HR191	**POSITION DESCRIPTION**	UNIVERSITY OF CAPE TOWN IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

NOTES

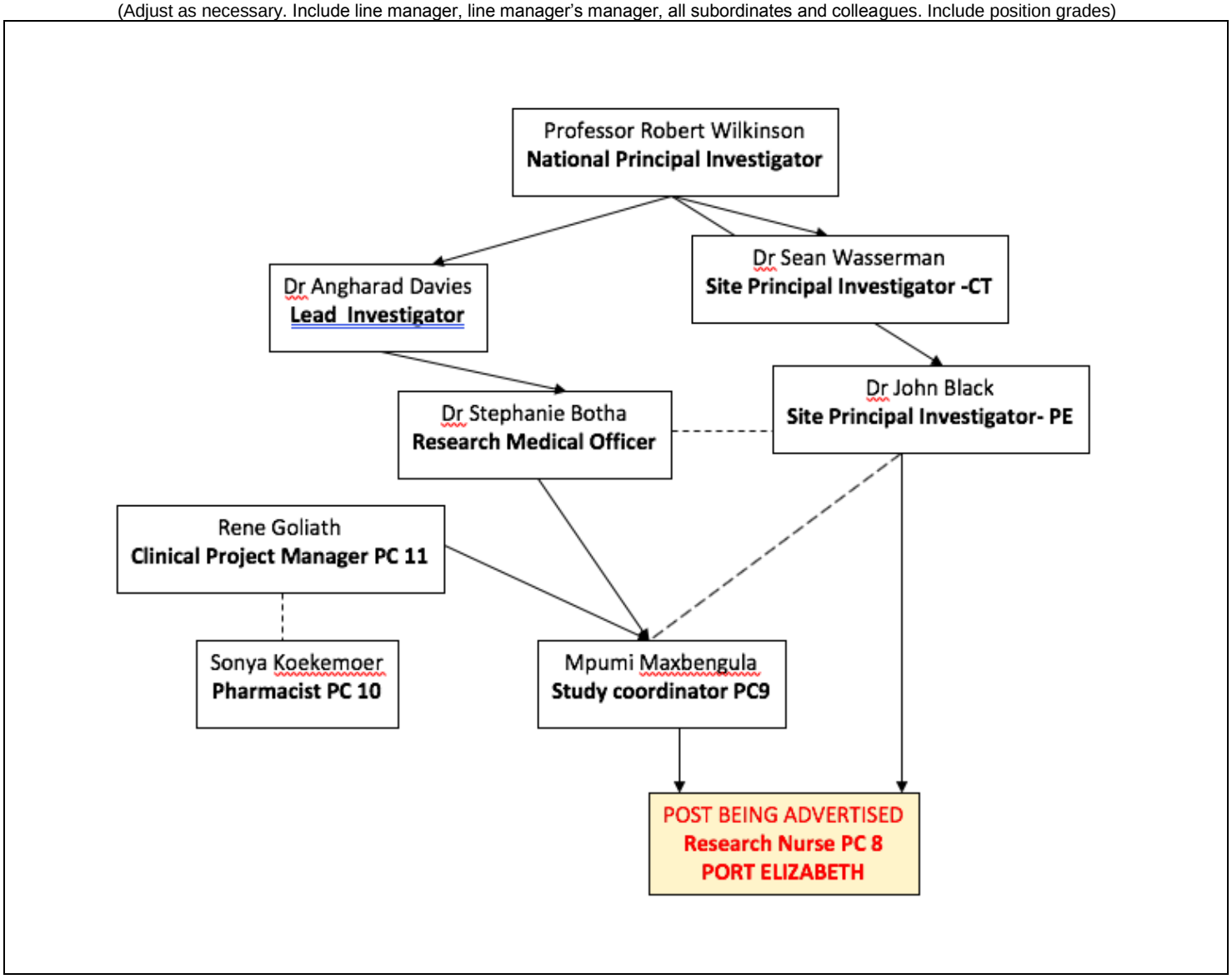
- Forms must be downloaded from the UCT website: http://forms.uct.ac.za/forms.htm
- This form serves as a template for the writing of position descriptions.
- A copy of this form is kept by the line manager and the position holder.

POSITION DETAILS

Position title	Research Medical Officer		
Job title (HR Practitioner to provide)			
Position grade (if known)	Clinical	Date last graded (if known)	
Academic faculty / PASS department	Health Science		
Academic department / PASS unit	Medicine/IDM		
Division / section	CIDRI-Africa: Wilkinson		
Date of compilation	30th January 2019		

ORGANOGRAM

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



PURPOSE

The LASER-TBM trial is a multi-site randomized trial to evaluate the safety of a novel treatment regimens in HIV-1 infected persons with Tuberculous Meningitis. The trial is funded by Wellcome and Sponsored by UCT and is due to start in April 2019 taking place over 4 years across 5 sites in South Africa. This includes 2 recruitment sites in the Port Elizabeth area - Livingstone and Dora Nginza Hospitals, which will start in May 2019.

We are seeking a full time Research Medical Officer (RMO) for the trial. The successful candidate will become part of the LASER-TBM team based across the two Port Elizabeth clinical recruitment sites. The RMO will work closely with a designated research nurses, the site PI, co-investigators and trial co-ordinator on the team. The primary responsibilities will be to recruit patients to the study, assess and manage trial participants in both an inpatient and outpatient setting, perform study procedures, collect clinical data, assist with data entry and management, engage with safety reporting, and play a key role in the administration and functioning of the clinical trial team.

The majority of time will be spent with trial participants at their respective clinical sites. There will also be opportunity to work with the well-established research team at CIDRI-Africa at the University of Cape Town.

CONTENT

Key performance areas		% of time spent	Inputs (Responsibilities / activities / processes/ methods used)	Outputs (Expected results)
1	Screening, enrolment and clinical follow-up	40	♦ To screen, enroll and follow-up study participants, clinical assessment, study procedures (including the performance of lumbar punctures and pharmacokinetic sampling), and clinical management of participants according to the trial protocol and GCP	Eligible candidates are enrolled. Enrolment and retention targets met. Clinical procedures performed safely and according to protocol and GCP. Clinical events are assessed and managed appropriately.
2	Completion of all relevant study documentation and adverse event reporting	30	♦ Familiarity with the trial protocol and all study documents. ♦ To complete all documentation according to study standard operating procedures (SOPs) and GCP. ♦ Reporting of adverse events to sponsor, ethics committee and regulatory authorities. ♦ Development or revision of study SOPs as needed. ♦ Assist with study administration including writing of documents and communication	Accurate and complete study information captured on designated case report forms Adverse events reported according to guidelines of sponsor and within stipulated timelines Standard Operating Procedures are relevant and updated at all times
3	Involvement in database management	10	♦ Entry of study data onto electronic database. Involvement in data QC/QA. ♦ To liaise with data management team	Clean data available for analysis
4	Communication with other staff and external bodies	10	♦ To closely liaise and maintain effective communication with the other study and site staff members. ♦ To liaise closely and maintain effective communication with the trial co-ordinator and site PI. ♦ Liaise with data management team and maintain of effective communication with the other study and site staff members including regulatory manager, trial co-ordinator and Clinical Projects Coordinator ♦ Maintain effective communication with the study monitors and trial sponsors. ♦ To manage, supervise and teach clinical research staff as required by the project.	Study protocols are understood and followed by the research team Sponsors are informed Safety and regulatory guidelines adhered to Effective communication

5	Obtaining and transporting samples	5	♦ May need to conduct or oversee all necessary study procedures like phlebotomy and collection of any other clinical samples as clinically indicated or required by the protocol. ♦ Transport of clinical specimens to the laboratory from the clinical site if required	Study procedures performed as required by protocol
6	Training and meeting attendance and participation	5	♦ Attend study and academic meetings and training as required, and to prepare for and present at the training sessions. ♦ Presentation of research findings at meetings at the clinical research site and IDM.	Self-development Clinical, laboratory and academic information is exchanged between research staff

MINIMUM REQUIREMENTS

Minimum qualifications	**Requirement:** • MBChB/ MBBCh degree
Minimum experience (type and years)	**Requirement:** • At least 1 year of clinical experience in treating patients with HIV infection or adult secondary health care • Completed community service training year
Skills	**Requirement:** • Computer literate: high level word processing skills
Knowledge	**Requirement:** • Experience of treating adults at secondary care level
Professional registration or license requirements	**Requirement:** Current HPCSA registration as an Independent Medical Practitioner
Other requirements (If the position requires the handling of cash or finances, other requirements must include 'Honesty to handle cash or finances'.)	• Valid work permit for South Africa if non-South African • Valid driver's license **Advantageous:** • Current accredited GCP certificate • Current accredited BLS/ACLS certificate • Experience working in clinical research and clinical trials • Experience in writing reports and analyzing data • Ability to communicate in isiXhosa • How to successfully work in a multidisciplinary clinical team

Competencies (Refer to UCT Competency Framework)

Competence	Level	Competence	Level
Management skills	2	Teaching skills	2
Teamwork/collaboration	2	Formal Presentation skills	2
Effective communication	2	Problem solving	2
Professional knowledge and skill	2	Decision making/ judgment	2

SCOPE OF RESPONSIBILITY

Functions responsible for	Clinical assessment, management and referral of participants for screening and trial follow up Completion of study documentation. Reporting of adverse events. Communication with clinical team, trial staff, and sponsor. Performance of study procedures and obtaining study specimens. Training and meeting attendance and preparation.
Amount and kind of supervision received	Supportive clinical and administrative supervision.
Amount and kind of supervision exercised	Supervise and support nursing staff in clinical assessments and obtaining study specimens as needed.
Decisions which can be made	Inclusion and exclusion of participants. Referral and reporting of adverse events which fall into mild or moderate categories. Communication within clinical team. Decisions involving performance of trial procedures and specimen collection (within limits of protocol and SOPs).

Decisions which must be referred	To be discussed with line manager: Including and excluding participants where decision to include is not clear from clinical trial protocol. Clinical management issues beyond the scope of training and experience of the employee. Referral and reporting of adverse events that are judged to be severe or above. Training and meeting preparation. Communication with sponsor.

CONTACTS AND RELATIONSHIPS

Internal to UCT	Wellcome Centre Infectious Diseases research in Africa (CIDRI-Africa) Institute of Infectious Disease and Molecular Medicine (IDM)
External to UCT	University of Cape Town (Sponsor)