Position Description

Position Title: Study Coordinator

Salary Range: Professional & Administrative level 5 Step1 – Level 5 Step 7

Reporting Manager: Clinical Trials Manager, Children's Cancer Centre

Direct Reports: Nil

Home Group: Cancer

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

As a member of the research team, the Study Coordinator (SC) will have responsibility for the delivery of direct and indirect clinical trial related care of patients and associated data collection for concurrent clinical trial research studies undertaken in the department, in accordance with the Therapeutic Goods Administration (TGA) Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research and applicable state/federal privacy laws. The SC will ensure the highest standard of care is delivered to all patients involved in clinical trials and, where relevant, their families, in partnership with all members of the multidisciplinary and research teams. The SC will maintain ethics and research governance.

The Principal Investigator/Unit Head is responsible for delegating authority to suitably qualified staff. Within this authority, the Study Coordinator will perform the role using the required qualifications and experience, within the Children's Cancer Centre. The SC will manage and oversee individual clinical trials to ensure their effective operation. The CCC has three (4) tumour streams; liquid, bone marrow transplant, solid and brain malignancies.

Key Accountabilities

- Organise and managed pharmacokinetic studies
- Participates in training and education to improve knowledge, follows guidelines and uses evidence based practice
- Conduct clinical research in accordance with TGA ICH GCP, the NHMRC National Statement on Ethical Conduct in Human Research and relevant state/federal privacy laws
- Make professional decisions related to clinical trial management on a daily basis
- Provide professional advice relating to the conduct of clinical research
- In conjunction with medical staff, analyse and assess each patient's condition according to the trial protocol and determine appropriate action to ensure the patient's future care and participation in the study
- In collaboration with other health professionals, act as a patient advocate at all times
- Within the guidelines of the employment contract, maintain a flexible approach to working hours in order to meet the requirements of the research protocols and patient recruitment
- Demonstrate a commitment to continuing professional development and participate in performance review/appraisal
- Maintain up-to-date clinical research skills and knowledge
- Demonstrate knowledge of Campus policies and procedures
- Conducts ethical research at the highest level of integrity and in line with the Australian Code for Responsible Conduct of Research and MCRI policies
- Assists and contributes to data generation for research, publications and literature reviews
- Collects documents needed to initiate the study and submit to the sponsor (where applicable)
- Ensure integrity in data collection and ensure compliance with state and national data protection and privacy legislation.
- Contribute to the development of new study/research protocols and ensure the effective management of the study and care requirements of the participants are fully considered
- Follows and initiates standard operating procedures (SOPs), study/research protocols and guidelines, and work improvement practices
- Monitor study progress and provide regular updates to investigators
- Maintain a flexible approach in order to meet the requirements of the study/research protocols and participant recruitment.
- Ensures study is undertaken in accordance with the terms approved by the institutional ethics committee and all relevant regulations and guidelines
- Understand ethics submission process, completes ethics and regulatory documentation that require submission to the Human Research Ethics Committee and/or research governance manager
- Prepare study materials for participants
- Respond to site and study related issues and recommend corrective actions and/or escalate to supervisors in a timely manner
- Liaise with all involved groups/departments to ensure all samples are collected, stored and processed as per the protocol and applicable storage and handling regulations
- Report serious adverse events and adverse events according to TGA, ICH GCP and local ethics guidelines and the study/research protocol to ensure participant safety (where applicable)
- Participate in study monitoring/auditing as required.
- Maintain effective communication processes with participants and relatives, investigators, and other members of the study team to ensure information is appropriately shared and the appropriate implementation of the study/research protocol
- Fosters relationships with key internal and external stakeholders
- Maintain user-friendly data management systems
- 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.

Selection Criteria

- Degree/Honours qualification in Science or related discipline OR an appropriate level of experience in a relevant field
- Appropriate level of expertise gained from a combination of experience, training or professional accreditation
- Experience in participating in the planning and coordination of projects
- Experience in data and database management, data collection and analysis
- Experience in the planning and conduct of research projects

- Demonstrated computer skills, including spreadsheets, database programs, statistics and word processing
- Demonstrated understanding of a range of research methodologies and their application in empirical research
- Strong ability to collaborate with patients and their families
- Demonstrated ability to build and maintain working relationships with key internal and external stakeholders
- Demonstrated ability to be well organise and have good coordination skills and attention to detail
- Ability to work both autonomously and as a team

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.