

VACANCY

Job title:	Study Coordinator
Type:	Permanent <input checked="" type="checkbox"/> Fixed Term <input type="checkbox"/> Temporary <input type="checkbox"/>
Main purpose of the job:	To administer, main and coordinate clinical trials according to good clinical practice, the study protocol, and the site standard operating procedures. Act as a pivotal point of contact for the clinical trial team and the study sponsor(s).
Location:	Chris Hani Baragwanath Hospital
Closing date:	22 August 2022
Submit detailed CV to:	sntuli@witshealth.co.za
Advert reference number:	Study Coordinator3 - Bara
<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. Our Organisation maintains a Mandatory COVID-19 requirement and as such only COVID-19 Vaccinated incumbents will be considered for positions.</p>	

Key performance areas

Study Management -:

- Primary SSC on trial to oversee all operations on trial, ensure protocol and GCP compliance.
- Attend Investigator meeting, SIV and any other in-person or virtual training to manage the study.
- Assist study team with efficient study start-up, conduct and close-out.
- Ensure access to online portals for self and support staff.
- Manage regulatory updates throughout the study (New ICF's, Protocol Amendments, etc).
- Manage site monitor visits according to GCP and Site SOP.
- Proactively resolve protocol queries and missing data with Investigators and Clinical Trials Assistants.
- Communicate with CRO, Sponsor and regulatory authorities regarding notifiable trial events.

Participant Management -:

- Prepare for and manage participant visits and data capturing in line with protocol and site SOP's.
- Assist in patient recruitment, screening, and enrolment of eligible patients according to protocol requirements.
- Perform and/or book procedures correctly per protocol within scope of practice.
- Manage lab kits and study samples according to protocol, procedures manual and local legislature.
- Administer study medication safely in line with scope of practice.
- Be able to manage medical emergencies within scope of practice.
- Communicate well with investigators regarding participant welfare while on study.
- Notify relevant parties of Serious Adverse Events or Events of Medical Importance within 24 hours.
- Quality control of patient files and data entries (i.e., eCRF's, CRF's).

Teamwork & Support -:

- Assist team members with an open helpful attitude, perform on-the-job training where necessary.
- Assist the Pharmacist with visit activities (IVRS, IP management, etc).
- Assist the administrative staff with arrangements to be made for participant visits (Patient transport with Uber, Vendor booking details, etc).

- Assist site finance staff with payments on study (pass-through, travel fees, etc).
- Assist the team with ad hoc assignments and duties as needed, delegated by line manager and within scope of practice.

Required minimum education and training

Nursing Diploma with Oncology (or equivalent). Certification in Project Management and good clinical practice (GCP) will be an advantage.

Required minimum work experience

Minimum two (2) years experience of working in an oncology unit and administering chemotherapy.

Professional body registration

Registration with SANC.

Desirable additional education, work experience and personal abilities

- Thorough with good attention to detail.
- Ordered and systematic in approach to tasks, with strict compliance to protocols.
- Exceptional organisational and administrative skills are required together with working knowledge of Microsoft Office.
- Able to exercise discretion and independent decision-making.
- Ability to prioritise own workload, take initiative (pro-active) and work to tight deadlines.
- Self-motivated with a high regard for work ethic, values, and integrity.
- Overtime and traveling will be required from time to time.
- Light physical activity required.

Should you be interested in applying for this vacancy, please send an email to sntuli@witshealth.co.za. The subject heading of the email must read **Study Coordinator3 - Bara** 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