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

NOTES

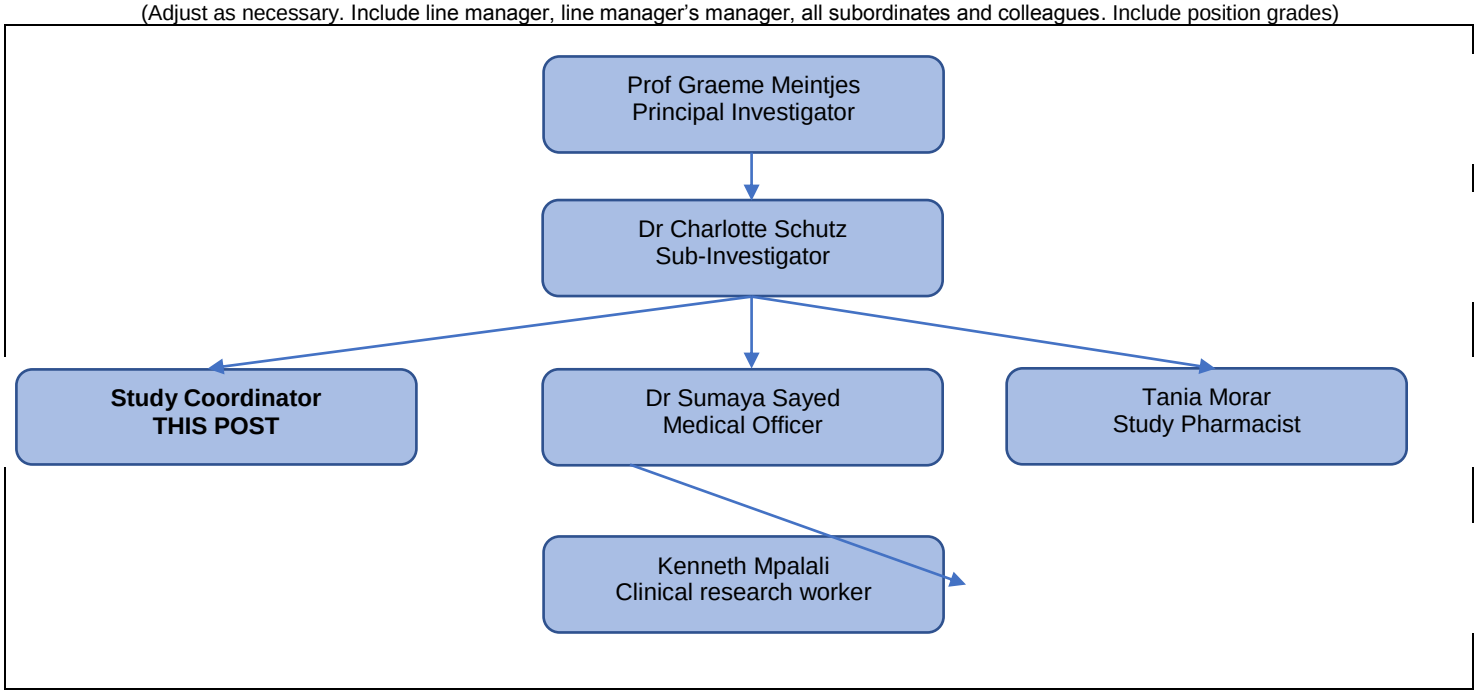
- Forms must be downloaded from the UCT website: http://forms.uct.ac.za/forms.htm
- This form serves as a template for the writing of position descriptions.
- A copy of this form is kept by the line manager and the position holder.

POSITION DETAILS

Position title	Study Coordinator (with research nurse duties)		
Job title (HR Practitioner to provide)			
Position grade (if known)	PC9	Date last graded (if known)	
Academic faculty / PASS department	Health Sciences		
Academic department / PASS unit	IDM		
Division / section	CIDRI-Africa		
Date of compilation	2 October 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 post is to work as study coordinator and research nurse on the Ambition-CM trial (and to complete follow-up and associated tasks for the PROBeX study). The trial is part of a multi-centre trial. The study coordinator is expected to help screening for and recruiting patients, obtain informed consent, collect blood and urine samples, assist study doctor with lumbar punctures, administer study medication, help monitor patients in the ward and organize and conduct follow up appointments. Study coordinator tasks will require being involved in all aspects of the trial that is required in order to adhere strictly to the study protocol and GCP requirements, including quality control, quality assurance and reporting to regulatory authorities and ethics committees.

Job descriptions cannot be exhaustive and the post-holder may, from time-to-time, be required to undertake other duties, which are broadly in line with the above key responsibilities.

CONTENT

	Key performance areas	% of time spent	Inputs (Responsibilities / activities / processes/ methods used)	Outputs (Expected results)
1	Nursing care and nursing related tasks related to study participants	25%	• Study participants will be monitored daily in hospital and all nursing tasks related to the study needs to be performed daily. • This includes, but is not limited to: - accurate administration of study medication, - monitoring administration of study drug, - inserting or replacing intravenous lines, phlebotomy, - assisting with lumbar punctures, - completing case report forms (electronic or hard copy) and - laboratory request forms, liaising with drivers regarding timeous transport of samples. • Follow study protocol and Work practice documents (WPD's) or Standard Operating Procedures (SOPs)	• Work within the outlines of Work Practice Documents (or SOP's) pertaining to clinical care of study patients • Study medication will be correctly administered to all patients • All relevant samples will be obtained, correctly labeled and transported timeously to the correct laboratory. • No (or minimal) Protocol and WPD/SOP deviations • GCP standards maintained
2	Overseeing and assisting with the informed consent process and counseling of patients and family members	10%	• Review informed consents prior to use, to ensure appropriate language is being used. • Overseeing the informed consent process and taking active part in this process. • Ensuring the study is explained properly to patients and or family members. Ensuring and that there is good understanding of the study and study related medication and procedures and revisiting these aspects when needed • Reviewing all informed consent documents after these are completed and ensuring these have been completed correctly.	• The informed consent Working Practice Document/SOP will be followed closely and all participants and or family members (if relevant) will have good understanding of the study medication and procedures. • Assessment of Understanding and Literacy assessment to be performed on all participants • Any problems with the informed consent process will be identified and brought to the attention of the study team timeously. • Accurate completion of source documentation related to the Informed Consent, GCP standards maintained

3	Study Coordination: Day to day tasks	30%	• Implementation of clinical quality management plan (CQMP) • Preparation of participant files. • Ensuring that all tasks are completed by all staff members every day, ranging from completion of relevant study documentation, ~~collection of relevant clinical samples~~, coordination of outpatient appointments and implementation of CQMP • Follow-up of participants by booking appointments and following up missed visits; have a clear understanding of hospital filing system • Supervise work of Clinical Research Worker • Enter all data on study specific EDC (Electronic Data Capturing) • Ensure correct collection of samples for relevant visits and co-ordinate transport to relevant processing labs	• There will be documented evidence that all study related procedures are completed at each time point for each patient. • Resolution and errors found during implementation of CQMP and modification of CQMP process as required • GCP standards maintained • Keep lost to follow-up to the minimum • There will be excellent communication with all staff members daily and everyone will be very clear on their daily tasks. • EDC is current, all queries are resolved as per requirements • Sample integrity is maintained
4	Study Coordination: Regulatory	30%	• Preparation and maintenance of study related documentation needed for monitoring and audit visits. • This includes maintenance of regulatory binders, patient folders and other essential documentation. • Reporting of adverse events, adverse drug reactions and patient deaths to the relevant ethics and regulatory authorities within the specified time lines. • Preparation of reports to these authorities, initially under supervision and later independently.	• The site will always be inspection ready and GCP guidelines will be followed in all aspects of the trial. • All regulatory reports will be prepared in advance and will be submitted on time. • Identification of all adverse events and adverse drug reactions timeously and reported within the specified time frames for this trial.
5	Meetings and training	5%	• Set up study group meetings and create agendas • Identify training needs of team (and ward staff) and ensure that own training is relevant	• Study team will be aware of any new developments and progress of study. • Training will be completed when appropriate

MINIMUM REQUIREMENTS

Minimum qualifications	Diploma in General Nursing
Minimum experience (type and years)	2 years general nursing experience 1 year in clinical research (including study coordination experience) Previous experience working with hospitalized patients or inpatients in a research setting
Skills	Clinical Nursing skills Co-ordination Communication
Knowledge	Understanding of clinical protocol Knowledge of the study drug Accurate completion of study documents Good Clinical Practice Basic Life Support
Professional registration or license requirements	SANC
Other requirements (If the position requires the handling of cash or finances, other requirements must include 'Honesty to handle cash or finances'.)	Ethical integrity

Competencies (Refer to UCT Competency Framework)

Competence	Level	Competence	Level
Attention to detail	2	Clinical skills	2
Staff management	2	Time management	2
Project management	2		
Good communication	2		

SCOPE OF RESPONSIBILITY

Functions responsible for	Nursing care and nursing related tasks related to study participants Overseeing and assisting with the informed consent process and counseling of patients and family members Study Coordination: Day to day tasks Study Coordination: Regulatory
Amount and kind of supervision received	Direction from study doctors
Amount and kind of supervision exercised	Supervision of the Clinical Research Worker
Decisions which can be made	Participant health Participant understanding – informed consent Completion of documents Scheduling of appointments
Decisions which must be referred	Any adverse events management

CONTACTS AND RELATIONSHIPS

Internal to UCT	Study team including Pharmacist and Principal Investigator
External to UCT	Study monitors and external auditors and study teams at collaborating multi-centre sites