UZ- UCSF COLLABORATIVE RESEARCH PROGRAMME

VACANT POST – CTU CENTRAL REGULATORY OFFICER

UZ-UCSF Collaborative Research Programme is seeking a suitably trained, competent, and qualified applicant to fill the position of Central Regulatory Officer. The incumbent will be responsible for providing support to the Clinical Research Sites (CRS) within the Clinical Trials Unit (CTU).He/She is expected to enhance efficiency related to Institutional Review Board (IRB) and regulatory authorities' applications within the CTU and be responsible for process standardization of regulatory work across the CRSs within the CTU, review, and follow-up of all IRB applications prior to submission.

RESPONSIBILITIES

- Responsible for submission of all applications to the various IRBs, tracking all submissions and make follow up directly with the IRB.
- Work closely with CRSs to expeditiously resolve or respond to queries raised during initial review of a protocol by IRBs.
- Establish electronic Trial Master Files for all studies in the CTU to enable internal virtual QA/QC audits and updating and reviewing the IRB SOP annually or more frequently if need arises.
- Ensure bookings for any pre-submission meetings are done as required.
- Communicates directly with the IRB to get updated information on application requirements, review dates, outcomes, queries and timelines for query responses; communicates any change or new requirements by the IRB to all CRSs within the CTU.
- Develop an automated reminder for all CRSs to inform them of protocol expiry/renewal dates.
- Communicates internally with CTU departments such as Accounts for tracking of payments, Pharmacy and Laboratory .Communicates externally with the IRBs to discuss any challenges.
- Communicates progress of IRB applications to the CTU leadership monthly.
- Ensure all applicable protocol documents are translated into local language.
- Train new staff engagements on SOP and expectations related to IRB requirements.
- Progress tracking of all IRB applications at the CRSs of new and existing protocols.
- Audit to assess minimum standards are adhered to as highlighted in the SOP and minimum performance measures as stipulated by the network of affiliation or CTU.

Required Qualifications & Experience

- Medical Degree/ Pharmacy Degree/ Public Health Degree/Biomedical degree
- Vast experience in project management, health research management an added advantage
- Excellent organizational, planning and analytical and problem solving skills
- Excellent written and oral communication skills
- Good IT skills with proficiency in creation and use of databases
- Ability to foster a culture of teamwork and the ability to lead a team
- Clean class 4 driver's licence.

Applicants wishing to be considered for this post should submit a detailed Curriculum Vitae, copies of academic and professional qualifications not later than Friday 24 March,2017 to:- Human Resources & Logistics Manager ,UZ-UCSF Research Programme,15 Phillips Avenue, BELGRAVIA: