MILDURA BASE PUBLIC HOSPITAL

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ABN: 73 543 496 421
P: (03) 5022 3333 **F:** (03) 5022 3228
A: Ontario Avenue, Mildura VIC 3500

POSITION DESCRIPTION

Position:	Clinical Trials Research Nurse
Directorate:	Medical Services
Division:	Clinical Trials
Business Unit:	Clinical Trials Research Unit
Enterprise Agreement:	Nurses and Midwives (Victorian Public Health Sector) (Single Interest Employers) Enterprise Agreement
Reports to:	Clinical Trials Research Unit Manager / Oncology Nurse Unit Manager

MILDURA BASE PUBLIC HOSPITAL

Mildura Base Public Hospital (MBPH) was established as a new entity in September 2020. From day one, MBPH has aspired to provide exceptional patient care and be a leading healthcare provider in the north west of Victoria, known for its high level of professionalism, quality care and community engagement and positive and aligned workplace culture.
MBPH employs over 1200 staff and has 172 beds and provides a range of acute services in emergency, maternity, intensive care, rehabilitation, community services, psychiatric in and out patient care, palliative care, renal dialysis and chemotherapy service to the people of North West Victoria. The hospital also provides medical imaging and pathology services.

VISION

Mildura Base Public Hospital – providing exceptional care.

PURPOSE

To improve health outcomes for our tri-state communities by creating partnerships, leading culture and building our team to deliver sustainable services.

VALUES

All employees of the Mildura Base Public Hospital are required to uphold the HEART values of our organisation. For information on our **HEART** values and the expectations to uphold the values, please refer to **page 7** of this document.

INCLUSION

At MBPH, we firmly believe that fostering diversity, equity, and inclusion is essential to the success of our health service, our employees, our patients, and the wider community. We wholeheartedly embrace diversity and highly value the diverse experiences of individuals from all ethnicities, faiths, ages, disabilities, cultures, languages, gender identities, sexes, and sexual orientations.

We extend a warm welcome to lesbian, gay, bisexual, transgender, gender diverse and non-binary, intersex, and queer (LGBTIQ+) individuals, inviting them to be a part of our inclusive health service.

Aligned with our HEART Values, we are dedicated to further enhancing accessibility and promoting inclusive practices across all aspects of our workplace.

STRATEGIC OBJECTIVES

CLINICAL TRIALS AND RESEARCH

Mildura Base Public Hospital Clinical Trials & Research (MBPH CT&R) is a newly established unit in 2023, to allow for improved access to clinical trials for patients located in the Northern Mallee region. Located adjacent to the Mildura Base Public Hospital, initially the MBPH CT&R will be undertaking cancer clinical trials, with a view to adding clinical trials in other specialities in the coming years.

POSITION SUMMARY

The Clinical Trials Research Nurse is a critical role in Clinical Trials and Research Unit (CTRU) assisting with conducting clinical research activities.

The role will be responsible for delivering both direct and indirect clinical trial-related care to patients, managing associated data collection, and coordinating concurrent clinical trials. This position will have dual reporting lines: operationally to the Clinical Trials Research Unit Manager and professionally to the Oncology Nurse Unit Manager. The role will also liaise closely with Principal Investigators, Clinical Trials Research Nurses, Clinical Trials Pharmacists, Specialist Clinic staff, and Oncology Day Unit staff.
Where applicable, the Clinical Trials Research Nurse will ensure all clinical trials research projects are performed in accordance with the study protocol and in line with regulatory, ethical and legal requirements as defined by:

- Good Clinical Practice (ICH-GCP);
- Therapeutic Goods Administration (TGA);
- Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95);
- NHMRC Statement on Ethical Conduct in Human Research;
- Applicable state/federal privacy laws; and
- Clinical Trials Standard Operating Procedures and Working Instructions.

KEY RESPONSIBILITIES AND DUTIES

Professional

- Practice at all times at a level of competence/experience within current appropriate nursing regulations to ensure that each participant's nursing needs are met.

