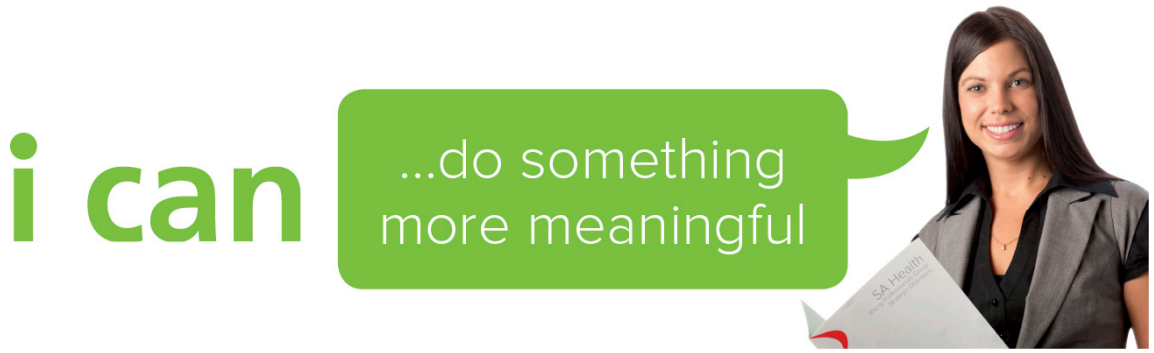

SA Health Job Pack

Job Title	Research - Clinical Trials Coordinator
Eligibility	Open to everyone
Job Number	719137
Applications Closing Date	3/7/20
Region / Division	Central Adelaide Local Health Network
Health Service	The Royal Adelaide Hospital
Location	Adelaide
Classification	PO-1
Job Status	More than one position. Full-time temporary positions up to 12 months
Total Indicative Remuneration	$71,596/ $87,209

Contact Details

Full name	Loredana Sterian
Phone number	7074 2341
Email address	Loredana.sterian@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:

- ☐ Working with Children Screening - **DHS**
- ☒ Vulnerable Person-Related Employment Screening - **NPC**
- ☐ Aged Care Sector Employment Screening - **NPC**
- ☐ General Employment Probity Check - **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 B (indirect 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 B (indirect 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

Government of South Australia
SA Health

ROLE DESCRIPTION

Role Title:	Clinical Trials Coordinator
Classification Code:	PO1
LHN/ HN/ SAAS/ DHW:	CALHN
Hospital/ Service/ Cluster:	Royal Adelaide Hospital
Division:	Cancer
Department/Section / Unit/ Ward:	Cancer Clinical Trials
Role reports to:	Clinical Trials Manager
Role Created/ Reviewed Date:	June 2019
Criminal and Relevant History Screening:	☐ Aged (NPC) ☐ Working With Children's Check (WWCC) (DHS) X Vulnerable (NPC) ☐ General Probity (NPC)
Immunisation Risk Category Requirements:	☐ Category A (direct contact with blood or body substances) X Category B (indirect contact with blood or body substances) ☐ Category C (minimal patient contact)

ROLE CONTEXT

Primary Objective(s) of role:

- The Clinical Trials Coordinator coordinates all Phases of clinical trials conducted by the Royal Adelaide Hospital Cancer Clinical Trials Unit, including assisting in the HREC, Governance and operational functions associated with their assigned trials, in accordance with Good Clinical Research Practice (GCRP), NHMRC guidelines and standard operational procedures (SOPs) in conjunction with the Investigator and the Clinical Trials Manager.

- In this capacity the Clinical Trials Coordinator contributes operational expertise to the coordination and implementation of research and administrative strategies that are essential to the successful management of clinical trials research conducted by the Cancer Clinical Trials Unit. This involves the conduct of a range of functions, including, but not limited to: managing the documentation and compilation of clinical research data, and providing operational support for the delivery of clinical trial submissions, reporting, and other approval requests that are required by Lead Ethics Committee and CALHN Research Governance Office.

- The Clinical Trials Coordinator coordinates the screening procedures for study entry and subsequent randomisation/registration to the study. Duties include but are not limited to: the discussion of study logistics with participants, the coordination of participant appointments and clinical follow-up ensuring protocol compliance, the close monitoring of participants while on study, the collection of source data and test results and the input of data into participant case report forms, the collation and processing of specimens and the immediate reporting of serious adverse events.

