# SPONSOR OPERATIONS SPECIALIST

## JULY 2026

## POSITION SUMMARY

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| Location: | Parkville | | |
| Functional area: | Research | | |
| Classification/ Salary: | $125,000 - $135,000 commensurate with skills and experience + 12% super + access to $15,900 NFP salary packaging | | |
| Job level: | 4 | | |
| Reports to: | Head of Sponsor Operations | | |
| Employment type: | Full time or part time (0.8-1.0 FTE) | | |
| Employment length: | 24 months | | |
| Direct reports | 0 | Indirect reports | 0 |

## POSITION PURPOSE STATEMENT

The Sponsor Operations Specialist will act in the capacity of Sponsor Clinical Research Associate within the Sponsor Operations team in the Research Office of Orygen.

The role will contribute to and support the regulatory compliance of Orygen research projects to ensure Good Clinical Practice compliance as well as assist in the development and maintenance of the Quality Management System (QMS) as it relates to the conduct of research globally. A key aspect of this role is to ensure all research projects across Orygen are conducted in accordance with best practice as they relate to all aspects of study operations and monitoring.

**About Research**

The research program at Orygen includes over 100 clinical research projects encompassing a diverse risk range from high-risk pharmaceutical interventions, Clinical Trials 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 of our Orygen-led services including the headspace services, Orygen Digital and Orygen Clinical Trials Unit located in Parkville.

The research division supports approximately 200 staff working across 20 different research areas of youth mental health. The research budget is over $40 million per annum with research funding coming from a variety of national and international competitive grants, government contracts and tenders, and philanthropic funding.

The Research Office is led by the Director of Research Operations and oversees grants, ethics, sponsor operations and other research management and support tasks.

## POSITION FOCUS

| | Key responsibility area | Percentage |
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| 1 | Study monitoring and reporting | 50% |
| 2 | Regulatory and operations advice | 20% |
| 3 | Systems and quality assurance | 10% |
| 4 | Research governance | 10% |
| 5 | Other | 10% |

## POSITION KEY RESPONSIBILITY AREAS

1. **Study monitoring and reporting**
   - Act in the capacity of Sponsor Clinical Research Associate/monitor upholding Sponsor responsibilities for Orygen-sponsored studies,
   - Provide the full scope of Clinical Operations Support including aspects of Project Management and/or Quality Assurance across the research portfolio.
   - Conduct risk assessments on research projects and develop and implement monitoring plans, with respect to Risk-Based Monitoring.
   - In association with medical and other clinical staff, assist in the evaluation of Serious Adverse Events (SAEs) in order to determine reportability criteria to relevant regulators and stakeholders.
   - Site feasibility, qualification, site initiation, monitoring, and close-out visits in accordance with Good Clinical and current best Practice.
   - Work in collaboration with Data Management to facilitate and improve electronic database builds, verification and query of research data, on-study, and final analyses.
   - Assist in the presentation and documentation of safety datasets for Data Safety Monitoring and general safety oversight of studies.
   - Support study teams in the start-up phase including the development and review of study documents (such as protocol, study manuals, etc.).
   - Assist in the presentation and documentation of safety datasets for Data Safety Monitoring and general safety oversight of studies.
   - Assist in the set-up of Investigational Product processes from sourcing GMP products, establishing pharmacy processes that meet regulatory requirements to the reconciliation and authorisation of destruction.
   - Establish regular lines of communication with study teams to support high quality research studies in accordance with regulatory requirements and Good Clinical Practice.
   - Manage study progress through Case Report Form completion, and data query generation and resolution via systems such as REDCap.
   - Assist in the management of post-approval reporting requirements.

2. **Regulatory and operations advice**
   - Review study documents including Study Protocols, PICFs, etc. and advise study teams on study design, regulatory compliance and best practice.
   - Provide general regulatory and operations advice and guidance to Investigators, Project Managers and study teams based on risk in the context of industry expertise.
   - Administer and actively participate in the sponsor operations helpdesk function in order to guide and assist study teams with compliance and operational management.
   - Assist in the delivery of regulatory, GCP and Quality Management System training.
   - Assist the research office and legal team with regulatory and clinical research operations aspects of contracts management.

**3. Systems and quality assurance**

- Management of serious breaches and oversight of corrective and preventive action (CAPA) implementation and documentation.
- Contribute to the continuous improvement of Sponsor Operations systems and processes ensuring coordination with overall Research Office processes, such as ethics advice, Sponsor Helpdesk (inbox), contract management and investigational product management.
- Develop and review new Standard Operating Procedures and forms as part of the Orygen QMS roll-out.
- Ensure all reporting is audit ready.
- Support the ongoing roll-out of Florence eBinders (eTMF and eISF document repository platform).
- Establish defined vendor assurance procedures and assist in their implementation.

**4. Research governance**

- Review Orygen research governance applications to ensure site activities are conducted in accordance with Orygen Research Governance Framework and associated processes.
- Assist the Research Office to improve and streamline how research is conducted across Orygen-governed research sites. This includes how young people are approached to participate in research, communication between researchers and clinical teams and general processes for researchers working at Orygen-governed research sites.

