Position Description

Position Title: Clinical Trial Coordinator

Salary Range: MCRI Research Salaries – Research Assistant/Research Nurse - Step 5 to Step 7

Reporting Manager: Angela Young, Project and Partnerships Manager

Direct Reports: Research Assistants (Stream studies including ADAPT and ARISE)

Home Group: Population Allergy (National Allergy Centre of Excellence)

Children are at the heart of everything we do.

The Murdoch Children's Research Institute (MCRI) is home to significant scientific discoveries. We believe there is an answer, a cure, or a better treatment for every childhood condition — and we are determined to find it.

We are a diverse team of world-leading researchers, doctors, engineers, and hardworking professionals in corporate and scientific services from all corners of the world with one shared goal — to transform child health worldwide.

Our strength lies in our partnership and co-location with The Royal Children's Hospital and the University of Melbourne — the Melbourne Children's Campus. This rare model amplifies opportunities to quickly translate research into clinical care.

At MCRI, you will also find our subsidiary organisation, the Victorian Clinical Genetics Services (VCGS), a specialist childhood, prenatal and adult genetics service. VCGS provides an integrated genetic consultation, counselling, testing and diagnostic support service to children, adults, families, and prospective parents.

Together, we share a powerful vision: re-imagine the future of child health.

What is it like to work for us?

We are committed to ensuring a positive working environment that values all backgrounds and experiences. We cultivate an inclusive culture that is underpinned by equal opportunity for all and a culture based on respect, consideration, and dignity. We are also committed to developing our People and fostering an environment where learning and development is central to our staff reaching their full potential.

Position Overview

The National Allergy Centre of Excellence (NACE)

In March 2022, a $26.9 million investment into allergy prevention and management was announced as part of the Federal Government's 2022 budget. This funding was in response to the 2019 bipartisan Parliamentary Inquiry into Allergies and Anaphylaxis, and the 24 recommendations in the 'Walking the allergy tightrope report', which highlighted the critical need for further investment to address this continuing public health challenge.

$10.2m of this investment has been directed towards establishment of the National Allergy Centre of Excellence (NACE) hosted at MCRI, to facilitate the development of research infrastructure to accelerate research and translation nationally across all allergy domains (drug, food, insect and respiratory) and to train the next generation of allergy researchers.

The key NACE activities are structured under four broad pillars: Allergy Research, Repository & Discovery P, Evidence & Translation and Training & Innovation.

The NACE Allergy Research Pillar is led by Professor Kirsten Perrett, Director of the NACE and an experienced clinician research and clinical triallist; and supported by the Projects and Partnership Manager and a team including this role of Clinical Trial Coordinator, Research and Project Officers, Research Assistants, Post-doctoral fellows and Data experts. The NACE Allergy Research Pillar are establishing four multi-site stream studies and the NACE Acute Allergy Registry. Each study will be conducted across at least three states, in each of the four allergy domains by June 2026.

We are looking for an enthusiastic individual with clinical trials experience to support the establishment and implementation of the four stream trials/studies. The role will involve scoping of potential sites and investigators, protocol and SOP\development, preparation and submission of ethics applications, the development of trial budgets and co-ordination of trial start-up activities including staff training and site initiation and overseeing trial/study implementation. This role will line manage NACE Research Nurse and Research Assistant positions supporting trial/study implementation and monitoring. Regular communication and coordination with a broad range of internal and external professional stakeholders across Australia will form a central part of this position. Interstate travel for monitoring visits may be required approx. 2-4 times annuals. Nursing experience highly regarded although not required for the position.

