

Austin Health Position Description



Position Title: Clinical Trial Coordinator (Radiation Oncology)

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| Classification: | Dependent on skills and qualifications of successful incumbent eg. Nurses or Health Professionals Award |
| Business Unit/ Department: | Radiation Oncology Department |
| Work location: | Austin Health [x] Heidelberg Repatriation [] Royal Talbot [] Other [x] (ONJ Centre) |
| Agreement: | Allied Health Professionals (Victorian Public Health Sector) Single Interest Enterprise Agreement 2021-2026 |
| | Nurses and Midwives (Victorian Public Sector) (Single Interest Employers) Enterprise Agreement 2020-2024 |
| | Victorian Public Health Sector (Medical Scientists, Pharmacists and Psychologists) Enterprise Agreement 2021 - 2025 |
| Employment Type: | Part-Time |
| Hours per week: | 16hrs p/w for 3 years |
| Reports to: | A/Prof. Sweet Ping Ng (Director of Research, Radiation Oncology) |
| Direct Reports: | |
| Financial management: | Budget: N/A |
| Date: | 3 October 2024 |

About Austin Health

Austin Health is recognised for high-quality, person-centred care. We're renowned for our specialist work in cancer, transplantation, infectious diseases, obesity, sleep medicine, intensive care medicine, neurology, endocrinology, mental health and rehabilitation.

We're the largest Victorian provider of training for specialist physicians and surgeons, and internationally recognised as a centre of excellence in hospital-based research.

Our services are delivered to patients across four main sites in Melbourne, in locations across our community, in people's homes, and within regional hospitals across Victoria.

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](#).

Commitment to Gender Equality

Austin Health is committed to gender equality in the workplace. In developing our [Gender Equality Action Plan](#) we have been guided by the gender equality principles set out in the Gender Equality Act 2020 (Vic). We believe that everyone should live in a safe and equal society, have access to equal power, resources and opportunities and be treated with dignity, respect, and fairness.

Position Purpose

The Clinical Trial Co-ordinator will, under supervision, have responsibility for the delivery of direct and indirect care and associated data collection for research studies undertaken at BAROC, ensuring clinical and research governance in accordance with the Therapeutic Goods Administration (TGA), Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) and the National Health and Medical Research Council (NHMRC) National statement on Ethical Conduct in research involving Humans. The Clinical Trial Co-ordinator will ensure the highest standard of care is delivered to patients involved in clinical trials and, where relevant, their families, in partnership with all members of the multidisciplinary and research teams.

About [Radiation Oncology]

Austin Health operates two radiation oncology centres in Victoria; one at the Olivia Newton-John Cancer Wellness and Research Centre (ONJCWRC) in Heidelberg and the other, Ballarat Austin Radiation Oncology Centre (BAROC), in the Ballarat Regional Integrated Cancer Centre (BRICC). The multidisciplinary teams at both sites provide Radiation Oncology treatment services to patients with cancer and are committed to excellence in practice and care. Staff undertake professional development activities, are involved in research and liaise and consult with a wide range of specialists and associates to ensure the care offered is world-class. The equipment at both sites is state-of-the-art, and the treatment options available ensure every tumour site is treated according to best practice. Services at both sites offer comprehensive integration with a range of unique wellness and supportive care programs. The service is committed to expanding its technical and research capabilities through teamwork.

ONJ has a growing portfolio of investigator-initiated collaborative clinical trials, predominantly run through Trans-Tasman Radiation Oncology Group (TROG).

Purpose and Accountabilities

Role Specific:

Organisational and time management skills

- Demonstrates ability to work in a self-directed manner and be highly person /patient focused
- Prioritise and respond in a timely fashion to all research and trial related matters

- Understand and follow requirements for the conduct of clinical research of the Institutional Ethics Committee according to the Therapeutic Goods Administration (TGA), guidelines for Good Clinical Research Practice (GCRP) and the “International Conference on Harmonization” (ICH) guidelines for Good Clinical Practice (GCP E6 R2)
- Provide advice to clinical staff as to the most suitable trials, ensuring open trials will be recruited to
- Coordinates submissions of all research to the Austin Health Research Ethics Committee

Interpersonal Communication, Influence and Leadership:

- Provide expert clinical knowledge and skills in clinical trial conduct.
- Act as a leader demonstrating and modelling exemplary professional conduct.
- Work effectively with all members of the research team across ONJ and BAROC
- Develop and foster strong relationships with key stakeholders within ONJ (eg Cancer Clinical Trials Centre) and BAROC.
- Demonstrate integrity by building trust and mutual respect between self, colleagues and stakeholders.
- Actively participate in committees and meetings as required, within Austin Health and BAROC.
- Ensure information about clinical trials is available to all staff by utilising a wide range and appropriate modes of communication.

Expansion of clinical trial portfolio:

- Undertake initial assessment and feasibility studies of potential trial opportunities.
- Where appropriate, work with the Austin Radiation Oncology Research team on joint Human Research Ethics Committee and Governance submissions, and co-ordinate / oversee such requirements for ONJ Site as required.
- Develop an understanding of timelines and human resourcing commitments across radiotherapy professional groups required to support trial participation and plan accordingly for trial requirements.
- 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.
- Develop an understanding of financial considerations such as travel costs, pharmacy fees, medical imaging and other examination fees. Assist the existing CTC and RT Site Manager in managing the Research Budget.

