

# INTERAGENCY POST EMPLOYEE POSITION DESCRIPTION

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

|                           |                         |                         |
|---------------------------|-------------------------|-------------------------|
| <b>1. POST</b><br>KAMPALA | <b>2. AGENCY</b><br>CDC | <b>3a. POSITION NO.</b> |
|---------------------------|-------------------------|-------------------------|

**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. Description of duties: This position replaces Human Subject Review Assistant  
 Position No. \_\_\_\_\_, \_\_\_\_\_ (Title) \_\_\_\_\_ (Series) \_\_\_\_\_ (Grade)
- b. New Position
- c. Other (explain)

| 5. CLASSIFICATION ACTION         | Position Title and Series Code                             | Grade  | Initials     | Date<br>(mm-dd-yyyy) |
|----------------------------------|--|--------|--------------|----------------------|
| a. Classification Authority      | Public Health Administrative Management Assistant, FSN 540 | FSN-09 | AFRC:<br>kmt | 5/30/17              |
| b. Other                         |  |        |              |                      |
| c. Proposed by Initiating Office |  |        |              |                      |

|  |                            |
|--|----------------------------|
| <b>6. POST TITLE POSITION (if different from official title)</b><br>Senior ADS Program Assistant | <b>7. NAME OF EMPLOYEE</b> |
|--|----------------------------|

|   |   |
|---|---|
| <b>8. OFFICE/SECTION</b><br>US Mission Kampala  | a. First Subdivision<br>Centers for Disease Control           |
| b. Second Subdivision<br>Office of the Director | c. Third Subdivision<br>Associate Director for Science Office |

**9. This is a complete and accurate description of the duties and responsibilities of my position.**

\_\_\_\_\_  
Printed name of Employee

\_\_\_\_\_  
Signature of Employee

\_\_\_\_\_  
Date(mm-dd-yyyy)

**10. This is a complete and accurate description of the duties and responsibilities of this position.**

\_\_\_\_\_  
Printed name of Supervisor for Science

\_\_\_\_\_  
Signature of Supervisor

\_\_\_\_\_  
Date(mm-dd-yyyy)

**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.**

\_\_\_\_\_  
Printed name of Section Chief or Agency Head

\_\_\_\_\_  
Signature of Section Chief or Agency Head

\_\_\_\_\_  
Date(mm-dd-yyyy)

**12. I have satisfied myself that this, in accordance with position management and classification precepts in 3 FAM 7000, is an accurate description of this position, and I certify that it has been classified appropriately.**

\_\_\_\_\_  
Printed name of Admin or Human Resources Officer

\_\_\_\_\_  
Signature of Management or Human Resources Officer

\_\_\_\_\_  
Date(mm-dd-yyyy)

**13. BASIC FUNCTION OF POSITION**

This position is located in the Associate Director for Science (ADS) office within the Office of the Director, CDC Uganda. The incumbent serves as the Senior ADS Program Assistant assisting the ADS for all related CDC activities. The purpose of this position is to provide guidance and expertise in human subjects protection and ethical conduct of science, and to examine and process protocol submissions, amendments, and continuation requests for all CDC/PEPFAR supported studies involving human subjects. The Senior ADS Program Assistant provides information and education on CDC clearance policies, procedures and processes, and examines new and continuing requests for completeness and scientific integrity. The Assistant also handles reports from CDC offices including

the Division of Global HIV/AIDS & TB Program's (DGHT) Associate Director for Science (ADS) Office (now called the DGHT Science Integrity Branch, SIB), the CDC Institutional Review Board (IRB), and responses from investigators. The Assistant acts as the primary liaison with local ethics regulatory bodies including Uganda National Council for Science & Technology and performs monitoring of study compliance with Good Clinical Practice. The Assistant's duties also include the education & provision of ethics and research technical guidance & support to CDC and implementing partner staff, provision of consultation to CDC Uganda program cooperative agreement, and scientific staff, as well as maintenance of organized records including of all regulatory submissions. In addition, this position is intended to consult with investigators, senior staff, Implementing partners and Head quarter staff regarding protocol submissions policies and procedures. The Assistant serves as backup for the Associate Director for Science.