- In addition to the above, the Clinical Trials Coordinator may be involved in the conduct of early phase studies and assist in their planning and implementation within the unit. This may involve participation in regular teleconferences with sponsors, clinical research organisations and other investigative sites.

- The Clinical Trials Coordinator assists with the training of all staff involved with their assigned trials

undertaken by the Clinical Trials Unit.

Direct Reports:

N/A

Key Relationships/ Interactions:

Internal

- Works collaboratively with staff and all members of the health care team.
- Contributes to the day to day operations of the Unit.

External

- Patients/carers/parents who are the research subjects.
- Relevant government and non-government organisations as required, to meet the needs of the client.

Challenges associated with Role:

Major challenges currently associated with the role include:

- Coordinating the operational conduct of effective clinical research functions, and working efficiently to strict timelines, which underpin the achievement of Unit goals within a complex, diverse and politically sensitive environment.
- Contributing to the ongoing maintenance of internal and external relationships that underpin the work of the Unit.
- Working with a high level of personal integrity and motivation, and supporting the maintenance of a positive, collaborative team.

Delegations:

- Nil

Key Result Area and Responsibilities

Key Result Areas	Major Responsibilities
Contribute to professional coordination for the operation of clinical trials that provide knowledge for the advancement of scientific research in relation to treatments for patients by:	> Contributing to professional input for the planning, implementation and conduct of trial protocols including but not limited to coordinating clinical trial subject's assessments required by study protocol and ensuring that relevant government, hospital and trial guidelines, protocols and policy are met. Undertaking maintenance of accurate and complete documentation, including but not limited to, regulatory documents, signed informed consent forms, relevant HREC approvals and submission of updated Protocols, Investigator Brochures and Patient Information and Consent Forms when required,, SAE reporting, and other approval requests that are required by the Lead Ethics Committee and CALHN Research Governance Office. > Providing professional support to the Clinical Trials Manager in the delivery of clinical trial submissions, reporting, and other approval requests that are required by the Lead Ethics Committee and CALHN Research Governance Office. > Coordinating the sourcing and recording of trial data, including ensuring the maintenance of data quality and accuracy to audit standards and undertaking the effective management of medical notes associated with the trials. > Being responsible for the coordination of the collection of pharmacokinetic and central laboratory blood samples and the centrifuging, packaging, storage of these samples within the protocol guidelines and in accordance with CASA Regulations. > Liaising with medical, nursing, technical and administrative staff when required or study purposes. > Communicating with study sponsors and clinical research associates (CRA) as required. > Coordinating preparations for the external audits of trials, as required, and maintaining appropriate reporting schedules and outcomes to ensure the achievement of all required objectives and targets.
Contributes to, and promotes a planned, integrated and outcomes focused approach to the delivery of high quality care whilst contributing to the day to day conduct of clinical trials by:	> Ensuring that own care professional delivery is consistent with the Unit/department and corporate objectives, philosophies, policies and procedures, including reprioritising activities in response to sudden changes in the care delivery context, and undertaking the continuous evaluation and reassessment of the outcomes of care. > Ensuring that trial requirements are effectively integrated into total patient management, and that protocols are effectively implemented, including liaising with medical, allied health and clerical/administrative staff to implement planned, systematic processes to specific protocols, and ensuring that subjects retain their dignity, comfort and safety. > Implementing and maintaining timely, accurate and appropriate verbal and written communication processes to facilitate effective working relationships that support the Unit's agreed model of care delivery. > Promoting the improvement of patient outcomes and recovery processes, including assisting in the development and delivery of research projects, policy and practice guidelines as required.
Contributes to the provision of professional advice and support, and the maintenance of effective relationships and networks by:	> Contributing to the maintenance and expansion of existing research networks, information-sharing and the building of research capacity across the Unit. > Liaising effectively with Unit stakeholders, including researchers in other agencies, and participate in a range of assigned seminars and meetings to support the research objectives of the Unit.

	> Preparing clear and professional advice, briefings, reports and presentations, as directed, to support future planning and directions for research and evaluation across the Unit.
Contributes to a safe and ethical working environment by:	> Ensuring that the work undertaken within the Unit complies with human ethics, animal ethics, privacy and other appropriate guidelines. > Ensuring ongoing compliance with relevant legislation, policies and guidelines, including reporting all incidents, supporting a pro-active approach to risk management, undertaking preventive behaviours and processes, and supporting positive ways to manage work pressures. Ensure that the work undertaken within the Unit complies with institutional and State Government policies on records management, reporting and intellectual property. > Ensuring the ongoing maintenance of the confidentiality of research proposals and research findings within the Unit. > Ensuring that staff and other persons in their work areas are safe from risks to health and safety by carrying out responsibilities as detailed in organisational occupational health, safety and injury management (OHSM&IM) policies and procedures, and implementing and monitoring relevant OHS&IM policies and procedures within their work area.
Contributes to the effective organisation, operation and continual improvement of the Unit's research programs and objectives by:	> Contributing to the Unit's research and evaluation functions and the identification of associated trends, issues and resources that inform Unit research programs and initiatives by participating in relevant continuous Quality Assurance and Improvement activities. > Work under close supervision to contribute to the implementation, review and maintenance of guidelines, plans, processes and systems, to support the achievement of ongoing standards of rigor and relevance across all evaluations and research conducted. > Support assigned research projects, including for the preparation of reports on research findings and a range of relevant data, information and advice from tertiary institutions, networks and other sources. > Provide assistance to other staff members, as required, to support the effective determination of priorities, and the achievement of the Unit's programs and quality and performance objectives. > Monitor and update systems, processes and procedures as directed, to support effective knowledge management, information-sharing and continuous improvement.

Knowledge, Skills and Experience

ESSENTIAL MINIMUM REQUIREMENTS

Educational/Vocational Qualifications

- An appropriate degree or higher qualification in a Health Sciences field or other relevant discipline.

Personal Abilities/Aptitudes/Skills

- Proven ability to work under limited professional direction, either autonomously, or in a team environment, and to deliver on performance objectives, plan activities and meet priorities, and to utilise an enthusiasm for acquiring knowledge in order to effectively analyse and resolve problems in a clear, innovative and resourceful manner.
- Demonstrated interpersonal and communication skills to support the involvement and co-operation of, and liaise and consult and negotiate with, a range of stakeholders, and provide timely, professional and responsive advice, reports and briefings.
- Demonstrated ability to work effectively under pressure.

Experience

- Well-developed experience in using computers and database packages for the recording, analysis and communication of information and data.
- Experience in contributing to, or undertaking, projects to support the delivery of research objectives.

Knowledge

- Proven knowledge of clinical research procedures, and guidelines for compliance with safety, risk management and equal opportunity, particularly within a specific field that is relevant to the assigned operational area.
- Well-developed knowledge of computer based information systems and their application within the clinical research and health fields.
- Proven knowledge of medical terminology, records practice and procedures, confidentiality standards and good clinical research practice.
- Knowledge and understanding of GCRP and ICH Guidelines and the Declaration of Helsinki.

DESIRABLE CHARACTERISTICS

Educational/Vocational Qualifications

- An honours or higher degree involving a research component.

Experience

- Demonstrated experience in working within a cancer care environment.
- Experience in coordinating clinical trials.

Knowledge

- Knowledge of state, national and international clinical research and health structures, systems, policies and procedures, and the inter-relationship of various hospital divisions and departments.

Special Conditions:

- It is mandatory that no person, whether or not already working in SA Health, may be appointed to a position in SA Health unless they have provided the a satisfactory current Criminal and Relevant History Screening, as required by the *SA Health Criminal and Relevant History Screening Policy Directive*.
- *For appointment in a Prescribed Position* under the *Child Safety (Prohibited Persons) Act (2016),* a current Working with Children Check (WWCC) is required from the Department for Human Services Screening Unit. For other positions, a satisfactory National Police Certificate (NPC) assessment is required.
- For *'Prescribed Positions'* under the *Child Safety (Prohibited Persons) Act (2016),* the individual's WWCCs must be renewed every 5 years from the date of issue; and for '*Approved Aged Care Provider Positions*' every 3 years from date of issue as required by the *Accountability Principles 2014* issued pursuant to the *Aged Care Act 1997* (Cth).
- Appointment is subject to immunisation risk category requirements. 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.
- Some out of hours work may be required to meet the needs of the clinical trials Unit. Interstate or overseas travel to attend meetings concerning clinical trials may be required.

