DEPARTMENT OF HEALTH

Statement of Duties

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| **Position Title:** | Registered Nurse - Clinical Trials |
| **Position Number:** | 513786 |
| **Classification:** | Registered Nurse Grade 3- Grade 4 |
| **Award/Agreement:** | Nurses and Midwives (Tasmanian State Service) Award |
| **Group/Section:** | Hospitals South – Sub Acute and Aged Care Services |
| **Position Type:** | Fixed-Term, Full Time/Part Time |
| **Location:** | South |
| **Reports to:** | Nurse Unit Manager |
| **Effective Date:** | May 2022 |
| **Check Type:** | Annulled |
| **Check Frequency:** | Pre-employment |
| **Essential Requirements:** | Registered with the Nursing and Midwifery Board of Australia as a Registered Nurse  *\*Registration/licences that are essential requirements of this role must remain current and valid at all times whilst employed in this role and the status of these may be checked at any time during employment. It is the employee’s responsibility to ensure that registration/licences remain current and to advise the Employer if their circumstances change. This includes notifying the Employer if a registration/licence is revoked, cancelled or has its conditions altered.* |
| **Desirable Requirements:** | Relevant postgraduate/tertiary clinical qualifications |

NB. The above details in relation to Location, Position Type and Work Pattern may differ when this position is advertised – please refer to these details within the actual advert. The remainder of the content of this Statement of Duties applies to all advertised positions.

### Primary Purpose:

Functions as a clinical resource and liaison person for medical investigators, national and international trial centres, drug regulatory authorities and other stakeholders in relation to clinical trials

Takes responsibility for a clinical trial portfolio coordinating trial participants and provides clinical case management support to the CNC and NUM Cancer Services and Medical Oncologists and Haematologists.

### Duties:

1. In accordance with defined clinical trial protocols, regulatory procedures and in conjunction with the Principal Investigator, identify potential trial participants and assess their suitability for the clinical trial.
2. Share responsibility with medical investigator and other colleagues, for the application and adherence of clinical trial protocols, collection, and maintenance of source data, file maintenance and the collection of information from patients receiving investigational treatments within the defined protocol guidelines.
3. Manage multiple aspects of the trials (investigator lead and clinical) within the defined protocol guidelines.
4. Ensure the scientific integrity of data and protect the rights, safety, and wellbeing of the patient’s involved clinical trials.
5. Using established nursing procedures take physiological measurements, and perform or coordinate clinical procedures as required, using clinical judgment to assess patients and inform the treating team of any concerns that may jeopardise their participation in the trial.
6. Maintain a record of specific trial related reimbursable costs and submit to Finance Officer for invoicing.
7. Collecting and processing blood samples in accordance with the schedule of assessments in a clinical trial and storing/shipping them in a timely manner.
8. Coordinate and liaise with medical, nursing, clerical, and other staff to ensure optimal clinical management of the clinical trial patient. Coordinate patient appointments for treatment, reviews and required medical imaging in accordance with clinical trial schedule.
9. Provide advice and education to other clinical staff throughout the organisation, regarding clinical trials and their requirements.
10. Using established procedures prepare applications for submission to State-wide Human Research Ethics committees or submission to the lead site under the National Mutual Acceptance (NMA), clinical trial amendments, and annual progress reports on current clinical trials as required.
11. Report safety information according to regulatory guidelines at a local level, sponsor level and escalate as appropriate under the supervision of the Principal Investigator.
12. Identifying any deviation in care protocol and ensuring appropriate immediate action and reporting
13. Accurately complete trial case record forms (CRFs), resolving data queries and maintaining trial documentation for regular monitoring visits by Clinical Research Associates (CRAs) from pharmaceutical companies or others as required, and liaise with other members of the research team to set timelines and resolve problems in meeting deadlines.
14. Develop, implement, and evaluate teaching plans for patients/clients that meet their learning needs and facilitate informed decision making.
15. Work effectively within a multidisciplinary team, contributing to a strong team approach by actively contributing to communication processes, including attending and participating in a variety team meeting.
16. Leading and conducting new trial training through organising site initiation visits in conjunction with external and internal stakeholders to ensure relevant staff are onboard with upcoming new trials
17. Contribute to the review and development of organisational documentation, procedures, policies, and best practice related to patient/client care. Evaluate the effectiveness of processes and procedures.
18. Maintain knowledge of innovations in clinical practice and research and participate and contribute to a learning environment, through continuing education, professional development and attendance at conferences and relevant fora.
19. Support the development of others through participation in orientation and preceptoring nurses and other members of the health team.
20. Actively participate in and contribute to the organisation’s Quality & Safety and Work Health & Safety processes, including in the development and implementation of safety systems, improvement initiatives, safeguarding practices for vulnerable people, and related training.
21. The incumbent can expect to be allocated duties, not specifically mentioned in this document, that are within the capacity, qualifications and experience normally expected from persons occupying positions at this classification level.

