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

NOTES

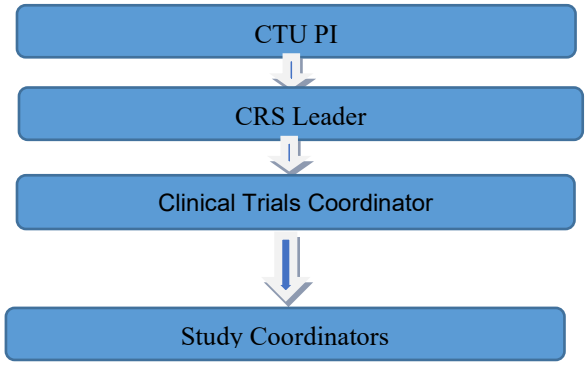
- Forms must be downloaded from the UCT website: http://forms.uct.ac.za/forms.htm
- This form serves as a template for the writing of position descriptions.
- A copy of this form is kept by the line manager and the position holder.

POSITION DETAILS

Position title	Clinical Trials Coordinator		
Job title (HR Business Partner to provide)	Clinical Trials Coordinator		
Position grade (if known)	10	Date last graded (if known)	09 Feb 2022
Academic faculty / PASS department	PASS		
Academic department / PASS unit	Health Sciences		
Division / section	Desmond Tutu HIV Centre		
Date of compilation	09 Feb 2022		

ORGANOGRAM

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



PURPOSE

The main purpose of this position is to fulfil the duties and responsibilities of a National Institute of Allergy and Infectious Diseases (NIAID) Division of AIDS (DAIDS) Clinical Trial CRS coordinator, and of a Clinical Trials Coordinator. These responsibilities include coordination and facilitation of activities across the CTU that may include administration, financial management, training, personnel supervision, evaluation, and logistics.

CONTENT

Key performance areas		% of time spent	Inputs (Responsibilities / activities / processes/ methods used)	Outputs (Expected results)
E.g.	General and office administration	25%	Takes, types up and distributes minutes and agendas for monthly departmental meeting. Greets visitors, enquires as to the nature of their visit and directs them to the appropriate staff member.	All staff members receive an electronic copy of accurate minutes and agendas, in the departmental template/format, a week before the meeting. Visitors are directed to appropriate staff member in a professional and efficient manner.
1	Operations (Network and CRS)	40%	• Coordinate the development and implementation of site standard operating procedures (clinical, regulatory, safety, recruitment and retention) and data and quality management plans which adhere to sponsor requirements, local regulatory guidelines and good clinical practices. • Oversight for adherence to NIH and network (HPTN, HVTN, MTN & CoVPN) policies and procedures with respect to site accreditation, protocol activation and study implementation. • Implement and monitor deliverable timelines for clinical operations, data entry and quality management, as agreed upon by CRS leader and management team. • Responsible for documenting operational and quality issues that arise and feed back to appropriate line managers. • In coordination with the CRS management team, implement, maintain, and evaluate the clinical quality assurance process, specifically relating to protocol adherence and data quality. • Develop and deliver progress reports, proposals, study documentation and presentations to sponsors, UCTCTU Steering Committee, Ethics, Regulatory and other stakeholders. • Give support to Study Coordinators to optimally conduct the study protocol in line with sponsor and regulatory requirements. • Assist Study Coordinators to ensure that specific administrative, operational, and clinical policies are adhered to for their staff including evaluation and retraining where indicated. • Oversee external evaluation monitoring (Clinical Trial Monitors) and manage the resolution of all queries.	• CRS SOPs are developed, implemented and adhered to. • Sponsor policies and procedures are implemented and adhered to. • CRS data quality management targets are met. • All reporting requirements are met. • Clinical trials are implemented and run according to CRS and Sponsor expectations.

