



## POSITION DESCRIPTION

Department of Infectious Diseases  
Melbourne Medical School  
Faculty of Medicine, Dentistry and Health Sciences

### Clinical Research Operations Manager

POSITION NO	0053238
CLASSIFICATION	UOM 7
SALARY	\$96,002.00 - \$103,921.00 p.a.
SUPERANNUATION	Employer contribution of 9.5%
WORKING HOURS	Full time (1.0 FTE)
BASIS OF EMPLOYMENT	Fixed Term position for 1 year
OTHER BENEFITS	<a href="http://about.unimelb.edu.au/careers/working/benefits">http://about.unimelb.edu.au/careers/working/benefits</a>
HOW TO APPLY	Online applications are preferred. Go to <a href="http://www.jobs.unimelb.edu.au">www.jobs.unimelb.edu.au</a> and use the Job Search screen to find the position by title or number.
CONTACT FOR ENQUIRIES ONLY	Dalrene De Silva Tel +61 (0)3 9342 9401 Email <a href="mailto:dalrene.desilva@mh.org.au">dalrene.desilva@mh.org.au</a> <i>Please do not send your application to this contact</i>

For information about working for the University of Melbourne, visit our websites:

[hr.unimelb.edu.au/careers](http://hr.unimelb.edu.au/careers)

## ***Position Summary***

The Department of Infectious Diseases based at the Peter Doherty Institute for Infection and Immunity (the Doherty Institute) is seeking to appoint a Clinical Research Operations Manager to project manage a range of clinical trials and research projects in the department. A major component of the role will be assisting in the establishment and management of a clinical trial unit focussing on human infection challenge (HIC) studies in infectious diseases, as well as management of a range of clinical research activities.

The Clinical Research Operations Manager will be responsible for the management and day-to-day activities of a range of research projects, including: establishing the clinical trial unit managing research projects, budgeting and reporting, coordination of ethics approvals, organisation of meetings, contribution to monitoring and evaluation processes and other administrative project tasks as required. The incumbent is required to demonstrate a high level of professionalism and initiative, and will work collaboratively with a wide range of stakeholders, engaging with local, national and international collaborators as required. The Clinical Research Operations Manager will be highly organised, able to set priorities to complete tasks to external deadlines and communicate effectively with a diverse range of individuals.

### ***1. Key Responsibilities***

- ▶ Assist with coordination of the establishment of the clinical trials unit.
- ▶ Provide operational leadership to ensure the successful execution of quality clinical research studies.
- ▶ Provide project coordination and administrative support for research programmes, including management of project work plans, development of ethics approvals, budgeting, monitoring of progress and milestones, and contribution to reporting.
- ▶ Assist partners in the planning and execution of clinical research studies, including operational planning and timeline management.
- ▶ Assist partners in managing ethics review, regulatory compliance, site governance approvals as required.
- ▶ Co-ordinate strategic planning, design, implementation and closure of clinical research studies.
- ▶ Identify and provide solutions to clinical trial issues and/or risk.
- ▶ Support clinical trial staff, resourcing and facilities.
- ▶ Communicate clinical strategy to external funding partners /senior leaders and provide regular updates on status of projects to plan and evaluate strategy effectiveness.
- ▶ Work collaboratively within a multi-disciplinary team, to promote project activities across multiple local, national and international stakeholders.
- ▶ Assist in record keeping and compliance reporting by minuting meetings, keeping detailed records of funding distributions to partners and external parties, and contributing to preparation and dissemination of reports to relevant parties.
- ▶ Occupational Health and Safety (OHS) and Environmental Health and Safety (EH&S) responsibilities as outlined in section 5.

## **2. Selection Criteria**

### **2.1 ESSENTIAL**

- ▶ Post graduate qualification in Biomedical Science or other relevant discipline; or an equivalent combination of relevant experience and/or education/training.
- ▶ Demonstrated excellent organisational skills in planning and organising work to meet competing deadlines.
- ▶ Demonstrated ability to work as both a member of a multi-disciplinary team and independently with minimal supervision, showing initiative and flexibility.
- ▶ Excellent organisational and administrative skills and the ability to work with a high level of attention to detail in relation to planning of clinical trials and research projects, preparation of documentation, compliance and reporting requirements.
- ▶ Demonstrated ability to develop clear project plans and timelines, communicate effectively with stakeholders, and monitor project progress.
- ▶ Proficient computer skills related to project management with proven ability to manage central document repositories, such as regulatory and institutional documentation.
- ▶ Outstanding oral communication and interpersonal skills with a demonstrated ability to liaise with and influence a diverse range of stakeholders, in order to achieve desired outcomes.

