



## POSITION DESCRIPTION

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

### Clinical Trial Database Support Officer

<b>POSITION NO</b>	0063083
<b>CLASSIFICATION</b>	UOM 5
<b>SALARY</b>	\$83,159 - \$95,518 p.a.
<b>SUPERANNUATION</b>	Employer contribution of 17%
<b>WORKING HOURS</b>	Full time (1.0 FTE)
<b>BASIS OF EMPLOYMENT</b>	Fixed term position for 12 months
<b>OTHER BENEFITS</b>	<a href="https://about.unimelb.edu.au/careers/staff-benefits">https://about.unimelb.edu.au/careers/staff-benefits</a>
<b>HOW TO APPLY</b>	Online applications are preferred. Go to <a href="http://about.unimelb.edu.au/careers">http://about.unimelb.edu.au/careers</a> , select the relevant option ('Current Opportunities' or 'Jobs available to current staff'), then find the position by title or number.
<b>CONTACT FOR ENQUIRIES ONLY</b>	Grace McPhee Tel +61 3 8344 3276 Email <a href="mailto:grace.mcphee@unimelb.edu.au">grace.mcphee@unimelb.edu.au</a> <i>Please do not send your application to this contact</i>

For information about working for the University of Melbourne, visit our website:  
[about.unimelb.edu.au/careers](http://about.unimelb.edu.au/careers)

## ***Acknowledgement of Country***

The University of Melbourne acknowledges the Traditional Owners of the unceded land on which we work, learn and live: the Wurundjeri Woi Wurrung and Bunurong peoples (Burnley, Fishermans Bend, Parkville, Southbank and Werribee campuses), the Yorta Yorta Nation (Dookie and Shepparton campuses), and the Dja Dja Wurrung people (Creswick campus).

The University also acknowledges and is grateful to the Traditional Owners, Elders and Knowledge Holders of all Indigenous nations and clans who have been instrumental in our reconciliation journey.

We recognise the unique place held by Aboriginal and Torres Strait Islander peoples as the original owners and custodians of the lands and waterways across the Australian continent, with histories of continuous connection dating back more than 60,000 years. We also acknowledge their enduring cultural practices of caring for Country.

We pay respect to Elders past, present and future, and acknowledge the importance of Indigenous knowledge in the Academy. As a community of researchers, teachers, professional staff and students we are privileged to work and learn every day with Indigenous colleagues and partners.

## ***Position Summary***

The Department of Infectious Diseases based at the Peter Doherty Institute for Infection and Immunity is seeking to appoint a Clinical Trial Database Support Officer to support database work within the Tong Research Group.

The Tong Research Group primarily manage investigator-initiated, large international, multicentre clinical trials in infectious diseases.

The two largest studies managed by the group are:

- ▶ The *Staphylococcus aureus* Network Adaptive Platform (SNAP) trial aims to determine the best combination of treatment options for patients with golden staph bloodstream infections. SNAP recruits patients from Australia, New Zealand, Singapore, Canada, Israel, Europe, South Africa and the United Kingdom. It is currently the largest clinical trial on *Staphylococcus aureus* bloodstream infections globally.
- ▶ The Australasian COVID-19 Trial (ASCOT) is an adaptive platform, randomised clinical trial which aims to identify treatment regimens that improve clinical outcomes in hospitalised patients with COVID-19 infections across Australia and New Zealand.

The successful applicant will have the necessary skills to support research sites and the trial managers in tasks relating to coordination of the databases (Spinnaker and REDCap). This includes assisting sites with database queries, liaising with sites and data coordinators to resolve data inconsistencies or missingness, developing manuals and Standard Operating Procedures (SOPs), attending data meetings, be involved in developing and testing the database with the external database providers and keeping records of database versions, updates, and change requests. There will also be opportunity to be involved in other trial duties such as assisting with governance and ethics submissions, agreements, study documentation and meetings if required or desired.

The Clinical Trial Database Support Officer will primarily work on the SNAP Trial with an opportunity to be involved with other trials within the Tong Research Group if needed.

Clinical Trial Research Assistants or Project Officers who wish to extend their study database and data experience are encouraged to apply.

The Clinical Trial Database Support Officer will report to the Clinical Trial Program Manager and Clinical Trial Managers.

## **1. Key Responsibilities**

- ▶ Set up database users, provide training, ongoing support for users and user access to research staff.
- ▶ Raise data queries and liaise with participating research sites to resolve queries or missing data.
- ▶ Liaise and attend meetings with the external database providers and analysis teams
- ▶ Primary point-of-contact for the study statisticians, Data Safety and Monitoring Committee, and data coordinators.
- ▶ Ensure the validity and integrity of research data including: ensure database applications reflect changes in users' and the studies' needs; develop user-friendly manuals, forms and SOPs for data entry, maintain audit trails with data correction logs and trackers.
- ▶ Assist with database design, test updates to the database to check it is user-friendly and accurate and keeping records of any changes or change requests to the database.
- ▶ Maintain privacy, confidentiality and security of all data.
- ▶ Participate in team meetings, including work summary presentations as required.
- ▶ Other tasks and duties commensurate with the level of appointment as required.
- ▶ Contribute to the co-production of conference and seminar papers and publications.
- ▶ Occupational Health and Safety (OH&S) and Environmental Health and Safety (EH&S) responsibilities as outlined in section 6.
- ▶ Effective demonstration and promotion of University values including diversity and inclusion and high standards of ethics and integrity

## **2. Selection Criteria**

### **2.1 ESSENTIAL**

- ▶ Completion of a degree in biomedical science, health science, nursing, data management or a public health related discipline or progress towards and relevant experience or an equivalent combination of relevant experience and/or education/training
- ▶ Excellent organisational and administrative skills with the ability to work with a high level of attention to detail in relation to preparation of documentation, compliance and reporting requirements.
- ▶ Working knowledge of ethics, confidentiality, security and privacy as they relate to clinical trial data.
- ▶ Sound written and verbal communication skills, including the ability to communicate with a range of stakeholders from policy and research environments, as well as the ability to write user manuals and protocols.

- ▶ Demonstrated ability to work as part of a team or independently as necessary and be self-motivated to consistently produce the best possible results in a timely manner.
- ▶ Evidence of ability to meet deadlines while producing high quality work.

## 2.2 DESIRABLE

- ▶ Relevant experience in supporting large clinical research projects in the higher education sector or research sector or an equivalent combination of relevant experience and/or education/training.
- ▶ Demonstrated experience conducting data management tasks including quality assurance activities, data checking and cleaning of small and large-scale datasets, data manipulation and extraction, and the preparation and management of data documentation.
- ▶ Highly skilled with Excel (e.g. formulas, macros, pivot tables) and/or experience with analysis software such as R or Stata.
- ▶ Demonstrated experience in querying, formatting and extracting clinical trial data, and familiar with clinical trial eCRF platforms.
- ▶ Current GCP accreditation.

## 2.3 OTHER JOB RELATED INFORMATION

- ▶ Occasional work out of ordinary hours, travel, etc.

# 3. Job Complexity, Skills, Knowledge

## 3.1 LEVEL OF SUPERVISION / INDEPENDENCE

The Clinical Trial Database Support Officer will be supervised by the Clinical Trial Program Manager, and work under broad direction from the Trial Managers, Coordinating Investigators and Trial Management Group with a considerable degree of autonomy. The appointee is expected to be highly motivated and will work as part of the research team. In this position the incumbent is expected to independently establish and prioritise an appropriate work-flow for the management of day-to-day tasks associated with the database.

## 3.2 PROBLEM SOLVING AND JUDGEMENT

The appointee is expected to demonstrate initiative in organisation, planning and problem solving in the assigned tasks, within a supportive environment. Under the direction and guidance of the Clinical Trial Managers, they are expected to implement processes to manage the different requirements of the database. They will be expected to contribute their ideas, relay feedback and work with the Clinical Trial Managers, Data Coordinators, Statisticians, Coordinating Investigators and the external database provider.

## 3.3 PROFESSIONAL AND ORGANISATIONAL KNOWLEDGE

The Clinical Trial Database Support Officer is required to be familiar with clinical trial co-ordination, including being familiar with data capture systems, managing data sets and data integrity, general data operations and processes in compliance with local and

international regulatory frameworks (eg. TGA, ICH-GCP). The Clinical Trial Data Support Officer is also expected to have an understanding of clinical research in hospital settings, higher education sector and research environments.

### **3.4 RESOURCE MANAGEMENT**

The incumbent will be responsible for using resources in line with Institute and University policies and procedures.

### **3.5 BREADTH OF THE POSITION**

The Clinical Trial Database Support Officer will provide database-specific operational support to assist the Trial Management Group, the Coordinating Investigators, Clinical Trial Managers, and broader research network. The role requires extensive interaction with hospital and University staff at all levels as well as key external stakeholders and partner organisations.

## ***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 Advancing Melbourne strategy that addresses 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 Advancing Melbourne.

## ***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:

<https://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 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, epidemiologists, public health physicians and microbiologists.

### 6.2 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. MMS is ranked 14th in the world (Times Higher Education World University Rankings 2022 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.

Under the leadership of Professor Sarath Ranganathan, MMS spans all major fields of medicine and is comprised of 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.

MMS has more than 1,000 academic and professional staff members located at the Parkville campus or embedded within health services throughout metropolitan Melbourne and rural Victoria. Staff are privileged to work alongside more than 2,725 honorary appointees from the health sector who generously contribute their time, knowledge, research and clinical expertise.

MMS is committed to improving community wellbeing through the discovery and application of new knowledge. With annual research income of \$165 million, the School's research effort is highly collaborative, spanning research programs from basic to translational. The School has research collaborations across the 47 partner organisations in the vibrant Melbourne Biomedical Precinct, as well as nationally and internationally.

These partnerships enable medical advances to impact healthcare delivery as rapidly and seamlessly as possible.

The School's flagship Doctor of Medicine (MD) degree was the first Masters level entry-to-practice qualification of its kind developed in Australia, setting a new benchmark in medical education. Now, the new curriculum launched in 2022 has created more responsive, modular, technology-enhanced learning for state-of-the-art curriculum delivery. Continuous research and discovery options, and an ability to tailor the degree, allows each student to gain deeper experience in areas of greatest interest. The MD Rural Pathway offers students the opportunity to undertake their entire program in rural Victoria, with a \$6.5 million expansion of facilities in Shepparton to accommodate this. There is also an expanded range of joint degree pathways on offer. The School utilises the Department of General Practice's continually expanding network of general practitioners and primary healthcare providers in the community to ensure that MD students are also provided with quality community-based medical education.

In addition to the MD, MMS has an ever-expanding portfolio of other vocationally oriented programs. These teach research skills, leadership and continuing professional development in specific disciplines. An emphasis on the clinician-scientist career trajectory – with training, support and ongoing career pathways at graduate and postgraduate levels – is central to the School's development of future leaders in all aspects of healthcare, education, research and policy. MMS has over 600 higher degree by research candidates located both within Departments and across its network of partners.

School staff and honorary appointees 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. The School also offers a range of initiatives and programs in support of its diverse and inclusive culture:

<https://medicine.unimelb.edu.au/about/diversity-and-inclusion>

MMS is always looking to recruit talented individuals across a wide range of medical disciplines which include leadership roles. This presents a wonderful opportunity for appointees to help drive the strategy, growth and continued excellence of Australia's leading medical school.

### 6.3 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.

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

<https://www.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.

#### 6.5 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>

#### 6.6 ADVANCING MELBOURNE

The University's strategic direction is grounded in its purpose. While its expression may change, our purpose is enduring: to benefit society through the transformative impact of education and research. Together, the vision and purpose inform the focus and scale of our aspirations for the coming decade.

Advancing Melbourne reflects the University's commitment to its people, its place, and its partners. Our aspiration for 2030 is to be known as a world-leading and globally connected Australian university, with our students at the heart of everything we do.

- ▶ We will offer students a distinctive and outstanding education and experience, preparing them for success as leaders, change agents and global citizens.
- ▶ We will be recognised locally and globally for our leadership on matters of national and global importance, through outstanding research and scholarship and a commitment to collaboration.
- ▶ We will be empowered by our sense of place and connections with communities. We will take opportunities to advance both the University and the City of Melbourne in close collaboration and synergy.



- ▶ We will deliver this through building a brilliant, diverse and vibrant University community, with strong connections to those we serve.

The means for achieving these goals include the development of the University of Melbourne's academic and professional staff and the capabilities needed to support a modern, world-class university. Those means require a commitment to ongoing financial sustainability and an ambitious infrastructure program which will reshape the campus and our contribution to the communities we engage with. This strategy, and the priorities proposed, is centred around five intersecting themes; place, community, education, discovery and global.

## 6.7 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 <https://about.unimelb.edu.au/strategy/governance>