

SENIOR CLINICAL TRIAL COORDINATOR

DEPARTMENT/UNIT	Monash University Clinical Trials Centre
FACULTY/DIVISION	Faculty of Medicine Nursing and Health Sciences
CLASSIFICATION	HEW Level 7
DESIGNATED CAMPUS OR LOCATION	553 St Kilda Road

ORGANISATIONAL CONTEXT

At [Monash](#), work feels different. There's a sense of belonging, from contributing to something groundbreaking – a place where great things happen. You know you're part of something special and purposeful because, like Monash, your ambitions drive you to make change.

We have a clear purpose to deliver groundbreaking intensive research; a world-class education; a global ecosystem of enterprise – and we activate these to address some of the [challenges](#) of the age, Climate Change, Thriving Communities and Geopolitical Security.

We welcome and value difference and [diversity](#). When you come to work, you can be yourself, be a change-maker and develop your career in exciting ways with curious, energetic, inspiring and committed people and teams driven to make an impact – just like you.

We champion an [inclusive workplace culture](#) for our staff regardless of ethnicity or cultural background. We have also worked to improve [gender equality](#) for more than 30 years. Join the pursuit of our purpose to build a better future for ourselves and our communities – [#Changelt](#) with us.

The Faculty of **Medicine, Nursing and Health Sciences** is the largest faculty at Monash University, a global university with campuses across Victoria and international locations in Indonesia, Malaysia, China, India and Italy.

Our Faculty offers the most comprehensive suite of professional health training in Victoria, consistently ranked in the top 40 universities worldwide for clinical, pre-clinical and health sciences.

We want to improve the human condition. That is our vision - it has no expiration date. By educating the current and future healthcare workforce, and undertaking medical research, both discovery and clinical, our students, staff and alumni all work to directly improve people's quality of life, reduce health inequality and promote greater health and social outcomes.

We're globally recognised for our quality education of over 63,000 doctors, nurses, and allied health professionals and health researchers. The future health of our communities is underpinned by the sustained excellence of our education and research capabilities.

We are ambitious and committed to maintaining our position as a leading international medical research and teaching university. We're recognised for the quality of our graduates, the scale and depth of our research, our commitment to translational research, and as a thriving biotechnology hub. To learn more about the Faculty, please visit www.monash.edu/medicine.

Our Faculty includes four Sub-Faculties: Health Sciences, Clinical and Molecular Medicine, Biomedical Medicines, and Translational Medicine and Public Health.

The **School of Public Health and Preventive Medicine** is committed to our vision of Health and wellbeing for all people and communities. We are one of the largest schools of public health in the Asia Pacific region. Through generating and synthesising impactful evidence, supporting the strengthening of our health systems and informing and transforming policy and practice, we can help overcome the health challenges being faced across Australia and more broadly. We have skills, knowledge and excellence across a range of disciplines including epidemiology, research methodology, biostatistics, research ethics, governance, clinical trials, clinical quality registries, qualitative research, evidence synthesis, implementation science, health economics, genomics, forensic science, health systems, services and policy, and clinical practice. This provides a strong foundation upon which we can inform, support and sustain equitable improvements in health for individuals and communities. The School is part of the Faculty of Medicine, Nursing and Health Sciences centred at the Alfred Hospital Campus with satellite units and partners embedded across other major Monash affiliated hospitals, research institutes and public health organisations.

The [Monash University Clinical Trials Centre](#) is an academic research organisation that aims to improve health and wellbeing across the globe through supporting innovative and impactful clinical research. The Centre provides a dedicated and specialised clinical trial support service for Monash University academics and our health service partners. The Centre delivers a critical mass of expertise to support the development and testing of innovative clinical trial methodological design, research processes and analytical approaches.

Led by Monash University, [The mitoHOPE \(Healthy Outcomes Pilot and Evaluation\) Program](#) has formed an Australian-wide consortium to conduct a mitochondrial donation and reproductive options pilot program. The mitoHOPE Program includes a clinical trial designed to enable women, who are predisposed to having a child with mitochondrial DNA (mtDNA) disease to have a biological child who does not share that predisposition. The trial will determine the safety, efficacy and feasibility of implementing mitochondrial donation in Australia. The program will also increase health practitioner knowledge about mitochondrial disease (mito) and provide data justifying its ongoing use in the Australian Health system.

The mitoHOPE Program was developed in collaboration with the Mito Foundation whose advocacy for the mito community led to the introduction of Maeve's Law. The program will continue to work with the Mito Foundation and the mito community to ensure optimal implementation of all aspects of the mitoHOPE Program, in particular the clinical trial.

The mitoHOPE Program is funded by the Medical Research Future Fund (MRFF) as well as contributions from partner organisations.

