

NOTES

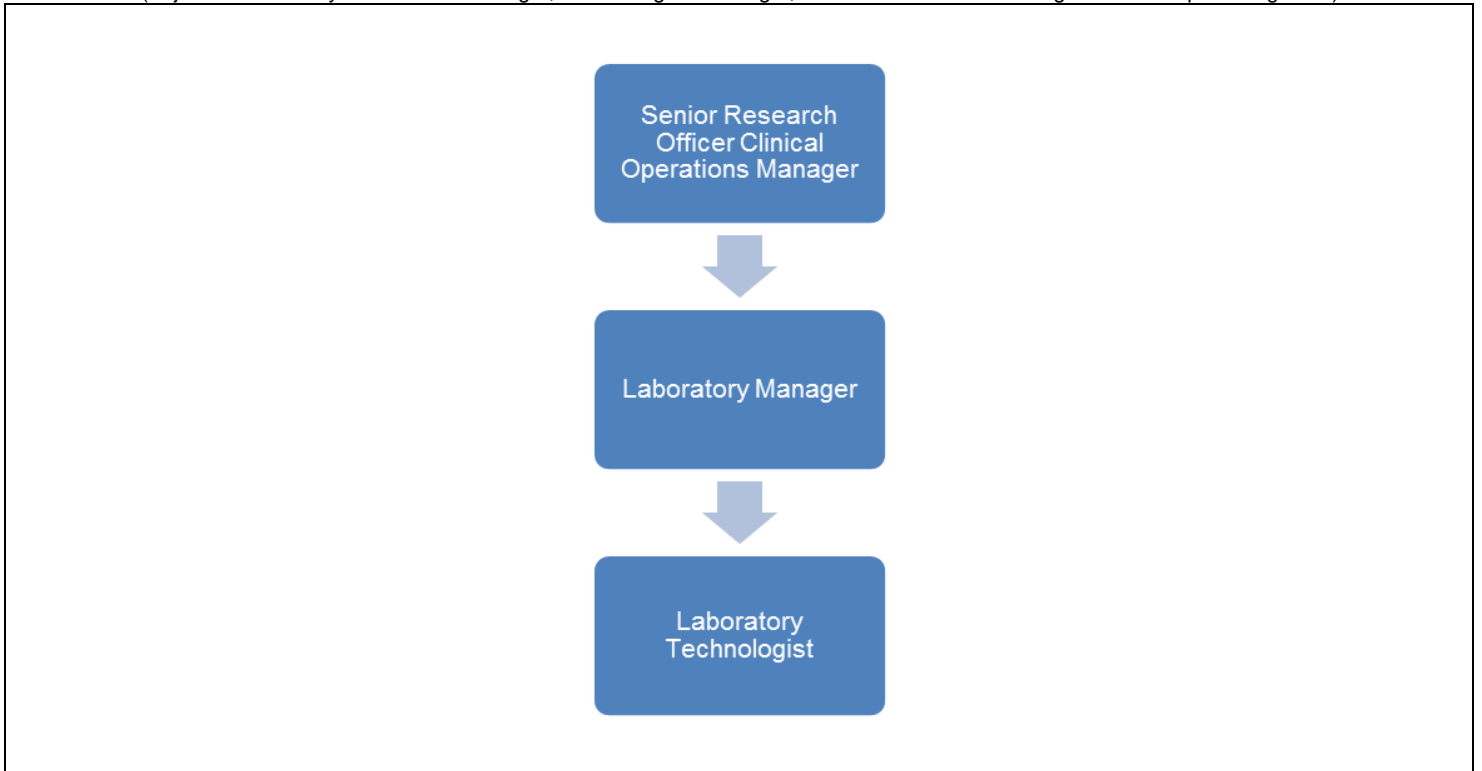
- Forms must be downloaded from the UCT website: <http://forms.uct.ac.za/forms.htm>
- This form serves as a template for the writing of position descriptions.
- A copy of this form is kept by the line manager and the position holder.

POSITION DETAILS

Position title	Laboratory Manager		
Job title (HR Practitioner to provide)	Laboratory Manager		
Position grade (if known)	10	Date last graded (if known)	
Academic faculty / PASS department	Health Sciences		
Academic department / PASS unit	Medicine		
Division / section	Desmond Tutu HIV Centre		
Date of compilation	May 2016		

ORGANOGRAM

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



PURPOSE

To manage all laboratory activities at the Emavundleni Research Site, including oversight of on site diagnostics, safe handling of specimens, QA / QC processes (IQC and EQA), reporting on GLP and GCP and accountability to all clinical trial sponsors including NIH, FDA, MCC and REC.

