Position Description

POSITION TITLE:	Project Manager/ Senior Project Manager (Clinical Trials)
LOCATION:	SAHMRI Women and Kids Theme Locations
REPORTS TO:	Theme Leader, SAHMRI Women and Kids
DEPARTMENT:	SAHMRI Women and Kids

PURPOSE AND SCOPE OF THE POSITION

The Project Manager is responsible for the operational leadership, coordination and delivery, including direct participant recruitment, informed consent, study visits, data collection and site management activities of the GIFT clinical trial within the SAHMRI Women and Kids (SWK) Theme. The role combines project management responsibilities with hands-on clinical trial delivery to ensure recruitment, retention, data quality and study milestones are achieved.
The role ensures the successful implementation of study activities across multiple sites, delivering recruitment, retention, governance, financial and project milestones while maintaining compliance with ICH GCP, Human Research Ethics Committee (HREC) and regulatory requirements.

Reporting to the Theme Leader of SAHMRI Women and Kids, the Project Manager will work closely with the Trial Leadership Team, participating sites and key stakeholders including health professionals and study participants, to provide strategic oversight and day-to-day management of trial operations to ensure high-quality outcomes and successful study delivery.

KEY PERFORMANCE INDICATORS

- Deliver trial milestones, recruitment targets and project outcomes within agreed timelines and budget.
- Ensure ongoing compliance with ICH-GCP, HREC approvals, protocol requirements and regulatory obligations.
- Achieve participant recruitment and retention targets within agreed timelines.
- Successfully screen, consent, enrol and follow participants in accordance with the study protocol and GCP requirements.
- Ensure high quality, complete and timely data collection, entry and verification across all study activities.
- Maintain accurate, complete and audit-ready trial documentation, governance records and financial reporting.
- Achieve high-quality participant recruitment, retention and data collection outcomes across all sites.
- Develop and maintain productive relationships with participating hospitals, investigators, sponsors and stakeholders.
- Identify, manage and mitigate project risks to support successful trial delivery.
- Provide accurate reporting and project insights to trial leadership, sponsors and governance committees.
- Support participating sites to maximise engagement, recruitment performance and protocol adherence.

KEY RESPONSIBILITIES

The specific duties include:

Project Management and Trial Delivery

- Lead the operational management and delivery of the GIFT trial across participating sites, ensuring study objectives, milestones and timelines are achieved.
- Develop and implement project plans, study procedures and operational workflows in accordance with approved protocols and regulatory requirements.
- Monitor trial performance against recruitment, retention, quality, budget and milestone targets, implementing mitigation or contingency strategies as required.
- Identify, manage and escalate project risks, issues and dependencies to support successful trial delivery.

Participant Recruitment, Retention and Study Delivery

- Lead and coordinate participant recruitment and retention activities to achieve agreed targets.
- Screen participants, obtain informed consent, enrol participants and coordinate study visits, interviews, questionnaires, follow-up assessments and participant communications.
- Ensure all participant-facing activities are conducted ethically, professionally and in accordance with approved protocols and GCP requirements.
- Monitor participant engagement and implement strategies to minimise loss to follow-up.

Data Management, Systems and Quality

- Collect, enter, review and maintain study data in electronic data capture and trial management systems, ensuring accuracy, completeness and timeliness.
- Oversee data quality across participating sites, including monitoring, query resolution, validation, reporting and support for data cleaning and database lock.
- Lead or support the implementation, testing, training and continuous improvement of study databases, participant management platforms and digital trial systems.
- Identify and implement process improvements to enhance operational efficiency, data quality, participant experience and study outcomes.

Investigational Product and Sample Management

- Coordinate study product procurement, receipt, storage, accountability, distribution, tracking and disposal in accordance with study protocols and regulatory requirements.
- Maintain product accountability records and liaise with suppliers, pharmacies and participating sites to support uninterrupted product availability.
- Oversee biological sample collection, processing, labelling, storage, shipment, tracking and biobanking activities, ensuring compliance with study and laboratory procedures.
- Monitor sample compliance and resolve issues affecting sample quality, integrity or completeness.

Governance, Documentation and Regulatory Compliance

- Prepare, submit and maintain ethics, governance and regulatory documentation throughout the study lifecycle.
- Establish and maintain TMF, ISF and other essential study documentation in accordance with ICH-GCP and regulatory requirements.
- Develop, review and maintain protocols, SOPs, manuals, forms, participant materials and other study documentation, ensuring documents are current, version controlled and audit-ready.
- Coordinate safety reporting, protocol deviations, amendments, annual reports, monitoring visits, audits, inspections and study closure activities.

