DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Request for Application (RFA) AA014]

Supporting Laboratory Training and Quality Improvement for Diagnosis and Laboratory Monitoring of HIV/AIDS Patients in Resource Limited Countries Through Collaboration With the American Society for Clinical Pathology (ASCP); Notice of Intent To Fund Single Eligibility Award

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the intent to award fiscal year (FY) 2005 funds for a cooperative agreement program to support laboratory training and quality improvement for diagnosis and laboratory monitoring of HIV/AIDS patients in resource-limited countries that are part of the President's Emergency Plan for AIDS Relief (PEPFAR). Ultimately, this program will serve to enhance laboratory testing practices, and enhance the quality of laboratory testing services, in order to improve the effectiveness of HIV diagnostic, care, and treatment services and interventions. The Catalog of Federal Domestic Assistance number for this program is 93.067.

B. Eligible Applicant

Assistance will be provided only to the American Society for Clinical Pathology (ASCP) for this project. No other applications are solicited or will be accepted. ASCP is a not-for-profit organization that has the largest and most unique data base of certified medical laboratory testing personnel. ASCP will be the only eligible applicant for the following reasons:

1. ASCP is the largest and most influential leader in the certification of Medical Technologists (MTs) and Medical Laboratory Technicians (MLTs) in the world.

2. ASCP is the world's largest organization representing the entire laboratory team of pathologists, clinical scientists, MTs and MLTs.

3. The Board of Registry (BOR) at ASCP has issued more than 340,000 certificates to date, since ASCP began in the late 1920's, and their unique data base of certified laboratorians comprise the largest majority of the medical laboratory work force in the U.S.

4. The ASCP BOR prepares appropriate standards and develops procedures to assure the competence of laboratory personnel.

5. The ASCP BOR certifies MTs and other medical laboratory personnel who meet specific academic and clinical prerequisites and who can attain acceptable performance levels through examination (*e.g.*, MT ASCP certification).

6. Additionally, ASCP has developed and maintains the largest continuing education activity in the world by offering courses targeted for pathologists and laboratory personnel to assure competency.

7. ASCP provides extensive venues for continuing education for pathologists and laboratory personnel, including web-based programs, teleconferences, on-site education programs, and regional and national settings.

PEPFAR activities focus on responding to an emergency situation while building long-term in-country capacity. Because of the complexity of the laboratory needs in each of the countries targeted, the number of countries (25) and regional programs (3) involved, the organization chosen to provide support should have both the technical competence and capacity to provide high quality simultaneous support to multiple countries. Selecting ASCP as the only eligible applicant is justified because of their vast membership and outstanding technical competence. Market research, through internet searches and interviews with leaders of laboratory service providers in international settings, indicates that ASCP is the only organization that is in a position to provide the required services to multiple countries simultaneously at the greatest value-for-service to the United States Government.

C. Funding

Approximately $2,000,000 is available in FY 2005 to fund this award. It is expected that the award will begin on or before August 31, 2005, and will be made for a 12-month budget period within a project period of up to four years. Funding estimates may change.

D. Where to Obtain Additional Information

For general comments or questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2700.

For program technical assistance, contact: Elyse Hill, Project Officer, CDC/NCHSTP/GAP, 1600 Clifton Road, NE (MS–E30), Atlanta, GA 30333, Telephone: 404–639–8181, E-mail: *elh8@cdc.gov*.

For financial, grants management, or budget assistance, contact: Diane Flournoy, Contract Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2072, E-mail: *dmf6@cdc.gov*.

Dated: June 17, 2005.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Request for Application (RFA) AA013]

Capacity Building Assistance for Global HIV/AIDS Laboratory Guidelines and Standards Development and Enhancing Laboratory Quality Improvement Skills Through Quality Systems Approach; Notice of Intent To Fund Single Eligibility Award

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the intent to award fiscal year (FY) 2005 funds for a cooperative agreement program to support capacity building assistance for global HIV/AIDS laboratory guidelines and standards development and enhancing laboratory quality improvement skills through quality systems approach. The purpose of the program is to provide support for the development and application of easy-to-use guidelines and standards for laboratory testing and quality systems development, and to foster development of in-country leaders to implement laboratory activities in Global AIDS Program (GAP) and Presidents Emergency Program for AIDS Relief (PEPFAR) countries based on internationally acceptable standards. The Catalog of Federal Domestic Assistance number for this program is 93.067.

B. Eligible Applicant

Assistance will be provided only to the CLSI. No other applications are solicited or will be accepted. This announcement and application will be sent to the CLSI.

