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

NOTES

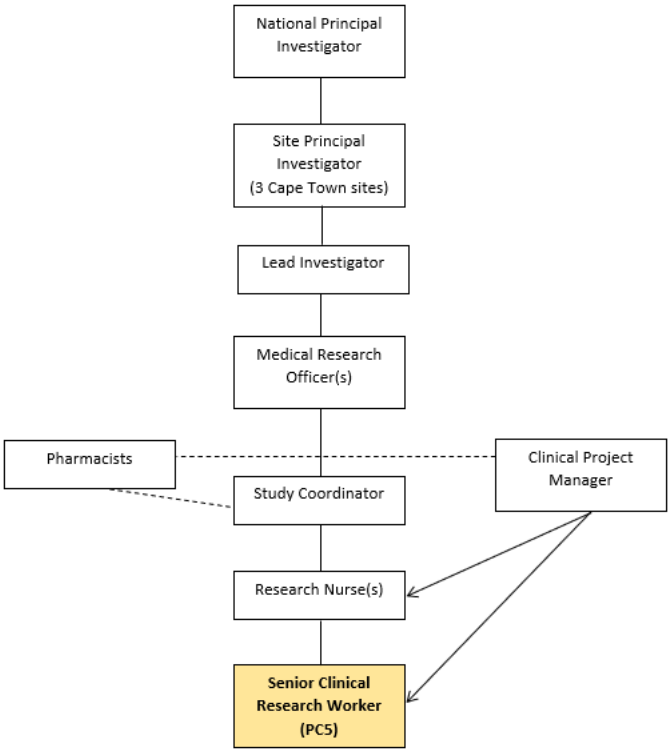
- Forms must be downloaded from the UCT website: http://forms.uct.ac.za/forms.htm
- This form serves as a template for the writing of position descriptions.
- A copy of this form is kept by the line manager and the position holder.

POSITION DETAILS

Position title	Senior Clinical Research Worker		
Job title (HR Practitioner to provide)			
Position grade (if known)	PC5	Date last graded (if known)	
Academic faculty / PASS department	Health Sciences		
Academic department / PASS unit	IDM		
Division / section	CIDRI-Africa		
Date of compilation	12 November 2021		

ORGANOGRAM

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



PURPOSE

The main purpose of this position is supporting studies being conducted within the group which include a Phase III clinical trial to test the efficacy of a novel treatment regimen in TB meningitis. This a Phase IIa clinical trial to test the safety of a novel treatment regimen in HIV-1 associated TB meningitis (ITBM). This clinical trial commenced recruitment in 2021, recruiting from five sites across South Africa. We seek one full time senior clinical research worker to join a research team based between the four clinical sites in Cape Town: Groote Schuur Hospital, New Somerset Hospital, Khayelitsha Hospital and Mitchell's Plain Hospital.

The successful candidates will work closely with the research medical officers, research nurses, trial pharmacists and trial coordinator. The main purpose of this position is to provide support to the clinical team and assistance in the clinical area and to perform clerical duties within this group. Counselling of participants with regard to their TB treatment and ARV adherence will be required. The duties also involve transportation of study drugs from central pharmacy to clinical sites and participant files from UCT to various sites. Occasional weekend work and maybe required and participants and families may need to be contacted after hours.

CONTENT

Key performance areas		% of time spent	Inputs (Responsibilities / activities / processes/ methods used)	Outputs (Expected results)
1	Literacy assessment and consenting	40	• Ensure that participants receive the appropriate information, including risks and benefits, about the research project. • Administering a literacy assessment tool and deciding if an impartial witness is required (for illiterate participants). • Administering an assessment of understanding tool to check if participant understands consent. • Obtain consent from participants/ family members • Ongoing informed consent discussions with participant and family members • Liaise with medical team with regard to participants ability to give informed consent	• Well informed participants who make an informed decision to join the trial or to decline enrolment. • Participants receive additional information and support as required. • Ensure fair participant selection, protect the privacy of research participants, and obtain meaningful informed consent • GCP guidelines maintained • Sample size for the study protocol is achieved
2	Counselling	30	• HIV pre- and post-test counselling, and risk and transmission reduction counselling. • Positively motivate behavioral change using accepted methodologies. • Ability to counsel and refer with regard to psychological and social issues • Ensuring that all trial participants receive access to the highest standard of HIV prevention information • Support participants through repeated HIV testing • Discuss TB transmission testing and prevention with participants • Active participation in patient information sessions with family members if participants are unable to consent for themselves • Updating participant and family about follow-up study appointments • Counselling and support of participants as required	• Informed participants who know what tests are being performed and when to expect the results. • Knowledge of TB and HIV transmission • Positive participant behavioral change • Understand the dynamics and social implications of TB/HIV infections • Participants are fully informed about aspects of their health
3	Participant telephone calls and retention	10	• Assist the study team with calls as needed e.g. appointment confirmation • Folder preparation, clinic preparation, filing of laboratory reports • Record telephone call outcomes	• Participants are retained in the study • Positive recall numbers with a decrease in lost to follow-up • Follow-up visits are conducted as per protocol • Participants and family members are confident in the study activity and study team • Well prepared clinic, well maintained records • 90% retention rate of enrolled participants.

4	Assisting with general clerical, quality control duties	10	• Collect required study medication from central pharmacy or site pharmacy. • Liaise with research nurse and ensure the sufficient study medication is at site • Assist with checking and packing collected samples into transport boxes • Ensure that transport boxes are at the correct temperature • Preparation and checking of clean participant files and visit documents and preparing for the next clinic day. • Quality checking completed CRFs	• On time delivery of study medication to hospital clinical team • Enough study drugs available for all participants on each site • Study clinical samples are collected as per protocol and transported • Temperature logs recorded daily and up to date • Excellent quality control process • Adherence to CQMP, SOPs and Protocol • Prepared participant folders to ensure smooth clinic flow. • Accurate data collection.
5	Translation and Interpretation for participants	5	• Ensure that Xhosa/Afrikaans speaking participants fully understand discussion with all staff members by acting as a translator. • Translation of English written documents into Xhosa/Afrikaans. • Checking and correcting of translated documents provided by sponsor • Respect for culture of all participants	• Participants freely communicate with all members of the study team. • Participants are offered documents in preferred language. • Participants freely share the choices they make which is important study data
6	Training and Meetings	5	• Attendance of all training sessions as required by the sponsor and Wilkinson group • Attend all study meetings and trainings, online and face to face. • Assist to train and familiarize new staff members on the counselling aspects of the study	• Proficiency testing after all training sessions and retraining as required • GCP and HSP compliant, regular input at site meetings. Completion of all required online training • Protocols and SOPs understood

MINIMUM REQUIREMENTS

Minimum qualifications	Grade 12 1-year experience in research and qualification as a TB/ARV counsellor Substantial advanced counselling course (eg. 1-2 year part-time course)
Minimum experience (type and years)	HIV counselling qualification Knowledge of Good Clinical Practice 1-year experience in research Work permit if not South African
Skills	12 months as adherence counselor in HIV/TB 1 years working in clinical research. Conduction Informed Consent Recruitment Contact Tracing Safe transporting of medication and confidential files
Knowledge	GCP knowledge Basic computer literacy Good Clinical Practice – (Advantageous) English and IsiXhosa spoken and written Knowledge of ARVs and TB
Professional registration or license requirements	N/A
Other requirements (If the position requires the handling of cash or finances, other requirements must include 'Honesty to handle cash or finances'.)	Interpersonal skills Valid driver's license Own transport

Competencies (Refer to UCT Competency Framework)

Competence	Level	Competence	Level
Counselling	1	Punctuality	1
Recruitment	1	Understanding protocols	1
Computer Literacy	1	Respect of confidentiality	1
Communication	1		

SCOPE OF RESPONSIBILITY

Functions responsible for	Conducting Informed Consent process HIV/TB treatment adherence and TB Counselling Active participation in patient information sessions Telephone contact and tracing Transportation of study medication from pharmacies to sites and participant files to and from sites
Amount and kind of supervision received	As directed by the lead investigator, trial coordinator, medical officer and research nurse
Or Amount and kind of supervision exercised	N/A
Decisions which can be made	N/A
Decisions which must be referred	Participants complains, problems encountered and unsuccessful tracing of a participant

CONTACTS AND RELATIONSHIPS

Internal to UCT	Lead investigator, medical officers, trial coordinator and research nurse
External to UCT	None