Northern Health

Team Leader (Cancer Services) and Senior Clinical Trials Nurse (Haematology), Northern Health. Victoria Full time or part time or job-share

An exciting opportunity exists for a Team Leader and Senior Clinical Trials Coordinator (Registered Nurse) to join our Cancer Services Clinical Trials team at Northern Health. We are seeking a full time employee, however, part time or job-share arrangements will be considered.

About our clinical trials unit

Cancer Services is a new Division at Northern Health, with a rapidly growing demand for both haematology and oncology services due to an expanding patient population and increasing workforce capabilities. Access to clinical trials for malignant haematology patients remains an important standard of care requirement and forms a critical component of Northern Health's Cancer Services growth strategy. To this end, we seek the appointment of a Team leader to manage a team of clinical trials nurses coordinating haematology and oncology trials. This full time role will also manage a small portfolio of haematology trials.

About the role

This role will be responsible for set up, review and oversight of Northern Health Cancer Services clinical trials, mentoring of junior staff within the team and for the conduct of a small trials portfolio.

Key accountablities

1. To provide expert clinical trials leadership, mentorship and support to the trials team
2. To effectively manage clinical research trials and deliver on key performance indicators and budget
3. Ensure quality data and patient safety at all times
4. Undertake and / or participate in professional development and education
5. To function as an integral member of the clinical research team
6. Provides support to Northern Health Manager, Clinical Trials

Selection criteria

1. Current registration with the Nurses Board of Victoria (AHPRHA) as a Division 1 nurse
2. Extensive clinical trials experience
3. Experience in managing commercially sponsored trials
4. Extensive medical oncology and haematology experience
5. Post graduate qualifications in Cancer nursing
6. Proven working knowledge of ICH GCP, current NH&MRC clinical trials policies and international regulatory and research governance requirements (FDA and EMA regulations and trial directives)
7. Demonstrated interest in leading, managing and mentoring clinical trials staff

For further information, please contact:

Maria Tucker, *Divisional Director, Nursing, Cancer Services*

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POSITION DESCRIPTION		
POSITION TITLE:	Team Leader and Senior Clinical Trials Research Nurse, Cancer Services	
DATE OF EFFECT:	November 2019	
TYPE OF EMPLOYMENT:	Full time	
REPORTING TO:	Divisional Director, Nursing, Cancer Services and Northern Health Clinical Trials Manager	
Enterprise Agreement	Nurses and Midwives (Victorian Public Sector) (Single Interest Employers) Enterprise Agreement 2016-2020	
Classification	YX13 – YX14 (dependent on experience)	
GENERAL RESPONSIBILITY STATEMENT	This role will be responsible for the for set up and oversight of Cancer Services clinical trials, mentoring of junior staff within their team and conduct of a portfolio of Clinical Trials within in the Haematology & Medical Oncology services if required. A high level of clinical trial oversite is expected including all elements pertaining to ethic applications, local governance application, budget negotiation and subsequent clinical trial completion including collection and maintaining of regulatory documents, data collection, and financial tracking of study specific milestones.	
LIAISES WITH:	Internal	• Research participants & their caregivers. • Multidisciplinary team members. • Clinical Trials Unit Staff. • All Northern Health Clinical Research staff. • Clinical nurses in all relevant patient care areas – including specialist clinics, ward nurses, diagnostic imaging nurses Principal Investigators, Co-investigators and associated clinical trials medical staff. • Departments implicated in clinical research external to the trials unit (pathology, diagnostic imaging, nuclear medicine, pharmacy). • Health information services department. • Internal human research ethics committee (HREC).
	External	• Clinical Trial Sponsor representatives from pharmaceutical companies and collaborative groups. • Cancer Trials Australia. • Research nurses and data managers at other hospitals. • External laboratories and diagnostic imaging centres. • Professional bodies such as VCOG & COSA & ARCS.

ORGANISATION INFORMATION

Introduction

Northern Health provides a diverse range of acute, sub-acute and community health services to the large and diverse population in the regions north of Melbourne. There are five campuses; Broadmeadows Health Service, Bundoora Extended Care Centre, The Northern Hospital at Epping and Craigieburn Health Service.

Strategic Plan 2016-2019

The Strategic Plan for Northern Health includes the following elements:

Our vision

Outstanding healthcare for our communities

We deliver the best healthcare through active engagement with our community.

Our care is responsive, localised and consistent because we use the resources we have effectively, and we build partnerships with the broader health sector to connect with services that complement ours.

We put back into the community, from being a major provider of jobs, to supporting the people of the north in their personal health journey. We are a model for health care organisations that aspire to work closely with their community to deliver outstanding care.