Key Accountabilities

- Assists in the scoping of potential sites and investigators for each of the four NACE embedded trials
- Coordinates the development of trial protocols, patient information and consent forms and SOPs
- Coordinates submission of ethics and governance applications, amendments and progress reports, both at MCRI and other sites
- Assists in the establishment and management of project working groups as required
- Works with the Data Manager, Senior Research Officer and statisticians to establish trial data capture instruments
- Assists in the training of trial staff at all trial sites and site initiation
- People management of NACE Research Nurses and Research Assistants (ARISE, ADAPT and other studies as required)
- Monitors study progress and budget and provides regular updates to stakeholders as required, including site visit
- Ensures each trial is undertaken in accordance with the terms approved by the institutional ethics committee and all relevant regulations and guidelines
- Responds to site and trial related issues and recommends corrective actions and/or escalates them to supervisors in a timely manner
- Participates in trial monitoring/auditing as required and oversees NACE Research Assistants conducting monitoring activities
- Conducts ethical research at the highest level of integrity and in line with the Australian Code for Responsible Conduct of Research and MCRI policies
- Ensures integrity in data collection and compliance with state and national data protection and privacy legislation
- Maintains a flexible approach to meet the requirements of the study/research protocols and participant recruitment
- Participates in Population Allergy Group activities including data presentations, journal club and business meetings
- Is engaged in the campus culture including professional development activities and attending internal/external campus conferences and seminars
- Is aware of, and adheres to, MCRI policy on Intellectual Property / Material Transfer Agreements / Contracts / Clinical and Public Health Outcomes
- Assists and contributes to data generation for research and publications
- Works to improve skill base in research productivity and methodology
- Assists in high calibre, competitive research
- Participates in, if applicable, patient recruitment, ethics application processes and adverse event reporting
- If a qualified nurse, demonstrates the knowledge, attributes and skills consistent with a Research Nurse working within a clinical research scope of practice. Understands and speaks to the contribution of research to quality improvement projects
- Provides training and mentorship to team members, patients, and families related to a specific research method, protocol, or program
- If a qualified nurse, leads and promotes nursing involvement in research, and advocates for patients and families participating in research projects
- Shares information and presents to others within the Research Group or Theme and seeks opportunities to contribute to the skill development of others
- Supervises students, contributes to teaching and examination in the area of research expertise
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- Is involved in the development of innovative approaches to research
- Is involved, where appropriate, in the promotion of research links with external stakeholders
- Fosters relationships with key internal and external stakeholders
- Is engaged in the campus culture, including participating in professional development activities and attendance at internal/external conferences and seminars

What we need from you

- Relevant Postgraduate Diploma or Masters desirable
- Bachelor of Nursing or Bachelor in Science highly regarded
- Applicable Nursing Registration – Division 1 with the Australian Health Practitioner Regulation Agency (AHPRA), highly regarded
- Appropriate level of expertise gained from a combination of experience and or training
- Demonstrated ability to complete ethics and governance applications
- At least 5 years' experience in clinical trial coordination
- Relevant experience as a people manager
- Knowledge of ICH Guidelines, GCP and NHMRC guidelines including international regulatory requirements for the conduct of clinical trials.
- Good Clinical Practice certification
- Demonstrated ability to coordinate projects and multiple stakeholders
- Demonstrated ability to manage and oversee staff
- Interstate travel to support site monitoring visits as required (approx. 2-4 times annually)
- Demonstrated ability to manage budgets highly regarded
- Outstanding interpersonal and communication skills with experience communicating to a wide range of audiences
- Familiarity of electronic research data bases and systems including REDCap
- Familiarity of electronic medical record data and systems including EPIC and Cerner
- Knowledge of embedded research

Conditions of Employment

- Working with Children & National Police Clearance (if appointed) in compliance with the Victorian Governments Child Safety Standards
- The right to reside and work in Australia and you meeting any applicable visa conditions

Health, Safety & Wellbeing

- We are committed to providing and maintaining a working environment which protects the health, safety and wellbeing of our people, partners and the community.
- Employees conducting duties on behalf of MCRI are expected to meet the environment, health and wellbeing requirements and responsibilities specifically required for the role.
- We are committed to supporting children in their right to be safe and adhere to the responsibilities we have to ensure their protection and safety as per the Child Safety Standards Policy.
- Specified positions may be subject to medical review to ensure that the inherent requirements of the role can be undertaken safely.

As MCRI evolves to meet its changing strategic and operational needs and objectives, so will the roles required of its employees. As such, this document is not intended to represent the position which the occupant will perform in perpetuity. This position description is intended to provide an overall view of the incumbent's role as at the date of this statement.