

POSITION TITLE	Clinical Trials Assistant (Targeted)
JOB PROFILE ID	RST_HEO5_SJP_02
JOB CATEGORY	Professional
JOB FAMILY	Research Support
COMPENSATION GRADE	HEO5
MANAGEMENT LEVEL	19 Individual Contributor

POSITION DESCRIPTION SUMMARY

The Clinical Trials Assistant (Targeted) works as part of the clinical trials research team in a support role to perform general administrative duties under direction, for one or more concurrent clinical trial projects. Tasks include preparing documents, maintaining records, data entry, updating and collating materials, responding to queries, exploring and sourcing solutions for NHMRC CTC trial team, managers, central services and collaborative groups, as required. This role requires strong administrative and organisational skills to coordinate and undertake a range of operational activities on an ongoing basis.

DECISION MAKING AND DELEGATIONS OF AUTHORITY

Responsible for the day-to-day administrative functions associated with Clinical Trials. Responsible for the design and implementation of systems and databases and developing work procedures for implementation under the general direction of the Trial Operations Coordinator and Research Operations Lead. Works within standard guidelines, policy and precedence and has the capacity to adapt and refine them to meet CTC needs. Works autonomously within agreed parameters.

This is a Targeted Aboriginal and Torres Strait Islander Position. Preference will be given to applicants of Aboriginal and Torres Strait Islander descent. This Exemption is claimed under Section 21 of the Anti-Discrimination Act 1977.

KEY RELATIONSHIPS

Relationships	Position Title
Supervisor	0103262 Project Manager - Clinical Trials - Ms Ellen Gao
Direct Reports	
Peer Relationships	Refer to the organisational charts in Workday to view peer relationships relevant to your role. Please Note- This option is only available to University staff.

RESPONSIBILITY DESCRIPTION

1. Provide high level administrative services and operational support to the work area.

- Complete office duties including telephone and email communication with sites and study personnel, document collation and distribution, general and study/participant/site filing, photocopying, scanning and/or electronic filing, mailing and maintaining stationery supplies.
- Deliver daily administration activities and services ensuring that high quality and efficient administrative support is provided in a pro-active manner to staff, clients and visitors.
- Review, updates and maintains relevant online/website content
- Conduct administrative functions associated with meetings including development and collation of materials, set-up of venue and organisation of catering, taking minutes of meetings, organising teleconferences, etc.
- Word-processing of correspondence, reports and documents associated with the role or group and according to SOPs/templates.
- Analyse incoming correspondence, independently initiates appropriate action where possible and/or ensure the matter is forwarded appropriately to the relevant individual/specialist for resolution.
- Proactively identify administrative issues and suggests solutions for improvement. Explores administrative matters and prepares advice, recommendations and solutions related to specific projects, policies and operational issues, identifying and ensuring all relevant initiation and/or followup of necessary action under broad direction from more senior staff.

2. Provide Centre specific administration services and support.

- Develop, prepare, reconcile and distribute trial documentation, equipment and other study related materials in accordance with CTC SOP's (particularly Trial Master File, site materials, trial supplies and others). Track and report on status of materials.
- Assist in the development, distribution and tracking of documentation for ethics and regulatory submissions, including safety data. Track, enter, process and file, study data using relevant project tracking tools and systems.
- Maintain and regularly update lists and tracking tools in accordance with SOP's, related to study recruitment, trial supplies (including investigational product) and site contacts (including Principal Investigators, Data Managers and Pharmacists)
- File, inspect and archive trial and study-related materials according to relevant SOPs and study timelines.
- Assist with the development, data entry and monitoring of database systems and participant data collection forms from a range of sites, in accordance with trial requirements.
- Updates databases, extracts and issues regular reports following established procedures.
- Tracks and processes payment of study sites and invoices, where required, in liaison with the Trial Operations Coordinator and Project Manager.

3. Commitment to training and development

- Maintain and improve on GCP knowledge of clinical trials through SOP, self-learning, participation at CTC seminars and mandatory in-house training appropriate to the role of CTA.

4. Undertake ad-hoc projects and other activities.

- Perform work activities relevant to the role's key accountabilities as approved by the Manager and commensurate to the role's classification level.

