Position Description

Position Title: Clinical Trials Coordinator Level 2

Classification:	Registered Nurse Div 1 Level 2 Research Nurse (Classification based on years of experience)
Business unit/department:	Cancer Clinical Trials Centre
Work location:	Austin Hospital
Agreement:	Nurses and Midwives (Victorian Public Sector) (Single Interest Employers) Enterprise Agreement 2024-2028
Employment type:	Fixed-Term Part-Time
Hours per week:	24hrs (3 days/week)
Reports to:	CCTC Tumour Stream Leader
Direct reports:	N/A
Financial management:	Budget: N/A
Date:	Jun25

Position purpose

As an integral member of the research team within the Cancer Clinical Trials Centre (CCTC), the **Clinical Trials Coordinator** works in accordance with professional, organisational, legal, and ethical standards governing Registered Nurse practice. They are responsible for managing the nursing care of individuals and groups within their scope of practice.

The role involves delivering both direct and indirect clinical trial-related care to patients, as well as collecting data for concurrent clinical studies conducted within the department. All activities must comply with the International Council for Harmonisation Guideline for Good Clinical Practice (ICH E6 R2), along with relevant ethical and regulatory requirements, ensuring strong clinical and research governance. Flexibility to move across teams may be required to meet operational needs.

The Clinical Trials Coordinator ensures the highest standard of care is provided to patients participating in clinical trials, working collaboratively with multidisciplinary and clinical research teams within the CCTC.

About the Directorate/Division/Department

Cancer Services

All metropolitan-based Cancer Services at Austin Health have been delivered through the Olivia Newton-John Cancer Wellness & Research Centre (ONJCWRC) at Austin Hospital. This state-of-the-art facility offers individualised cancer care, supporting both patients and their families.

Clinical services are provided across a variety of inpatient and ambulatory settings. Inpatient care includes an acute oncology and clinical haematology ward, as well as a dedicated palliative care ward. Ambulatory services encompass Radiation Oncology, Day Oncology, Apheresis, and a range of multidisciplinary cancer clinics. Complementing this clinical care, the ONJ Centre also offers a comprehensive suite of wellness programs designed to support the physical, emotional, and spiritual wellbeing of patients throughout their cancer journey.

Austin Cancer Clinical Trials Centre (CCTC)

The Cancer Clinical Trials Centre (CCTC) is an integral part of Austin Health Cancer Services, conducting therapeutic and interventional cancer clinical trials across the Medical Oncology and Clinical Haematology tumour streams. The CCTC manages over 250 clinical trials concurrently ranging from Phase 1 (including First-in-human) to Phase 3, including a mix of investigator-initiated research, collaborative group studies, and pharmaceutical company-sponsored trials. There are over 60 dedicated and highly experienced staff working alongside more than 20 principal investigators to provide direct patient care and ensure the highest quality management of clinical trials.

CCTC comprises six tumour stream teams, each led a Team Leader. These teams include Trial Coordinators (Registered Nurses), a Research Assistant, and a Clinical Research Fellow, supported by dedicated staff in ethics submissions, data management, finance, and quality assurance.

The atmosphere within the CCTC is energetic, friendly, and cohesive, underpinned by a strong work ethic shared by all team members.

Position responsibilities

Clinical Trial Conduct and Compliance

- Ensure all clinical research activities comply with the International Conference on Harmonisation Good Clinical Practice (ICH GCP) guidelines and the NHMRC National Statement on Ethical Conduct in Human Research.
- Ensure compliance with the National Clinical Trials Governance Framework.
- Support the Principal Investigator and research team in the optimal clinical management of eligible and consenting trial participants, in accordance with study protocols.
- Comply with all clinical trial policies and procedures, including privacy, confidentiality, and adverse event reporting requirements.

Trial Coordination and Patient Care

- Coordinate a portfolio of clinical trials as directed by Team Leaders, demonstrating effective workload prioritisation and collaboration.
- Maintain a flexible approach to working hours to meet protocol and recruitment requirements.
- Perform or coordinate protocol-specific procedures and investigations within scope of practice, under the supervision of the Principal Investigator.
- Assist in assessing patient eligibility based on protocol inclusion/exclusion criteria.
- Support Investigators in obtaining and maintaining informed consent in accordance with ICH GCP, hospital policy, and NHMRC guidelines.
- Administer (once certified) or support the administration of investigational and standard therapies, including cytotoxic drugs, antibodies, cytokines, tumour vaccines, GMOs, and radioactive isotopes.
- Report safety data in accordance with protocol and regulatory requirements, escalating issues as appropriate.
- Collect and coordinate timely review of pathology results by Investigators.
- Liaise with relevant departments to ensure biological samples are collected, processed, stored, and shipped per protocol specifications.
- Manage workload to ensure patient care and protocol compliance are maintained.
- Facilitate comprehensive assessment, care, and follow-up of trial participants in collaboration with clinical units and support services.

Standards and Professional Practice

- Demonstrate knowledge and application of ICH GCP, NHMRC guidelines, and unit standard operating procedures (SOPs).
- Practice in accordance with the Australian Nursing and Midwifery Accreditation Council (ANMAC) National Standards for the Registered Nurse. link
- Adhere to Austin Health and Cancer Clinical Trials (CCTC) policies, procedures, and guidelines.
- Maintain competency in line with the CCTC matrix expectations via the ATLAS learning management system, including Anti-cancer Drug Administration Course (ADAC) credentialling.
- Recognise personal scope of practice and seek guidance from senior staff or subject matter experts when required.
- Maintain a professional practice portfolio to support ongoing education, development, and career planning.

