Position Description

1. General Information

Position Title:	Clinical Research Nurse
Division/Department:	Academic & Medical Services
Position Reports to:	Clinical Research Nurse Team Leader – Multiple Speciality Clinical Trial Unit
Enterprise/Individual Agreement:	EBA
Classification/Grade:	Clinical Research Nurse/Midwife
Location:	Epworth Corporate
Employment Status:	Full Time, Fixed Term 1 year
Resource Management (for Management positions only) **Number of Direct Reports:** **Budget under management:**	Not Applicable
Key Relationships - internal and external	**Internal:** • MSCTU employees • Epworth Office for Research and Groupd Manager Research Operations • Clinical Trials and Research staff • Principal investigators, Co-investigators and associated clinical trials medical staff • Multidisciplinary team members • Hospital emploees as required including the Maternity Unit staff • Research participants and their carers • Epworth Medical Foundation as required **External:** • Patients / Consumers • Appropriate Funding bodies and benefactors • State and government bodies • External hospitals, laboratories, and diagnostic imaging centres

	• Pathology and other clinical staff at key collection centres • Clinical Research Sponsor representatives from pharmaceutical companies and collaborative groups • Appropriate Professional bodies

2. Overview of Epworth HealthCare

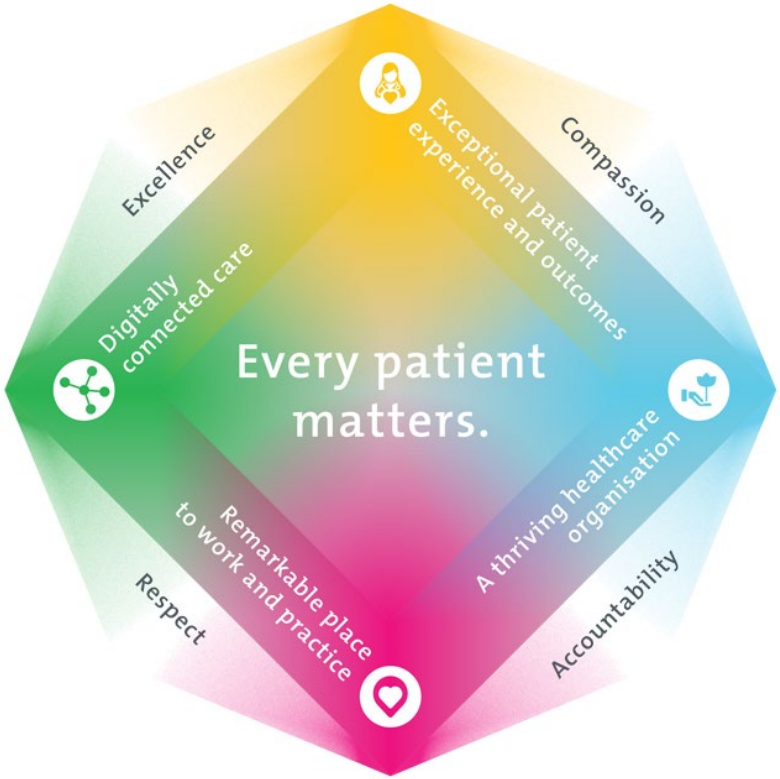
Epworth HealthCare is Victoria's largest not-for-profit private health care group, renowned for excellence in diagnosis, treatment, care and rehabilitation. Epworth is an innovator in Australia's health system, embracing the latest in evidence-based medicine to pioneer treatments and services for our patients.

Epworth's values define our approach and our delivery. We pride ourselves on communicating our values and delivering on them in a real and meaningful way. Our Values are Compassion, Accountability, Respect and Excellence. More information can be found on the Epworth website.

Epworth's purpose is Every Patient Matters.

Our Vision is Delivering another 100 years of exceptional healthcare and innovation to the Victorian community.

3. Epworth HealthCare Strategy



All roles are linked to the Epworth strategy and are fundamental in achieving its vision and purpose.

Exceptional patient experience and outcomes - To empower our patients and deliver compassionate, expert and coordinated care.
A thriving healthcare organisation - To adapt and grow in a changing healthcare landscape by delivering a unique private not-for-profit healthcare organisation.
Remarkable place to work and practice - To ensure Epworth is an outstanding place to work and practice through a culture of care and investment in our people.
Digitally connected care - To innovate and improve the digital experience, interactions and outcomes for our patients, staff and doctors.

