Eastern Health

POSITION DESCRIPTION

Position Title:	Cardiology Services Clinical Research Coordinator, Eastern Health
Award Classification:	Research Nurse YX13
Award / Agreement Name:	Nurses and Midwives (Victorian Public Health Sector) (Single Interest Employers) Enterprise Agreement 2024-2028
Position Reports to:	Operationally to Director of Cardiology Professionally to Director of Nursing Box Hill Hospital, Critical Care and Access, DDO Intensive Care Services and Cardiology

EASTERN HEALTH – HEALTHIER TOGETHER

Eastern Health is one of Melbourne's largest metropolitan public health services. We provide a comprehensive range of high quality acute, sub-acute, palliative care, mental health, drug and alcohol, residential care, community health and statewide services to people and communities that are diverse in culture, age and socio- economic status, population and healthcare needs. *'Being part of Eastern Health is being part of a welcoming team of healthcare experts*' is achieved through Eastern Health's strategic goal of HEALTHIER TOGETHER.

1. POSITION PURPOSE

Context

Eastern Health Cardiology Services provide cardiac care for Eastern Health patients at Box Hill Hospital. As a major metropolitan service, Clinical Research is an integral part of the service, and is led by the Head of Cardiology Research. The Cardiology Department undertakes a comprehensive approach to clinical services, teaching, research and the community. The department has a comprehensive cardiology program and currently undertakes research in the areas of acute coronary syndromes, heart failure, antiarrhythmics and interventional cardiology. The position will support ongoing and new clinical trials within the department as well as contribute to ongoing registry data.

Purpose

The Clinical Research Coordinator (CRC) will have responsibility for the delivery of direct and indirect care and associated data collection for concurrent research studies undertaken in the cardiology department, in accordance with the Therapeutic Goods Administration (TGA) note for Guidance on Good Clinical Practice and the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research. The CRC will deliver the highest standard of care to all patients involved in clinical trials and their families, in partnership with members of the multidisciplinary/research team. The CRC will also be responsible for coordination, supervision and assistance with all relevant reporting to research ethics and governance organisations internally and externally where relevant.

The CRC will also be responsible for ensuring relevant registries are kept up to date e.g. VCOR and CIED.

2. MAJOR DUTIES AND/OR RESPONSIBILITIES

The CRC will work within the Eastern Health Cardiology Service. The CRC will take charge of individual clinical trials, partnering with a principal investigator for each one, to ensure their effective operation as well as overseeing the conduct of other clinical trials coordinated by junior staff, as appropriate.

The CRC will oversee the day-to-day running of the research office as well as managing individual trials. The dimensions and the numbers and types of clinical trials may vary in accordance with the dynamic nature of clinical research.

2.1 Operational Responsibilities

- Coordinate and assist in preparation of health service Human Research and Ethics Committee submissions, amendments and reports in line with required timelines.
- Attain a thorough understanding of nominated clinical trial protocols.
- Coordinate and assist in set up, conduct and complete clinical trials in line with relevant guidelines, trial protocol, timelines and targets for recruitment.
- Assist with educating staff (nursing, medical and allied health) from all departments involved in the conduct of clinical studies.
- Liaise with clinical trial monitors, data managers, research contract organisations and pharmaceutical sponsors (for data query resolution, source document verification, study product records).
- Liaise with other health professionals within the hospital in the conduct of studies as required (such as ethics committee, pharmacy, laboratories, health information services, other wards).
- Coordinate and assist in screening hospital patients for eligibility for clinical studies and maintain a screening log when required by the study protocol.
- Coordinate and assist in seeking informed consent from patients and/ or their next of kin and maintain accurate and complete records of consent obtained by self and other colleagues in the cardiology service.
- Ensure accurate and timely completion of case reports and other study documentation such as patient follow-ups and laboratory investigations.

