Position Description

1. General Information

Position Title:	Clinical Trials Coordinator – Haematology
Division/Department:	Academic & Medical Services, Professor Molecular Oncology
Position Reports to:	Manager – Haematology Clinical Trials Unit
Enterprise/Individual Agreement:	Individual Employment Agreement
Classification/Grade:	Not Applicable
Location:	Epworth Freemasons
Employment Status:	Full Time, Fixed Term
Resource Management (for Management positions only) **Number of Direct Reports:** **Budget under management:**	Not Applicable
Key Relationships - internal and external	**Internal:** • Principal Investigators & Co-investigators • Clinical Staff in all relevant patient care areas – including Chemotherapy day unit (CDU), outpatient department (OPD), Ward nurses, diagnostic imaging and associated clinical trials medical staff. **External:** • Research participants and their carers • Precision Haematology and other private consulting suite staff • External Hospitals, Laboratories, Diagnostic imaging centres and Universities • Clinical trial sponsor representatives from pharmaceutical companies and collaborative groups. • Surgical, pathology and other clinical staff at key collection centres • Appropriate Professional bodies • Research coordinators and data managers at other hospital and research centres. • Professional bodies such as VCOG, COSA and ARCS.

2. Overview of Epworth HealthCare

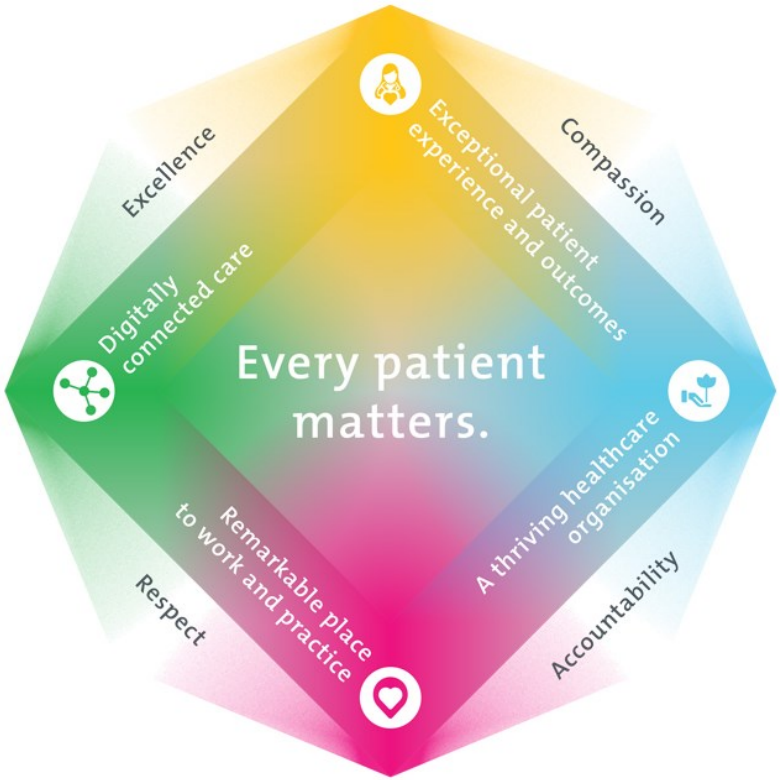
Epworth HealthCare is Victoria's largest not-for-profit private health care group, renowned for excellence in diagnosis, treatment, care and rehabilitation. Epworth is an innovator in Australia's health system, embracing the latest in evidence-based medicine to pioneer treatments and services for our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

- Commercially funded research activities according to Good Clinical Practice.
- Manage a wide range of clinical studies and recruit patients within the Haematology Clinical Trials Unit (may include coordinating medical oncology trials)
- Contribute to the expanding Haematology Clinical Trial Unit portfolio through supporting upcoming trials and working with colleagues to ensure a high quality of data and trial management.

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	• Actively participate in participant assessment of suitability for enrolment in cancer clinical trials. • Ensure all clinical trials documentation is complete and compliant with GCP before trial commencement, during the trial and until trial close out

	• Ensure all study requirements are completed both before and after IP administration
Research Excellence • Successful completion of essential clinical trial research activities	• Screen and support consent of appropriate patients • Maintain high site performance with accurate and comprehensive research study files and documentation • Meet or exceed study recruitment targets • Complete accurate and timely study data entry and query resolution • Implement and maintain all study related records and data within the clinical trials management system. • Assist with monitoring study related financial, invoices and payments
Communication • Professionally engage key internal and external stakeholders	• Maintain appropriate communication with key internal and external parties • Communicate effectively with investigators, sponsors, patients and other research participants • Liaise with sponsors for all trial related activities including monitoring visits, data query resolution, audits and other participant or site related issues • Coordinate and manage all third party service provider activities (pharmacy, pathology and radiology) • Prepare high quality written reports as required.
Education • Maintain the highest standard of knowledge and skills in haematological and solid organ malignancies required for undertaking the role	• Provide research participants with accurate, timely, study related knowledge at appropriate intervals • Conduct study specific in-service education sessions for relevant health professional staff • Assists in the orientation of new research staff to the Haematology Clinical Trials Unit.

Team • Successful team integration and support • Provide support for other colleagues associated with the research programs of the Unit • Undertake key tasks or projects as requested by management	• Demonstrate the Epworth values and behaviours • Strive to meet corporate KPIs with respect to absenteeism and professional development • Attend research meetings as required
Governance • Assist in the preparation of HREC documentation for study submissions or amendments, and provide study progress and final reports as required • Ensure all clinical research is conducted according to study protocols and relevant legal and regulatory bodies including Good Clinical Practice (GCP) and other relevant guidelines such as the International Conference of Harmonisation (ICH) guidelines and APMA guidelines • Adhere to, support and participate in the development of research specific policies, standard operating procedures and guidelines	• Meet all governance standards and benchmarks required for clinical research • Compliance to GCP, ICH & NHMRC Guidelines
Personal and Professional Development • Participates in all professional and personal development requirements	• Undertake and maintain all required training including Good Clinical Practice and all internal training as required • Undertake self-directed and formal research topic learning • Participate in and support Epworth research related activities including Research Breakfasts, Research Week, Research Report
Working hours • Flexible approach to working hours	• Maintain a flexible approach to working hours in order to meet the requirements of study protocols and sample collection
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. Role model and actively promote a culture of high quality patient care.	• Build customer relationships and greet customers and patients promptly and courteously • Actively seek to understand patients' and their families expectations and issues, using effective strategies including leader rounding on patients and team members • Uses data (such as compliments, complaints and Press Ganey) to identify breakdowns in internal processes and systems that directly impact patient care and customer service

	• Responds quickly and proactively escalate concerns when necessary • Consistently meet or exceed the expectations of our patients and customers at all times
Safety and Wellbeing To ensure a safe workplace is provided for all employees and other personnel including contractors, agency staff, volunteers and students. All employees and other personnel under the authority of the manager are fully informed of the hazards associated with their work activities, adequately trained and instructed in safe work procedures and appropriately supervised.	• Implement and adhere to Epworth OHS policies, protocols and safe work procedures • Ensure all hazards, incidents and injuries are reported in Riskman within 24 hours • Ensure all hazards, incidents and injuries are investigated and corrective actions implemented within agreed timeframes • Integrate and review OHS performance in staff PDPs • Ensure all direct reports are held accountable for safety performance and actions • Actively participate in risk management activities

7. Position Requirements/Key Selection Criteria

COMPONENT	
Qualifications	**Essential** • Degree level education or other relevant further education in health and/or science
Previous Experience	**Essential** • A minimum of 2 years' experience as a clinical research coordinator **Desirable** • Research experience including working knowledge of Australian and International statutory and regulatory requirements including – TGA, FDA, EMEA • Research experience and/or knowledge in haematology and/or medical oncology
Required Knowledge & Skills	**Essential** • Experience in clinical research with tissue/blood sample collections, processing and storage • Demonstrated data collection and management skills • Demonstrated computer literacy • Highly organised with a proven ability to prioritise tasks in a busy clinical research environment

	• Proven ability to work independently and interact well as part of a busy team • Proven ability to undertake clinical research related tasks in a timely and effective manner
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 • Excellent problem solving and decision making skills • Demonstrated ability to contribute positively within a research team • Demonstrated ability to effectively prioritise • A professional and engaging approach to research • Professional work ethic and flexible work style

Document Control

Date Developed:	Date Last Reviewed:	Developed and Reviewed By (Position Title):
January, 2017	July, 2020	Director – Haematology Clinical Trials

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: _____