

Location:	Parkville
Division:	Research
Classification/ Salary Range:	Commensurate with experience + not for profit salary packaging of \$15,900 + 10% super
Employment type:	2 year, full time contract.
Position reports to:	Chief of Research
Direct Reports	3 – 6 Direct reports + 15 indirect reports across facilitation, ethics and research data. Curently reviewing setting up new teams that focus on grant and contracts, quality and impact, policies & procedures

POSITION SUMMARY

Orygen is one of the leading Mental Health Medical Research Institutions nationally and has clinical research embedded in specialist and primary services across North Western Melbourne.

Orygen has seen significant growth in its Research Program over the last 10 years. Over this time, operational processes to support Orygen's research endeavours have been developed as needed. To support the current expanded research portfolio of Orygen, and to facilitate continued development in the scope and scale of our research in an integrated or coordinated manner we are appointing a Director Research Operations.

The Operations Director, Research will drive operational improvement to align our research operations with Industry best practice in the sector and facilitate partnerships with collaborators relevant to delivering our program of research.

This position reports directly to the Chief of Research and works closely and in parallel with the Orygen Sponsor Operations Department. The role will develop, lead and implement the research operations strategy and framework necessary to deliver processes and research compliance across the Division. The role will liaise closely with all relevant Orygen internal stakeholders including our clinical services to support our clinical research, as well as external national and international stakeholders.

2. POSITION CONTEXT

Orygen delivers cutting-edge research and translation, policy development, innovative clinical services, and evidence-based training and education for the mental health workforce to ensure that there is continuous improvement in the treatments and care provided to young people experiencing mental ill-health.

We are both an integrated and complex organisation. Our activities and workforce are diverse and include:

• Five headspace centres in Craigieburn, Glenroy, Melton, Sunshine and Werribee that deliver primary clinical services to young people and are operated by Orygen.

- The Centre for Youth Mental Health, a University of Melbourne research and teaching department that is wholly seconded into Orygen. Centre staff are provided with Orygen email addresses and have the use of Orygen systems.
- Orygen Specialist Program, a tertiary clinical service that is currently operated by North Western Mental Health, co-located with us at Parkville, Sunshine and Glenroy and also operating at sites in Footscray, and Wyndham. Whilst not under the governance of Orygen, Orygen Specialist Program works in close partnership with us and will come under governance in accordance with recent Royal Commission proposals
- Orygen Digital, which develops and rolls out online clinical platforms that are fully integrated with 'in-person' clinical services.
- A training and development unit providing online and face to face training for the mental health workforce both nationally and internationally.
- A policy think tank drawing on Orygen's research and clinical expertise and partnering and collaborating with key content experts from Australia and around the world to advise government policymakers.
- Centralised professional support functions enabling the organisation to achieve strategic, compliance and operational objectives from the Sponsor and Site perspectives.

The research program at Orygen includes over 100 clinical research projects encompassing a diverse risk range from high-risk medicinal interventions, Clinical Trials Network notified studies through to Negligible and Low Risk and Quality Assurance projects. The majority of our studies are Sponsored by Orygen as the responsible Corporate Entity.

In addition, Orygen retains research governance via the Research Governance Office of our Orygen-led services including the headspace services, and the Parkville Community Hub (Parkville Primary Health Clinic) with the Orygen Clinical Trials Unit located in Parkville.

Academically, the Research Division supports approximately 160 staff working across 17 different research areas of youth mental health. the research programme budget is over \$30 million per annum with research funding coming from a variety of national and international competitive grants, government contracts and tenders, and philanthropic funding.

ABOUT ORYGEN

VISION	Young people to enjoy optimal mental health as they grow into adulthood.
MISSION	Reduce the impact of mental ill-health on young people, their families and society.
VALUES	Respect, accountability, teamwork, excellence & innovation.
COMMITMENTS	First Nations people of Australia, young people and their families, LGBTIQA+ people & culturally and linguistically diverse people.

