

Position Description

POSITION TITLE:	Clinical Project Manager / Clinical Research Coordinator
LOCATION:	SAHMRI, North Terrace
REPORTS TO:	Senior Manager, SAHMRI Clinical Trials Platform
DEPARTMENT:	SAHMRI Clinical Trials Platform

ORGANISATIONAL SUMMARY

The South Australian Health and Medical Research Institute (SAHMRI) is South Australia's flagship, not-for-profit medical research institute, committed to improving health outcomes through excellence in research, innovation, and collaboration.

Located in the heart of the Adelaide Biomedical Precinct, SAHMRI's Clinical Trials Platform (CTP) plays a unique dual role as both an Academic Research Organisation (ARO) and an outpatient clinical trial site. This integrated model enables us to deliver high-quality, participant-centred services across the full clinical trial lifecycle, from Phase Ib to IV, supporting both investigator-initiated and industry-sponsored research. The CTP also contributes to broader SAHMRI research initiatives aligned with our capabilities.

Formally established in 2021, the CTP is a dynamic team of Clinical Project Managers, Clinical Research Coordinators, Research Nurses and Clinical Research Associates working together to accelerate the translation of research into real-world impact. We pride ourselves on fostering a collaborative, purpose-driven environment that supports innovation, integrity, and excellence in clinical trial and research project delivery.

PURPOSE AND SCOPE OF THE POSITION

The Clinical Project Manager / Clinical Research Coordinator is a hybrid role responsible for both the project management and operational coordination of clinical trials and research projects within the SAHMRI Clinical Trials Platform. The position combines clinical trial project management responsibilities with hands-on clinical research coordination, supporting studies across the full clinical trial lifecycle from feasibility and start-up through to participant recruitment, study conduct, close-out and reporting.

The role is responsible for the planning, coordination and delivery of assigned clinical trials and research projects, including study start-up, ethics and governance submissions, stakeholder management, study budget oversight, risk management and study close-out activities. In parallel, the role contributes to participant-facing and site-level clinical trial activities to support successful study delivery, including participant recruitment and screening, appointment scheduling, telephone follow-up, study visits, data collection and other delegated study responsibilities within the individual's qualifications, training and competency.
The role will support haematology clinical trials, although involvement in studies across a broad range of therapeutic areas is expected. The balance of project management and clinical research coordination responsibilities will vary according to project requirements, study portfolio and individual experience.

The Clinical Project Manager / Clinical Research Coordinator works closely with internal teams across SAHMRI and engages with a broad range of external stakeholders including investigators, health services, sponsors, Contract Research Organisations (CROs), Ethics Committees, Governance Offices, vendors, regulators and government agencies.



KEY RESPONSIBILITIES

Project Management

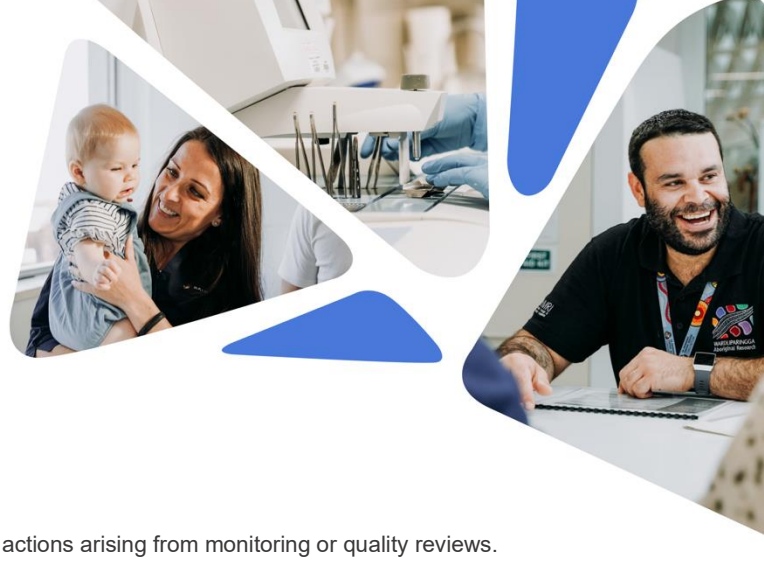
- Lead assigned clinical trials and research projects from feasibility through to study close-out.
- Develop and maintain project plans, timelines, study trackers, risk registers and project documentation.
- Coordinate study start-up activities, including feasibility assessments, budgeting, ethics and governance submissions, contracts, site activation and vendor management.
- Monitor project timelines, budgets, milestones, recruitment targets, risks and deliverables.
- Identify project risks and implement mitigation strategies to support successful study delivery.
- Lead or contribute to ethics, governance and regulatory submissions, amendments and ongoing compliance activities.
- Coordinate study-related procurement, service providers and external vendors.
- Collaborate with investigators, sponsors, vendors and other stakeholders to resolve issues and achieve study objectives.
- Support the identification, documentation and reporting of adverse events and serious adverse events in accordance with protocol, sponsor and regulatory requirements.
- Prepare study reports, project updates and governance documentation for internal and external stakeholders.
- Manage budgets, contracts, invoicing and financial tracking for allocated projects.
- Review participant reimbursement, study invoicing, vendor payments and sponsor pass-through costs as required.
- Participate in study team meetings, sponsor meetings and other stakeholder meetings required to support clinical trial delivery.
- Contribute to feasibility assessments, proposal development and budget preparation for new clinical trial opportunities.
- Provide guidance, mentoring and support to junior research staff and contribute to onboarding and training activities.

