Position Description

Position Title: Clinical Trials Coordinator Level 1

Classification:	Registered Nurse Div 1 (Grade 2) Level 1 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** (Level 1) 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, however is not responsible for primary management of trials. 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 (level 1) 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

- Assist in ensuring 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.
- Support compliance with the National Clinical Trials Governance Framework, as directed by more senior staff.
- Provide assistance to the Principal Investigator and research team in the optimal clinical management of eligible and consenting trial participants, in accordance with study protocols.
- Adhere to all clinical trial policies and procedures, including privacy, confidentiality, and adverse event reporting requirements, with guidance from more senior staff.

Trial Coordination and Patient Care

- Support the coordination of clinical trials as directed by Team Leaders.
- 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 supervision.
- Assist in assessing patient eligibility based on protocol inclusion/exclusion criteria, under supervision.
- Support Investigators in obtaining and maintaining informed consent in accordance with ICH GCP, hospital policy, and NHMRC guidelines.
- Administer (once certified and under supervision) 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 to senior staff 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 as per protocol specifications.
- Contribute to patient care and protocol compliance, under guidance.
- Assist in the assessment, care, and follow-up of trial participants in collaboration with clinical units and support services.

Standards and Professional Practice

- Demonstrate foundational 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

- Assist in clinical trial start-up activities under the direction of more senior staff.
- 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.
- Support the use of 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.
- Assist in preparing monitoring visits and audits by Sponsors or regulatory bodies.
- Support Sponsor driven data submission deadlines, including database lock timelines.
- Respond promptly to data queries and ensure data accuracy with guidance from more senior staff.

Communication

- Communicate trial progress and patient-related updates to the research team as directed.
- 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, as relevant.
- Escalate concerns to senior staff for timely resolution.
- Foster respectful and professional relationships with internal colleagues, other disciplines, external stakeholders, and Sponsor representatives.
- Demonstrate professional and courteous email communication.

Education

- Support patient and family education regarding trial participation.
- Engage in ongoing education and professional development of self and support the learning of colleagues.
- Demonstrate initiative in pursuing further educational opportunities.
- Participate in local professional networks and forums to share knowledge, as appropriate, and foster collegial support.
- Assist in the orientation and onboarding of new staff to the CCTC team.

Support of Systems

- Promote awareness of Austin Health's vision and strategic priorities in daily practice.
- Support staff in understanding and applying the National Safety and Quality Health Service Standards (NSQHSS) and the National Clinical Trials Governance Framework (NCTGF), under guidance.
- Contribute to the development and review of CCTC SOPs and guidelines, as appropriate.
- Participate in quality improvement initiatives under supervision.

Professional Leadership

- Assist in managing workload, under direction.
- Demonstrate a commitment to high performance, accountability, and sustainable service delivery.
- Recognise and celebrate the contributions and achievements of colleagues.
- Work within scope of practice and seek support when needed.
- 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.
- Demonstrates sound clinical skills in patient care, including effective organisation, and clear communication.
- Understands and upholds principles of patient confidentiality and privacy.
- Shows awareness of ICH-GCP and relevant ethical guidelines relevant to clinical research, with willingness to develop further knowledge.
- Proven ability to work autonomously while contributing effectively within a multidisciplinary team environment.
- Competency in venipuncture and ECG recording procedures.
- Demonstrates good 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.
- Possesses strong interpersonal and listening skills, with a willingness to seek guidance when resolving problems.
- 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:

- Exposure to or interest in clinical trial coordination, including early-phase (Phase I) trials.
- Familiarity with data entry and clinical data management systems.
- Basic skills in handling and processing blood and urine samples.
- Competent in peripheral IV cannulation and the management of Central Venous Access Devices (CVADs)
- Completion of, or working towards, Anti-cancer Drug Administration Course (ADAC) or equivalent credentialing.

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.