4. Purpose of the Position

- The Clinical Research Nurse coordinates and delivers investigator-initiated, Cooperative trial group and commercially funded clinical research activities within the Multiple Speciality Clinical Trials Unit (MSCTU).
- The role ensures clinical research is conducted safely, ethically and in compliance in accordance with TGA guidelines, ICH GCP and the NHMRC National Statement on Ethical Conduct in Research Involving Humans and Epworth policies, while supporting high-quality patient care.
- Working closely with investigators, clinical teams and external stakeholders, the position manages multiple studies, coordinates participant recruitment and study visits, maintains accurate study documentation and data, and supports governance and ethics processes across the MOCTU trials portfolio.

5. Clinical Governance Framework

This role is required to put into practice the Clinical Governance Framework at Epworth as every employee is accountable for ensuring that our patients and community receive safe, high quality and person-centred care in every interaction with Epworth. This is achieved through active participation in the five domains of clinical governance at Epworth:

Clinical Governance Domain	Role
Leadership and culture	Promote and participate in a supportive, fair and transparent culture where lessons from previous outcomes are learned and patient safety and quality is a priority at all levels of the organisation.
Consumer Partnerships	Understand and where relevant, ensure that each patient is actively involved in their own care and treatment including families/carers wherever possible.

Effective Workforce	Develop and maintain one's own competency, skills and knowledge to ensure high quality service provision and care.
Clinical Safety and Effectiveness	Understand and where relevant, ensure, that the right care is provided to the right person at the right time, in the right place and patient outcomes are monitored and improved.
Risk Management	Be responsible for identifying and reporting risks, hazards and near misses for people in our care and participating in risk mitigation strategies.

6. Key Accountabilities

KEY RESPONSIBILITIES	MEASURES/KPIs TO BE ACHIEVED
Clinical Responsibilities • Participate and contribute to clinical evaluation, treatment and care of participants in clinical trials within MSCTU • Clinical trial coordination that ensures trial conduct is performed according to protocol requirements • Coordinate and perform protocol-required procedures for allocated clinical trials, ensuring optimal care of consented participants. • Coordinate participant recruitment, including identifying eligible participants and supporting the informed consent process. • Book and support participant study visits and trial-related activities. • Maintain accurate and complete study documentation, including electronic and paper CRFs and trial databases. • Manage study governance and ethics documentation and reporting requirements. • Ensure research activities are conducted in compliance with GCP and relevant regulatory and organisational standards. • Coordinate biological sample collection, processing, storage and transport for allocated studies. • Respects and upholds the dignity and rights of consumers, relatives, carers, colleagues and members of the community • Respects and upholds the dignity and rights of consumers, relatives, carers, colleagues and members of the community	• Participant study recruitment and evaluation • Practice in accordance with the National Safety and Quality Health Service (NSQHS) Standards • Practices in accordance with legislative and common law requirements • Patient and customer service satisfaction surveys to be within organisational targets • Sound relationships developed and maintained with customers • Compliance with Information Privacy Act (2000) and the Health Records Act (2000) • Compliance with EEO & Social Medial Policies and Protocols of Epworth HealthCare • Practices in accordance with NMBA National Competency Standards for Registered Nurses • Minimal unplanned protocol deviations • Participant recruitment and study visits are delivered within protocol-defined timeframes. • Biological samples are managed in accordance with protocol and laboratory requirements.

