Position Description

Position Title: Clinical Research Assistant Coordinator

Classification:	Administrative Officer –Grade 3
Business unit/department:	Cancer Clinical Trials Centre
Work location:	Austin Hospital
Agreement:	Victorian Public Health Sector (Health and Allied Services, Managers and Administrative Officers) (Single Interest Employers) Enterprise Agreement 2021-2025
Employment type:	Full-Time
Hours per week:	40hrs (with ADO)
Reports to:	CCTC Manager
Direct reports:	NA
Financial management:	Budget: NA
Date:	Jun 2025

Position purpose

The Clinical Research Assistant Coordinator plays a critical role in supporting the oversight and management of the Clinical Research Assistant (CRAA) team within the Cancer Clinical Trials Centre (CCTC).

These primary responsibilities will be:

- Lead the development of CRAA competencies, including orientation, skill-building and ongoing mentorship, with the support of the CCTC leadership team.
- Supervise the CRAA team collectively, fostering a supportive and collaborative environment.
- In collaboration with CCTC Management, coordinate CRAA workloads to ensure equity, and manage coverage for absences and leave
- Advise CCTC leadership team on operational processes and workload distribution for CRAAs, providing strategic input to enhance team performance.
- Perform all CRAA duties as required, providing active support to the team on a regular basis.

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 Study 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

Role Specific:

<u>Team Support</u>

- With support from the CCTC Leadership team, assist in the development of CRAA competencies, including orientation, skill-building, and ongoing mentorship.
- Collaborate with the CCTC leadership team to deliver a structured orientation and competency program for new CRAAs.
- Work with individual CRAAs to ensure they meet role competencies and maintain performance standards.

- Provide ongoing mentorship and act as a resource for CRAAs in their day-to-day responsibilities.
- Supervise the CRAA team collectively, fostering a supportive and collaborative environment.
- Perform all CRAA duties as required, providing active support to the team.
- Promote a positive team culture that values respect, accountability, and collaboration.
- Facilitate regular team meetings and huddles to promote communication and continuous improvement.
- Respond to staff feedback and enquiries professionally and escalate issues as needed.
- Participate in the recruitment and selection of CRAA candidates, in collaboration with the CCTC leadership team.
- Support Team Leaders in developing and appraising CRAAs, including contributing to annual performance reviews.
- Identify and escalate concerns regarding individual CRAA performance and assist in developing improvement plans.
- Recognise and respond to high workload situations by providing or arranging appropriate assistance and notifying the CCTC leadership team.
- Attend meetings, trial initiation sessions (SIV), and other relevant forums as required.
- Represent the CRAA team in relevant forums, working groups, or projects as required.
- Contribute to a culture of continuous improvement by identifying opportunities for innovation and service enhancement.
- Support the integration of new systems, tools, or practices that improve CRAA effectiveness and quality.

<u>Clinical Trial Support</u>

- Assist Clinical Trial Coordinators, Team Leaders, and Principal Investigators in the day-to-day management of clinical trials in accordance with study protocols and Good Clinical Practice (ICH GCP) guidelines.
- Ensure imaging uploads to trial portals are completed in accordance with protocol requirements, both directly and be supervising compliance.
- Assist with patient follow-up data collection and survival tracking, under supervision.
- Assist in the support of patient reimbursement paperwork for travel and parking expenses.
- Assist with coordination of the retrieval and shipment of archival tumour tissue.
- Support in the retrieval and coordination of patient medical records from external sources.
- Support CRAAs in documentation handling, archiving, and monitor/auditor visit preparation.
- Assist in maintaining mandatory study team trackers with training records and essential trial record information, and support CCTC leadership in unit-wide compliance reviews.
- Respond to enquiries and requests from internal and external stakeholders in a professional and timely manner.
- Oversee and participate in specimen processing, ensuring correct identification, handling, labelling, and documentation in accordance with protocols, lab manuals, and overarching safety standards.
- Prepare, inventory, and restock biospecimen kits and trial-related supplies, and assist in the supervision of CRAAs in these tasks.
- In accordance with study-specific protocols and laboratory manuals, assist in the management of:

