Position Description

POSITION TITLE:	Project Manager / Clinical Trial Coordinator
LOCATION:	SAHMRI Women and Kids Theme Locations
REPORTS TO:	Business and Operations Manager
DEPARTMENT:	SAHMRI Women and Kids

PURPOSE AND SCOPE OF THE POSITION

Participate in the management and coordination of single or multi-centre trial activity/ies within the SAHMRI Women and Kids (SWK) Theme to a high standard of quality and in accordance with relevant regulations and guidelines.

Reporting to the Business and Operations Manager the position will also work closely with the Trial Leadership Team, other team members within the SAHMRI Women and Kids Theme and other staff members at SAHMRI and relevant study site/s. The role will also interact with a range of external stakeholders including health professionals, internal and external investigators, study researchers, clinical staff and study participants.

There are no direct reports to this role.

KEY PERFORMANCE INDICATORS

- Project manage, coordinate and conduct SAHMRI clinical trial/s in accordance with study protocols and targets and with successful adherence to Good Clinical Practice guidelines (GCP) and HREC requirements.
- Demonstrate comprehensive study knowledge and insight to proactively identify and rectify issues alongside the trial leadership team.
- Plan, initiate and monitor recruitment strategies, including the development of workflows and processes, ensuring adherence to the study protocol, GCP guidelines and all regulatory requirements.
- Oversee and maintain the integrity of electronic data capture (EDC) systems to ensure quality and timely data entry, sample collection and milestone completion. .
- Develop, prepare and distribute regular progress reports on trial progress to trial leadership team, sponsors, regulatory bodies and other stakeholders.
- Establish and maintain good working relationships with trial leadership team other research and medical staff, external stakeholders and study participants.

KEY RESPONSIBILITIES

The specific duties include:

- Assist the facilitation and implementation of the trial protocol as directed by the trial leadership team.
- Liaise and maintain productive relationships with an extensive network including health professionals, internal and external investigators, researchers, clinical staff and study participants.

- Identify and implement strategies to enhance the recruitment, data quality, compliance and retention of participants.
- Continuously monitor trial processes and recruitment status and recommend improvements to meet project milestones and to adhere to quality standards.
- Develop accurate and meaningful numerical reports and graphing for tracking and monitoring study progress and interpret and report on these regularly to project leadership.
- Monitor and provide support to any external participating centres (i.e. private obstetric clinics, general practice clinics, pathology centres, hospitals etc) including tracking data quality, responding to queries, providing training on trial conduct, data collection platforms and trial procedures.
- Contribute to the project review process by identifying and reporting on project risks and implementing efficient risk-management and contingency strategies as directed.
- Work with stakeholders to scope and plan project deliverables.
- Ensure samples collected from study participants are collected, processed, recorded, labelled and stored in accordance with trial protocol.
- Prepare, submit and maintain records of ethics applications for various committees including hospital approval processes.
- Coordinate the development of forms, questionnaires, procedure manuals, trial protocols, CRFs, SOPs and other documents as required.
- Organise, attend and present at healthcare professional seminars and educational workshops to increase engagement and encourage active participation in SWK research initiatives.
- In conjunction with IT experts, actively contribute to the design and development of web-based software to manage clinical trial/s and data collection.
- Manage a schedule of project meetings.
- Provide executive support to the steering committee, working groups and other project meetings.
- Prepare meeting materials including agendas, minute taking and the follow up of action items.
- Conduct all aspects SWK clinical trials in accordance with ICH GCP guidelines and the trial protocol.
- Manage the day-to-day operations of the project.
- Act as the first point of contact in relation to project progress and objectives.
- Oversee the ethical conduct of the study and lodge amendments and reports to the ethics committees.
- Monitor and report against timeframes and other performance indicators.
- Draft briefings, reports and presentations for a range of audiences.
- Report Serious Adverse Events in accordance with reporting guidelines.
- Provide support to a range of other small projects as required.
- Successfully screen and enrol research participants from various settings to achieve recruitment targets in accordance with GCP guidelines and trial protocol.
- Participate in special projects to continuously improve processes, tools, systems and organisation.
- 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

- Primarily located at either Women's and Children's Hospital with some travel required between hospital and SAHMRI sites including SAHMRI North Terrace or other participating centres.
- Interstate travel may be required.
- Some out of hours work may be required.
- DCSI WWCC Employment Screening is required
- All employees are required to be immunised in accordance with the requirements of the Hospital in which they are working or be willing to be vaccinated at the cost of the Institute.

Person Specification

QUALIFICATIONS

- Hold a degree in a relevant field and/or demonstrated experience managing projects.
- Training in ICH-GCP highly desirable.

EXPERIENCE, KNOWLEDGE AND SKILLS

- Proven experience in the coordination of clinical trials, involving women, children and/or infants preferable.
- Experience in clinical trial management.
- Demonstrated skill in project management including project planning, executing plans, monitoring and reporting, achieving milestones and managing relationships.
- Proven experience in a clinical trials environment, including recruitment, enrolment and data management.
- Demonstrated high-level project skills through to completion.
- Excellent planning and organisational skills, with the ability to establish priorities and allocate resources to meet tight deadlines.
- The ability to provide formal and informal leadership in a complex project.
- Experience in preparing and submitting ethics and local governance applications.
- Extensive relationship management skills, including the ability to interact with, and gain cooperation from with a variety of stakeholders, including health professionals.
- Excellent interpersonal and communication skills, including experience in developing professional documentation and presenting information.
- Advanced computer literacy with experience in the use of project management software and related programs.
- Well-developed numeracy skills, including ability to apply logic checks when reviewing or preparing reports and working with numerical data.
- Experience in using web-based platform/s to successfully recruit, randomise and manage clinical trials.
- Experience in or knowledge of Australian health/hospital systems and experience in working in a hospital setting, including ability to understand the implications and maintain confidentiality and privacy.

- Knowledge of Good Clinical Practice (GCP).
- Ability to write clear, succinct and accurate reports.
- High-level communication and interpersonal skills.
- Excellent attention to detail skills.
- Ability to demonstrate flexibility and adaptability in the workplace, including the ability to deal with emerging issues in a timely manner.
- Excellent organisational and time management skills including the ability to quickly prioritise competing demands with strict deadlines.
- Ability to work independently as appropriate.
- Exhibits a caring, empathetic and positive attitude.
- Enthusiasm and integrity.
- Excellent people skills and communication skills.
- Computer literate in Microsoft Office (intermediate level).
- Ability to work within a team environment whilst setting personal targets to achieve required results.
- Able to communicate with a broad network of health professionals and academic staff to foster a productive working environment.
- 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

LICENCES

- Current Driver's Licence