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SA Health Job Pack

Job Title	Respiratory Clinical Trials Manager
Eligibility	Open to everyone
Job Number	692826
Applications Closing Date	Thursday, 27 June 2019
Region / Division	Southern Adelaide Local Health Network
Health Service	Medicine, Cardiac & Critical Care - Respiratory and Sleep Services
Location	Bedford Park
Classification	RN/M2C
Job Status	Temporary Part Time until 30.06.2020
Total Indicative Remuneration	\$87,817 – \$112,041 p.a. (pro-rata)

Contact Details

Full name	Kathrina Bartolay, Senior Clinical Trial Coordinator
Phone number	8204 2202
Email address	kathrina.bartolay@sa.gov.au

Criminal History Assessment

Applicants will be required to demonstrate that they have undergone an appropriate criminal and relevant history screening assessment/ criminal history check. Depending on the role, this may be a Department of Communities and Social Inclusion (DCSI) Criminal History Check and/or a South Australian Police (SAPOL) National Police Check (NPC). The following checks will be required for this role:

- ☒ Child Related Employment Screening – DCSI
- ☒ Vulnerable Person-Related Employment Screening - NPC

Further information is available on the SA Health careers website at www.sahealth.sa.gov.au/careers - see Career Information, or by referring to the nominated contact person below.

Immunisation

Risk Category A (direct contact with blood or body substances)

This role carries specific immunisation requirements. To be eligible for appointment in this role you will be required to meet the immunisation requirements associated with Category A (direct contact with blood or body substances). [Please click here for further information on these requirements.](#)

Guide to submitting an application

Thank you for considering applying for a position within SA Health. Recruitment and Selection processes across SA Health are based on best practice and a commitment to a selection based on merit. This means treating all applications in a fair and equitable manner that aims to choose the best person for the position.

A well presented, easy to read application will allow the panel to assess the information they need from your application. To give yourself the best opportunity to reach interview, the application should clearly and concisely demonstrate to the selection panel that you are suitably equipped to perform the role, and that you possess all of the stated minimum essential skills, abilities, knowledge, experience and educational qualifications (where required).

The online application form to apply for this position will ask for employment history, education, qualifications and referees however to understand the position and requirements we suggest you become familiar with the attached Job and Person Specification.

We request that you attach the following to your application -

- ✎ **A covering letter** of up to 2 pages introducing yourself to the selection panel and describing your skills, abilities, knowledge, qualifications and experience in relation to the position;
- ✎ **A current Curriculum vitae/Resume** that includes your personal details, relevant employment history, education, training courses, qualifications and professional memberships.

* Refer to <http://www.sahealthcareers.com.au/information/> for further information regarding

- The Indicative Total Remuneration which is inclusive of Award salary, superannuation and other monetary benefits.
- Information for Applicants
- Criminal History Assessment requirements



ROLE DESCRIPTION

Role Title:	Respiratory Clinical Trials Manager
Classification Code:	Registered Nurse (Level 2)
Position Number:	M56034
LHN/ HN/ SAAS/ DHA:	SALHN
Hospital/ Service/ Cluster	Flinders Medical Centre
Division:	Medicine, Cardiac & Critical Care
Department/Section / Unit/ Ward:	Respiratory and Sleep Services
Role reports to:	Operationally: Director Respiratory Clinical Research Professionally: Director Respiratory Clinical Research
Role Created/ Reviewed Date:	February 2019
Criminal History Clearance Requirements:	<input type="checkbox"/> Aged (NPC) <input checked="" type="checkbox"/> Child- Prescribed (DCSI) <input type="checkbox"/> Vulnerable (NPC) <input checked="" type="checkbox"/> General Probity (NPC)
Immunisation Risk Category:	<input checked="" type="checkbox"/> Category A (direct contact with blood or body substances) <input type="checkbox"/> Category B (indirect contact with blood or body substances) <input type="checkbox"/> Category C (minimal patient contact)

ROLE CONTEXT

Primary Objective(s) of role:

The Respiratory Clinical Trials Manager is responsible for the planning, provision, maintenance of standards and management of independent and sponsored clinical research being conducted by principle investigator(s) within the Department of Respiratory and Sleep Medicine. The clinical trials manager is responsible for the development, coordination and implementation of activities essential to the success of clinical research.

