| VACANCY | |
|---|---|
| **Job title:** | Regulatory & Compliance Officer |
| **Type:** | Permanent ☒ Fixed Term ☐ Temporary ☐ |
| **Main purpose of the job:** | To monitor and ensure compliance with regulatory and good clinical research practice requirements within research studies within the Shandukani Research |
| **Location:** | 7 Esselen Str, Hillbrow, Johannesburg. |
| **Closing date:** | 10 January 2024 |
| **Submit detailed CV to:** | Vacancy5@wrhi.ac.za |
| **Advert reference number:** | **UM 01-2024** |
| In accordance with our Employment Equity goals and plan, preference will be given to suitable applicants from designated groups as defined in the Employment Equity Act 55 of 1998 and subsequent amendments thereto. | |

## Key performance areas

Maintain a positive attitude and respond openly to feedback.
Maintain regulatory systems for Wits RHI Shandukani studies per SAHPRA, WHREC, sponsor and DOH DRC requirements.
Support in drafting submissions of technical reports to IRB's, SAHPRA and sponsors as needed.
Initial Submissions for IMPAACT & Pharma Studies: Ethics, SAHPRA preparation, submissions, communication and follow up.
Recruitment Approvals: Gauteng Research District, COJ, CEOs, Clinic Managers submissions and approvals on the NHRD.
Amendments, LOA, CM: Ethics, SAHPRA preparation, submissions, communication, follow up and updating tracking log.
Annual Recertification: Ethics, preparations, submissions and follow up.
Six-Monthly Progress Reports: Ethics, SAHPRA, DRC tracking all events for the last six months (bi- weekly reports for studies for public health outbreaks).
Safety Updates: Ethics and SAHPRA line listings submissions and updating tracking log.
Retain current research staff CVs, GCP, MPS, HPCSA, SAPC, SANC certificates.
Informed Consent review.
Participate in monitoring visits, internal (Sponsor) and external regulatory (FDA and EMA) inspections.
Review systems and recommend improvements to streamline the creation and maintenance of trial documentation i.e., Project Management.
Provide guidance on the requirements of local and international regulatory bodies and frameworks, and support the department to comply with those requirements i.e., Community & Stakeholders Workshop
Review and ensure that the study has all essential regulatory documentation.
Assist sponsors / monitors before, during and after monitoring visits.
Study insurance- renewals, liaising with sponsor regarding approval of insurance funds.
Take ownership and accountability for tasks and demonstrates effective self-management.
Follow through to ensure that quality and productivity standards of own work are consistently and accurately maintained.
Maintain a positive attitude and respond openly to feedback.
Take ownership for driving own career development by participating in ongoing training and development activities such as conferences, workshops etc.

**Required minimum education and training.**

3-year diploma or degree in a health-related field.

**Required minimum work experience**

Minimum 3 years relevant work experience within a clinical research environment (if possible, in the regulatory compliance department).

**Desirable additional education, work experience and personal abilities**

Understanding of the research language, detailed knowledge and understanding of the relevant studies and SOP's, knowledge of clinical research documentation.
Detailed knowledge of regulatory application and approval processes.
Computer literate with ability to create or work with databases/excel logs.
Fluent in English, fluency in one of the other official SA languages particularly Zulu or Sesotho would be an added advantage.
Good written and verbal communication skills. Strategic thinking and problem-solving skills.
Conscientious and precise delivery of work even when under pressure.
Effective self-management, resourcefulness, and initiative to solve problems.
Excellent communication and presentation skills.

Should you be interested in applying for this vacancy, please send an email to vacancy5@wrhi.ac.za. The subject heading of the email must read **UM 01-2024** and the job title of position applying for. Please include the following documentation:

- A cover letter (maximum one page) that clearly states which vacancy you are applying for
- A detailed CV