    - Setting up trial specimen kits
    - Processing blood and urine samples (centrifugation, aliquoting, freezing)
    - Preparing blood smear slides and managing sample storage
    - Coordinating sample shipments and maintaining shipment logs
- Maintain laboratory logs, freezer maintenance records, and ensure compliance with infection control and IATA shipping standards.
- Troubleshoot and escalate issues related to specimen integrity, transport, or documentation to ensure accuracy.
- Assist in maintaining the specimen processing area, equipment, and supplies to support efficient and safe operations.
- Collaborate with other teams and stakeholders such as Vic Biobank to ensure seamless service delivery and continuity of care.
- Monitor and respond to service demands, ensuring timely and accurate completion of CRAA tasks.

Operational Oversight

- In collaboration with CCTC Management, monitor CRAA workloads to ensure equity, and manage coverage for absences, leave and periods of increased demand.
- Oversee the CRAA unit roster to ensure responsive adequate cover across the unit, including support for time-sensitive activities such as specimen processing and courier collections.
- Recognise when CRAAs are experiencing high workload and arrange assistance or escalate to CCTC management, as needed.
- Actively participate in weekly CCTC leadership meetings to ensure two-way communication, provide updates on team performance, identify areas requiring attention or support, and offer strategic input on operational processes to enhance team coordination.
- Collaborate in the development and implementation of procedures, SOPs and guidelines that enhance efficiency, clarity, and consistency across CRAA functions and responsibilities.
- Conduct biannual inspections of the CCTC processing room with the CCTC Manager and complete required documentation.
- Be actively involved in the review of protocol deviations, RiskMan incidents and associated CAPAs (Corrective and Preventative Actions) related to CRAA activities, supporting continuous improvement and risk mitigation.
- In collaboration with CCTC Quality Lead, ensure CRAAs hold current IATA (International Air Transport Association) certification required for the shipping of biological specimens.
- Identify and escalate performance gaps, collaborating with CCTC leadership to implement appropriate support measures for individual CRAAs.

General Duties and Compliance

- Work flexibly across tumour streams and adapt to changing priorities and operational needs.
- Maintain a clean, organised, and safe work environment.
- Ensure your own and CRAA members comply with Austin Health policies and participate in training and development opportunities.
- Uphold confidentiality, workplace safety, and quality improvement standards.

- Participate in performance reviews and contribute to departmental goals.
- Perform other duties as directed to support the success of the Cancer Clinical Trials Centre.

Selection criteria

Essential skills and experience:

- Commitment to Austin Health's values—*Our actions show we care, We bring out our best, Together we achieve, We shape our future.*
- Tertiary qualification in Science, Health Care, or a related field, or equivalent relevant experience.
- Proven competency in all aspects of the CCTC Clinical Research Assistant role, with solid knowledge of ICH-GCP guidelines and key aspects of clinical trial management.
- Ability to contribute effectively within a multidisciplinary team, mentor staff, and foster a positive and productive team culture.
- Ability to lead by example, and promote a culture of professionalism, collaboration, and continuous improvement.
- Excellent organisational and problem-solving skills, with the ability to prioritise, multi-task, and resolve issues in a dynamic environment.
- Proactive approach to continuous improvement, contributing to optimal workflows and team performance.
- Advanced computer skills, particularly in Microsoft Office, and has experience with databases and electronic records systems.
- High level of accuracy in record-keeping, specimen processing, and data-entry with strong attention to detail and adherence to integrity standards for both data and specimens, as well as procedural compliance.
- Ability to work autonomously and collaboratively, showing initiative, self-motivation, and accountability. Adapts well to changing priorities and workplace dynamics, with a professional and engaged approach to responsibilities.
- Reliable, enthusiastic, and committed to supporting team operations, with an appreciation for the importance of all tasks—regardless of complexity—in contributing to the smooth and efficient functioning of the unit.

Desirable but not essential:

- Solid understanding of Oncology/Haematology diseases and/or the patient care pathway.
- Formal training or experience in mentoring or leadership roles.

Professional qualifications and registration requirements

Tertiary degree in Science, Health Care, or a related field, or equivalent relevant experience.

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.