POSITION TITLE	**Research Development Lead**
JOB PROFILE ID	**RAL_HEO8_SJP_01**
JOB CATEGORY	**Professional**
JOB FAMILY	**Research Alliances**
COMPENSATION GRADE	**HEO8**
MANAGEMENT LEVEL	**19 Individual Contributor**

POSITION DESCRIPTION SUMMARY

The Research Development Lead is responsible for the development of new clinical trials/concepts and other research projects relevant to a specific research therapeutic area (cardio-kidney-metabolic, or other therapeutic area in which the Sydney Clinical Trials Centre (CTC) undertakes research activities). Furthermore, the Research Development Lead is responsible for the end-to-end process of drafting, preparing and obtaining input and feedback and then submitting grant or industry funding applications to obtain required funding to enable development and conduct of such research projects and for maintaining strategic relationships with internal and external stakeholders who drive development and facilitate funding of new research projects. The Research Development Lead manages the pipeline of new trials within their assigned therapeutic area (cardio-kidney-metabolic) through facilitating the identification of gaps and facilitating development of new clinical trials/concepts.

The Research Development Lead works in collaboration with internal and external stakeholders, including clinical trial funder representatives (commercial and not-for-profit), collaborative group scientific committees (including subcommittees and working parties), CTC academic leads, Associate Director Trials Development, and CTC senior managers.

DECISION MAKING AND DELEGATIONS OF AUTHORITY

The Research Development Lead works under broad direction by the Associate Director, Trials Development, and the CTC Academic Lead, and actively contributes to the development of new research projects in their research therapeutic area(s). The Research Development Lead works in compliance with CTC SOPs, University policies, clinical trial protocols and other regulatory requirements.

They work in close collaboration with the Study Chair/Chief Investigator, Senior Academic Researchers and CTC management to ensure that the requirements of the clinical trial are addressed appropriately. The Research Development Lead resolves complex matters related to clinical trial development and will typically draw on their extensive clinical trial experience to provide sound advice and recommendations, exercise independent judgement and apply extensive professional know-how to achieve their key accountabilities.

KEY RELATIONSHIPS

Relationships	Position Title
Supervisor	5042871 Professor and Director, Sydney Clinical Trials Centre - Professor Meg Jardine
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

1. Responsible for development of clinical trials and research projects, including:
* Identify key research project/clinical trial requirements with regards to resourcing, activities, data collection, tools and third party involvement for new concepts;
* Coordinate the development of clinical trial concepts by investigators, researchers, scientific committees;
* Assess the feasibility of clinical trial concepts and protocols through expression of interest and feasibility surveys;
* Lead and contribute to the development of clinical trial protocols in close collaboration with the Associate Director, Trials Development, CTC academic lead and relevant senior managers.
* Develop clinical trial budgets and costings in close collaboration with the Research Operations Lead and relevant stakeholders (e.g. other CTC departments);
* Ensure completion of a clinical trial risk assessment in close collaboration with the Research Operations Lead (if applicable) and relevant stakeholders (e.g. other CTC departments);
* Obtain required approvals to commence start-up of a clinical trial or research project;
* Initiate development and execution of agreements with third parties involved in the trial, including external sponsor, funding organisations, collaborative organisations and service providers, in collaboration with the Research Operations Lead and CTC contracts team;
2. Responsible for securing funding for clinical trials and research projects, including:
* Lead research grant applications for clinical trials and research projects;
* Lead CTC infrastructure/development grant applications as relevant to therapeutic area
* Liaise and negotiate with public, private and commercial funding providers with regards to financial contributions to infrastructure/ development support, clinical trials and research projects;
* Lead reporting to funding organisations concerning infrastructure/development funding.
3. Responsible for establishing and maintaining strategic relationships with research project generating stakeholders, including:
* Establish and maintain effective relationships with clinical trial program stakeholders, including strategic partners or collaborative group staff and members, scientific committees (including subcommittees and working parties), (senior) investigators, CTC directors and CTC Functional Heads;
* Actively contribute to scientific committees/working parties/research concept development committees, etc.;
* Actively contribute to strategic partners or collaborative group operations executive committees, reporting on the status of trials/projects in development;
* Initiate and facilitate discussions with and between relevant stakeholders for ongoing development of new research projects/clinical trials that are relevant to CTC research areas of interest, or that are of potential interest to the CTC research portfolio.
4. Responsible for reporting on clinical trials and research projects results, including:
* Coordinate and/or contribute to the preparation of trial publications in close collaboration with the Research Operations Lead; in collaboration with Clinical Lead and authors, investigators, researchers, scientific committees;
* Coordinate and contribute to the presentation/dissemination of trial results, including posters/presentations at conferences, publication of results on relevant websites, reporting of results to funding organisations in close collaboration with the Research Operations Lead;
* Contribute to trial/project educational and process improvement sessions.
5. Responsible for administrative and other support tasks associated with clinical trials and research projects, including:
* Contribute as a CTC member of future strategic directions of the CTC;
* Implement changes and work practice improvements with respect to current CTC clinical trials practices, as required;
* Promote and maintain a safe, ethical and equitable work environment;
* Lead CTC training sessions and staff meetings as relevant to role;
* Maintain a working knowledge and ensuring compliance with applicable ICH-GCP Guidelines, local regulatory requirements and CTC SOPs, guidance documents and study specific procedures;
* Complete routine administrative tasks in a timely manner (e.g. timesheets, metrics, office and travel expense claims);
* Undertake any other duties relevant and appropriate to this level.

EDUCATION

Education
Bachelor's Degree - In a relevant field
Other - An equivalent combination of 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
Not applicable - specific certification requirements may apply to an individual positions under this job profile - No Issuer.

SKILLS

Skills
Ability and willingness to travel (<30% of time).
Demonstrated ability to effectively work as part of a team.
Demonstrated ability to maintain high work standards with minimal supervision, comply with organisational SOPs, and implement continuous improvement measures in response to identified issues.
Excellent interpersonal, verbal and written communication skills; superior relationship management, conflict resolution and negotiating skills; and a demonstrated level of tact and discretion in dealing with day to day operational matters.
Excellent time and workload management skills with demonstrated ability to prioritise effectively, manage multiple tasks, meet deadlines and achieve required outcomes.
Extensive knowledge of clinical trial requirements during their lifecycle from start up to close out, including a detailed understanding of the regulatory, ethical and governance processes and requirements in Australia (including a thorough knowledge of ICH GCP).

WORK EXPERIENCE

Work Experience
Financial management experience and literacy, including experience in preparing clinical trial budgets, securing funding, and financial reporting.
Minimum three years' clinical trial experience and working knowledge of Good Clinical Practice and all applicable regulations and guidelines in the relevant regions.

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
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
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
Responds to changing contexts	Anticipates and monitors demand and develops considered responses to continually improve student, staff and community outcomes	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
Drives commercial value	Understands the commercial constructs that underpin University operations and makes informed decisions and trade-offs to deliver the best value for the University and while enhancing outcomes for students, staff and the community.	INT
Fosters strong partnerships	Develops, sustains and strengthens internal and external relationships for the betterment of 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

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
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
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
Takes action	Takes initiative, achieving results through a commitment to excellence and quality outcomes for the University, Australia and the wider world.	INT
Thinks and solves problems	Makes informed and considered decisions by thinking critically and comprehensively to progress and enhance outcomes for the University.	INT