Austin Health
Position Description

Position Title: Clinical Trial Coordinator Level 2

Classification:	Registered Nurse Div 1 (YU13/14) Level 2 Research Nurse (Classification based on years of experience)
Business Unit/ Department:	Cancer Clinical Trials Centre
Work location:	Austin Health
Agreement:	Nurses and Midwives (Victorian Public Sector) (Single Interest Employers) Enterprise Agreement 2020-2024
Employment Type:	Parental Leave Cover
Hours per week:	40hrs with ADO (or less by negotiation)
Reports to:	CCTC Clinical Trials Tumour Stream Leader
Direct Reports:	N/A
Financial management:	Budget: N/A
Date:	Apr24

About Austin Health

Austin Health is one of Victoria's largest health care providers. We deliver services for patients across four main sites in Melbourne, in locations across our community, in people's homes, and within regional hospitals across Victoria. We are an internationally recognised leader in clinical teaching, training, and research, with numerous university and research institute affiliations.

We employ approximately 9,500 staff and are known for our specialist work in cancer, infectious diseases, obesity, sleep medicine, intensive care medicine, neurology, endocrinology, mental health, and rehabilitation.

Our vision is to shape the future through exceptional care, discovery, and learning. This is supported by our values which define who we are, shape our culture and the behaviours of our people.

We aim to provide an inclusive culture where all staff can contribute to the best of their ability and strive to develop further. We recognise that our people are our greatest strength. We want them to thrive, be their best selves and feel engaged, safe, and empowered. To achieve this, diversity and inclusion is essential to our culture and our values. You can view our current Diversity and Inclusion Plan here.

Position Purpose

As a member of a research team within CCTC, the Clinical Trial Coordinator works in accordance with professional, organisational, legal, and ethical standards affecting Registered Nurse practice, and manage nursing care of individuals and groups within the scope of Registered Nurse practice.

There will be responsibility for the delivery of direct and in-direct clinical-trial-related care of patients and associated data collection for concurrent clinical studies undertaken the department in accordance with the Guideline for Good Clinical Practice ICH E6 (R2) and associated ethical and regulatory requirements, maintaining clinical and research governance. Movement across teams within the department may be required to ensure operational needs are met.

The Clinical Trial Coordinator will ensure the highest standard of care is delivered to patients involved in clinical trials in partnership with all members of the multidisciplinary and clinical research teams within CCTC.

About ONJ Centre and Cancer Clinical Trials

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 Services has a strong research focus that is recognised internationally and has a close affiliation with the Olivia Newton-John Cancer Research Institute (ONJCRI). The ONJCRI is a cancer research organisation, which has both laboratory and major clinical programs at Austin Health.

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 Trial Coordinators (Registered Nurses), Clinical Research Administration Assistants, Clinical Research Fellows, an Ethics Submission Coordinators, Data Managers, and a Finance Officer. 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 a strong work ethic amongst all members and regular meetings with Investigators to discuss study management issues.

Purpose and Accountabilities

Role Specific:

- Ensure conduct of clinical research trials is in accordance with "International Conference on Harmonization" (ICH) guidelines for Good Clinical Practice (GCP) and the NHMRC National Statement on Ethical Conduct in Research Involving Humans.
- Ensure compliance with National Clinical Trial Governance Framework.
- Assist as a key member of the CCT research team to ensure optimal clinical management of eligible, consenting trial patients under the supervision of the Principal Investigator according to study protocol criteria.
- Adhere with the standard practice involved in conducting a clinical trial, including the policy and procedures, restrictions, adherence to privacy and confidentiality and adverse event reporting procedures.
- Provide clinical and professional advice relating to the conduct of clinical research to the Investigators and multidisciplinary team in accordance with ICH GCP, National Statement, department operating procedures and hospital policies.
- Coordinate a portfolio of clinical trials as directed by the Team Leaders, showing the ability to appropriately prioritise workload and seek assistance from team members when required.
- Maintain a flexible approach to working hours in order to meet the requirements of trial protocols and subject recruitment.
- Coordinate and /or perform all procedures and investigations within scope of practice required for protocol treatment of patients involved in Cancer Clinical Trials under supervision of the Principal Investigator.
- Assist in the assessment of the suitability of patients referred for clinical trials according to the protocol inclusion/exclusion criteria under supervision of the Principal Investigator.
- Administer (if qualified) or support the process of administering investigational and standard therapies including cytotoxic drugs, antibodies, cytokines, tumour vaccines, Genetically Modified Organism (GMO)and radioactive isotopes to clinical trial patients.
- Report safety information according to regulatory guidelines and at a local level and escalate as appropriate under supervision of the Principal Investigator.
- Collect, and coordinate the timely review of trial related pathology sample results by Investigators.
- Liaise with all involved staff/departments to ensure all biological samples are collected, processed, stored, and shipped as per the clinical trial protocol requirements.
- Demonstrate the ability to manage workload to ensure interests of patients on clinical trials are met and protocol requirements are followed.

