JOB DESCRIPTION
TELETHON KIDS INSTITUTE

Why is this Job Description being written?	☒ New Position ☐ Replacement Position ☐ Position re-designed ☐ Position not previously described			
POSITION DETAILS:	**Position Title:**	**RESEARCH ASSISTANT/COORDINATOR**		
Division:	Wesfarmers Centre of Vaccines & Infectious Disease		**Department:**	Implementation Research
Position reports to: (role)	Business Manager			
Location: *include all possible locations*	100 Roberts Road Subiaco			

POSITION PURPOSE: In one or two sentences briefly summarise the overall purpose of this role, i.e. broadly, **what** this role does and **why**

The key objective of the role is to facilitate the set up and day to day running of clinical research studies, including ensuring that they are conducted efficiently and in accordance with Good Clinical Practice (GCP) and the National Statement on Ethical Conduct of Research in Humans.

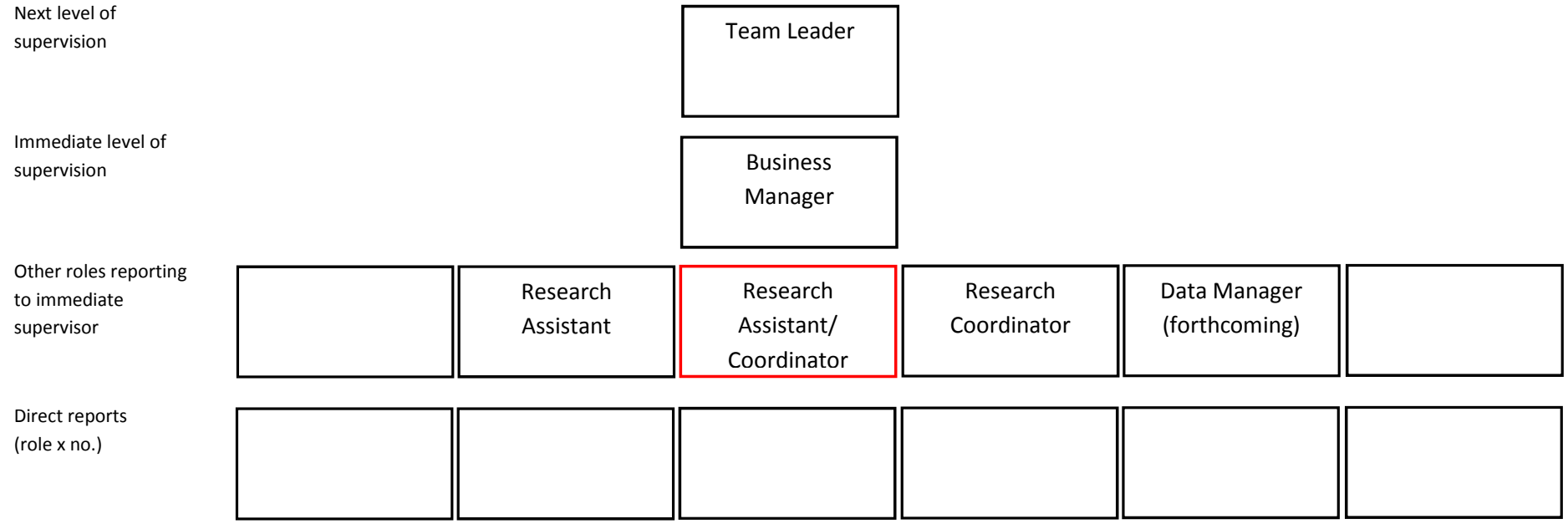
KEY RESPONSIBILITY AREAS *(Please list in order of importance)*				
Key Position Accountabilities	***% of Total Role***	***Inputs:*** What are the key activities or tasks to be carried out?	***Outputs:*** What are the expected end results?	***Measures:***
Project Management	40	• Coordination and day-to-day management of research projects, problem solving and ensuring Principal Investigators are up to date with all matters • Coordination and supervision of set-up and continual running of clinical research projects across multiple sites, including monitoring of study metrics e.g. Case Report Form (CRF) completion, recruitment and overall tracking of the project • Effective communication with clinical study sites to ensure compliance with GCP and local standards • Monitoring study progress (e.g. participant recruitment, adverse safety events) at clinical study sites and implementing strategies to ensure compliance with study protocol • Effective coordination of meetings and communications with collaborators as required, including Data and Safety Materials Committee (DSMC), Investigators and stakeholders • Participation in continuous quality improvement and GCP compliance activities	• Complete and correct documentation for submissions and/or updates • Activities effectively communicated to sites and stakeholders • All projects comply with GCP and local standards • Projects comply with protocol • Projects delivered according to plan	• All projects delivered on time and budget • All projects in compliance with GCP • Study team and stakeholder feedback • Feedback from Principal Investigator

