



NOTES

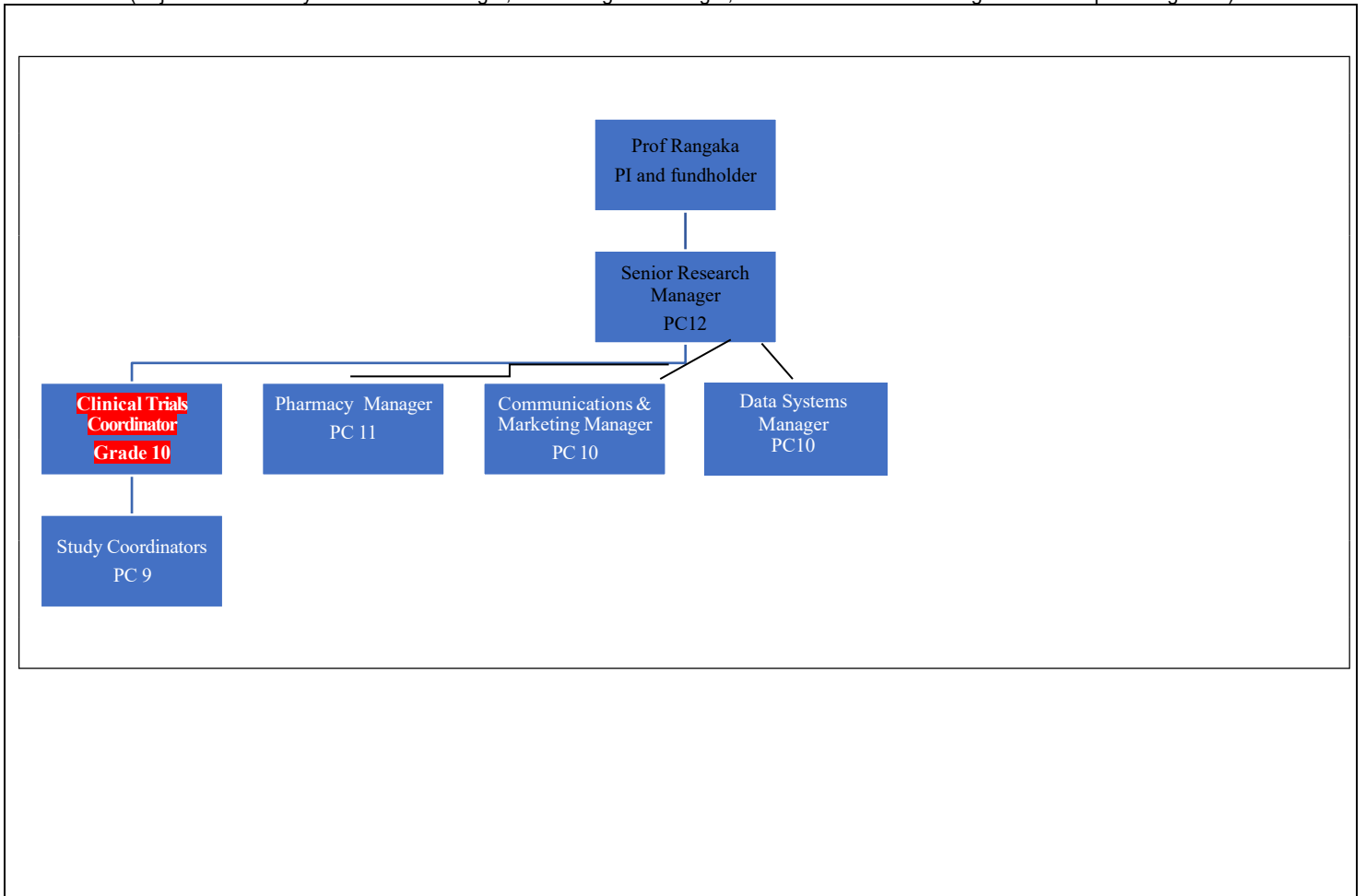
- Forms must be downloaded from the UCT website: <https://forms.uct.ac.za/forms.htm>
- This form serves as a template for the writing of position descriptions.
- A copy of this form is kept by the line manager and the position holder.

POSITION DETAILS

Position title	Clinical Trials Coordinator		
Job title (HR Business Partner to provide)			
Position grade (if known)	10	Date last graded (if known)	
Academic faculty / PASS department	Health Sciences		
Academic department / PASS unit	PASS		
Division / section	IDM-CIDRI-Africa		
Date of compilation	December 2024		

ORGANOGRAM

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



PURPOSE

Primarily responsible for overseeing and supporting the PI and study coordinators with a view to improving effectiveness, efficiency and forward planning across the various studies. Manage the coordination of the clinical trials in collaboration with scientists and the data management group. Interact closely with the Statisticians, Clinical project managers, Project leads, Data Managers, and Data scientists.