Conduct of clinical trials:

- Comply with the requirements of the Institutional Ethics Committee regarding the conduct of clinical research according to the Therapeutic Goods Administration (TGA) guidelines for Good Clinical Research Practice (GCRP) and the “International Conference on Harmonization” (ICH) guidelines for Good Clinical Practice (GCP).
- Ensure optimal clinical management of eligible, consenting trial patients under the supervision of the Principal Investigator according to study protocol criteria.
- Coordinate and /or perform all procedures and investigations required for protocol treatment of patients involved in Clinical Trials under the supervision of the Principal Investigator.
- Assess the suitability of patients referred for clinical trials according to the protocol inclusion/exclusion criteria under supervision of the Principal Investigator.

- Report safety information according to regulatory guidelines and at a local level and escalate as appropriate under supervision of the Principal Investigator.
- Collect, process and coordinate timely review of results by Investigator of trial related biological samples.
- Follow relevant Austin Health and Grampians Health policies, processes and guidelines.
- Assist in ensuring adequate assessment, care and follow-up of patients by liaising with BAROC medical, nursing and ancillary services staff.
- Maintain a flexible approach to working hours in order to meet the requirements of the clinical trials.
- Ensure clear accountability for quality and safety within the ONJ Research program.
- Ensure investigators and other personnel involved in the clinical trials process are kept informed about progress, serious adverse events, complications and tolerance of treatments.

Data Management:

- Be responsible for co-ordinating and preparing all trial pre-requisites in a timely manner.
- Engage with ROs, RT's and Radiation Oncology Medical Physicists (ROMPs) in collating and storing all paperwork submitted, as part of trial credentialing, in a central location.
- Accurate collection, documentation and archiving of source data according to clinical trial protocol, Regulatory requirements, ICHGCP and CCT guidelines.
- Ensure patient confidentiality is maintained at all times.
- Facilitate monitoring of Case Report Forms by Clinical Research Associates and other Auditors.
- Respond to data queries as they arise
- Maintain up to date information on current clinical trials, including related paper and/or electronic databases and collation of statistics as required.

Quality, Safety and Risk Orientation:

- Provide education and act as a resource to staff, patients and their families to enhance understanding of the aims, expectations and procedures for clinical trials in which they are involved.
- Participate in and promote educational programs (eg. Seminars/Workshops) pertaining to clinical trials to further own knowledge base and keep abreast of current issues and clinical practice in clinical trials in Oncology.
- Be a key resource in the development of the National Clinical Trials Governance Framework in ONJ. Assist with the development and implementation of a project plan and ensure progress of key milestones are monitored and reported internally. This can include:
 - Ensuring there is an ongoing focus on quality improvement within clinical trials
 - Create/update clinical trial policy documents
 - Participate in developing the organisational structure to identify where and how consumers are engaged in clinical trials
- Collaborate with Research Committee members, CTCs and ONJ leadership team to ensure ONJ is prepared for TGA Good Clinical Practice (GCP) inspection program

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 by following organisational safety, quality & 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 centred care.
- Comply with requirements of National Safety & Quality Health Service Standards and other relevant regulatory requirements.
- Comply with Austin Health mandatory training and continuing professional development requirements.
- Work across multiple sites as per work requirements and/or directed by management.

People Management Roles:

- Maintain an understanding of individual responsibility for safety, quality & risk and actively contribute to organisational quality and safety initiatives
- Ensure incident management systems are applied and a response to local issues and performance improvement occurs
- Support staff under management to comply with policies, procedures and mandatory training and continuing professional development requirements

Selection Criteria

Essential Knowledge and skills:

- Relevant tertiary qualification in Nursing, Radiation Sciences, Science, Allied Health, Psychology and/or related discipline.
- Clinical Trial Coordination experience, with awareness of ICH-GCP Guidelines and relevant regulatory / statutory guidelines.
- Well-developed interpersonal and communication skills.
- A sound understanding of information technology, data entry experience and familiarity with Microsoft Office.
- Excellent organisation, time-management skills, attention to detail and autonomy.
- Excellent interpersonal skills; including verbal and written communication, problem solving, team-work.
- Enthusiasm, and a willingness to learn and contribute to the ONJ team.
- A commitment to Austin Health values: Integrity, Accountability, Respect and Excellence.

Desirable but not essential:

- Familiarity with Oncology, Radiotherapy, Trans-Tasman Radiation Oncology Group (TROG) Cancer Research and Austin Health Research processes and procedures is an advantage.

- Further education (post-graduate certification/diploma) in a relevant field.
- Relevant procedural skills: venepuncture and ECG recording, blood and urine processing.
- Where appropriate, provide research support to staff members undertaking low risk research projects

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

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| Manager Signature | |
| Employee Signature | |
| Date | |

People Management Role-Direct Reports