Financial, Contract and Resource Management

- Develop and manage study budgets, forecasts, expenditure, resource utilisation and financial reporting processes.
- Coordinate development, review, negotiation, execution and ongoing management of CTRAs, site agreements, service agreements and other research contracts.
- Liaise with legal, governance, finance and external stakeholders to support timely contract execution, study activation and compliance with approved budgets.
- Coordinate project resources, workforce planning, staffing requirements, onboarding and training.

Site Management, Stakeholder Engagement and Team Coordination

- Establish and maintain effective relationships with investigators, clinicians, participating sites, sponsors, Trial Leadership Team members and external stakeholders.
- Provide training, guidance and operational support to participating centres to promote protocol adherence, recruitment performance and site engagement.
- Manage site communications and support resolution of operational, recruitment and performance issues.
- Coordinate project meetings, working groups and steering committee activities, including agendas, minutes, action registers and follow-up.
- Organise presentations, workshops and engagement activities to support study participation, awareness and dissemination.
- Contribute to publications, grant applications, presentations and research dissemination activities.

General Responsibilities

- Provide support to other research projects and initiatives as required.
- Participate in special projects to continuously improve processes, tools, systems and organisation.
- 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

- Primarily located at 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.
- Interstate travel may be required.
- Some out of hours work will be required.
- DCSI WWCC Employment Screening and National Police Check are required
- SAHMRI is required to implement the Addressing vaccine preventable disease: Occupational assessment, screening and vaccination policy for SAHMRI employees carrying out work in any SA Health Facility.
    - Immunisation Risk for this position is - Category A

Person Specification

QUALIFICATIONS

- A tertiary qualification in a relevant field and/or demonstrated experience managing complex projects.
- Current ICH-GCP certification or willingness to obtain certification.

EXPERIENCE, KNOWLEDGE AND SKILLS

- Demonstrated experience managing complex clinical research projects or clinical trials, preferably within a healthcare, hospital or research environment.
- Experience coordinating multi-centre clinical trials, including study start-up, participant recruitment, study delivery, monitoring and close-out activities.
- Demonstrated experience recruiting, consenting and managing research participants in accordance with approved study protocols and Good Clinical Practice (GCP) requirements.
- Experience in clinical research data collection, management and quality assurance, including the use of electronic data capture systems and clinical trial management platforms.
- Experience preparing and managing ethics, governance and regulatory submissions within a health or research setting.
- Experience coordinating research contracts and agreements, including Clinical Trial Research Agreements (CTRAs), site agreements and service agreements.
- Experience developing, maintaining and managing clinical trial documentation, including protocols, standard operating procedures, Trial Master Files (TMFs), Investigator Site Files (ISFs) and governance records.
- Demonstrated experience managing project budgets, expenditure, resources, timelines, risks and competing priorities.
- Highly developed project management skills, including planning, implementation, monitoring, reporting and stakeholder engagement.
- Demonstrated ability to lead complex projects and influence stakeholders across multidisciplinary teams to achieve project objectives and deliverables.
- Strong understanding of ICH-GCP guidelines, human research ethics requirements and clinical trial regulatory frameworks.
- Exceptional organisational skills and attention to detail, with demonstrated ability to manage competing priorities, meet deadlines and maintain a high standard of accuracy.
- Highly developed written and verbal communication skills, including the preparation of reports, presentations, governance documentation and professional correspondence.
- Strong analytical and problem-solving skills, with the ability to identify risks, develop solutions and drive continuous improvement.
- Advanced computer literacy, including Microsoft Office applications, project management software, databases and web-based clinical trial systems.
- Well-developed numeracy skills, including the ability to analyse, interpret and report clinical trial and project performance data.
- Demonstrated ability to work independently while contributing positively to a multidisciplinary team environment.
- Experience working within Australian healthcare and hospital systems, including an understanding of privacy, confidentiality and research governance requirements.
- Demonstrated professionalism, integrity, initiative and adaptability when managing emerging issues and changing priorities.
- Commitment to participant-centred research and the ability to engage effectively and sensitively with diverse participant populations.

- 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** – Bold, Driven, Dynamic
  - **Excellence** – Persistent and Focused
  - **Courage** – Collaborative and Enabling
  - **Integrity** – Embrace Diversity, Demand Equity
  - **Teamwork** – Friendly, Fast, Flexible, Fun

LICENCES

- Current Driver's Licence