Position Description

1. General Information

Position Title:	Clinical Research Coordinator
Division/Department:	Academic and Medical Services
Position Reports to:	Centre Program Manager
Enterprise/Individual Agreement:	Individual agreement
Classification/Grade:	Clinical Research Coordinator
Location:	Epworth, 185-187 Hoddle St, Richmond
Employment Status:	Full Time, Fixed term (12 months)
Resource Management (for Management positions only) **Number of Direct Reports:** **Budget under management:**	- Research project budgets
Key Relationships - internal and external	**Internal:** • Julia Argyrou Endometriosis Centre at Epworth Staff • Group Manager - Research Operations • Clinical Trials and Research Centre staff • Principal investigators, Co-investigators and associated clinical trials medical staff • Multidisciplinary team members • Hospital staff as required • 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 • Surgical, pathology and other clinical staff at key collection centres • Clinical Research Sponsor representatives from pharmaceutical companies and collaborative groups • Appropriate Professional bodies

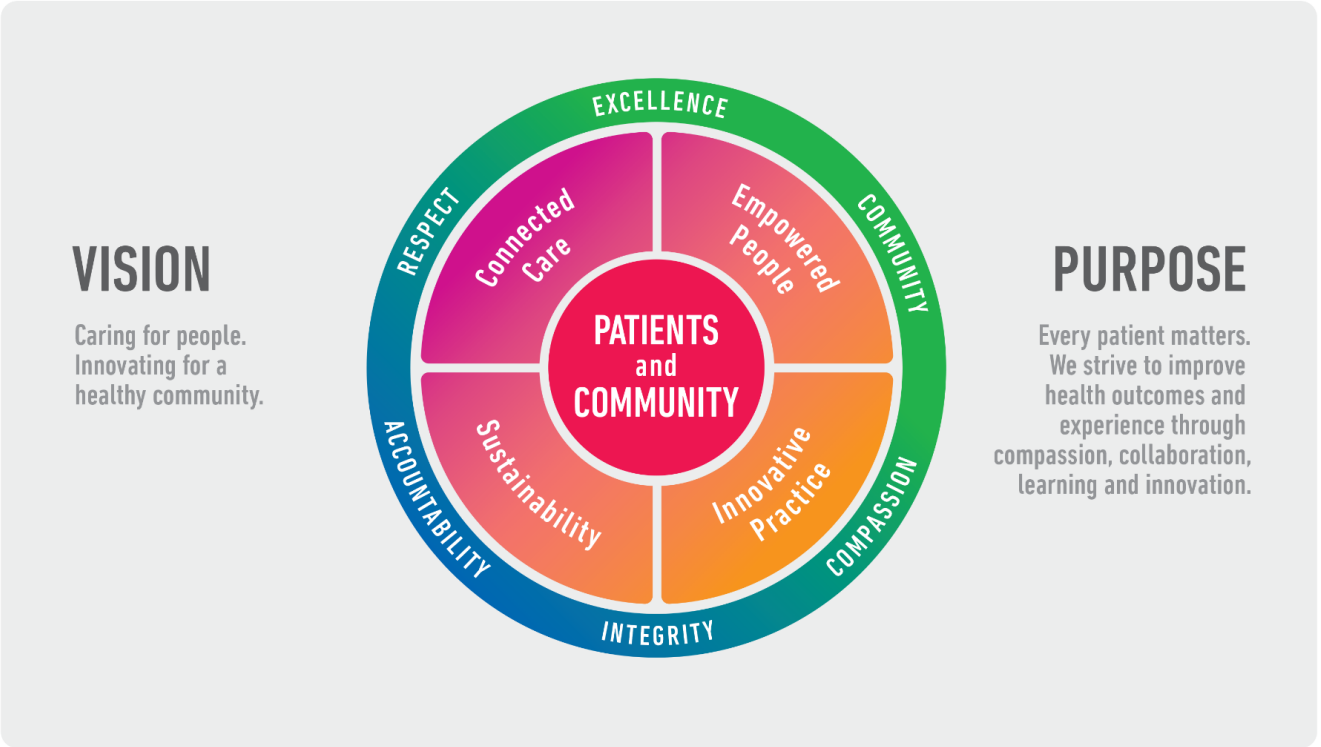
2. Overview of Epworth HealthCare

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 Respect, Excellence, Community, Compassion, Integrity and Accountability. More information can be found on the Epworth website.

Epworth's purpose is Every Patient Matters. We strive to improve health outcomes and experience through compassion, collaboration, learning and Innovation. Our Vision is Caring for People. Innovating for a healthy community.

3. Epworth HealthCare Strategy



All roles are linked to the Epworth strategy and are fundamental in achieving its vision and purpose.
Connected Care – Partner with our patients and doctors to provide high-quality care through an integrated, holistic experience tailored to their needs and choices
Empowered People – Enable and empower our people and teams to be their best and make a difference to the patient experience
Innovative Practice – Informing and enabling health within our community through encouraging the ideas of our people and finding new and better ways to care and support care delivery
Sustainability – Be accountable to use resources wisely; to ensure organisational and environmental sustainability, enhance access, support the patient journey and create greater capacity for care.

4. Purpose of the Position

In this fixed-term (12-month), full-time role the Clinical Research Coordinator is responsible for coordinating investigator-initiated and sponsored clinical research that aims to improve the health outcomes for those affected by endometriosis. This position engages with Epworth clinicians and researchers and their collaborators to facilitate the design and conduct of research within the Centre. The position will:

- coordinate clinical research projects under the leadership of the Centre Directors and Centre Program Manager.
- coordinate study administration including feasibility assessments, assisting with funding applications, start-up activities including ethics and governance applications, database building, recruitment, data collection, specimen collection, reporting as required, and study closure.
- support Centre Director with regular Centre meetings including scheduling and recording and circulating agendas/minutes.
- be responsible for project related finances, invoices and payments and collaborate with internal staff and external staff and service providers.