4. KEY RESPONSIBILITIES AND OUTCOMES

Strategy

- Lead the development, establishment and implementation of a dedicated Research Operations strategy and framework which supports the delivery of the diverse portfolio of research projects.
- Work with the Chief of Research to achieve strategic goals and meet business needs.
- Lead the development of a research Quality Management System.
- Lead the development of a staff professional development programs (including ASIST, MOCA, assessment training modules)

Relationships

- Be a member of, and contribute to, the Orygen Research Leadership Team.
- Work in collaboration and closely with the Orygen Sponsor Operations Department who represent the corporate entity responsible for research portfolio oversight (Sponsor and Research Governance) as per requirements outlined in the National

Statement on Ethical Conduct in Human Research and in ICH-GCP as adopted by the Therapeutic Goods Administration

Manage and mentor a team of approx. 20 to deliver strategic outcomes

Operations

- In conjunction with the Chief of Research take appropriate action to hold others accountable and promote a workplace culture that is safe, diverse and inclusive.
- Plan and implement a Research Support and Project Management Office to identify and support applications for an increasing array of funding opportunities, capture publication data and collation of data around other research and impact outputs, support planning and delivery of complex projects with a view to increasing accountability around project delivery in terms of quality, time and budget while also supporting the research portfolio to manage contract negotiations, deliverables reporting and other relationships
- Ensure existing best practice and systems developed as part of individual projects are systematised and communicated across the Division through knowledge transfer in order to support growth of Research Operations by minimizing duplication of effort.
- Liaise with People and Culture to improve processes around on-boarding and exiting staff.
- Work directly with Orygen Finance to ensure all research costs are accounted for, and funding is available to meet study delivery, compliance and outcomes for Orygen.
- Ensure consistency in communications with approving ethics and governance offices by centralizing communications and ensuring research teams comply with all regulatory requirements.

Quality, Assurance and Risk

- Ensure Orygen Policies, Standard Operating Procedures, Quality Assurance and Control
 activities comply with all legal and regulatory obligations pertaining to Investigator site
 operations.
- Lead continuous improvement and quality assurance across the Research Division including clinical research conducted at Orygen-led recruitment sites.
- Ensure the maintenance of the Research Division risk register and report to the Director Corporate Services to ensure our insurer's obligations are met.
- Ensure compliance with and support Orygen internal and external stakeholders to comply with Orygen's policies and procedures.
- Support the Chief of Research to operationalize implementation and translation including measurement of "impact" of research results and driving partnership with Translation teams as well as Strategy and Planning teams

5. SELECTION CRITERIA

The following criteria must be met for consideration for this position:

5.1 Essential

- Experience working in a business focused-operational role where you have developed, established and implemented a strategy,
- Substantial experience working in a senior clinical operations/clinical research operations role managing global compliance and reporting in the commercial clinical trial and investigator-initiated trial sector.
- Tertiary qualifications in a relevant health or science discipline.
- Experience in contracts management, ethics and governance reporting, study budgeting, site operations and stakeholder management to deliver operational outcomes to support business need.
- Experience in the direct operational translation and implementation of the National Statement on Ethical Conduct in Human Research and Australian Code for the Responsible Conduct of Research.
- Ability to collaborate, influence and build successful stakeholder relationships to ensure positive outcomes aligned to strategic initiatives
- Managed, mentored and developed an outcome focused team to deliver commercial outcomes

5.2 Desirable

- Clinical operational experience in the Not-For-Profit sector or equivalent within a Medical Research Institute.
- Working knowledge of translation and implementation science

- Experience in conducting complex research projects across hospital and private service providers.
- Experience in managing and reporting to funding agencies such as NHMRC, The Wellcome Trust and National Institute of Mental Health.
- Experience in Mental Health terminology and research is highly desirable.
- Experience in consumer engagement (e.g. Lived Experience groups, patient advocacy groups)

6. SPECIAL REQUIREMENTS

- Unrestricted right to live and work in Australia.
- A current National Police Check will be required.
- Any offer of employment is conditional upon receipt and maintenance of a satisfactory Working with Children Check.
- A current Victorian driver's licence (if relevant to role).
- You may be required to work across more than one of Orygen's sites, which are currently located within the north and west of Melbourne.
- In line with Government guidelines, this position may need to be based at home during certain periods. As such a reliable internet connection will be required.
- Successful applicants will be required to provide proof of full COVID-19 Vaccination prior to commencement.

7. ACKNOWLEDGEMENT

Confirming this position description has been read and understood by:

Name:	
Signature:	
Date:	