MONASH University

Position description

Clinical Trial Project Officer (STAREE)

Department/Unit	Department of Epidemiology & Preventive Medicine
Faculty/Division	Medicine, Nursing and Health Sciences
Classification	HEW Level 6
Employment type	Casual
Work location	The Alfred Centre or other designated Monash hub
Date document created or updated	22 April 2016

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

Monash School of Public Health & 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 beside the Burnet Institute. It plays a prominent role in public health medicine in Australia. The Department of Epidemiology and Preventive Medicine (DEPM) is the largest member of the School. The core skills of the department relate to epidemiology (the study of the distribution, risk factors and causes of disease) and its application to problems in clinical medicine and public health. The department provides a strong research capability in a series of areas of particular relevance to infectious disease control including large database skills, emergency care research, therapeutics (including clinical trials, post-marketing surveillance and pharmaco-economics)

Position purpose

The Clinical Trial Project 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 Project 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 Project Officer will be responsible for the tasks associated with the implementation and conduct of pharmaceutical sponsored and investigator initiated studies.

The Project 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 STAREE principal investigators and Project Manager
Supervisory responsibilities : None
Financial delegation and/or budget responsibilities : This position has no financial delegation

Key responsibilities

Coordination of allocated Clinical Trials

- 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
- Communicate and liaise in a collegiate manner with representatives of the hospital medical, nursing, pathology and clerical departments as necessary
- Liaise with various pathology laboratories and diagnostic facilities regarding provision of data or services required by various studies
- 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
- Recruit general practitioners as co-investigators, providing them with study related information and then assisting the GPs to locate, recruit and manage study participants
- 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
- 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
- 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
- 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
- Oversee and improve Quality Assurance activities and confidentiality issues as required
- Ensure all equipment used for the project is sound and consistent

Contributions to the team

- Attend regular meetings and participate in activities of the unit as required
- Design and discuss innovative procedures to increase the efficiency of the project
- Be willing to work at general practices and pathology centres as needed and attend to all requirements of the role without need for close supervision
- Demonstrate strong initiative and decision making in prioritizing work load to accomplish given tasks and to provide support for other staff members
- Ability to work independently as well as an integral part of a team

Key selection criteria

Essential:

1. A degree in a relevant area, from a recognised university with subsequent relevant work experience or extensive experience leading to the development of specialist expertise or an equivalent combination of experience and/or education
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 fairly independently and as part of a team, along with a demonstrated capacity to work with others in the workplace in a collegiate manner
9. Possession of a current Driver's license

Desirable:

10. Previous clinical trials research experience
11. Specific clinical expertise in desired area of research
12. Training or education in research related topics

Other job related information

- Shift work, overtime and out of hours work (including evenings, weekends and public holidays) may be required
- On-call (including rostered on-call requirements) may be required
- Peak periods of work during which the taking of leave may be restricted
- Possession of a current driver's license
- 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
- The normal working week for Monash staff covers 36.75 hours over five days, between 8:00am and 6:00pm. Because of the nature of this work, and the needs of patients, it may occasionally be necessary to work outside of these hours. Any overtime performed will be agreed to by the incumbent and supervisor prior to its occurrence
- Any information obtained in the course of employment is confidential and as with standard procedures relating to patient information and privacy laws, it must not be used for any purpose other than the performance of the duties for which the person was employed

Legal compliance

Ensure you are aware of and adhere to legislation and University policy relevant to the duties undertaken, including: Equal Employment Opportunity, supporting equity and fairness; Occupational Health and Safety, supporting a safe workplace; Conflict of Interest (including Conflict of Interest in Research); Paid Outside Work; Privacy; Research Conduct; and Staff/Student Relationships.