The CLSI is the appropriate and only qualified institution to provide the services specified under this cooperative agreement because:

1. CLSI is the only officially established and accredited United States

(U.S.) organization for developing consensus standards for clinical and laboratory testing. CLSI members, approximately 2,000, are organizations (not individuals) representing the three major sectors contributing to assuring the quality of laboratory testing in the health field. They are the professional sector, the government sector, and industry. The professional sector is comprised of: (a) Clinical and medical science health services delivery organizations such as hospitals, health clinics, public health laboratories; and (b) clinical and laboratory science professional organizations. The government sector is represented by agencies such as the Centers for Disease Control and Prevention (a founding member), the Food and Drug Administration, the National Institute for Standards and Technology, and the Department of Veteran Affairs. The industry sector is represented by laboratory device and reagent manufacturers, the pharmaceutical industry, and the informatics industry.

2. CLSI is a global, nonprofit, standards-developing organization that promotes the development and use of voluntary consensus standards and guidelines within the healthcare community. CLSI is recognized worldwide for the application of its unique consensus process. CLSI is based on the principle that consensus is an efficient and cost-effective way to improve patient testing and services.

3. CLSI is a global leader in the development of medical laboratory standards.

a. One-fourth of CLSI members are located outside the U.S.

b. CLSI is the Executive Secretariat for the International Organization for Standardization (IOS) Technical Working Group. The IOS group develops internationally applicable medical laboratory testing standards.

c. CLSI is designated the World Health Organization (WHO) Collaborating Center for Clinical Laboratory Standards and Accreditation

d. Standards developed by CLSI are recognized and used throughout the world.

4. CLSI portfolio of more than 200 standards is recognized worldwide and provides a core for modification and expansion to better meet the needs in resource limited settings.

5. CLSI volunteers who develop laboratory standards represent CLSI member organizations. The volunteers are recognized as experts and world leaders. The accredited consensus process assures that all views are accounted for and adequately addressed. Consequently, standards developed by CLSI are considered authoritative and recognized among federal agencies, large segments of the health industry, and the professional sector.

6. CLSI staff and volunteers are actively engaged in numerous HIV activities to improve the quality of testing for diagnosing infection, staging disease in those infected, monitoring therapy, and detecting opportunistic infections. Venues for these interactions include CLSI workgroups developing standards in related technical areas, CLSI's Limited Resource Laboratories Working Group, and interaction with the Forum for Collaborative HIV Research.

7. CLSI Quality Systems Standards are a key building block for work that has already been done by the U.S. Government efforts to assure laboratory capacity to meet the needs of HIV prevention, care and treatment, surveillance, prevention of mother-to-child-transmission (PMTCT), voluntary counseling and testing (VCT), and blood safety programs. Quality systems training using CLSI standards has already been initiated in Africa and Southeast Asia countries. Laboratory leaders in these countries recognize CLSI as the world leader in developing these standards and would value and consider authoritative and credible additional contributions by CLSI.

C. Funding

Approximately $6,000,000 is available in FY 2005 to fund this award. It is expected that the award will begin on or before August 31, 2005, and will be made for a 12-month budget period within a project period of up to three years. Funding estimates may change.

D. Where To Obtain Additional Information

For general comments or questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146; Telephone: 770–488–2700.

For program technical assistance, contact: Elyse Hill, Project Officer, CDC/NCHSTP/GAP, 1600 Clifton Road, NE. (MS–E30), Atlanta, GA 30333, Telephone: 404–639–8181; E-mail: *elh8@cdc.gov*.

For financial, grants management, or budget assistance, contact: Diane Flournoy, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2072; E-mail: *dmf6@cdc.gov*.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

STD Surveillance Network (SSuN)

Announcement Type: New.

Funding Opportunity Number: AA055.

Catalog of Federal Domestic Assistance Number: 93.977.

Key Dates:

Letter of Intent Deadline: July 8, 2005.

Application Deadline: July 25, 2005.

I. Funding Opportunity Description

Authority: Sections 317(k)(2) and 318 of the Public Health Service Act [42 U.S.C. Sections 247b(k)(2) and 247c], as amended.

Background: A dynamic STD surveillance network, comprised of local enhanced STD surveillance systems following common protocols, has the potential to fill several important gaps in the existing national STD surveillance system. National STD surveillance data, reported through the National Electronic Telecommunication Surveillance System (NETSS), currently involves a limited number of demographic data elements collected from all states for a limited number of sexually transmitted diseases (chancroid, chlamydia, gonorrhea, and syphilis). Weekly reporting through NETSS is insufficient for rapid identification of many trends in disease, and does not support the collection and reporting of data on many relevant STD risk behaviors. Furthermore, even if trends in disease or risk behaviors are identified, the national STD morbidity surveillance infrastructure comprised of NETSS reporting from all states has limited capacity to be easily and rapidly modified. Even though the transition to the National Electronic Disease Surveillance System (NEDSS) is intended to improve the timeliness and flexibility of national STD surveillance, the flexibility of national morbidity reporting will always be restricted by the scale of the system.

CDC has traditionally relied on supplemental activities such as prevalence monitoring projects and special studies to enhance STD surveillance at a national level. While these types of activities focus on