



Job description and selection criteria

Job title	Clinical Research Manager
Division	Medical Sciences Division
Department	Nuffield Department of Women's & Reproductive Health (NDWRH)
Location	Level 3, Women's Centre, John Radcliffe Hospital, Oxford
Grade and salary	Grade 8: £45,585 to £54,395 (with a discretionary range to £59.421) per annum pro rata
Hours	Part time (30 hours/0.8 FTE) with the possibility of increasing to full time <i>Applications for flexible working arrangements are welcomed and will be considered in line with business needs</i>
Contract type	Fixed term for one year in the first instance
Reporting to	Senior Clinical Research Operations Manager
Vacancy ID	169058



The Post

Overview of the Role

The Women's & Reproductive Health Clinical Research Group (WRH-CRG) is a joint venture between the University of Oxford and the Oxford University Hospitals NHS Foundation Trust (OUHFT). WRH-CRG has the aim of facilitating translational clinical research in Maternal, Fetal and Perinatal medicine and provides a vehicle for patient and public involvement. WRH-CRG coordinates current and future projects.

The Clinical Research Manager is responsible for planning and overseeing the set up and management of a variety of trials conducted within WRH-CRG and the Nuffield Department of Women's and Reproductive Health (NDWRH) and provides essential support to the Senior Clinical Research Operations Manager. The Clinical Research Manager must work both as a member of the research team and independently, using their initiative to seek solutions to problems and provide support to the Research Midwives, Nurses and Support staff. Considerable experience in coordinating and monitoring large complex multi-site clinical trials, thorough working knowledge of the relevant ethical, legislative and research governance requirements relevant to clinical trials and experience of supervising, mentoring or training staff are essential.

Responsibilities

The post-holder's responsibilities will include:

Trial and Data Management

- Have responsibility for the general oversight of all studies running within the department.
- Oversee the project management of the NDWRH WRH-CRG portfolio of clinical trials through the development and maintenance of strong and effective stakeholder relationships and providing management and guidance to researchers undertaking academic and NHS clinical research within the Women's Centre.
- Provide up-to-date guidance and information to academic and NHS research staff and manage all aspects of Research Governance both within NDWRH and the Women's Centre.
- Maintain oversight of the overall conduct and performance of trials within the portfolio. This will include predicting, identifying and resolving problems that are critical to the conduct of trials managed by the department and planning to strategically avoid any issues.
- Discuss studies daily, if necessary, with the lead or supporting midwife or nurse regarding individual studies. Write and disseminate weekly/monthly reports based on the information provided by the research midwife/nurse including recruitment numbers and any challenges with recruitment.
- Monitor recruitment, providing support and motivation to recruiting staff as required and oversee uploading of recruitment data to the Local Portfolio Management System (Siteline) and NIHR Central Portfolio Management System. Promote the trial in innovative ways to ensure possible participants are approached and informed about the trial.

- Support researchers in submitting grant applications and provide technical advice on the development of data management plans and robust data governance and storage.
- Review potential non-commercial and industry funded studies for feasibility, protocol design, staffing resource and cost, and support the research midwives and nurses in identifying any new studies that could be supported by the team
- Meeting, supporting and working closely with NHS and University researchers (especially focusing on midwifery led research), in the development, set up and gaining of the necessary approvals for a new study.
- Use appropriate organisational and leadership skills to ensure new trials are appropriately set-up and initiated ready to commence recruitment within a specific timeframe and feedback first participant recruited information.
- Meet regularly with senior staff from both the University of Oxford Research Governance, Ethics and Assurance Team (RGEA) and Trust R & D to discuss study set up issues or issues relating to study amendments.
- Write, review and approve risk assessments, communication plans, trial monitoring plans and reports.
- Oversee the administration of Serious Adverse Events, resolving queries, logging and reconciliation of events and notification of events to the relevant committees and authorities.
- Write and submit both non-substantial and substantial study amendments, working closely with the Health Research Authority, Research Ethics Committees and local R & D in gaining the necessary approvals.

Quality Assurance

- Undertake quality control and quality assurance activities to ensure compliance to ethical and regulatory requirements as well as to measure progress and improve quality standards.
- Take overall responsibility for the development, review and implementation of local SOPs to encourage best practice and standardise procedures in order to maintain safety, quality, data integrity as well as compliance to regulations.
- Support the team in identifying, assessing and managing deviations and areas of non-compliance including reporting and developing Corrective and Preventative Action (CAPA) plans as appropriate.
- Lead on the use of iPassport (an online quality management system) for managing controlled documents, non-compliances and mandatory clinical research training.
- Take responsibility for preparing staff and study materials for audits/inspections by internal and external bodies, supporting staff during audit/inspection and with any follow-up actions that may be required.

