

Position Description



1. General Information

Position Title:	Clinical Research Coordinator
Division/Department:	EJ Whitten Prostate Cancer Research Centre at Epworth (EJWPCRC)
Position Reports to:	Research Program Manager, EJ Whitten Prostate Cancer Research Centre at Epworth
Enterprise/Individual Agreement:	Individual Agreement
Classification/Grade:	N/A
Location:	Epworth Corporate
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	<p>Internal:</p> <ul style="list-style-type: none">• Director, EJWPCRC• Research Program Manager, EJWPCRC• Clinical Research Coordinator, EJWPCRC• EJWPCRC Team• Epworth Research, Development and Governance Unit• Department of Molecular Oncology and Cancer Immunology (MOCI)• Principal investigators, Co-investigators <p>External:</p> <ul style="list-style-type: none">• External hospitals, laboratories, and diagnostic imaging centres• Surgical, pathology and other clinical staff at key collection centres• Research Coordinators and Data Managers at other hospitals and academic institutes• Sponsors for Clinical Research Trials

2. Overview of Epworth HealthCare

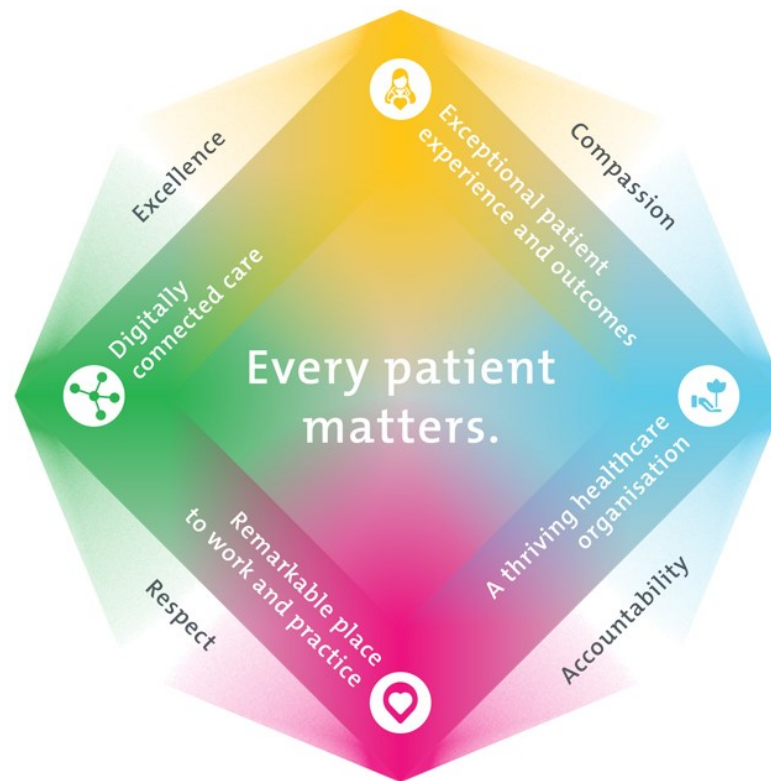
Epworth HealthCare is Victoria's largest not-for-profit private health care group, renowned for excellence in diagnosis, treatment, care and rehabilitation. Epworth is an innovator in Australia's health system, embracing the latest in evidence-based medicine to pioneer treatments and services for our 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 Coordinator (CRC) will assist in recruitment of potential participants into research studies as well as providing administrative and clerical support to ensure effective and efficient team operations. In conjunction with team members the CRC will assist in maintaining appropriate regulatory documents and ensuring regulatory compliance in the conduct of clinical research

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 Responsibilities: Participate and contribute to clinical research studies within EJWPCRC Support the Research Program Manager within EJWPCRC in any and all research activities	<ul style="list-style-type: none">Working closely with the clinical trials team assisting with biological sample requirements for clinical research and trials allocated to oneself such as:<ul style="list-style-type: none">Biological sample collectionProcessing of biological samples in the laboratory

	<ul style="list-style-type: none"> • Storage of biological samples • Working with couriers as required <p>For allocated clinical trials and research study</p> <ul style="list-style-type: none"> • Manage data management in all relevant databases • Be responsible for research governance and ethics documents and requirements <p>Liaises with relevant clinical teams and patient databases to identify patients suitable to participate in studies</p> <ul style="list-style-type: none"> • Supporting the Research Manager with research activities such as seminars, symposiums and conferences. • Ensure clinical research is performed at an appropriate standard (GCP, GLP, ISO etc) • Review and seek advice as appropriate on legal and contractual issues • Manage and maintain both electronic and paper case report forms (CRFs) • Ensure the implementation and maintenance of all study related records and data within the nominated study management system. • Works under the direction of their line manager to fulfil key tasks related to recruitment of participants into research projects • Provides information sheets and consent forms to potential participants and where authorised obtains their consent • Maintains appropriate records related to the consent process
<p>Research Excellence:</p> <p>Successful completion of essential research activities</p>	<ul style="list-style-type: none"> • 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

