The role

This is an important post within the Jenner Institute to provide support in project management and quality assurance for all aspects of clinical trial immunology, HTA compliance and biobanking within the themes of emerging pathogens and pre-erythrocytic malaria. Ensuring compliance with Good Clinical Practice and other regulatory requirements in all areas will be important. You will be part of the clinical immunology team reporting to Associate Professor Teresa Lambe and Associate Professor Katie Ewer. You will be responsible for the management of the day to day logistical and quality functions for the transfer, processing and storage of clinical trial samples. This will involve quality assurance, logistical support and other types of project management as well as providing day-to-day professional support for the PIs. You will also manage the overseas collection of samples held under our HTA licence, with responsibility for auditing, compliance and annual returns.

Responsibilities

The responsibilities below will be undertaken as required, further to ongoing discussions with the PIs where priorities will be established and targets set and regularly reviewed.

**Project Management**

- Be responsible for project and resource planning, identifying shortfalls and issues, and providing feasible solutions to existing problems based on their own experience.
- Ensure the work is conducted within the University, funder and legal standards and also within the terms and conditions.
- Co-ordinating submissions and reports to meet deadlines.
- To be responsible for the correct preparation of project-related documents by them or any other members of the team including:
  1. Funding applications in collaboration or on behalf of the PI for the continuation of the project.
  2. Project plans, milestones, milestone reviews and project budgets.
  3. Legal and contractual agreements in collaboration with the PI, the administration team, research services and the purchasing department.
  4. To prepare or assist in the preparation of other project-related documents (MTA's, CDA's, and Patents).
  5. Biobanking documentation.

- Coordinate reagents, cells and vaccines with overseas clinical units and other logistical duties as required by the PI.
- Communicate with a wide range of internal and external partners, including: clinical trial physicians, clinical research co-ordinators, laboratory staff, NDM HR and Finance, and external collaborators.
- Assist in all aspects of the team’s activities as appropriate, according to the principles of Good Clinical Practice (GCP) and the Jenner Group Standard Operating Procedures (SOPs).
- Complete any other trial related work as required by the Head of Regulatory Affairs or Chief and/or Principal Investigator.

**Quality Assurance**

- Maintain an overview of all aspects of data management and analysis, including the provision of scientific, technical reports and co-ordination of the timely delivery of project work packages and milestones.
- Use databases to enter and collate sample data and manage database validation.
- Responsible for the management and maintenance of all Human Tissue Act (HTA) and biobanking critical documentation (standard operating procedures (SOPs), biobanking records, reports, deviations, etc.).
- QA Review SOPs, specifications and other documents/records.
- Proactively identify opportunities for continual improvement.
- Author SOPs as required.
- Take responsibility for preparing staff and ensuring documentation is up to date for audits/inspections by external bodies.
- Use databases to enter and collate trial data for formal trial reports and assist in database validation.

**Good Clinical Practice (GCP)**

- Work within and interpret legislation and regulatory frameworks related to ICH GCP.
- Provide assistance to all staff regarding validation requirements.
- To provide support for all staff employed on the project to ensure:
  1. They are following all University and project specific directives.
  2. They receive the appropriate training and follow current Health and Safety regulations.
Pre-employment screening

All offers of employment are made subject to standard pre-employment screening, as applicable to the post.

If you are offered the post, you will be asked to provide proof of your right-to-work, your identity, and 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 so that we can discuss appropriate adjustments with you), and a declaration of any unspent criminal convictions.

We advise all applicants to read the candidate notes on the University’s pre-employment screening procedures, found at: www.ox.ac.uk/about/jobs/preemploymentscreening/.

