

#### UNIVERSITY OF NAIROBI

### **EXTERNAL JOB VACANCIES (PROJECT POSITIONS)**

Applications are invited for the following position.

# CLINICAL RESEARCH ASSOCIATE, NDOVU STUDY, DEPARTMENT OF CLINICAL MEDICINE AND THERAPEUTICS – AD/7/30/25, 1 POST.

#### Background information

The Ndovu Study is a two-year multi-site, multi-county study nested in the Department of Clinical Medicine and Therapeutics at the Faculty of Health Sciences.

#### Purpose of the position

The holder of this position will ensure all studies are conducted in accordance with the protocol, International Council for Harmonisation Good Clinical Practice (ICH GCP) guidelines, ethical review committees and regulatory guidelines, and all other applicable laws so that human subjects are protected and data produced is of integrity. He/she will lead study monitoring and quality assurance and advise the Principal Investigator on study design and conduct and oversee GCP and human subjects' protection (HSP) training, certification and adherence for all study personnel.

Job Title: Clinical Research Associate (CRA)

Duty Station: University of Nairobi

Reporting to: Chief Investigator

#### Job Description

- 1. Champion participant safety and wellbeing, rights and confidentiality
- 2. Ensure appropriate GCP and HSP training, certification and practice for all study personnel
- Participate in study design and planning including pre-study assessment for study sites, development of study materials, compilation of the investigator site file, and pre-study trainings
- 4. Work with the study team to oversee ERC and regulatory submissions, responses, renewals, amendments, notifications and communications
- 5. Ensure appropriate training of study personnel on the study, including protocol, refresher and remedial trainings
- 6. Oversee the informed consenting process
- 7. Assist the Study Coordinator in the maintenance of investigator site files
- 8. Develop monitoring plan for all supported studies
- 9. Conduct site monitoring visits as per the monitoring plan including oversight of independent monitors.

- 10. Regularly review study data including conducting source data verification, raise data queries, and review resolution of queries to ensure integrity of study data.
- 11. Prepare sites and participate in sponsor, ERC and regulatory audits
- 12. Work with study sites to address monitoring and audit findings
- 13. Oversee study close-out including ensuring appropriate disposal of investigational products, archiving of study documents, and closure of study sites as needed
- 14. Any other duties assigned by the supervisor

#### **Job Specifications**

- i. Bachelor degree in a health-related field
- ii. Registered healthcare practitioner with a valid practice certificate
- iii. MUST have a current Certificate of Good Clinical Practice
- iv. MUST have a current certificate in Human Subject Protection
- v. Certificate in clinical trial monitoring
- vi. Previous experience working as the main Study Monitor for at least two large clinical trials
- vii. Previous experience supporting regulatory compliance for multiple clinical trials
- viii. Experience with a multi-country clinical trial is an added advantage
- ix. Good communication skills
- x. Willing to travel extensively and on short notice

#### Terms of appointment

The appointment is on contractual terms of one year, renewable based on performance and mutual agreement.

#### Notes

- Applicants should email their application letters, certified copies of certificates and curriculum vitae (CV) giving details of their qqualificationons, experience and three (3) referees indicating their telephone contacts and e-mail contacts;
- 2. Applications and related documents should be forwarded addressed to the Director, Human Resource, University of Nairobi;
- 3. Applicants should state their current designations, salaries and other benefits attached to those designations;
- 4. The application letter must bear the reference code indicated in the advertisement;
- 5. Late applications will not be considered and
- 6. Applications should be emailed as one file in PDF to: <u>recruitClinicalresearchassociate@uonbi.ac.ke</u>

## CLOSING DATE: JULY 17, 2025

THE UNIVERSITY OF NAIROBI IS AN EQUAL OPPORTUNITY EMPLOYER ONLY SHORTLISTED APPLICANTS WILL BE CONTACTED