Our mission

At Northern Health, we are committed to the wellbeing of the people of Melbourne's north.

We draw upon the richness, knowledge and strength of northern communities as we partner with them in their care.

We also understand that we are an important part of a larger health system. We are therefore experts at connecting our communities to the services they need within a larger system.

We are technical experts in our fields and take the big picture view of the social, cultural and personal influences on the health of the people we care for. We know that in partnership with us, patients and their families are better able to manage their health.

At Northern Health, we help our patients move smoothly through the health care system. We do this by improving systems and processes to minimise wasted time, effort and resources.

We ensure that everyone feels welcomed and cared for in every interaction that we have.

We foster a culture of respect and understanding by ensuring that employment, services and activities are inclusive of and responsive to the diversity of our staff, patients and communities

Our commitment:

We are committed to providing our patients and their families with outstanding health care. This care will be characterised by our actions – at all times we aspire to be:

Passionate – we care.

We love what we do and we inspire others with our energy. We take pride in our work, knowing that it contributes to the better health of our community.

We demonstrate our respect and consideration for the members of our community and as a result they feel cared for and supported.

Dedicated – we are focused.

We understand our individual role and how it contributes to the health of our community. This clarity gives us the determination and confidence to do our best work. We have the commitment and faith to achieve our vision. This focus maintains our motivation and belief in what we do.

Progressive – we look to improve.

We strive to find better ways of working, of teaching, of leading in research. We understand our environment and we are flexible to change that moves us towards our vision. We are responsive. We ensure that all improvements support the health of our community.

Collaborative – we are a team.

We work together to achieve our vision. We are effective because we support, appreciate and believe in each other. We know how to ask for help and offer assistance. We listen to and empower our community to attain the best in health through our collective decision-making, because we are all part of the team.

Partnership – we collaborate.

We build partnerships to underpin and support our endeavours, including both local and metropolitan health services, community health services, local government agencies and non-government bodies. We utilise a collaborative approach to planning and delivering care to provide a more effective, efficient and sustainable way to achieve improved health for Melbourne's northern community.

NOTE: Northern Health policy prohibits smoking on all sites, including outdoor areas.

1. ROLE STATEMENT

This role will be responsible for the for set up and oversight of Cancer Services clinical trials, mentoring of junior staff within their team and conduct of a portfolio of Clinical Trials within in the Haematology & Medical Oncology services if required.

A high level of clinical trial oversite is expected including all elements pertaining to ethic applications, local governance application, budget negotiation and subsequent clinical trial completion including collection and maintaining of regulatory documents, data collection, and financial tracking of study specific milestones.

This person will lead the expansion of clinical research within the Cancer Services Division, including managing research operational activities, special purpose funds, clinical trial budget development and management, ethics and governance applications and clinical trial coordination.

This role will coordinate a small portfolio of clinical trials.

2. KEY RESULT AREAS and MAJOR RESPONSIBILITIES

Key Accountabilities	Demonstrated by / Key Performance Indicators
1. To provide expert clinic trials related patient care	• Evaluate clinical trials for clinical risk and logistic implications and provide appropriate solutions • Ensure a full nursing assessment is performed on all clinical trial patients at screening and repeated as necessary throughout the trial • Provide Day Oncology and ward staff with education, training and guidance to safely meet the trial related clinical needs of the patients on trial • Able to make appropriate clinical and professional autonomous decisions as required & seek clarification where necessary. • Provide clinical nursing advice relating to the conduct of the trial to the Investigators & multidisciplinary team taking into account the risk profile of the trial and the clinical status of the patient • Advocate for the patient at all times • Provide clinical advice concerning the management of investigational drug side effects
2. To effectively manage clinical research trials	• Ensure the conduct of clinical research trials is in accordance with TGA ICH GCP and the NHMRC National Statement on Ethical Conduct in Research Involving Humans. • Effectively manage a portfolio of clinical trials if required. • Practice at all times within current appropriate state and federal regulations and hospital policy. • Able to make appropriate trial related and professional autonomous decisions as required & seek clarification where necessary. • Provide clinical & professional advice relating to the conduct of clinical research to the Investigators & multidisciplinary team that is in accordance with TGA ICH GCP and the NHMRC National. • Statement on Ethical Conduct in Research Involving Humans, unit operating procedures & hospital policy. • Maintain a flexible approach to working hours in order to meet the requirements of research protocols and subject recruitment. • Liaise with all involved groups/departments to ensure all biological samples are collected, processed, stored and shipped as per the clinical trial protocol requirements. • Participate in clinical trial monitoring/auditing internally and externally as required in order to meet the regulatory and scientific requirements. • Work effectively with pharmaceutical company representatives (CRAs) during monitoring of clinical trial data, internal company audits and external reviews.