Some out of hours work will be expected in this role. Ability to be flexibility in working hours/days is highly desirable.

Travel between campuses is necessary (namely between the Richmond, Hoddle St site and the two Freemasons campuses in East Melbourne). Travel to the Geelong and Eastern campuses may also be required from time to time.

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 Research Coordination Manage the day to day running of multiple clinical research projects	• Trial activities completed within agreed timelines and in compliance with ICH GCP and Centre SOPs • Accurate, complete, and audit-ready regulatory and Trial Master Files maintained at all times • Electronic and hard-copy documentation filed accurately and within required timeframes • Monitoring visits coordinated effectively, with timely follow-up of actions • Study invoices and authorised payments processed accurately and within agreed timelines • Study meetings, travel, and administrative support delivered efficiently to support project needs • Study materials and supplies managed effectively, with accurate tracking, reconciliation, and disposal • Administrative and operational study issues proactively identified and escalated as required
Database/s and Clinical Trial Management	• REDCap databases designed, maintained, and configured in line with study protocols and regulatory requirements • Study data entered accurately into relevant databases within agreed timelines • All data verified against source documents, with minimal data queries or discrepancies • Data entry requests completed within specified turnaround times

	• Required database and system training completed prior to database access and use
Laboratory Operations Ensures accurate sourcing, tracking and processing of biological samples safely and carefully within the trial environment	• Required training completed for handling and processing biological specimens, including blood processing where applicable • Samples prepared, tracked, and dispatched via couriers in accordance with study protocols and timelines • Safe Transport of Infectious Substances training completed and maintained where required
Research Excellence Effectively manage and successful completion of clinical research studies	• Research activities conducted in compliance with ICH GCP, TGA guidelines, the NHMRC National Statement, and sponsor requirements • Participant recruitment, visits, and study procedures organised and delivered in accordance with approved protocols and timelines • Research study files, clinical documentation, and CTMS records maintained accurately and updated within required timeframes • Contribution to grant or funding applications, including coordination, documentation support, and submission activities, as required.

Communication Professionally engage key internal and external stakeholders	• Clear and appropriate communication maintained with key internal and external stakeholders • Effective liaison with investigators, sponsors, participants, and research teams to support study delivery • Sponsor and CRO interactions managed effectively, including monitoring visits, audits, and data query resolution • Third-party service providers coordinated efficiently to meet study and protocol requirements • High-quality written reports and correspondence prepared accurately and within required timeframes
Education Maintain the highest standard of knowledge and skills required for undertaking the role	• Required and study-specific training completed to support implementation of new protocols across clinical specialties • Participation in relevant research forums, including attendance and presentation where appropriate • Accurate and protocol-consistent information provided to participants and their family or carers to support informed and ongoing participation
Team Successful team integration and support	• Collaborative and professional working relationships maintained with colleagues, Epworth staff, and external partners • Required research team and study meetings attended consistently • Support provided to team members and studies as needed, with workload shared appropriately when capacity allows • Unit priorities and delegated tasks completed as directed by research unit management

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	• Active participation in departmental quality improvement activities • Demonstrated improvements in clinical research processes, performance, or outcomes attributable to quality initiatives
Governance Meet all governance standards and benchmarks required for clinical research	• Clinical research and trials conducted in accordance with approved study protocols and applicable regulatory frameworks, including ICH GCP guidelines • Compliance maintained with all research-specific and clinical policies, including drug policies, standard operating procedures, and organisational guidelines
Personal and Professional Development Participates in prescribed performance development system annually Evaluates personal performance and plans self-development	• Annual performance appraisal completed within required timeframes • Individual development objectives achieved and supported by evidence • Mandatory and role-specific training completed and maintained, including GCP, Dangerous Goods, study-specific, and required internal training

7. Position Requirements/Key Selection Criteria

COMPONENT	
Qualifications	**Essential** • An undergraduate degree in science, healthcare or relevant scientific discipline **Desirable** • Additional qualifications in clinical research competency (eg GCP, GDP training etc) • Post-graduate qualification, certification, or ongoing professional development relevant to clinical research
Previous Experience	**Essential** • A minimum of 2 year's experience as a Clinical Research Coordinator or equivalent • Experience with National Mutual Acceptance (NMA) and Human Research Ethics Committee applications

	Desirable • Experience working with Australian and International regulatory frameworks (e.g. TGA, FDA, EMEA) • Experience contributing to grant or research funding applications
Required Knowledge & Skills	**Essential** • Knowledge of the National Statement on Ethical Conduct in Human Research, Good Clinical Practice and Guidelines governing clinical trials • Practical knowledge of the development and conduct of clinical research • Demonstrated experience in REDCap design and implementation • Sound computer literacy, including research databases and standard office applications • Evidence of Good Clinical Practice Training **Desirable** • Understanding of the research development lifecycle • Experience in clinical research with tissue/blood sample collections, processing and storage
Personal Attributes & Values All employees are expected to consistently work in accordance with Epworth's values and behaviours • Compassion • Accountability • Respect • Excellence • Community • Integrity	**Essential** • Strong communication and interpersonal skills • High attention to detail with effective time management and prioritisation • Demonstrated problem-solving and decision-making capability • Ability to work collaboratively within a research team • Professional, engaged approach to research work • Strong work ethic with flexibility to support research demands

Document Control

Date Developed:	Date Last Reviewed:	Developed and Reviewed By (Position Title):

August 13, 2021	May 4, 2026	Sarah Holdsworth-Carson (RPM) Veronica Abruzzo (JAECE Centre 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: _____