



POSITION DESCRIPTION

The Peter Doherty Institute for Infection and Immunity
Doherty Department
Faculty of Medicine, Dentistry and Health Sciences

Clinical Trial Manager

POSITION NO	0050608
CLASSIFICATION	UOM 7
SALARY	\$93,935 - \$101,684 p.a.
SUPERANNUATION	Employer contribution of 9.5%
WORKING HOURS	Full-time
BASIS OF EMPLOYMENT	Full-time 1.0 FTE (fixed term) position for 1 year
OTHER BENEFITS	http://about.unimelb.edu.au/careers/working/benefits
HOW TO APPLY	Online applications are preferred. Go to http://about.unimelb.edu.au/careers , select the relevant option ('Current Opportunities' or 'Jobs available to current staff'), then find the position by title or number.
CONTACT FOR ENQUIRIES ONLY	Steven Tong Tel +61 3 9342 9406 Email steven.tong@mh.org.au <i>Please do not send your application to this contact</i>

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about.unimelb.edu.au/careers

Position Summary

Based in the Doherty Department at the Peter Doherty Institute for Infection and Immunity, the Clinical Trial Manager will set up and manage a large international, multicentre clinical trial in infectious diseases. The Australasian COVID-19 Trial (ASCOT) is a randomised clinical trial which aims to enrol ~2,000 patients with COVID-19 infections, at over 80 sites in Australia and New Zealand.

The Clinical Trial Manager will conduct ethics and regulatory submissions and operational aspects of the clinical trial, including data management, safety, and quality. The Clinical Trial Manager will also provide support to participating centres and site investigators and research coordinators for the duration of the trial.

1. Key Responsibilities

- ▶ Assume overall responsibility for the preparation and maintenance of template documentation for study protocols, case report forms, informed consent forms and other clinical research documentation as necessary
- ▶ Assist in oversight of study database, design and functionality, data quality and entry
- ▶ Liaise with University of Melbourne Office of Research Ethics and Integrity regarding trial sponsorship and contracts
- ▶ Undertake Human Research Ethics Committee approval processes and trial registration
- ▶ Undertake participating site identification and recruitment
- ▶ Undertake participating site initiation and training, and support site investigators and research coordinators with the ethics and governance of research by developing appropriate procedures and processes in relation to approval processes study documentation and clinical trial materials, study progress, study reporting and compliance with appropriate standards
- ▶ Support investigators and project managers with operational aspects of research by developing appropriate procedures and processes to guide project managers in relation to recruitment strategies, documentation, liaison with external study sites, collection of clinical data (databasing) and any research specimens (biobanking)
- ▶ Coordinate data quality monitoring, site audit monitoring and site visits
- ▶ Coordinate data safety monitoring, including Data Safety Monitoring Committee activity and meetings, and reporting, collation and monitoring of adverse events by participating sites
- ▶ Maintain, manage and archive internal clinical trial files and documentation systematically
- ▶ Occupational Health and Safety (OH&S) and Environmental Health and Safety (EH&S) responsibilities as outlined in section 5

2. Selection Criteria

2.1 ESSENTIAL

- ▶ Post graduate qualification in nursing, science, health science or biomedical science or progress towards and extensive relevant experience or an equivalent combination of relevant experience and/or education/training

- ▶ Significant experience with responsible roles in the planning, conduct, coordination or management of clinical research, including clinical trials, and experience in managing international, multi-centre clinical trials
- ▶ Good working knowledge of medical and laboratory terminology, a sound understanding of the principles of Good Clinical Practice (GCP) and an excellent knowledge of applicable Australian and international regulations and guidelines
- ▶ Proficient computer skills related to project management with proven ability to manage central document repositories, GCP template documentation, ethics submissions and other regulatory and institutional documentation
- ▶ Effective organisational skills to plan and organise work to meet competing deadlines with the ability to work as both a member of a multi-disciplinary team and independently with minimal supervision, showing initiative and flexibility
- ▶ 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

- ▶ A higher degree in clinical trials research or clinical research methods (such as a Graduate Certificate, Diploma or Masters in Clinical Research or Public Health)
- ▶ Extensive experience in the coordination and management of clinical trials in infectious diseases or critical care
- ▶ Significant direct experience in planning and managing large multicentre clinical trials

3. Job Complexity, Skills, Knowledge

3.1 LEVEL OF SUPERVISION / INDEPENDENCE

The Clinical Trial Manager will work under broad direction from the Trial Principal Investigators and the Trial Steering Committee with a considerable degree of autonomy. The Clinical Trial Manager will be expected to develop and implement strategies within a broad framework defined by the Trial Steering Committee and the Department's strategic and operational goals.

The Clinical Trial Manager will have management responsibility for the trial project office, including recruiting and managing other staff including the Clinical Trial Project Officers.

3.2 PROBLEM SOLVING AND JUDGEMENT

High level problem solving and independent judgement is required for this position. The Clinical Trial Manager would be expected to set up and manage the trial committees (Trial Steering Committee, Data and Safety Monitoring Board, Therapeutic Advisory Committee). The Clinical Trial Manager would be required to contribute as an active member of these committees, and make policy recommendations to the committee members and others. The Clinical Trial Manager will implement trial-related processes and systems. The Clinical Trial Manager is responsible for monitoring the conduct of, and assisting in negotiations for, contracts with sites in Australia and overseas. The Clinical Trial Manager is expected to provide trial-related strategic support and advice to the relevant committees, 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 Trial Manager is required to be an expert in international, multicentre trial management, including overseeing large trial budgets, complex legal negotiations, monitoring and auditing practices, trial databases, and general trial operations and processes in compliance with local and international regulatory frameworks (eg. TGA, ICH-GCP). The Clinical Trial Manager is also expected to have an excellent understanding of clinical research in hospital settings, higher education sector and research environments.

3.4 RESOURCE MANAGEMENT

The Clinical Trial Manager will oversee the administration of a large trial budget.

3.5 BREADTH OF THE POSITION

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

4. Equal Opportunity, Diversity and Inclusion

The University is an equal opportunity employer and is committed to providing a workplace free from all forms of unlawful discrimination, harassment, bullying, vilification and victimisation. The University makes decisions on employment, promotion and reward on the basis of merit.

The University is committed to all aspects of equal opportunity, diversity and inclusion in the workplace and to providing all staff, students, contractors, honorary appointees, volunteers and visitors with a safe, respectful and rewarding environment free from all forms of unlawful discrimination, harassment, vilification and victimisation. This commitment is set out in the University's People Strategy 2015-2020 and policies that address diversity and inclusion, equal employment opportunity, discrimination, sexual harassment, bullying and appropriate workplace behaviour. All staff are required to comply with all University policies.

The University values diversity because we recognise that the differences in our people's age, race, ethnicity, culture, gender, nationality, sexual orientation, physical ability and background bring richness to our work environment. Consequently, the People Strategy sets out the strategic aim to drive diversity and inclusion across the University to create an environment where the compounding benefits of a diverse workforce are recognised as vital in our continuous desire to strive for excellence and reach the targets of Growing Esteem.

5. 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/people/community/responsibilities-of-personnel>

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

6. Other Information

6.1 THE PETER DOHERTY INSTITUTE FOR INFECTION AND IMMUNITY

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.

6.2 FACULTY OF MEDICINE, DENTISTRY AND HEALTH SCIENCES

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 \$628m 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.

6.3 THE UNIVERSITY OF MELBOURNE

Established in 1853, the University of Melbourne is a leading international university with a tradition of excellence in teaching and research. The main campus in Parkville 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. With outstanding performance in international rankings, the University is at the forefront of higher education in the Asia-Pacific region and the world.

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>.

6.4 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.

6.5 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/governance>