Position Description

Clinical Trials Team Leader

Classification:	Registered Nurse Div 1 Research Nurse Level 3 (YX13) Administration Officer Grade 5 (HS5)
Business unit/department:	Cancer Clinical Trials Centre (CCTC)
Work location:	Austin Hospital
Agreement:	Nurses and Midwives (Victorian Public Sector) (Single Interest Employers) Enterprise Agreement 2024-2028
	Victorian Public Health Sector (Health and Allied Services, Managers and Administrative Officers) (Single Interest Employers) Enterprise Agreement 2025-2027
Employment type:	Part-Time
Hours per week:	24hrs (3 days a week)
Reports to:	CCTC Manager
Direct reports:	Approx. 6
Financial management:	Budget: NA
Date:	November 2026

Position purpose

The Team Leader is recognised as the leader of a tumour stream team, forming part of the overall CCTC leadership team. The Team Leader works as a delegate of the CCTC Manager to model the core values of Austin Health through effective leadership and management of assigned team trial coordinators and support staff. The Team Leader provides effective oversight of daily operations, using expertise to provide guidance, direction, supervision, and supportive professional development.

The Team Leader will work in accordance with the Guideline for Good Clinical Practice ICH E6 (R2) and associated ethical and regulatory requirements, maintaining clinical and research governance. A high-quality service is provided that fosters a positive team culture, maintenance of a safe working environment and effective utilization of financial resources, whilst supporting the Manager to drive change and implement continuous service improvement.

About the Directorate/Division/Department

ONJ Centre

Since September 2013 all Austin Health metro based Cancer Services are delivered within the Olivia Newton-John Cancer Wellness & Research Centre (ONJCWRC) at the Austin Hospital. This state of the art facility provides a new model of individualised cancer care for patients and their families.

Clinical Services are provided in a range of inpatient and ambulatory settings. Inpatient services include an acute oncology/clinical haematology ward, an oncology/surgical oncology ward and a palliative care ward. Ambulatory services include Radiation Oncology, Day Oncology, Apheresis, and multidisciplinary cancer clinics.

Cancer Clinical Trials

The Cancer Clinical Trials Centre (CCTC) is part of Austin Health Cancer Services conducting a wide variety of cancer clinical trials nationally and internationally and has a reputation for excellence. The CCTC has expertise in managing studies from Phase I to Phase 3 and participates in a mix of Investigator-initiated research, Collaborative Group studies and Pharmaceutical Company sponsored clinical trials.

CCTC comprises a team of full time and part time Study Co-ordinators (Registered Nurses), Clinical Research Assistants, Clinical Research Fellows, Ethics Submission Co-ordinators, Data Managers and a specialised Finance staff. The study coordinators are organised into teams, each with a Clinical Team Leader and a Clinical Research Assistant.

The atmosphere within CCTC is energetic, friendly, and cohesive, with strong work ethic amongst all members and regular meetings with Investigators to discuss study management issues.

Position responsibilities

Role Specific:

- Works in accordance with Ethical and Regulatory bodies locally, nationally and internationally.
- In collaboration with the CCTC Manager, ensure the tumour stream team's clinical trials are properly resourced, managed and executed within budget.
- Works closely with Principal Investigators with clinical feasibility process.
- Complies with the requirements of the reviewing Ethics Committee with regards to the conduct of the clinical research project.
- Lead regular strategic meetings with tumour stream Principal Investigators to ensure regular updated information about current and upcoming trial portfolio and team resources.
- Supports staff in identifying the training and education implications of each protocol and oversees the development of appropriate strategies to meet these needs to ensure the safe and accurate implementation of the study.
- Overseeing in-line reports with regards to ensuring all clinical trial information is recorded, handled and stored in a way that allows accurate reporting interpretation and verification.
- Oversees and participates where required in data collection and data entry for tumour stream team clinical trial protocols.
- Oversee and support team members in the maintenance of the trial protocol Investigator Site Files, ensuring compliance with essential document requirements in accordance with ICH-GCP.

