Position Description

Ethics Submission Coordinator

Classification:	HS3
Business unit/department:	Cancer Clinical Trials Centre (CCTC)
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:	Fixed Term Full-Time or Part-Time
Hours per week:	40hrs with ADO (less by negotiation)
Reports to:	CCTC Ethics Lead
Direct reports:	Nil
Financial management:	Budget: NA
Date:	Feb26

Position purpose

The role supports the efficient start-up and ongoing conduct of cancer clinical trials by coordinating ethics and governance submissions, maintaining accurate documentation, and facilitating communication between study teams, sponsors and regulatory bodies. The coordinator ensures submissions are completed to a high standard, supports compliance with ethical and legislative requirements, and contributes to smooth trial operations across CCTC.

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:

- Coordinate cancer clinical trials ethics and governance submissions and facilitate them through the HREC/RGO process, including Lead, Participating and Single Site submissions.
- Maintain a standard of high-quality work across all levels of the ethics/governance process whilst maintaining accurate coordination of multiple lead/single site submissions at any point in time.
- To be the main point of contact, along with the study coordinator, and to liaise with all participating sites whilst assuming lead site responsibility for the life of all lead site studies, pre and post submission/approval.
- Ensure that all participating sites are sent any approved submissions (i.e. Protocol Amendments, updated PICFs (Participant Information and Consent Forms)post initial HREC approval in a timely manner for their site governance submissions.
- Create and quality check new study site files, including all internal department agreements, laboratory reference ranges and all Sponsor communication regarding the initial study submission.
- Facilitate departmental agreements and service level agreements.
- Write, review, liaise with study team and provide feedback on Participant Information and Consent Forms in conjunction with Principal Investigators and Sponsors.
- Assist the study coordinators with the submission of annual reports, protocol deviations, Breaches (Serious & Non-Serious) and Significant Safety Issues via Ethics Review Manager (ERM).

- Deal with insurance/indemnity/contract issues in liaison with Austin Health Corporate Counsel, Sponsor(s) and Austin Health Office for Research.
- Facilitate the budget and clinical trial agreement processes in conjunction with the CCTC Manager.
- Ensure Study Coordinator/Team Leader/Admin Assistant has up-to-date information for the study files/shared drive and data management system.
- Monitor and ensure all correct and up to date documentation is within department SharePoint folder and ensure the documents are saved with the correct naming convention.
- Maintain effective working relationships with other site Ethics Submissions Coordinators/Specialists (and/or equivalent at site); Study Coordinators, Sponsors, Human Research Ethics Committees, Research Governance Officer, Cancer Trials Australia, clinical trial-related authorities such as TGA (Therapeutic Goods Administration), internal and external hospital departments, the CCTC team and Principal/Sub- Investigators.
- Educate sites and Sponsors regarding the relevant and applicable ethics and regulatory requirements for all Lead and Participating sites relevant to Austin Health CCTC.
- Work to very tight deadlines and ensure timely follow ups of outstanding matters.
- Improve own processes and undertake new suggested processes, by way of external presentations, relevant workshops, and attendance at relevant seminars.
- Track all new and existing study submissions in conjunction with CCTC Manager.
- To be responsible for the coordination, timely submission and liaise with relevant site and Sponsor regarding the addition of a new participating site to an existing study.
- Ensure reporting of any serious and urgent issues to the CCTC Manager and/or Principal Investigator in a timely manner to ensure required follow-up is enforced.
- Liaise with the Austin Health Radiation Safety Officer and Medical Physicist regarding addition of studies to the Austin Health/Department of Health radiation licence in a timely manner.
- To have knowledge of and be familiar with all current local and external SOPs (Standard operating procedures), including relevant research guidelines and documents (i.e. National Statement) and to ensure all correct templates are being used as part of any submission to the HREC/RGO. This also including relevant legislation (i.e. Mental Health Act, Guardianship Act etc.).
- Participate in ad hoc project work related to clinical trials as per Manager's instructions.
- Maintain the master ethics tracker and the study specific ethics tracker.
- Update Site Docs with current information and study protocol essential documents, ensuring CCTC processes/tools for communication to study team are maintained.
- Ensure timely and effective communication of information.
- Help promote and maintain a supportive team approach within CCTC to ensure good working relationships.
- Maintain a flexible approach to managing assigned workload

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 the future.
- Understanding of cancer/biology with appropriate tertiary qualification and/or equivalent experience in an administrative/life science field.
- Understanding of various research guidelines including the National Mutual Acceptance scheme.
- An ability to work independently, meet strict deadlines and multi-task
- Ability to understand technical information and turn it into lay language.
- Proficient in the use of Microsoft Office Suite especially Word and Excel, database work as well as email and the Internet.
- Ability to develop and maintain good working relationship with internal and external parties.
- Excellent time management and organisational skills.
- Willingness and ability to take accountability.
- Experience in working to tight deadlines and multi-tasking.
- Demonstrated excellent oral and written communication skills, including punctuation, spelling, grammar and attention to detail. Including high level of efficiency whilst maintaining accuracy.
- Enthusiasm and flexibility.
- Commitment to high quality, professional service with a pleasant manner.
- Demonstrated ability to work as a constructive team member.

Desirable but not essential:

- Sound knowledge and experience in ethics and research governance submissions and procurement of approvals for clinical research projects.
- A working knowledge of ERM (Ethics Review Manager), the HREA (Human Research Ethics Application) and the SSA (Site Specific Assessment) Form, or equivalent submission platforms.

Professional qualifications and registration requirements

Understanding of cancer/biology with appropriate tertiary qualification and/or equivalent experience in an administrative/life science field.

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.