University of Cape Town Lung Institute
CENTRE FOR LUNG INFECTION AND IMMUNITY

QUALITY CONTROL OFFICER

The **Centre for Lung Infection and Immunity (CLII)** (http://www.lunginstitute.co.za), invites applications for a Full-Time **QUALITY CONTROL OFFICER*** position.

CLII is based within the Division of Pulmonology in the Department of Medicine at UCT and is committed to the pursuit of excellence in research, treatment, training, and prevention of TB in Southern Africa.
CLII conducts various HIV/ TB/COVID-19 related research projects that are conducted at numerous sites in Cape Town and across South Africa.

The main purpose of this position is to ensure processes are conducted in accordance with good clinical practice guidelines and regulations.
The successful candidate will perform quality assurance activities and ensure that all study-related documents and files are audit-ready. This will include but not be limited to the maintenance of site files and monitoring of patient folders. The successful candidate will also be required to coordinate actions for corrective and preventative measures to ensure quality.

Essential Requirements:

- Bachelor of Science Degree or Degree in Health Sciences (advantageous) OR Grade 12 / Senior Certificate with exceptional work experience
- At least 3-5 years' experience working in a clinical research setting
- Valid GCP Certificate (advantageous)
- Experience in auditing, monitoring, and maintaining clinical trials according to GCP standards (site files and patient folders)
- Experience in obtaining and adhering to regulatory requirements (SAHPRA, HREC)
- Experience in data collection and capturing within research is advantageous
- Knowledge of medical terminology (especially TB/HIV/COVID-19)
- Good Computer Literacy (MS Word, MS Excel, MS Outlook, and Internet; Data Management Systems advantageous)
- Excellent work ethic, interpersonal, communication and time management skills
- Ability to work independently and display initiative Language: English. Afrikaans/Xhosa advantageous

Responsibilities include (but not limited to):

- Maintaining and preparation of the Site Investigator Files (ISF) and Trial Master Files (TMF)
- Ensuring superior quality assurance and quality control of Investigator Site Files, by frequent monitoring and general oversight
- Performing the Informed Consent, Inclusion and Exclusion criteria QC processes and ensuring completion of corrections in all participant folders
- Ensuring superior quality assurance and quality control across participant folders by per-visit monitoring and utilisation of all department trackers
- Escalating all deviations and safety or general concerns timeously as per organisational chart.
- Following up on all corrective actions to ensure completion
- Ensuring that the latest versions of the Clinical Trials Protocols, Investigator Brochures and ICFs are filed in the Investigator Site File, and tracked as necessary
- Supporting the QA department and Manager with administrative tasks as required
- Assisting with all the preparation and management of all monitoring and auditing visits (internal and external) as required
- Supporting other site staff with day-to-day quality control activities and training as required
- Ensuring familiarity with protocol overviews for each study

Additional Information:

- This position will be based in Cape Town
- Working hours 40 hours per week, Monday to Friday
- 6-month contract

Application Process:

To apply, interested applicants are requested to submit **an** application form**, cover letter and updated CV** to: uctlirecruitment@uct.ac.za

Reference (in subject line): QC Officer: CLII-0009 **Closing Date:** 15 October 2023

Only shortlisted candidates, who **respond with the correct reference**, will be contacted. Should you not receive a response within 30 days of the closing date, please consider your application unsuccessful.

***Please Note: This Position is not on UCT Conditions of Service.**