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

NOTES

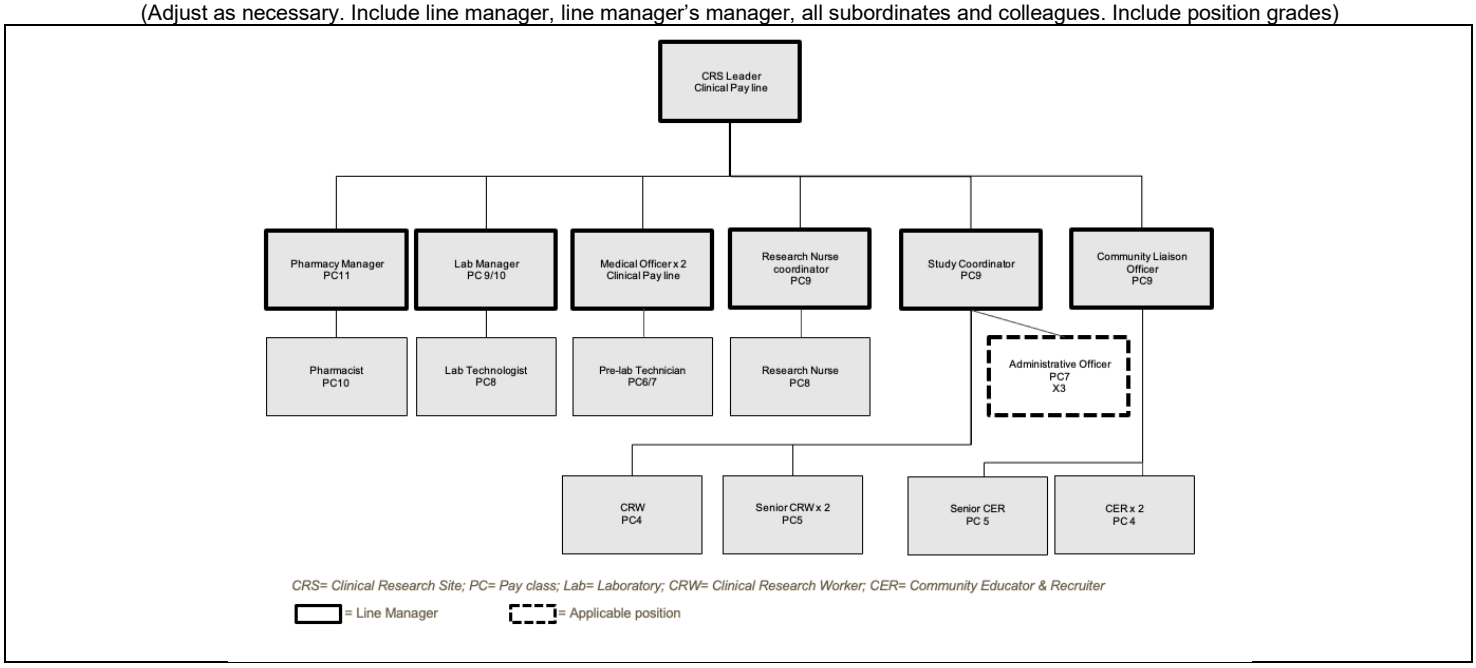
- Forms must be downloaded from the UCT website: http://forms.uct.ac.za/forms.htm
- This form serves as a template for the writing of position descriptions.
- A copy of this form is kept by the line manager and the position holder.

POSITION DETAILS

Position title	Administrative Officer		
Job title (HR Business Partner to provide)	Administrative Assistant		
Position grade (if known)	PC07	Date last graded (if known)	
Academic faculty / PASS department	Health Sciences		
Academic department / PASS unit	IDM		
Division / section	Meintjes Group- VUKA		
Date of compilation	26 April 2024		

ORGANOGRAM

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



PURPOSE

The main purpose of these positions is to:

1. Execute all **data, regulatory, logistic, and quality** processes at the Vuka Research Clinic according to leadership's plans, Standard Operating Procedures (SOPs), institutional, sponsor, and regulatory requirements.

2. To maintain an ordered electronic and paper audit trail for all **data, regulatory, logistic, and quality** processes.

