

Position Description



1. General Information

Position Title:	Clinical Research Coordinator
Division/Department:	Jreissati Pancreatic Centre at Epworth (JPCE)
Position Reports to:	Research Program Manager, Jreissati Pancreatic Centre at Epworth
Enterprise/Individual Agreement:	Individual Agreement
Classification/Grade:	N/A
Location:	Epworth Corporate
Employment Status:	Full Time, Fixed Term (24 months)
Resource Management (for Management positions only) Number of Direct Reports: Budget under management:	Not Applicable
Key Relationships - internal and external	Internal: • Director, JPCE • Research Program Manager, JPCE • JPCE Team • Principal Investigators & Co-investigators • Ward and outpatient unit Nurse Unit Managers (NUMs) • Staff in all relevant patient care areas across all Epworth hospitals – including Day Oncology Unit (DOU), outpatient department (OPD), hospital wards, diagnostic imaging, pathology and associated clinical trials medical staff. • Epworth Research, Development and Governance Unit • Epworth research groups and laboratory staff External: • Research participants and their carers • Private consulting suite staff of trial investigators • External hospitals, laboratories, diagnostic imaging centres and universities

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| | <ul style="list-style-type: none">• Representatives from clinical trial sponsors, clinical research organisations (CRO) s and collaborators.• Surgical, pathology and other clinical staff at key collection centres• Relevant professional bodies such as Victorian Cooperative Oncology Group (VCOG), Clinical oncology Society of Australia (COSA), A-CTEC and ARCS Australia. |
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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*.

2. Epworth HealthCare Strategy

All roles at Epworth contribute to the successful delivery of the **Epworth 2030 strategy**, which sets our direction for the future through three strategic priorities:

- **Excellence in care, every time.**
Uncompromising standards delivering safe, consistent, high-quality care. No exceptions.
- **Growth with purpose.**
Intentional growth in the services, specialties and settings our communities need most, at a scale that sustains investment, innovation and quality.
Growth that gives back: as a not-for-profit, every dollar we earn is reinvested in care.
- **A place where great people do great work.**
Where our staff and doctors are backed to set the standard for exceptional healthcare.

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

- Conduct investigator-lead, collaborative group and commercially-funded research activities according to Good Clinical Practice (GCP).
- Manage the screening, enrolment, and trial assessments for participants within the JFPC.
- Contribute to the expanding JPCE research portfolio through supporting upcoming trials and working with colleagues to ensure a high quality of data and trial management.

5. Key Accountabilities

KEY RESPONSIBILITIES	MEASURES/KPIs TO BE ACHIEVED
Clinical Research Responsibilities - Assist Principal Investigator in completing site feasibility assessment, site selection visits and start-up activities from Sponsor - Prepare site-specific assessments including seeking departmental approvals - Prepare trial budget in association with Project Manager - Actively participate in participant assessment of suitability for enrolment in clinical trial (i.e. pre-screening). - Undertake participant screening and enrolment activities - Maintain trial participants on the clinical trial as specified in trial protocol - Collect trial data and enter into Case Report Forms and/or trial database in a timely manner and in accordance with trial-specific procedures and Sponsor requirements - Maintain essential documents in the trial Investigator Site File (ISF) - Coordinate reporting and monitoring activities, including adverse events, incidents, and monitoring visits - Receive, store and document all drugs and other investigational products relating to clinical trials according to protocol and trial procedure - Coordinate and manage all third-party service provider activities (pharmacy, pathology and radiology)	- Ensure all clinical trial documentation is complete and compliant with GCP and GDP before trial commencement, during the trial and until trial close out - Ensure all study requirements are completed both before and after IP administration according to protocol - Review and seek advice as appropriate on legal and contractual issues - Ensure study/trial milestones and project work at met within agreed timeframes and budgetary framework - Work collaboratively with all people involved in the development and successful completion of clinical trials/studies - Ensure incidents and safe - Complies with regulations, institutional policies and sponsor requirements governing source data and documentation - Displays ability to analyse situations and make appropriate decisions in a timely manner that meets the needs of patients, staff, organisation, trial investigator and trial sponsor.
Research Excellence	