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- Develop the role by using evidence-based practice and continuously improving knowledge following training and education guidelines.
- Ensure adherence to unit specific and MBPH policies and procedures ensuring safe working practices are maintained for both participants and staff involved in clinical trials research projects.
- Ensure participants are consented to clinical trials according to the principles of ICH GCP, unit specific and MBPH policies.
- Conduct clinical trials in accordance with TGA, ICH GCP and the NHMRC National Statement on Ethical Conduct in Human Research and relevant state/federal privacy laws.
- Make clinical and professional decisions related to clinical trials research projects protocols, whilst also recognising the importance of escalating clinical issues to the Principal Investigator(s) when required.
- Provide clinical and professional advice relating to the conduct of clinical research trials projects to the multidisciplinary team.
- Analyse and assess each participant's condition to establish the continuing care plan, appropriate action and future participation in a clinical trial in consultation with the treating doctor and/or the Principal Investigator.
- Report serious adverse events and adverse events according the TGA ICH GCP guidelines and the trial protocol to ensure patient safety.
- Act as a participant advocate at all times.
- Maintain a flexible approach to working hours in order to meet the requirements of the clinical trials research projects protocols and participant recruitment.
- Demonstrate a commitment to continuing professional development and participate in performance review/appraisal.
- Undertake additional training where required in order to acquire the knowledge and skills needed to implement new study protocols.
- Propose and develop working practices and innovative processes within the clinical trial and research unit and assist in their implementation.
- Attend feasibility meetings, unit meetings, investigator and site initiation visits as directed by the MBPH Director of Research.

Clinical Research Practice and Management

- Organise own workload to ensure that the interests of the participants on the clinical trials research projects are met.
- Maintain effective communication processes with participants and relatives, investigators, and other members of the multidisciplinary team to ensure information is appropriately shared.
- Work within and monitor standard of care in the defined clinical trial protocols and the policies, procedures and standards of the clinical trials & research unit to ensure adherence to, and delivery of, a high-quality service.
- Gain knowledge of each clinical trials research project protocol including procedures and documentation to ensure the safe and accurate conduct and recording of the clinical trials research project.
- Contribute to the development of policies and procedures within the unit and/or clinical trial network conducting clinical trials as directed by the MBPH Director of Research to ensure that clinical research practice is underpinned by current best evidence.
- Screen/register appropriate participants for clinical trial participation as per clinical trial inclusion/exclusion criteria, and if eligible consent according to the principles of ICH GCP and specific unit policies.
- Follow participants as per protocol and, where necessary, facilitate participant withdrawal from a study in order to ensure the participant's best care and the effective achievement of the study aims.
- Provide ongoing advice and information to participants and be actively involved in the ongoing informed consent process.

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- Liaise with all involved groups/departments to ensure all biological samples are collected, stored and processed as per the clinical trial protocol requirements.
- Ensure schedules of events activities are completed as per the trial protocol, minimising deviations at all times.
- Perform schedule of events activities including dosing, blood draws, ECG's, vital signs as per trial protocol.
- In the absence of senior unit staff, assume responsibility for daily operational issues in regard to clinical trials research protocols.
- Recognise the importance of resolving complaints in a timely manner and effectively at local level and seek assistance as necessary. All complaints involving patient care to be reported to the MBPH Director of Research in the first instance.
- Participate in clinical trial monitoring/auditing internally and externally as required in order to meet the regulatory and scientific requirements of each study. Work and cooperate with pharmaceutical company representatives (CRAs) when they come to monitor ongoing clinical data, internal company audits and external reviews.
- In collaboration with the MBPH Director of Research, develop and utilise study specific documentation to ensure that data is recorded accurately and in accordance with regulatory requirements.

Communication

- Communicate with the Principal Investigator regarding the participants condition and ongoing clinical trials research participation.
- Ensure effective communication processes with patients, relatives and investigators and CT&R staff to ensure information is appropriately shared for accurate and appropriate implementation of the clinical trials research project protocol.
- Communicate with MBPH Director of Research regarding workload issues and personal development.
- Communicate with other relevant contract providers regarding clinical trials research studies and requirements.
- Report adverse events/serious adverse events in a timely effective manner according to the protocol to the approving ethics committee and TGA ICH GCP guidelines.
- Participate in team meetings, relevant hospital meetings, external professional meetings/conferences related to clinical trials research projects as appropriate or requested by the MBPH Director of Research.
- Liaise with other clinical trial centres and multidisciplinary research teams where required.
- Liaise with collaborators and sponsor organisations.
- Liaise with external regulatory and statutory research bodies as required.