Research Excellence Effectively manage and successful completion of clinical research trials • Demonstrated compliance with the requirements of ICH GCP, TGA guidelines and the NHMRC National Statement on Ethical Conduct in Research Involving Humans, ensuring that research is performed within these guidelines and in accordance with the policies of the pharmaceutical and/or device companies sponsoring the research • Efficiently organise all elements related to patient recruitment, visits, assessments, administration of medication and any other elements as described in the clinical trial protocol • Maintenance of accurate research study files, clinical documentation and related records and data both in hard copy and within the clinical trials management system (CTMS) within specified time frames • Assist project team with other study related activities sauch as organizing study meetings and scheduling travel, producing agendas and minutes for study-related meetings, assembling training and study materials, updating contact details, maintaining study documentation, assisting in the preparation of administrative documents and other tasks as required	• Coordinate onsite/virtual monitoring visits, as required • Ensure all requestsfor data entry are responded to and completed within allocated timelines • Work with attention to detail all data entered is accurate and verifiable against source data • Undertake appropriate training where required to allow access to required databases • Accountable for the management of study materials and supplies - distribution, ordering, tracking, storage, reconciliation and destruction • Proactively identify study administrative issues • Minimal unplanned protocol deviations
Laboratory Operations Ensures accurate sourcing, tracking and processing of biological samples safely and carefully within the trial environment	• Undertake appropriate training for taking and handling biological specimens as required • Organise couriers for shipping of samples

	• Undertake additional training for Safe Transport of Infectious Substances, as required
Communication • Professionally engage key internal and external stakeholders • Liaise with study sponsors or contract research organisation for all trial related activities including monitoring visits, data query resolution, audits and other participant or site related issues • effective and excellent working relationships with all trial personnel, including Principal Investigators, Co-investigators, nursing and medical staff, all 3rd parties involved in trials pharmaceutical/device company personnel and patients in a courteous and non-discriminatory manner	• Resolution of complaints in a timely manner and effectively at local level as necessary • Prepare high quality written reports as required
Education Maintain the highest standard of knowledge and skills required for undertaking the role: • Undertake additional training to maintain and develop the knowledge and skills required to implement new clinical trial protocols across a range of clinical specialties. • Deliver study-specific in-service education to relevant health professional staff to support protocol compliance and safe trial conduct. • Attend and, where appropriate, present at research forums to maintain contemporary knowledge of clinical research practices. • Assist with the orientation and ongoing support of new research staff within the MSCTU.	• 100% compliance with required training and professional development activities. • Conduct study specific in-service education sessions for relevant health professional staff • Attend and present at various research forums contributing to the continuous improvement and knowledge sharing within the research team. • Provide/reinforce information to participants and their family/carers as required for continual participation and/or as per the study protocol, explaining practical aspects of clinical trials • New research staff are supported effectively during orientation, with positive feedback from supervisors and team members.

Team Demonstrate the Epworth values and behaviours and provide support for colleagues associated with the research programs of the Centre • Work cooperatively and collaboratively with colleagues, Epworth staff and external stakeholders to support the effective delivery of research activities. • Attend research team and research meetings as required and feasible. • Provide support to colleagues and contribute to other studies as required to meet team and organisational priorities. • Assist with *ad hoc* research and quality improvement activities, including point prevalence studies, under the direction of the Research Program Manager	• Works cooperatively and collaboratively with all colleagues, Epworth staff and broarder stakeholders • Attend all research team and research meetings as is required and/or feasible • Provide support for other colleagues and studies as required • Undertake key tasks or projects as requested by the management of the research unit • *Ad hoc* research and quality activities are completed as directed and within agreed timeframes. • Corporate KPIs relating to attendance, engagement and professional development are met.
Quality Improvement Strives to consistently improve service delivery Provides suggestions and feedback to the Director on quality activities Actively participates in quality improvement activities within the department	• Evidence of participation in quality improvement activities • Improvement in performance of clinical research
Governance Meet all governance standards and benchmarks required for clinical research • Ensure clinical trials are conducted in accordance with approved protocols and applicable regulatory and ethical requirements, including GCP and ICH. • Adhere to and support research-specific policies, standard operating procedures and clinical guidelines. • Coordinate trial visits, procedures and participant assessments in accordance with protocol requirements. • Assist the Research Program Manager with study feasibility, site initiation activities and governance support. • Support the preparation and submission of required reports to the approving HREC.	• Demonstrate that all clinical trials are conducted according to study protocols and relevant legal and regulatory bodies including Good Clinical Practice (GCP), the International Conference of Harmonisation (ICH) guidelines, and APMA guidelines • Adherence to and compliance with research specific policies, clinical policies, including drug policies, standard operating procedures and guidelines • Minimal unplanned protocol deviations. • Trial visits and assessments are delivered efficiently and within protocol-defined timelines. • HREC documentation is accurate and submitted within required timeframes. • Governance support contributes to audit-ready studies and effective trial delivery.

