

## PROPOSED POSITION DESCRIPTION

<b>POSITION TITLE</b>	Senior Clinical Research Data Officer - Endocrinology
<b>STAFFLINK POSITION NO.</b>	TBA
<b>COST CENTRE</b>	259352
<b>CLASSIFICATION</b>	Admin Officer Level 5
<b>AWARD</b>	Health Employees' Administrative Staff (State) Award
<b>REGISTRATION/LICENCE REQUIREMENTS</b>	N/A
<b>VACCINATION CATEGORY</b>	Category A
<b>PRE-EMPLOYMENT SCREENING CHECKS</b>	Working With Children and National Criminal Record Check
<b>RESPONSIBLE TO</b>	Clinical Research Manager, Endocrinology
<b>RESPONSIBLE FOR</b>	N/A
<b>PRIMARY PURPOSE OF THE ROLE</b>	<p>The successful applicant will provide high-level and accurate research administrative management support to the Department of Endocrinology Clinical Trials and Research Unit in relation to clinical trials and research projects, and ensure that they are undertaken in an efficient, professional, and timely manner.</p> <p>The Clinical Research Data Officer will report to the Clinical Research Manager and/or the Principal Investigator of each study. The position will be required to work independently, and data manage a large number of complex studies under minimal supervision.</p>
<b>KEY ACCOUNTABILITIES</b> <i>(Maximum of 8)</i>	<p>Perform research-specific tasks such as:</p> <ul style="list-style-type: none"> <li>• Set up study-specific databases on NSLHD REDCap portal</li> <li>• Perform data entry into electronic study-specific information systems such as REDCap, Medidata Rave, and Inform</li> <li>• Data manipulation and analysis working with software programmes such as REDCap, Excel and SPSS</li> <li>• Update departmental patient databases as necessary to aid in clinical trial and study recruitment</li> </ul> <p>Data entry for clinical trials and research projects within the unit to expected high research standards, with high level of accuracy and attention to detail.</p> <p>This will include working with pharmaceutical study sponsors who monitor the studies, responding to sponsor-generated queries on trial-specific online workbooks such as Medidata Rave and Inform, and ensuring that database locks are able to be completed on time.</p> <p>Research-specific administration tasks – Including maintenance clinical trial Investigator folders and documentation, managing correspondence with study participants involved in a number of clinical trials/studies conducted by the unit, as well as interacting with study patients to complete study-specific questionnaires and other documents.</p>

	<p>The applicant is required to hold competency certification to use the NSW Health's Clinical Trial Management System (CTMS)</p>	
	<p>The Clinical Research Data Officer will be required to evaluate current and the ever changing research and data privacy legislation and regulations. They will assist with the implementation of standard operating procedures (SOPs) set out by the NSW Health's Office of Health and Medical Research (OHMR) and the Australian Commission on Safety and Quality in Healthcare's (ACSQH) National Clinical Trials Governance Framework, working towards accreditation of the research unit.</p>	
	<p>Update clinical trials finance schedules to ensure timely financial documentation and reports are sent to the Clinical Research Manager.</p>	
	<p>Ensure study- and protocol-specific training is up to date for study staff</p>	
	<p>Complying with the requirements of the directive on 'Management of Data and Information in Research' set out by the Australian Government, National Health and Medical Research Council and Australian Research Council. Maintain records to ensure accurate recording, organise archiving of clinical trial data for the required retention time (1yr, 5yrs, 15yrs, or permanently). Assist Clinical Research Manager, contact relevant study sponsor, and liaise with the Museums of History to organise data destruction following the requisite period of archiving</p>	
	<p>Provide general administrative support including, but not limited to: handling correspondence, telephone calls, filing, scanning, photocopying, ordering stationery and other office consumables, sending of files to medical records and other general administrative support duties as required.</p>	
	<p>Maintain strict confidentiality in relation to all patient, staff, workplace and NSLHD matters</p>	
<p><b>KEY CHALLENGES</b> <i>(Maximum of 3)</i></p>	<p>Time management and prioritisation of tasks in a busy clinical environment. Ability to manage numerous complex studies at any one time, work independently and with minimal supervision.</p>	
	<p>Achieve project deadlines and milestones to the required (high) standards and targets of clinical trial research.</p>	
	<p>Keep informed of research and other factors such as legislation and policy decisions which impact on research data collection, management and distribution as this is often marked by rapid change and development.</p>	
<p><b>KEY INTERNAL RELATIONSHIPS</b> <i>(Maximum of 3)</i></p>	<p><b>WHO</b></p>	<p><b>WHY</b></p>
	<p>Clinical Research Manager, Endocrinology; Principal &amp; Associate Investigators; Head of Department</p>	<p>Allocation of workload</p>
	<p>Clinical Trial Coordinators</p>	<p>Daily workload, advice and collaboration on tasks</p>
	<p>Other departmental research project officers and administrative staff</p>	<p>Advice and collaboration on tasks</p>
<p><b>KEY EXTERNAL RELATIONSHIPS</b></p>	<p><b>WHO</b></p>	<p><b>WHY</b></p>
	<p>Study participants</p>	<p>As part of the daily business of conducting clinical trials</p>

<i>(Maximum of 3)</i>	NSLHD Research Office	Research-related queries and advice
	Service/maintenance personnel	For assistance, if required, with the NSLHD REDCap and other databases being used within the department and hospital.
<b>SELECTION CRITERIA</b> <i>(Minimum of 3 maximum of 8)</i>	Consistently demonstrates behaviours that reinforce the CORE Values of our organisation; Collaboration, Openness, Respect and Empowerment. Demonstrates these behaviours with all stakeholders; colleagues, direct reports, as well as our patients and consumers, and those that care for them.	
	Previous demonstrated experience in research database set-up and database entry with a high level of accuracy and attention to detail. Statistical analysis experience preferred	
	Previous administrative experience particularly in a client-focussed and/or health research environment, or similar. ICH-GCP certification required.	
	Demonstrated experience and expertise with data manipulation, working with software programs such as SPSS, Excel, and REDCap. Certified user of NSW Health's CTMS research software.	
	Demonstrated ability to work collaboratively as part of a team of varied professionals, as well as independently under general direction	
	Demonstrated ability to manage a large workload of complex studies and prioritise competing demands within time constraints. Ability to work independently and with minimal supervision.	
	High level of written and verbal communication skills	
	Demonstrated competency in general computing skills, especially email, Microsoft Office Suite, research web-based applications such as REDCap, CTMS, and industry-sponsored e-CRF databases.	

## JOB DEMANDS CHECKLIST

The purpose of this checklist is to manage the risk associated with the position in relation to the occupant. It may be used to provide information about the position to a Health Professional required to perform a pre-employment medical assessment. Identification of possible risk can also assist with the development of a training plan for the occupant to ensure the risks are minimised.

Each position should be assessed at the site as to the incumbent's (or future incumbent's) OHS responsibilities specific to the position. This form is to be completed in consultation with the manager/supervisor of the position being recruited for.

Infrequent: intermittent activity exists for a short time on a very infrequent basis  
 Occasional: activity exists up to 1/3 of the time when performing the job  
 Frequent: activity exists between 1/3 and 2/3 of the time when performing the job  
 Constant: activity exists for more than 2/3 of the time when performing the job  
 Repetitive: activity involved repetitive movements  
 Not Applicable: activity is not required to perform the job

Physical Demands	Frequency
<b>Sitting</b> - remaining in a seated position to perform tasks	Repetitive
<b>Standing</b> - remaining standing without moving about to perform tasks	Occasional
<b>Walking</b> - Floor type: even / uneven / slippery, indoors / outdoors, slopes	Constant
<b>Running</b> - Floor type: even / uneven / slippery, indoors / outdoors, slopes	Not applicable
<b>Bend/Lean Forward from Waist</b> - Forward bending from the waist to perform tasks	Occasional
<b>Trunk Twisting</b> - Turning from the waist while sitting or standing to perform tasks	Occasional
<b>Kneeling</b> - remaining in a kneeling posture to perform tasks	Occasional
<b>Squatting / Crouching</b> - Adopting a squatting or crouching posture to perform tasks	Occasional
<b>Leg / Foot Movement</b> - Use of leg and / or foot to operate machinery	Not applicable
<b>Climbing (stairs/ladders)</b> - Ascend / descend stairs, ladders, steps	Infrequent
<b>Lifting / Carrying</b> - Light lifting & carrying: 0 - 9 kg	Occasional
<b>Lifting / Carrying</b> - Moderate lifting & carrying: 10 - 15 kg	Infrequent
<b>Lifting / Carrying</b> - Heavy lifting & carrying: 16kg & above	Infrequent
<b>Reaching</b> - Arms fully extended forward or raised above shoulder	Occasional
<b>Pushing / Pulling / Restraining</b> - Using force to hold / restrain or move objects toward or away from the body	Occasional
<b>Head / Neck Postures</b> - Holding head in a position other than neutral (facing forward)	Occasional
<b>Hand &amp; Arm Movements</b> - Repetitive movements of hands and arms	Frequent
<b>Grasping / Fine Manipulation</b> - Gripping, holding, clasping with fingers or hands	Infrequent
<b>Work At Heights</b> - Using ladders, footstools, scaffolding, or other objects to perform work	Infrequent
<b>Driving</b> - Operating any motor powered vehicle	Infrequent

<b>Sensory Demands</b>	<b>Frequency</b>
<b>Sight</b> - Use of sight is an integral part of work performance e.g. Viewing of X-Rays, computer screens	Repetitive
<b>Hearing</b> - Use of hearing is an integral part of work performance e.g. Telephone enquiries	Repetitive
<b>Smell</b> - Use of smell is an integral part of work performance e.g. Working with chemicals	Infrequent
<b>Taste</b> - Use of taste is an integral part of work performance e.g. Food preparation	Not applicable
<b>Touch</b> - Use of touch is an integral part of work performance	Repetitive
<b>Psychosocial Demands</b>	<b>Frequency</b>
<b>Distressed People</b> - e.g. Emergency or grief situations	Infrequent
<b>Aggressive &amp; Uncooperative People</b> - e.g. drug / alcohol, dementia, mental illness	Infrequent
<b>Unpredictable People</b> – eg dementia, mental illness, head injuries	Occasional
<b>Restraining</b> - involvement in physical containment of patients / clients	Infrequent
<b>Exposure to Distressing Situations</b> - e.g. Child abuse, viewing dead / mutilated bodies	Infrequent
<b>Environmental Demands</b>	<b>Frequency</b>
<b>Dust</b> - Exposure to atmospheric dust	Occasional
<b>Gases</b> - Working with explosive or flammable gases requiring precautionary measures	Occasional
<b>Fumes</b> - Exposure to noxious or toxic fumes	Infrequent
<b>Liquids</b> - Working with corrosive, toxic or poisonous liquids or chemicals requiring PPE	Infrequent
<b>Hazardous substances</b> - e.g. Dry chemicals, glues	Occasional
<b>Noise</b> - Environmental / background noise necessitates people raise their voice to be heard	Frequent
<b>Inadequate Lighting</b> - Risk of trips, falls or eyestrain	Occasional
<b>Sunlight</b> - Risk of sunburn exists from spending more than 10 minutes per day in sunlight	Infrequent
<b>Extreme Temperatures</b> - Environmental temperatures are less than 15C or more than 35C	Infrequent
<b>Confined Spaces</b> - areas where only one egress (escape route) exists	Occasional
<b>Slippery or Uneven Surfaces</b> - Greasy or wet floor surfaces, ramps, uneven ground	Infrequent
<b>Inadequate Housekeeping</b> - Obstructions to walkways and work areas cause trips and falls	Frequent
<b>Working At Heights</b> - Ladders / stepladders / scaffolding are required to perform tasks	Infrequent
<b>Biological Hazards</b> - e.g. exposure to body fluids, bacteria, infectious diseases	Infrequent