DESMOND TUTU HEALTH FOUNDATION

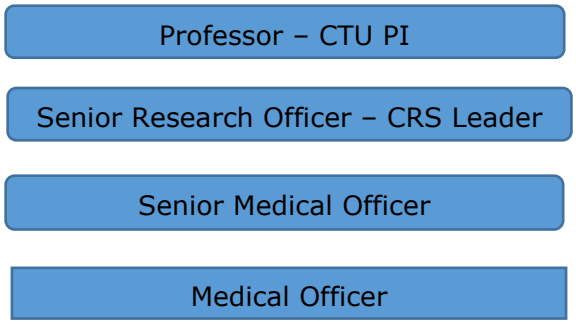
3 Woodlands Rd, Woodstock, 7925, Cape Town, South Africa

(T) +27 021 301 2020 (E) info@hiv-research.org.za
P O BOX 13801, MOWBRAY, 7705, Cape Town, South Africa
VAT No. 4750185565

JOB DESCRIPTION

POSITION DETAILS	
Position Title	Senior Medical Officer
Site	Emavundleni CRS
Project	Emavundleni
Date of compilation	27 July 2023

ORGANOGRAM *(Adjust as necessary. Include line manager, line manager's manager, all subordinates and colleagues)*



PURPOSE

The main purpose of this position is to perform the duties of Investigator of Record / Principal Investigator (approximately 40% of time); and see participants for study visits (approximately 60% of time).

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Job Content

Key performance areas (4 – 6)		% of time spent	Activities / Objectives / Tasks	Results / Outcomes
1	Protocol-specific procedures	60%	• Clinically assess, examine, diagnose and manage the health of participants. • Complete prescriptions of pharmaceuticals appropriately. • Monitor clinical examinations and procedures undertaken by study nurses when necessary. • Interpret and act on laboratory results. • Manage participants with Adverse Events or Expedited Adverse Events. • Refer participants to other clinical or specialist care as required. • Liaise with Pharmacist on study products and site drugs. • Ensure all research activities are performed according to Medical Control Council (MCC), protocol, the Declaration of Helsinki, International Conference on Harmonisation (ICH), Good Clinical Practice Guidelines and other relevant legislation. • Oversee the recruitment, screening and enrollment participants as per protocol-specific inclusion/exclusion requirements. • Oversee and advise on the management of AEs and other participant safety issues until considered resolved or stable across all clinical trials implemented at the research site.	• Participants are managed according to relevant local legislation/guidelines and HPCSA policies and procedures. • Participants are managed according to protocol requirements. • Participants are managed according to medical ethical standards. • Recruitment is successful. • Participants remain on study. • Participant confidentiality maintained at all times. • Research protocol is followed correctly. • Study documentation is accurate and complete.

2	Principal Investigator / Investigator of Record duties	40%	• Ensure all Adverse Events or Expedited Adverse Events are managed timeously and effectively as per Standard Operating Procedures (SOP) and protocol requirements. • Coordinate responses to clinical queries from sponsors. • Liaise with Study Coordinators and Data Team to identify problem areas, and implement corrective actions and training programmes. • Assist with staff training in new and updated protocols. • Assist with visits by sponsors and partners. • Assist in preparing study documentation for audits, monitoring visits and site visits from external study monitors and auditors. • Attend protocol specific clinical calls. • Assist with operational research related management issues. • Assist with the design and enactment of standard operating procedures for clinical management and research projects	• All protocol activities are effectively implemented. • Clinical Study staff are supported • Staff are informed of all necessary changes/ updates to study requirements/processes. • Training needs identified and relevant training delivered.

Other duties
Perform other related duties as assigned

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MINIMUM REQUIREMENTS

Minimum requirements	• MBChB
Minimum experience	• 2 or more years in a lead/supervisory role within the clinical research environment - managing clinical staff • 3 or more years of clinical drug trial experience • Previously registered with SAHPRA as Investigator of Record / Principal Investigator of a clinical drug trial
Professional registration/ License	• HPCSA registration as a medical practitioner (independent practice)

COMPETENCIES	
Client service orientation	Strong communication skills
Building interpersonal relationships	People management, including performance management
Decision-making and problem-solving	Facilitating change
Building partnerships	Functional leadership
Technical knowledge and skill	Work standards