University of the Sunshine Coast Australia

POSITION DESCRIPTION

Position:	6594 Senior Clinical Trials Coordinator
Work Area:	UniSC Clinical Trials
Classification:	Level 7
Supervisor:	4653 Clinical Trials Operations Manager
Incumbent:	Vacant

VISION

To become Australia's premier regional university.

MISSION

Enriching our regions, connecting with our communities and creating opportunities for all.

VALUES

At UniSC we will:

- Advocate for equitable access to education and knowledge
- Recognise and embrace diversity and inclusion
- Champion environmental sustainable principles and practices
- Commit to fair and ethical behaviour
- Respect our people, our communities, and their potential
- Be accountable to ourselves and each other
- Strive for excellence and innovation in all that we do

OVERVIEW OF UNISC CLINICAL TRIALS

UniSC has established a world class Clinical Trials (CT) which builds the region's collective clinical research capacity and delivers innovative and regionally relevant research in consultation with key stakeholders, including local healthcare professionals, pharmaceutical executives, regulatory bodies, ethics and governance, vendors, and other key thought leaders.

PRIMARY OBJECTIVES OF THE POSITION

1. Apply clinical trial expertise to manage the implementation and conduct of clinical research, and designated clinical trial teams, in accordance with the appropriate quality standards including International Conference on Harmonization (ICH)/Good Clinical Practice (GCP), UniSC CT's standard operation procedures (SOPs), and applicable regulations, rules and guidance.
2. Collaborate with the CT's team and sponsors to monitor and ensure the successful conduct and timely completion of clinical trials.

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NATURE AND SCOPE OF POSITION

Under the broad direction of the Clinical Trials Operations Manager, UniSC Clinical Trials, the position is responsible for leadership and guidance of assigned clinical trial teams to ensure the clinical trials designated to them are conducted in accordance with the appropriate quality standards including ICH/GCP, UniSC CT SOPs, and applicable regulations, rules and guidance. The position autonomously performs diverse high-level trial coordination duties requiring independent analysis, problem solving, sound judgment, innovation, and extensive knowledge of clinical research procedures to achieve assigned objectives.

KEY ACCOUNTABILTIES OF THE POSITION

1. Provide high-level clinical research expertise to manage the conduct of assigned research studies from study start-up through to close-out and archiving.
2. Lead allocated and multiple clinical trials simultaneously, and manage multiple Principal Investigator relationships, ensuring full compliance with local, state, and federal policies and procedures.
3. Supervision of assigned project teams including Clinical Trial Coordinators and Investigators.
4. Utilise expert knowledge to provide solutions to complex problems that impact the timely and accurate conduct of designated clinical trials.
5. Serve as the liaison with the sponsor and third-party vendors for assigned studies.
6. Provide high-level administrative support for designated research projects and programs, including maintaining/using relevant information systems, databases, and record-keeping systems.
7. Support the orientation and aid with training and ongoing development of new Clinical Trial Coordinators and Nurses.
8. Make high-level contributions to the planning, management and effective implementation of continuous improvement activities relating to relevant practices, protocols, quality assurance standards and customer service excellence.

KNOWLEDGE SKILLS AND EXPERIENCE NECESSARY

Applicants need to demonstrate they meet the following **Selection Criteria**:

1. Completion of a degree in Health Science/Nursing/Bio Medical and extensive relevant experience as a Clinical Trial Coordinator/Research Nurse or similar, or an equivalent combination of experience and/or education/training. Registered Nurses must have current registration with AHPRA and meet the Nursing and Midwifery Board of Australia professional standards.
2. Demonstrated experience, expertise, and broad knowledge in ethics/regulatory affairs frameworks.
3. Detailed knowledge of clinical research practices, including an understanding of the contractual and ethical obligations of clinical trials, and ICH Good Clinical Practice and applicable regulations.
4. High level computing skills (including databases, clinical trial electronic data entry, word processing and spreadsheets).

5. Sound understanding of privacy principals governing health information.
6. Demonstrated ability to work independently as well as collaboratively with peers, colleagues, and other team members.
7. Ability to be flexible to travel to differing site locations

Additional Requirements

It is a condition of employment for this position that you may be required to provide periodic evidence of immunisation against communicable diseases. This may include COVID-19.

Additionally, in accordance with UniSC's Staff Code of Conduct – Governing Policy, all staff are expected to display professional behaviour, communicate respectfully, and perform their duties responsibly.

A position description is not intended to limit the scope of a position but to highlight the key aspects of the position. The requirements of the position may be altered in order to meet the changing operational needs of UniSC.

UniSC is committed to creating a work and study environment that values diversity, facilitates equitable access and full participation.