### **2.2 DESIRABLE**

- ▶ Familiarity with GCP and GMP regulatory requirements.
- ▶ Experience in coordinating clinical trials.
- ▶ A graduate degree in clinical trials research or clinical research methods (such as a Graduate Certificate, Diploma or Masters in Clinical Research or Masters in Public Health).
- ▶ Experience in infectious diseases or microbiology research.
- ▶ Familiarity with the reporting requirements of external agencies (e.g. NHMRC; NIH)

### **2.3 SPECIAL REQUIREMENTS**

- ▶ Some flexibility in days and hours of work may be required.

## **3. Job Complexity, Skills, Knowledge**

### **3.1 LEVEL OF SUPERVISION / INDEPENDENCE**

The Clinical Research Operations Manager will work under the broad direction of Professor James McCarthy and Professor Deborah Williamson with a considerable degree of autonomy. The successful candidate will be expected to assist in the establishment and management of a clinical research unit focussing on HIC studies in infectious diseases, as well as working towards achieving the Department's strategic and operational goals.

The Clinical Research Operations Manager will be responsible for management and support of staff across a range of disciplines in both hospital and university facilities.

### 3.2 PROBLEM SOLVING AND JUDGEMENT

- High level problem solving and independent judgement is required and will collaborate with colleagues across the University and hospitals to propose best practice solutions.
- Expected to support the development of the clinical trials unit and implement trial-related processes and systems.
- Responsible for monitoring the conduct of, and assisting in negotiations for, contracts with stakeholders.
- Expected to provide strategic support and advice to the relevant stakeholders, requiring integration of a range of university policies and external requirements, and an ability to achieve objectives operating within complex organisation structures.

### 3.3 PROFESSIONAL AND ORGANISATIONAL KNOWLEDGE

The Clinical Research Operations Manager is required to have high level project management skills, including overseeing large research and trial budgets, complex legal negotiations, monitoring and auditing projects, clinical trial operations and processes in compliance with local and international regulatory frameworks (eg. TGA, ICH-GCP). The Clinical Research Operations Manager is also expected to have a good understanding of clinical research in hospital settings, higher education sector and research environments.

The incumbent will be expected to develop a deep knowledge of the Australian Code of for the Responsible Conduct of Research, its associated guidelines and the University's policies and procedures relating to research integrity.

### 3.4 RESOURCE MANAGEMENT

The Clinical Research Operations Manager will oversee the administration of a unit budget.

### 3.5 BREADTH OF THE POSITION

The Clinical Research Operations Manager will have a wide range of management capabilities and be able to manage all aspects of complex clinical research including trials. The role requires extensive interaction with hospital and University staff at all levels as well as key external stakeholders. The Clinical Research Operations Manager will have a depth or breadth of expertise developed through extensive relevant industry experience and application.

## 4. *Occupational Health and Safety (OHS)*

All staff are required to take reasonable care for their own health and safety and that of other personnel who may be affected by their conduct.

OHS responsibilities applicable to positions are published at:

<http://safety.unimelb.edu.au/topics/responsibilities/>

These include general staff responsibilities and those additional responsibilities that apply for Managers and Supervisors and other Personnel.

## 5. *Other Information*

### 5.1 ORGANISATION UNIT

#### DEPARTMENT OF INFECTIOUS DISEASES

<https://medicine.unimelb.edu.au/school-structure/infectious-diseases>

The Department of Infectious Diseases is a recently established department of the Melbourne Medical School, Faculty of Medicine, Dentistry and Health Sciences that is based at The Peter Doherty Institute for Infection and Immunity (Doherty Institute). Research within the department encompasses infectious diseases including antimicrobial resistance and healthcare associated infections, malaria, HIV, tuberculosis, influenza, viral hepatitis, sexually-transmitted infections, skin pathogens and emerging infectious diseases such as COVID-19. Our researchers come from diverse backgrounds, including discovery research and basic scientists, clinician researchers, public health physicians and microbiologists

### 5.2 MELBOURNE MEDICAL SCHOOL

<https://medicine.unimelb.edu.au>

Established in 1862, Melbourne Medical School (MMS) in the Faculty of Medicine, Dentistry and Health Sciences at The University of Melbourne is the oldest medical school in Australia. It is internationally renowned for global leadership in teaching and training, health research, policy and practice. The School is ranked 14th in the world (Times Higher Education World University Rankings 2020 for clinical, pre-clinical and health), has strong academic partnerships and ground-breaking collaborative research programs with leading public and private hospitals, as well as leading medical research institutes and centres in Australia and internationally.

