

THE UNIVERSITY OF NOTTINGHAM RECRUITMENT ROLE PROFILE

Job Title:	Senior Trial Manager	
School/Department:	Nottingham Clinical Trials Unit, School of Medicine	
Job Family and Level:	Research & Teaching, level 5	
Contract Status:	Permanent post	
Hours of Work:	Full time. Applications from those wishing to work part time will be considered (minimum 29 hours per week). Please indicate on your application the hours you wish to work.	
Location:	Nottingham Clinical Trials Unit, Queen's Medical Centre	
Reporting to:	Associate Professor of Clinical Trials, Nottingham Clinical Trials Unit	

The Purpose of the Role:

To support the development and delivery of the Unit's portfolio of high quality clinical trials of national and international relevance. A significant responsibility of the post is to lead a team of trial managers, coordinators and administrators responsible for the delivery of a portfolio of clinical trial projects. The post holder will oversee the management of their trial portfolio from conception to completion, requiring extensive experience of trial design and trial management, of multidisciplinary working on clinical trials, and of delivering research excellence within trials. The post holder will be expected to work within the multidisciplinary NCTU project development team that supports chief investigators in developing their trial protocol and preparing high quality grant applications, by providing specialist trial management advice. The post holder will be expected to work closely with other members of the Unit's Operations Team to provide effective oversight of NCTU operational management, ensuring effective, high quality and timely project delivery. This will include contributing to publication of the trial protocol and results.. Over time, the post holder will be expected to develop a portfolio of trial methodology-related research.

The unit's mission is to conduct high quality, high impact multicentre trials to improve health and well-being. NCTU is based in the School of Medicine at the University of Nottingham, and 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. The unit is a UK Clinical Research Collaboration registered Clinical Trials Unit (<u>http://www.ukcrc-ctu.org.uk</u>).

NCTU has a broad portfolio of trials including studies evaluating medical devices, CTIMPs and complex interventions. Particular strengths currently are trials of skin conditions and wound healing, perinatal trials, gastroenterology, respiratory, stroke, mental health, surgery (particularly hand surgery), emergency trials, and genitourinary medicine. Other research includes methodological studies to improve the efficiency and quality of trial conduct, and systematic reviews and meta-analysis.

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.	 RESEARCH: Contributing to developing the NCTU portfolio of high quality research, by working within the NCTU multidisciplinary team supporting chief investigators to develop their protocol and prepare high quality grant applications, for example to the NIHR boards, MRC and charities. Working closely with other members of the Unit's Operations Team to provide effective oversight of NCTU operational management, including developing and implementing standardised 'fit for purpose' processes for high quality trial conduct. Maintaining research excellence by providing high quality project management and trial management expertise to a specific programme of trials within the NCTU portfolio. This will include leading a team of trial management staff responsible for the administration of a portfolio clinical trial projects, ensuring high quality compliance with appropriate regulatory and governance requirements. For this specific programme of trials: taking a leadership role in ensuring prompt publication of the protocol; and contributing to the writing of the results papers, with timely submission to a peer reviewed journal. Developing specific expertise in clinical topic areas and/or types of trial design relevant to the NCTU portfolio of work. Providing project management and trial management expertise to trials which are supported by NCTU, but are primarily co-ordinated from outside the unit. Contributing to developing an NCTU programme of methodological research in trial design and conduct. Helping ensure NCTU remains up to date with developments in the methodology of clinical trials, by attending relevant conferences and training, and by proving training within NCTU. Working with other members of the Operations Team to ensure NCTU is up to date with research regulations and governance. 	55%
2.	 MANAGEMENT: Workload planning, monitoring capacity and allocation of projects against measurable metrics. Direct line management of trial managers within their team, and providing support to trial managers with line management responsibility for trial coordinators and administrators. Providing induction training, mentoring and personal development and performance reviews for Trial Managers. Ensuring that NCTU trials are delivered on target and within budget. Ensuring that the NCTU programme of work complies with the appropriate requirements of research governance and regulation. Managing recruitment of new trial project staff including drafting job descriptions, short-listing, and interviewing. Managing the offer and acceptance process, liaising with HR as appropriate. Working with the Senior Data Manager to developing effective systems for monitoring NCTU trial-specific activity, and data quality. Liaise with appropriate groups/staff both within the University and local organisations on project management issues 	40%
3.	Any other duties appropriate to the grade and role of the post holder.	5%

Knowledge, Skills, Qualifications & Experience

	Essential	Desirable
Qualifications/ Education	PhD or equivalent and/or Degree in health related sciences	PhD / MSc or equivalent, preferably in clinical trial related subject.
	OR	
	Extensive experience in a clinical trials research.	
Skills/Training	Excellent project management skills, with evidence of effective project management within multi-centre trials and other complex trial designs.	Financial awareness and financial management skills. Evidence of the ability to publish
	Excellent knowledge and expertise in the trial design, trial conduct and trial delivery.	in international journals. Experience of developing successful grant applications.
	Ability to communicate and work effectively with academics and clinicians.	Experience in presenting to national and/or international scientific meetings.
	Evidence of the ability to publish in national and international journals	
	Strong leadership skills.	
	Ability to work collaboratively across disciplines.	
	Evidence of being self-motivated within research, and able to take appropriate responsibility.	
	Excellent ability to prioritise, and to work flexibly and effectively under pressure. Able to enjoy and work effectively in a demanding and challenging environment.	
	Up to date knowledge of Clinical Trial Regulations, and research governance guidelines.	
Experience	Experience in clinical trial coordination/ management and a track record of successfully completed trials.	Track record of publication in peer reviewed journals.
	Experience of contributing to successful grant applications.	

	Experience of writing trial protocols, trial materials, regulatory documentation, and research papers. Proven record in delivering multi- centre, and other complex randomised trials. Extensive knowledge of the set-up, costing, management and delivery of clinical trials. Experience of managing staff	
Statutory/Legal		Experience of MHRA and sponsor audits
Other	Willingness to adopt the Ethos and Principles of the School of Medicine. Travel within the UK sites will be required.	



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.

The School of Medicine holds a Silver Athena SWAN in recognition of our achievements in promoting and advancing the representation of women in science, technology, engineering, medicine and mathematics (STEMM). Please see <u>http://www.nottingham.ac.uk/medicine/about/athena-swan.aspx</u>

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

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 – Tourismhttp://www.experiencenottinghamshire.com/University of Nottinghamhttp://www.experiencenottinghamshire.com/Zoopla (Guide to local properties)http://www.zoopla.co.uk/

My Nottingham (information on schools, term dates, school transport etc.) <u>http://www.nottinghamcity.gov.uk/index.aspx?articleid=8524</u>