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:

- Night working (11pm-6am)
- Lone Working
- Working with blood, human products and human tissues

Selection criteria

Essential selection criteria

- A first degree in a relevant biological subject
- Ability to manage financial and operational resources
- Ability to communicate effectively to a high standard, including relatively complex scientific matters, orally and in writing skills, such as funding reports
- Ability to work well both independently and in a team
- Highly organised with an ability to manage a vast amount of relatively complex information and to prioritise a demanding workload with competing deadlines
- Critical thinking ability and good problem-solving skills, an eye for detail and an ability to work to high standards consistently.
- Knowledge of translational or clinical trials management and associated legal requirements including understanding and previous experience of Good Clinical Practice and the regulations and guidelines applicable to clinical trials in the UK
- Past experience of HTA compliance
- Project management experience, ideally in a relevant area
- Knowledge of IT software including Microsoft Office

Desirable selection criteria

- Previous experience working in a similar clinical/academic environment
- Good understanding of the vaccine development process especially immunology.
• Competent and experienced in managing all aspects of Quality Assurance and compliance management procedures within a GMP regulated environment
• Understanding and previous experience of Good Clinical Practice and the regulations and guidelines applicable to clinical trials in the UK.
• Previous experience of setting up and/or managing a biobank
• Past experience of managing HTA compliance

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. Income from external research contracts in 2016/17 exceeded £564m and we rank first in the UK for university spin-outs, with more than 130 companies created to date. 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.

Medical Sciences
The Medical Sciences Division is an internationally recognized centre of excellence for biomedical and clinical research and teaching. We are 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: www.medsci.ox.ac.uk

Nuffield Department of Clinical Medicine (NDM)…fostering your career in science
The Nuffield Department of Clinical Medicine (NDM) is one of the largest departments of the University of Oxford and is part of the Medical Sciences Division, with responsibility for a significant part of the teaching of clinical students within the Medical School.

NDM has significant financial turnover and complexity, resulting from its diverse research portfolio, its geographical spread and its close links with NHS funding and strategic teams involved in the development and delivery of increasingly integrated clinical research platforms. For more information please visit: http://www.ndm.ox.ac.uk/home

The Nuffield Department of Clinical Medicine has been presented with a Departmental Athena SWAN Silver award in recognition of the commitment made to promote gender equality through our organisational and cultural practices and our efforts to improve the working environment for
both men and women. For more information please see our Departmental Athena SWAN pages: www.ndm.ox.ac.uk/working-for-ndm/aboutndmatheneswan/.

The Jenner Institute

The Jenner Institute was founded in November 2005 to develop innovative vaccines against major global diseases. Uniquely it focuses both on diseases of humans and livestock and tests new vaccine approaches in parallel in different species. A major theme is translational research involving the rapid early-stage development and assessment of new vaccines in clinical trials.

For more information please visit: department website http://www.jenner.ac.uk/

How to apply

Before submitting an application, you may find it helpful to read the ‘Tips on applying for a job at the University of Oxford’ document, at www.ox.ac.uk/about/jobs/supportandtechnical/.

If you would like to apply, click on the Apply Now button on the ‘Job Details’ page and follow the on-screen instructions to register as a new user or log-in if you have applied previously. Please 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)

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

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).

Should you experience any difficulties using the online application system, please email recruitment.support@admin.ox.ac.uk. Further help and support is available from www.ox.ac.uk/about_the_university/jobs/support/. 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 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 at: www.admin.ox.ac.uk/councilsec/compliance/gdpr/privacynotices/job/. The University’s Policy on Data Protection is available at: www.admin.ox.ac.uk/councilsec/compliance/gdpr/universitypolicyondataprotection/.

The University’s policy on retirement

The University operates an Employer Justified Retirement Age (EJRA) for all academic posts and some academic-related posts. The University has adopted an EJRA of 30 September before the 69th birthday for all academic and academic-related staff in posts at grade 8 and above. The justification for this is explained at: www.admin.ox.ac.uk/personnel/end/retirement/acrelretire8+.

For existing employees, any employment beyond the retirement age is subject to approval through the procedures: www.admin.ox.ac.uk/personnel/end/retirement/acrelretire8+.

There is no normal or fixed age at which staff in posts at grades 1–7 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 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 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.