

AMENDMENT II (7/29/2015)

1. **Pages 5, 11, 13, and 19:** adds “Ebola”
2. **Page 8, Statutory Authority:** Adds the following language to the end of the sentence:

...and the Ebola Supplemental Appropriation, Title VI, Division G of the Consolidated and Further Continuing Appropriations Act, 2015, Pub. L. 113-235 (2014), section 601.
3. **Page 26, Award Information:** Changes the “Approximate Total Project Period Funding” amount from \$140,000,000 to “None.” Also deletes the following language from this line: (This amount is an estimate, and is subject to availability of funds and includes direct costs for international organizations or direct and indirect costs for domestic grantees for all years.)
4. **THIS IS NOT A SOLICITATION FOR NEW APPLICATIONS**

AMENDMENT NOTICE (6/28/2015)

THE CHANGES BELOW ARE FOR INFORMATIONAL PURPOSES ONLY. UPDATES ARE INDICATED IN RED FONT AND CAN BE FOUND IN PART 2, SECTION I UNDER PURPOSE, PROGRAM AREA C AND PROGRAM AREA C OBJECTIVES AND ACTIVITIES. ADDITIONAL CHANGES CAN BE FOUND IN SECTION IV APPLICATION AND SUBMISSION INFORMATION UNDER FUNDING RESTRICTIONS. THIS IS NOT A SOLICITATION FOR APPLICATIONS.

Table of Contents

- Part 1. Overview Information**
- Part 2. Full Text of the Announcement**
 - Section I. Funding Opportunity Description**
 - Section II. Award Information**
 - Section III. Eligibility Information**
 - Section IV. Application and Submission Information**

Section V. Application Review Information

Section VI. Award Administration Information

Section VII. Agency Contacts

Section VIII. Other Information

PART 1. OVERVIEW INFORMATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Federal Agency Name: Centers for Disease Control and Prevention (CDC)

Funding Opportunity Title: “Supporting Laboratory Strengthening Activities in Resource-Limited Countries under the President's Emergency Plan for AIDS Relief (PEPFAR)”

Announcement Type: New – Type 1

Agency Funding Opportunity Number: CDC-RFA-GH13-1366

Catalog of Federal Domestic Assistance Number: 93.067

Key Dates:

Application Deadline Date: **September 29, 2015** on www.grants.gov, 11:59pm Eastern Standard Time

Program outcomes, by program area and objective, will include:

Program Area A: Supporting Laboratory Training and Quality Improvement for Diagnosis and Laboratory Monitoring of HIV/AIDS Patients

Program Area A Objective: Training of Laboratorians in PEPFAR-supported Countries

Short-term (1-2 years):

- Training packages developed for a total of at least 2 countries
- Existing training packages reviewed and revised as necessary to provide tier-specific training in at least 2 countries
- Provide long-term mentors to a cumulative total of at least 10 laboratories
- Training curricula reviewed/revised or developed for a total of at least 2 schools of medical technology

- Initiate the Strengthening Laboratory Improvement Process Toward Accreditation (SLIPTA) (or like step-wise approach to accreditation) process in a total of at least 10 PEPFAR-supported laboratories. Provide a total of at least 10 Strengthening Laboratory Management Toward Accreditation (SLMTA) trainings
- Train/mentor at least 2 National Reference Laboratories (NRL) to develop external quality assurance (EQA) panels
- Provide at least 20 webinars/teleconferences with at least 50 attendees for each event
- Assist a laboratory network/society in the African Region to develop a certification/recertification program for laboratorians

Intermediate (3-4 years):

- Training packages developed for a total of at least 5 countries
- Existing training packages reviewed and revised as necessary to provide tier-specific training in at least 5 countries
- Provide long-term mentors to a cumulative total of at least 25 laboratories
- Training curricula reviewed/revised or developed for a total of at least 5 schools of medical technology
- Initiate the SLIPTA (or like step-wise approach to accreditation) process in a cumulative total of at least 30 PEPFAR-supported laboratories. Provide a cumulative total of at least 25 SLMTA trainings
- Train/mentor a cumulative total of at least 10 NRLs to develop EQA panels
- Provide at least 30 webinars/teleconferences with at least 75 attendees for each event
- Provide certification for 300 laboratorians in PEPFAR-supported countries.

Long (5th year):

- Training packages developed for a total of at least 8 countries
- Existing training packages reviewed and revised as necessary to provide tier-specific training in at least 8 countries
- Provide long-term mentors to a cumulative total of at least 40 laboratories

- Training curricula reviewed/ revised or developed for a total of at least 8 schools of medical technology
- Initiate the SLIPTA (or like step-wise approach to accreditation) process in a cumulative total of at least 100 PEPFAR-supported laboratories. Provide a cumulative total of at least 40 SLMTA trainings
- Train/mentor a cumulative total of at least 20 NRLs to develop EQA panels
- Provide at least 30 webinars/teleconferences with at least 100 attendees for each event
- Provide certification/recertification for 1000 laboratorians in PEPFAR-supported countries.

Program Area B: Capacity Building Assistance for Global HIV/AIDS Laboratory Guidelines and Standards Development and Enhancing Laboratory Quality Improvement Skills through a Quality Systems Approach

Program Area B Objective: Provide laboratory capacity building assistance for laboratory guidelines and standards development and enhance laboratory quality improvement skills through a quality systems approach. Assist in implementing a step-wise process of improving laboratory quality toward accreditation in PEPFAR-supported laboratories, either through the SLIPTA sponsored by the African Society for Laboratory Medicine (ASLM), or similar step-wise processes.

Short-term (1-2 years):

- 2 countries/yr
- 25 PEPFAR-supported laboratories/yr
- At least 20 PEPFAR-supported national, regional or district level laboratories/yr
- 20 PEPFAR-supported laboratories/yr
- 20 PEPFAR-supported laboratories/yr
- 10 mentor events/year
- 5 new twinning relationships/yr
- 2 memberships per requesting participant country

Intermediate (3-4 years):

- 3 countries/yr

- 30 PEPFAR-supported laboratories/yr
- At least 30 PEPFAR-supported national, regional or district level laboratories/yr
- 30 PEPFAR-supported laboratories/yr
- 30 PEPFAR-supported laboratories/yr
- 15 mentor events/year
- 7 new twinning relationships/yr
- 3 memberships per requesting participant country

Long (5th year):

- 4 countries/yr
- 35 PEPFAR-supported laboratories/yr
- At least 50 PEPFAR- national, regional or district level supported laboratories/yr
- 50 PEPFAR-supported laboratories/yr
- 50 PEPFAR-supported laboratories/yr
- 20 mentor events/year
- 10 new twinning relationships/yr
- 5 memberships per requesting participant country

Program Area C: Capacity Building Assistance for Global HIV/AIDS Microbiological Laboratory Program Development

Program Area C Objective: Increase the capacity of laboratories to perform quality laboratory testing for infections by Mycobacterium tuberculosis, **Ebola**, and other opportunistic diseases, including malaria; and improve nationwide the laboratory infrastructure, including implementation of necessary training and institutionalization of Quality Management Systems procedures in PEPFAR-supported countries.

