

PROPOSED POSITION DESCRIPTION

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| POSITION TITLE | SENIOR CLINICAL TRIALS COORDINATOR-ENDOCRINOLOGY |
| STAFFLINK POSITION NO. | |
| COST CENTRE | 259352 |
| CLASSIFICATION | Health Manager Level 2 |
| AWARD | Health Manager's (State) Award |
| REGISTRATION/LICENCE REQUIREMENTS | N/A |
| VACCINATION CATEGORY | Category A |
| PRE-EMPLOYMENT SCREENING CHECKS | Working With Children and National Criminal Record Check |
| RESPONSIBLE TO | Clinical Research Manager, Endocrinology |
| RESPONSIBLE FOR | All aspects of clinical trial and research-related activities within the Endocrinology Clinical Research Unit of the Department of Endocrinology |
| PRIMARY PURPOSE OF THE ROLE | <p>The purpose of the Senior Clinical Trials Coordinator (SCTC) is to coordinate, at any one time, a number of complex international clinical trials (including Endocrinology, Diabetes, Thyroid and Endocrine Cancers, Obesity, Menopause, Bone and Mineral, and Rare Disease trials). The role of the SCTC includes managing the patient caseload for each study, conducting, and coordinating all aspects of study-specific and study-required procedures.</p> <p>The SCTC is responsible for the recruitment of patients into these studies and for the trial-specific care of patients participating in these studies. The role provides leadership and guidance in all aspects of clinical trial activity and a high level of mentoring of other staff is required. The SCTC is expected to assist, provide guidance to, and supervise medical students and PhD candidates with regards to their research projects.</p> <p>The position will liaise with the wider research team as required: the NSLHD Research Office, study-specific pharmaceutical and/or research organisation sponsors, Clinical Research Associates and trial monitors, and clinical trial staff at other centres. Liaise with the patient's treating team to ensure quality and continuity of care for patients participating in clinical trials</p> |
| KEY ACCOUNTABILITIES <i>(Maximum of 8)</i> | Ensure all clinical trials are conducted in accordance with all regulatory, state, national, and internationally accepted guidelines for Good Clinical Practice (ICH-GCP). |
| | Maintain an ongoing caseload of patients participating Diabetes, Endocrinology, and Metabolism clinical trials including the more complex cancer and rare disorder trials. Coordinate all required treatment programmes and testing schedules for these patients as per study-specific guidelines |

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| | Identify suitable patients for recruitment into clinical studies, applying the study-specific inclusion and exclusion criteria, via referrals, multidisciplinary team meetings, and other clinical settings. | |
| | Ensure study investigators are continually updated with the current circumstances of the studies they are involved with: the ongoing conduct of the trial, the welfare of the study participants, and any notifications which may arise during the course of the study. | |
| | Preparation and submission of study documents required by the Human Research Ethics Committee or the Research Governance Office for new studies, study amendments, safety reports, and serious adverse events as required during the conduct of the study. | |
| | Develop and implement strategies to manage study documentation and maintain knowledge of relevant policies and procedures related to operating within the NSW Health Service. | |
| | Ensure accurate collection, maintenance, and storage of study data in a timely manner, including the use of study-specific case report forms (CRFs) and databases, and ensure that data is reported to sponsors and other key parties within the timeframe agreed to in the Clinical Trial Research Agreement. | |
| | Management of NSW Health's mandatory web-based programmes: the REGIS research platform and the Clinical Trial Management System. | |
| KEY CHALLENGES <i>(Maximum of 3)</i> | Working on multiple complex research/trial projects at any one time and ensuring all these trials, with their competing priorities and demands, are managed equitably and as per each study-specific protocol. Achieving recruitment targets and project deadlines and milestones, with minimal supervision | |
| | Ability to meet challenges as they arise, prioritising a busy workload and assisting or supervising other team members as required. | |
| | Displaying a high level of knowledge in all areas of Diabetes, Endocrinology, and Metabolism | |
| KEY INTERNAL RELATIONSHIPS <i>(Maximum of 3)</i> | WHO | WHY |
| | Clinical Research Manager, Endocrinology | The position holder is the SCTC's direct report. They are responsible, in collaboration with Principal Investigators, to make decisions regarding allocation of workload, the safe management of allocated trial patients, and ensuring appropriate use of resources |
| | Principal Investigators (PI) | The PIs are responsible for overseeing all the clinical and safety aspects of the trials; ensuring the safety of trial patients; and ensuring that research/trial staff are performing all study-specific procedures as per study protocols. |
| | Clinical Trial Staff, NSLHD Research Office, and other clinical researchers | Effectively communicate and assist with, and collaborate on trials/research studies. Ensure ethical and governance submissions are submitted and approved in a timely manner; |

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| | | ensure all safety reporting to regulatory bodies are adhered to. |
| KEY EXTERNAL RELATIONSHIPS <i>(Maximum of 2)</i> | WHO | WHY |
| | Study participants | As part of the daily business of conducting clinical trials. Patient safety monitoring, and ensuring trial patients are kept well informed of all aspects of the study and the investigational product that they may be taking. |
| | Pharmaceutical Industry Sponsors, Collaborative Research Groups, and referring doctors such as Endocrinologists, Physicians, and Specialists | Collaborative partnerships to ensure productive working relationships. |
| SELECTION CRITERIA <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. | |
| | Relevant tertiary qualification/s in Endocrinology and/or equivalent experience in the planning, coordination and conducting of industry-sponsored international multi-centre clinical research trials. | |
| | Excellent communication and organisational skills with meticulous attention to detail. | |
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| | Ability to manage a number of complex clinical trials at the one time, prioritising work load to meet conflicting and critical deadlines. | |
| | Highly developed communication, negotiation and interpersonal skills with demonstrated ability to work independently and within a multidisciplinary team. | |
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| | Demonstrated understanding of the legal, ethical and regulatory requirements for research as per ICH-GCP and other statutory guidelines; and current GCP certification. | |
| Working knowledge and proven experience with NSW Health's mandatory web-based programmes: the REGIS research platform and the Clinical Trial Management System. | | |
| Proficiency with the use of computer applications including Microsoft Office Suite. Previous experience and proficiency with clinical trial electronic case reporting forms and databases such REDCap, Medidata Rave, and Inform. | | |

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 or the time when performing the job
 Repetitive: activity involved repetitive movements
 Not Applicable: activity is not required to perform the job

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

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