- Coordinate and assist in maintaining an accurate record of study supply orders, receipts, inspection, distribution, usage and wastage as required.
- Attend relevant educational and investigator meetings.
- Assist in generating and participating in the presentation of study progress reports and findings to the Cardiology Department staff and other health professionals locally, interstate and internationally as required.
- Organise research meetings as required.
- Be responsible for daily operational issues in regard to clinical trial protocols.
- Recognise the importance of resolving complaints effectively and in a timely manner at a local level and seek assistance as necessary. Report all complaints involving patient care to the Clinical Trial Manager and Principal Investigator.

2.2 Learning and Improving Everyday

- Promote research staff development.
- Where appropriate, participate in teaching/supervision of other clinical research staff, including registrars, pre and post registration nursing students, medical students and junior medical staff attached to the cardiology unit.
- Demonstrate a commitment to continuing professional development and participate in regular performance review/appraisal.
- Undertake additional training as required in order to acquire the knowledge and skills needed to implement new study protocols.
- Participate in ongoing education activities/in-services/forums as appropriate or as directed by Principal Investigator/manager.
- Assist/supervise training of new staff during day-to-day operations.
- Support Cardiology Advanced Trainees with their research projects.
- As a staff member of Eastern Health you are required to comply with Eastern Health performance standards and participate in continuous monitoring and improvement as part of your role. You are also required to comply with legislation, professional standards and accreditation standards.
- Maintain the appropriate skills and knowledge required to fulfil your role and responsibilities within the organisation. In addition, you must ensure that you practice within the specifications of this position description, and where applicable within the agreed scope of practice for the role, setting and specialty, being cognisant of any legislative, educational and competency requirements of extended practice

2.3 Clinical trials management

- Organise workload to ensure that the interests of clinical trial participants are met.
- Maintain effective communication with trial participants and relatives, Investigators and other members of the multidisciplinary team to ensure information is shared appropriately.
- Work in accordance with the policies, procedures and standards of the clinical trial department and Eastern Health to ensure adherence to and delivery of a high quality service.
- Coordinate all aspects of care of clinical trial participants and associated data collection in accordance with the defined clinical research protocol.
- Ensure appropriate use and dissemination of trial participants' medical records in accordance with relevant privacy principles.
- Actively recruit and manage the treatment of trial participants.
- Contribute to the development of policies and procedures related to clinical trials to ensure that clinical practice is underpinned by current best evidence.
- Ensure that studies are undertaken in accordance with the terms approved by the relevant ethics committee/s and the TGA.
- Be familiar with the relevant clinical trial protocols, including all relevant procedures and documentation to ensure the safe, accurate and timely collection and recording of trial data.

- Screen/register only appropriate patients for clinical trial participation as per clinical trial eligibility criteria. Schedule participants follow up as per protocol and where necessary, facilitate participant withdrawal from a study.
- Develop and utilise study specific documentation to ensure research data is recorded cleanly, accurately, is able to be verified and is reported in a timely manner in accordance with regulatory requirements and project timelines.
- Provide ongoing advice and information to participants including provision of project visit schedules and reminders.
- Provide and discuss information about trial participation including time commitment and procedures to be performed with potential/actual research participants.
- Participate in informed consent discussions; where possible, be present at the signing of participant information consent forms and be actively involved in the ongoing informed consent process.
- Collect, store and process biological samples as per the clinical trial protocol including centrifuging, separating plasma/serum and other processing requirements as required.
- Ensure that all participant data (including biological samples) leaving the research site are appropriately de-identified to maintain participant privacy but coded with the appropriate study specific identifiers.
- Liaise with internal and external stakeholders as required in order to meet the regulatory and scientific requirements of each study.
- Work cooperatively with pharmaceutical company representatives (Clinical Research Associates/Project managers) for the purpose of verifying and monitoring clinical trial data and to ensure the success of the clinical trial at this site.
- Work collaboratively with clinical registries staff (eg VCOR) for the purpose of verifying and monitoring registry data submissions.
- Assist with writing of ethics submissions to a high standard and acquiring ethical review and approval of new research protocol as designated by the Principal Investigator/Clinical trials manager.
- Assist with ongoing regulatory reporting to the Human Research Ethics Committee in accordance with relevant regulatory guidelines.
- Accurately report adverse events in a timely and effective manner to all relevant parties including trial sponsor and relevant ethics committee.