EDUCATION

Education
Bachelor's Degree - In a relevant field
Other - An equivalent combination of relevant training and experience

Only one Field of Study needs to apply. The Education requirements should be considered in conjunction with the Work Experience requirements.

CERTIFICATIONS

Certifications

SKILLS

Skills
Ability to Communicate Effectively
Attention to Detail.
Computer Literacy.
Customer Service..
Data Analysis
Organisation and Time Management.
Research Software
Teamwork and Collaboration.

WORK EXPERIENCE

Work Experience
Clinical trial management.
Knowledge of ICH Guidelines and Good Clinical Practice.
Supporting clinical trials
Working in a research-intensive environment.

CAPABILITIES

Priority Core Capability	Behavioural Indicators *FOU – Foundational, *INT – Intermediate, *ADV – Advanced, *EXP – Expert	Level
Communicates with impact	Interacts with others clearly and effectively, using respectful verbal and non-verbal communication for the benefit of our students, staff and the communities we serve	FOU
Responds to changing contexts	Anticipates and monitors demand and develops considered responses to continually improve student, staff and community outcomes	FOU
Thinks and solves problems	Makes informed and considered decisions by thinking critically and comprehensively to progress and enhance outcomes for the University.	FOU
Priority Professional Capability	Behavioural Indicators *FOU – Foundational, *INT – Intermediate, *ADV – Advanced, *EXP – Expert	Level
Actively manages opportunities, risks and issues	Actively manages opportunities, potential risks and uncertainties to achieving the strategic objectives of the University.	FOU



Priority Professional Capability	Behavioural Indicators *FOU – Foundational, *INT – Intermediate, *ADV – Advanced, *EXP – Expert	Level
Delivers service excellence	Understands customer needs and wants, both now and in the future, to agree, meet and manage service expectations and deliver an excellent service experience for University staff, students and the community.	FOU
Enables compliance and integrity	Cultivates an environment in which students and staff act with integrity and comply with relevant laws, regulations and policies applicable to the University.	FOU
Fosters strong partnerships	Develops, sustains and strengthens internal and external relationships for the betterment of the University.	FOU
Negotiates effectively	Understands own and others needs to communicate professionally and openly, making appropriate trade-offs to reach optimal outcomes for the University	FOU
Seeks insights to inform decisions	Gathers, consolidates and evaluates a range of information to uncover key insights and inform business decisions across the University.	FOU
Understands the nature of research	Understands the nature of research work, research timeframes, the legislative and funding environment and navigating this landscape to support staff to deliver on the research objectives of the University.	FOU
Core Capability	Behavioural Indicators *FOU – Foundational, *INT – Intermediate, *ADV – Advanced, *EXP – Expert	Level
Acts responsibly	Understands constraints and works to optimise value for the University by balancing safety, sustainability, risk, opportunity, and finite resources to deliver, directly or indirectly, on the objectives of the University.	FOU
Acts with courage, respect and integrity	Acts with honesty, demonstrating ethical and professional behaviour, with the courage to speak up for respect and integrity.	FOU
Collaborates with others	Builds networks, models collaboration and works effectively with others to encourage inclusivity and impact.	FOU
Contributes to the University	Shows an appreciation of the higher education sector and role of the University in the local and international community, supporting the University's strategy of excellence in research, education, engagement and student experience.	FOU
Displays adaptability	Remains committed and persistent in the pursuit of goals, maintaining composure and professionalism, regardless of changing circumstances.	FOU
Displays cross-cultural understanding	Collaborates in an inclusive way demonstrating an understanding of cultural differences and how our views can shape the way we operate.	FOU
Excels in discipline, field or profession	Strives to develop and improve own proficiency and profile in areas of focus, creating a positive impact for the University.	FOU
Strives to learn	Exhibits a commitment to continuously learn, having the courage to embrace new practices, behaviours and mindsets and be open to new ideas and perspective.	FOU
Takes accountability	Takes accountability for own actions and contributes to an inclusive, psychologically safe and high performance culture where people are inspired to thrive and realise their potential.	FOU
Takes action	Takes initiative, achieving results through a commitment to excellence and quality outcomes for the University, Australia and the wider world.	FOU