- Assist in ensuring adequate assessment, care, and follow-up of trial patients by liaising with the managing clinical unit, medical, nursing, and ancillary services staff.
- Demonstrate through practice, knowledge of ICH GCP, associated NHMRC guidelines, and unit standard procedures.
- Practices in accordance with the Australian Nursing and Midwifery Accreditation Council (ANMAC) National Standards for the Registered Nurse. For further details see under 'competency standards' via the following link http://www.nursingmidwiferyboard.gov.au/Codes-Guidelines-Statements/Codes-Guidelines.aspx
- Follow Austin Health Nursing and CCT policies, processes, and guidelines.
- Organise clinical trial start-up meetings. This includes liaison with Investigators, Study Sponsors and Monitors, members of the Human Research Ethics Committee and various other departments and staff.
- Update and maintain CCTC coordinator management hub and other department processes to ensure management have oversight and transparency of work progress.
- Support Investigators to ensure clinical trial informed consent is obtained according to ICH GCP, standard hospital practice and the NHMRC National statement on Ethics Conduct in Research Involving Humans and be actively involved in the ongoing informed consent process.

Data Management:

- Accurate and timely collection, documentation, and entry of data according to clinical trial protocol, Regulatory and Ethical requirements, Clinical Trial Research Agreement, ICH-GCP and CCT guidelines.
- Ensure patient confidentiality is always maintained.
- Facilitate monitoring of Case Report Forms by Sponsor representatives and Auditors/Inspectors.
- Meet Sponsor driven database lock deadlines.
- Respond within expected timeframes to data queries as they arise.
- Use work practice guidelines and study specific documentation to ensure that data is recorded accurately and in accordance with regulatory requirements.

Communication:

- Ensure investigators and other personnel involved in the clinical trials process are kept informed about trial progress, serious adverse events, complications, and tolerance of treatments.
- Maintain effective communication processes with investigators, managers, and other members of the multidisciplinary team to ensure information is appropriately documented and shared.
- Attend and participate in all relevant CCT, and hospital wide meetings.
- Identify areas of concern and act/escalate as appropriate.
- Maintain professional working relationships with colleagues, other disciplines, with Sponsor representatives and other external stakeholders.
- Demonstration of professional email etiquette at all times.

Direct Clinical Care:

- Act as mentor/ preceptor to all point of care nursing staff
- Utilise and interpret patient assessment information to inform ongoing treatment.
- Provide expert clinical knowledge through communication, modelling, and teaching
- Provide clinical expertise and advocacy to the patient/family in the ongoing management, adaptation, and delivery of goals of care, within scope of practice.
- Demonstrate clinical reasoning and a comprehensive understanding of abnormal findings and patient conditions in complex situations with immediate escalation to trial investigators.
- Demonstrate competence within relevant CCTC matrix expectations via ATLAS learning management system.
- Recognise scope and limitations of practice and seek advice from other experts where required.

