

POSITION DESCRIPTION

POSITION TITLE:	Clinical Trial Coordinator/ Senior Clinical Trial Coordinator
DIVISION / SECTION:	Global and Tropical Health
SUPERVISOR:	Principal Research Fellow
CLASSIFICATION LEVEL:	GSL7 - GSL8
SALARY RANGE:	GSL 7 \$87,586 - \$ 95,051 (pro rata) GSL 8 \$100,524 – \$109,478 (pro rata)
STATUS (FTE):	0.6-1.0 FTE (negotiable)
DIRECT REPORTS:	0
INDIRECT REPORTS:	6
SPECIAL PROVISIONS:	Willingness to travel internationally several times per year (four to six times per year, one to two weeks at a time), pending COVID-19 related travel restrictions being lifted.

ABOUT MENZIES:

As one of Australia's leading medical research institutes dedicated to improving the health and wellbeing of Indigenous Australians, and a leader in global and tropical research into life-threatening illnesses, Menzies School of Health Research continues to translate its research into effective partnerships and programs in communities across Australia and the Asia-Pacific region.

SUMMARY OF POSITION:

As part of the Malaria group in the Global and Tropical Health Division at Menzies, this position will work on a range of clinical trials and feasibility studies for the research programs. The research program involves investigating the safety, efficacy and feasibility of better treatment strategies for vivax malaria at study sites in Bangladesh, Indonesia, Cambodia, Nepal and Ethiopia.

This position will be responsible for the co-design, implementation and coordination of the studies in close contact with overseas partners. This would include the responsibility of co-development of protocols, ethics submission, obtaining regulatory approvals and overseeing the management of trial investigator files. The position will also develop study related documents such as SOPs and monitor plans, training materials, and deliver the training and support to the field staff. The latter will include both virtual and on-site monitoring.

PRIMARY RESPONSIBILITIES:

The following responsibilities are not exhaustive and may include others as directed by the supervisor:

1. Day-to-day management of the research project and regular communication with overseas recruitment sites.
2. Develop and update Study Specific Procedures, Case Record Forms, training materials, monitor plans and ethics submissions.
3. Maintain and keep essential documents and investigator files up to date.
4. Training and support of study staff to ensure the research is conducted in accordance with Good Clinical Practice (GCP) guidelines.
5. Conduct formal monitoring visits and deliver training, both onsite and using

- online platforms.
6. Undertake basic data management.
 7. Maintain and nurture existing working relationships with overseas collaborators.
 8. Communicate effectively with various stakeholders, study participants, investigators and other members of the study team.
 9. Attend, participate and contribute to team meetings and presentations.
 10. Participate in reporting on research progress including writing reports to funders, ethic committees and other stakeholders
 11. An understanding and awareness of relevant Workplace Health and Safety as well as Equal Opportunity principles and legislation along with a commitment to maintaining a healthy and safe workplace for all Menzies staff, students, volunteers and visitors.

Additional responsibilities for appointment at GSL 8:

12. Establish and manage all processes for effective clinical trial and research management, including governance and ethics; FDA approvals; risk management and mitigation; supervision of trial conduct at overseas field sites.
13. Manage administration of the Data Safety Monitoring Committee and Trial Steering Committee.
14. Independently write reports and provide these to various stakeholders.
15. Provide guidance and/or mentoring to other trial staff.

SELECTION CRITERIA:

Essential:

1. Tertiary qualification in related field (nursing, public health, etc.) and at least four (4) years of relevant work experience or extensive experience and management expertise or an equivalent combination of relevant experience and/or qualification/training.
2. Demonstrated clinical trial monitoring experience, including knowledge of Ethical Conduct in Research, Good Clinical Practice and applicable regulatory guidelines.
3. Good organisational and time management skills with demonstrated ability to set priorities and meet deadlines whilst keeping attention to detail.
4. Demonstrated ability in writing progress reports against study milestones.
5. Demonstrated ability to work independently and take initiative.
6. Highly developed ability to communicate effectively, both orally and in writing, with a range of audiences including diverse cultures and a multidisciplinary team.
7. Demonstrated experience and competency with a range of computer software including the Microsoft Office Suite.
8. The ability to interact effectively with people from diverse cultures.

Additional selection criteria for appointment at GSL 8:

9. Postgraduate qualifications or progress towards postgraduate qualifications and extensive relevant experience or extensive experience and management expertise or an equivalent combination of relevant experience and/or qualification/ training.
10. Capacity to independently supervise trial staff at the field sites in LMICs, including remote locations, to ensure adherence to GCP, data quality, safe clinical specimen storage and transportation.
11. Demonstrated ability to independently train and mentor trial staff at overseas field sites.

Desirable:

1. Understanding of the clinical management of patients and study participants.
2. Experience working with and knowledge of malaria and/or other infectious diseases,

- including international experience.
3. Experience in data management (RedCap or other systems), and familiarity with data analysis using standard softwares.

Aboriginal and/or Torres Strait Islander people are strongly encouraged to apply.

Approved by: Menzies Human Resources

Date: 2 June 2021

<u>GSL 7/8</u>		
PACKAGE COMPONENT	Minimum Value GSL 7/1 (\$)	Maximum Value GSL 8/4 (\$)
Gross Salary (position advertised accross General Staff Levels 7 and 8)	87,586	109,478
Superannuation (14% superannuation contribution depends on employee contributing 3% of pre tax salary)	12,262	15,327
Salary Packaging Grossed Up (Based on utilising the full \$15,900 salary packaging component plus the \$2,550 Meal Entertainment Card.)	9,765	9,765
Leave Loading (Payable on the last pay before Christmas (first year will be a pro rata payment))	1,607	1,607
Total Salary Package	111,220	136,177