3. Ensure quality data and patient safety at all times	• Demonstrated ability to manage workload to ensure interests of patients on clinical trials are met and protocol requirements are followed. • Maintains effective communication processes with patients and carers, investigators, and other members of the multidisciplinary team to ensure information is appropriately shared. • Work within and monitor standards of care in the defined clinical trial protocols, SOPs and practice guidelines of the clinical trials unit, hospital policies & procedures to ensure adherence to and delivery of, a high quality service. • Contribute to the development of policies and procedures within the clinical trial unit & organisation to ensure that clinical research practice is underpinned by current best practice. • Ensure that studies are undertaken in accordance with the terms approved by the institutional ethics committee and TGA. ICH GCP and the NHMRC National Statement on Ethical Conduct in Research Involving Humans. • Demonstrates thorough practice, knowledge of ICH GCP and the NHMRC National Statement on Ethical Conduct in Research Involving Humans. • Demonstrates knowledge of each designated clinical trial protocol including procedures and documentation to ensure the safe and accurate conduct and recording of the study. • Uses practice guidelines and study specific documentation to ensure that data is recorded accurately and in accordance with regulatory requirements. • Able to screen/register only appropriate patients for clinical trials as per clinical trial eligibility criteria. Follow patients as per protocol and, where necessary, facilitate participant withdrawal from a study in order to ensure the patients best care and the effective achievement of the study aims. • Ensures informed consent is obtained according to standard hospital practice, ICH GCP and the NHMRC National Statement on Ethical Conduct in Research Involving Humans and be actively involved in the ongoing informed consent process.
4. To undertake and participate in professional development and education	• Provide mentoring for junior clinical trial staff • Participate regularly in the teaching of nursing & medical staff and other members of the multidisciplinary team in regard to clinical research and associated guidelines & regulations. • Demonstrates a commitment to personal continuing professional development and participate in performance review/appraisal. • Undertakes additional training in order to acquire the knowledge and skills needed to implement new study protocols from a variety of clinical specialties and share the acquired knowledge with junior staff. • In conjunction with their manager, identify professional development goals and work towards meeting these within agreed timeframes. • Maintain up-to-date clinical skills and knowledge delivering care to allocated study clinical trial patients. • Maintain mandatory training requirements as defined by hospital and nursing policy.
5. To function as an integral member of the clinical research team	• Develops & participates in appropriate quality activities. • Conducts and chairs regular team meetings. • Takes on additional responsibilities in the team, as agreed with the Northern Health Clinical Trials Manager • Takes responsibility for ensuring trial patients are seen in primary Research nurse's absence and that protocol requirements are carried out according to protocol and without incident.
6. Provides support to the Northern Health Manager Clinical Trials	• Takes on additional functions within the team as discussed and decided with the Northern Health Manager, Clinical Trials • In the absence of the team leader, provides support and supervision to the team members on a daily basis • Can act as 2iC in the prolonged absence of the Northern Health Manager, Clinical Trials • Assists with the start-up processes of new protocols to ensure efficient and problem free commencement. • Assists with the mentoring of new staff to the team and provides feedback with the team leader to assist their competency development

3. SELECTION CRITERIA

Essential Requirements	• Current registration with the Nurses Board of Victoria (AHPRA) as a Division 1 nurse • Extensive clinical trials experience • Experience in the management of Commercially Sponsored trials • Extensive experience in Medical oncology and/or Haematology • Post graduate qualification in Medical Oncology, Haematology and/ or Clinical trials Research or post graduate qualifications in another nursing field in combination with Medical oncology and / haematology clinical experience. • Proven working knowledge of ICH GCP, the current NH&MRC Clinical trial policies and an understanding of the international regulatory and research governance requirements (eg FDA and EMA regulations and trial directives) • Personal integrity and discretion. • Demonstrated excellent team working skills with ability to work using own initiative. • Effective listening and interpersonal skills. • Time management skills and the ability to prioritize a clinical trial portfolio. • Demonstrated interest in mentoring junior staff
Desirable Requirements	• Experience in Early Phase trials • Comprehensive IT skills. • Post graduate qualifications in Health Service Management or working towards the same

INCUMBENT STATEMENT

I _____ have read, understand and accept the above Position Description.

(Please print name)

Signature: _____ Date: __ __ __ __ __ __ __ __