MODULE D - CLINICAL RESEARCH NURSING (Private Studies) **Name:**

PERFORMANCE EXPECTATION	SA	ASSESSMENT OF LEARNER OUTCOMES	PERFORMS INDEPENDENTLY (DATE/INITIALS)	PRACTICED/ REVIEWED
D1. 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 & PDC Policy & Procedure Manual appropriately		
D2. Evidences Knowledge about GOOD CLINICAL PRACTICE		Monitors protocol approval process involving the sponsor, IRB and DAIDS		
		Collaborates with regulatory personnel throughout protocol approval process		
		Initiates designated changes throughout protocol version changes		
		Implements informed consent process per FDA/sponsor after IRB approval & informed consent per sponsor protocol guidelines		
		Documents study practices per Sponsor/GCP Source Documentation Guidelines		
D3. Evidences Knowledge about INVESTIGATIONAL MEDICINE		Reviews monthly safety reports involving study medications		
		Reviews and implements dispensation of study medications per protocol guidelines in collaboration with clinical pharmacist		
		Documents dispensation of study medications per sponsor source documentation guidelines		
		Utilizes ACTG resources for patient education/teaching		
		Collaborates with pharmacist/physician when initiating and/or changing study treatment following appropriate study/sponsor permission		
D4. Implements Study Practices per IRB/SPONSOR GUIDELINES		Reviews informed consent and obtains appropriate signatures per FDA/sponsor & Protocol guidelines		
		Performs screening tests and procedures per sponsor and protocol 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 & works collaboratively to submit exemptions to IRB		
		Performs all components of study visits per sponsor-directed & GCP source documentation guidelines.		
D5. Evidences Participation in QUALITY MANAGEMENT		Documents all aspects of clinical trials process in patient chart		
		Documents all reportable components of study visits in source document		
		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		

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		Case Report Forms are completed per sponsor standards		
		Identifies 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 AE's/SAE's per protocol		
		Completes CRF's per Sponsor & Protocol specifications		
		Initiates drug orders & medication dispensation per protocol in collaboration with pharmacist		
		Assures collection of patient blood samples, cultures, tissues & specimens per protocol		
		Collects information & data from patient charts & records, patient interviews & other Sources pertinent to protocol screening & implementation		
		Reviews & interprets collected data, statistical reports, adverse trends per protocol		
		Communicates with protocol team to implement changes or clarify questions		
		Communicates with clinical research associates (monitors) assigned to private studies with any questions/problems.		
		Oversees the shipment of collected specimens in compliance with Federal Dangerous Goods Regulations by laboratory processors		
D7. Follows PERSONNEL, CLINIC & SPONSOR POLICIES/PROCEDURES		Participates in review of performance expectations & appraisals		
		Attends weekly staff meetings & Protocol Planning Meetings		
		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 as necessary Collaborates with principal investigator and/or primary care provider regarding clinical findings		