
CLINICAL TRIAL COORDINATOR – AFFINITY STUDY

SEPTEMBER 2021



Location:	Parkville
Division:	Research
Classification/ Salary Range:	\$90,000 – \$110,000 p.a. (pro rata) (commensurate with skills and experience) plus superannuation and access to salary packaging
Employment type:	Part-time (0.8 FTE) Fixed term position available for 12 months with possibility of extension
Position reports to:	A/Prof Simon Rice Tel +61 419 497 599 Email simon.rice@orygen.org.au

1. POSITION SUMMARY

Orygen's Mood and Anxiety Disorders Research Group and Orygen Digital are currently seeking a Clinical Trial Coordinator. The Clinical Trial Coordinator will play a crucial role in the successful delivery of a randomised-controlled trial of the Affinity intervention, recently funded by NHMRC. The Clinical Trial Coordinator should be highly motivated, proactive and organised to ensure the trial protocol is developed, approved and subsequently executed to a high standard.

The Clinical Trial Coordinator will lead the development of all study protocols for data collection and risk management, in addition to contributing to the development of new digital therapeutic content for a new suicide prevention online therapy module to be used in the intervention(s), based on graphic medicine (digital comics) methods (e.g., <https://doi.org/10.1111/cp.12222>)

The successful candidate will be responsible for providing high-level trial co-ordination and stakeholder engagement, managing the day-to-day operations, conducting strategic planning, and documented reporting to stakeholders in relation to the progress of the trial. In addition, the incumbent will oversee research assistant staff conducting direct recruitment and data collection, ensuring the safety and quality of the trial while working towards achieving recruitment targets. The successful candidate will also assist with recruitment and assessment.

This position will report to A/Prof Simon Rice, Principal Research Fellow and Senior Clinician in Orygen's Youth Mood Clinic. The incumbent will initially commence work from home, and will eventually be based at Orygen's Parkville office.

2. POSITION CONTEXT

Orygen delivers cutting-edge research, 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 a 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 (formerly referred to as Orygen Youth Health Clinical 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.
- 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 and operational objectives.

The Affinity trial aims to determine whether Affinity (a theory-driven, targeted digital social networking intervention developed by Orygen Digital) can reduce suicidal thoughts and behaviour, relative to a non-targeted website, in young people receiving treatment for major depressive disorder at Orygen's Youth Mood Clinic. Participants will be recruited via liaison with Youth Mood Clinic treating clinicians randomised to receive access to the suicide-specific Affinity intervention or an active control website for 12 weeks, with assessments conducted across this period. Background research on the development and piloting of the Affinity intervention are available here:

- <https://doi.org/10.1016/j.jad.2018.06.028>
- <https://doi.org/10.1186/s12910-020-00479-1>
- <https://www.jmir.org/2021/4/e24260>

More information on the work of Orygen Digital is available here:

- <https://www.orygen.org.au/Our-Research/Research-Areas/Orygen-Digital>

3. 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

The Clinical Trial Coordinator will:

- Establish effective working relationships with Youth Mood Clinic team members to facilitate study recruitment, in addition to collaborative working relationships with researchers across the University and study collaborators
- Contribute to the development of content for online therapy modules as part of the Affinity and/or active control interventions
- Contribute to the development of study protocols for data collection and risk management in the trial, in addition to publication of protocols where necessary
- Oversee participant recruitment and ongoing assessments as part of the trial, ensuring protocol adherence and safety requirements are upheld
- Management of the study research management system and database
- Training and supervision of research assistants in assessments and study procedures
- Prepare and submit Research Ethics Committee and governance applications, amendments, safety reports, annual reports and other relevant compliance documentation related to clinical trials
- Manage clinical trial costings, including budget preparation
- Undertake other relevant duties as requested by the Principal Investigator
- Occupational Health and Safety (OH&S) and Environmental Health and Safety (EH&S) responsibilities as outlined in section 5
- 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.

5. SELECTION CRITERIA

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

5.1 Essential

- Tertiary qualifications in psychology/health sciences related fields plus significant relevant experience or equivalent combination of relevant experience and education/training
- Strong relationship management skills and experience working within multidisciplinary teams, with the ability to quickly earn the trust of internal/external stakeholders and colleagues
- Significant experience recruiting research participants from clinical settings, including effective liaison with clinicians
- Experience with serious adverse event/adverse event monitoring among vulnerable research participants
- Experience in coordinating clinical trials among vulnerable populations, including the submission of hospital-based Research Ethics Committee applications, protocol amendments and governance proposals, clinical trial procedures, documentation and auditing of clinical trials
- Demonstrated understanding of the conduct of research including the collation and management of human research data, and an awareness of the principles underpinning Good Clinical Practice.

- Well-developed organisational and time management skills with the capacity to meet strict deadlines and balance competing demands, and to work effectively under pressure and respond to changing priorities and deadlines
- Excellent teamwork, negotiation, and leadership skills, including the proven ability to resolve conflict and to successfully lead, mobilise and motivate teams

5.2 Desirable

- AHPRA registration as a mental health practitioner
- Current Honorary role with the Royal Melbourne Hospital / Melbourne Health
- Demonstrated ability to facilitate research programs in association with academic and/or clinical staff

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.
- 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.

7. ACKNOWLEDGEMENT

Confirming this position description has been read and understood by:

Name:	
Signature:	
Date:	