

POSITION TITLE	Clinical Trials Project Manager
JOB PROFILE ID	PMD_HEO8_01_SJP
JOB CATEGORY	Professional
JOB FAMILY	Program / Project Management and Delivery
COMPENSATION GRADE	HEO8
MANAGEMENT LEVEL	19 Individual Contributor

POSITION DESCRIPTION SUMMARY

PRIMARY FUNCTION

The Clinical Trial Project Manager provides clinical trial oversight and project management to the Investigators and Research Academics. They lead clinical trial operations to manage the set-up, conduct and close-out of clinical trials. This includes project planning and reporting, budget management, operational oversight of trial processes, line management of clinical trials operations team members, and collaboration with the Senior Principal Research Fellow Clinical Trial Program Manager, other members of the academic research team, key University of Sydney stakeholders and funders.

DECISION MAKING AND DELEGATIONS OF AUTHORITY

The Clinical Trial Project Manager works under broad direction but with a degree of autonomy. This role is responsible for the progress of various work streams within their delegated clinical trials. They will work collaboratively with the Chief Investigator and other senior members of the trial team to ensure the overall progress and success of the clinical trials they manage. The incumbent is expected to exercise a high degree of initiative and judgement to coordinate multiple activities and teams concurrently on projects, and resolve complex issues associated with project delivery. They work with a range of staff across multiple project teams and stakeholders in the University environment to meet trial objectives. Using previous project management and administration experience they are expected to resolve complex issues and fully utilise their extensive experience in clinical trials and knowledge of project management to be successful in their role.

KEY RELATIONSHIPS

Relationships	Position Title
Supervisor	0097449 Clinical Trials Program Lead - Dr Karen Bracken
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. Managing the development of high-quality clinical trials
Support the development of external funding and grant opportunities including developing the trial budget.
Oversee development and maintenance of study-specific documents.
Prepare materials for ethical and governance review and respond to feedback following this review.
Oversee development and maintenance of the trial database/s.
Develop and maintain clinical trial project plans for efficient and timely conduct of clinical trials.
Manage the clinical trial budget and finances; ensuring that funding and expenditure are appropriately managed.
Identify issues with clinical trial conduct and finances and provide recommendations to the Principal Investigator and Clinical Trial Program Manager to proactively address these issues.
Ensure compliance with the ethical and governance requirements related to trials.
Provide subject matter expertise, advice, and guidance regarding ICH GCP, work group SOPs and relevant University policies and procedures.
2. Facilitating clinical trials activities in accordance with the trial protocol and ethics and governance requirements
Monitor study compliance by ensuring that participant safety is assessed throughout participation in the study.
Identify and track adverse events, protocol deviations, and ensure onward reporting as appropriate.
Appropriately escalate issues to the Principal Investigator
3. Managing recruitment of trial participants and conduct of participant study visits/assessments.
With input from the clinical trial team, develop recruitment strategies and implement these strategies to ensure recruitment targets are met.
With input from the clinical trial team, develop and implement processes for the conduct of participant visits/assessments.
4. Managing trial data
Ensure appropriate source documentation is maintained by the clinical trial team.
Oversee trial data collection, entry, and integrity checks to ensure timely and high-quality data is available for analysis.
For industry-sponsored trials, liaise with the company-appointed Clinical Research Associate (CRA) to facilitate access to trial records and timely resolution of queries and issues raised by the CRA.
5. Undertaking other project-based tasks associated with clinical studies.
Monitor trial progress and produce progress reports for trial committees, stakeholders, and ethics committee/s.
Oversee the preparation of amendments and updates to trial documents including the protocol and submit for ethical and governance review as appropriate.
Ensure the trial is closed out in a timely and orderly manner following completion of trial activities.
Provide project management support and advice to other clinical studies conducted within the research group.
Assist the Clinical Trial Program Manager to implement program-wide process evaluation and improvement.
6. Providing effective leadership and people management of clinical trial team
Provide performance management and development for clinical trial staff including allocation of work, provision of mentoring/coaching, completion of PPDs, and the identification and/or provision of training and development opportunities.
Manage and coordinate the appointment of clinical trial staff including preparing accurate position descriptions, engaging with HR, and undertaking the recruitment process in accordance with University policy and practice.
Support other members of the clinical trial team to gain and maintain knowledge of the ethical and governance requirements related to trial.
7. Developing and maintaining good working relationships with clinical trial stakeholders
Actively participate in and provide leadership in working group meetings.
Create, develop, and maintain a productive working relationship with all research staff and Investigators.
Display discretion in dealing with fellow staff and patients.
8. Supporting the development of research publications
Source information, research and assist with preparing drafts for research publications including assisting with literature reviews and data extractions.
Support the team in the preparation of documentation for publication and presentations aligned with team projects.
9. Undertakes 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



THE UNIVERSITY OF
SYDNEY

RESPONSIBILITY DESCRIPTION

level.

EDUCATION

Education
Other - An equivalent combination of training and experience.
Postgraduate 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
Not applicable - specific certification requirements may apply to an individual positions under this job profile - No Issuer.

SKILLS

Skills
Demonstrated high-level project management skills, including sound understanding and consistent application of project scope, time, cost, quality, HR, communications, cost, risk, procurement and integration.
Demonstrated problem-solving skills, including identifying existing and potential problems, proposing solutions and implementing strategies to minimise the risk of future problems.
Excellent leadership skills and experience leading a team, taking initiative and exercising sound judgement in resolving matters that may arise as part of normal daily work.
High-level interpersonal, verbal and written communication skills with sound negotiating and conflict resolution skills.

WORK EXPERIENCE

Work Experience
Experience managing a diverse group of key internal/external stakeholders including consumers, industry sponsors, researchers and clinicians on large or complex projects.
Experience project managing multiple work streams, or leading large complex projects and ability to work according to strict deadlines and manage various demands.
Financial management experience and literacy, experience managing budgets and controlling income and expenditure for a project.
Minimum three years of relevant working experience in clinical trial management, as a project manager, senior clinical trial operations coordinator, or similar role.

CAPABILITIES

Priority Core Capability	Behavioural Indicators *FOU – Foundational, *INT – Intermediate, *ADV – Advanced, *EXP – Expert	Level
Collaborates with others	Builds networks, models collaboration and works effectively with others to encourage inclusivity and impact.	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
Takes action	Takes initiative, achieving results through a commitment to excellence and quality outcomes for the University, Australia and the wider world.	INT
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



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.	INT
Drives strategic alignment	Scopes, develops and manages projects/programs that underpin education, research, engagement and student experience outcomes (directly or indirectly) to ensure successful delivery for students, staff 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
Facilitates organisational readiness	Facilitates, encourages and sustains the acceptance and adoption of new strategies, technologies, and processes, supporting University staff to adapt and respond to change.	INT
Financial accountability	Applies prudent financial management practices when undertaking tasks and makes decisions with a consideration of the short and longer term financial implications on organisational effectiveness, and the impacts on University staff, students and community.	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

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