MMS is committed to working with the communities we serve to improve health and advance health care. We will do this through our teaching, learning, research, clinical care and advocacy.

With thirteen clinical departments (Baker Department of Cardiometabolic Health, Clinical Pathology, Critical Care, General Practice, Medical Education, Infectious Diseases, Medicine, Obstetrics and Gynaecology, Paediatrics, Psychiatry, Radiology, Rural Health and Surgery) the MMS has more than 900 academic and professional staff members at our Parkville campus or embedded within health services throughout metropolitan Melbourne and rural Victoria. MMS staff are privileged to work alongside more than 2400 honorary appointees from the health sector who tirelessly contribute their time, knowledge and clinical expertise to the education of our students. The School has partnerships and research collaborations across the 30 partner organisations in the vibrant Melbourne Biomedical Precinct, as well as national and international partnerships.

MMS delivers a suite of health-related graduate programs including the Doctor of Medicine (MD), the School's flagship program. It was the first Masters level entry-to-practice medicine qualification developed in Australia, setting a new benchmark in medical education.

MMS is committed to improving community wellbeing through the discovery and application of new knowledge. With annual research income of \$95 million, the School's research effort is highly collaborative, spanning basic and translational research. MMS has over 500 higher degree by research candidates.

School staff members also lead and participate in public debate and advocacy around key health issues and policy based on the MMS values of commitment, integrity, compassion, respect and service.

Under the leadership of Professor John Prins, MMS is undertaking exciting new developments, including a major review of the MD curriculum, an emphasis on the clinician-scientist career trajectory (in partnership with affiliated hospitals, medical research institutes and foundations), and a reinvigorated focus on clinically relevant research.

Commencing in 2022, the MD redesign will allow students to build their own unique medical degree. Practical time in clinics and research options will start in the first year. The core units will be available online, allowing flexibility. And discovery subjects will offer a chance to explore a wide range of topics or deep dive into a future specialty including the choice to learn extra skills and even take part in a joint degree.

These initiatives are being enhanced by a number of recruitment opportunities (through retirements, resignations and recent funding acquisitions) for a range of leadership positions across the School. These positions present a wonderful opportunity for appointees to help drive the strategy, growth and continued excellence of Australia's leading medical school.

### 5.3 FACULTY OF MEDICINE, DENTISTRY AND HEALTH SCIENCES

[www.mdhs.unimelb.edu.au](http://www.mdhs.unimelb.edu.au)

The Faculty of Medicine, Dentistry & Health Sciences has an enviable research record and is the University of Melbourne's largest faculty in terms of management of financial resources, employment of academic and professional staff, teaching of undergraduate and postgraduate (including research higher degree) students and the conduct of basic and applied research. The Faculty's annual revenue is \$630m with approximately 55% of this income related to research activities.

The Faculty has a student teaching load in excess of 8,500 equivalent full-time students including more than 1,300 research higher degree students. The Faculty has approximately 2,195 staff comprising 642 professional staff and 1,553 research and teaching staff.

The Faculty has appointed Australia's first Associate Dean (Indigenous Development) to lead the development and implementation of the Faculty's Reconciliation Action Plan (RAP), which will be aligned with the broader University – wide plan. To enable the Faculty to improve its Indigenous expertise knowledge base, the Faculty's RAP will address Indigenous employment, Indigenous student recruitment and retention, Indigenous cultural recognition and building partnerships with the Indigenous community as key areas of development.

### 5.4 THE PETER DOHERTY INSTITUTE FOR INFECTION AND IMMUNITY

[doherty.edu.au](http://doherty.edu.au)

The Doherty Institute is a world-class institute combining research, teaching, public health and reference laboratory services, diagnostic services and clinical care into infectious diseases and immunity. It was officially opened in September 2014 and is a joint venture between the University of Melbourne and Melbourne Health. The Doherty Institute has a major focus on diseases that pose serious public and global health threats such as influenza, tuberculosis, HIV, viral hepatitis, Ebola and drug resistant bacteria. The Doherty's activities are multi-disciplinary and cross-sectoral, placing great emphasis on translational research and improving clinical outcomes. Teams of scientists, clinicians and epidemiologists collaborate on a wide spectrum of activities - from basic immunology and discovery research, to the development of new vaccines and new preventative and treatment methods, to surveillance and investigation of disease outbreaks.