KEY RESPONSIBILITY AREAS *(Please list in order of importance)*				
Key Position Accountabilities	***% of Total Role***	***Inputs:*** What are the key activities or tasks to be carried out?	***Outputs:*** What are the expected end results?	***Measures:***
Project Delivery	30	• Contribute to protocol development • Development and management of the trial documentation (ISF/TMF) – ensure essential documents are filed and kept up to date per GCP and other applicable regulatory guidelines • Preparation and submission of Ethics Committee, governance and regulatory applications • Creation of manuals and charters e.g. DSMC charter, monitoring plans • Coordination of stakeholder input into documentation e.g. protocol review • Coordination of drug supply, packaging and labelling with service providers • Coordination of randomisation with statistician(s) • Training of site staff in GCP and study procedures • Monitoring of data quality and adherence to regulations across research projects including on-site monitoring, site initiation and closeout • Safety monitoring including reporting of safety events to relevant authorities with input from investigators and data monitoring committees where applicable	• Projects set-up and delivered effectively • High quality data produced from projects • Project documentation (protocol, manuals and charters etc.) complete • Safety reporting requirements met	• Projects completed to the standards required by regulation and best practice • Trial documentation (ISF/TMF) complete • Project outcomes met • Successful submission of required documentation (e.g. ethics applications, safety event reporting) • All study staff trained in GCP and study procedures • Adverse safety events reporting complete and within set timeframes • Protocol deviations and violations reported • Feedback from Principal Investigator
Data Management	10	• Develop CRFs and associated documents • Liaision with Data Manager to help develop and manage databases and ensure compliance with data management plan	• Full data compliance, full documentation of data and tracking system	• 100% compliant database and tracking system • Feedback from Principal Investigator
Other	10	• Other duties as directed by the Business Manager or Principal Investigator	N/A	• Feedback from Principal Investigator and Business Manager

ESSENTIAL SKILLS, KNOWLEDGE AND EXPERIENCE:	
Qualifications: what are the minimum educational, technical or professional qualifications required to competently perform role	• Bachelor degree in biological sciences, allied health, nursing or other relevant discipline OR equivalent work experience
Skills, Knowledge & Experience:	1. Experience in a clinical research environment, preferably across different phases of development 2. Knowledge of GCP and applicable regulatory guidelines 3. Ability to work independently, take initiative, communicate and work within a team 4. Ability to be highly organised, with a proven ability to prioritise tasks appropriately in a busy working environment 5. Excellent interpersonal, verbal and written communication skills 6. Evidence of well-developed problem-solving ability 7. Ability to apply meticulous attention to detail 8. A high level of computer literacy including word processing, spreadsheets and databases 9. Ability to be flexible with working hours and travel interstate/overseas depending on study requirements
DESIRABLE SKILLS, KNOWLEDGE AND EXPERIENCE:	
Qualifications: what are the minimum educational, technical or professional qualifications required to competently perform role	• Registered allied health, nursing or other clinical professional
Skills, Knowledge & Experience:	1. Previous experience in a hospital or clinical environment 2. Familiarity with hospital medical records, medical terminology and confidentiality/privacy requirements 3. GCP or clinical trials accreditation/qualification 4. Dangerous Goods Handling Certificate 5. Previous experience in clinical data management 6. Previous experience in infectious diseases and/or vaccinology
SCOPE:	
Financial accountability: Does this role have accountability for a budget?	
• No	
People responsibility: Does this role have any direct reports or indirect reports (through direct reports)?	

No. of direct reports	0	No. of indirect reports	0

ORGANISATIONAL CHART:



ADDITIONAL INFORMATION: is there any additional information that needs to be understood to explain this role?