### Key Accountabilities and Responsibilities:

* Responsible to and receives guidance and support from the CNC and NUM Cancer Services for the efficient and effective management of all delegated activities.
* Responsible for own practice within professional guidelines and for the intervention in instance of unsafe, illegal or professional conduct.
* Receives guidance from the Medical Oncologist and Haematologists regarding events impacting on patient care.
* Practice in accordance with Nursing and Midwifery Board of Australia as a Registered Nurse.
* Comply with the requirements of the Tasmanian Ethics Committee regarding the conduct of clinical research according to the Therapeutic Goods Administration (TGA) guidelines for Good Clinical Research Practice and the “International Conference on Harmonisation” (ICH guidelines for Good Clinical Practice (GCP).
* Champion a child safe culture that upholds the *National Principles for Child Safe Organisations*. The Department is committed to the safety, wellbeing, and empowerment of all children and young people, and expect all employees to actively participate in and contribute to our rights-based approach to care, including meeting all mandatory reporting obligations.
* Where applicable, exercise delegations in accordance with a range of Acts, Regulations, Awards, administrative authorities and functional arrangements as mandated by Statutory office holders including the Secretary and Head of State Service. The relevant Unit Manager can provide details to the occupant of delegations applicable to this position.
* Comply at all times with policy and protocol requirements, including those relating to mandatory education, training and assessment.

### Pre-employment Conditions:

*It is the Employee’s responsibility to notify an Employer of any new criminal convictions during the course of their employment with the Department.*

The Head of the State Service has determined that the person nominated for this job is to satisfy a pre‑employment check before taking up the appointment, on promotion or transfer. The following checks are to be conducted:

1. Conviction checks in the following areas:
   1. crimes of violence
   2. sex related offences
   3. serious drug offences
   4. crimes involving dishonesty
2. Identification check
3. Disciplinary action in previous employment check.

### Selection Criteria:

1. Demonstrated well developed level of clinical expertise and knowledge, skills and experience as a Registered Nurse with previous experience in coordinating multi-centre clinical trials.
2. Highly developed interpersonal, written and oral communication skills with the ability to function effectively in a multidisciplinary team environment and relate to members of the internal and external research team and Oncology/Haematology Clinical Trial participants.
3. Current knowledge of, and the ability to apply nursing principles, procedures and practices in the deliver patient/ client care in a designated practice area and in line with legal requirements, including Australian Nursing and Midwifery Council (ANMC) competencies, code of practice and current GCP qualifications.
4. Experience in the use of computers and relevant software including word processing, spreadsheet, email, internet packages and vendor software, with a demonstrated understanding of clinical information systems and data collection in the clinical setting.
5. Demonstrated motivation, organisational ability and attention to detail to achieve desired outcomes in Oncology/Haematology Clinical Trials.

### Working Environment:

The Department of Health is committed to improving the health and wellbeing of patients, clients and the Tasmanian community through a sustainable, high quality and safe health system. We value leading with purpose, being creative and innovative, acting with integrity, being accountable and being collegial.

The Department of Health is committed to improving the way we work with vulnerable people, in particular implementing strategies and actions to promote child safety and wellbeing, empower, and prevent harm to children and young people.

The Department upholds the *Australian Charter of Healthcare Rights* in our practice and is committed to the safeguarding and protection of the welfare and rights of all people, particularly those that may be at risk of abuse, neglect, or exploitation. We place emphasis on the provision of culturally safe, respectful, and inclusive care that is responsive to diverse needs.

The Department seeks to provide an environment that supports safe work practices, diversity and respect, including with employment opportunities and ongoing learning and development. We value the diverse backgrounds, skills and contributions of all employees and treat each other and members of the community with respect. We do not tolerate discrimination, harassment or bullying in the workplace. All employees must uphold the *State Service Principles* and *Code of Conduct* which are found in the *State Service Act 2000.* The Department supports the [Consumer and Community Engagement Principles](http://gormpr-cm01/pandp/showdoc.aspx?recnum=P19/000365).