Short-term (1-2 years):

- At least 4 mentoring events in each participant country/year
- Training packages developed for a total of at least 2 countries
- 25 PEPFAR-supported laboratories/yr
- 25 PEPFAR-supported laboratories/yr

- 2 countries/yr

Intermediate (3-4 years):

- At least 6 mentoring events in each participant country/year
- Training packages developed for a total of at least 5 countries
- 30 PEPFAR-supported laboratories/yr
- 30 PEPFAR-supported laboratories/yr
- 3 countries/yr

Long (5th year):

- At least 6 mentoring events in each participant country/year
- Training packages developed for a total of at least 8 countries
- 35 PEPFAR-supported laboratories/yr
- 35 PEPFAR-supported laboratories/yr
- 4 countries/yr

Program Area D: Capacity Building Assistance to Support Sustainable HIV/AIDS

Integrated Laboratory Program Development

Program Area D Objectives:

1. Provide public health laboratorians, national AIDS control program officials in PEPFAR-supported countries, and officials of international agencies with technical assistance for a broad range of public health laboratory systems, infrastructure and services.
2. Provide expert participation on HHS/CDC teams for laboratory assessment activities in PEPFAR supported countries.
3. Identify and implement training opportunities for public health laboratorians in PEPFAR-Supported countries.
4. Develop training, reference and procedural documents, web sites, videos, job aids and other materials to facilitate the work of public health laboratorians in PEPFAR supported countries.
5. Monitor, document and analyze best practices, less than successful activities and lessons learned in cooperation with HHS/CDC.

Short-term (1-2 years):

- 25 PEPFAR-supported laboratories/yr
- Baseline assessments of at least 25 PEPFAR-supported laboratories/yr
- Initiate the SLIPTA (or like step-wise approach to accreditation) process in a total of at least 10 PEPFAR-supported laboratories.
- Provide a total of at least 10 SLMTA trainings
- 2 Ministries of Health (MOH)/yr

Intermediate (3-4 years):

- 30 PEPFAR-supported laboratories/yr
- Baseline assessments of at least 30 PEPFAR-supported laboratories/yr
- Initiate the SLIPTA (or like step-wise approach to accreditation) process in a cumulative total of at least 30 PEPFAR-supported laboratories.
- Provide a cumulative total of at least 25 SLMTA trainings
- 3 MOHs/yr

Long (5th year):

- 35 PEPFAR-supported laboratories/yr
- Baseline assessments of at least 35 PEPFAR-supported laboratories/yr Initiate the SLIPTA (or like step-wise approach to accreditation) process in a cumulative total of at least 100 PEPFAR-supported laboratories.
- Provide a cumulative total of at least 40 SLMTA trainings
- 4 MOHs/yr

This announcement is only for non-research activities supported by CDC. If research is proposed, the application will not be reviewed. For the definition of research, please see the CDC Web site at the following Internet address:

<http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf>

PART 2. FULL TEXT OF THE ANNOUNCEMENT

I. FUNDING OPPORTUNITY DESCRIPTION

Statutory Authority:

This program is authorized under Public Law 108-25 (the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003) [22 U.S.C. 7601, et seq.] and Public Law 110-293 (the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008) and the **Ebola Supplemental Appropriation, Title VI, Division G of the Consolidated and Further Continuing Appropriations Act, 2015, Pub. L. 113-235 (2014), section 601.**

Background:

The President's Emergency Plan for AIDS Relief (PEPFAR) has called for immediate, comprehensive and evidence based action to turn the tide of global HIV/AIDS. As called for by the PEPFAR Reauthorization Act of 2008, initiative goals over the period of 2009 through 2013 are to treat at least three million HIV infected people with effective combination anti-retroviral therapy (ART); care for twelve million HIV infected and affected persons, including five million orphans and vulnerable children; and prevent twelve million infections worldwide (3,12,12). To meet these goals and build sustainable local capacity, PEPFAR will support training of at least 140,000 new health care workers in HIV/AIDS prevention, treatment and care. The Emergency Plan *Five-Year Strategy* for the five year period, 2009 - 2014 is available at the following Internet address: <http://www.pepfar.gov>. The overarching purpose of this FOA is to fund activities to prevent or control disease or injury and improve health, or to improve a public health program or service. Recipients may not use funds for research. Certain activities that may require human subjects review due to institutional requirements but that are generally considered *not* to constitute research (e.g., formative assessments, surveys, disease surveillance, program monitoring and evaluation, field evaluation of diagnostic tests, etc.) may be funded through this mechanism.

Purpose:

Under the leadership of the U.S. Global AIDS Coordinator, as part of the President's Emergency Plan, the U.S. Department of Health and Human Services' Centers for Disease Control and Prevention (HHS/CDC) works with host countries and other key

partners to assess the needs of each country and design a customized program of assistance that fits within the host nation's strategic plan and partnership framework.

HHS/CDC focuses primarily on two or three major program areas in each country. Goals and priorities include the following:

- Achieving primary prevention of HIV infection through activities such as expanding confidential counseling and testing programs linked with evidence based behavioral change and building programs to reduce mother-to-child transmission;
- Improving the care and treatment of HIV/AIDS, sexually transmitted infections (STIs) and related opportunistic infections by improving STI management; enhancing laboratory diagnostic capacity and the care and treatment of opportunistic infections; interventions for intercurrent diseases impacting HIV infected patients including tuberculosis (TB); and initiating programs to provide anti-retroviral therapy (ART);
- Strengthening the capacity of countries to collect and use surveillance data and manage national HIV/AIDS programs by expanding HIV/STI/TB surveillance programs and strengthening laboratory support for surveillance, diagnosis, treatment, disease monitoring and HIV screening for blood safety; and
- Developing, validating and/or evaluating public health programs to inform, improve and target appropriate interventions, as related to the prevention, care and treatment of HIV/AIDS, TB and opportunistic infections.

In an effort to ensure maximum cost efficiencies and program effectiveness, HHS/CDC also supports coordination with and among partners and integration of activities that promote Global Health Initiative principles. As such, grantees may be requested to participate in programmatic activities that include the following activities:

- Implement a woman- and girl-centered approach;
- Increase impact through strategic coordination and integration;
- Strengthen and leverage key multilateral organizations, global health partnerships and private sector engagement;

- Encourage country ownership and invest in country-led plans;
- Build sustainability through investments in health systems;
- Improve metrics, monitoring and evaluation; and
- Promote research, development and innovation (research is not supported by this FOA).

The provision of quality laboratory services and the conduct of reliable diagnostic testing are challenging in many international settings where resources are limited. Quality laboratory testing is an integral element of the clinical diagnosis scheme, infectious disease surveillance, and the formation of public health policy. Good laboratory practices prove to be cost-effective, promote reliable and accurate results, contribute to good patient care, and promote a positive attitude towards testing from a patient's perspective.

Program Area A: There is a need to strengthen college and university biomedical laboratory science programs and to increase the knowledge and core competencies of the next generation of laboratory professionals, through: 1) revision of the existing curriculum or development of new curriculum, 2) assist in the development of new course content, and 3) improve faculty members' teaching and training skills. The ultimate goal is to prepare students for the work of clinical lab professionals. The entire health system is improved by developing a sustainable mechanism to produce capable, confident, and skilled laboratory professionals. The approach of the program is to develop a long-term strategy in PEPFAR-supported countries to accomplish two goals: (1) to ensure the sustainability of activities involved in capacity building of clinical laboratories; and (2) to gradually transition the ownership of those activities to indigenous organizations and governments in each country.

Program Area B: Very few laboratories in PEPFAR-supported countries are accredited by national or international standards. These countries often lack the technical expertise to develop laboratory standards relevant to the needs of their specific country, and therefore, require technical assistance from standards development organizations outside their country.

Program Area C: The need to further develop and strengthen laboratories is crucial.

