Position Description

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

PURPOSE AND SCOPE OF THE POSITION

Participate in the management and coordination of 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 Clinical Trials 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 study participants, health professionals, internal and external investigators, study researchers and clinical staff.

KEY PERFORMANCE INDICATORS

1. Manage, conduct and coordinate SAHMRI clinical trial/s across multiple sites in accordance with study protocols and targets and with successful adherence to GCP and HREC requirements.
2. Successfully recruit and enrol participants in accordance with GCP and recruitment targets.
3. Maintain and collect accurate data and samples in accordance with relevant regulations and Good Clinical Practice guidelines (GCP).
4. Monitor and prepare reports on trial progress against timeframes and other performance indicators.
5. Maintain good working relationships with study participants, research and medical staff and other external stakeholders.

KEY RESPONSIBILITIES

The specific duties include:

- Assist the facilitation and implementation of the trial protocol across multiple hospital locations as directed by the trial leadership team.
- Work with stakeholders to scope and plan project deliverables.
- Liaise and maintain productive relationships with an extensive network including health professionals, internal and external investigators, researchers, clinical staff and trial product suppliers.
- 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.
- In conjunction with IT experts, actively contribute to the design and development of web-based software to manage clinical trial/s.

- 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.
- Successfully screen and enrol research participants from various settings to achieve recruitment targets in accordance with GCP guidelines and trial protocol.
- Identify and implement strategies to enhance the recruitment, management and retention of participating hospitals.
- 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 the participating centres (i.e. hospitals) 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.
- 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.
- Assist with co-ordinating the development and submission of research presentations, publications and grants for the work area.
- Take responsibility to ensure a smooth interface of trial product between suppliers and clinical areas, including product delivery, tracking and discarding.
- Ensure samples collected from study participants are collected, processed, recorded, labelled and stored in accordance with 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, Flinders Medical Centre and / or Lyell McEwin Hospital with some travel required between hospital and SAHMRI sites including SAHMRI North Terrace.
- Some out of hours work may be required.
- DCSI WWCC Employment Screening is required.
- Interstate travel 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 complex 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 large scale multi-centre 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 multicentre 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