, the Clinical Skills Centre, NIHR Design Service East Midlands, Nottingham Clinical Trials Unit, PRIMIS and Medical Imaging Unit.

The School of Medicine brings together in one School staff undertaking research for the benefit of the health of patients. It includes all primary care and hospital-based medical and surgical disciplines, principally in the Queen's Medical Centre and City Hospital Nottingham Campuses, Royal Derby Hospitals NHS Foundation Trust and also at the University's main campus and at the King's Meadow and Jubilee Campuses. Most of our School's Senior Researchers and Teachers are also clinicians who dedicate 50% of their time to patient care within the Nottingham University Hospitals NHS Trust & Royal Derby Hospitals NHS Trust. This close juxtaposition brings cutting-edge clinical care to our patients and clinical relevance to our research and teaching. We are closely integrated with our full time NHS clinical colleagues, many of whom are themselves leaders in research and teaching and who work closely with the University and this increases the mutual benefit from integration between the University and NHS.

Mission:

Our mission is to improve human health and quality of life locally, nationally and internationally through outstanding education, research and patient care.

Priorities:

1. **Teaching and learning**, particularly training tomorrow's doctors and teaching specialised postgraduates
2. **Research and research training:** We will perform and support the highest quality "big" research which impacts on human health and disease
3. **Partnership with the NHS** and other healthcare providers
4. **Visibility and profile of the School of Medicine:** We will do what we do better, and we will tell others about it

Ethos and principles:

1. **Having people and patients at the heart of all we do:** our teaching and learning, our research and our patient care
2. **Contribution within the School of Medicine and to society** beyond our immediate roles; helpfulness and service
3. **Openness and fairness**, with particular emphasis on communication (both internal and external) and on equality and diversity among students and staff
4. **Personal and group responsibility** for all aspects of our work, within a culture of opportunity and reward

Our research spans 11 major themes, ranging from cancer to vascular medicine. We work closely with industry and the NHS. Our world-leading research ranges from basic and translational science through to clinical trials, epidemiology, and health services research. Our clear theme is improving human health,

underpinning a vibrant postgraduate research training programme leading to PhD or DM. Many of our academics are clinicians, using their expertise to provide cutting edge specialised treatment to NHS patients; reflecting our ethos that patients are at the heart of all we do.

The partnership between University of Nottingham and Nottingham University Hospitals NHS Trust was recently awarded by NIHR, a transformational £23.6 million to expand their pioneering work into new treatments and diagnostics for a wide range of health problems, establishing a new Biomedical Research Centre (BRC), which will incorporate two existing smaller Biomedical Research Units in the city. The Nottingham BRC will be the leading UK hub in five key areas of health research:

- Deafness and hearing loss
- Gastrointestinal and liver disease
- Respiratory medicine
- Musculoskeletal disease
- Mental health technology

At the core of the Biomedical Research Centre will be Nottingham's world-leading expertise in magnetic resonance imaging (MRI). It means the latest medical imaging research and technology pioneered here can be translated into real benefits for patients in all five of the BRC's research areas.

In the 2014 Research Excellence Framework the four Units of Assessment included in the School of Medicine were among the six most improved in the whole University since RAE 2008: Over 80% of our research in 2014 was graded as world-leading or internationally excellent. Our research spans 11 major themes and ranges from basic and translational science through to clinical trials, epidemiology, and health services research. We work closely with industry and the NHS. Our research is underpinned by a strong postgraduate research training programme leading to PhD or DM. Our major research themes are in Cancer and Stem Cells; Child Health, Obstetrics & Gynaecology; Clinical Neurosciences; Dermatology; Digestive Diseases; Epidemiology and Public Health; Mental Health; Musculoskeletal physiology and disease; Primary Care; Rehabilitation and Ageing; Respiratory Medicine; and Renal Medicine.

The School of Medicine trains tomorrow's doctors on a vibrant undergraduate medical course with a unique intercalated BMedSci, as well in a specialised graduate-entry programme built around clinical problem solving. We teach medicine and related disciplines at both undergraduate and postgraduate level. We have a dedicated clinical academic training programme and are committed to training PhD and doctoral research students and to supporting postdoctoral clinicians and scientists in their research.

Professor Tony Avery is Dean of the School of Medicine.

For further information, please see our website <http://www.nottingham.ac.uk/medicine>

Nottingham

Central within the East Midlands, Nottingham is a vibrant and prosperous city with something to offer everyone. It is one of the UK's leading retail centres and has a huge variety of restaurants, bars and nightclubs which attract people from all over the UK. Culturally, it has good theatres, an arena which attracts both national and international performers and a range of historical interests relating to subjects such as the lace industry, Lord Byron and DH Lawrence. Nottingham is also known for sport, being the home of Trent Bridge Cricket Ground, Nottingham Forest and Notts County Football Clubs, the National Water Sports Centre and the Nottingham Tennis Centre. There is a good network of roads with easy access to the M1 and the A1, a fast frequent rail service to London and other major cities. Nottingham East Midlands Airport is only eighteen miles away.

The city is set within a county of outstanding natural beauty which includes Sherwood Forest, Wollaton Park, lively market towns and wonderful historic buildings. Housing is relatively inexpensive and, in addition to the two Universities, there are excellent schools and colleges available.

To find out more about Nottingham, use the following links:

Nottingham County Council – Tourism

<http://www.experiencenottinghamshire.com/>

University of Nottingham

<http://www.nottingham.ac.uk>

Zoopla (Guide to local properties)

<http://www.zoopla.co.uk/>

My Nottingham (information on schools, term dates, school transport etc.)

<http://www.nottinghamcity.gov.uk/index.aspx?articleid=8524>