General Requirements:

Managers and staff are required to work in accordance with the Code of Ethics for South Australian Public Sector, Directives, Determinations and Guidelines, 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 by the *Immunisation for Health Care Workers in South Australia Policy Directive.*
- Equal Employment Opportunities (including prevention of bullying, harassment and intimidation).
- *Children and Young People (Safety) Act 2017* (SA) 'Notification of Abuse or Neglect'.
- Disability Discrimination.
- *Independent Commissioner Against Corruption Act 2012* (SA).
- *Information Privacy Principles Instruction.*
- 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.

The SA Health workforce contributes to the safety and quality of patient care by adhering to the South Australian Charter of Health Care Rights, understanding the intent of the National Safety and Quality Health Service Standards and participating in quality improvement activities as necessary.

Performance Development:
The incumbent will be required to participate in the organisation's Performance Review and 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.

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.

White Ribbon:
SA Health has a position of zero tolerance towards men's violence against women in the workplace and the broader community. In accordance with this, the incumbent must at all times act in a manner that is non-threatening, courteous, and respectful and will comply with any instructions, policies, procedures or guidelines issued by SA Health regarding acceptable workplace behaviour.

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

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 Wellbeing. The Department for Health and Wellbeing is an administrative unit under the Public Sector Act 2009.

The legal entities include but are not limited to the Central Adelaide Local Health Network Inc., Northern Adelaide Local Health Network Inc., Southern Adelaide Local Health Network Inc., Women's and Children's Health Network Inc., Barossa Hills Fleurieu Local Health Network Inc., Eyre and far North Local Health Network Inc., Flinders and Upper North Local Health Network Inc., Limestone Coast Local Health Network Inc., Riverland Mallee Coorong Local Health Network Inc., Yorke and Northern Local Health Network Inc.and SA Ambulance Service Inc.

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:

Central Adelaide Local Health Network:

Central Adelaide LHN is responsible for promoting and improving the health of central metropolitan Adelaide and the broader community by providing integrated health care and hospital services. Central Adelaide LHN brings together the hospitals of (Royal Adelaide Hospital [RAH] as a major tertiary facility, The Queen Elizabeth Hospital [TQEH] as a general hospital, and our rehabilitation hospitals Hampstead Rehabilitation Centre [HRC] and St Margaret's Rehabilitation Hospital [SMRH]), and a significant number of mental health and primary health care services. Central Adelaide LHN also governs a number of statewide services including SA Dental Service, SA Prison Health Service, BreastScreen SA and DonateLife SA, and has financial administrative responsibility for Statewide Clinical Support Services incorporating SA Pathology, SA Medical Imaging and SA Pharmacy.

The Royal Adelaide Hospital (RAH) Cancer clinical Trials Unit conducts clinical and translational research in most types of cancer. Led by Professor Michael P. Brown, the unit has an extensive portfolio of over 40 active clinical trials in medical oncology, radiation oncology and supportive care in cancer. These clinical trials are conducted in all phases of cancer therapeutic research, which include Phase 1 (for safety), Phase 2 (for efficacy), Phase 3 (for comparison with standard treatment), and Phase 4 (in post-marketing setting).

The RAH Cancer Clinical Trials Unit has specialist experience and expertise in conducting Phase 1 clinical trials, which are often first time use of new anti-cancer drugs in humans. Clinical trials for new anti-cancer drugs are generally supported by pharmaceutical companies and some of the trails are sponsored by national or international co-operative study groups, which are often disease focused professional associations, or through competitively awarded research grant.

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:

- Democratic Values - Helping the government, under the law to serve the people of South Australia.
- Service, Respect and Courtesy - Serving the people of South Australia.
- Honesty and Integrity- Acting at all times in such a way as to uphold the public trust.
- Accountability- Holding ourselves accountable for everything we do.
- Professional Conduct Standards- Exhibiting the highest standards of professional conduct.

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

Approvals

Role Description 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 understood the responsibilities associated with role, the organisational context and the values of SA Health as outlined within this document.

Name: **Signature:** **Date:**