POSITION PURPOSE

The Senior Clinical Trials Coordinator is responsible for overseeing and delivering high-quality research services to support the operations of the Clinical Trials Centre, specifically including overseeing and undertaking delivery of the MitoHOPE Program clinical trial. The Senior Clinical

Trials Coordinator performs a range of significant and complex research activities that play a critical role in supporting the delivery of the mitoHOPE clinical trial outcomes.

This position supports the mitoHOPE clinical trial through a range of activities including site set up, staff training at hospital sites, ongoing liaison and data monitoring for quality control, preparation of Human Research Ethics Committee (HREC) and license applications, regulatory documentation, clinical trials contracts and organising site and investigator meetings.

The Senior Clinical Trials Coordinator is a subject matter expert with relevant experience in the assisted reproductive technology environment. The Senior Clinical Trials Coordinator provides specialist advice to clients, stakeholders and colleagues and delivers efficient research services in accordance with research protocols and standards.

Reporting Line: The position reports to the MUCTC Operations Manager with direction from the Monash IVF Chief Scientific Officer

Supervisory Responsibilities: Not applicable

Financial Delegation: Not applicable

Budgetary Responsibilities: Not applicable

KEY RESPONSIBILITIES

1. Oversee and co-ordinate the day-to-day operations of the clinical trial including participant recruitment, coordinating and supporting clinical trial visits and procedures, coordination of data collection from multiple sources, completion of case report forms, overseeing OHS or patient safety measures, maintaining site files and study materials.
2. Provide a high-level research administration program which may include providing advice on, developing and supporting; clinical trial documentation, development of a database, research or technical procedures, grant applications, reports and license applications.
3. Work alongside research staff and Investigators to collect clinical data from medical records, enter study data into study database within timelines and facilitate regular monitoring of data quality, security, and confidentiality.
4. Liaise with National Clinical Coordinator and referring local clinical care team to coordinate participant entry into the clinical trial, and to schedule study visits and follow-ups.
5. Support the delivery of a high-quality clinical trial and ensure adherence to the study protocol, Good Clinical Practice (GCP), the NHMRC statement on Ethical Conduct in Human Research and all relevant legislation and regulatory requirements.
6. Contribute to and attend planning and committee meetings as required, to share knowledge and expertise in the area of research specialisation.
7. Provide specialist and technical advice and/or training to clients, staff, students and other stakeholders in the area/s of research specialisation.
8. Develop and maintain up-to-date specialist knowledge of new and innovative research methodology, equipment, technology and data management in the field of research specialisation.
9. Manage and track expenditure related to clinical trial activities to support overall budget management and reporting of the research program.
10. Build and sustain partnerships, collaborations and networks with academic and other staff, relevant research bodies, service providers and functional area, regularly engaging with clinicians, patient advocacy/ support groups, and research participants.
11. Offer administrative and research support, including ethics and research governance reporting and providing data reports to team members and external stakeholders, as required.

12. Contribute to troubleshooting and developing various aspects of the project.
13. Other duties as directed from time to time.

KEY SELECTION CRITERIA

Education/Qualifications

1. The appointee will have:
 - A degree qualification in a relevant field with extensive relevant experience; or
 - extensive experience and management expertise in technical or administrative fields; or
 - an equivalent combination of relevant experience and/or education/training.

Knowledge and Skills

2. Demonstrated experience in overseeing a successful clinical trial or service, with a focus on operational excellence
3. Demonstrated experience working in the assisted reproductive technology or hospital environment
4. Highly-developed planning and organisational skills, with experience establishing priorities, implementing improvements and meeting deadlines
5. Demonstrated project management skills, with a proven record of successfully supporting research projects through to completion
6. Demonstrated ability to work as an effective member of a team as well as the ability to exercise high levels of independence, judgement and initiative
7. Demonstrated analytical, research and problem-solving skills and the ability to identify and recommend solutions to challenging issues
8. Highly-developed interpersonal and communication skills with the ability to prepare professional documentation for various audiences and provide expert advice in areas of specialist or research knowledge
9. Demonstrated relationship management and consulting skills, including the ability to interact with, negotiate with and gain co-operation from internal and external stakeholders.

OTHER JOB RELATED INFORMATION

- Travel to [Monash IVF](#), Cremorne will be required
- Travel to other Monash IVF sites and campuses of the University may be required
- There may be a requirement to work additional hours from time to time
- There may be peak periods of work during which taking of leave may be restricted

GOVERNANCE

Monash University expects staff to appropriately balance risk and reward in a manner that is sustainable to its long-term future, contribute to a culture of honesty and integrity, and provide an environment that is safe, secure and inclusive. Ensure you are aware of and adhere to University policies relevant to the duties undertaken and the values of the University. This is a standard which the University sees as the benchmark for all of its activities in Australia and internationally.