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• Conduct clinical trials in accordance with skills and experience relating to the conduct of clinical trials • Ensure all trial and research activities are carried out in accordance with study protocol • Liaise with sponsors for all trial related activities including monitoring visits, data query resolution, audits and other participant or site related issues • Prepare high quality written reports as required	• Ensures minimal protocol deviations (planned and unplanned) • Maintain timely and appropriate communication with key internal and external parties • Ensures all data points can be verified with source documentation • Maintain ALCOA principles in all trial documentation • Respond to sponsor queries within required timeframe
Communication • Professionally engage key internal and external stakeholders regarding all research-related activities • Assist with the preparation of high-quality written reports as required • Maintain appropriate communication with key internal and external parties • Communicate effectively with investigators, sponsors, CROs, research participants and their carers	• Communicate trial updates as appropriate to trial investigators, JPCE management, OfR, and HREC • Ensure trial participants and carers are thoroughly informed of requirements and timing of study visits • Ensure relevant parties involved in trial activities have clear understanding of their responsibilities and study requirements prior to site activation •
Education Maintain the highest standard of knowledge and skills in pancreatic 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 JPCE	• Attendance at departmental educational opportunities (such as poster presentations and symposia) • Maintain relevant training and credentialing (e.g. eLearning, GCP, GDP, A-CTEC, IATA). • Continue to develop pancreatic-specific knowledge to aid in the efficient and effective conduct of pancreas clinical trials

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Team Demonstrate the Epworth values and behaviours and provide support for colleagues associated with the research programs of the Centre • Attend all team and research meetings as required • Undertake key tasks or projects as requested by the management of the JPCE. • Undertakes Epworth and JPCE supporting activities	• Successful team integration and support • Strive to meet corporate KPIs with respect to absenteeism and professional development
Governance Adhere to, support and participate in the development of research specific policies, standard operating procedures and guidelines • Assist trial investigators and researchers with their trial coordination processes to ensure it is carried out in a timely and efficient manner • Assist in the preparation of HREC and Governance documentation for study submissions or amendments, and provide study progress and final reports, as required • Manage safety reporting in line with requirements of the TGA, Human Research Ethics Committees (HRECs) and granting bodies	• 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
Personal and Professional Development Participate in all professional and personal development requirements	• Undertake and maintain all required training including GCP, Dangerous Goods, study specific, and all internal training as required • Undertake self-directed and formal clinical and research topic learning • Participate in and support JFPCE with research-related activities, including Research Breakfasts, Research Week and Research Reporting
Customer Service	• Provide excellent, helpful service to patients, visitors and staff • Communicate with clear and unambiguous language in all interactions, tailored to the audience

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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.	• Actively seek to understand patients' and their family's (customers) expectations and issues • 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 meet or exceed the expectations of the JPCE and customers at all times
Safety and Wellbeing Participate actively and positively in the area of health and safety to reduce all hazards and incidents within the workplace	• 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

6. Position Requirements/Key Selection Criteria

COMPONENT	
Qualifications	Essential - Degree level education or other relevant further education in health and/or science Desirable - Extra qualifications in clinical research competency (e.g. GCP, GDP, IATA training) - Evidence of further education including post-graduate certification/diploma/continuous professional development
Previous Experience	Essential - A minimum of 2 years' experience as a clinical research coordinator or equivalent experience - Research experience and knowledge in medical oncology - Experience working in a clinical / hospital environment Desirable - Research experience and/or knowledge in pancreatic cancer
Required knowledge and skills	Essential - 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 and diverse team - Proven ability to undertake tasks in a timely and effective manner - Ability to interact professionally with a variety of stakeholders Desirable - Working knowledge of Australian and International statutory and regulatory requirements (e.g. TGA, FDA) - Experience with tissue/blood sample collections, processing and storage

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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
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Document Control

Date Developed:	Date Last Reviewed:	Developed and Reviewed By (Position Title):
August, 2020	October 2026	Research Program Manager - JPCE

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: _____