- In close collaboration with the CCTC Manager and Principal Investigators, the Team leader's responsibilities include trial protocol feasibility assessment, and trial budget and contract negotiations within the CCTC established framework.
- Maintains a flexible approach to working hours in order to meet the requirements of research protocols, subject recruitment and Team Leader role expectations.
- Undertake additional training and attend national/international meetings as required, to acquire the knowledge and skills needed to assist in the implementation of new trial protocols.
- Ensure optimal clinical management of eligible, consenting trial patients under the supervision of the Principal Investigator according to study protocol criteria.
- Demonstrates a solid understanding of the roles and responsibilities of Ethics/RGO submission requirements and processes, and carry out essential document submission as required, or delegate where applicable.
- Supports the ongoing informed consent process for trial research participants, providing advice and information.
- Contributes to the development of processes within the clinical trial unit to ensure that practice aligns with research ethical and regulatory guidelines, and within Austin policies.
- Ensures team members meet all trial protocol requirements, data entry requirements, database lock timelines and responds to data queries within expected timeframes as they arise.
- Ensure CCTC processes are maintained for the accurate collection, documentation and archiving of data according to clinical trial protocol, ICH GCP guidelines and Austin/department policies.
- Holds a current TransCelerate mutually recognised Good Clinical Practice (GCP) Certificate.
- Ensure patient confidentiality is maintained at all times.
- Facilitate monitoring of Case Report Forms by Clinical Research Associates and other Auditors

Business & Financial Acumen:

- Executes trial protocol budget and contract negotiations, liaising with Austin departments and external vendors and stakeholders as required, with the support of the CCTC Finance Office and CCTC Manager.
- Supports the CCTC Manager is explaining financial implications of business decisions to staff.
- Identifies cost effective and efficient approaches to managing resources.
- Works with the CCTC Manager and leadership team to analyse clinical trial costs and financial data to develop strategies and plans.
- Identify and escalate emerging issues regarding financial implications for clinical trial activities
- Manages trial protocol budgets effectively within targets and timelines.
- Understands the impact of financial decisions on the broader organization.

Direct Clinical Care (nursing) and/or indirect clinical care (both nursing and non-nursing);

- Provides expert clinical knowledge and direction to ensure that clinical standards, policies and procedures promote a patient focused model of care.
- Lead and advise in partnership with multidisciplinary team, to address abnormalities in assessment information in all clinical situations.
- Provide expert clinical knowledge to point of care nurses through communication, modelling, and teaching.
- Provide expert clinical trial advice in collaboration with the patient/family and research team.
- Recognise scope and limitations of practice and seek advice from other experts where required.
- Lead others to develop skills in utilisation and interpretation of assessment information.
- Provide expertise in management of complex situations and generate alternative course of action.

Education;

- Facilitate staff learning through development of cross discipline relationships and networks.
- Provide mentorship/ coaching of other staff for career development.
- Where applicable (nursing), utilise and maintain professional practice portfolio to plan for future continuing education, professional development and employment goals for self and others.
- Identify and implement strategies to support staff with their learning needs.
- Create a climate where self-development and improvement is valued.
- Act as a resource person for colleagues, staff and patients on all aspects of clinical trials.

Research;

- Ensure achievement and maintenance of national quality within the National Clinical Trials Governance Framework (NCTGF) and clinical research quality standards, at local level.
- Demonstrate in-depth and developed knowledge of the translation of research into practice.
- Create, participate and support others in the development of evidence-based guidelines.

Support of Systems;

- Lead initiatives aligned to NSQHSS, in particular the National Clinical Trials Governance Framework to drive practice improvement at the local level.
- Support and lead others to develop and undertake evidence-based quality activities based on clinical audit results.
- Lead staff to adhere to organisational EMR policy and practice, and ensures all staff are aware of clinical trial source documentation requirements.
- Assists the CCTC Manager to identify opportunities for process redesign and supports clinical trials staff in the implementation of redesign projects and activities.
- Uses department clinical trial management systems (CTMS) to inform decision making and evaluate outcomes.
- Overseen by the CCTC Manager and Quality Coordinator, support team members through Corrective Action and Preventative Action (CAPA) process when required.
- Directly support staff through audit and/or regulatory inspection process.

