

INTERAGENCY POST EMPLOYEE POSITION DESCRIPTION

Prepare according to instructions given in Foreign Service National Handbook, Chapter 4 (3 FAH-2)

1. POST Gaborone, Botswana	2. AGENCY Centers for Disease Control (CDC), HPR Program	3a. POSITION NO. CDC/M-
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3b. SUBJECT TO IDENTICAL POSITIONS? AGENCIES MAY SHOW THE NUMBER OF SUCH POSITIONS AUTHORIZED AND/OR ESTABLISHED AFTER THE "YES" BLOCK. Yes No

4. REASON FOR SUBMISSION

a. Redescription of duties: This position replaces
 Position No. _____, Medical Officer (Title) 505 (Series) 10 (Grade)

b. New Position

c. Other (explain) Additional duties

5. CLASSIFICATION ACTION	Position Title and Series Code	Grade	Initials	Date (mm-dd-yyyy)
a. Post Classification Authority	Clinical Trials Medical Officer	12	CG	
b. Other	FSN - 505			
c. Proposed by Initiating Office				

6. POST TITLE POSITION (if different from official title) MEDICAL OFFICER	7. NAME OF EMPLOYEE
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8. OFFICE/SECTION Centers for Disease Control	a. First Subdivision HIV Prevention Research (HPR), Gaborone
b. Second Subdivision	c. Third Subdivision

9. This is a complete and accurate description of the duties and responsibilities of my position. _____ Typed Name and Signature of Employee Date(mm-dd-yyyy)	10. This is a complete and accurate description of the duties and responsibilities of this position. _____ Typed Name and Signature of Supervisor Date(mm-dd-yyyy)
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11. This is a complete and accurate description of the duties and responsibilities of this position. There is a valid management need for this position. _____ Typed Name and Signature of Section Chief or Agency Head Date(mm-dd-yyyy)	12. I have satisfied myself that this is an accurate description of this position, and I certify that it has been classified in accordance with appropriate 3 FAH-2 standards. _____ Typed Name and Signature of Admin or Human Resources Officer Date(mm-dd-yyyy)
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13. BASIC FUNCTION OF POSITION

The medical officer serves as a co-investigator on clinical trials. He or she is responsible for evaluation of potential participant per study protocol, performance of appropriate clinical evaluation and treatment of study participants, training and supervision of clinicians, and training and supervision of other study personnel as needed. The medical officer assists in the development and modification of study protocols and instruments as well as in data analysis and dissemination. The medical officer is also the Pharmacy Officer.

14. MAJOR DUTIES AND RESPONSIBILITIES **100 % OF TIME**

See Attached.

Clinical Trials Medical Officer

Duties and Responsibilities

<i>Task</i>	<i>% time</i>
<p>1. Serves as co-investigator in clinical trials</p> <p>Helps ensure that the research trial is conducted in accordance with US federal regulations, Botswana regulations, and any provisions imposed by the Botswana Health Research Development Committee (HRDC) and the CDC IRB. Participates in the development and modification of trial protocols. Participates in the development and review of clinical trials Standard Operating Procedures (SOPs) and procedure manuals. Participates in the analysis, publication, and presentation of trial data/results. Assists the Protocol Operations Manager (POM), in the running of the study site. Works closely with the co-Principal Investigator and the POM for optimal unit and study coordination. Participates in the hiring/selection of new staff members within BOTUSA. . Maintains good working relationships with both internal and external research partners. Maintains professional and technical knowledge by reading current scientific literature relevant to ongoing clinical trials.</p>	(25%)
<p>2. Manages the medical care of participants: Clinical Duties</p> <p>Maintains current licensure to practice medicine. Conducts physical examinations and clinical interviews to establish clinical trial eligibility are met. Makes informed decisions regarding subjects' participation or continuation in clinical trials based upon sound medical, scientific and ethical knowledge. Conducts procedures, on participants, that nurses have difficulties in carrying out (e.g. pelvic examinations and difficult blood draws). Examines sick participants and makes the necessary/appropriate referrals. Reviews/completes the case report forms, AF11 and AF12, against the subjects' medical records for completeness, legibility and accuracy. Correctly resolves discrepancies between case report forms and source documents, as per clinical trial monitors' reports. Evaluates laboratory results and identifies signs and symptoms for adverse events. Arranges recalls of participants through Recruitment Retention Officers, as needed. Clearly explains laboratory results to participants with AE/SAEs. Reviews sexually-transmitted infection (STI) results and provides appropriate treatment. Provides education on more complex issues about HIV to participants that seroconvert which cannot be addressed by other staff. Provides and discusses results of CD4 and viral load to seroconverters. Makes the appropriate referrals to other centers of care, for seroconverters. Maintains and ensures constant consultation with colleagues on study related issues. Ensures the successful and timely completion of clinical data collection forms. Ensures the successful and timely resolution of queries regarding clinical data which arise from the Data Safety Monitoring Board (DSMB) quarterly reports. Requests Medical Record Abstraction consent from hospitalized participants and arranges appointments with hospitals where participants where would have been hospitalized, for purposes of medical history abstraction.</p>	(30%)
<p>3. Serves as Pharmacy Officer</p> <p>Ensures the proper storage and use of study products. Reads the current investigator's brochure and other source information, about the investigational drug. Assumes responsibility for the study drugs at the trial site. Ensures the study products are stored appropriately and securely to ensure freshness and potency, as required by the sponsor. Checks the pharmacy temperature, daily, and records the temperatures in a pharmacy temperature log.</p>	(20%)