	• CAPAs are completed accurately, within agreed timeframes and with evidenced preventative measures.
Personal and Professional Development Participates in prescribed performance development system annually Evaluates personal performance and plans self-development	• Completion of annual performance appraisal • Completion of objectives outlined in self-development plan (provide evidence of) • Undertake and maintain all required training including Good Clinical Practice, Dangerous Goods, study specific, and all internal training as required
Customer Service Epworth is committed to the provision of excellent customer service to all of our people, customers and stakeholders including patients and external suppliers. Superior patient service leads to improved healing in a trusting, caring environment and creates a safe environment for patients and employees. • Provide excellent, helpful service to patients, visitors and staff • Communicate with clear and unambiguous language in all interactions, tailored to the audience • Build customer relationships and greet customers and patients promptly and courteously • Actively seek to understand patients' and their family's (customers) expectations and issues • Maintain effective, professional relationships with investigators, clinical teams, sponsors and participants through courteous and inclusive communication.	• Patient and customer service satisfaction surveys within agreed targets • Use AIDET principles in all interactions • Issues are escalated to the manager and resolved in a timely manner • Consistently positive collaboration with trial stakeholders, with no substantiated concerns regarding professionalism or conduct.
Safety and Wellbeing Participate actively and positively in the area of health and safety to reduce all hazards and incidents within the workplace	• Adhere to infection control/personal hygiene precautions • Implement and adhere to Epworth OHS policies, protocols and safe work procedures • Mandatory training completed at agreed frequency

• Report all hazards, incidents, injuries and near misses immediately to your manager and log them in RiskMan	

7. Position Requirements/Key Selection Criteria

COMPONENT	
Qualifications	**Essential** • An undergraduate degree in nursing • Current registration with the Australian Health practitioner Regulation Agency (AHPRA) **Desirable** • Evidence of further education including post-graduate qualification specific to clinical research • Evidence of furtheere education including post-graduate qualification in Nursing
Previous Experience	**Essential** • At least 2 years Nursing experience **Desirable** • Experience in either Anaesthetics of Cardiology • Demonstrated experience in clinical trial coordination or clinical research
Required Knowledge & Skills	**Essential** • Knowledge and understanding of National Standards for Clinical Excellence and ACHS Accreditation Standards • Sound computer literacy and a sound understanding of word, excel, email etiquette • Demonstrate role model behaviour • Demonstrable excellence in customer service • Effective communication and interpersonal skills • Demonstrated time management skills • Demonstrates attention to detail **Desirable** • Demonstrable understanding of the research development cycle • Knowledge of the National Statement on Ethical Conduct in Human Research, Good Clinical Practice and Guidelines governing clinical trials

	• Demonstrated ability to develop collaborative and mutually beneficial relationships with internal and external stakeholders • Sound knowledge of research databases/online systems • Practical knowledge in regards to the development and conduct of clinical research • Knowledge of Research Ethics and Governance, procedures, requirements and legislation • Evidence of Good Clinical Practice Training
Personal Attributes & Values All employees are expected to consistently work in accordance with Epworth's values and behaviours • Compassion • Accountability • Respect • Excellence	**Essential** • Excellent communication skills • Belief in patient centred care • Committed to providing a safe environment for patients & colleagues • Commitment to continuous improvement and customer service • Commitment to self-development & learning • Demonstrate an innovative, proactive and creative mindset • Professional work ethic • Practices within the ethos of the Epworth HealthCare Values & Behaviours • Self-motivated and self-directed

Document Control

Date Developed:	Date Last Reviewed:	Developed and Reviewed By (Position Title):
March 2019	February 2026	Clinical Research Nurse Team Leader Group Research Operatios Manager

8. Employee Position Declaration

I have read and understand the requirements and expectations of the above Position Description. I agree that I have the physical ability to fulfil the inherent physical requirements of the position, and accept my role in fulfilling the Key Accountabilities. I understand that the information and statements in this position description are intended to reflect a general overview of the responsibilities and are not to be interpreted as being all-inclusive.

Employee Signature: _____

Print Name: Date: