Position Description	
POSITION TITLE	Senior Clinical Research Associate
CAREER STEP	Independent
REPORTING RELATIONSHIP	Project Manager
TEAM	Academic Project Operations
EMPLOYMENT DURATION	See contract
TYPE OF EMPLOYMENT	See contract
DATE	June 2022

The George Institute for Global Health

'The George' is 700+ people focused on improving the health of millions of people worldwide. An independent 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.

The Institute's 2025 strategic plan has three key priorities:

1. Better treatments: Finding better treatments for the world's biggest health problems
2. Better care: Transforming primary health care to deliver better health to more people
3. Healthier societies: Harnessing the power of governments, markets, and communities to improve health

Here is just a sample of the things we're doing to have the greatest impact on global health:

- Better treatments:
  - We are identifying better and safer treatments for our biggest killers like stroke, heart disease and high blood pressure
  - We're developing an affordable dialysis machine, with potential to save millions of lives each year and transform the way kidney disease is treated globally.
- Better care:
  - 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've shown that mobile technology can help diagnose mental health issues, as well as help treat cardiovascular disease, and we're looking at similar approaches to treating chronic diseases in Indonesia and China
  - We've shown that simple text messaging can help prevent heart attack and stroke. Now, we're working to roll this out globally to prevent chronic diseases affecting millions of people.
- Healthier societies:
  - Together with Aboriginal communities in NSW, Australia, we've developed an innovative community led program to assist young Aboriginal drivers attain their license, now implemented in a dozen of locations
  - In many countries, our award winning FoodSwitch smartphone app is helping people make healthy food choices when shopping.

And much more…

Context of the Role

The Academic Project Operations group works closely with our Research staff to ensure studies/projects are delivered. The Academic Project Operations group comprises of multiple project teams, some overlapping. The project teams work closely with Research teams on specific projects, which form part of specific research programs.

The Role

The Senior Clinical Research Associate (SCRA) will support the Project Manager (PM) in the development and execution of various research projects (clinical and /or non-clinical trials) within the academic research programs of work, priority based on business requirements at that time.

In addition to site management responsibilities, the SCRA will support the PM on project management-related tasks allocated to them. The scope and level of responsibility is negotiated between the SCRA and PM. In conjunction with the PM, the SCRA ensures that these research projects are performing according to the quality standards and deadlines required.

Reporting Relationships

The Senior Clinical Research Associate reports to the Project Manager within the Academic Project Operations team. The SCRA may also have line-management responsibilities for junior members within the Academic Project Operations teams.

Duties and Key Responsibilities

Clinical Trial Start-up Phase:

- Participate in the clinical trial feasibility assessment, identify, and selects investigators with the PM
- Site management responsibilities:
    - Prepares and ensure the Human Research Ethics Committee (HREC) and relevant Regulatory submissions are completed within the project timelines.
    - Prepares/collects all documents needed prior to study initiation.
    - Conducts site initiation meetings to ensure compliance with SOPs and all study specific and regulatory requirements are met.
    - Develops and maintains a good working relationship with the Investigational site staff.
    - Management of the local study files, including in-house and site file
- Prepares, organises, and participates in, Investigator meetings.

Site management

- Conduct on site and remote monitoring of participating centres to ensure:
    - Quality, accuracy, completion, and timeliness of data entry.
    - Complete and efficient resolution 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.
- On occasion, conduct co-monitoring with regional coordinating centre staff to ensure adherence to study protocol and study procedures manual
- Review and sign-off monitoring visit reports.

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 programs on project specific deliverables.

Project Management Delegated Tasks:

The SCRA may be asked to support the PM on project management-related tasks including:

- Developing tracking, monitoring and filing systems
- Developing investigator payment tracking system
- Developing project-specific documents
- Investigational product management
- Manages project related logistics
- Case Report Form development
- Data management support of research projects.

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

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 TGI's Performance Management and Development Policy
- Demonstrate commitment to TGI's organisational values, including performing to an exceptionally high ethical standard and focus on integrity, collaboration, and teamwork in all efforts.

As a Team Manager:

- Ensure direct reports understand and comply with TGI's Policies and procedures, standard operating practices, ethical practice (with respect to research) and the legislative environment
- Be responsible for managing performance of direct reports, including the completion of plans, and agreeing on work and personal objectives and reviewing such plans and objectives, in accordance with TGI's Performance Management and Development Policy
- Act as a role model and ensure the team's commitment to TGI's values, ensuring direct reports perform to a 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
- At least 2 years of 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
- Understanding of medical terminology
- Excellent 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.

Desirable

- Experience working on oncology randomized controlled trials