THE GEORGE INSTITUTE | AUSTRALIA
for Global Health

Job Description	
JOB TITLE	**Clinical Research Associate**
REPORTING RELATIONSHIP	Project Manager, Neurological and Mental Health division
START DATE	September 2015
TYPE OF EMPLOYMENT	1 FTE, 12 month fix term contract

The George Institute for Global Health

The George Institute for Global Health is an internationally-recognised health research organisation, undertaking high impact research across a broad health landscape. Affiliated with the University of Sydney, the Institute is a leader in the clinical trials, health policy and capacity-building areas. The Institute was established in 1999 and has a global network of top medical experts in a range of research fields as well as expertise in research design, project management and data and statistical analysis. With a respected voice among global policy makers, the Institute has attracted significant funding support from governments, philanthropic organisations and corporations. George Institute research is regularly published in the top tier of academic journals internationally.

Our mission is to improve the health of millions of people worldwide. We will achieve this by:

- Providing the best evidence to guide critical health decisions
- Engaging with decision makers to enact real change
- Targeting global epidemics, particularly of chronic diseases and injury
- Focusing on vulnerable populations in both rich and poor countries

In achieving that mission, we are committed to ensuring the integration of good business practices throughout all our operations.

The Institute has grown rapidly since its inception, and currently employs approximately 450 staff at its centres in Australia, China, India, East Asia, New Zealand and the UK. Research is currently conducted at around 300 collaborating centres in approximately 50 countries worldwide.

The George Institute is made up of several divisions and programs that oversee numerous large-scale international and regional projects funded by a diverse range of sponsors, both public and private. The research portfolio of the institute includes randomized trials of new treatment and prevention strategies, surveys, and observational studies of the causes and outcomes of disease and injury. For more information about the Institute, visit www.georgeinstitute.org.

The George Institute is dedicated to the recruitment, development, and retention of the best people from around the world. The pursuit of academic, scientific and operational excellence in a "can do" culture is actively promoted in all our activities.

Context

This role will work on studies across the division, initially focusing on SAVE. They are:

SAVE (Sleep Apnea and cardioVascular Endpoints) study. The SAVE study is an investigator-initiated and conducted, industry-academic collaborative, large scale, open, randomised controlled trial to determine the effectiveness of continuous positive airway pressure (CPAP) in preventing cardiovascular events in moderate-severe obstructive sleep apnea (OSA) patients with co-existing coronary or cerebrovascular disease. The trial commenced recruitment in 2009 and recruited 2700 patients across 80 sites in Australia, New Zealand, China, Spain, Brazil, India and the USA. Sites are commencing end of study visits in September and data lock is planned for 31st March 2016.

The Role

The Clinical Research Associate will provide support to the SAVE study initially then move to other studies within the division. .

Reporting Relationships

The Clinical Research Associate will report to the Project Manager.

Duties and Key Responsibilities

All activities must be conducted in accordance with project specific documentation, applicable SOPs, ICH GCP (if applicable) and applicable regulatory requirements.

Study Star-up and Maintenance

- Prepare for, plan, organise and conduct site initiation visits and investigator meetings with the Project Manager
- Assist in the preparation of ethics committee submissions
- Motivate and train investigators and ensure that the study site personnel have a good understanding of the protocol, the investigational product and the requirements of the study and that they can fulfil their obligations to conduct the study accurately and to deadlines

- Site management responsibilities, including but not limited to:
    - Remote and some on-site monitoring of trial progress and implement strategies as required to ensure adherence to the study protocol, study procedure manual, SOPs, ICH/GCP and other applicable ethical guidelines
    - Assist participating site personnel in the local management of the study where required
    - Ensure serious adverse events and medical events of interest are appropriately documented and reported according to the study protocol and applicable regulatory and ethical requirements
    - Organise and manage the trial files, including in-house and site trial files, to ensure they are appropriately filed, managed and stored
    - Detect and report protocol deviations and implement corrective measures as required
- Create and review monitoring visit and progress reports accurately and within the predetermined timeframe and send to the project manager
- Create and review site activation check list and essential documents with the project manager
- Regularly update project tracking tools and systems
- Coordinate, track and process invoices for study payments to investigational sites and vendors, accurately and in a timely manner

Study Execution and Closure

Site management

- Conduct on site and remote monitoring of participating centres to ensure:
    - Quality, accuracy, completion, and timeliness of data entry.
    - Complete and efficientresolution of data issues and audit findings.
    - Adherence to the study protocol and study procedures manual.
    - Adherence to ICH/GCP and other regulatory guidelines and requirements as relevant to this trial including reporting of adverse events/serious adverse events are reported

- Complete all monitoring visit and progress reports accurately and within study specified timeframe.
- Collect and review essential documents from study sites and ensure they are complete at study close-out and appropriately stored/managed in-house.

Overseas regional co-ordinating centre management

- Manage and assist regional coordinating staff in the local management of the study where required.
- Conduct co-monitoring with regional co-ordinating centre staff to ensure adherence to study protocol and study procedures manual
- Review and sign-off monitoring visit reports

Endpoint adjudication

- Responsible for reviewing data and documents for outcome events and authorising them for endpoint adjudication
- Liaise with regional coordinating centres to ensure timely provision of appropriate documents
- Provide training to adjudicators and assist with their queries, when required
- Be available as back up for the end point coordinator

Quality, accuracy and completeness of data

- Ensure adherence to regulatory requirements e.g. ICH/GCP, SOPs
- Assist project team to deliver clean, accurate and verifiable data for final analyses
- File and archive clinical study data at end of project
- Ensure patient safety and adverse/serious adverse events are reported according to regulatory requirements
- Where applicable liaise with staff in Data Management and Statistics Divisions on project specific deliverables

General

- Manage effective communication with the key stakeholders (outside vendors, Research Coordinators, etc).

As a Team Member:

- Actively participate in team meetings and activities
- Participate in special projects to improve processes, tools, systems and organisation;
- Demonstrate commitment to The Institute's organizational values, including performing to an exceptionally high ethical standard and focus on integrity, collaboration and teamwork in all efforts.

Work, Health and Safety

- Comply with Occupational Health and Safety legislation and operate in accordance with established Occupational Health and Safety practice and procedures at the Institute;
- Promote and contribute to a safe, secure environment for staff and visitors.

Skills, Knowledge and Experience

Specific

- Tertiary qualifications in a related science or health care discipline.
- Previous monitoring experience working on clinical projects within an academic, CRO or pharmaceutical environment.

- Working knowledge of, and ability to implement project activities in accordance with, ICH/GCP and all applicable regulations and guidelines in the relevant regions.

General

- Technological proficiency including Microsoft Office suite (Word, Excel, PowerPoint, Outlook, Project), clinical trials databases and management software, and the Internet.
- Strong problem solving, analytical skills, and strategic thinking
- Excellent interpersonal skills and the ability to work well and flexibly i.e. autonomously, and in virtual teams in a cross cultural environment
- Ability to be flexible and adaptable in the face of changing organisational priorities and ambiguous environments.
- Excellent time management and organisation skills
- Excellent written and verbal communication skills
- Ability to see the big picture, yet still focus on detail and quality of work
- Ability to travel domestically and internationally