CLINICAL TRIAL OFFICER

DEPARTMENT/UNIT: Metabolism Aging and Genomics, School of Epidemiology and Preventive Medicine

FACULTY/DIVISION: Faculty of Medicine Nursing & Health Sciences

CLASSIFICATION: HEW Level 5

DESIGNATED CAMPUS OR LOCATION: Brisbane

ORGANISATIONAL CONTEXT

Monash is a university of transformation, progress and optimism. Our people are our most valued asset, with our academics among the best in the world and our professional staff revolutionising the way we operate as an organisation. For more information about our University and our exciting future, please visit www.monash.edu.

The Faculty of Medicine, Nursing and Health Sciences, is the largest faculty at Monash University, and offers the most comprehensive suite of professional health training in Victoria. We consistently rank in the top 40 universities worldwide for clinical, pre-clinical and health sciences.

We want to improve the human condition. That is our vision - it has no expiration date. Through academic health centres, other translational models and by educating the healthcare workforce of the future, our staff, students and alumni directly improve quality of life.

Setting the global health care agenda, the Faculty aspires to lead in all areas of research activity and influence local, national and international policy to improve health and social outcomes and health inequalities. We’ve made a major impact in the world of medical research and become globally recognised for our quality education of over 41,000 doctors, nurses, and allied health professionals.

We are ambitious and aim to maintain our position as a leading international medical research university. We’re recognised for the breadth and depth of our research, for our commitment to translational research, for the quality and scale of our research capability, and as a thriving biotechnology hub.

To learn more about the Faculty, please visit www.monash.edu/medicine.

Monash School of Public Health and Preventive Medicine is a teaching and research unit of the Faculty of Medicine, Nursing and Health Sciences and is centred at the Alfred Hospital Campus. It plays a prominent role in public health medicine and works closely with the major Monash affiliated hospitals, research institutes and public health units within Victoria. It plays a prominent role in public health medicine in Australia and has a strong record for training individuals with the capacity and skills to assume leadership roles in Australia in this
field. We work closely with the major Monash affiliated hospitals, research institutes and public health units within Victoria. Our skills provide a key resource underpinning translational research within our faculty.

The Metabolism, Ageing and Genomics unit is based within the School of Public Health and Preventive Medicine at the Alfred Campus. The Unit is led by Professor Sophia Zoungas and has a core focus on conducting clinical research studies that have a direct translational impact in terms of improving the public health of older Australians. The core skills of the Unit include conducting randomised controlled trials within the primary care setting, strengthening clinical research capacity with primary care and providing clinical research opportunities in regional and rural areas of the country.

**POSITION PURPOSE**

The Clinical Trial Officer (Field Officer) provides key support to clinical research projects undertaken by the Clinical Trial Centre. The projects will vary and may involve the evaluation of interventional therapies in randomised controlled trials. The main responsibility of the Clinical Trial Officer will be directly supporting the STAREE principal investigators and Project Manager in all aspects of conduct and implementation of a clinical trial. They will assist in ensuring milestones are achieved allowing the engagement of future clinical trials. In addition, the incumbent will be responsible for the tasks associated with the implementation and conduct of pharmaceutical sponsored and investigator initiated studies.

The Clinical Trial Officer will liaise with internal and external stakeholders, including physicians and nursing staff at general practices and/or hospitals, and trial participants. The conduct of the research project will comply with the NHMRC guidelines on Good Clinical Practice (GCP) and those from the International Harmonisation Conference (ICH).

**Reporting Line:** The position reports to the Unit Head under general direction

**Supervisory Responsibilities:** Not applicable

**Financial Delegation:** Not applicable

**Budgetary Responsibilities:** Not applicable

**KEY RESPONSIBILITIES**

1. Demonstrate an understanding of customer service for internal and external customers and be committed to effectively meeting their needs in a helpful and professional way

2. Communicate and liaise in a collegiate manner with representatives of the hospital medical, nursing, pathology and clerical departments as necessary

3. Liaise with various pathology laboratories and diagnostic facilities regarding provision of data or services required by various studies

4. Liaise with individual physicians and with relevant service providers for correct completion of requests in accordance with study protocol and collect, view, record and follow up diagnostic test results as required

5. Oversee interviews with patients to assess their suitability for inclusion in the research study, provide them with information about the aims of the study and instruct them in the study methods, e.g. medication regimes, importance of study appointments and procedures

6. Coordinate trial procedures, trial visits, and education of the patient regarding their condition and trial medication as appropriate and provide a referral for further clinical management as required

7. Ensure that all studies are conducted strictly according to study protocols and legal and regulatory bodies such as Good Clinical Practice (GCP), ICH guidelines, VMIA (Victorian Medical Insurance Authority) and APMA guidelines
8. Identify and document any problems associated with the conduct of the study including ethics reports, data collection and data entry and to bring these to the attention of the STAREE investigators or Project Manager in a timely manner

9. Oversee and improve Quality Assurance activities and confidentiality issues as required

10. Ensure all equipment used for the project is sound and consistent

11. Other duties as directed from time to time

KEY SELECTION CRITERIA

Education/Qualifications

1. The appointee will have:
   - A degree in a medical or medical sciences field without subsequent relevant work experience; or
   - substantial relevant skills and work experience; or
   - an equivalent combination of relevant experience and/or education/training

Knowledge and Skills

2. Ability to solve problems discretely by using innovation and exercising diagnostic skills within areas of functional responsibility or professional expertise

3. Highly organised with proven ability to appropriately prioritise tasks in a busy environment

4. High-level of written and verbal communication skills, experience in customer service and business ethics

5. Computer literacy in databases, word processing and spreadsheets

6. Sharp attention to detail and evidence of ability to adhere strictly to protocol and working guidelines

7. Thorough understanding of human research ethics principles

8. Ability to work independently as well as part of a team

OTHER JOB RELATED INFORMATION

- Travel to general practices and various pathology locations within the region is required, but will be arranged by consultation. Staff are expected to maintain a mileage log book detailing work related travel. Some lifting is required in transferring equipment and work files to and from vehicles. Occasional contact with phone study participants may be required out of hours. In such instances staff are expected to maintain a log book of phone calls and staff will be reimbursed for call charges

- Overtime and out of hours work (including evenings, weekends and public holidays) may be required

- There may be peak periods of work during which taking of leave will be restricted

GOVERNANCE

Monash University expects staff to appropriately balance risk and reward in a manner that is sustainable to its long-term future, contribute to a culture of honesty and integrity, and provide an environment that is safe, secure and inclusive. Ensure you are aware of and adhere to University policies relevant to the duties undertaken and the values of the University. This is a standard which the University sees as the benchmark for all of its activities in Australia and internationally.