Limited diagnostics and laboratory capacity represent a major barrier to the success of prevention, diagnostic, and treatment programs. Often, disease-specific laboratories have been established and supported, typically with varying levels of resources. **Development of laboratories may include identifying needs in existing facilities and supporting minor renovations to support functional design in physical facilities.** Efforts are currently underway to improve health care services to support the surveillance, diagnosis, and treatment of HIV/AIDS, HIV related diseases, STIs, **Ebola**, and tuberculosis (TB) through integrated services and networks.

Program Area D: Many PEPFAR-supported countries lack National Laboratory Strategic Plans (NLSPs) which incorporate laboratory quality strengthening activities. These countries lack training in how to prepare the NLSP, training in laboratory management, and personnel trained in auditing laboratories according to nationally or internationally accepted standards.

The goal and objectives of the program in each country is, by program area, as follows;

Program Area A: The measurable outcomes of the program will be in alignment with the following performance goal(s) for the President's Emergency Plan for AIDS Relief:

- Develop, customize and deploy country specific training packages for laboratory testing essential for accurate diagnosis and monitoring of HIV/AIDS patients (topics such as: Hematology, Chemistry, CD4 Monitoring, Laboratory Quality Systems, Laboratory Management, Phlebotomy.)
 - Train 400 laboratorians
- Build capacity by providing long-term technical assistance support for laboratorians
 - Fulfill, coordinate and support 12 requests for Technical Assistance; scope of work will be country specific (i.e., Clinical Chemistry, Hematology, CD4, Quality Management, etc.)

- Provide technical assistance in the review and development of pre-service curricula for schools of medical technology.
 - Conduct Initial Pre-Service Workshops (gap analysis and teaching techniques) involving at least 60 faculty members
 - Conduct Curriculum Finalization Workshops (Training of Trainers [TOT] with new materials, interactive teaching techniques, etc.) involving at least 60 faculty members:
 - Strengthen infrastructure at 3 Schools of Medical Technology through long-term (2-3 months) mentorship/Technical Assistance
- Provide ongoing continuing education (i.e. distance education and teleconferences.)
 - Provide distance education to 200 laboratorians

Program Area B: The goals of the program are to strengthen laboratory capacity building needs in PEPFAR-supported countries through two focal areas:

- Laboratory Guidelines and Standards Development, and
- Enhancing Laboratory Quality Improvement Skills through a Quality Systems Approach.

The main outcomes of this program will be:

- Nationally accepted laboratory guidelines and standards for laboratory testing and quality systems approach to providing services in countries where programs are implemented, and
- In-country leaders with the requisite skill sets to implement the internationally accepted standards that are developed. Both activities are critical to capacity building and sustainability of laboratory efforts in resource limited countries.

Program Area C: The goals of this program are in alignment with the performance goals of the President's Emergency Plan:

- Increase the capacity of laboratories to perform quality laboratory testing for infections by Mycobacterium tuberculosis, **Ebola**, and other opportunistic diseases, including malaria; and
- Improve nationwide the laboratory infrastructure, including implementation of necessary training and institutionalization of Quality Management Systems procedures.

Program Area D: The goals of this program are to

- Strengthen strategic planning for national laboratory policy development and implementation
- Assess and provide recommendations for developing laboratory capacity
- Implement activities to develop quality laboratory testing
- Provide expertise in development of integrated, sustainable clinical laboratory networks

The purpose of this FOA is listed by program area below;

Program Area A. The purpose of this program is 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. This does not include the delivery of direct HIV diagnostic, care, or treatment services and interventions.

Program Area B. The purpose of this 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 the President’s Emergency Program for AIDS Relief (PEPFAR)-supported countries based on internationally acceptable standards. These activities are critical to building capacity and the sustainability of laboratory efforts in PEPFAR- and GAP-supported countries. Capacity building assistance in this case means the provision

of information, technical assistance, training, and technology transfer for individuals and organizations to improve the delivery and effectiveness of HIV prevention, care and treatment services, and interventions

Program Area C. The purpose of this program is to address microbiological laboratory capacity-building need in Emergency Plan countries in two focus areas: (1) strengthening laboratory organizational and technical infrastructure, especially as it relates to training of laboratory personnel and development of processes of Quality Management Systems in the laboratory setting; (2) assuring the quality of laboratory testing for Mycobacterium tuberculosis and other opportunistic infections, including malaria, by instituting systematic approaches to delivering clinical microbiology services to HIV/AIDS, TB, and OI, prevention, treatment and care programs.

Program Area D. The purpose of this program is to provide assistance for the PEPFAR laboratory program development projects. The work is to be done with HHS/CDC in collaboration with national ministries of health, other PEPFAR partners and other implementing partners who are providing assistance in PEPFAR supported countries. The work will include, but not be limited to, strategic planning for national laboratory policy development and implementation, assessment and recommendations for developing laboratory capacity, implementation of activities to develop quality laboratory testing, and to provide expertise in development of integrated, sustainable clinical laboratory networks.

Applicants are expected to respond to one or more of the following program areas:

- A. Supporting Laboratory Training and Quality Improvement for Diagnosis and Laboratory Monitoring of HIV/AIDS Patients
- B. Capacity Building Assistance for Global HIV/AIDS Laboratory Guidelines and Standards Development and Enhancing Laboratory Quality Improvement Skills through a Quality Systems Approach
- C. Capacity Building Assistance for Global HIV/AIDS Microbiological Laboratory Program Development

D. Capacity Building Assistance to Support Sustainable HIV/AIDS Integrated Laboratory Program Development

Applicants must submit a separate application for the program areas they intend to implement or work in. In addition to the program narrative, the applicant must include a separate budget for each proposed program areas and in form SF 424 item number 14, the applicant should state the program areas they are applying to work in. Failure to indicate the area of work will make the application non-responsive. Applicants should consider linkages between the various program areas within their application, either by proposing to provide linked services or by proposing to ensure linkages to existing services not specifically provided by the applicant. Competitive advantage is not given based on the number of activities proposed across program areas. Applicants will be evaluated according to the strength of their responses per program areas. More than one applicant will not be funded for the same program areas under this award.

Program Implementation

Recipient Activities:

Partners receiving HHS/CDC funding must place a clear emphasis on developing local indigenous capacity to deliver HIV/AIDS related services to people in PEPFAR-supported countries and must also coordinate with activities supported by agencies in PEPFAR-supported countries, international or USG agencies to avoid duplication. Capacity-building plans should address systems, policy, organizational and workforce requirements for strengthening sustainable indigenous capacity to respond to the epidemic. Partners receiving HHS/CDC funding must collaborate across program areas whenever appropriate or necessary to improve service delivery.

The selected applicant(s) of these funds is responsible for activities in multiple program areas.

The grantee will implement activities both directly and, where applicable, through sub-grantees; the grantee will, however, retain overall financial and programmatic management under the oversight of HHS/CDC and the strategic direction of the Office of the U.S. Global AIDS Coordinator. The grantee must show measurable progressive reinforcement of the capacity of health facilities to respond to the national HIV epidemic as well as progress towards the sustainability of activities.

Applicants should describe activities in detail that reflect the policies and goals outlined in the *Five-Year Strategy* for the President's Emergency Plan and the Partnership Framework for each country. The grantee will produce an annual operational plan, which the U.S. Government Emergency Plan team on the ground in each country will review as part of the annual Emergency Plan review-and-approval process managed by the Office of the U.S. Global AIDS Coordinator and HHS/CDC.

The grantee may work on some of the activities listed below in the first year and in subsequent years, and then progressively add others from the list to achieve all of the Emergency Plan performance goals as cited in the previous section. HHS/CDC, under the guidance of the U.S. Global AIDS Coordinator and HHS/CDC, will approve funds for activities on an annual basis, based on availability of funding and USG priorities, and based on documented performance toward achieving Emergency Plan goals, as part of the annual Emergency Plan for AIDS Relief Country Operational Plan review-and-approval process.

Grantee activities and associated outputs for this program are as follows:

Program Area A: Supporting Laboratory Training and Quality Improvement for Diagnosis and Laboratory Monitoring of HIV/AIDS Patients

Program Area A Objective: Training of Laboratorians in PEPFAR-supported Countries

Activity # 1: Develop, customize and deploy country specific training packages for laboratory testing essential for accurate diagnosis and monitoring of HIV/AIDS patients (topics such as Hematology, Chemistry, CD4 Monitoring, Laboratory Management)

Output #1: Country-specific training packages developed for those PEPFAR-supported countries requesting these packages

Activity #2: Ensure the complexity level of the training packages is adaptable to the network model of central, regional and peripheral laboratory services (i.e., health center and ART sites);

Output #2: Network tier specific training packages developed

Activity #3: Build capacity by providing long-term technical assistance support for laboratorians

Output #3: Provide long-term (greater than 6 weeks in duration) mentors to PEPFAR-supported laboratories

Activity # 4: Provide technical assistance in the review and development of pre-service curricula for schools of medical technology

Output #4: Pre-service curricula reviewed/revised or developed outright for schools of medical technology in PEPFAR-supported countries

Activity #5: Support country specific phased-in approaches to laboratory accreditation, e.g. Strengthening Laboratory Improvement Process Toward Accreditation (SLIPTA)

Output #5: Initiate the SLIPTA (or like step-wise approach to accreditation) process in PEPFAR-supported laboratories. Provide SLMTA training courses.

Activity # 6: Support development of EQA programs

Output #6: Provide training and mentoring to those PEPFAR-supported NRLs expressing an interest in developing in-country proficiency testing panels

Activity #7: Provide ongoing continuing education (i.e., distance education and teleconferences).

Output #7: Provide easily accessible webinars and teleconferences geared toward maintaining the current relevance of training of laboratory personnel in PEPFAR-supported countries

Activity #8: Certification of laboratorians

Output #8: Assist in the design and promotion of a certification program for laboratorians in PEPFAR-supported countries, particularly in the African region.

Program Area B: Capacity Building Assistance for Global HIV/AIDS Laboratory Guidelines and

Standards Development and Enhancing Laboratory Quality Improvement Skills through a Quality Systems Approach

Program Area B Objective: Provide laboratory capacity building assistance for laboratory guidelines and standards development and enhance laboratory quality improvement skills through a quality systems approach. Assist in implementing a step-wise process of improving laboratory quality toward accreditation in PEPFAR-supported laboratories, either through the Strengthening Laboratory Improvement Process Toward Accreditation (SLIPTA) sponsored by the African Society for Laboratory Medicine (ASLM), or similar step-wise processes.

Activity #1: Facilitate and institute standards development activities within participating member countries, utilizing recognized international standards, such as ISO15189 or CLSI GP26-A4

Output #1: Laboratory testing quality standards developed according to the participating country's National Laboratory Strategic Plan

Activity #2: Advise and conduct a gap analysis/quality management system program, identify baseline, assess progress on recommendations and help prioritize ongoing implementation

Output #2: Using the WHO/AFRO sponsored SLIPTA checklist (or similar ISO-15189 linked checklist), conduct baseline assessments in those laboratories identified by participating member countries

Activity #3: Develop and distribute practical technically sound guidance for all aspects of laboratory testing processes ranging from how to collect samples and maintaining sample inventories to archiving laboratory records

Output #3: Guidance documents distributed

Activity #4: Assist with preparation for accreditation, personnel competency evaluation, and ensuring work processes and procedures function as needed

Output #4: Laboratories supported by the partner enrolled in a step-wise process toward accreditation

Activity #5: Provide training and technical assistance on the development of Standard Operating Procedures manuals

Output #5: Number of new laboratories supported which are developing SOPs

Activity #6: Illustrate methods for performing external audits, including quality control, retesting of patient specimens, and monitoring laboratory errors

Output #6: Number of mentors teaching methods of conducting laboratory assessments

Activity #7: Create and support relationships between laboratory QA leaders in PEPFAR countries and their counterparts in key partner countries. Such twinning relationships should be built on shared values of laboratory quality improvement

Output #7: Twinning relationships developed

Activity #8: Provide discounted memberships to nationally or internationally recognized professional laboratory standards development organizations (e.g., Clinical and Laboratory Standards Institute (CLSI)) to participant countries and sponsor active participation in the standards development process. Output #8: Memberships provided to nationally or internationally recognized laboratory standards development organizations

Program Area C: Capacity Building Assistance for Global HIV/AIDS Microbiological Laboratory Program Development

Program Area C Objective: Increase the capacity of laboratories to perform quality laboratory testing for infections by Mycobacterium tuberculosis, **Ebola**, and other opportunistic diseases, including malaria; and improve nationwide the laboratory infrastructure, including implementation of necessary training and institutionalization of Quality Management Systems procedures in PEPFAR-supported countries.

In particular the program objectives will focus on:

1. Building capacity by providing long-term technical assistance support for laboratorians in the form of mentoring: Fulfill, coordinate, and support six requests for technical assistance; scope of work will be country specific, i.e. TB

diagnostics (AFB smear microscopy, culture, drug susceptibility testing, identification, and molecular testing), malaria (microscopy and rapid testing), and other OIs (basic benchtop and automated procedures)

2. Assisting with the development, customization, and deployment of country specific training packages for laboratory testing essential for accurate diagnosis of HIV/AIDS-related OIs (areas include bacteriology, parasitology, and mycology),
3. Supporting development of external quality assurance programs (areas include mycobacteriology and bacteriology),
4. Providing technical guidance on laboratory physical infrastructure and procurement of laboratory equipment and supplies, **including identifying needs in functional design and procuring minor renovations in infrastructure to ensure laboratory capacity.**
5. Providing technical input to strategic plans of host countries.

Activity #1: Build capacity by providing long-term technical assistance (TA) support for laboratorians in the form of mentoring. Mentoring for TB, malaria, and other HIV/AIDS-related Opportunistic Infections (OIs) may include human resource development, training in basic diagnostic procedures, implementation of new diagnostics, quality control and quality assurance, strengthening of referral networks, and reporting

Output #1: Long term (greater than 4 weeks in length) mentoring events related to TB, malaria, and other HIV/AIDS related Opportunistic Infections

Activity #2: Assist with the development, customization, and deployment of country specific training packages for laboratory testing essential for accurate diagnosis of HIV/AIDS-related OIs (areas include mycobacteriology, bacteriology, parasitology, and mycology)

Output #2: Demonstrated development of training packages related to OIs

Activity #3: Support development of external quality assurance (EQA) programs:

- a) Provide TA to National TB Reference Laboratories enrolling in international EQA programs for TB culture and drug susceptibility testing
- b) Provide TA to national TB laboratory networks strengthening EQA for AFB smear microscopy
- c) Provide TA to

national clinical microbiology laboratory network for development and strengthening of bacteriology EQA

Output #3: Technical Assistance relating to external quality assurance programs as requested by participant PEPFAR-supported countries

Activity #4: Provide technical guidance on laboratory physical infrastructure and procurement of laboratory equipment and supplies: a) Provide guidance for laboratory design plans; b) Provide monitoring of progress for laboratory renovations; c) Provide specifications for procurement of equipment, supplies, and reagents; **d) Provide for minor renovations in laboratory infrastructure to improve capacity.**

Output #4: Technical Guidance relating to laboratory infrastructure as requested by participant PEPFAR-supported countries

Activity #5: Support development of strategic plans focused on clinical microbiology laboratory strengthening

Output #5: Incorporation of clinical microbiology laboratory strengthening activities in the national laboratory strategic plan of participant countries

Program Area D: Capacity Building Assistance to Support Sustainable HIV/AIDS Integrated Laboratory Program Development

Program Area D Objectives:

6. Provide public health laboratorians, national AIDS control program officials in PEPFAR-supported countries, and officials of international agencies with technical assistance for a broad range of public health laboratory systems, infrastructure and services.
7. Provide expert participation on HHS/CDC teams for laboratory assessment activities in PEPFAR supported countries.
8. Identify and implement training opportunities for public health laboratorians in PEPFAR-Supported countries.
9. Develop training, reference and procedural documents, web sites, videos, job aids and other materials to facilitate the work of public health laboratorians in PEPFAR supported countries.

10. Monitor, document and analyze best practices, less than successful activities and lessons learned in cooperation with HHS/CDC.

Activity #1: Provide public health laboratorians, national AIDS control program officials in PEPFAR supported countries and officials of international agencies with technical assistance for a broad range of public health laboratory systems, infrastructure and services. This technical assistance may include developing quality assurance and safety systems, assessing and selecting diagnostic assays, developing procedures for procuring, installing and maintaining laboratory equipment, planning national surveillance systems and strategic plans, advising on laboratory functional design and developing procedures for renovations and improvements in physical facilities including high containment laboratory facilities, and designing and implementing laboratory information systems.

Output #1: Provision of technical assistance for a broad range of public health laboratory systems, infrastructure and services

Activity #2: Provide expert participation on HHS/CDC teams for laboratory assessment activities in PEPFAR supported countries. These activities may vary widely in geographic scope and programmatic focus and will be tailored to meet the particular needs of the country's laboratory infrastructure

Output #2: Provide base line assessments of laboratories expressing interest in pursuing the Strengthening Laboratory Improvement Towards Accreditation process

Activity #3: In collaboration with HHS/CDC, national AIDS control programs in PEPFAR supported countries and other partners, identify and implement training opportunities for public health laboratorians in PEPFAR-Supported countries. These training opportunities may include training experiences at U.S. state and territorial public health laboratories, tutoring/mentoring activities in PEPFAR supported countries, group training exercises in PEPFAR supported countries, participation of PEPFAR supported country laboratorians in international and U.S. based training courses, conferences and meetings, distance-learning and other appropriate opportunities to facilitate the transfer of public health laboratory knowledge and best practices.

Output #3: Provide laboratory management-related training opportunities for laboratorians from participant countries.

Activity #4: Monitor, document and analyze best practices, less than successful activities and lessons learned in cooperation with HHS/CDC. Based on these experiences, suggest modifications of existing strategies or new initiatives to reduce transmission and improve HIV/AIDS care and support through the public health laboratory infrastructure.

Output #4: Assist Ministries of Health in PEPFAR-supported countries to develop or modify existing 5-year national public health laboratory strategic plans to include a step-wise laboratory quality improvement approach towards accreditation.

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC Activities:

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring. CDC activities for this program are as follows:

1. Organize an orientation meeting with the grantee to brief it on applicable U.S. Government, HHS, and Emergency Plan expectations, regulations and key management requirements, as well as report formats and contents. The orientation could include meetings with staff from HHS agencies and the Office of the U.S. Global AIDS Coordinator.
2. Review and make recommendations as necessary to the process used by the grantee to select key personnel and/or post-award subcontractors and/or subgrantees to be involved in the activities performed under this agreement, as part of the Emergency Plan for AIDS Relief Country Operational Plan review and approval process, managed by the Office of the U.S. Global AIDS Coordinator.
3. Review and make recommendations to the grantee's annual work plan and detailed budget, as part of the Emergency Plan for AIDS Relief Country Operational Plan review-and-approval process, managed by the Office of the U.S. Global AIDS Coordinator.
4. Review and make recommendations to the grantee's monitoring-and-evaluation plan, including for conduct of routine data quality assurance processes and periodic

data quality assessments and for compliance with strategic information guidance established by the Office of the U.S. Global AIDS Coordinator.

5. Meet on a monthly basis with the grantee to assess monthly expenditures in relation to approved work plan and modify plans, as necessary.
6. Meet on a quarterly basis with the grantee to assess quarterly technical and financial progress reports and modify plans as necessary.
7. Meet on an annual basis with the grantee to review annual progress report for each U.S. Government Fiscal Year, to evaluate grantee's performance (including quality of products and achievement of project goals and objectives), and to review annual work plans and budgets for subsequent year, as part of the Emergency Plan for AIDS Relief review and approval process for Country Operational Plans, managed by the Office of the U.S. Global AIDS Coordinator.
8. Provide technical assistance, as mutually agreed upon, and revise annually during validation of the first and subsequent annual work plans. This could include expert technical assistance and targeted training activities in specialized areas, such as strategic information, project management, confidential counseling and testing, palliative care, treatment literacy, and adult-learning techniques.
9. Provide in-country administrative support to help grantee meet U.S. Government financial and reporting requirements approved by the Office of Management and Budget (OMB) under 0920-0428 (Public Health Service Form 5161).
10. Collaborate with the grantee on designing and implementing the activities listed above, including, but not limited to the provision of technical assistance to develop program activities, evaluate program implementation, manage and analyze data, conduct quality assurance, present and possibly publish program results and findings, and track finances.
11. Provide technical assistance or advice on any data collections on 10 or more people that are planned or conducted by the awardee. All such data collections-- where CDC staff will be or are approving, directing, conducting, managing, or owning data-- must undergo OMB project determinations by CDC and may require OMB PRA clearance prior to the start of the project.

12. Provide consultation and scientific and technical assistance based on appropriate, HHS/CDC and Office of the U.S. Global AIDS Coordinator documents to promote the use of best practices known at the time.
13. Assist the grantee in developing and implementing quality-assurance criteria and procedures.
14. Facilitate in-country planning and review meetings for technical assistance activities.
15. Provide technical oversight for all activities under this award.
16. Conduct service delivery site visits through the Site Monitoring System (SMS) to monitor and evaluate site capacity to provide high-quality HIV/AIDS services in all program areas by assessing and scoring key program area elements of site performance and work with the grantee on identified gaps and continuous quality improvement.
17. Provide ethical reviews, as necessary, for evaluation activities, including from HHS/CDC headquarters. Evaluations can be process, outcome or impact.
 - a. Process Evaluation: measures how the intervention was delivered, what worked/did not, differences between the intended population and the population served, and access to the intervention.
 - b. Outcome Evaluation: determines effects of intervention in target population(s) (e.g., change in knowledge, attitudes, behavior, capacity, etc.).
 - c. Impact Evaluation: measures net effects of program and prove of causality
18. Supply the grantee with protocols for related evaluations.
19. Provide awardee opportunity to participate in development of monitoring and evaluation indicators used for all grantees.
20. Provide opportunity for annual meeting among all ILB-centrally held cooperative agreement awardees for the purpose of reporting on activities and develop coordinated approach to accomplishing mission driven technical assistance.

Please note: Either HHS staff or staff from organizations that have successfully competed for funding under a separate HHS contract, cooperative agreement or grant will provide technical assistance and training.

II. AWARD INFORMATION

Type of Award: Cooperative Agreement.

Award Mechanism: U2G – Global HIV/AIDS Non-Research Cooperative Agreements

Fiscal Year Funds: 2013

Approximate Current Fiscal Year Funding: \$ 28,000,000

Approximate Total Project Period Funding: **None**

Approximate Number of Awards: Four (one in each program area)

Approximate Average Award: \$ 7,000,000 (This amount is for the first 12 month budget period, and includes direct costs for international organizations or direct and indirect costs for domestic grantees.)

Floor of Individual Award Range: \$100,000

Ceiling of Individual Award Range: \$10,000,000 (This ceiling is for the first 12 month budget period and includes direct costs for international organizations or direct and indirect costs for domestic grantees.)

Anticipated Award Date: September 2013

Budget Period Length: Twelve months

Project Period Length: Five years

Throughout the project period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal government.

Note: Applicants should only apply for the first budget period funding, taking into consideration the floor of the individual award range and the ceiling of the individual award range. The proposed budget for the first budget period must not exceed the ceiling of the individual award range. If a funding amount greater than the ceiling of the individual award range is requested, the application will be considered non-responsive and will not be entered into the review process.

III. ELIGIBILITY INFORMATION

Eligible Applicants

Eligible applicants that can apply for this funding opportunity are listed below:

- Nonprofit with 501C3 IRS status (other than institution of higher education)
- Nonprofit without 501C3 IRS status (other than institution of higher education)
- For-profit organizations (other than small business)
- Small, minority, and women-owned businesses
- Universities
- Colleges
- Research institutions
- Hospitals
- Community-based organizations
- Faith-based organizations
- Federally recognized or state-recognized American Indian/Alaska Native tribal governments
- American Indian/Alaska native tribally designated organizations
- Alaska Native health corporations
- Urban Indian health organizations
- Tribal epidemiology centers
- State and local governments or their Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau)
- Political subdivisions of States (in consultation with States)
- Non-domestic (non-U.S.) entity

A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with “Other Attachment Forms” when submitting via www.grants.gov.

PEPFAR Local Partner definition:

Under PEPFAR, a “local partner” may be an individual or sole proprietorship, an entity, or a joint venture or other arrangement. However, to be considered a local partner in a given country served by PEPFAR, the partner must meet the criteria under paragraph (1), (2), or (3) below:

(1) an individual must be a citizen or lawfully admitted permanent resident of and have his/her principal place of business in the country served by the PEPFAR program with which the individual is or may become involved, and a sole proprietorship must be owned by such an individual; or

(2) an entity (e.g., a corporation or partnership):

(a) must be incorporated or legally organized under the laws of, and have its principal place of business in, the country served by the PEPFAR program with which the entity is or may become involved;

(b) must be at 75% for FY2013 beneficially owned by individuals who are citizens or lawfully admitted permanent residents of that same country, per sub-paragraph (2)(a), or by other corporations, partnerships or other arrangements that are local partners under this paragraph or paragraph (3);

(c) at least 75% for FY 2013 of the entity’s staff (senior, mid-level, support) must be citizens or lawfully admitted permanent residents of that same country, per sub-paragraph (2)(a), and at least 75% for FY 2013 of the entity’s senior staff (i.e., managerial and professional personnel) must be citizens or lawfully admitted permanent residents of such country; and

(d) where an entity has a Board of Directors, at least 51% of the members of the Board must also be citizens or lawfully admitted permanent residents of such country; or

(3) a joint venture, unincorporated association, consortium, or other arrangement in which at least 75% for FY 2013 of the funding under the PEPFAR award is or will be provided to members who are local partners under the criteria in paragraphs (1) or (2) above, and a local partner is designated as the managing member of the organization. Partner government ministries (e.g., Ministry of Health), sub-units of government ministries, and parastatal organizations in the country served by the PEPFAR program are considered local partners.* A parastatal organization is defined as a fully or partially government-owned or government-funded organization. Such enterprises may function through a board of directors, similar to private corporations. However, ultimate control over the organization rests with the government.

Note: To be considered a local partner, the applicant must submit supporting documentation demonstrating their organization meets one of the three criteria listed above.

Required Information

There are a total of three registrations needed to submit an application on www.grants.gov.

- a. Data Universal Numbering System: All applicant organizations must obtain a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal awards or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An Authorized Organization Representative (AOR) should be consulted to determine the appropriate number. If requested by telephone, a DUNS number will be provided immediately at no charge. If requested via the internet, obtaining a DUNS number may take one to two days at no charge. If your organization does not know its DUNS number or needs to register for one, visit Dun & Bradstreet at <http://fedgov.dnb.com/webform/displayHomePage.do>. An AOR should complete the US D&B D-U-N-S Number Request Form online or contact DUN and Bradstreet by telephone directly at 1-866-705-5711 (toll-free)

to obtain one. This is an organizational number. Individual Program Directors do not need to register for a DUNS number.

If funds are awarded to an applicant organization that includes sub-awardees, sub-awardees' must provide their DUNS numbers prior to accepting any sub-awards.

- b. System for Award Management: All applicant organizations must register in the System for Award Management (SAM). The SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as an awardee. The SAM number must be maintained with current information at all times during which it has an application under consideration for funding by CDC, and if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. The SAM registration process requires three to five business days to complete. SAM registration must be renewed annually. Additional information about registration procedures may be found at www.SAM.gov.

- c. Grants.gov: Registering your organization through www.grants.gov, the official HHS E-grant website, is the first step in submitting an application online. Registration information is located on the "Get Registered" screen of www.grants.gov.

All applicant organizations must register with www.grants.gov. The "one-time" registration process will take three to five days to complete. However, it is best to start the registration process as early as possible.

Cost Sharing or Matching

Cost sharing or matching funds are not required for this program.

Maintenance of Effort

Maintenance of Effort is not required for this program.

Other

If a funding amount greater than the ceiling of the individual award range is requested, the application will be considered non-responsive and will not be entered into the review process. The applicant will be notified that the application did not meet the eligibility requirements.

Special Requirements:

- Late submissions will be considered non-responsive. See section “V.3. Submission Dates and Times” for more information on deadlines.
- If the total amount of appendices includes more than 90 pages, any pages after page 90 of the application will not be considered for review. For this purpose, all appendices must have page numbers and must be clearly identified in the Table of Contents as appendices.

Note: Title 2 of the United States Code Section 1611 states that an organization described in Section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting a grant, loan, or an award.

Funding under this award will be subject to preferences based on programmatic needs and in-country strategic priorities. Applicants meeting the criteria specified in “Section V. Application Review Information” will receive additional points beyond the possible total of 100.

IV. APPLICATION AND SUBMISSION INFORMATION

Submission Dates and Times

This announcement is the definitive guide on application content, submission, and deadlines. It supersedes information provided in the application instructions. If the application submission does not meet the deadline published herein, it will not be eligible for review and the applicant will be notified the application did not meet the submission requirements.

Application Deadline Date: [INSERT DATE ## DAYS AFTER DATE OF PUBLICATION ON WWW.GRANTS.GOV, 11:59pm Eastern Standard Time. The recommended time period is 30, 45, 60 or 90 days after publication.]

Applicants must download the SF424 application package associated with this funding opportunity from www.grants.gov. If access to the Internet is not available or if the applicant encounters difficulty in accessing the forms on-line, contact the HHS/CDC Procurement and Grant Office Technical Information Management Section (PGO TIMS) staff at (770) 488-2700 email: pgotim@cdc.gov Monday-Friday 7:00am – 4:30pm U.S. Eastern Standard Time for further instruction. CDC Telecommunications for the hearing impaired or disabled is available at: TTY 1-888-232-6348.

If the applicant encounters technical difficulties with www.grants.gov, the applicant should contact Grants.gov Customer Service. The Grants.gov Contact Center is available 24 hours a day, 7 days a week, with the exception of all Federal Holidays. The Contact Center provides customer service to the applicant community. The extended hours will provide applicants support around the clock, ensuring the best possible customer service is received any time it's needed. You can reach the Grants.gov Support Center at 1-800-518-4726 or by email at support@grants.gov. Submissions sent by e-mail, fax, CD's or thumb drives of applications will not be accepted.

Content and Form of Application Submission

All applicants are required to sign and submit CDC Assurances and Certifications that can be found on the CDC Web site at the following Internet address:

<http://www.cdc.gov/od/pgo/funding/grants/foamain.shtm>

Print, scan and upload as an additional attachment into the application package.

Letter of Intent (LOI):

A letter of intent is not applicable to this funding opportunity announcement.

A Project Abstract must be completed in the www.grants.gov application forms. The Project Abstract must contain a summary of the proposed activity suitable for dissemination to the public. It should be a self-contained description of the project and should contain a statement of objectives and methods to be employed. It should be informative to other persons working in the same or related fields and insofar as possible understandable to a technically literate lay reader. This abstract must not include any proprietary/confidential information.

A Project Narrative must be submitted with the application forms. The project narrative must be uploaded in a PDF file format when submitting via www.grants.gov. The narrative must be submitted in the following format:

- Maximum number of pages: 25 (If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.);
- Font size: 12 point, unreduced, Times New Roman;
- Double spaced;
- Page margin size: One inch;
- Number all narrative pages; not to exceed the maximum number of pages.

Note: The applicant should take into consideration the Criteria listed in “Section V. Application Review Information” when composing the project narrative.

The narrative should address activities to be conducted over the entire project period and must include the following items in the order listed:

- **Project Context and Background (Understanding and Need):** Describe the background and justify the need for the proposed project. Describe the current infrastructure system; targeted geographical area(s), if applicable; and identified gaps or shortcomings of the current health systems and AIDS control projects;
- **Project Strategy - Description and Methodologies:** Present a detailed operational plan for initiating and conducting the project. Clearly describe the applicant’s technical approach/methods for implementing the proposed project. Describe the existence of, or plans to establish partnerships necessary to implement the project. Describe linkages, if appropriate, with programs funded by the U.S. Agency for International Development;
- **Project Goals and Objectives:** Include the goals of the project and its SMART objectives (specific, measurable, achievable, relevant, and time-bound). These need to be consistent with the expected targets of the Country/Regional Operational Plan and for this Cooperative Agreement program as provided in the “Purpose” Section at the beginning of this Announcement;
- **Work Plan and Description of Project Components and Activities:** Be sure to address each of the specific tasks listed in the activities section of this announcement. Clearly identify specific assigned responsibilities for all key professional personnel;
- **Project Outputs:** List the products (i.e. outputs) that will result from the activities to be implemented in this project and that are relevant to the objectives specified in the previous section (e.g., conduct data quality assessment once a year);
- **Project Outcomes:** Include the expected effects (i.e. outcomes) of project activities in the target populations and/or organizations (e.g., increased adherence to ART) that are relevant to the project goals and objectives. This will represent the project’s effectiveness;
- **Performance Indicators:** Include measures that will show progress in the achievement of project goals and objectives (e.g., percent of health care workers who graduated from a pre-service training at the end of the reporting period)
- **Timeline** (e.g., GANTT Chart); and

- **Management of Project Funds and Reporting.** Reporting should also address quarterly reports and PEPFAR Semi-Annual (SAPR) and Annual (APR) progress reports with robust data quality assurance and assessment procedures for reported data.

Project Budget Justification

With staffing breakdown and justification, provide a line item budget and a narrative with justification for all requested costs *for the first budget period*. Be sure to include, if any, in-kind support or other contributions provided by the national government and its donors as part of the total project, but for which the applicant is not requesting funding.

Budgets must be consistent with the purpose, objectives of the Emergency Plan and the program activities listed in this announcement and must include the following: line item breakdown and justification for all personnel, i.e., name, position title, annual salary, percentage of time and effort, and amount requested. The detailed budget should identify costs associated with potential data collection activities from persons, personal records, or for laboratory specimen collection and testing that may result in a public report. For each of the potential data collection activities also state the costs for any preparatory activities (e.g., protocol development, training, equipment, reagents, and site preparation).

The Project Budget Justification must be included as a separate attachment of the application, not to be counted in the narrative page limit. All budget justification pages must be numbered.

The recommended guidance for completing a detailed budget justification can be found on the HHS/CDC Web site, at the following Internet address:

<http://www.cdc.gov/od/pgo/funding/budgetguide.htm>.

For each contract, list the following: (1) name of proposed contractor; (2) breakdown and justification for estimated costs; (3) description and scope of activities the contractor will

perform; (4) period of performance; (5) method of contractor selection (e.g., competitive solicitation); and (6) methods of accountability. Applicants should, to the greatest extent possible, employ transparent and open competitive processes to choose contractors;

Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit. **The total amount of appendices must not exceed 90 pages and can only contain information related to the following:**

- ***Project Evaluation:*** Include an evaluation plan that will describe how outputs and outcomes will be evaluated. The plan should address the following:
 1. *list up to 3 evaluation questions to be answered about the main activity or intervention addressed in this project (e.g., Is the intervention implemented as intended? (process evaluation) What barriers do clients experience in accessing the intervention? (process evaluation) Did the intervention cause the expected outcomes? (outcome evaluation)*
 2. *specify how you will engage stakeholders (national and others)*
 3. *specify briefly data sources and methods for each evaluation question (up to 1 page per evaluation question, if needed)*
 4. *specify how results will be disseminated and used*
- ***Curricula vitae*** of current key staff who will work on the activity such as Principal Investigator;
- ***Job descriptions*** of proposed key positions to be created for the activity, if applicable, Principal Investigator, Grants Manager, Accounting staff assigned to the project, and consultants;
- ***Applicant's Corporate Capability Statement;***
- ***Letters of Support*** (5 letters maximum) from any consultants and subcontractors to be utilized to carry out project activities;
- ***Evidence of Legal Organizational Structure; and***
- ***If applying as a Local Indigenous Partner,*** provide documentation to self-certify the applicant meets the PEPFAR local partner definition listed in "Special Requirements," Part III. ELIGIBILITY INFORMATION section of the FOA.
- Organizational chart delineating lines of authority;

- Listing of all staff positions to be utilized in carrying out the activities of the project, and overall anticipated percentage of effort, including all staff in any type of management or project oversight role

Additional information submitted via www.grants.gov should be uploaded in a PDF file format, and should be named accordingly. i.e.: Letters of support should be named “letters of support”

Additional requirements for additional documentation with the application are listed in Section VII. Award Administration Information, subsection entitled “Administrative and National Policy Requirements.”

