

Job description

Job title	Trial Manager
Division	Medical Sciences Division
Department	Oxford Population Health (Nuffield Department of Population Health, University of Oxford)
Location	Old Road Campus, Headington, Oxford, OX3 7LF
Grade and salary	Grade 7: £36,024-£44,263 per annum
Hours	Full time (37.5 hours)
Contract type	Fixed-term (12 months) Maternity Leave cover
	This post is to cover the absence of the substantive postholder who is taking a period of maternity leave. The post is available for the fixed term period or the actual return of the substantive postholder, or the resignation of the substantive postholder and employment of a new postholder, whichever is the earliest
Reporting to	Head of Operations, NPEU CTU
Vacancy reference	169074













About Oxford Population Health

Oxford Population Health (the Nuffield Department of Population Health) provides an excellent environment for multi-disciplinary research and teaching and for professional and support staff. We work together to answer some of the most important questions about the causes, prevention and treatment of disease.

The Department has around 900 staff, students and academic visitors working in a number of world-renowned population health research groups, including the Clinical Trial Service Unit and Epidemiological Studies Unit (CTSU), the Cancer Epidemiology Unit (CEU), the National Perinatal Epidemiology Unit (NPEU) and other groups working on public health, health economics, ethics and health record linkage. It is also a key partner in the Oxford University's Big Data Institute.

In the 2021 Research Excellence Framework (REF), 96% of the research submitted to Unit of Assessment 2: Public Health, Health Services and Primary Care, was ranked either 4* (world-leading in terms of originality, significance and rigour) or 3* (internationally excellent in terms of originality, significance and rigour). This comprised research from Oxford Population Health and research from the Nuffield Department of Primary Care Health Sciences. We scored particularly well for having an environment that is conducive to producing research of world-leading quality and enabling outstanding impact, in terms of its vitality and sustainability.

In addition to its research activities, the Department is home to the <u>MSc in Global Health Science and Epidemiology</u>, the <u>MSc in Clinical Trials</u>, and a variety of short courses. Students also come to undertake research for <u>DPhil degrees</u>. Teaching is provided for undergraduates reading for Medicine and for public health doctors in specialist training.

For more information please visit the **Oxford Population Health website**.

About the Medical Sciences Division

The Medical Sciences Division is an internationally recognised centre of excellence for biomedical and clinical research and teaching, and the largest academic division in the University of Oxford.

World-leading programmes, housed in state-of-the-art facilities, cover the full range of scientific endeavour from the molecule to the population. With our NHS partners we also foster the highest possible standards in patient care.

For more information please visit the **Medical Sciences Division website**.

About the University of Oxford

Welcome to the University of Oxford. We aim to lead the world in research and education for the benefit of society both in the UK and globally. Oxford's researchers engage with academic, commercial and cultural partners across the world to stimulate high-quality research and enable innovation through a broad range of social, policy and economic impacts.

We believe our strengths lie both in empowering individuals and teams to address fundamental questions of global significance, while providing all our staff with a welcoming and inclusive workplace that enables everyone to develop and do their best

work. Recognising that diversity is our strength, vital for innovation and creativity, we aspire to build a truly diverse community which values and respects every individual's unique contribution.

While we have long traditions of scholarship, we are also forward-looking, creative and cutting-edge. Oxford is one of Europe's most entrepreneurial universities and we rank first in the UK for university spin-outs, and in recent years we have spun out 15-20 new companies every year. We are also recognised as leaders in support for social enterprise.

Join us and you will find a unique, democratic and international community, a great range of staff benefits and access to a vibrant array of cultural activities in the beautiful city of Oxford.

For more information please visit the **Oxford University website**.

National Perinatal Epidemiology Unit

The NPEU is an internationally recognised, multi-disciplinary research unit based within the Nuffield Department of Population Health at the University of Oxford, Old Road Campus in Headington, Oxford. The Unit undertakes research about pregnancy, childbirth and newborn babies. This is reflected in the backgrounds of the people working in the Unit (obstetrics, midwifery, paediatrics, epidemiology, social science, economics, statistics, programming, plus administrative and clerical staff). Funding is provided by grants from a variety of sources including the Department of Health Policy Research Programme, the National Institute for Health Research (NIHR), other funding agencies and medical research charities.

For more information please visit: http://www.npeu.ox.ac.uk/

NPEU Clinical Trials Unit (NPEU CTU)

Randomised Controlled Trials (RCTs) make up a large component of the NPEU's work and the external funding that the Unit attracts. The ongoing programme of trials at the NPEU Clinical Trials Unit (NPEU CTU) evaluates a broad range of interventions for women and babies in the perinatal health services. These are typically large multi-centre trials, involving many hospitals both nationally and sometimes internationally. The NPEU CTU aims to maintain its position at the forefront of trials within the perinatal field by exploring innovative methodology and also by providing support and training for trials run from outside the CTU. The current NPEU CTU portfolio consists of around 15 trials that are either in set-up (funding awarded), open to recruitment, in follow-up or at analysis and dissemination stages.

A multi-disciplinary CTU core trials team, currently comprising the CTU Director, CTU Clinical Director, Head of Operations, Senior Trial Manager, Head of Trials Programming, Senior Trials Programmer, Lead Medical Statistician, Quality Assurance Manager and Assistant Trials Manager, who work across all aspects of the trials programme and provide senior capacity and leadership to support project-based staff who are contracted to work on the individual trials.

The NPEU CTU has full registration with the UK Clinical Research Collaboration (UKCRC) following the 2017 review process which was led by an International Review Committee of experts. Clinical Trials Units awarded UKCRC registration are required to demonstrate (i) their capability to centrally coordinate multicentre clinical trials and other well-designed studies, and (ii) the presence of established robust systems to ensure conduct and delivery of clinical trials to the highest quality standards, in line with the appropriate regulations.

The NPEU CTU receives National Institute for Health Research (NIHR) CTU Infrastructure Support Funding. This funding has been awarded to support the unit in developing and supporting NIHR trials.

For further information regarding trial-related activities within the NPEU CTU, please visit our website (http://www.npeu.ox.ac.uk/trials).

The role

This pivotal role is to provide project management for the BASE Trial. You will be the central administrative contact at the Coordinating Centre maintaining effective and efficient systems to ensure the trial delivers according to milestones. You will co-ordinate the design, implementation and running of the clinical trial across participating hospital sites in the UK, ensuring timely data collection and Good Clinical Practice (GCP) compliance, and ensure the study complies with NPEU CTU Standard Operating Procedures. This is a new trial, the post will be based within the NPEU CTU and with the Chief Investigator based at Imperial College London.

Responsibilities

- Work closely with the Chief Investigator, Trial Statistician and Trial Programmers and to liaise with the CTU Directors, Head of Operations, Senior Trial Manager and the Quality Assurance Manager to ensure the successful project management of the BASE Trial.
- Secure all necessary approvals for the trial and participating sites. Ensure the trial is run
 to UK Clinical Trial Regulations including the UK Research Governance Framework,
 GDPR and the Data Protection Act 2018, ensuring relevant documentation is
 maintained.
- Line manage the Administrative Assistant / Data Coordinator whose role involves establishing effective project and data management systems that adhere to CTU standard operating procedures.
- Work closely with the Research Nurse to monitor recruitment and provide training, support and motivation to recruiting staff as required. Promote the trial in innovative ways to ensure parents of possible participants are approached and informed about the trial.

- Work with Research Nurse to develop and maintain good relationships with Parent,
 Patient and Public Involvement partners ensuring trial collaboration on all project aspects.
- To be the first point of contact for trial stakeholders. Ensure that good communication is maintained between the BASE Trial Co-ordinating Centre and all stakeholders.
- To write and present reports and provide updates on the progress of the trial to all stakeholders including the funders, charities, the Project Management Group, Trial Coinvestigators, Collaborators, Data Monitoring and Trial Steering Committees.
- Co-ordinate the writing, design, and distribution of trial documentation, including newsletters and website. Produce mailshots, documentation and prepare communication as required. To market the trial through social media, online and with sites, as required ensuring successful trial awareness and recruitment.
- Work within budget restraints in liaison with the Senior Trials Manger and NDPH finance team.
- Represent the trial at conferences, meetings and internal unit meetings as necessary.
- Keep the relevant literature searches up to date.
- Ensure the trial is established and run in accordance with NPEU CTU Standard Operating Procedures (SOPs).
- Undertake mandatory training as required by the Unit, University, Division and Department.

The above list is not exhaustive and the role-holder is required to undertake such duties as may reasonably be requested within the scope of the post. All staff are required to act in a professional, cooperative and flexible manner, in line with the requirements of the post.

Selection criteria Essential

- Degree in a biomedical or associated subject, or other relevant qualification
- Proven experience in clinical research
- Experience in line managing staff and supporting their professional development
- Understanding of clinical research methodology, good clinical practice, knowledge of all UK regulations for clinical trials, GDPR and the research governance framework
- Experience of working on a clinical trial or in medical research
- Experience and understanding of techniques for the management of medical research information e.g. data coding, entry validation and reporting
- Proven administrative, data and project management skills
- Demonstration of a critical and intelligent attention to detail and high standards of accuracy
- Ability to work on own initiative and problem solve

- Negotiation, presentation and interpersonal skills
- Excellent organisational skills and ability to prioritise workload
- Effective written and oral communication skills
- Understanding of the confidential nature of this role

Desirable

- Willingness to travel within the UK
- Previous experience of using OpenClinica
- Experience of managing a budget

Pre-employment screening

Standard checks

If you are offered the post, the offer will be subject to standard pre-employment checks. You will be asked to provide: proof of your right-to-work in the UK; proof of your identity; and (if we haven't done so already) we will contact the referees you have nominated. You will also be asked to complete a health declaration so that you can tell us about any health conditions or disabilities for which you may need us to make appropriate adjustments.