2	Resource Management	20%	• Annually: participate in CRS management consolidation. Assess and develop “other” resources requirement plans as per research budgets/projects, ensuring optimal and efficient procurement and utilization of all other resources. • Participate in the identification and management of strategic operational site requirements, e.g. space requirements; renovations, fundraising needs. Bi-annually: review and update actual resource utilization against plans. • Conduct thorough workforce planning for all studies in collaboration with CRS management in order to predict staff requirements 12-24 months in advance. • Coordinate staff requirements and recruitment for CRS specific activities. • Assist with coordination of staff training and development needs. Staff management includes: • Direct line management of staff (Study coordinators). • Ensure that staff are developed to their full potential by identifying training needs and coordinating training and development. • Manage the performance appraisals of all line management, including agreeing on objectives, assessing competencies against objectives, drawing up a development plan if needed. • Through mentoring and interaction, develop action plans to resolve barriers to performance. • Assist with staff interviews and disciplinary hearings. • Ensure that staff render a service to all stakeholders of an acceptable standard and that they work within UCT Finance and HR Policies & Procedures AND NIH Policies and Regulations. • Ensure fair allocation of workload amongst portfolios. • Develop specific goals and plans to prioritize, organize, and accomplish work. • Develop or review all job descriptions for new posts. • Monitor operational activities. • Schedule staffs leave and maintain staff records. • Ensure effective communication with managers of multifunctional staff.	• Contribute to the strategic management planning of the CRS. • Staff needs are assessed on a regular basis. • Effective action is taken with regards to staff needs and recruitment. • Staff are managed and performance appraised according to company policies and procedures. • Effective communication across all teams working at the CRS.

3	Study Protocol Implementation and Execution specific to EMA CRS work	30%	• Ensure that specific administrative, operational, and clinical policies are adhered to for multiple studies. • Manage and perform study procedures in compliance with regulatory and ethical standards, as well as study protocols. • Oversight of screening, consenting, enrolment and follow-up of participants. • Oversight of line management and staff to coordinate day to day activities as required by protocol (booking participants, clinical procedures, documentation, clinic flow, etc.). • Participate and provide feedback in conference calls, local and international meetings. • Act as back-up Study Coordinator, for all studies, when required. • Work with Quality Control Officer to ensure that Quality Control and Quality Assurance activities are conducted as per Quality Management Plan.	• EMA CRS protocols, SOPs and Good Clinical Practices are implemented and adhered to. • Activities are monitored, issues are identified and resolved timeously. • CRS is represented at international meetings and conference calls. • In-depth knowledge of the requirements of each protocol. • Effective quality management procedures are in place.
4	Maintain Unit Viability through Research Support	10%	• Provide input on protocol and protocol revision as required and ensure staff are trained on updates. • Host visitors to the research site, including investigators of other studies. • Compile site research efforts to submit abstracts and assist with publications. • Support the grant writing and management process, e.g. RPPR	• DTHC presence is maintained at various strategic conferences and platforms.

MINIMUM REQUIREMENTS

Minimum qualifications	• University degree or equivalent in a field relevant to the role
Minimum experience (type and years)	• 4 years' experience as a study coordinator in a clinical drug or vaccine trials environment • Experience as primary Study Coordinator in a minimum of 3 separate drug/vaccine trials including at least one trial initiation and one trial close-out • 4 years' experience in managing staff in a clinical study team in a clinical drug trials environment
Skills	• Computer skills: Email, Microsoft word, Excel, Powerpoint • Excellent ability to build interpersonal relationships • Strong communication skills – verbal and written • Strong client focus • Team Leadership/Management • Project Management • Problem solving and decision making • Strong work ethic and standards • Detail oriented and strong administration skills
Knowledge	• Technical knowledge of Clinical Trials environment, particularly DAIDS-sponsored trials
Professional registration or license requirements	• Not applicable
Other requirements (If the position requires the handling of cash or finances, other requirements must include 'Ability to handle cash or finances'.)	• Not applicable

Competencies (Refer to UCT Competency Framework)

Competence	Level	Competence	Level
Client service orientation	2	Strong communication skills	2
Building interpersonal relationships	2	People management, including performance management	2
Decision-making and problem-solving	2	Facilitating change	2
Building partnerships	2	Functional leadership	2

SCOPE OF RESPONSIBILITY

Functions responsible for	The main purpose of this position is to fulfil the duties and responsibilities of a National Institute of Allergy and Infectious Diseases (NIAID) Division of AIDS (DAIDS) Clinical Trial CRS coordinator, and of a Clinical Trials Coordinator. These responsibilities include coordination and facilitation of activities across the CTU that may include administration, financial management, training, personnel supervision, evaluation, and logistics.
Amount and kind of supervision received	Minimal
Amount and kind of supervision exercised	In charge of professional staff who need medium level of supervision.
Decisions which can be made	People management, budgeting and clinical trial management.
Decisions which must be referred	Allocation of study funds.

CONTACTS AND RELATIONSHIPS

Internal to UCT	Medical Professionals, Researchers at various levels.
External to UCT	Funders, Fellow Researchers and Study Participants