CONTENT

Key performance areas		% of time spent	Inputs (Responsibilities / activities / processes/ methods used)	Outputs (Expected results)
1	Staff Management	10%	<ul style="list-style-type: none"> Line manage laboratory staff and set up rosters / manage timesheets and leave forms Conduct performance assessments of relevant staff and provide constructive feedback to staff as per UCT HR PPS. Communicate with and assist HR department with regards to HR related processes. Training of all clinical and lab staff in correct specimen collection, diagnostic use, specimen handling, documentation and distribution 	<ul style="list-style-type: none"> Efficient and effective use of resources Staff perform to required lab technical standards and research outcomes are met
2	Quality Assurance Management	25%	<ul style="list-style-type: none"> Enrol on all relevant external quality assessment programmes (EQA) and ensure results are submitted by the due date. Send SMILE any documents if required QC all new kit lots Monitor/perform the internal quality control (IQC) weekly 	<ul style="list-style-type: none"> All laboratory procedures are done according to SOPs, GCP and GCLP standards Quality Management activities are conducted and documented adequately

3	<p>Laboratory and Studies Management</p>	40%	<ul style="list-style-type: none"> • Liaising with suppliers and ordering of goods. • Ensuring all instruments are serviced and calibrated timeously. • Ensure that processes are in place to ensure that laboratory equipment and all software is maintained regularly and according to SOPs. • Ensure that all laboratory databases are updated and maintained. • Ensure and oversee laboratory safety. • Facilitate communication between laboratory staff members, clinical staff and sponsor. • Develop and maintain relevant SOPs and Work Process Guidelines. • Ensure training and processes are in place to ensure that all shipping is done according to IATA standards. • Ensure SOPs are maintained to ensure temperature monitoring is done and documented. • Conduct and document competency and training assessments for lab staff on lab related tests. • Respond to lab audit findings and all deviations to be documented and filed. • Draw up CAPAs and /or file notes when required. • Ensure that all data clarification forms (DCFs) are completed in time. • Conduct lab stock taking regularly and ensure there are sufficient kits and reagents for study purposes. 	<ul style="list-style-type: none"> • Creating a cohesive working environment in compliance with GCLP • Lab environment is of the highest standard and meets Sponsors and research outcomes
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4	Specimen Management	25%	<ul style="list-style-type: none"> • Ensure appropriate collection, processing, storage and transportation of specimens. • Liaise with external laboratories and clinical staff to establish effective transport arrangements for specimens. • Ensure specimens are transported timeously. • Ensure appropriate processing of specimens in laboratories. • Monitor the return of results from outsourced laboratories. • Ensure clinical staff have processes in place to ensure ordering of sufficient equipment (e.g. stickers, bottles, bags, requisition forms, masks) to appropriately collect, label and process specimens. • Ensure specimens are appropriately stored or shipped as required. • Obtain import / export permits when needed. • Book international shipments and ensure that samples are correctly processed for shipping. • Perform laboratory assays as required. 	<ul style="list-style-type: none"> • Clinical and lab staff are confident in specimen management • All specimens are processed according to protocol and laboratory standard operating procedures • All staff to be IATA certified • Result data is entered accurately and timeously
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MINIMUM REQUIREMENTS

Minimum qualifications	National Diploma in Medical Technology Post Graduate Qualification advantageous(research and data management content to the qualification is recommended) GCLP/QMS trained or experienced working in a GCLP compliant or accredited laboratory. IATA dangerous good training (past or present)			
Minimum experience (type and years)	Minimum of 1-3 Years working experience, preferably in a research environment			
Skills	Computer literacy			
Knowledge	Clinical research environment			
Professional registration or license requirements	HPSCA			
Other requirements (If the position requires the handling of cash or finances, other requirements must include 'Honesty to handle cash or finances'.)				
Competencies (Refer to UCT Competency Framework)	Competence	Level	Competence	Level
	Organizational skills	2	Accountability	2
	Management Skills	2	Interpersonal skills	2
	Communication Skills	2	Work independently	2
	Initiative	2	Lateral, analytical and systematic thinking	2
	Report writing	2	Flexible to change	2
	Problem solving	2	Computer skills	2
	Build interpersonal relationships	2	Detailed oriented	2
Lab management	2	Teamwork	2	

SCOPE OF RESPONSIBILITY

Functions responsible for	<ul style="list-style-type: none"> - To ensure that all specimens are processed and stored as per site lab and protocol specific SOPs -Lab aspects of the protocol are implemented and managed as per sponsor requirements -QM activities are conducted and documented as per site lab SOPs and sponsor requirements -lab staff are trained, function effectively and provide lab cover (leave management) so that research outcomes are met.
Amount and kind of supervision received	- Review of Lab SOPs, responses to lab audit findings, track that implementation items for site activation of protocols are timeously being attended to, intervene when required with respect to staff management issues. 20 % of supervision required
Amount and kind of supervision exercised	-Supervision of lab staff.
Decisions which can be made	<ul style="list-style-type: none"> - staff training requirements - leave management to ensure adequate staffing of lab - may interact with sponsor on protocol specific lab issues
Decisions which must be referred	<ul style="list-style-type: none"> - some sponsor interactions - decisions on which outsourced labs to contract with per protocol

CONTACTS AND RELATIONSHIPS

Internal to UCT	UCT/DTHC support functions such as HR/ IT etc.
External to UCT	Protocol/ sponsor appointed auditors Outsourced labs suppliers