These positions will form the administrative team of the Vuka Research Clinic that functions within the broader research team. All position holders will cover all **4 domains** (**data, regulatory, logistic, and quality)** of the position.

The position is full-time and based 100% at the Vuka Research Clinic in Khayelitsha.

CONTENT

Key performance areas		% of time spent	Inputs (Responsibilities / activities / processes/ methods used)	Outputs (Expected results)
1	Data	25%	• Capture clinical research data from source documentation into sponsor required databases (including web-, application- and cloud document-based databases). • Routine checks of each database for queries raised by sponsor Data Management (DM), query triage, and query resolution including facilitating resolution by other staff members as applicable. • Data cleaning and query resolution ahead of data-base locks, interim assessment timepoints, or other predefined time points, and for announced monitoring visits, audits and/or inspections. • Ad hoc cleaning and query resolution for the purposes of unannounced monitoring visits, audits and/or inspections. • Generate reports from data bases to support research team in tracking site metrics. • Electronic database password policies are adhered to.	• Data is entered and available to sponsor within specified timelines. • Site operations are driven by up-to-date data, site performance metrics can easily be calculated, and site level reports generated as needed. • Sponsors and site are easily able to track regulatory aspects for specimen use. • Referral laboratories have accurate specimen data to ensure effective sample tracking. • Trial data provided to the sponsor is complete and accurate and meets the terms as specified in the protocol, clinical trial agreement and/or data transfer agreement. • Complete and accurate trial data drives trial interim analyses and endpoints. • Data queries are resolved according to sponsor defined timeframes. • An audit trail is available for each data point submitted.
2	Regulatory	25%	• Work with site staff to draft and compile documents required for initial submissions (CV, declarations, workloads, GCP certificates, professional registrations, and indemnity insurance) for each study. • Participate in site preparation and initiation visits and assist in completing readiness tasks per sponsor/CRO requirements. • Maintain the investigator site files updating as required due to expiry etc., and the electronic equivalent where required. • Work with the SC/ PI to ensure participant documents are organized and filed in an ordered manner. • Work with SC to prepare participant and regulatory files for monitoring visits and audits. • Assist monitors during monitoring visits, including but not limited to file retrieval, venue set up, remote connection sessions as required.	• Essential & Source documentation for each study is organized and available for monitoring and audit purposes. • Study start-up timelines are adhered to. • No backlog with study filing. • The site remains in a constant state of audit readiness. • Study monitors are comfortable and are able to work effectively during site visits.

3	Logistics & Clinic Admin	25%	• Oversee reception (booking systems, electronic voucher management), participant file retrieval, and flow through the clinic. • Real-time feedback to Study Coordinators on logistical tasks. • Facilitate transport of documents, samples, stock and equipment, staff, visitors, and participants, according to the daily requirements of the clinic as determined by the Study Coordinator. This includes but is not limited to travel between the research clinic, UCT campus, local health care facilities, vendors, participant homes, and event venues. This does not include personal travel for any persons. • Documenting transport logs, home visit feedback forms, etc. • Assist with checking of equipment to trigger maintenance and repairs as required.	• Vuka Research Clinic runs efficiently and there is no bottleneck at reception, the Study Coordinator is aware of the progress made throughout the day. • The safe and timeous transport of all persons making use of Vuka Research Clinic transport. • Research samples and documents are delivered to required endpoints such within the sponsor, clinic, and/ or protocol requirements. • Clinic stock and equipped arrives timeously. • Clinic teams are sufficiently equipped to conduct operations within the sponsor, clinic, and/ or protocol requirements.
4	Quality Management	20%	• Participate in the quality control process of site-level and/or sponsor quality management plans. • Adhere to site-level and/or sponsor requirements for ensuring all documentation is ALCOA-CCE compliant. • Perform quality assurance activities including but not limited to participant and regulatory chart review, and quality summary report generation.	• All site operations and outputs are performed to the highest quality. • Error trends are noted and corrected. High regulatory compliance on all studies. High quality data is produced. • Evidence of quality management systems is available to sponsors as needed.
5	Meetings and training	5%	• Attend daily meetings where activities are discussed, planned, and tasks allocated. • Attend monthly meetings where medium-term study and clinic plans are discussed. • Maintain all sponsor and regulatory required certifications/ trainings (e.g., IATA, GCP). • Attend sponsor required trainings. • Attend internal and/ or external trainings and requested or recommended by line management. • Relevant training sessions inclusive of protocol training and regulatory and ethics workshops. • Meetings with study teams and sponsors.	• Clinic team area aware of each member's function and responsibilities so that there is a person accountable to each task. • Daily, monthly, and longer-term study targets and clinic plans are understood and executed efficiently. • Compliant transport of people and research samples. • Work is protocol and sponsor policy compliant. • Incumbent keeps skills up-to-date and relevant for required work. • Aware of all current protocols and their status. • Up to date with current ethics and regulatory changes Current GCP certification

