University of Cape Town Lung Institute
ALLERGY AND IMMUNOLOGY UNIT

ETHICS AND REGULATORY OFFICER

The **Allergy and Immunology Unit** (AIU), based at the University of Cape Town Lung Institute(www.lunginstitute.co.za), requires applications for an **ETHICS AND REGULATORY OFFICER*** to work on a **Fixed Term Contract**.

The purpose of Ethics and Regulator Officer is to ensure that the correct preparation and presentation of all necessary documentation required to be submitted to the South African Regulatory Authority, Ethics Committee(s) and other local regulatory authorities (e.g. City of Cape Town, Provincial Department of Health) in order to obtain the authorization of all clinical trials conducted at the site and to enable future follow-up of the same.

Minimum Requirements:

- Grade 12 / National Senior Certificate or Equivalent
- Tertiary education in a medical or related field
- Valid GCP Certificate (advantageous)
- 3 – 5 Years relevant clinical research experience would be preferred
- Thorough knowledge of local clinical trial regulatory and ethical requirements and applicable laws
- Experience with Regulatory (SAHPRA) and Ethics clinical trial submissions recommended
- In depth knowledge of the Regulatory environment and laws including ICH GCP
- Knowledge in Ethics Committee(s) requirements
- Computer Literacy (Web applications and MS Office applications)
- Proactive and ability to work under pressure and in a fast-paced environment
- Ability to solve problems analytically and creatively
- Excellent organization, co-ordination and administrative skills

Responsibilities include (but not limited to):

- Assist with submission of appropriate documentation for UCT Ethics Committee (serious adverse event reports, 6-monthly project updates, continuing review of research activities, protocol deviations)
- Assist with submission of documentation from the South African Regulatory Authority (6-monthly reports)
- Inform site investigator when ethics submissions are due
- Prepare all Ethics Committee submissions/applications and correspondence to the Ethics Committee for submission on behalf of the PI, which includes initial study submissions, protocol amendments, SAHPRA progress reports, investigator brochures and other safety submissions, annual re-approvals, protocol deviations, trial completion/termination.
- Prepare SAHPRA CVs for new site staff for submission to SAHPRA and Ethics Committee.
- Weekly follow up with Sponsors regarding SAHPRA approvals of newly submitted site staff.
- Review documents received at site for Ethics Committee submissions/application ensuring all site and Ethics Committee requirements have been met.
- Track and review all outgoing and incoming Ethics communication by maintaining tracking logs. , this will also apply to Regulatory communication.
- Ensure staff complete SOP, study-specific training; and read and sign for applicable Standard Operating Procedures (SOP)
- Maintenance of regulatory binders and investigator site files
- Responsible for the maintenance of site staff records and training records.
- Assist with the maintenance of the Site Personnel Authorized Signatures and Delegation log per study.
- Maintain documentation of staff meetings and training

Additional Information:

- Position based in Mowbray
- 12-month Fixed Term Contract
- 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 and updated CV

Closing Date: 24 December 2024

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

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.

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