#### 14. MAJOR DUTIES AND RESPONSIBILITIES

% OF TIME

**1. Acts the primary contact in processing new protocol submissions, amendments and protocol continuation requests; abstracts and journal article submissions and other informational products; and research/non-research determinations. (45 %)**

- Incumbent conducts detailed review and analysis of new scientific protocols submitted. This includes ensuring completeness and consistency of all required information defining and describing such items as compliant with federal regulations and CDC procedures, proposed consent forms, questionnaires, clearance forms, ensuring investigators have had relevant scientific/ethics training for the protection of Human subjects and other relevant materials. Identifies areas of major concern, reviews current policy and guidelines to see whether protocols are in compliance and brings this to the attention of the ADS, investigators and Branch Chiefs. Reviews and advises on project determination categorization of whether the project is research or non-research and provides guidance on clearance procedure for the different categories. Identifies relevance of the proposed study to CDC/PEPFAR Country priorities. Alerts the CDC Uganda ADS as to whether the protocol is an intramural or extramural activity. For cooperative agreements and contract studies, coordinates with the ADS, and others as needed.
- Incumbent conducts similar detailed review of amendments, continuation, protocol termination and closure requests, identifying whether they are complete. Identifies areas of major concerns and judges whether any modifications to the protocol warrant attention prior to submitting to the CDC Atlanta office and local IRBs. Judges whether any clarification or correction prior to submission to the ethics review boards in Atlanta and Uganda is needed or whether they will be addressed by the ADS. Makes recommendations to the CDC Uganda Associate Director for Science (ADS) as to whether protocols qualify for exempt, expedited, or full board review. Provides information and guidance to program, science staff and implementing partners on the requirements for U.S Federal wide Assurance (FWA) for the protection of human subjects and assists partner organizations on the process of obtaining FWA numbers.
- Receives reports and scientific publications and ensures that the submitted packages are complete and in compliance with the regulations and guidelines of CDC and local ethics regulatory bodies. Reviews whether the conclusions in the information products are supported by the objectives and ensures reported data received prior ethical review and documented approval. Ensures all staff have completed relevant scientific training. Brings inconsistencies or deficiencies to the attention of the CDC Uganda ADS and investigators. Updates DGHT publication data base and other tracking systems with all published scientific products.
- Sends reports to investigators in a timely fashion. Maintains a system of records for all regulatory activities so as to be in compliance with federal regulations. Tracks status of active protocols, research and non-research determinations, and schedules required continuing reviews. Maintains logs and tracking databases to capture, track, and review all of the above regulatory requirements. Develops standard operating procedures for all review processes and disseminates to staff and partners for reference. Develops working handbook with all clearance materials and policies to serve as a quick

guide. Ensures all clearance forms, guidelines and policies are stored on the public share drive for quick and easy access.

**2. Serves as a resource for investigators and programmatic staff on federal regulations for protecting human research subjects. (15 %)**

- Incumbent serves as a resource for human subjects contacts (usually Project Officers, Activity Managers, investigators and implementing partners) and all Branch staff on CDC human subjects policies, procedures and Federal Regulations for Protecting Human Research Subjects (45 CFR 46). Incumbent also analyzes inquiries and directs them to others in the office as appropriate. Uses knowledge of policies, procedures and regulations to respond to inquiries regarding human subjects protection processes, protocol submission format, and Federal Wide Assurance, etc. Provides advice and assistance on a daily basis to program officials, investigators and implementing partners etc.
- Incumbent handles inquiries from investigators regarding the status of their manuscripts, abstracts, protocols, amendments, policies, and continuation requests. Liaises with CDC Uganda ADS, DGHT Atlanta and others on status of submission. Prioritizes handling of submissions by CDC Uganda ADS based on organizational priorities.
- Keeps current on changes in policy and procedures regarding human subjects review. Works with the CDC Uganda ADS and others as applicable on a wide range of human subjects matters involving such issues as international research agreements as related to human subject protection.
- Performs other tasks as required such as setting up meetings and writing minutes, logging in protocols, and sending reminders of IRB approval expiration dates. Performs other duties as assigned by the CDC Uganda ADS.

**3. Interagency Collaborations and Communications (10 %)**

- Incumbent will assist the CDC Uganda ADS with coordination and facilitation of scientific workshops and trainings.
- Regularly meets with the local ethics committees and Uganda National Council for Science and Technology and coordinates meetings with the CDC headquarters Science Integrity Branch to discuss different areas of collaboration and familiarize with the clearance processes of the two countries. Provides technical assistance and information to the Government of Uganda and other partner institutions and staff on the review of CDC -funded research and non-research protocols.

**4. Compliance Monitoring (10 %)**

- The incumbent assists the ADS to conduct routine monitoring visits and provides information and tools which research teams will use to promote regulatory compliance in the conduct of research. This includes conducting study/site initiation visits to assess preparedness of the research team and to ensure the team fully understands the regulatory requirements and terms of the ethics regulatory approval, and to assure that identified gaps are addressed before the study starts. Other visits will include compliance support visits during study conduct (to assess progress and agree on areas of corrective/preventive action), and closure visits. Additionally, the incumbent will work with the headquarter teams and auditors, write reports and follow up on action areas.
- Participates in monthly conference calls for the various studies and provides guidance and technical assistance to the research teams.