Professional Leadership;

- Communicates information and expectations in a way that builds effective and collaborative working relationships with others.
- Ensures information is available to all team members by utilising a wide range and appropriate modes of communication.
- Provides timely performance feedback, coaching and guidance when needed in accordance with the performance management policy.
- Acts as a role model for staff, setting and clearly communicating clinical and behavioural expectations.
- Influence nursing clinical leadership and provide advice related to NMBA Decision Making Framework across Austin Health and wider context.
- Demonstrate high levels of self-agility and maintain focus even during times of uncertainty and change.
- Maintain an understanding of individual responsibility for safety, quality & risk and actively contribute to organisational quality and safety initiatives
- Ensure incident management systems are applied and a response to local issues and performance improvement occurs
- Support staff under management to comply with policies, procedures and mandatory training and

continuing professional development requirements
- Creates a team environment, which promotes a positive culture, opportunity for learning and development, safety and welfare of employees and fosters innovation in practice that results in a high level of staff satisfaction, high staff retention rates and low absenteeism.

Selection criteria

Essential skills and experience:

- A commitment to Austin Health values: Our actions show we care, We bring our best, Together we achieve and We shape our future.
- Direct working experience as a clinical trial coordinator or clinical research associate managing a portfolio of complex cancer clinical trials.
- Demonstrated leadership ability.
- Ability to understand fundamental trial protocol budget processes.
- A background of experience which enables excellent competencies and skills for the management of clinical trials and staff coordinating trials.
- Demonstrated expertise in communicating and liaising effectively with a range of personnel, key stakeholders, and organisations.
- Working knowledge of international and national regulatory, ethical and research governance requirements.
- Ability to build a dynamic team which works effectively within a multidisciplinary environment.
- Commitment to quality, best practice and environmental safety.
- Effective listening and interpersonal skills.
- Time management skills/ability to prioritise workload.
- Ability to communicate effectively in both written and verbal form, and problem solve in a variety of complex situations.
- Experience and proficiency in Microsoft Office Suite.
- A thorough understanding of issues concerning patient confidentiality.

Desirable but not essential:

- Previous management experience.
- A sound understanding of information technology including clinical systems, applications relevant to the management of rostering and risk management reporting or as required for the role and/or department.
- Demonstrated experience in leading quality initiatives.
- Post Graduate Qualification – clinical or management.

Professional qualifications and registration requirements

- A registered Nurse with Nursing and Midwifery Board of Australia ***or*** Relevant Health Sciences Background.

Quality, safety and risk – all roles

All Austin Health employees are required to:

- Maintain a safe working environment for yourself, colleagues and members of the public by following organisational safety, quality and risk policies and guidelines.
- Escalate concerns regarding safety, quality and risk to the appropriate staff member, if unable to rectify yourself.
- Promote and participate in the evaluation and continuous improvement processes.
- Comply with the principles of person-centered care.
- Comply with requirements of National Safety and Quality Health Service Standards and other relevant regulatory requirements.

Other conditions – all roles

All Austin Health employees are required to:

- Adhere to Austin Health's core values: *our actions show we care, we bring our best, together we achieve, and we shape the future.*
- Comply with the Austin Health's Code of Conduct policy, as well as all other policies and procedures (as amended from time to time).
- Comply with all Austin Health mandatory training and continuing professional development requirements.
- Provide proof of immunity to nominated vaccine preventable diseases in accordance with Austin Health's immunisation screening policy.
- Work across multiple sites as per work requirements and/or directed by management.

General information

Cultural safety
Austin Health is committed to cultural safety and health equity for Aboriginal and/or Torres Strait Islander People. We recognise cultural safety as the positive recognition and celebration of cultures. It is more than just the absence of racism or discrimination, and more than cultural awareness and cultural sensitivity. It empowers people and enables them to contribute and feel safe to be themselves.

Equal Opportunity Employer
We celebrate, value, and include people of all backgrounds, genders, identities, cultures, bodies, and abilities. We welcome and support applications from talented people identifying as Aboriginal and/or Torres Strait Islander, people with disability, neurodiverse people, LGBTQIA+ and people of all ages and cultures.

Austin Health is a child safe environment
We are committed to the safety and wellbeing of children and young people. We want children to be safe, happy and empowered. Austin Health has zero tolerance for any form of child abuse and commits to protect children. We take allegations of abuse and neglect seriously and will make every effort to mitigate and respond to risk in line with hospital policy and procedures.