Clinical Trial Site Delivery

- Support the delivery of investigator-initiated and industry-sponsored clinical trials conducted by the Clinical Trials Platform.
- Contribute to participant recruitment activities, including pre-screening review and participant engagement initiatives.
- Conduct participant contact activities, including telephone screening, appointment scheduling, study reminders and participant follow-up.
- Support participant-facing study activities where required, including informed consent discussions, screening visits, study visits and collection of study data, in accordance with individual qualifications, training and delegated responsibilities.
- Perform delegated study-related procedures and research activities within scope of practice and competency.
- Maintain accurate and contemporaneous study documentation, investigator site files and essential trial records.
- Support management of study data and trial systems, including Electronic Data Capture (EDC) platforms (e.g. REDCap), electronic Trial Master File (eTMF) systems and other clinical trial databases.
- Work collaboratively with Research Nurses, Clinical Research Associates and Study Coordinators to ensure efficient delivery of study visits and participant care.
- Provide operational support during periods of peak workload to ensure continuity of clinical trial delivery.

Quality & Compliance

- Ensure studies are conducted in accordance with ICH-GCP, protocol requirements, regulatory requirements and SAHMRI policies.
- Support and facilitate monitoring visits, audits and regulatory inspections, including timely resolution of findings and implementation of corrective and preventive actions (CAPAs).
- Contribute to quality improvement initiatives and process optimisation activities.
- Develop, review and maintain Standard Operating Procedures (SOPs), templates and quality documentation.
- Maintain risk management and incident documentation as required.



- Support implementation of corrective and preventive actions arising from monitoring or quality reviews.

Operational Excellence

- Contribute to the continuous improvement of systems, processes and workflows across the Clinical Trials Platform.
- Foster collaborative relationships with internal and external stakeholders.
- Contribute to a positive team culture aligned with SAHMRI's values and strategic objectives.
- Support strategic initiatives that enhance the growth, sustainability and reputation of the Clinical Trials Platform.

Organisational Responsibilities

- Take reasonable care to protect own health, safety and welfare at work and avoid affecting the health and safety of any other person at work
- Participate in the implementation of the Institute's Work, Health and Safety Management System and related laws, regulations and guidelines.
- Ensure that duties are performed in keeping with the principles outlined in SAHMRI's Vision, Mission and Values and the Code of Conduct Policy.

SPECIAL REQUIREMENTS

- Some out of hours work may be required.
- National Police Check and WWCC Employment Screening may be required.



Person Specification

QUALIFICATIONS

- Qualifications in Health, Science or a related discipline, with relevant experience in clinical research and/or clinical trial project management.

EXPERIENCE, KNOWLEDGE AND SKILLS

- Demonstrated experience in clinical research and/or clinical trial project management. Experience in haematology clinical trials is highly desirable.
- Strong understanding of clinical trial conduct, ICH-GCP guidelines, applicable regulatory requirements, and the Australian clinical trial and research governance environment.
- Experience preparing and managing ethics, governance and regulatory submissions.
- Experience managing clinical trial budgets, timelines, deliverables, risks and competing priorities.
- Experience working with investigators, research teams, sponsors, Contract Research Organisations (CROs) and other stakeholders, with strong communication and relationship management skills.
- Well-developed organisational, problem-solving and decision-making skills, with a high level of attention to detail and commitment to quality.
- Experience working within an Academic Research Organisation (ARO), clinical trials unit, CRO or sponsor environment is desirable.
- Experience with REDCap, electronic data capture systems, clinical trial management systems and eTMFs is desirable.
- Well-developed computer skills across the Microsoft Office suite.
- Demonstrated ability to work collaboratively within multidisciplinary teams while also working independently, exercising initiative, sound judgement and accountability for outcomes.
- Proactive, adaptable and able to respond effectively to changing priorities and operational requirements.
- Support SAHMRI's commitment to reconciliation and acknowledge the importance of working in partnership with Aboriginal and Torres Strait Islander People
- Able to demonstrate the following SAHMRI Values and Culture:
  - **Innovation** – Persistent and Focused
  - **Excellence** – Bold, Driven, Dynamic
  - **Courage** – Collaborative and Enabling
  - **Integrity** – Embrace Diversity, Demand Equity
  - **Teamwork** – Friendly, Fast, Flexible, Fun