**5. Review of ADS restrictions, restriction release, and human subjects review of new and continuing**

## applications

(20%)

- The incumbent works with the cooperative agreement team to prevent and mitigate human subject data collection funding restrictions ensuring minimal interruptions to program work. Reviews applications of Funding Opportunity Announcements (FOA) and continuations advises on human subjects-related activities, protocol development and review to release ADS funding restrictions.
- Assists the ADS and plans and deliver training on CDC review process and how to avoid or address data collection human subject related restrictions. Tracks and follows-up on cooperative agreement (CoAg) human subject restrictions and brings these to the attention of the ADS, CoAg team, Project Officers and implementing partners for action and resolution.
- Develops and implements a standard operating procedure to guide the identification, tracking and release/redirection of restricted funds.

### **15. QUALIFICATIONS REQUIRED FOR EFFECTIVE PERFORMANCE**

#### **a. Education:**

Master's degree in Public Health (Epidemiology, Behavioral Science/Health Education, International Health, Public Health Management, Biostatistics) or other health-related field is required; Bachelor degree is required.

#### **b. Prior Work Experience:**

Five years' experience working in a public health program or research project with a research organization, university, or public health services implementing agency is required.

#### **c. Post Entry Training:**

Orientation to project and review of current regulatory records. Additional training (i.e., good clinical practice and research ethics training, training in HIV/AIDS epidemiology and public health is required to conduct the tasks specified and will be provided by CDC in direct accordance with US Government and US Embassy policies and regulations.

#### **d. Language Proficiency: List both English and host country language(s) proficiency requirements by level (I, II, III)**

Level 4 Fluency (speak/read/write) in English is required.

Level 4 2 Fluency (speak/read/write) of Luganda or other local Ugandan language.

#### **e. Job Knowledge:**

Knowledge of research principles and HIV/AIDSs required. Knowledge and thorough understanding of CDC Human Subjects policies and the Federal Regulations for protecting human research subjects (45 CFR 46). Knowledge of CDC's organizational structure and operations in order to relate to commitments and work processes of the human subjects activities/ADS office.

#### **f. Skills and Abilities:**

Organizational skills are imperative. Must be self-motivated, able to work with minimal supervision. Position requires both oral and written skill at writing and presenting reports on human subjects activities and responding to both written and verbal requests for information. Skill in developing and maintaining effective working relationships utilizing positive interpersonal skills. Skill in analyzing, interpreting, and making decisions related to human subjects protocols, amendments and continuation requests, manuscripts and abstracts. Computer knowledge and experience and skills with Word Processing (Word); familiarity with spreadsheets (Excel) is required for maintenance of the data bases of the office and preparation of reports.

### **16. POSITION ELEMENTS**

#### **a. Supervision Received:**

Works under the supervision of the CDC Uganda ADS, who sets overall objectives. Employee independently plans and carries out duties required by the position. Overall effectiveness is measured by effectiveness in accomplishment of overall goals.

**b. Supervision Exercised:**

None.

**c. Available Guidelines:**

CDC Ethics Guidelines, CDC DGHT Program Strategies, Uganda national guidelines and policies in HIV/AIDS. The incumbent is expected to work within CDC policies, guidance and Federal regulations covering the use of human subjects for research.

**d. Exercise of Judgment:**

Considerable judgment is required in planning and evaluating the relevance and reliability of information and in organizing and presenting guidance during the preparation of documents. Incumbent must exercise good judgment in appropriate professional areas in making the best use of available resources, equipment and personnel. Must interface diplomatically with counterpart and employees of collaborating organizations. The work involves the review of both new and continuing scientific protocols for human subjects research. Incumbent is expected to identify areas of concern and make recommendations for compliance and consistency. Incumbent must record and track all active protocols and schedule continuing reviews. Sets up review board meetings and reports findings to project officers, and acts as a resource for completion of protocols with high scientific integrity and value. The work requires ensuring that procedural requirements are followed, as well as compliance with regulations and policies. The incumbent exercises initiative and resourcefulness in identifying problem areas and finding resolution. S/he exercises judgment in choosing, interpreting, and/or adapting guidelines to specific situations.

**e. Authority to Make Commitments:**

None.

**f. Nature, Level and Purpose of Contacts:**

Incumbent's internal contacts are with CDC scientists and investigators, programmatic project officers and activity managers, and CDC headquarters staff. Incumbent's external contacts are with Uganda National Council Science Technology, National Drug Authority, and Uganda Ministry of Health contacts such as the Uganda Virus Research Institute. The purpose of the work is to provide review, scientific rigor and ethical integrity of scientific protocols with regard to the policies and procedures of CDC and federal regulations. Contacts are with CDC project officers, CDC personnel, and extramural organizations involved in collaborative research or program evaluations with CDC. The purpose of the contacts is to relay information, explain policies, procedures and regulations, and assist project officers in bringing activities into compliance and completion.

**g. Time Expected to Reach Full Performance Level:**

52 weeks.