Please read the <u>candidate notes</u> on the University's pre-employment screening procedures.

How to apply

Applications are made through our e-recruitment system and you will find all the information you need about how to apply on our **Jobs website**.

Your application will be judged solely on the basis of how you demonstrate that you meet the selection criteria stated in the job description.

As part of your application you will be asked to provide details of two referees and indicate whether we can contact them now.

You will be asked to upload a CV and a supporting statement. The supporting statement must explain how you meet each of the selection criteria for the post using examples of your skills and experience. This may include experience gained in employment, education, or during career breaks (such as time out to care for dependants).

Please upload your CV and supporting statement as PDF files with your name and the document type in the filename.

All applications must be received by **midday** UK time on the closing date stated in the online advertisement.

Information for priority candidates

A priority candidate is a University employee who is seeking redeployment because they have been advised that they are at risk of redundancy, or on grounds of ill-health/disability. Priority candidates are issued with a redeployment letter by their employing departments.

If you are a priority candidate, please ensure that you attach your redeployment letter to your application (or email it to the contact address on the advert if the application form used for the vacancy does not allow attachments).

If you need help

Help and support is available from the <u>HR Systems Recruitment support webpage</u>. If you require any further assistance please <u>email the Recruitment Support team</u>.

To return to the online application at any stage, please go to the <u>University's recruitment</u> <u>website</u>. Please note that you will receive an automated email from our e-recruitment system to confirm receipt of your application. **Please check your spam/junk mail** if you do not receive this email.

Important information for candidates

Data privacy

Please note that any personal data submitted to the University as part of the job application process will be processed in accordance with the GDPR and related UK data protection legislation. For further information, please see the University's Privacy Notice for Job
Applicants. The University's Policy on Data Protection is available on the University's Compliance webpages.

The University's policy on retirement

The University operates an Employer Justified Retirement Age (EJRA) for very senior research posts at grade RSIV/D35 and clinical equivalents E62 and E82, which with effect from 1 October 2023 will be 30 September before the 70th birthday. The justification for this is explained at: https://hr.admin.ox.ac.uk/the-ejra.

For existing employees on these grades, any employment beyond the retirement age is subject to approval through the procedures: https://hr.admin.ox.ac.uk/the-ejra.

There is no normal or fixed age at which staff in posts at other grades have to retire. Staff at these grades may elect to retire in accordance with the rules of the applicable pension scheme, as may be amended from time to time.

Equality of opportunity

Entry into employment with the University and progression within employment will be determined only by personal merit and the application of criteria which are related to the duties of each particular post and the relevant salary structure. In all cases, ability to perform the job will be the primary consideration. No applicant or member of staff shall be discriminated against because of age, disability, gender reassignment, marriage or civil partnership, pregnancy or maternity, race, religion or belief, sex, or sexual orientation.

Benefits of working at the University

Employee benefits

University employees enjoy 38 days' paid holiday, generous pension schemes, travel discounts, and a variety of professional development opportunities. Our <u>range of other employee benefits and discounts</u> also includes free entry to the Botanic Gardens and University colleges, and discounts at University museums.

University Club and sports facilities

Membership of the <u>University Club</u> is free for all University staff. The University Club offers social, sporting, and hospitality facilities. Staff can also use the <u>University Sports Centre</u> on Iffley Road at discounted rates, including a fitness centre, powerlifting room, and swimming pool.

Information for staff new to Oxford

If you are relocating to Oxfordshire from overseas or elsewhere in the UK, the University's <u>Welcome Service website</u> includes practical information about settling in the area, including advice on relocation, accommodation, and local schools. There is also a <u>visa loan scheme</u> to cover the costs of UK visa applications for staff and their dependents.

Family-friendly benefits

With one of the most generous family leave schemes in the Higher Education sector, and a range of flexible working options, Oxford aims to be a family-friendly employer. We also subscribe to the Work+Family Space, a service that provides practical advice and support for employees who have caring responsibilities. The service offers a free telephone advice line, and the ability to book emergency back-up care for children, adult dependents and elderly relatives.

The University has excellent childcare services, including five University nurseries as well as University-supported places at many other private nurseries. For full details, including how to apply and the costs, see the <u>Childcare Services webpages</u>.

Disabled staff

We are committed to supporting members of staff with disabilities or long-term health conditions. For further details, including information about how to make contact, in confidence, with the University's Staff Disability Advisor, see the <u>Disability Support webpages</u>.

Staff networks

The University has a number of staff networks including the Oxford Research Staff Society, BME staff network, LGBT+ staff network and a disabled staff network. You can find more information on the <u>Equality and Diversity at Oxford webpages</u>.

The University of Oxford Newcomers' Club

The University of Oxford <u>Newcomers' Club</u> is an organisation run by volunteers that aims to assist the partners of new staff settle into Oxford, and provides them with an opportunity to meet people and make connections in the local area.