KENYA MEDICAL RESEARCH INSTITUTE

KEMRI –CCR PHRD clinical trials Project is currently looking for a motivated individual to fill in the following position:

Position: **Quality Assurance Officer (1 position) KMR 6**

Location: **Thika**

Reporting to: **Site Coordinator**

JOB PURPOSE

The incumbent will be responsible for ensuring compliance with the clinical trial protocol; ensure site adheres to Good Documentation Practice (GDP); handling of the data and other materials at the site, including the Investigator Site File, completed CRFs, and the original medical records or files for each participant; internal quality checks in accordance with required study procedures and Good Clinical Practice (GCP) standards.

Essential Requirements:

- Diploma /BSc. degree in Nursing and Clinical Officer.
- Experience in clinical trials with at least two (2) year clinical work experience.
- Have a good working knowledge of GCP requirements for clinical trials.
- Attention to detail and systematic approach to their work.
- Work with minimal supervision and have a high standard for research ethics

Duties and Responsibilities:

- Monitor study team compliance with required study procedures as outlined in the protocol and GCP standards.
- Review participant files for accuracy and ensure specific visit on CRF are completed as per GCP standards.
- Assess and ensure site complies with GCP principles on study participant safety throughout participation in trial
- Assist in monitoring, documenting and reporting adverse events to IRB and Sponsor
- Maintain documents as required by regulatory agency guidelines
- Resolve data queries and record discrepancies identified during in-house reviews
- Report the problems requiring action to the clinical research coordinator and PI
- Ensure that study ICFs are complete and obtained according to GCP standards and site SOP
- Conduct staff training on quality assurance issues
- Perform real-time quality control checks on Source documents and performing updates (if any)
- Performs source data verification (SDV).
- Supervision of maintenance of subject screening and enrollment logs
- Writing and reviewing of study Standard Operating Procedures (SOPs)
- Knowledge of protocol submission to IRB / Regulatory authorities is an added advantage
- Perform other duties as assigned by the CRC, PI or clinical management team

Terms of employment

Employment is a one year renewable contract with a probation period for the first 3 months. Salary is negotiable within the appropriate grade depending on education, experience and demonstrated competency.

HOW TO APPLY

a) All applicants must meet each selection criteria detailed in the minimum requirements.
b) Must include a current CV with names of at least 2 referees.
c) Must include copies of academic and professional certificates.

A duly signed application letter indicating the vacancy reference with copies of documents listed above should be sent to: phrdrecruit@pipsthika.org not later than **28th February, 2022.**

KEMRI IS AN EQUAL OPPORTUNITY EMPLOYER COMMITED TO DIVERSITY; PERSONS WITH DISABILITY, WOMEN, YOUTH AND THOSE FROM MARGINALIZED AREAS ARE ENCOURAGED TO APPLY. KEMRI DOES NOT CHARGE A FEE AT ANY STAGE OF ITS RECRUITMENT PROCESS INCLUDING APPLICATION, INTERVIEW AND PROCESSING OF OFFER LETTER. IF ASKED FOR A FEE, REPORT SUCH REQUEST IMMEDIATELY.

Only short listed candidates will be contacted.