2.4 Communications

Internal

- Communicate and liaise with research participants, their relatives and the multidisciplinary team.
- Communicate with the Principal Investigator and/or Clinical Lead Research and/or Clinical Trial manager and/or colleagues regarding patients care, medical condition and ongoing trial participation.
- Communicate with Principal Investigator and/or Clinical Trial manager regarding workload and personal development
- Communicate with the relevant research ethics/governance committee regarding clinical trial approvals, management and monitoring.
- Communicate and liaise with relevant hospital departments as necessary, including pharmacy, IT, human resources, fire officer, infection control, education, health and safety and risk management where appropriate.

External

- Liaise with other health care providers regarding patient participation as appropriate.
- Liaise with collaborators and sponsor organizations.
- Liaise with external regulatory and research bodies as required.

3. SAFE PRACTICE AND ENVIRONMENT

Eastern Health is a child safe organisation, committed to promoting the wellbeing and cultural safety of Aboriginal children, children with disabilities and all children in their diversity. More information here.

Occupational Health and Safety

Eastern Health is committed to provide and maintain a working environment for all staff that is safe and without risk to health. All staff are to take care of their own health and safety and the health and safety of any other person who may be affected by your acts or omissions at the workplace. Understand responsibilities and accountabilities to yourself and others in accordance with OH&S legislation and Eastern Health policies and promote a working environment that is congruent with these guidelines. This includes staff reporting of all clinical and OHS incidents and near misses, in particular those related to Occupational Violence, Manual Handling and Slips, trips and falls.

Staff are required to comply with all state legislative requirements in respect to the Occupational Health and Safety Act 2004 and the Workplace Injury Rehabilitation and Compensations (WIRC) Act 2013.

Complies with NMBA Code of Professional conduct and professional standards.

4. TRAINING AND DEVELOPMENT

Relevant, practical and timely education should direct, facilitate, enhance and support the professional growth and practice of employees in a health environment characterised by change. All programs should endeavour to promote evidence-based practice, a problem solving approach and to be competency based.

You are expected to participate in the personal development process on an annual basis.

5. QUALITY

As a staff member of Eastern Health staff are required to comply with Eastern Health performance standards and participate in continuous monitoring and improvement as part of your role. You are also required to comply with legislation, professional standards and accreditation standards.

As a staff member employed by Eastern Health services you must have and maintain the appropriate skills and knowledge required to fulfil your role and responsibilities within the organisation. In addition, you must ensure that you practice within the specifications of this position description, and where applicable within the agreed scope of practice.

You are responsible for ensuring safe high quality care in your work. This will include complying with best practice standards, identifying and reporting any variance to expected standards and minimising the risk of adverse outcomes and patient harm. In addition, you will ensure that service and care is consistent with the EH approach to patient and family centered care.

6. CONFIDENTIALITY

Any information obtained in the course of employment is confidential and should not be used for any purpose other than the performance of the duties for which the person was employed. Staff are bound by the Information Privacy Act 2000 and the Health Records Act 2001.

7. EQUAL EMPLOYMENT OPPORTUNITY

You agree to adhere to the Equal Employment Opportunity policies and practices of the Health Service. Discriminatory practices, including sexual harassment, are unlawful. The Health Service will not tolerate discriminatory behaviour, and any such conduct may lead to the invoking of the Disciplinary Policy and Procedure, which may result in termination of employment.

Our commitment to Diversity, Equity & Inclusion

Eastern Health is committed to creating a diverse and inclusive environment that welcomes and values all people. We recognise that diversity is essential in ensuring Eastern Health provides the best service to its consumers.

Aboriginal and/or Torres Strait Islander peoples, people from the LGBTIQA+ community, people living with disability and those from a culturally and linguistically diverse background, are strongly encouraged to apply.

For more information, please click here.

8. PERFORMANCE DEVELOPMENT

A Performance Review, that includes agreed targets, will occur three (3) months from commencement and then annually on the basis of the duties and responsibilities outlined in this position description. This is an opportunity to review personal and the allocated work unit's service performance, facilitated by the setting of objectives/goals and ongoing evaluation of performance and achievement. Objectives will be developed annually, documented, discussed and agreed with the immediate line manager, who will act as the assessor. The incumbent is expected to demonstrate and show evidence annually of on-going self and allocated work unit's service development.

