POSITION TITLE	**Clinical Trials Program Lead**
JOB PROFILE ID	**RST_HEO9_SJP_02**
JOB CATEGORY	**Professional**
JOB FAMILY	**Research Support**
COMPENSATION GRADE	**HEO9**
MANAGEMENT LEVEL	**19 Individual Contributor**

POSITION DESCRIPTION SUMMARY

Primary Function of the Role
The Clinical Trials Program Lead is responsible for the overall management of all clinical trials in the research group and provides operational leadership, guidance, and support to members of the research group's clinical trials team. They direct the activities of clinical trial staff engaged in clinical research projects to ensure compliance with protocols and overall research objectives. The Clinical Trials Program Lead provides high level clinical trial knowledge and expertise to the Chief Investigator and the research team to support the clinical trial requirements for the work area.

The Clinical Trials Program Lead works closely with internal and external stakeholders including clinical trial sponsors, external funding bodies, collaborative group representatives and project team members to oversee all clinical trials from project start-up to delivery and closeout.

Decision Making and Delegations of Authority
The Clinical Trials Program Lead works under broad direction of the Chief Investigator and is responsible for making decisions relating to all operational aspects of the work area. They are expected to draw on their extensive clinical trial experience to provide sound advice and recommendations, exercise independent judgement and apply extensive professional knowledge to resolve complex issues that arise.

KEY RELATIONSHIPS

Relationships	Position Title
Supervisor	0084925 Associate Director, Trial Operations - Mr Martijn Oostendorp
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.

THE UNIVERSITY OF SYDNEY

RESPONSIBILITY DESCRIPTION

Leads clinical trial operations and oversees the timely delivery of all clinical trials in the research group:

- Oversees the establishment, implementation, ongoing evaluation, prioritisation, and reporting of all clinical trials. Ensures compliance with study protocols, ethics, Good Clinical Practice (GCP) guidelines, institutional policies, and relevant local and international regulatory requirements.
- Oversees the Quality Management System and associated quality processes including planning, risk management, development and maintenance of SOPs, training and competency management, deviation and non-conformance management, corrective and preventive actions (CAPA), audit and inspection readiness, and continuous quality improvement activities.
- Develops and manages the budget for all clinical trials, with the Operations Manager. Provides effective financial governance and control by conducting financial audits, identifying trends and issues, preparing, and completing financial reports, action plans and implementing change where required.
- Provides high-level advice and recommendations to the Chief Investigator, sponsors, external funding bodies and other University staff and stakeholders. Resolves complex matters relating to the work area with discretion, tact and diplomacy when communicating, utilising extensive experience and knowledge of University policy and practice.
- Provides strategic and operational guidance to clinical trial teams and study statistician/s to ensure high-quality data collection, management and analysis processes that support reliable study outcomes and successful publication of research findings.
- Manages the development and execution of agreements with third parties involved in the clinical trials including sponsors, funding organisations, collaborative organisations and service providers, in collaboration with the University and NSLHD research support teams.
- Ensures appropriate staff resourcing across all clinical trials.
- Prepares progress reports and leads progress meetings with stakeholders.
- Initiates and leads clinical trial process improvements.

Provides strategic leadership and stakeholder management for clinical trials:

- Establishes and maintains effective and productive relationships with internal and external clinical trial program stakeholders including Chief Investigators, trial sponsors, other external funding organisations and clinical trial staff.
- Contributes to the strategic direction of clinical trial operations and the development of funding opportunities.

Provides effective leadership and people management:

- Provides leadership and direction to clinical trial team members and is responsible for the team’s performance and development.
- Supports the career development of staff in the work area through performance and development reviews, regular feedback and coaching to build an effective and high performing team.
- Develops and fosters a culture of continuous improvement and collaboration to drive project deliverables.
- Manages workforce planning, recruitment, and resourcing to ensure future staffing needs for clinical trials are appropriately met, while balancing funding constraints

Undertakes ad-hoc projects and other activities:

- Performs work activities relevant to the role’s key accountabilities as approved by the Manager and commensurate to the role’s classification level.
- Assumes direct project management responsibility for clinical trials as required.

EDUCATION

Education
Postgraduate qualifications - An equivalent combination of training and experience.
Tertiary qualifications - In a relevant field

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
Excellent interpersonal and communication skills with sound conflict resolution skills and a demonstrated level of tact and discretion in dealing with day to day administrative and communication matters
Excellent time and workload management skills with demonstrated ability to prioritise effectively, manage multiple tasks, meet deadlines and achieve required outcomes.
Financial management experience and literacy, experience managing budgets and controlling income and expenditure.
High level computing skills with common electronic data capture systems (such as Oracle, Medidata Rave, InForm, etc) Technological proficiency including Microsoft Office suite.
Knowledge of clinical trial requirements during their lifecycle from start up to close out including a detailed understanding of the regulatory and ethical approval process across Australia.
Thorough knowledge of ICH Guidelines and GCP. Well-developed project planning, coordination, organisation and time management skills.

WORK EXPERIENCE

Work Experience
Demonstrated experience in the supervision, training and development, mentoring, and performance management of staff; experience managing and resolving a diverse range of HR issues. Working understanding and current knowledge of relevant aspects of the Work Health and Safety Policy and relevant legislation.
Experience at the University of Sydney will be preferable
Extensive experience in a research-intensive environment.
Extensive experience in developing and working on research projects, including expertise in using research protocols, experimental design, ethics submissions and grant applications.
Financial management experience and literacy, experience managing budgets and controlling income and expenditure.
Relevant experience in clinical trial coordination, or managing research projects encompassing multiple stakeholders including monitoring and data management, and an understanding and working knowledge of Good Clinical Practice.

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	INT
Responds to changing contexts	Anticipates and monitors demand and develops considered responses to continually improve student, staff and community outcomes	INT
Thinks and solves problems	Makes informed and considered decisions by thinking critically and comprehensively to progress and enhance outcomes for the University.	INT

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Priority Core Capability	Behavioural Indicators *FOU – Foundational, *INT – Intermediate, *ADV – Advanced, *EXP – Expert	Level

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.	INT
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.	INT
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.	INT
Fosters strong partnerships	Develops, sustains and strengthens internal and external relationships for the betterment of the University.	INT
Negotiates effectively	Understands own and others needs to communicate professionally and openly, making appropriate trade-offs to reach optimal outcomes for the University	INT
Seeks insights to inform decisions	Gathers, consolidates and evaluates a range of information to uncover key insights and inform business decisions across the University.	INT
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.	INT

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.	INT
Acts with courage, respect and integrity	Acts with honesty, demonstrating ethical and professional behaviour, with the courage to speak up for respect and integrity.	INT
Collaborates with others	Builds networks, models collaboration and works effectively with others to encourage inclusivity and impact.	INT
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.	INT
Displays adaptability	Remains committed and persistent in the pursuit of goals, maintaining composure and professionalism, regardless of changing circumstances.	INT
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.	INT
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.	INT
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.	INT
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.	INT

Core Capability	Behavioural Indicators *FOU – Foundational, *INT – Intermediate, *ADV – Advanced, *EXP – Expert	Level
Takes action	Takes initiative, achieving results through a commitment to excellence and quality outcomes for the University, Australia and the wider world.	INT