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

NOTES

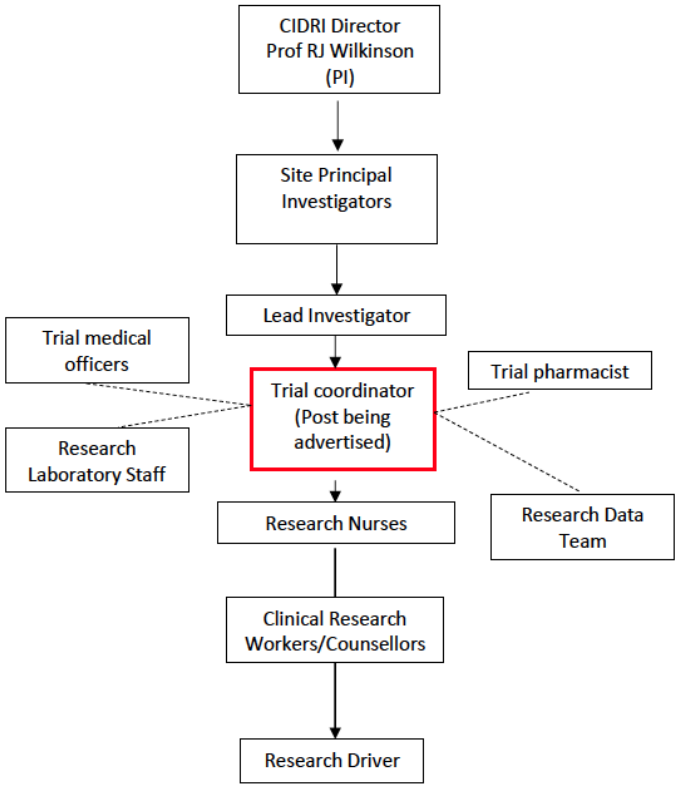
- Forms must be downloaded from the UCT website: http://forms.uct.ac.za/forms.htm
- This form serves as a template for the writing of position descriptions.
- A copy of this form is kept by the line manager and the position holder.

POSITION DETAILS

Position title	Study Coordinator (Clinical Trial)		
Job title (HR Practitioner to provide)			
Position grade (if known)	PC 9	Date last graded (if known)	
Academic faculty / PASS department	Health Sciences		
Academic department / PASS unit	IDM		
Division / section	CIDRI-Africa - Wilkinson		
Date of compilation	01 July 2018		

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 to fulfill the role as a clinical trial coordinator to support the conduct of a Phase II clinical trial to test a novel drug regimen in HIV-associated TB meningitis (LASER-TBM). The role will entail the day to day running of the trial including coordinating patient recruitment and follow up visits, data management, monitoring, and adverse event reporting according to protocol requirements and GCP. The trial coordinator will ensure that the trial is conducted, documented and reported according to the protocol, SOPs, GCP, and applicable international and national regulations

CONTENT

Key performance areas		% of time spent	Inputs (Responsibilities / activities / processes/ methods used)	Outputs (Expected results)
1	Ensure that the trial is conducted, documented and reported according to the protocol, SOPs, GCP, and applicable international and national regulations	10	○ Set up and maintain the Site Investigator file according to GCP at each site ○ Ensure that the latest approved versions of all the trial SOPs, protocol, study documents are available on site ○ Ensure that clinical investigators submit all reportable adverse events appropriately to HREC, regulatory authorities, and DSMB ○ Monitor the progress of the study and assist with preparation of progress reports ○ Liaise with study monitors, sponsors and the DSMB ○ Staff education and training regarding the trial MOP	○ Submission of SAE/AE as required by HREC and sponsor ○ Maintenance of IS file ○ Compliance with GCP and study protocol ○ Progress reports to sponsor and SAPHRA ○ Coordination of monitoring visits and feedback ○ Reporting of protocol deviations to HREC ○ Maintain clinical documents ○ Training of study team in trial procedures
1	Participant Recruitment	20	○ Coordinate study teams in Cape Town and Port Elizabeth to ensure timely patient screening and enrollment ○ Establish enrollment targets and monitor recruitment rates ○ Produce regular enrollment reports	○ Ensure that enrollment targets are met ○ Ensure study retention
2	Manage patient follow up visits	20	○ Use electronic booking system to coordinate timely patient follow up at all sites, according to trial protocol ○ Liaise directly with study participants and with clinical trials team	○ Ensure that follow up visits take place according to trial protocol window period ○ Avoid protocol deviations ○ Ensure relevant staff are able to plan for upcoming clinic visits

3	Data management and recording and maintenance of trial records	20	○ Keep accurate records of all study activities including source documents and CRFs in a timely manner and in accordance with protocol and GCP ○ Adhere to quality control checks of documents, report missing values/data ○ Ensure data is recorded, handled, stored and reported accurately and promptly on case report forms and the clinical trial database, and that confidentiality is maintained	○ Design and Implement and clinical quality management plan ○ Daily checks done on all study documents completed, as per the data management plan and GCP ○ Liaise with the trial data manager, ensure high quality data ○ Liaise where necessary with study monitors, sponsors and the DSMB
4	Trial Management	20	○ Maintain adequate stock of consumables ○ Assist with purchasing of consumables and equipment ○ Coordinate IP stock levels, delivery and management with trial pharmacist ○ Assist with staff recruitment	○ Sufficient supplies, equipment, and personnel to carry out trial procedures ○ Availability of IP
4	Staff liaison and time management	5	○ Team liaison as per organogram ○ Ensure good communication with team members	○ Support of study PIs and investigators ○ Responsible timekeeping and timeous submission of leave forms ○ Understand UCT HR policies
5	Meeting and Training	5	○ Attendance of all training sessions as required by the sponsor and the group ○ Chairing of regular team meeting ○ Input into management meeting	○ Proficient in all trial procedures and the trial protocol ○ Retraining were required ○ GCP certified ○ Accurate minutes of site meetings filed

MINIMUM REQUIREMENTS

Minimum qualifications	Bachelor's degree or equivalent higher education			
Minimum experience (type and years)	Demonstrable experience in clinical trials research (> 1 year) Experience and knowledge of public health care systems in South Africa Experience as a study coordinator or monitor on an interventional trial			
Skills	Proficient in Microsoft Office applications, internet applications, use of electronic databases Team management and leadership skills Verbal and written communication skills			
Knowledge	Good Clinical Practice (GCP) certification English – spoken and written			
Professional registration or license requirements	Clinical Research Coordinator Certification (CRCC) - advantageous			
Other requirements (If the position requires the handling of cash or finances, other requirements must include 'Honesty to handle cash or finances'.)	Honesty to handle cash and/or finances			
Competencies (Refer to UCT Competency Framework)	Competence	Level	Competence	Level
	Time Management	2	Punctuality	2
	Accuracy in recording	2		
	Good communication	2		
	Attention to detail	2		

SCOPE OF RESPONSIBILITY

Functions responsible for	Set up and maintenance of Investigator Site File Coordination of participant recruitment and follow up Maintenance of all trial documents according to GCP Assisting with quality control and data management Trial management, including maintenance of consumables and equipment Adverse event reporting Progress reporting
Amount and kind of supervision received	As directed by the site principal investigators and lead investigator
Amount and kind of supervision exercised	Direction to study research nurses and medical officers as well as trial pharmacists
Decisions which can be made	Procedures according to trial protocol and SOPs
Decisions which must be referred	Procedures outside of trial MOP, protocol, or when course of action unclear

CONTACTS AND RELATIONSHIPS

Internal to UCT	Principal investigators, lead investigator, medical officers, research nurses, data managers, trial pharmacist, drivers
External to UCT	None