Trial Start-Up, Data Management and Oversight

- Coordinate clinical trial start-up meetings, liaising with Investigators, study team members, Sponsor representatives and internal departments.
- Maintain accurate records and updates in the CCTC Coordinator Management Hub to ensure transparency and oversight of trial progress and enable accurate invoicing of trial activities performed.
- Maintain mandatory CCTC study specific data collection tools, including the study team checklist and the checklists for study start-up, amendments, and close-out activities.
- Ensure accurate and timely data collection, documentation and entry, in compliance with protocol, regulatory, and ethical standards, and CCTC guidelines.
- Maintain patient confidentiality at all times.
- Facilitate monitoring visits and audits by Sponsors or regulatory bodies.
- Meet Sponsor driven data submission deadlines, including database lock timelines.
- Respond promptly to data queries and ensure data accuracy using study-specific documentation and regulatory guidelines.

Communication

- Ensure investigators and other relevant personnel are kept informed of trial progress, adverse events, treatment complications, and patient tolerance to therapies.
- Maintain effective communication with investigators, managers, and multidisciplinary team members to ensure accurate and timely documentation and information sharing.
- Attend and actively participate in relevant Cancer Clinical Trials (CCTC) and hospital-wide meetings.
- Identify and escalate concerns appropriately to ensure timely resolution.
- Foster and maintain professional relationships with internal colleagues, other disciplines, external stakeholders, and Sponsor representatives.
- Demonstrate professional and courteous email communication at all times.

Education

- Educate patients and families to enhance understanding of clinical trial objectives, procedures, and therapeutic agents.
- Actively contribute to the education and professional development of self and colleagues within the department.
- Demonstrate initiative in pursuing further educational opportunities.
- Participate in local professional networks and forums to share knowledge and foster collegial support.
- Assist in the orientation and onboarding of new staff to the CCTC team.

Support of Systems

- Promote understanding of Austin Health's vision and strategic priorities, integrating them into clinical practice.
- Support staff in understanding and applying the National Safety and Quality Health Service Standards (NSQHSS) and the National Clinical Trials Governance Framework (NCTGF).
- Contribute to the development and review of CCTC SOPs and guidelines.
- Participate in quality improvement initiatives to address identified service gaps.

Professional Leadership

- Assist staff in managing competing priorities and contribute to effective workload distribution within the department.
- Demonstrate a commitment to high performance, accountability, and sustainable service delivery.
- Recognise and celebrate the contributions and achievements of colleagues.
- Support staff to work autonomously within their scope of practice.
- Role model Austin Health values in all professional interactions.
- Collaborate with the CCT team to ensure service demands are met through shared workload coverage.
- Complete and maintain all mandatory training relevant to the role.
- Contribute to a safe, healthy, and supportive work environment.
- Promote a culture of safety, wellbeing, and continuous improvement.
- Serve as a resource for colleagues, staff, and patients on clinical trial processes, with support from senior staff as needed.

Selection criteria

Essential skills and experience:

- Demonstrates a strong commitment to Austin Health core values: *We care, We bring our best, Together we achieve, We shape the future.*
- Holds a current registration as a **Division 1 Registered Nurse** with the Nursing and Midwifery Board of Australia (AHPRA).
- Possesses clinical experience in Oncology and/or Haematology nursing, with a sound understanding of the complexities involved in theses specialities.
- Exhibits strong clinical skills in patient care, including effective organisation, and clear communication.
- Understands and upholds principles of patient confidentiality and privacy.
- Demonstrates awareness of ICH-GCP and relevant ethical guidelines relevant to clinical research.
- Proven ability to work autonomously while contributing effectively within a multidisciplinary team environment.
- Skilled in venipuncture and ECG recording procedures.
- Demonstrates excellent time management, attention to detail, and the ability to prioritise tasks in a dynamic clinical setting.
- Highly developed verbal and written communication skills, with the ability to convey information clearly and empathetically.
- Displays enthusiasm, initiative, and a commitment to continuous learning and team collaboration.
- Strong interpersonal, active listening, and the ability to resolve problems effectively
- Flexible and innovative in approach, with a strong orientation towards teamwork to achieve optimal outcomes.
- Maintains positive attitude toward change, embraces diversity, and actively contributes to ongoing service improvement.
- Demonstrates a compassionate, patient-centred approach to care delivery.
- Competent in using Microsoft Office applications, particularly Word, Excel, and Outlook.

Desirable but not essential:

- Experience in coordinating clinical trials, including early-phase (Phase I) trials.
- Proficient in data entry and clinical data management systems.
- Skilled in simple processing of blood and urine specimens.
- Competent in peripheral IV cannulation and the management of Central Venous Access Devices (CVADs)
- Hold credentials in Anti-cancer Drug Administration Course (ADAC) or equivalent training.

Professional qualifications and registration requirements

- Current registration with the Australian Health Practitioner Regulation Agency (AHPRA) as a Registered Nurse.
- Undertake continuing professional development (CPD) activities in accordance with Nursing Board of Australia requirements, maintaining relevant competencies.

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.