DESMOND TUTU HEALTH FOUNDATION

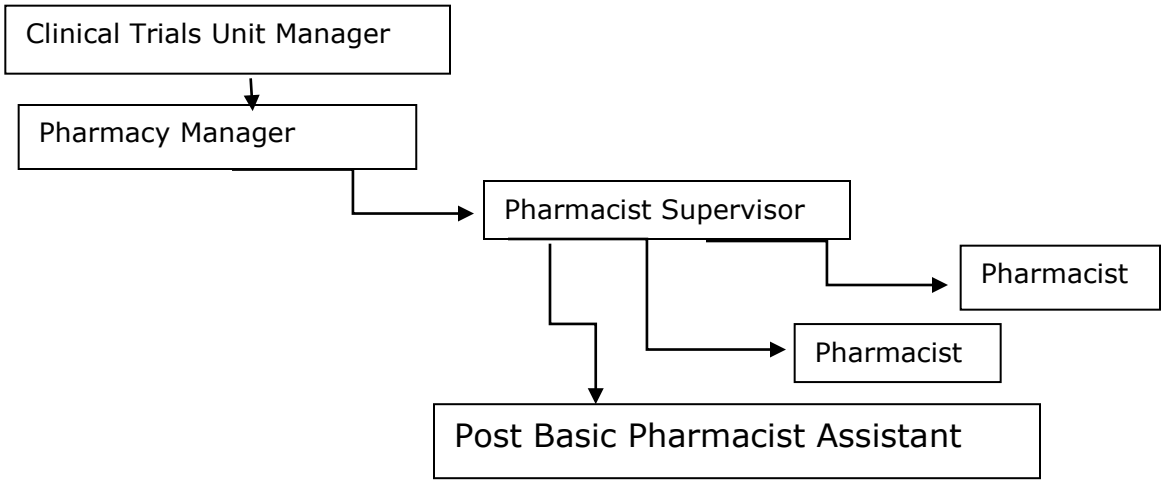
Level One, Wernher & Beit Building North, Faculty of Health Sciences
Anzio Road, Observatory, 7925, Cape Town, South Africa

P O BOX 13801, MOWBRAY, 7705, Cape Town, South Africa
(T) +27 021 406 6966 (E) info@hiv-research.org.za
VAT No. 4750185565

JOB DESCRIPTION

POSITION DETAILS	
Position Title	Post Basic Pharmacist Assistant
Site	J52 Trials Unit
Project	Trials Unit
Date of compilation	14 November 2023

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



PURPOSE

The main purpose of this position is to assist with the management of the pharmacy according to South African Pharmacy Council (SAPC), Medicines Control Council (MCC), National Institutes of Health (NIH), Good Clinical and Good Pharmacy Practice Guidelines (GCP and GPP).
The Pharmacy Assistant (Post Basic) will be responsible for:

a) Pharmacy Regulatory Compliance including
b) Investigational Product (IP) Management
c) Family Planning and Sexually Transmitted Infection medication management
d) Record Management

Non-Profit Company : Registration no. 1999/005072/08 : NPO no. 148-956
Public Benefit no. 18/11/13/51
Directors: Prof R Wood; Prof L-G Bekker;
Ms Z Ebrahim (Chair); Ms T Tutu-Gxashe; Mr P Grant; Ms M K Ndebele; Dr A M Kubeka
www.desmondtutuhealthfoundation.org.za

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JOB CONTENT

Key performance areas (4 – 6)		% of time spent	Activities / Objectives / Tasks	Results / Outcomes
1	**Pharmacy Regulatory Compliance**	10%	• Assist Pharmacy Manager with implementation and maintenance of Pharmacy Standard Operating Procedures and Pharmacy Establishment Plans according to international regulatory standards as specified by multiple research agencies (protocols include Phase I, II, III and experimental investigational product). • Ensure the pharmacy is run according to South African pharmacy and research ethical standards. • Maintain Pharmacy technical appliances – including maintenance of all pharmacy equipment and calibration of all required temperature monitoring devices • To respond appropriately to equipment malfunction / alarms including after hours • Maintain restricted access control to the pharmacy • Assist with pharmacy quality assurance and quality control processes	• Pharmacy is in compliance with all related legislation. • Review SOPs on Pharmacy and IP management and response to Equipment failure when requested • All documentation accurate and up to date at any time checked. • Maintenance logs are up to date. All equipment fully operational and malfunctions are attended to timeously • Report on Monitoring of logs and service records by study monitors is positive