Data Management

This role is required to use and maintain all forms of data collection systems used for clinical trials research projects including both paper and electronic. Both to be used in compliance with state and national data protection and privacy legislation.

- Ensure the data systems used within the unit and MBPH for clinical trials are up to date with patient information and activities to ensure accurate tracking of recruitment and study data.
- Ensure all clinical trial data is entered within 5 working days. When applicable the unit administration staff can assist with this if required.
- Ensure all patient screening/visit clinical observations are entered into the unit electronic medical record, the patient physical medical record and any relevant database at the time of visit for access by the Principal Investigator/Oncologist at the patient appointment time.
- Assist with ensuring that all delegation logs and site files are up to date with clinical information.

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GENERAL RESPONSIBILITIES

Employees are required to comply with the **Victorian Government's Code of Conduct**. All staff must ensure they comply with **policies, procedures** and standard ways of work practices when carrying out their work.

Employees are responsible to take reasonable care of their own **health and safety** and the safety of others, to cooperate with the group's OH&S policies and to participate in appropriate safety education and evaluation activities. All staff are expected to participate in reporting any health, safety and wellbeing issues. All staff must adhere to the policies and procedures as set out in the hospital's **infection control** manuals.

All information concerning Mildura Base Public Hospital, its patients, clients, residents and staff should remain strictly **confidential**. Any unauthorised disclosure of such information may result in disciplinary action. As a Mildura Base Public Hospital employee, you have a responsibility to participate in and commit to ongoing **quality improvement** activities using the framework of the NSQHSS (National Safety and Quality Health Service Standards).

Any breach in compliance to any of the above general responsibilities may result in disciplinary action.

KEY SELECTION CRITERIA

Essential

- Current registration as a Registered Nurse with the Australian Health Practitioner Regulation Agency (AHPRA) with a minimum of 3 years post graduate nursing, demonstrating appropriate competencies and skills for the job and clinical setting
- Venepuncture and collection of trial specimens from participants
- 12-lead ECG
- Highly developed interpersonal and communication skills
- Highly developed planning and organisational skills, experience setting priorities, implementing improvements and meeting deadlines whilst working under pressure
- Demonstrated ability to work as an effective team member as well as the ability to exercise high levels of independence, judgement and initiative
- A demonstrated understanding of confidentiality, privacy and information handling principles
- A demonstrated ability to work with sensitive information and maintain discretion at all times
- Demonstrated stakeholder relationship skills including the ability to interact with and gain cooperation from internal and external stakeholders

Desirable:

- Experience in Oncology nursing
- Experience working in clinical trials in Australia
- Demonstrated knowledge of professional standards and knowledge of legal and ethical requirements in clinical trials including Good Clinical Practice (GCP)
- Research experience including working knowledge of Australian and International statutory and regulatory requirements including TGA and FDA

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MANDATORY REQUIREMENTS

Registration with Professional Association:

For example, AHPRA, AHRI, etc. The work to be performed is set out in this position description and, where relevant, any professional standards and codes of conduct and ethics issued by the relevant professional association.

National Police Record Check

A current and satisfactory National Police Record Check must be presented to the Division of People and Culture by all new staff prior to commencement at Mildura Base Public Hospital.

Working with Children Check:

Mildura Base Public Hospital has a responsibility to provide a child safe environment. This position is a defined "child-related role" at Mildura Base Public Hospital. As such you must maintain a valid working with children check. In addition, you will be required to assist Mildura Base Public Hospital in providing a child safe environment by participating in any training or reporting required to ensure the protection of children in our care.

Immunisation Requirements

As part of your employment conditions, you will be asked to provide documented evidence of healthcare worker immunisation or immunity to communicable vaccine-preventable diseases prior to commencing employment with MBPH. If you do not provide satisfactory evidence that you have the required immunisation and you have commenced employment, consideration will be given to your ongoing employment and termination may result.

Drivers Licence

A current Victorian driver's licence is required for this position

All Mildura Base Public Hospital sites, workplaces and vehicles are smoke free.

This position description is intended to describe the general nature and level of work that is to be performed by the person appointed to the role. It is not intended to be an exhaustive list of all responsibilities, duties and skills required. Any elements of this document may be changed at Mildura Base Public Hospital's discretion and activities may be added, removed or amended at any time.