## 5.5 THE UNIVERSITY OF MELBOURNE

The University of Melbourne is a leading international university with a tradition of excellence in teaching and research. With outstanding performance in international rankings, Melbourne is at the forefront of higher education in the Asia-Pacific region and the world. The University of Melbourne is consistently ranked among the world's top universities. Further information about our reputation and global ranking is available at

<http://futurestudents.unimelb.edu.au/explore/why-choose-melbourne/reputation-rankings>.

Established in 1853, shortly after the founding of Melbourne, the University is located just a few minutes from the centre of this global city. The main Parkville campus is recognised as the hub of Australia's premier knowledge precinct comprising eight hospitals, many leading research institutes and a wide range of knowledge-based industries.

The University employs people of outstanding calibre and offers a unique environment where staff are valued and rewarded. Further information about working at The University of Melbourne is available at <http://about.unimelb.edu.au/careers>.

## 5.6 GROWING ESTEEM, THE MELBOURNE CURRICULUM AND RESEARCH AT MELBOURNE: ENSURING EXCELLENCE AND IMPACT TO 2025

- ▶ Growing Esteem describes Melbourne's strategy to achieve its aspiration to be a public-spirited and internationally-engaged institution, highly regarded for making distinctive contributions to society in research and research training, learning and teaching, and engagement <http://about.unimelb.edu.au/strategy-and-leadership>
- ▶ The University is at the forefront of Australia's changing higher education system and offers a distinctive model of education known collectively as the Melbourne Curriculum. The new educational model, designed for an outstanding experience for all students, is based on six broad undergraduate programs followed by a graduate professional degree, research higher degree or entry directly into employment. The emphasis on academic breadth as well as disciplinary depth in the new degrees ensures that graduates will have the capacity to succeed in a world where knowledge boundaries are shifting and reforming to create new frontiers and challenges. In moving to the new model, the University is also aligning itself with the best of emerging European and Asian practice and well-established North American traditions.
- ▶ The University's global aspirations seek to make significant contributions to major social, economic and environmental challenges. Accordingly, the University's research strategy *Research at Melbourne: Ensuring Excellence and Impact to 2025* aspires to a significant advancement in the excellence and impact of its research outputs.

<http://research.unimelb.edu.au/our-research/research-at-melbourne>

The strategy recognises that as a public-spirited, research-intensive institution of the future, the University must strive to make a tangible impact in Australia and the world, working across disciplinary and sectoral boundaries and building deeper and more substantive engagement with industry, collaborators and partners. While cultivating the fundamental enabling disciplines through investigator-driven research, the University has adopted three grand challenges aspiring to solve some of the most difficult problems facing our world in the next century. These Grand Challenges include:

- Understanding our place and purpose – The place and purpose grand challenge centres on understanding all aspects of our national identity, with a focus on Australia's 'place' in the Asia-Pacific region and the world, and on our 'purpose' or mission to improve all dimensions of the human condition through our research.

- Fostering health and wellbeing – The health and wellbeing grand challenge focuses on building the scale and breadth of our capabilities in population and global health; on harnessing our contribution to the ‘convergence revolution’ of biomedical and health research, bringing together the life sciences, engineering and the physical sciences; and on addressing the physical, mental and social aspects of wellbeing by looking beyond the traditional boundaries of biomedicine.
- Supporting sustainability and resilience – The sustainability and resilience grand challenge addresses the critical issues of climate change, water and food security, sustainable energy and designing resilient cities and regions. In addition to the technical aspects, this grand challenge considers the physical and social functioning of cities, connecting physical phenomena with lessons from our past, and the implications of the technical solutions for economies, living patterns and behaviours.
- Essential to tackling these challenges, an outstanding faculty, high performing students, wide collaboration including internationally and deep partnerships with external parties form central components of *Research at Melbourne: Ensuring Excellence and Impact to 2025*.

## 5.7 EQUITY AND DIVERSITY

Another key priority for the University is access and equity. The University of Melbourne is strongly committed to an admissions policy that takes the best students, regardless of financial and other disadvantage. An Access, Equity and Diversity Policy Statement, included in the University Plan, reflects this priority.

The University is committed to equal opportunity in education, employment and welfare for staff and students. Students are selected on merit and staff are selected and promoted on merit.

## 5.8 GOVERNANCE

The Vice Chancellor is the Chief Executive Officer of the University and responsible to Council for the good management of the University.

Comprehensive information about the University of Melbourne and its governance structure is available at <http://www.unimelb.edu.au/unisec/governance.htm>