



## POSITION DESCRIPTION

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<b>Position:</b>	7038 Clinical Trials Contracts Administrator
<b>Work Area:</b>	UniSC Clinical Trials
<b>Classification:</b>	Level 5
<b>Supervisor:</b>	4660 Regulatory and Start-Up Manager
<b>Incumbent:</b>	Vacant

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### 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. Assist in the triage of clinical trials contracts and agreements to assess requirements for due diligence and administrative contracts management.
2. Support the governance required for clinical trials contracts and agreements from initial negotiation with external partners to execution.
3. Ensure researchers comply with internal requirements and understand the contractual milestones and other key obligations.



## NATURE AND SCOPE OF POSITION

Under general direction of the Regulatory and Start-Up Manager and routine supervision of the Regulatory and Contracts Specialist, the Clinical Trials Contracts Administrator supports the provision of all aspects of UniSC Clinical Trials ('UniSC CT') contracts administration. This will include assisting in conducting due diligence, governance processes and liaising with stakeholders, both internal (BD and Finance) and external (Sponsors, CROs, third party vendors) to support the negotiation and finalisation of all aspects of UniSC CT contracts, to manage risk to UniSC and facilitate clinical trials.

## KEY ACCOUNTABILITIES OF THE POSITION

1. Provide comprehensive administrative support to finalise UniSC CT's contracts and agreements, facilitate internal approval and circulate for execution using the Adobesign electronic signature platform.
2. Support maintenance of the UniSC Clinical Trials contract template library, including liaising with UniSC Legal to update contract templates as appropriate.
3. Support the maintenance of the UniSC Clinical Trials Contract Management System (CMS), including CDAs, research contracts and third-party agreements.
4. Perform due diligence review of contracts and agreements, and where appropriate, make requests to UniSC Legal for their review.
5. Identify potential risks to ensure that contract conditions are not detrimental to UniSC and UniSC CT interests and that successful contract outcomes and clinical trial research are achieved.
6. Liaise with internal and external stakeholders to ensure efficient, timely, pragmatic, and compliant approvals and execution of UniSC CT contracts and agreements. Act as a point of contact for the UniSC CT Finance Team for queries related to invoicing and payment terms.
7. Contribute to the review, development and implementation of standard operating procedures and work instructions in line with UniSC policies and procedures, ICH Good Clinical Practice (GCP), the NHMRC guidance and other relevant legislation and guidance. Undertake administrative tasks such as the production and distribution of correspondence, reports and/or presentations relating to contract management, administration, and performance of the Regulatory and Start-Up team.
8. Contribute to a positive and safe work environment for you and others, by modelling and promoting conduct that is culturally capable, inclusive, respectful, and ethical.

## KNOWLEDGE SKILLS AND EXPERIENCE NECESSARY

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

1. Completion of a degree, or an associate diploma with at least two years subsequent experience or an equivalent alternate combination of relevant knowledge, training and experience.
2. Sound knowledge of ICH GCP and applicable regulations.
3. Excellent written and verbal communication skills combined with strong attention to detail.
4. Sound understanding of privacy principals governing health information.



5. Ability to work independently and as part of a team.
6. High level of digital literacy (including databases, Microsoft Word and Excel).

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.***