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 ASSOCIATE – RESPIRATORY CLINICAL TRIALS**	
Division:	Chronic and Severe Diseases	**Department:**	P4 Respiratory Health for Kids
Position reports to: (role)	Project Manager – Respiratory Clinical Trials		
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**

To set up, coordinate and manage clinical trial sites with the aim of meeting protocol and GCP compliance. To assist with the development and implementation of standard operating procedures and management systems.

KEY RESPONSIBILITY AREAS *(Please list in order of importance)*				
Key Position Accountabilities What are the main areas for which the position is accountable	***% of Total Role***	***Inputs:*** What are the key activities or tasks to be carried out?	***Outputs:*** What are the expected end results?	***Measures:*** How it is measured
Clinical trial conduct	75	Study start-up – • Assist Project Manager and Investigators with development of clinical trial protocols and other relevant documentation. • Provision of start-up, project management, protocols and other relevant documentation. • Manage and support preparation, ethics approvals and setup of the clinical trials. • Prepare contracts and agreements for clinical studies. Site Initiation and Monitoring – • Site staff training on study protocol as appropriate • Regular on-site and remote monitoring of studies in multi-centre clinical trial to ensure compliance to ICH GCP standards. • Reporting, follow-up and site support in issue resolution. Study Management Support - • Reporting - Assist in preparing reports to the Project Manager, Investigators on clinical trial activities. • Communications - Effective coordination of meetings and communications as required. • Data Management – Collaborate with Data Manager and Biostatistician where appropriate. • Finance and Contract Management – support financial management for clinical trials and collaborative grants.	• Clinical trial documentation complies with ICH GCP and other regulatory guidelines. • Clinical trials are conducted according to ICH GCP and other regulatory guidelines. • Clinical trial data is clean and verifiable. • Clinical studies are conducted to budget. • Completion of project milestones and targets. • Provision of regular and accurate reports.	• Clinical trials are performed to the highest standards and ensuring respect for the rights and safety of participants. • Investigators are able to demonstrate that they are compliant with regulatory guidelines. • Source documentation is complete and accurate. • Compliant risk management. • Accurate and secured storage of data. • Feedback from CI group. • Feedback from Project Manager.

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Processes and systems	25	• Implement systems and processes to ensure the clinical trials group stores and makes available knowledge so the group can operate effectively. • Design, implement and manage selected infrastructure projects in collaboration with Project Manager, investigators and research management team. • Risk Management – Provide input and support implementation of governance arrangements and processes.	Publication of up to date policies and SOPs on group collaborative workspace.	• Updated policies and SOPs. • Processes and systems are optimal. • Effective teamwork and productivity.

ESSENTIAL SKILLS, KNOWLEDGE AND EXPERIENCE:	
Qualifications: what are the minimum educational, technical or professional qualifications required to competently perform role	• Undergraduate Degree in Biomedical Sciences
Skills, Knowledge & Experience:	• Minimum of 2 years' experience in setting up and monitoring clinical trials. • Working knowledge of the Australian regulatory environment for clinical trials • Ability to work as part of a multidisciplinary team • Confidence to work independently • Ability to manage multiple priorities and a demanding schedule • Excellent interpersonal and communication (both written and verbal) skills • Excellent planning and organizational skills • Excellent attention to detail
DESIRABLE SKILLS, KNOWLEDGE AND EXPERIENCE:	
Qualifications: what are the minimum educational, technical or professional qualifications required to competently perform role	• Degree in the life sciences
Skills, Knowledge & Experience:	• Experience with both industry-sponsored and investigator-initiated clinical trials. • Experience in paediatric studies.

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

ORGANISATIONAL CHART: (please complete using position titles or insert diagram below)

Next level of supervision		Program Manager, ARESTCF			
Immediate level of supervision		Project Manager, Respiratory Clinical Trials			
Other roles reporting to immediate supervisor		Research Associate, Respiratory Clinical Trials	Research Associate, Respiratory Clinical Trials	Clinical Trials Assistant, Respiratory Clinical Trials	
Direct reports (role x no.)					

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

Inter-state travel will be required for site monitoring visits and meeting attendance.