This position will be based at the Flinders Medical Centre site with rotations to other SALHN sites as required or directed by the Director of Respiratory Clinical Research.

Direct Reports:

Clinical Trials Coordinators
Research Medical Scientist

Key Relationships/ Interactions:

Internal

- > Head of Respiratory Sleep Services
- > Clinical Trials' Investigators
- > Consultant Physicians
- > Research Nurses and Scientists

- > Research and Ethics Committee
- > SALHN Governance Office
- > SALHN Finance Department

External

- > Pharmaceutical sponsors companies
- > General Practitioners
- > National, state and local hospital personnel
- > Care givers involved in the provision and participation of clinical research

Handling of Official Information:

By virtue of their duties, SA Health employees frequently access, otherwise deal with, and/or are aware of, information that needs to be treated as confidential.

SA Health employees will not access or attempt to access official information, including confidential patient information other than in connection with the performance by them of their duties and/or as authorised.

SA Health employees will not misuse information gained in their official capacity.

SA Health employees will maintain the integrity and security of official or confidential information for which they are responsible. Employees will also ensure that the privacy of individuals is maintained and will only release or disclose information in accordance with relevant legislation, industrial instruments, policy, or lawful and reasonable direction.

Challenges associated with Role:

Main challenges currently associated with the role include:

- > Soliciting contracts for pharmaceutical industry-sponsored clinical trials
- > Working effectively with SALHN Ethics and Governance to expedite approval of new clinical trials
- > Working with the Director of Respiratory Clinical Research, SPF trustees and SALNH Finance Department to ensure sound and transparent financial operation of the research operation

Delegations:

Financial	N/A
Human Resources	N/A
Procurement	N/A

Resilience:

SA Health employees persevere to achieve goals, stay calm under pressure and are open to feedback.

Performance Development

The incumbent will be required to participate in the organisation's Performance Review & Development Program which will include a regular review of the incumbent's performance against the responsibilities and key result areas associated with their position and a requirement to demonstrate appropriate behaviours which reflect a commitment to SA Health values and strategic directions.

General Requirements:

- > Managers and staff are required to work in accordance with the Code of Ethics for South Australian Public Sector, Policies and Procedures and legislative requirements including but not limited to:
- > *Work Health and Safety Act 2012* (SA) and when relevant WHS Defined Officers must meet due diligence requirements.
- > *Return to Work Act 2014* (SA), facilitating the recovery, maintenance or early return to work of employees with work related injury / illness.
- > Meet immunisation requirements as outlined in the *Immunisation for Health Care Workers in South Australia Policy Directive*.
- > Equal Employment Opportunities (including prevention of bullying, harassment and intimidation).
- > *Children's Protection Act 1993* (Cth) – 'Notification of Abuse or Neglect'.
- > Disability Discrimination.
- > Information Privacy Principles.
- > Relevant Awards, Enterprise Agreements, *Public Sector Act 2009*, Health Care Act 2008, and the SA Health (Health Care Act) Human Resources Manual.
- > Relevant Australian Standards.
- > Duty to maintain confidentiality.
- > Smoke Free Workplace.
- > To value and respect the needs and contributions of SA Health Aboriginal staff and clients, and commit to the development of Aboriginal cultural competence across all SA Health practice and service delivery.
- > Applying the principles of the South Australian Government's Risk Management Policy to work as appropriate.

Special Conditions:

- > It is mandatory that no person, whether or not currently working in SA Health, will be eligible for appointment to a position in SA Health unless they have obtained a satisfactory Background Screening and National Criminal History Clearance.
- > Prescribed Positions under the Children's Protection Act (1993) must obtain a satisfactory Background Screening and National Criminal History Clearance through the Screening and Licensing Unit, Department for Communities and Social Inclusion.
- > Background Screening and National Criminal History Clearances must be renewed every 3 years thereafter from date of issue for 'Prescribed Positions' under the Children's Protection Act 1993 (Cth) or 'Approved Aged Care Provider Positions' as defined under the Accountability Principles 1998 made in pursuant to the Aged Care Act 2007 (Cth).
- > Appointment is subject to immunisation risk category requirements (see page 1). There may be ongoing immunisation requirements that must be met.
- > Depending on work requirements the incumbent may be transferred to other locations across SA Health to perform work appropriate to classification, skills and capabilities either on a permanent or temporary basis subject to relevant provisions of the Public Sector Act 2009 for Public Sector employees or the SA Health (Health Care Act) Human Resources Manual for Health Care Act employees.
- > The incumbent may be required to participate in Counter Disaster activities including attendance, as required, at training programs and exercises to develop the necessary skills required to participate in responses in the event of a disaster and/or major incident.

