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

CLINICAL TRIAL / STUDY COORDINATOR

The **Centre for Lung Infection and Immunity (CLII)** (http://www.lunginstitute.co.za), is currently establishing a database for potential **CLINICAL TRIAL / STUDY COORDINATORS***.

The **Clinical Trial / Study Coordinator** will function under the supervision of the Research Nurse Manager with input from the Principal Investigator (PI) / Clinical Lead. Primary Responsibilities include but are not limited to the following:
onsite project coordination, activities associated with efficient data collection, general study administration, including set-up, launch, running, completion and closure of clinical trials, adhering to Good Clinical Practice (GCP) compliance.

Essential Requirements:

- Diploma/Degree in General Nursing Science (Registered Nurse)
- Valid Registration with the South African Nursing Council (SANC) as a Registered Nurse
- Previous Research experience / minimum 5 years' experience in coordinating research projects or clinical trial/multi-site projects
- Fluency in English and Afrikaans or isiXhosa
- Excellent interpersonal, communication (both verbal and written) and time management skills.
- Computer Literacy (proficiency in MS Office - Word, Excel, PowerPoint, and Internet)
- Valid Driver's license
- Willingness to travel to various CLII research sites within Cape Town
- Ability to work in a team and to foster a collaborative relationship with local clinics and hospitals
- Credit and Criminal Clear

The following will be advantageous:

- Post Basic Nursing Qualification
- Interest in Infectious Diseases Research
- Knowledge of Good Clinical Practice (GCP) with current GCP certification
- Previous experience working with TB patients, especially drug-resistant TB patients.
- Own reliable transport
- Proficiency in Data Management systems

Responsibilities include (but not limited to):
Study Management / Coordination:

- Oversee and ensure that effective recruitment strategies of eligible participants for research projects(s) are implemented and monitored
- Conduct and supervise participant enrolment, collection of informed consent from participants and their parents / legal guardians, information from participant folders, interviews, questionnaires and other sources in line with Good Clinical Practice
- Communication with all relevant study team members (PI's / Clinical Leads, Senior Managers, QC) to ensure study related approvals are up to date; and with sponsor to report AE's, SAE's SUSAR's, etc.
- Establish, maintain contact with key stakeholders and visit research sites as part of coordinating team
- Assist in compiling and monitoring trial-related reports (recruitment / screening rates and strategies, quality logs and trackers), meeting agendas and minutes.

Clinical:

- Coordinate all participant visits for clinical examination and follow up, specific to the protocol.
- Oversee and ensure that all study-related clinical requirements are collected / completed on participants (and recorded) i.e. collection of medical history, phlebotomy, clinical assessments routine BP, urine analysis, performance of ECG's etc. to determine eligibility, and coordinate transportation of participant specimen samples to the laboratories
- Assisting with pre and post counselling for research participants
- Ensure that recruitment staff are adequately trained to explain study procedures to potential participants
- Ensure research nursing standards and participant care meet good clinical practice standards and requirements

Quality Control / Assurance and Data Control

- Oversee/administer all data collection activities (completion of Informed Consent, Case Report Form's) as per specified protocol,
- Verifying data validity - ensure the completion of all study related documentation/source documents as per protocol and GCP guidelines
- Work closely with the Quality Control and the Data team to ensure all data queries is resolved within the required timeline.
- Assess record management i.e. monitor the flow of participant files.
- Ensure that all relevant participant results are printed and filed
- Assist with archiving study records when required

Administrative / General Duties

- Oversee and coordinate the process of coordinating participant reimbursement (petty cash) for the relevant study
- Assist Manager, to identify development needs of staff, and the available training, coordinating training activities.
- Assist Manager to maintain inventory of material and supplies and order new supplies when required
- Coordinate / schedule and attend regular team and unit meetings.
- Perform other research-related duties as assigned.

Additional Information:

- Position will be based in Mowbray (incumbent will be required to travel to various research sites)
- Contract based
- Working hours: 40 hours per week, Monday to Friday

To apply, interested applicants are requested to **click here** to complete the online application process with a cover letter, updated CV and at least two contactable references.

This is an open-ended advertisement, as we seek to establish a comprehensive database of potential candidates.
We look forward to receiving your application and considering you for the potential CLINICAL TRIAL / STUDY COORDINATORS role within our organization.

EMPLOYMENT EQUITY STATEMENT
The University of Cape Town Lung Institute is committed to equity in our employment practices and reserves the right not to appoint. The selection process will be guided by the Employment Equity Plan and Targets of the University of Cape Town Lung Institute (Pty) Ltd.

POPIA STATEMENT
Please note that when applying for any position, reference checks will be completed, and personal information defined in the protection of personal information Act 4 of 2013 will be processed. In applying for this position, applicants will be deemed to have consented to such processing as defined in the policy statement.

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