DESMOND TUTU HEALTH FOUNDATION

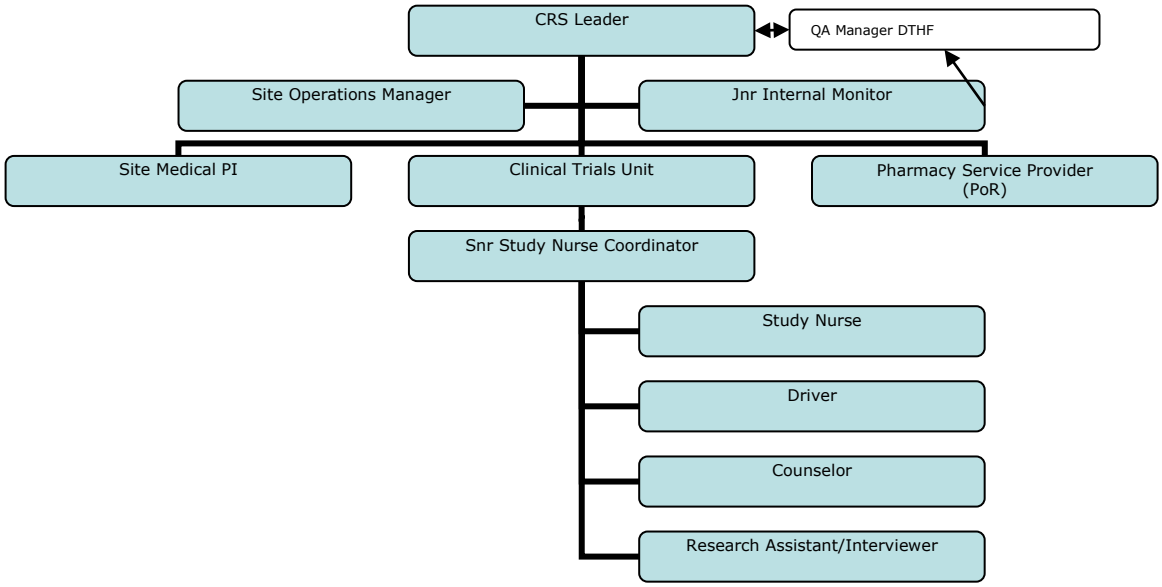
3 Woodlands Rd, Woodstock, 7925, Cape Town, South Africa

(T) +27 021 301 2020 (E) info@hiv-research.org.za
P O BOX 13801, MOWBRAY, 7705, Cape Town, South Africa
VAT No. 4750185565

JOB DESCRIPTION

POSITION DETAILS	
Position Title	Junior Internal Monitor
Site	Cape Town – Emadvudleni and Philippi Village
Project	M72 and Prepare to Choose
Date of compilation	10 Jan 2024

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



PURPOSE
The purpose of the position is to provide onsite Quality Control and Regulatory activities for the allocated study as an

extension of the DTHF HQ QA Department. The incumbent together with the study team would be responsible for all aspects of quality control and quality assurance for the study. Duties, amongst other will require reviewing and monitoring of study data within the source documents and electronic data capturing systems. Assisting the site with the development and maintenance of site and study standard operating procedures and processes. Document management and compliance with applicable regulations such as South African Good Clinical Practice, Protocol, Sponsor requirements and other Regulatory bodies as applicable.

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Job Content

	Key performance areas (4 – 6)	% of time spent	Activities / Objectives / Tasks	Results / Outcomes
1	Implementation of Clinical Quality Management Plans (CQMP) and Assurance checks and processes at the clinical site.	10 %	• Provide input regarding Clinical Research Site clinical quality management plan (CQMP) and the development and implementation, in line with requirements by sponsors funders and Regulatory Guidelines governing the study and site. • Give guidance to the site in developing Quality Control (QC) and Quality Assurance (QA) checklists per protocol/site. • Govern the compliance to the CQMP • Liaise with QA Manger, support and advise the PI, Study team and site in their QC/QA activities and policies • Review QC and QA Monitoring reports to identify trends • Create CAPA's and follow through until implementation and resolution of the event.	• CQMP are in line with required Policies, Regulators and SA GCP • QM Plans are relevant and practical • QC and QA checklists are effective. • Trends are identified, corrected and staff are retrained