STATEMENT OF KEY OUTCOMES AND ASSOCIATED ACTIVITIES

Ensure that a safe and healthy work environment, free from discrimination is provided for employees by:

- a) *implementing departmental human resource policies*
- b) *ensuring that the principles of Equal Employment Opportunity and Ethical Conduct are a normal part of doing business*
- c) *managing industrial relations issues appropriately as they arise*
- d) *managing compliance to the National Safety & Quality Health Service Standards*

Key Result Areas	Major Responsibilities
Ensure Maximum potential of the Respiratory Clinical Trials unit is reached by;	<ul style="list-style-type: none"> • Providing leadership to build a dynamic and innovative work place • Contribute to development and monitoring the budget(s) by ensuring adequate negotiation of individual requirements with sponsor companies taking into account, wage estimates, training and development, equipment and materials. • Ensuring learning from trials assists in building knowledge of staff and contributes to the organisations goals • Preventing and resolution of problems and/or inconsistencies prior to and during each research project • Being actively involved in the evaluation, preparation or, set up conduct and completion of internal, company sponsored and regulatory body audits regarding the completion of and accuracy of clinical research data • Ensuring approval of all trials through SALHN Research Governance • Reinforcing professional ethics and standards, as per local HREC, NHMRS and Good Clinical Practice (GCP) guidelines • Building partnerships with agencies, external companies and specialised groups to assure capacity to perform contracted clinical research • Collaborating with other unit heads to supervise staff, and manage space and other communal resources effectively • Provide timely quality clinical care and facilitate the appropriate and ongoing medical care relating to the continued well-being of all respiratory clinical trial participants • Participating in clinical research self-development activities, as required, at training programs and exercises to enhance the necessary skills required to provide ongoing high quality care to trial participants
Contribute to the professional knowledge base about services within the team, office and extended community by:	<ul style="list-style-type: none"> • Analysis of individual trial protocols and review of primary outcomes/hypothesis to ensure reasonable final outcomes are sought • Maintaining statistics on the work of the Respiratory Clinical trials unit and preparation of this for submission to the Head and Director of Respiratory and Sleep Services, Investigators, Sponsor Companies and regulatory authorities as required • Responding quickly and accurately to enquiries and responses from a wide range of interested parties • Implementing a range of professional development activities and research evaluation independently or in collaboration as required • Maintaining active participation in meetings to improve knowledge within the respiratory clinical trials and general research field and advance primary outcomes
Contributing to the promotion and implementation of the general public sector	<ul style="list-style-type: none"> • Delegations of authority • Disability Discrimination Act • Privacy Act 1988

management aims, personnel management standards and employee conduct standards and in particular Equal Opportunity and Occupational Health Safety and Welfare by adhering to the provisions of relevant legislative requirements such as;	<ul style="list-style-type: none"> • Freedom of information Act • SA Information Privacy Principles • Code of Conduct for Public Sector Employees • Information Privacy Principles Instruction Occupational Health Safety and Welfare Act • Workers Rehabilitation and Compensation Act • AS/NZS 4360:2004 Risk Management Standard • Equal Opportunity Act • Health Care Act 2008
Improving nursing and patient/client care procedures and practices;	<ul style="list-style-type: none"> > Provide direct nursing care and/or individual clinical trial case management to patient/trial subjects on a day to day basis in the Department of Respiratory and Sleep Medicine > Within the various study protocol requirements, assess individual patient/subject needs, plan and implement or coordinate appropriate service delivery from a range of accepted options; > Provide health education, counselling and/or therapeutic/rehabilitation programs to improve the health outcomes of individual patient/subjects or groups; > In accordance with study protocols, plan and coordinate services with other disciplines or agencies in providing individual's health care needs and meeting protocol investigations; > Contribute to patient/subject safety, risk minimisation and safe work activities within the practice setting; > Practice as a Registered Nurse within a nursing model established to support patient/subject centred care; > Contribute to procedures for effectively dealing with people exhibiting challenging behaviours > Participate in quality assurance and/or evaluative research activities within practice setting; > Use foundation theoretical knowledge and evidence based guidelines and apply these to a range of activities to achieve agreed patient/client care outcomes; >
Contributing to the human resource management of the Respiratory Clinical Research unit/service by;	<ul style="list-style-type: none"> > Review decisions, assessments and recommendations from less experienced Registered Nurses and Enrolled Nurses and students > Provide support and guidance to newer or less experienced staff, Enrolled Nurses student nurses and other workers providing basic nursing care; > Support nursing practice learning experiences for students undertaking clinical placements, orientation for new staff and preceptorship of graduates; > Manage and coordinate vacancy management for ongoing and new Respiratory Clinical Research staff members, following the SALHN Vacancy Management policy as Hiring Manager > Providing adequate supervision, regular performance development planning and staff development opportunities including resolution of conflicts and addressing disciplinary matters as these occur, following Public Sector Act and SALHN Policies
Contributes to the achievement of professional expertise through the maintenance of ongoing personal professional development/continuing	<p>Continue own professional development, seek learning opportunities and develop and maintain own professional development portfolio of learning and experience.</p>