	<p>performed within these guidelines and in accordance with the policies of the pharmaceutical companies sponsoring the research</p> <ul style="list-style-type: none"> • Efficiently organise all elements related to patient recruitment, visits and all elements as described in the clinical trial protocol • Demonstrated 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 • In consultation with the Research Project manager monitor study related finance and budget milestones, invoices and payments
Communication Professionally engage key internal and external stakeholders	<ul style="list-style-type: none"> • Demonstration of 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 company personnel and patients in a courteous and non-discriminatory manner
<p>Education: Maintain the highest standard of knowledge and skills in the field of Prostate and Urological Cancers and in clinical research practice required for undertaking the role</p>	<ul style="list-style-type: none"> • Undertake additional training in order to acquire the knowledge and skills needs to implement new study protocols from a variety of clinical specialties • Conduct study specific in-service education sessions for relevant health professional staff • Attend and present at various research forums • Assist in the orientation of new research staff to the EJWPCRC
<p>Team: Demonstrate the Epworth values and behaviours and provide support for colleagues associated with the research programs of the Centre</p>	<ul style="list-style-type: none"> • Works cooperatively and collaboratively with all colleagues, Epworth staff and external parties • Attend all research team and research meetings as is required and/or feasible • Provide support for other colleagues and studies as required

	<ul style="list-style-type: none"> Assist with ad hoc research and quality activities as directed Strive to meet corporate KPIs with respect to absenteeism and professional developmentAssist with and participate in point prevalence and other <i>ad hoc</i> research and quality activities under the direction of the Research Program Manager
Governance: Meet all governance standards and benchmarks required for clinical research	<ul style="list-style-type: none"> 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 Page 7 of 9 Adherence to and compliance with research specific policies, clinical policies, including drug policies, standard operating procedures and guidelines Assist Research Program Manager with study feasibility and site initiation visits Conduct coordination of all trial visits, appointments, procedures and assessments with research participants Submitprogress and final reports to the approving HREC as required Assist the Research Program Managerwith key stakeholders, investigators and clinicians on research governance standards, procedures and documentation requiredEnsure all Studies are conducted according to study protocols and relevant legal and regulatory bodies Adhere to, support and develop research specific policies, standard operating procedures and guidelines
Personal and Professional Development: Participates in prescribed performance development system annually Evaluates personal performance and plans self-development	<ul style="list-style-type: none"> Completion of annual performance appraisal Completion of objectives outlined in self-development plan (provide evidence of) Undertake and maintain all required training including GCP, Dangerous Goods, study specific, and all internal training as required

	<ul style="list-style-type: none"> • Undertake self-directed and formal clinical and research topic learning • Participate in and support EJWPCRC with research-related activities, including Research Breakfasts, Research Week and Research Reporting
<p>Customer Service</p> <p>Epworth is committed to the provision of excellent customer service to all of our people, customers and stakeholders including patients and external suppliers.</p> <p>Superior patient service leads to improved healing in a trusting, caring environment and creates a safe environment for patients and employees.</p>	<ul style="list-style-type: none"> • 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 expectations and issues, using multiple strategies • Patient and customer service satisfaction surveys within agreed targets • Consistently meet or exceed the expectations of the EJWPCRC and customers at all times • Use AIDET principles in all interactions • Issues are escalated to the manager and resolved in a timely manner
<p>Safety and Wellbeing</p> <p>Participate actively and positively in the area of health and safety to reduce all hazards and incidents within the workplace</p>	<ul style="list-style-type: none"> • Report all hazards, incidents, injuries and near misses immediately to your manager and log them in RiskMan • 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

7. Position Requirements/Key Selection Criteria

COMPONENT	
Qualifications	Essential <ul style="list-style-type: none"> A relevant tertiary qualification in science, health care or a related field
Previous Experience	Essential <ul style="list-style-type: none"> Prior experience working in a clinical research environment. Data management skills Desirable <ul style="list-style-type: none"> Research experience and/or knowledge in oncology
Required Knowledge & Skills	Essential <ul style="list-style-type: none"> 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 Desirable <ul style="list-style-type: none"> Knowledge of medical terminology 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	Essential <ul style="list-style-type: none"> 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

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Epworth's values and behaviours <ul style="list-style-type: none">• Compassion• Accountability• Respect• Excellence• Community• Integrity	<ul style="list-style-type: none">• Professional work ethic and flexible work style
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Document Control

Date Developed:	Date Last Reviewed:	Developed and Reviewed By
June 2019	April 2024	Research Program Manager EJWPCRC

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: _____