Financial Management

- Oversee and manage trial specific budgets.
- Work with the departmental finance team to cost up both non-commercial and commercial studies ensuring all costs are included.

- Develop and maintain a resourcing model to predict and plan for resource needs and ensure that clinical trials are adequately resourced.
- Ensure that members of the WRH-CRG team have continually funded posts to strengthen the research teams and deliver the clinical trials strategy.
- Submit funding applications to a variety of funding bodies to secure the necessary funding to accommodate this.

Team Management

- Operational line management responsibility for the WRH-CRG and research teams on a day-to-day basis.
- Lead the future development of the WRH-CRG team by identifying the needs of the group and individuals.
- Provide effective leadership, direct line-management, support and role development for a number of Research Midwives, Nurses and support staff.
- Demonstrate excellent communication skills working collaboratively within a multidisciplinary team.
- Line management of the WRH-CRG Senior Research Midwives
- Ensure effective change management systems are implemented and manage the changing research environment.
- Participate in the recruitment, training and supervision of new members of the team and the ongoing training and supervision of team members.
- Work with the HR Manager and team to facilitate the team change from fixed term to open ended contracts.

Selection criteria

Essential

Applications will be judged only against the criteria that are set out below. Applicants should ensure that their application shows very clearly how their skills and experience meet these criteria within the supporting statement. This should describe, with specific examples, how you meet each item listed below. See <https://www.jobs.ox.ac.uk/cv-and-supporting-statement> for further guidance on writing an effective supporting statement; you should list each of the criteria in turn, and explain briefly how your skills and experience match these requirements.

1. A University degree and an MSc in a relevant subject (or the equivalent relevant education and experience) with evidence of continuing professional development and proven experience in clinical research.
2. Understanding and in-depth experience of clinical research methodology, good clinical practice, knowledge of all UK regulations for clinical trials and the research governance framework.
3. Extensive clinical trials experience including protocol development and implementation. Proven record of accomplishment of GCP: monitoring and/or audit in a commercial and/or non-commercial environment.

4. Extensive experience of staff management, with the ability to lead, support, motivate and delegate, working as an autonomous practitioner as well as be a team player.
5. High level of change management skills. Enthusiasm for implementing change and the ability to bring fresh thinking to research processes enabling the team to develop and improve their knowledge, skill set and improve their systems.
6. Proven organisational and project management skills with the ability to prioritise workload and use own initiative to problem-solve.
7. Well-established administrative and data management skills with critical and intelligent attention to detail and high standards of accuracy.
8. Effective written and oral communication skills, including effective negotiation, presentation and interpersonal skills.
9. Excellent IT literacy including evidence of competence with MS Office, particularly Excel, Word, PowerPoint and Access.
10. An understanding of the confidential nature of this role.

Desirable

Please note that the criteria listed below would be an advantage in this role, but you do not need to meet them to be eligible to apply.

1. NMC Registered Midwife/Nurse
2. Leadership and/or management qualification.
3. Project Management qualification i.e., PRINCE Foundation and Practitioner level.
4. Use of Asana project management software

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 candidate notes on the University's pre-employment screening procedures at: <https://www.jobs.ox.ac.uk/pre-employment-checks>

Hazard-specific / Safety-critical duties

This job includes hazards or safety-critical activities. If you are offered the post, you will be asked to complete a health questionnaire which will be assessed by our Occupational Health Service (OHS), and the offer of employment will be subject a successful outcome of this assessment.

The hazards or safety-critical duties involved are as follows:

- Working with blood, human products and human tissues
- Work in clinical areas with direct contact with patients

How to apply

Applications are made through our online recruitment portal. Information about how to apply is available on our Jobs website <https://www.jobs.ox.ac.uk/how-to-apply>.

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 also 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 note that if you do not upload a supporting statement, we will be unable to consider your application.

Please upload all documents **as PDF files** with your name and the document type in the filename.

All applications must be received by **midday** 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 department(s). 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

Application FAQs, including technical troubleshooting advice is available at: <https://staff.web.ox.ac.uk/recruitment-support-faqs>

Non-technical questions about this job should be addressed to the recruiting department directly by emailing recruitment@wrh.ox.ac.uk.

To return to the online application at any stage, please go to: www.recruit.ox.ac.uk.

Please note that you will receive an automated email from our online recruitment portal to confirm receipt of your application. **Please check your spam/junk mail** if you do not receive this email.

Assessment

It is anticipated that interviews for this post will take place in the week commencing on Monday 11th December and will be held at Level 3 Women's Centre, John Radcliffe Hospital, Oxford, OX3 9DU, where possible (online options may also be available, if required). You will be notified by the end of Monday 4th December if you have been shortlisted for interview.

During the interview, you will be asked questions based around the selection criteria listed in this job description.

If you are selected for interview you will be invited to disclose any special requirements which we might need to consider in relation to the interview arrangements, for example, in the case of disability, access to facilities or equipment. These will not be taken into account in the selection process.

In advance of the interview, you will be asked to complete an online McQuaig Word Survey. You can read more about McQuaig at <https://mcquaig.co.uk/candidate-section/>.

You can find more information and guidance about the recruitment and selection process at the Nuffield Department of Women's & Reproductive Health at <https://www.wrh.ox.ac.uk/candidate-briefing>.

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 at: <https://compliance.admin.ox.ac.uk/job-applicant-privacy-policy>. The University's Policy on Data Protection is available at: <https://compliance.admin.ox.ac.uk/data-protection-policy>.

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** of 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.

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 www.ox.ac.uk/about/organisation.

Nuffield Department of Women's & Reproductive Health (NDWRH)

The Nuffield Department of Women's & Reproductive Health (NDWRH) is one of the largest and most successful academic departments in the world in its field. There are approximately 160 people working in the department, including senior academic staff, research support staff, clerical and technical staff, and graduate students (including clinicians) carrying out research towards a higher degree. There are also a number of visiting researchers from many parts of the world. The average annual income is approximately £10 million, of which over 75% comes from outside sources.

NDWRH encompasses multi-disciplinary research across the full spectrum of women's health. Our work has four overarching themes; Cancer, Global Health, Maternal & Fetal Health and Reproductive Medicine & Genetics. We focus on genetic studies, the dissection of molecular, biochemical and cellular mechanisms underlying normal and aberrant reproductive tissue function, and clinical studies in women's health, assisted reproduction and pregnancy, as well as growth and development across the first 1000 days of life.

The clinical and laboratory programmes are based in the Women's Centre, John Radcliffe Hospital; Weatherall Institute of Molecular Medicine; Institute of Reproductive Sciences, and the Big Data Institute, and there are collaborations with the School's Institutes, the University's Science Departments and with researchers outside Oxford, in both the UK and abroad, especially in low-middle income countries.

For more information please visit: www.wrh.ox.ac.uk

The University of Oxford is a member of the [Athena SWAN Charter](#) and holds an institutional Silver Athena SWAN award. NDWRH holds a departmental Silver Athena Swan award to recognise advancement of gender equality: representation, progression and success for all.

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 range of other employee benefits and discounts also includes free entry to the Botanic Gardens and University colleges, and discounts at University museums. See www.admin.ox.ac.uk/personnel/staffinfo/benefits.

University Club and sports facilities

Membership of the University Club is free for all University staff. The University Club offers social, sporting, and hospitality facilities. Staff can also use the University Sports Centre on Iffley Road <https://web.maillist.ox.ac.uk/ox/info/ndog-graduate-students> at discounted rates, including a fitness centre, powerlifting room, and swimming pool. See www.club.ox.ac.uk and www.sport.ox.ac.uk/oxford-university-sports-facilities.

Information for staff new to Oxford

If you are relocating to Oxfordshire from overseas or elsewhere in the UK, the University's Welcome Service website includes practical information about settling in the area, including advice on relocation, accommodation, and local schools. See www.welcome.ox.ac.uk.

There is also a visa loan scheme to cover the costs of UK visa applications for staff and their dependents. See www.admin.ox.ac.uk/personnel/permits/reimburse&loanscheme/.

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 My Family Care, 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. See www.admin.ox.ac.uk/personnel/staffinfo/benefits/family/mfc/.

Childcare

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 www.admin.ox.ac.uk/childcare/.

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 www.admin.ox.ac.uk/eop/disab/staff.

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 at www.admin.ox.ac.uk/eop/inpractice/networks/.

The University of Oxford Newcomers' Club

The University of Oxford Newcomers' Club 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. See www.newcomers.ox.ac.uk