



## CRC RESEARCH GOVERNANCE OFFICER

(Payclass 10;5-years)

### Clinical Research Centre

### Faculty of Health Sciences

The Clinical Research Centre (CRC) invites applications from suitably qualified candidates to fill the CRC Research Governance Officer post on a 5-year full-time contract. The incumbent will be based at the CRC offices at the Old Main Building at Groote Schuur Hospital, but will attend other faculty sites as required.

The CRC aims to support its staff in their conduct of high-quality clinical research through advice, services and facilities. We are seeking an experienced, dynamic individual to work with investigators and their teams in their conduct of their clinical trials (or other clinical research projects). You will work with a friendly and dynamic team in a Centre of Excellence in trials.

#### Requirements:

- Tertiary degree (NQF7) or Diploma (NQF6), in a health-related field
- 3-5 years' experience in a similar environment
- In-depth knowledge of clinical research systems, procedures, and institutional standards / processes
- Effective communication and interpersonal skills
- Ability to work independently and to effectively prioritize tasks
- Ability to work on multiple projects
- Knowledge and ability to apply GCP/ICH and applicable regulatory guidelines
- Knowledge of applicable regulatory requirements, including local regulations, SOPs and company's Corporate Standards
- Understanding of the regulated clinical trial environment and knowledge of drug development processes
- Ability to establish and maintain effective working relationships with co-workers, managers and clients
- Ability to review research protocols, set site study budgets and manage contract approval processes.
- Maintaining confidentiality with regard to review and access to investigator contracts/budgets as well as ongoing studies at the institution

#### Responsibilities:

Oversee and lead all study start up related activities in collaboration with other clinical research stakeholders. This includes the management and conduct of all research related regulatory duties as well as costings, negotiations and contracting of clinical trials, including (but not limited to):

- Preparing collations and copies for SAHPRA, Ethics Committee and Healthcare Facility level applications
- Ensure accurate record keeping and timeous reporting to regulatory authorities
- Manage regulatory tracker and create regulatory metric reports
- Oversee the maintenance of investigator site files with all essential documents
- Formulate and update and circulate internal policies, templates and SOPs as related to regulatory and ethical affairs and where applicable implement training
- Review of protocols seeking UCT No fault insurance with Risk assessment analysis
- Lead site feasibility meetings and follow up regarding site selection
- Prepare budgets based on cost to company
- Draft (where applicable) and review of Clinical Trial Agreements (CTA, MOUs, MTAs, letters of liability) prior to submission to legal office and coordinate review processes
- Manage study fund opening and prompting invoicing procedures and review thereof
- Attend and participate in management meetings, providing expertise and presenting updated and relevant information
- Provide specialist input and direct investigators with regards to all aspects of study start up i.e. regulatory, funding, CTA, Funds, Insurance, professional Indemnity etc.

The annual cost of employment, including benefits, is between R547 299 and R643 880.

**To apply**, please e-mail the below documents in a **single pdf file** to Ms Tracy Moore at [recruitment05@uct.ac.za](mailto:recruitment05@uct.ac.za)

- UCT Application Form (download at <http://forms.uct.ac.za/hr201.doc>)
- Letter of motivation that speaks to the specific requirements of the position
- Curriculum vitae (CV)
- Copy of South African Good Clinical Practice (GCP) certification, if applicable

Please ensure the title and reference number are indicated in the subject line.

An application which does not comply with the above requirements will be regarded as incomplete.

Only shortlisted candidates will be contacted and may be required to undergo an assessment.

**Telephone:** 021 650 5405

**Reference number:** E220309

**Website:**

[www.crc.uct.ac.za](http://www.crc.uct.ac.za)

**Closing date:**

21 August 2022

*UCT is a designated employer and is committed to the pursuit of excellence, diversity and redress in achieving its equity targets in accordance with the Employment Equity Plan of the University and its Employment Equity goals and targets. Preference will be given to candidates from the under-represented designated groups including candidates with disabilities. Our Employment Equity Policy is available at [www.hr.uct.ac.za/hr/policies/employ\\_equity](http://www.hr.uct.ac.za/hr/policies/employ_equity).*

UCT reserves the right not to appoint.