CLINICAL RESEARCH COORDINATOR

PERFORMANCE EXPECTATION	SA	ASSESSMENT OF LEARNER OUTCOMES	PERFORMS INDEPENDENTLY (DATE/INITIALS)	PRACTICED/ REVIEWED
1. Evidence knowledge about SITE ORGANIZATIONAL STRUCTURE		Utilizes computer & e-mail system to communicate with research staff, principal investigators & essential personnel.		
		Utilizes proper hospital/clinical/research terminology in communication/documentation		
		Monitors protocol development process for assigned protocols		
		Utilizes Hospital Policy & Procedure, study and GCP Regulations appropriately.		
2. Evidences Knowledge about GOOD CLINICAL PRACTICE		Monitors protocol approval process involving the sponsor and IRB /IEC.		
		Collaborates with regulatory personnel throughout protocol approval process		
		Initiates designated changes throughout protocol version changes post informed consent		
		Implements informed consent process per FDA/sponsor after IRB approval & informed consent per sponsor protocol guidelines		
		Documents study practices per KCMC, Sponsor/, and GCP Source Documentation Guidelines.		
3. Evidences Knowledge about INVESTIGATIONAL and/or STUDY MEDICINE		Reviews monthly safety reports involving study medications		
		Reviews and implements dispensation of study medications per protocol guidelines in collaboration with clinical research pharmacist		
		Documents dispensation of study medications per sponsor source documentation guidelines		
		Utilizes available resources for patient education/teaching		
		Collaborates with pharmacist/physician when initiating and/or changing study treatment following appropriate study/sponsor permission, and documenting as per KCMC source documentation SOP.		
4. Implements Study Practices per IRB/SPONSOR and KCMC GUIDELINES		Reviews approved informed consent and obtains appropriate signatures per sponsor, regulatory authorities, and protocol guidelines, documenting inclusion/exclusion criteria, the process used to obtain consent, and providing source documentation of the signed consent form.		
		Performs screening tests and procedures per sponsor, protocol, and KCMC research SOPs and guidelines.		
		Utilizes protocol eligibility criteria & eligibility checklist to determine eligibility status prior to study entry.		
		Requests waivers for eligibility exemptions or protocol departures from protocol team and sponsor, and works collaboratively to submit exemptions to IRB/IEC.		
		Performs all components of study visits per sponsor-directed protocol, GCP, and KCMC source documentation SOPs and guidelines.		
5. Evidences Participation in QUALITY MANAGEMENT		Documents all aspects of clinical trials process in patient chart or other source document, i.e., essential document binder, laboratory result or inventory log. Provides a clear audit		

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		trial of all research data for substantiation/verification.		
		Documents all reportable components of study visits in source document as outlined in KCMC source document SOP.		
		Cooperates and collaborates with monitors during external monitoring process		
		Reviews quality assurance chart audits and implements corrective action as necessary		
		Reports Adverse Events or Serious Adverse Events per sponsor, protocol & IRB guidelines		
		Case Report Forms are completed per sponsor standards		
		Identifies and documents clinical endpoints per protocol guidelines & initiates process per protocol		
		Reviews & maintains copy of Good Clinical Practice Guidelines-		
D6. Implements PROTOCOLS		Reviews and maintains copy of assigned protocol (current version)		
		Identifies potential study candidates		
		Implements protocol-specific inclusion/exclusion criteria in screening process		
		Discusses protocol with patient's primary care provider(s)		
		Implements study tests/procedures per current IRB version of protocol		
		Reports AEs and /SAEs per protocol		
		Completes CRFs per sponsor & protocol specifications		
		Initiates drug orders & medication dispensation per protocol in collaboration with clinical research pharmacist		
		Assures collection of patient blood samples, cultures, tissues & specimens per protocol		
		Collects and documents nformation & data from patient charts & records, patient interviews & other sources pertinent to protocol screening & implementation		
		Reviews collected data, statistical reports, adverse trends per protocol and reports to Principal Investigator for interpretation and action.		
		Communicates with protocol team to implement changes or clarify questions		
		Communicates with collaborators and clinical research associates (monitors) assigned to research studies with any questions or problems.		
		Oversees the shipment of collected specimens in compliance with International Air Transportation Association regulations by laboratory processors		
D7. Follows PERSONNEL, CLINIC & SPONSOR POLICIES/PROCEDURES		Participates in review of performance expectations & appraisals		
		Attends study research meetings and conference calls		
		Follows confidentiality policies per site/clinic		
		Reviews policies for payroll, vacation, absences, compensatory time, sick leave, professional meetings, continuing education, & travel reimbursement		
		Reviews & implements occupational exposure (OSHA requirements, use of universal precautions, post-exposure management)		
D8. Demonstrates CLINICAL KNOWLEDGE OF HIV/AIDS		States knowledge of HIV viral transmission States knowledge of current antiretroviral medications & common side effects States knowledge of common HIV-related opportunistic infections & malignancies		
D9. Performs CLINICAL ASSESSMENT FOR STUDY PATIENTS PER HOSPITAL POLICY & PROCEDURE		Performs protocol-specific physical assessments Performs protocol-specific venipuncture procedures if necessary Collaborates with principal investigator and/or primary care provider regarding clinical findings		