Working with key members both locally and international ensuring the successful delivery of the study. Training the site staff on the trial procedures, writing documentation, coordinating and monitoring of the data and ensuring that all regulatory requirements are met. Ensuring best practices and standards are implemented and adhered to across all clinical research studies, including the development and implementation of monitoring, training and mentoring plans and optimal staff allocation. Ensure workforce planning across different studies, general study administration, staff recruitment, training and supervision, and guidance to study coordinators.

Relieve Study coordinators of their duties, when necessary, as well as perform other administrative functions as required by management.

CONTENT

Key performance areas		% of time spent	Inputs (Responsibilities / activities / processes/ methods used)	Outputs (Expected results)
1	Projects support and standardization across studies	65	<ul style="list-style-type: none"> Producing trial documentation according to scientific requirements of the protocol and in line with the regulations and Unit's guidelines for data collection and management. Promoting trials to ensure wide participation and good accrual of patients. This may include assisting in the production of newsletters, visiting sites, attendance at scientific conferences and meetings and presenting information about the trials. Standardize systems and processes across studies for study planning, implementation, activation, recruitment, enrollment, data cleaning and close out. Develop best practices and tools for project execution and management Design study related material with the Principal Investigator, Study coordinator, Regulatory, Clinical Quality Specialist and Data Departments e.g. Consent document, Source documents and Case Report Forms (CRF). Give support to SC's to optimally conduct the Study administration functions. Ensuring all documentation is in place at trial sites in preparation for regulatory inspections and trial closure. Coordinate on-site monitoring of the clinical sites, where necessary , to ensure that sites are following the protocols and Good Clinical Practice (GCP) guidelines; to perform source data verification of critical data as detailed in the Monitoring/Data Management Plan. Oversee the purchasing, delivery and coordination of the trial drug supplies. Function in close collaboration with international counterparts and management 	<ul style="list-style-type: none"> Funder policies and procedures are implemented and adhered to. Ensure effective communication with managers of multifunctional staff. Study tools available and standardized Ensure study activities are booked and scheduled on respective electronic platforms to ensure effective planning and preparation by investigators, laboratory and pharmacy Source documents and CRF's that are unambiguous and contribute to good documentation practices. Project management tools available to all coordinators. Project execution well tracked via status reports, activity reports and monitoring reports. Weekly status reports available for all studies. Quality management (risk based) meeting minutes and contingency plans available Serious Adverse Events, clinical endpoints and significant issues are referred to the Chief Investigator and/or Trial Physicians.

2	Mentoring and Training	20	<ul style="list-style-type: none"> • Provide training, information and advice to Trial Clinicians, Research Nurses and Pharmacists on all protocol requirements. • Training of all Study Coordinators on the effective conduct of Clinical research projects • In collaboration with the regulatory officer, ensure that all staff's yearly SANC/HPCSA renewal are done timely and placed on file • Evaluate quality of work conducted and implement training and re- evaluation where needed • Coach, mentor, influence, and supervise Study coordinators and clinical team members to take positive action and accountability for their assigned work. 	<ul style="list-style-type: none"> • Protocol training records on file for all personnel. • Records of SOP training available for all studies. • Records of WPD training available for all studies. • Study coordinators are up to date on current operational, clinical and administrative policies for their respective studies and are confident on the execution of these policies resulting in minimal protocol deviations and favorable monitoring reports. • Relevant regulatory documents pertaining to all studies are filed in the institutional site files.
3	Human Resource Management	10	<ul style="list-style-type: none"> • Conduct thorough workforce planning for all studies in liaison with PIs, Field Site Manager and Study coordinators (SC's) to predict staff requirements 12 months in advance. • Allocate staff to studies to ensure maximum efficiency and effectiveness and delegate tasks and responsibilities to appropriate personnel. • Determine and assess need for additional staff and initiate recruitment if necessary. • Manage Study coordinators and assist them in managing their staff • Develop and evaluate appropriate job descriptions 	<ul style="list-style-type: none"> • Ensure all studies are adequately staffed in relation to what was budgeted for the study. • Arrange meetings with relevant people as needed. Manage clinic planning across all studies to ensure even distribution of visits, especially when lab, pharmacy or investigators have indicated personnel limitations for a specific period. • Monthly meetings with all SC's and weekly stats update. • Study teams function optimally and all objectives set by sponsor are met. • SC's function independently and take full responsibility for the execution of their respective protocols