education:	
To provide competent care to Clients/Patients in the course of their involvement in clinical trials in a caring, cost-effective and timely manner;	<ul style="list-style-type: none"> > Assist with the preparation and submission of research protocols for clinical trials; > Assist with patient recruitment/information for clinical trials; > Assist with collection of data and maintenance of trial records > Interact with patients to collect data specimens, monitor response or any other clinical information related to clinical trials; > Be involved in new trial development through participation in trial development meetings; > Ensure that research is conducted in accordance with clinical research guidelines and requirements of the Flinders Clinical Research Ethics Committee; > Complete documentation according to policy; > Collaborate with medical staff and members of other disciplines to provide patient/client care; > Provide information which assists patients/clients to make informed decisions about their care in accordance with their differing values, beliefs and biases; > Maintain the patient's/client's comfort and dignity and safeguarding his/her personal privacy; > Maintain confidentiality in matters relating to patients/clients and staff; > Actively participate as a member of the unit team by applying appropriate interpersonal and communication skills and effectively participating and contributing as a member of the clinical unit.

Acknowledged by Occupant:_____ Date:____/____/____

Knowledge, Skills and Experience

ESSENTIAL MINIMUM REQUIREMENTS

Educational/Vocational Qualifications

- > Registered or eligible for registration as a Nurse by the Nursing and Midwifery Board of Australia, and who holds, or who is eligible to hold, a current practicing certificate
- > Post Graduate qualification in research, health counselling, epidemiology or similar
- > Completed Certificate in Good Clinical Practice

Personal Abilities/Aptitudes/Skills:

- > Punctual and trustworthy
- > Demonstrated ability to evaluate, review and discuss clinical trial protocols with external sponsor companies and principle investigators
- > Ability to communicate effectively verbally and in writing with staff at all levels including external sponsor companies, clients and other agencies
- > Proven ability to take initiative, problem solve, manage competing priorities effectively, multi task and work with professional independence
- > Ability to build and nurture partnerships with external sponsor companies, other groups and service providers
- > Demonstrated design, production and implementation of creative recruitment campaigns to facilitate and encourage patient participation and retention of trial participants
- > ***“Demonstrated commitment to the principles and practices of Equal Employment Opportunity and Ethical Conduct, and an understanding of, experience in, and ability to manage to the spirit and principles of the Premier’s Safety Commitment and the legislative requirements of the Work Health & Safety Act 2012, utilising AS/NZS 4360 Risk Management, or to an equivalent set of standards.”***

Experience

- > Proven experience in basic computing skills, including email and word processing
- > Experience in effectively leading, managing and supervising a multi-disciplinary team and allocating work according to priorities and deadlines
- > Extensive clinical research experience

Knowledge

- > Working knowledge of commonly used trial specific information technology and computing programs.
- > Sound knowledge of Work Health Safety principles and procedures
- > Sound knowledge of Quality Management principles and procedures
- > Understanding of delegated safety roles and responsibilities
- > Understanding of the Charter of Health and Community Services rights.
- > Knowledge of National Safety and Quality Health Service Standards
- > Working knowledge of Microsoft Applications

DESIRABLE CHARACTERISTICS

Educational/Vocational Qualifications

- > Relevant post graduate qualifications

Experience

- > Extensive use of paper and electronic case record files to accurately provide the required information relating to protocol outcomes in a timely manner

Knowledge

- > Nil

Organisational Context

Organisational Overview:

Our mission at SA Health is to lead and deliver a comprehensive and sustainable health system that aims to ensure healthier, longer and better lives for all South Australians. We will achieve our objectives by strengthening primary health care, enhancing hospital care, reforming mental health care and improving the health of Aboriginal people.