ACKNOWLEDGEMENT BY EMPLOYEE

I acknowledge having received and read the content of this position description (including but not limited to aspects of the role contained within) and understand the requirements of the position.

Employee Name: _____

Employee Signature: _____

Date: _____

MILDURA BASE PUBLIC HOSPITAL — OUR VALUES AND BEHAVIOURS

Happy
WE ARE POSITIVE

As an organisation
We aspire to be happy in all our dealings with people. Everyday we strive to be the best version of ourselves, and we seek to continuously improve our organisation, ourselves and each other through personal and professional growth. We believe that happy people do their best work. We know that joy in our journey is invaluable to a sustainable and lasting success.

Individually
- Use positive language in interactions with staff, patients and community
- Honour the work we do and choose candour, respect and kindness everyday
- Focus on the positive aspects of a situation, what is going well and what can be learned
- Share in moments of joy
- Welcome others to MBPH
- Bring an energy to work that is infectious to others
- Provide growth opportunities and effective feedback to staff to ensure they are supported to achieve their best

Empathetic
WE ARE CARING

As an organisation
We put our patients first, and we listen and deal with their needs. We are compassionate people who make MBPH a place for healing, growth and success for patients, their families and our staff.

Individually
- Make time to actively listen and understand one another
- Walk in others' shoes
- Consider an individual person's needs when making decisions and recommendations
- Treat others how I would like to be treated
- Recognise and support one another
- Make decisions based on patient's needs and in consultation with others involved in care

Accountable
WE ARE COMMITTED

As an organisation
We take ownership of the actions and decisions made. We do the right thing in all our interactions. We reward based on great outcomes, and we are transparent in both our successes and failures. We use good judgement and everyday we make our patients' journey better.

Individually
- Be courageous in challenging the process to get a better result
- Ensure the project is clear on roles, responsibilities and timeframes
- Be engaged throughout
- Keep a 'whole of life' picture
- Comply with Code of Conduct; company policies and procedures; industry standards and legislation
- Be responsible for monitoring the right way to do things.

Respectful
WE ARE OPEN TO OTHERS

As an organisation
We build effective relationships and emphasise the importance of diversity and inclusion in our workplace. We recognise and value the views and the experiences our staff and patients bring to our organisation.

Individually
- Show pride in our roles and our workplace
- Recognise and understanding the influence of a person's situation, background and beliefs and how they can be shown due respect
- Include all backgrounds – gender/ age/sex/abilities/race/religion/sexual orientation/culture
- Be aware of assumptions and biases when making decisions
- Take care of and sustain our workplace, equipment and environment
- Embrace awareness for other perspectives and experiences

Team-based
WE ARE ONE TEAM

As an organisation
We do our best work when we collaborate within and across teams. Everyday we strive to be our best selves. We know that individual differences can strengthen teams and we trust and respect each others' contribution. We make sure we have the right people in the right jobs with the right tools, resources and equipment. And we know, no single person is bigger than the team.

Individually
- Acknowledge contributions of team members
- Seek to understand the bigger picture, collaborate with others openly and honestly
- Lend a hand, always
- Encourage connections with relevant internal and external stakeholders to meet patients' needs
- Collaborate and share knowledge within and across teams
- Connect with exceptional industry leaders to build capabilities
- Recognise and foster talents in others

LANGUAGE WE USE
- "I choose..."
- "I care..."
- "I prefer..."
- "I will..."
- "I can..."
- "Is there a better way to do this?"
- "Can we explore that more so I can understand it better?"
- "We will...us...we can...."

LANGUAGE WE DON'T USE
- "I have to..."
- "I must ..."
- "If only..."
- "Ah well, that is because of XYZ.."
- "Our processes do not let us do it"
- "Things have always been done this way"
- "Them and us"

THINGS WE DON'T DO
- Negativity, sledging, rumours or gossip
- Unprofessional, inconsistent or showing lack pride in our work
- See only problems, block progress
- Wait for others to do the work
- Do nothing
- Find fault, see obstacles
- Victim mentality
- Lack of understanding for others' needs
- Emphasis on status, hierarchy, egos
- Ignore, disregard and show lack of appreciation for a person's situation, background and experience when making decisions and reacting to situations
- We will not waste others' time or keep people waiting
- Dismiss the efforts of others to achieve an outcome