2	Regulatory and Ethics Quality Assurance	20%	• Together with the PI would be responsible for the compilation of submissions to HREC and SAHPRA. • Responses to HREC, SHAPRA, and continual communication on behalf of the site to the Regulatory bodies. • Tracking of correspondence within a filing system and tracker • Adherence to National and International research guidelines as needed • Conduct review of Regulatory files • Ensure communications are filed in Regulatory files • Review Regulatory trackers and give input into their design as needed	• Regulatory files are complete, audit and Inspection ready • Regulatory correspondence submitted and followed up within the required timelines.
3	Plan and Conduct internal auditing visits for each of the CRS's	60%	• Perform QA Activities • Compliance verification to approved study protocol • Adherence to SA GCP by sites in conducting studies • Verify study conduct in accordance with site SOP's, Study SSP's and protocol • Review Case report forms (CRF's) and electronic data forms (EDC) for completion and accuracy, participant safety and data integrity. • Review and report outstanding issues at sites • Ensure deviations are identified, recorded and reported to funders and relevant authorities.	• Activities are conducted on a regular basis Trends are identified and corrected Findings are documented in internal reports and resolved. Adherence of Protocol and data guidelines

4	QA administration	10%	• Internal monitoring activities are documented, tracked and communicated with the site PI and other relevant staff. • Have regular documented feedback to the site • Establish and maintain a good rapport with all staff and vendors • Identify staff weakness and operational deficiencies and advise on corrective actions and preventative actions • Bi weekly feedback and report meetings with DTHF QA Manager.	Continuous overview of Quality on site.

Perform other related duties as assigned

- Review of the source data against the entries in the study database eCRF to confirm accuracy (QC)
- Review the source data (SDV) against guidelines to confirm compliance to protocol, procedures, patient safety, data integrity, and SA GCP and Quality Management plan amongst others.
- Log and review protocol deviations and suggest corrective and preventative actions.
- Ensure implementation of corrective action and preventative actions within a reasonable time.
- Follow the monitoring plan for the study, site and or DTHF.
- Review all the HREC and SHAPRA approvals and communication to ensure that all applicable approvals and notifications are in place.
- Review the Investigator Site File for completeness and accuracy assisting the site to keep it up to date
- Write Monitoring Report after each visit and communicate findings to the PI and site staff for corrections.
- Review and report outstanding issues at the site, for example Serious Adverse Events (SAEs), adherence to protocol and data quality issues.
- Verify study conduct in accordance with national and International Guidelines, site SOP's, Study SSP's and protocol
- Assist the sites with Audit preparations.
- Prepare reports to DTHF/C QA Manager for review.

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MINIMUM REQUIREMENTS

Minimum requirements	• Grade 12 with a tertiary qualification in a Health related field. • Working Knowledge of procedural document such as Standard Operating Procedure (SOP), Study Specific Procedures (SSP) and Manual of Operational Procedures (MOP) • In depth knowledge and understanding of SA ICH GCP (Good Clinical Practice) guidelines • In depth understanding and knowledge of Regulatory (SAHPRA) and Ethics Guidelines • Previous experience in SAHPRA and Ethics submissions will be advantageous • In depth knowledge of Investigator Site File and Essential documents, requirements and management. • Strong written and verbal proficiency in English and other local languages • Excellent ability to build interpersonal relationships and partnerships within a diverse community • Strong problem-solving and decision-making abilities • Ability to work under pressure and independently • Attention to detail • Excellent Planning and organization abilities • Valid Driver's Licence
Minimum experience	• At least 2 years' working experience in a Clinical/Research environment • At least 2 years' experience conducting internal monitoring/quality assurance/quality control • Experience in using Databases e.g. Imedidata • Intermediate knowledge of computer applications like Microsoft Word , Excel and Power Point
Professional registration/ License	• **SA GCP / Professional body if Medically Qualified**

COMPETENCIES	

AGREED BY

	PRINT NAME	SIGNATURE	CONTACT NO.	DATE

Position Holder				
Line Manager				