SA Health is committed to a health system that produces positive health outcomes by focusing on health promotion, illness prevention and early intervention. We will work with other government agencies and the community to address the environmental, socioeconomic, biological and behavioural determinants of health, and to achieve equitable health outcomes for all South Australians.

Our Legal Entities:

SA Health is the brand name for the health portfolio of services and agencies responsible to the Minister for Health and Ageing and the Minister for Mental Health and Substance Abuse.

The legal entities include but are not limited to Department for Health and Ageing, Central Adelaide Local Health Network, Northern Adelaide Local Health Network, Southern Adelaide Local Health Network, Women's and Children's Health Network, Country Health SA Local Health Network and SA Ambulance Service.

SA Health Challenges:

The health system is facing the challenges of an ageing population, increased incidence of chronic disease, workforce shortages, and ageing infrastructure. The SA Health Care Plan has been developed to meet these challenges and ensure South Australian's have access to the best available health care in hospitals, health care centres and through GPs and other providers.

Health Network/ Division/ Department:

The Southern Adelaide Local Health Network (LHN), provides care for around 341,000 people living in the Southern Metropolitan area of Adelaide as well as providing a number of state-wide services, and services to those regional areas. More than 7,000 skilled staff provides high quality patient care, education, research and health promoting services.

Southern Adelaide LHN provides a range of acute and sub acute health services for people of all ages, and has two hospitals, Flinders Medical Centres and Noarlunga Hospital.

Southern Adelaide LHN Intermediate Care Services will deliver multi-disciplinary clinical care, addressing complexity through targeted approaches to complex chronic disease management in the community, and supported hospital discharge and avoidance programs. There is a key focus on building partnerships across the care continuum supporting interfaces between acute sites, GPs, Primary Care and Community based services.

Mental Health Services provides a range of integrated services across community and hospital settings, targeted at all age groups, in collaboration with non-Government organisations and General Practice Network South

Values

SA Health Values

The values of SA Health are used to indicate the type of conduct required by our employees and the conduct that our customers can expect from our health service:

- > We are committed to the values of integrity, respect and accountability.
- > We value care, excellence, innovation, creativity, leadership and equity in health care provision and health outcomes.
- > We demonstrate our values in our interactions with others in SA Health, the community, and those for whom we care.

Code of Ethics

The Code of Ethics for the South Australian Public Sector provides an ethical framework for the public sector and applies to all public service employees; it sets out the South Australian Public Sector values as:

- > Service – Proudly serve the community and Government of South Australia.
- > Professionalism – Strive for excellence.
- > Trust – Have confidence in the ability of others.
- > Respect – Value every individual.
- > Collaboration & engagement – Create solutions together.
- > Honesty & integrity – Act truthfully, consistently, and fairly.
- > Courage & tenacity- Never give up.
- > Sustainability – Work to get the best results for current and future generations of South Australians.

The Code recognises that some public sector employees are also bound by codes of conduct relevant to their profession.

Domestic and Family Violence

The Southern Adelaide Local Health Network (SALHN) recognises the devastating impact domestic or family violence can have on the lives, of those who experience abuse and are committed to supporting employees who experience domestic or family violence by providing a workplace environment that provides flexibility and supports their safety.

SALHN Vision

We believe in providing the standard of health care that we desire for our own families and friends.

SALHN core value TRUST

Building positive relationships; with our patients, employees and partners.

Approvals

Job and Person Specification Approval

I acknowledge that the role I currently occupy has the delegated authority to authorise this document.

Name:

Role Title:

Signature:

Date:

Role Acceptance

Incumbent Acceptance

I have read and understand the responsibilities associated with role, the role and organisational context and the values of SA Health as described within this document.

Name:

Signature:

Date: