Position Description	
POSITION TITLE	Clinical Research Associate
CAREER STEP	Intermediate
REPORTING RELATIONSHIP	Project Manager
TEAM	Academic Project Operations
EMPLOYMENT DURATION	2 years
TYPE OF EMPLOYMENT	Full-time
DATE	July 2022

The George Institute for Global Health

The George Institute ('TGI') employs 600+ people, focused on improving the health of millions of people worldwide. As a medical research institute affiliated with leading universities and with projects in approximately 50 countries, we are challenging the status quo in healthcare to find the best ways to prevent and treat chronic disease and injury, and to influence policy and practice worldwide. Our innovative commercial enterprises help maximise our impact.

Here is a sample of the things we are doing to achieve our goal of having the greatest possible impact on global health:

- We are identifying better and safer treatments for our biggest killers like stroke, heart disease and high blood pressure;
- In many countries, our award winning FoodSwitch smartphone app is helping people make healthy food choices when shopping;
- In China, we ran a successful education and awareness program to reduce the amount of salt eaten by people by 25% each day, potentially saving up to 125,000 lives a year;
- In rural India, we have shown that mobile technology can help diagnose mental health, as well as help treat cardiovascular disease, and we're looking at similar approaches to treating chronic diseases in Indonesia and China;
- Together with Aboriginal communities in NSW, Australia, we have developed an innovative community led program to assist young Aboriginal drivers attain their license, now implemented in a dozen of locations;
- We are developing an affordable dialysis machine, with potential to save millions of lives each year and transform the way kidney disease is treated globally.
- And much more.

Context of the Role

The Academic Project Operations (APO) team works closely with our research team to ensure study aims are achieved. The team is primarily responsible for the set-up, conduct and overall delivery of a projects across all research programs in The Institute, according to best practice guidelines and research budgets.

The Role

The Clinical Research Associate (CRA) is required to assist the Project Manager with various tasks associated with running a large scale clinical trial. Generally, the Clinical Research Associate performs all monitoring tasks required at study sites, including source data

verification, safety reporting, drug accountability and the maintenance of study documentation. The CRA provides regular study updates and monitoring visit reports to the project manager and updates clinical study tracking systems as necessary.

Reporting Relationships

The Clinical Research Associate reports to the Project Manager within the Academic Project Operations team. The Clinical Research Associate will also develop effective working relationships with the programs study site staff.

Duties and Key Responsibilities

Study Design

- Assist with the identification and selection of investigators to undertake the study
- Conduct feasibility assessment
- Assist in the preparation of documentation for ethics submission
- Create, organise and collate documents required by the project team prior to the start of the study (e.g. protocols, questionnaires, feasibility, confidentiality agreements, etc.)
- Assist in the development of appropriate monitoring tools
- Organise and participate in investigator meetings
- Prepare, plan, organise and conduct pre-study (site selection) visits and report on these visits to assist in site selection
- Prepare for, plan, organise and conduct site initiation visits
- Collect and review essential documents from study sites
- Motivate and train investigators.

Study Execution

- Perform study monitoring by visit, email and telephone to the participating centres to ensure:
    - Data quality, accuracy, completeness and timeliness of data completion
    - Complete and efficient resolution of data queries
    - Adherence to the study protocol and study procedures manual
    - Adherence to ICH/GCP and other guidelines and requirements as relevant to this trial
- Complete monitoring visit reports accurately and within the predetermined timeframe
- Coordinate distribution, tracking, handling and destruction of study supplies per site
- Assist participating centre research staff in the local management of the study where required.

General

- Assist Project Manager with other study related activities such as organising study meetings and scheduling travel, producing agendas and minutes for study-related meetings, responding to protocol and data collection enquiries, maintaining study documentation, assisting in the preparation of budgetary and administrative documents and other tasks as required.
- Manage effective communication with the key stakeholders (including the Study Management Committee, Principal Investigators, Research Coordinators, etc.).

As a Team Member:

- Participate in special projects to improve processes, tools, systems and organisation;
- Take responsibility for personal learning and development and for setting achievable and meaningful work objectives and managing personal targets, meeting obligations of The Institute's Performance Management and Development Policy;
- Demonstrate commitment to The Institute's organisational 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 Work 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

Essential

- 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.
- Basic understanding of medical terminology
- Knowledge of ICH/ GCP guidelines
- Understanding of confidentiality and privacy laws and all guidelines relevant to medical research
- Excellent skills in MS Office applications including Excel and Word
- Excellent interpersonal skills and the ability to work well and flexibly i.e. autonomously, in small teams and with a wide range of varying stakeholders
- Strong focus on producing the highest quality of work and on ensuring optimum accuracy of outputs
- Ability and willingness to travel.