Education

- Provide education to patients and their families to enhance understanding of the aims, expectations, and procedures for therapeutic agents they are receiving.
- Actively engage and contribute to the education and professional development of self and others at department level.
- Utilise and maintain professional practice portfolio to plan for future continuing education, professional development and employment goals for self and others.
- Support and lead staff with ward/unit portfolios, utilising data driven approach to practice improvement.
- Demonstrate self-initiative in undertaking further educational opportunities.
- Participate in local networks and forums to share and extend professional knowledge and build collegial support.
- Participate in orientation of new staff to CCTC, as required.
- Utilise and maintain professional practice portfolio to plan for future continuing education, professional development and employment goals for self and others.

Support of Systems

- Support others to understand the Austin Health vision and integrate strategic priorities into clinical practice.
- Support others to understand the National Safety and Quality Health Service Standards (NSQHSS) and National Clinical Trials Governance Framework (NCTGF) and the implications for practice.
- Contribute to new or revised guidelines or procedures relevant to local clinical area.
- Be involved in quality improvement initiatives to address identified gaps at the local level.

Professional Leadership

- Support staff to manage priorities and actively assist in managing department workload.
- Demonstrate a commitment to deliver sustainable, excellent performance and accountability within the local context.
- Seek opportunities to celebrate other's contributions and achievements in the local

context.

- Support others to work autonomously within scope of practice.
- Demonstrate and role model Austin values.
- Work within the CCT team to cover the existing workload to meet service demands.
- Comply with the Requirements of the National Safety & Quality Health Service Standards.
- Complete and maintain all mandatory/required training relevant to area of practice.
- Contribute to a safe and healthy working environment.
- Promote a no blame culture of safety and wellbeing.
- Act as a resource person for, colleagues, staff, and patients on all aspects of clinical trials with assistance from more experienced staff as necessary

All Employees:

- Comply with Austin Health policies & procedures as amended from time to time
- Comply with the Code of Conduct and uphold our values, and diversity and inclusion commitments.
- Maintain a safe working environment for yourself, colleagues, and members of the public. Escalate concerns regarding safety, quality, and risk to the appropriate staff member, if unable to rectify yourself
- Comply with the principals of patient centred care.
- Comply with Austin Health mandatory training and continuing professional development requirements including participation in performance review.
- Work across multiple sites as per work requirements and/or directed by management.

Selection Criteria

Essential Knowledge and skills:

- A commitment to Austin Health values: Our actions show we care, We bring our best, Together we achieve and We shape the future.
- Division 1 Registered Nurse registered with the Nursing and Midwifery Board of Australia holding a current Australian Health Practitioner Regulation (AHPRA) Certificate.
- Oncology/Haematology nursing experience.
- Demonstrated excellence in patient management, organisation and communication.
- A thorough understanding of issues concerning patient confidentiality.
- Awareness of ICH-GCP Guidelines and relevant ethical guidelines.
- Excellent team working skills with ability to work autonomously.
- Venipuncture and ECG recording experience.
- Excellent organisation, time-management skills and attention to detail and an ability to prioritise workload.
- Demonstrated excellent verbal and written communication skills.
- Enthusiasm, willingness to learn and contribute to the research team.

- Demonstrated excellent listening, interpersonal skills, and problem-solving ability.
- A flexible, innovative team-oriented approach to service delivery
- A positive approach to change and diversity
- A patient focused approach to care
- A positive approach to ongoing self-education and skill development
- Computer skills, especially Microsoft Word and Excel and Outlook.

Desirable but not essential:

- A sound understanding of information technology including clinical systems, and applications relevant to risk management reporting.
- Clinical Trial Coordination experience
- Experience coordinating Phase I trials.
- Data entry experience.
- Blood and urine processing skills
- Competency in peripheral IV cannulation and Central Venous Access Devices

General Information

Austin Health is a Child Safe Environment

Austin Health is committed to child safety. We want children to be safe, happy, and empowered. We support and respect all children, as well as our staff and volunteers. Austin Health has zero tolerance of child abuse, and all allegations and safety concerns will be treated seriously in line with legal obligations and our policies and procedures.

Equal Opportunity Employer

We welcome applications from Aboriginal and Torres Strait Islander people. For any support throughout the recruitment process or further information about working at Austin Health, please follow this link to Aboriginal Employment on our website

Document Review Agreement

Manager Signature	
Employee Signature	
Date	