

### VACANCY

<b>Job title:</b>	Regulatory and Compliance Officer
<b>Type:</b>	Permanent <input type="checkbox"/> Fixed Term <input type="checkbox"/> Temporary <input checked="" type="checkbox"/>
<b>Main purpose of the job:</b>	To monitor and ensure compliance with regulatory and good clinical research practice requirements within research studies within Clinical Research Centre.
<b>Location:</b>	7 Esselen Street, Hillbrow, Wits RHI Research Centre Clinical Research Site (CRS)
<b>Closing date:</b>	22 April 2026
<b>Submit detailed CV to:</b>	<a href="mailto:Vacancy5@wrhi.ac.za">Vacancy5@wrhi.ac.za</a>
<b>Advert reference number:</b>	UM 18-2026
<p>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.</p>	

#### Key performance areas

Prepare applications and submissions to IRB's, SAHPRA, DOH, NHRD as needed.

Create, establish and maintain regulatory systems for Wits RHI studies per SAHPRA, HREC, sponsor and DOH requirements. Print and file regulatory documentation.

Work with the Regulatory Oversight Group (ROG) and Research Review Committee (RRC) as needed and provide expert guidance on the requirements of local and international regulatory bodies and frameworks and support the department to comply with those requirements.

Track annual recertification submissions to HREC.

Review systems and recommend improvements to streamline the creation and maintenance of trial documentation and review and advise on improvements and standardisation of quality control and assurance systems with respect to improved compliance with regulatory frameworks.

Actively participate in the submission of research protocols and where appropriate assist in writing funding proposals for improvements of monitoring, evaluation and quality control of data.

Ensure site delegation logs are updated when there are staffing changes.

Ensure adequate training completed by staff members and training logs completed.

Ensure staff adhere to responsibilities defined in site delegation logs per qualifications and training.

Ensure that all SOPs have been read and signed by all staff. When SOPs revised circulate new signage sheets for completion on review.

Prepare site informed consent forms and prepare, review and revise standard operating procedures per study specific needs.

Review and ensure that the study has all essential regulatory documentation.

Assist sponsors / monitors before, during and after the review.

Perform duties per study Delegation of Authority Logs.

Ensure participants are enrolled per defined eligibility criteria.

Provide training to staff in areas of expertise to reduce repetitive errors noted during study file review.

Assist in completion of corrective action for both internal and external monitoring reviews.

Ensure site is well prepared for internal and external lab, pharmacy, clinical, social science and community monitoring reviews.

Ensure documentation is adequate on study specific procedures.

Assess compliance to Good Clinical Practice (GCP), Standard Operating Procedures (SOPs) and Regulatory Essential Documents per sponsor requirements and to determine the accuracy of research records.

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 Degree in a health related field.

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

A post graduate degree in Quality Management would be an added advantage.

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.

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.

**Required minimum work experience**

Minimum 1-3 years relevant work experience within a clinical research environment in regulatory compliance.

Should you be interested in applying for this vacancy, please send an email to [vacancy5@wrhi.ac.za](mailto:vacancy5@wrhi.ac.za). The subject heading of the email must read **UM 18-2026** 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