9. EASTERN HEALTH'S PROMISE

Our promise to our communities, patients, consumers and staff is that we will be **HEALTHIER TOGETHER**. Bolder than a vision for the future, our promise calls us to action. We know that working together is the only way we can achieve what is necessary for a healthier future.

Our values are ones in action and are the behaviours that matter most.

- Respect for all
- Safe always
- Partnering in care
- Learning and improving everyday

Learning from the challenges of the past and looking to the future, we understand that we are building towards a more engaged, more reliable, always safe health service in partnership with our people to improve every day.

10. ATTACHMENTS

- Attachment 1 Key Selection Criteria
- Attachment 2 EH Nursing & Midwifery Domains of Practice Professional Framework

11. NOTE

Prior to accepting any offer of employment, prospective employees will be required to undertake a National Criminal Check/ working with children or NDIS Screening check as applies to their specific role.

Statements included in this position description are intended to reflect in general the duties and responsibilities of this position and are not to be interpreted as being all-inclusive. Staff employed by Eastern Health may, by negotiation, be required to work at any campus or facility of Eastern Health.

Prior to accepting any offer of employment, prospective employees will be required to read and commit to the Eastern Health Code of Conduct, including (but not limited to) issues of Occupational Health and Safety, Equal Opportunity and Confidentiality.

Healthcare workers are strongly recommended to follow COVID vaccination recommendations provided in the Australian Immunisation handbook (based on ATAGI advice). Seasonal vaccination against influenza is a mandatory requirement of this role and employment is conditional on this being up to date prior to employment.

Signed: _____ Date: ____/____/____

Manager

INCUMBENT STATEMENT *I _____(Incumbent Name) have read, understood and accepted the above Position Description and associated Attachments.* Signed: _____ Date: ____/____/____

Aboriginal & Torres Strait Islander Candidates

Eastern Health's Aboriginal Workforce Plan 2023 – 2026 was released in February 2023. With a strong focus on cultural safety and belonging, actions included in the Workforce Plan provide practical supports for all Aboriginal and/or Torres Strait Islander staff.

An Aboriginal Employment Coordinator is available to ensure each person has culturally safe and positive employee experiences which foster belonging and access to diverse experiences and career pathways. Should you require further information regarding this position or support to complete an application, please contact the Recruitment Manager for this position or Eastern Health's Aboriginal Employment Coordinator at Aboriginal.Workforce@easternhealth.org.au

ATTACHMENT 1

KEY SELECTION CRITERIA

Position Title:	Cardiology Services Clinical Research Coordinator, Eastern Health
Award Classification:	Level 3 Research Nurse/Midwife YX13/RN37
Award / Agreement Name:	Nurses and Midwives (Victorian Public Health Sector) (Single Interest Employers) Enterprise Agreement 2024-2028
Position Reports to:	Operationally to Director of Cardiology Professionally to Director of Nursing Box Hill Hospital, Critical Care and Access, DDO Intensive Care Services and Cardiology

