

DEPARTMENT OF HEALTH

Statement of Duties

Position Title:	Clinical Trials Liaison Officer
Position Number:	527359
Classification:	General Stream Band 6
Award/Agreement:	Health and Human Services (Tasmanian State Service) Award
Group/Section:	Clinical Quality, Regulation and Accreditation - Clinical Governance
Position Type:	Fixed-Term, Full Time/Part Time
Location:	South, North, North West
Reports to:	Deputy Chief Medical Officer
Effective Date:	July 2022
Check Type:	Annulled
Check Frequency:	Pre-employment
Desirable Requirements:	<p>Tertiary qualifications (postgraduate certification, Diploma or Masters) in a relevant discipline with high-level practical experience in the implementation, conduct and coordination of research and clinical trials within the health setting</p> <p>Registration with the Australian Health Practitioner Regulation Agency (AHPRA)</p> <p>Practical experience (minimum of three years) in research and clinical trials, preferably with experience as a clinical trial coordinator, study coordinator, research nurse, research assistant or equivalent would be advantageous</p> <p>Contemporary knowledge of the National Health and Medical Research Council (NHMRC), Good Practice Process (GPP) for Site Assessment and Authorisation Phases of Clinical Trial Research Governance, Australian Code for the Responsible Conduct of Research, International Centre for Harmonisation, Good Clinical Practice (GCP) Guidelines, and the National Principles for Teletrials</p>

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.

Background:

Clinical Trials Liaison Officer (CTLO)

Central to the GPP is the role of the Clinical Trial Liaison Officer (CTLO), who works across clinical trial sponsors, researchers and the research office to facilitate communication, coordinate activities and shepherd applications through an often-complex workflow. Through good communication and coordination, CTLOs can speed up the review and approval processes. The following are key areas of focus for the CTLO:

- Reviewing and streamlining a site's clinical trial start-up processes.
- Early assessment of the feasibility of the clinical trial with applicable service areas within the health service to ensure there are sufficient resources to enable completion of the clinical trial.
- Open communication with sponsors and on site/institution capability, the organisation's strategic objective and patient clinical needs.
- Providing a central point of contact and information, and improving communication between sponsors, researchers and site administrative staff.
- 'Shepherding' applications through the site assessment and authorisation process.

Primary Purpose:

The position supports the conduct and expansion of research and clinical trials with internal and external stakeholders in accordance with the National Health and Medical Research Council (NHMRC), Good Practice Process (GPP) for Site Assessment and Authorisation Phases of Clinical Trial Research Governance and shares responsibility for the provision of support and training within the Tasmanian publicly funded health service under the leadership of the Deputy Chief Medical Officer.

The Clinical Trials Liaison Officer (CTLO) participates in state and national committees, and forums to support the conduct and strategic objectives for research and clinical trials within the Tasmanian publicly funded health service and the broader national research reform agenda.

Duties:

1. Assists in identifying delays in the overall research governance process (ethics and site assessment) within the institution and play a vital role in attracting clinical trials to the health service that meet the health needs of the community.
2. Responsible for streamlining clinical trial end-to-end processes, from start-up to site authorisation, including site feasibility assessment, site assessment document preparation and submission, to improve governance review and site authorisation timeframes.
3. Provide high-level expertise, strategic advice and support to sponsors, researchers and site administrative staff with regards to clinical trial start-up processes and site research capabilities and interests.
4. Develop resources relating to the Good Practice Process and clinical trial start-up process, including Standard Operating Procedures and Key Performance Indicators.
5. Implement the Good Practice Process and monitoring progress to ensure milestones, key performance indicators and resources align with those identified by the unit and Agency.
6. Track the progress of individual applications including 'shepherding' applications through site assessment and authorisation process and intervene as necessary to minimise delays.
7. Establish a central repository for the documentation required by external sponsors ensuring all relevant documentation is available to conduct the capacity planning exercise with local service departments.

8. Work with site staff to assess infrastructure and staff availability required for the conduct of clinical trials with each department.
9. Assists the Deputy Chief Medical Officer in the provision of education, training and dissemination of appropriate research governance information and promoting Good Clinical Practice in the conduct of research throughout the public health organisation.
10. Provide education and support to researchers internal and external to the Department on ethics and governance processes to improve efficiencies in clinical trial start up times.
11. Provide high quality, authoritative and timely advice to the Deputy Secretary Clinical Quality, Regulation and Accreditation, the Deputy Chief Medical Officer, senior executives and other stakeholders around policy advice and achievements of the Department of Health's research objectives.
12. 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:

Under the leadership of the Deputy Chief Medical Officer and working closely with the Research Governance - Project Coordinator, the Teletrial Coordinator and other staff in the Research Governance Office, the incumbent is expected to work with a significant degree of independence and autonomy, ensuring work undertaken is thorough, well researched, accurate and timely, and will demonstrate initiative, sensitivity and exercise sound judgement in the completion of tasks.

The CTLO Officer is expected to:

- Provide high-level expertise, strategic advice and support to sponsors, researchers and site administrative staff with regards to clinical trial start-up processes and site research capabilities and interests.
- Work collaboratively at all levels within the Tasmanian publicly funded health service to coordinate the research governance reviews and research initiatives across the Tasmanian publicly health sector.
- Promote the Tasmanian publicly funded health service to attract Sponsored clinical trials that aligns to the organisations strategy and health priorities and meet the health needs of the community.
- Maintain high level knowledge of State and Commonwealth legislation, policy directions and service delivery relating to research governance.
- Operate with considerable independence and autonomy in determining priorities and apply initiative and judgement in the planning, organisation and prioritisation of workloads.
- Develop and maintain effective relationships by actively collaborating with key stakeholders.
- 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.
- 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.

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:
 - a. crimes of violence
 - b. sex related offences
 - c. serious drug offences
 - d. crimes involving dishonesty
2. Identification check
3. Disciplinary action in previous employment check.

Selection Criteria:

1. Demonstrated experience in research and clinical trials in the health setting including a contemporary understanding of research governance processes.
2. Experience in developing research resources, including Standard Operating Procedures in for the conduct of research and clinical trials.
3. Experience in providing professional advice and support relating to the regulation, management and conduct of clinical trials.
4. Excellent interpersonal skills and the proven ability to establish and manage productive professional relationships and networks with a variety of stakeholders.
5. Flexible and agile professional mindset and approach, including the ability to manage multiple and complex responsibilities, show initiative, problem solve complex tasks and work autonomously.

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 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](#).