**5. Other**

- Assist the Head of Sponsor Operations and Director of Research Operations as required.
- Involvement in addition projects and/or services as part of the development of Orygen.
- Comply with and support others to comply with Orygen's policies and procedures, including taking appropriate action to hold others accountable and promote a workplace culture that is safe, diverse and inclusive.

## EDUCATION / QUALIFICATIONS

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| Essential | • Minimum bachelor's degree or comparable qualification in Science, Life Sciences or other Healthcare-related discipline. |
| Desirable | • A master's degree or PhD in a mental health related discipline. |

## EXPERIENCE / SKILLS

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| Experience / skills | • Operational expertise in the conduct of the full scope of Sponsor responsibilities as a Clinical Research Associate with operational knowledge of study start-up, conduct and close-out of study activities (including Teletrials).<br>• Demonstrated extensive experience in the Pharmaceutical, Contract Research Organisation and/or Biotech Industries or similar position in the medical research or academic sector.<br>• Monitoring of studies in accordance with ICH GCP, study protocols and regulatory requirements.<br>• Proven capacity to implement GCP at the Sponsor and Investigator site level ideally across different site categories such as public hospitals and primary healthcare services.<br>• Proficient in the use of electronic Case Report Forms such as REDCap and Study Management Systems.<br>• Demonstrated experience in pharmacovigilance; SAE documentation and reporting including expedited reporting to regulatory authorities.<br>• Sound experience in review of protocols, participant information and consent forms and other study documents such as study manuals.<br>• Thorough knowledge of clinical study essential records, Trial Master Files and file reconciliation including sound working knowledge of medical and clinical study terminology. |

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| | • In-depth understanding of research in both investigator-initiated and commercially-sponsored environments from both the Sponsor and Investigator Site perspective.<br>• Experience in the development and implementation of research Standard Operating Procedures (SOPs) and supporting forms/templates.<br>• Knowledge of clinical environments and their role within the conduct of clinical studies.<br>• Interpretation of regulatory guidelines in the context of a varied study portfolio.<br>• Implementation, use and/or review of Quality Management Systems and Quality Assurance procedures such as Change Control.<br>• Thorough knowledge and experience in Clinical Trials Pharmacy processes including drug accountability, etc (desirable).<br>• Experience in the manufacture of, and logistical management of investigational products for use in clinical research with knowledge of GMP requirements (desirable).<br>• Experience in the conduct of vendor assurance and internal audits (desirable).<br>• Experience in study budgeting especially as applicable to health services (desirable).<br>• Experience in Mental Health research (desirable) including use of instruments and measures commonly employed in mental health assessments. |
| Personal attributes | • High quality interpersonal and communication skills (written and verbal)<br>• An ability to work under pressure and manage conflicting priorities with ease.<br>• Highly organised, demonstrates initiative and is outcome focused.<br>• Excellent attention to detail.<br>• Ability to express complex ideas and extract critical information.<br>• Flexible and adaptable to changing work requirements.<br>• Strategic thinker and pragmatic problem solver.<br>• Can quickly grasp concepts<br>• Proven ability to build rapport, negotiate and maintain effective relationships with both internal and external stakeholders.<br>• Continuous improvement mindset.<br>• Highly collaborative and emotionally intelligent, will contribute to positive team and organisational culture. |

## KEY RELATIONSHIPS

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| Internal | • Director, Research Operations<br>• Head of Sponsor Operations<br>• Orygen Executive Sponsor<br>• Chief of Research and Knowledge Translation<br>• Sponsor Operations and Research Office Teams<br>• General Counsel and Legal Team<br>• Researchers<br>• Clinical Quality and Safety Team<br>• Research site staff and clinicians |
| External | • TGA<br>• External research offices, HRECs, vendors and suppliers of clinical services and goods<br>• Various clinical trial and industry associations including A-CTEC, ACTA, AAMRI<br>• Pharmacy service providers and GMP manufacturers |

## 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.
- 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.
- A current Victorian driver's licence is desirable.
- 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.
- Occasional out of hours, evening and/or weekend work may be required.

## SAFETY, HEALTH AND WELLBEING RESPONSIBILITIES

Employees are required to comply with all workplace health, safety and wellbeing policies and procedures of Orygen.

In addition, employees are expected to:

- Promote and demonstrate Orygen's high standards in relation to health, safety and wellbeing, championing a culture of safety in the workplace.
- Take responsibility for their own safety, health and wellbeing and for their colleagues and others they work alongside, as far as they are able.
- Follow policies, training and guidelines related to Workplace health, safety and wellbeing, including reporting of unsafe work practices, incidents, hazards and near miss events.
- Be committed to promoting and protecting the safety and well-being of all children and young people and embedding safeguarding practices into all our programs and services.
- You may encounter sensitive information related to mental health as part of your work. Being aware of this and how it could affect you and planning accordingly is essential.

## ACKNOWLEDGEMENT

Confirming this position description has been read and understood by:

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| Name | [insert name] |
| Signature | [insert signature] |
| Date | [insert date] |