2	Family Planning, Sexually Transmitted Infection medication and general con-med management	25%	• Assist with procurement of pharmaceuticals required by the pharmacy • Receive medication from supplier – document receipt and resolve discrepancies • Store medication under correct conditions at the site • Dispense medication as per pharmacy regulations under the supervision of a Pharmacist • Maintain stock control over pharmaceuticals • Maintain record of dispensed medication • Dispose of pharmaceuticals under supervision of pharmacist • Monthly reports sent to DoH	• Medication is handled according to South African Pharmacy Council (SAPC) and Medicines Control Council (MCC) requirements • All inventories are current and balance • Stats and orders are reported monthly and are filed • DoH monitoring/audit reports are favourable

3	Investigational Product (IP) Management	45%	• Maintain randomization (blinding / unblinding) of participants in order to prevent research bias and maintain participant confidentiality • Verify that Informed Consent has been signed by participant as per study and Pharmacy SOP requirements. • Maintain adequate stock levels of IP at the site • Receive IP from supplier – document receipt and resolve discrepancies • Store IP under correct conditions at the site • Label IP prior to dispensing under the supervision of a Pharmacist • Dispense IP as per specific protocol requirements under the supervision of a Pharmacist • Receive and reconcile IP returns • Store IP (used and unused) on site until monitor confirms IP accountability • Dispose of used IP as per sponsor requirements under the supervision of a Pharmacist • Return unused IP to supplier for storage until IP destruction permitted • Perform QC on all study product dispensed • Perform QA on all IP and study documentation • Check IP and Pharmacy files prior to monitoring visits • Participant and assist in monitoring visits • Participate and assist in funder regulatory and compliance audits	• Study product is distributed according to protocol • All trial participants receive IP on time according to protocol • All ppts receive the correct IP as per study assignment • Optimal stock levels maintained at all times • Trial monitoring reports regarding Pharmacy always favourable • All documentation accurate and up to date at any time checked. • QA Audit tools and QC documentation complete, up to date and filed in study files

4	Record Management	20%	• Maintain IP accountability records in accordance with the standards required by the SAPC, MCC, ICH-GCP and IPM • Maintain prescription records against which IP is dispensed • Maintain Pharmacy sections of the Research Site Files • Knowledge of Good Clinical Practice and Good Pharmacy Practice guidelines • QA and QC checks on completed pharmacy documentation for studies as per Pharmacy Quality Management plan • Capture data on Pharmacy systems and any other related systems • Capture all required data on Tier.net	• Records are accurately and timeously captured according to study protocol • All documentation accurate and up to date at any time checked. • QA Audit tools and QC documentation complete, up to date and filed in study files • Dispensing systems and Databases current and up to date • Tier.net data is current and active and all required data is reflected as per reports

Other duties

Perform any other related duties as assigned

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MINIMUM REQUIREMENTS

Minimum requirements	• **Post basic Pharmacy Assistant certification** • **Registration with SAPC** • **GCP Certificate**
Minimum experience	• **3-5 years Post Basic Pharmacy experience,** • **Clinical trials experience,** • **Aseptic injection or infusion preparation experience**
Professional registration/ License	• **Current registration with SAPC** • **Indemnity insurance**

COMPETENCIES	
Excellent verbal and written communication skills	Good Clinical Practice Certification
Good planning and organising skills	Human Subjects Protection Certification
Client focused	Previous Clinical Trial experience
Ability to work well under pressure and to maintain effectiveness during changing conditions	Computer Literacy (Microsoft Office)
Work according to high work standards	Detail-oriented
Able to multitask and be flexible	Problem solving skills
Must be able to work within a team	Good administrative skills