4	Active Role In Management	5	<ul style="list-style-type: none"> • Assist with developing programs and agendas for regular national and international meetings. • Preparation and presentation of written and oral reports to key role players at seminars and scientific meetings • Assist in unit audit processes • Regular meeting conducted between Study Coordinators and managers of Data, Lab, Pharmacy, Logistics, IT and Communication Departments • Assist with writing papers • Any other comparable tasks as required by the Line Manager. 	<ul style="list-style-type: none"> • Minutes of meetings between the operation support structures and study coordinators available. • Have data available for report requests.
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MINIMUM REQUIREMENTS

Minimum qualifications	Degree/Diploma as Registered Nurse or Degree in Biomedical/Health-related field MPH or project certification/degree					
Minimum experience (type and years)	<p>4 years' experience in clinical research management (Study coordinator) either in a clinical drug or vaccine trial environment, including the management of staff</p> <p>Experience as primary Study Coordinator in a minimum of three separate drug/vaccine trials including experience in all stages of the clinical study lifecycle, from study initiation to close out</p> <p>Good level of scientific understanding to degree level or through equivalent experience</p> <p>Previous experience or knowledge of coordinating multi-centered international clinical trials in HIV or Tuberculosis trials</p> <p>Recent experience in the conduct of clinical trials involving Investigational Medicinal Products</p> <p>Good working evidence of implementing GCP</p> <p>Experience of study trial document development including protocols, CRFs, manuscripts, study reports and Standard Operating Procedures</p> <p>Understanding of clinical trials methodology and stages in the testing of new products and other interventions, and an excellent knowledge of current regulatory requirements governing clinical trials including a practical understanding of GCP.</p> <p>Understanding of the regulations and governance environment for clinical research in South Africa</p>					
Skills	<p>Intermediate Computer skills: Email, Microsoft word, Excel, Powerpoint</p> <p>Excellent ability to build interpersonal relationships and work within a diverse group of people</p> <p>Change Management</p> <p>Team Leadership/Management</p> <p>Strong planning, organizing and problem-solving skills</p> <p>Strong work ethic and standards</p> <p>Excellent verbal and written communication skills</p> <p>Excellent time management and self-management skills</p> <p>Workforce planning and data proficiency</p> <p>Training, mentoring and coaching skills</p> <p>Project Management</p>					
Knowledge	<p>Technical knowledge of Clinical Trials environment</p> <p>Ethical conduct of clinical trials</p> <p>Knowledge of South African Health Products Regulatory Authority (SAHPRA) and Department of Health Processes and Procedures</p> <p>Good Clinical Practice & Good Clinical Laboratory Practice Intermediate knowledge of Human Resources Management</p>					
Professional registration or license requirements	<p>South African Nursing Certificate (SANC)</p> <p>Health Professions Council of South Africa (HPSCA), if applicable</p>					
Other requirements (If the position requires the handling of cash or finances, other requirements must include 'Ability to handle cash or finances'.)	<p>Available to work after hours (including after hours and/or weekend) if required</p> <p>Ability to work independently and in a team of clinicians, sponsors, pharmacy, nursing and administrative staff</p> <p>Good Clinical Practice & Good Clinical Laboratory Practice</p> <p>Willingness to travel internationally</p>					
Competencies (Refer to UCT Competency Framework)	Competence		Level	Competence		Level
	Communication		2	Stress Tolerance		2
	Adaptability & Flexibility		2	Teamwork/Collaboration		2
	Analytical thinking & Problem Solving		2	Continuous Learning		2
	Planning & organizing / Work management		2	Client Services and Support		2
	Quality Commitment & Work Standard		2	Professional knowledge and skills		2
	Safety Awareness		2	Resilience & Tenacity		2
	Coaching		2	Managing Conflict		2
Building Interpersonal Skills		2	University Awareness		2	

SCOPE OF RESPONSIBILITY

Functions responsible for	<p>Mentoring and Training</p> <p>Projects support and standardization across studies. Active Role In Management</p>
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Amount and kind of supervision received	Limited from PI
Amount and kind of supervision exercised	High level across Clinical staff
Decisions which can be made	Purchases under R20 000
Decisions which must be referred	New requests from Sponsors Content of papers

CONTACTS AND RELATIONSHIPS

Internal to UCT	CIDRI-Africa Executive and their teams, Faculty of Health Sciences Communications and Marketing, UCT, Public Engagement teams already active within CIDRI- Africa.
External to UCT	UCL Clinical trial team