Job Description	
JOB TITLE	Clinical Trials Assistant
CAREER STEP	Foundation/Projects
REPORTING RELATIONSHIP	Project Manager
DIVISION	Academic Project Operations
EMPLOYMENT DURATION	Until 30 June 2022
TYPE OF EMPLOYMENT	0.5 FTE, fixed term
DATE	October 2021

The George Institute for Global Health

We are a medical research institute affiliated with leading universities aiming to challenge the status quo in health care. With 700+ people around the world, and projects in over 40 countries, our Strategy 2025 is all about impact – specifically, the impact of The George Institute's activities on the health of millions of people, particularly those living in disadvantaged circumstances around the world.

Our strategy focuses on three key research priorities:

- Better Treatments: finding better treatments for the world's biggest health problems
- Better Care: transforming primary health care to support better health for more people
- Healthier Societies: harnessing the power of communities, governments, and markets to improve health

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
- 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 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 at TGI, according to best practice guidelines and research budgets.

The Role

The Clinical Trials Assistant (CTA) is responsible for providing project administrative and tracking support to all staff involved in the projects. The CTA is required to assist the Project Manager and study team with various tasks associated with running a large scale clinical trial. Generally, the CTA is responsible for assisting the project team in the ongoing start up and execution of the trial.

Reporting Relationships

The Clinical Trials Assistant reports to the Senior Project Officer. This role will work closely with other clinical research staff including CRAs, SCRAs and with Project Managers across designated projects.

Duties and Key Responsibilities

Projects

- Track the progress of a clinical trial including patient recruitment, trial supplies and trial documentation
- Provide administrative support for designated clinical research personnel, including Project Managers, SPO, SCRAs and CRAs
- Process and track invoices and authorised clinical trial payments to selected vendors and investigational sites, accurately and in a timely manner
- Organise and schedule appointments/meetings, internally and externally, as necessary and prepare minutes of these meetings
- Coordinate clinical trial supplies and documents to investigational sites, as directed
- Act as a liaison between the PM/CRA and investigator sites, as required
- Assist in monitoring of timelines and resources
- Assist in pharmacovigilance activities such as collating & tracking Serious Adverse Events (SAEs) and reporting to investigators
- Regularly update project tracking tools and systems.

Study Start-up

- Assist in the preparation of study documentation, forms and the development of administrative systems and processes
- Assist in the distribution of study documents to investigators, site staff and the International Coordinating Centre
- Assist in the planning and preparation of Investigator meetings.

Study Execution

- Maintain up to date participating centres' information (including all contact details, contracts and reports).
- Assist with the collection, review and tracking of regulatory documents and endpoint data
- Assist with preparation of communication materials
- Proactively identify study administrative issues.

Endpoint Responsibilities

- Liaise with Endpoint Committee Members
- Coordinate and arrange collection and distribution of endpoint documents to Endpoint adjudicators
- Arrange payment for Endpoint adjudicators

- Monitor Endpoint progress.

General Administration Duties

- Accountable for the management of study materials and supplies – distribution, ordering, tracking, storage, reconciliation and destruction.
- Provide administrative technical support to study team.
- Assist with the preparation of study-related presentation materials
- Responsible for the maintenance and filing of study administrative files
- Assist project team with other study related activities such as organizing study meetings and scheduling travel, producing agendas and minutes for study-related meetings, assembling training and study materials, updating contact details, maintaining study documentation, assisting in the preparation of administrative documents and other tasks as required.
- Assist in managing effective communication with the study team
- Participate in special projects to continuously improve processes, tools, systems and organisation.

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 qualification in a health or science discipline
- Some understanding of medical terminology
- Relevant experience in a clinical research environment
- Basic knowledge of clinical trial processes and ICH/GCP guidelines desirable
- Strong general administration skills and experience.
- High proficiency in the use of the Microsoft Office suite of products, including Word, Excel, PowerPoint, Publisher and Outlook and the Internet.
- 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
- Ability to see the big picture, yet still focus on detail
- Ability to be flexible and adaptable in the face of changing organisational priorities and ambiguous environments
- Strong focus on quality of work.