Position Description

POSITION TITLE:	Senior Clinical Project Manager
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 independent, 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-centered 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, Study 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 Senior Clinical Project Manager is a proactive, hands-on, adaptable professional responsible for the day-to-day operational activities of the SAHMRI Clinical Trials Platform team and direct involvement in trial-related activities. Given the dual functionality of the CTP as both an ARO and outpatient clinical trial facility, the role offers exposure to every stage of a study, from initial proposal through to study closeout.

This position requires active engagement in project management, study start-up, proposal/budget development, contract management, alongside a strong focus on staff mentorship. The primary objective is to ensure the efficient, high-quality, and compliant execution of clinical studies in accordance with Good Clinical Practice (GCP) and applicable regulatory requirements.

The Senior Clinical Project Manager works closely with the CTP Senior Manager, SAHMRI Business Development Manager, and other internal teams. The role also involves collaboration with senior researchers, study investigators, hospital staff, Ethics and Governance Officers, external vendors, industry sponsors, regulators, and government agencies.

KEY RESPONSIBILITIES

The Senior Clinical Project Manager will play a hands-on role in supporting the delivery of clinical trials and research projects within the SAHMRI Clinical Trials Platform, while contributing to wider SAHMRI initiatives.

Operational Management

- Provide oversight and actively participate in the setup, conduct, and close-out of clinical trials, including both investigator-led and commercial trials. This includes the flexibility to personally manage projects and lead study startup activities which relate to the CTP being selected as a site, as well as various ethics and governance submissions.
- Maintain a strong working knowledge of regulatory, ethics and government requirements including health-related submissions and compliance.
- Actively support and provide guidance to a team of clinical trial professionals, ensuring consistent trial delivery and protocol adherence.
- Foster a culture of collaboration, accountability, and continuous learning through mentorship and coaching.
- Work closely with investigators, sponsors, Contract Research Organisations (CROs), and institutional partners to align operational goals and troubleshoot issues.
- Represent the CTP in governance meetings, steering committees, and other stakeholder meetings.

Project, Resource & Budget Management

- Manage trial timelines and resource allocation across multiple concurrent studies.
- Actively participate in the negotiation of research agreements and manage clinical trial/study budgets to ensure projects remain on time and within scope.
- Adaptable in contributing to all stages of the clinical trial lifecycle, including direct project involvement.
- Monitor workload distribution and proactively address capacity issues.
- Support onboarding and training of new staff to ensure readiness and confidence.

Quality & Compliance

- Ensure all trial activities comply with ICH-GCP and regulatory standards.
- Contribute to CTP quality improvement initiatives and lead the implementation of quality systems.
- Develop, revise, and maintain standard operating procedures and templates for the CTP and SAHMRI more broadly.
- Maintain detailed documentation of risk management activities, including risk assessments, mitigation plans, and incident reports.

Organisational Responsibilities

- Provide employees with safe work practices and ensure that their welfare is secured.
- 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.
- DCSI Employment Screening may be required.

Person Specification

QUALIFICATIONS

- Tertiary qualifications in Health, Science or related discipline and extensive relevant experience (a minimum of 2 years at management level, desirable).
- Project Management qualifications (desirable).

EXPERIENCE, KNOWLEDGE AND SKILLS

- Demonstrated experience in health research, including clinical trials (minimum 2 years at management level desirable).
- Strong understanding of the clinical study process, ICH-GCP guidelines, and relevant local regulations and quality principles for conducting clinical research.
- Sound knowledge of the clinical trials regulatory environment.
- Experience preparing health-related regulatory, ethics, and governance submissions, including protocol development and documentation.
- Experience supporting grant submissions and contributing to funding proposals/trial costings and research agreement negotiations.
- Proven ability to manage multiple and competing priorities in a dynamic research setting.
- Strong problem-solving skills, with the ability to identify issues, recommend solutions, and implement effective outcomes.
- Superior attention to detail and commitment to quality.
- Well-developed computer skills across the Microsoft Office suite; experience with REDCap and other data management platforms (highly desirable).
- 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:
  - **Excellence** – Bold, Driven, Dynamic
  - **Innovation** – Persistent and Focused
  - **Courage** – Collaborative and Enabling
  - **Integrity** – Embrace Diversity, Demand Equity
  - **Teamwork** – Friendly, Fast, Flexible, Fun