Essential

- Registered Nurse Division 1 (General) with current registration with Australian Health Practitioner Regulation Agency (AHPRA), leading to condition free registration in Australia.
- Minimum 5 years post registration nursing experience demonstrating appropriate clinical assessment skills and delivery of patient care.
- Post graduate qualification in coronary care nursing with at least 3 years clinical nursing experience in cardiology, experience in cardiac catheter laboratory desirable.
- Minimum 2 years' experience in clinical drug/device trials including experience in negotiating and monitoring trial budgets/finances and responsibility for maintaining Human Research Ethics and Governance requirements.
- Excellent interpersonal skills and ability to collaborate effectively with a diverse range of individuals and groups.
- Demonstrated ability to work collaboratively within a multidisciplinary team.
- Capacity to think analytically to critically review and redefine procedures and processes to generate improvements and efficiencies within research management work processes.
- Demonstrate ability to communicate effectively (both written and verbal) with all levels of staff including clinicians, other research nurses, service department personnel and external stakeholders.
- Strong planning, organisation and project management skills with clinical change management in a health care organisation.
- The ability to organise tasks, meet timelines with accurate and appropriate information and manage conflicting pressures. Ability to prioritise workload.
- Advanced computer skills including excel, database management, web-based data entry / storage, and data analytical skills including working knowledge of REDCap database, Infonetica online forms database, the National Ethics Application Form (NEAF) and the Site Specific Assessment (SSA) form.
- Demonstrate understanding of study sponsors including pharmaceutical companies.
- Experience in writing and establishing approval for, clinical research ethics submissions.
- Understanding and commitment to professional standards, codes and behaviours as legislated through the Health Act, Nursing Midwifery Board of Australia, other relevant professional bodies and Eastern Health Policy, Standards and Practice Guidelines.
- Awareness and understanding of National Standards and Accreditation Standards.
- Demonstrated knowledge of professional standards, legal and ethical requirements including but not limited to:
    - National Statement on Ethical Conduct in Human Research (2007).
    - International Guidelines for Good Clinical Practice (ICH-GCP).
    - Australian Code of Responsible Conduct of Research (2007).

- Privacy Act (1988), Information Privacy Principles and Section 95 Guidelines, Health Records Act (2001), Health Privacy Principles and Statutory Guidelines on Research (2002).

Essential Skills and Attributes

- Exhibits behaviour which reflects the Eastern Health values and NMBA Codes and Standards.
- Promotes and contributes to a supportive and engaged team environment.
- Commits to providing a safe environment for all.
- Respectful, collaborative and kind.

ATTACHMENT 2 – NURSING & MIDWIFERY DOMAINS OF PRACTICE

The **Nursing Midwifery Domains of Practice** resource has been developed by the Eastern Health Nursing Midwifery Executive using the domains of nursing as identified by Ackerman et al. (1996)(1) and the National Common Health Capability Resource (2013). Its aim is to support the individual clinician by promoting common behaviours and skills which comprise and represent the complex role of nursing and midwifery.

There are five domains of practice which are considered integral components of the role of all Eastern Health nurses and midwives; comprehensive patient care, support of systems, education, research and professional leadership. (See summary at Table 2)

Recognising that the level of skills acquisition will be dependent on nurses and midwives' specific roles and experience, the domains have been referenced to the 'novice to expert' skills acquisition model first developed by Dreyfus(2) and adapted for nursing by Benner.(3)
Behaviours are specified at five different levels, and reflect an increasing degree of autonomy, complexity, awareness and activity being performed.

Table 1: Summary of Behaviour Levels

Novice	Advanced Beginner	Competent	Proficient	Expert
Works within a known and stable context, consulting when abnormalities arise before taking action	Works within a known and stable context, consulting when abnormalities arise	Acts independently in routine situations within scope, and responds to known dilemmas	Acts independently in complex situations within scope, and responds to unknown dilemmas	Provide vision and direction and shape and implement strategies and initiatives that enable others to perform as required

Levels do not equate to roles or hierarchy within the workforce. Instead, the levels reflect what level of behavioural skill is required to achieve the desired care goals or outcomes in a given situation. Levels should be treated as cumulative, meaning that behavioural indicators at subsequent levels in the scale should be read in conjunction with the behaviours specified at any lower level.

Some levels may serve as an aspirational standard in some instances, rather than accurately reflecting behaviours of current practice. Where a gap exists between current and future practice behavioural skill requirements, there should be aspiration to meet the standard specified to enhance or effectively meet individual and community health needs.

Table 2: Domains of Practice

Domains of Practice				
Direct comprehensive care	**Support of systems**	**Education**	**Research**	**Professional leadership**
• Patient history • Patient assessment • Perform and deliver care • Monitor & Evaluate Care	• Planning for the Future • Safety and Quality • Recruitment & Retention	• Education of patients & families, relationship building • Own professional education • Professional education of others	• Knowledge of research evidence relevant to area of practice • Involvement and dissemination of research	• Professional conduct • Accountability