He/She ensures that the study product is kept below 25 degrees Celsius, at all times. Monitors stocks of the study products, and other medicines, and informs the PI, well in time, of the need to have refills. Maintains proper monthly audits of the study drug and therapeutic medications as per FDA regulations. Prescribes the study drug to study participants. Monitors to ensure that nurses adhere to good pharmacy practices when they dispense drugs to participants.

4. Supervises clinical trial nursing staff.

(25%)

The two Medical Officers at each site provide direct supervision of 3-6 clinical trial research nurses. Trains junior staff on complex sub-studies, within the protocol. Develops the training materials, in line with the protocol. Provides ongoing training for nurses on new clinical trials procedures. Conducts post-training evaluations for nurses e.g. on performance of rapid finger-stick blood testing for HIV and Syphilis. Ensures Clinical Trial Research Nurses adequately maintain clinical supply inventory.

5. Performs other duties as assigned by the Associate Director for HIV Prevention Research.

15. DESIRED QUALIFICATIONS

a. Education:

A Medical degree from a recognized institution (M.D., M.B.B.S) is required.

b. Prior Work Experience:

5 years of post degree specialist experience working in a medical setting.

2 years experience in a clinical management position.

c. Post Entry Training:

Post-employment, the incumbent must complete Good Clinical Practice (GCP) training on an annual basis. The incumbent must also maintain Basic Life Support (BLS) certification by attending annual training.

d. Language Proficiency:

Fluency in English (Level 4) required.

e. Knowledges:

Must be knowledgeable about clinical issues related to HIV and STI transmission, diagnosis, and treatment; as well as diagnostic procedures for evaluating the reproductive health of women (e.g., PP smears, pelvic exams) and men (e.g., genital exams).

f. Skills and Abilities:

Registration or eligible for registration with the Botswana health professions council is a pre-requisite for employment.

The Medical Officer will have advanced clinical skills. Good oral and written communication skills are required.

Computer literacy is also required.

16. POSITION ELEMENTS

a. Supervision Received:

Direct supervision from the BOTUSA HIV Prevention Research Associate Director. Incumbent will perform clinical work independently and with supervisor providing broad, general guidance.

b. Available Guidelines:

Clinical trials and other research protocols (including protocol-specific standard operating procedures). U.S. FDA Good Clinical Practice (GCP) guidelines. CDC occupational safety and research guidelines. U.S. Embassy administrative procedures.

c. Exercise of Judgment:

Complex judgments involving the planning and conduct of clinical trials in an ethical, scientifically valid and medically safe manner; assessing trial participant medical status and treatment requirements; and coordinating with colleagues from several disciplines and collaborating institutions (both medical and government).

d. Authority to Make Commitments:

Within the constraints of the research protocols and budget, the incumbent will have authority to make commitments on clinical procedures.

e. Nature, Level and Purpose of Contacts:

Contacts are with health care providers in the community, hospitals, and clinics to which referrals will be made; with community advisory groups related to the trial; with local and national health officials; and with study staff at other trial sites for the purpose of provide factual information about the trial, providing training on clinical procedures and presenting scientific results.

f. Supervision Exercised:

With a second Medical Officer, the incumbent will provide direct supervision of 3-6 clinical trial research nurses. In the absence of the Protocol Operations Manager, the Medical Officer provides administrative oversight for the entire clinic

setting. including supervision of 3-6 clinical trial research interviewers, 2-6 clinical trial research counselors, 2-3 intake officers, 3-6 recruitment and retention officers, and 1 community liaison officer.

g. Time Expected to Reach Full Performance Level:

Three months.