MINIMUM REQUIREMENTS

Minimum qualifications	NQF 4.
Minimum experience (type and years)	At least 2 years' experience in administration/ data/ logistics/ regulatory management in the medical / research/ NGO/ University sector.
Skills	Professional interaction with people and teamwork. Fleet maintenance and transport coordination. High levels of attention to detail Ability to design and manage complex administrative processes Organizational skills. Computer proficiency- MS 365, web-based data bases, mobile applications Good writing skills
Knowledge	Good Clinical Practice and the Protection of Human Participants in Research, relevant legislation, and best practices
Professional registration or license requirements	IATA Dangerous Goods Training (advantageous) Valid Driver's License and PDP (advantageous) GCP Certification (advantageous)
Other requirements (If the position requires the handling of cash or finances, other requirements must include 'Ability to handle cash or finances'.)	Ethical conduct Respect for privacy of participants. Ability to manage cashless voucher system. Ability to work harmoniously with participants of diverse backgrounds and cope with vulnerable participants, showing sensitivity & empathy to the needs of others. Ability to work within a diverse team, with members ranging from lay health workers to registered medical professionals, of all races, cultures, and sexual and gender orientations.

Competencies (Refer to UCT Competency Framework)

Competence	Level	Competence	Level
Analytical thinking/Problem solving	2	Planning and organizing/work management	2
Building Interpersonal relationship	2	Safety awareness	2
Client service and support	2	Teamwork/Collaboration	2
Communication	2	University awareness	1

SCOPE OF RESPONSIBILITY

Functions responsible for	• Refueling vehicles, vehicle cleaning, reporting required vehicle repairs and maintenance. • Filing room(s) organization and cleanliness. • Data capture, query monitoring and facilitation of query resolution. • Adhering to site- and sponsor-level data deadlines. • Maintaining Investigator Site File and Participant document filing
Amount and kind of supervision received	• Supervised by study coordinator, task priorities set by research team. • Receives broad supervision. • Site Director assigns work by broadly defining assignments, objectives, priorities, and deadlines. • Plans and executes work by determining the appropriate use of established methods and sequences, where choices are made which require some understanding of a well-defined policy framework. • Problems and deviations are solved with reference to instructions, policies, and accepted practices, and guidance is available. • Supervisor provides more general assistance in unusual situations that do not have clear objectives. • Duties at the discretion of Supervisor.
Amount and kind of supervision exercised	• None, but maintain close working relations with Study Coordinator, Community team, PI, Ethics personnel, and CRO.
Decisions which can be made	• Traffic route changes as required. • Requesting quotes for stock and services. • Resolving queries where reason is Data Entry Error, Date Overdue, where source content is not required to be changed. • Executes rules according to interpretive decision-making levels. • Decides 'how" the rule is to be carried out from established processes, practice, systems, trade knowledge and rules and regulations.
Decisions which must be referred	• Adjusting travel schedule, minimum/ maximum stock levels, participant scheduling outside of the allowed visit window. • Procurement approval. • Resolving queries where source content changes is required. • Priority of capture deadlines is set by sponsor and research PI, and this must not be overridden. • Institutional Review Committee (IRC), UCT HREC, UCT IBC, UCT Clinical Research Sites, Principal Investigators (PIs), UCT Procurement office and all UCT VUKA Research Clinic staff

CONTACTS AND RELATIONSHIPS

Internal to UCT	VUKA Research Clinic staff UCT – FHS & Dept of Medicine; IDM
External to UCT	Clinics, participants, third-party vendors, contract research organizations (CROs) and associates (CRA).