Funding Restrictions

Restrictions, which must be taken into account while writing the budget, are as follows:

- All plans for data collection from persons or personal records and for laboratory specimen collection and testing that are expected to result in public reports will require protocols for technical review and review of institutional human subjects protection considerations by CDC. Funds for implementing these activities will be restricted until all necessary institutional protocol approvals have been obtained. Funds for preparatory activities (e.g., protocol development, training, equipment, reagents, and site preparation) may be provided prior to protocol approval. To facilitate the early availability of funding, the budget and narrative should clarify which activities are preparatory.
- Human subjects data collection funding restrictions which require submission of protocols will be submitted within six months of notification of such requirement, but no later than the end of the first budget year. Requests for exceptions to these deadlines will need to be submitted in writing to the Grants Management Officer. All protocol approvals should be obtained no later than the end of the second budget period after the award or Continuation has been made, provided that the Grantee submits their protocol no later than the deadline.

- Needle Exchange – No funds made available under this award may be used for needle exchange programs
- The recipient must use funds provided under the agreement for costs incurred in carrying out the purposes of the award which are reasonable, allocable, and allowable in accordance with applicable cost principles. Unallowable costs will be determined in accordance with the applicable cost principles.
 1. “Reasonable” means the costs do not exceed those that would ordinarily be incurred by a prudent person in the conduct of normal business.
 2. “Allocable” means the costs are necessary to the award.
 3. “Allowable” means the costs are reasonable and allocable, and conform to any limitations set forth in the award.
- The recipient is encouraged to obtain the Grants Management Officer’s written determination in advance whenever the recipient is uncertain as to whether a cost will be allowable.
- Recipients may only expend funds for reasonable program purposes, including personnel, travel, supplies, and services, such as contractual.
- Awardees may not generally use HHS/CDC/ATSDR funding for the purchase of furniture or equipment. **Recipients may purchase equipment and complete renovations if deemed necessary to accomplish program objectives, and if authorized by, and in accordance with, applicable U.S. Federal Government law and HHS/CDC policy and the funding stream for this activity; however, recipients must request prior approval by HHS/CDC officials in writing, and conduct procurements in a transparent and competitive manner.** Any such proposed spending must be identified in the budget.
- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project objectives and not merely serve as a conduit for an award to another party or provider who is ineligible.
- Reimbursement of pre-award costs is not allowed.
- The costs that are generally allowable in grants to domestic organizations are allowable to foreign institutions and international organizations, with the following exception: With the exception of the American University, Beirut and

the World Health Organization, Indirect Costs will not be paid (either directly or through sub-award) to organizations located outside the territorial limits of the United States or to international organizations regardless of their location.

- The applicant may contract with other organizations under this program; however the applicant must perform a substantial portion of the activities (including program management and operations, and delivery of prevention services for which funds are required.)
- All requests for funds contained in the budget, shall be stated in U.S. dollars. Once an award is made, CDC will not compensate foreign grantees for currency exchange fluctuations through the issuance of supplemental awards.
- Public Financial Management Assessment Clause: The Parties acknowledge that HHS/CDC has assessed the recipient's systems required to manage the activities supported with US Government funds under this Agreement and that this Agreement is expressly conditioned upon that assessment, as well as any measures, mitigation or means by which the recipient has or will address the vulnerabilities or weaknesses, if any, found in that assessment. The recipient agrees to take the necessary action(s) to address the recommendations or requirements of the assessment as agreed separately in writing with HHS/CDC in accordance with an action plan to be jointly developed to address such recommendations or as otherwise contained in this agreement.
- It is the policy of HHS/CDC to seek to ensure that none of its funds are used, directly or indirectly, to provide support to individuals or entities designated for United Nations Security Council sanctions. In accordance with this policy, the applicant agrees to use reasonable efforts to ensure that none of the funds provided under this grant are used to provide support of individuals or entities designated for UN Security Council sanctions (compendium of Security Council Targeted Sanctions Lists at: http://www.un.org/sc/committees/list_compend.shtml). This provision must be included in all sub-agreements, including contracts and sub-awards, issued under this award.

- Prohibition on Assistance to Drug Traffickers
 1. HHS/CDC reserves the right to terminate this Agreement or take other appropriate measures if the Applicant or a key individual of the Applicant's Organization is found to have been convicted of a narcotics offense or to have been engaged in drug trafficking as defined in 22 CFR Part 140.
 2. HHS/CDC reserves the right to terminate assistance to, or take other appropriate measures with respect to, any participant approved by HHS/CDC who is found to have been convicted of a narcotics offense or to have been engaged in drug trafficking as defined in 22 CFR Part 140.
 3. The Applicant agrees not to disburse, or sign documents committing the Applicant to disburse, funds to a sub-recipient designated by HHS/CDC ("Designated Sub-recipient") until advised by HHS/CDC that: (1) any United States Government review of the Designated Sub-recipient and its key individuals has been completed; (2) any related certifications have been obtained; and (3) the assistance to the Designated Sub-recipient has been approved.
 4. The Applicant shall insert the following clause, or its substance, in its agreement with the Designated Sub-recipient:
 - a) The Applicant reserves the right to terminate this Agreement or take other appropriate measures if the [Sub-recipient] or a key individual of the [Sub-recipient] is found to have been convicted of a narcotic offense or to have been engaged in drug trafficking as defined in 22 CFR Part 140.

- U.S. Government funds under this award must not be used to finance the travel, per diem, hotel expenses, meals, conference fees or other conference costs for any member of a foreign government's delegation to an international conference sponsored by a multilateral organization, as defined below, unless approved by HHS/CDC in writing.

1. Definitions:

- a) A foreign government delegation is appointed by the national government (including ministries and agencies but excluding local, state and provincial entities) to act on behalf of the appointing authority at the international conference. A conference participant is a delegate for the purposes of this provision, only when there is an appointment or designation that the individual is authorized to officially represent the government or agency. A delegate may be a private citizen.
- b) An international conference is a meeting where there is an agenda, an organizational structure, and delegations from countries other than the conference location, in which country delegations participate through discussion, votes, etc.
- c) A multilateral organization is an organization established by international agreement and whose governing body is composed principally of foreign governments or other multilateral organizations.

- Abortion and Involuntary Sterilization Restrictions:

1. Funds made available under this award must not be used to pay for the performance of involuntary sterilization as a method of family

planning or to coerce or provide any financial incentive to any individual to practice sterilization.

2. Prohibition on Abortion-Related Activities:

- a) No funds made available under this award will be used to finance, support, or be attributed to the following activities:
 - (i) procurement or distribution of equipment intended to be used for the purpose of inducing abortions as a method of family planning;
 - (ii) special fees or incentives to any person to coerce or motivate them to have abortions;
 - (iii) payments to persons to perform abortions or to solicit persons to undergo abortions;
 - (iv) information, education, training, or communication programs that seek to promote abortion as a method of family planning; and
 - (v) lobbying for or against abortion. The term “motivate”, as it relates to family planning assistance, must not be construed to prohibit the provision, consistent with local law, of information or counseling about all pregnancy options.

- b) No funds made available under this award will be used to pay for any biomedical research which relates, in whole or in part, to methods of, or the performance of, abortions or involuntary sterilizations as a means of family planning. Epidemiologic or descriptive research to assess the incidence, extent or consequences of abortions is not precluded

- Trafficking in Persons Provision: No contractor or subrecipient under this Agreement that is a private entity may, during the period of time that the award is in effect:

1. Engage in trafficking in persons, as defined in the Protocol to Prevent, Suppress, and Punish Trafficking in Persons, especially Women and Children, supplementing the UN Convention against Transnational Organized Crime;
 - a) procure any sex act on account of which anything of value is given to or received by any person; or
 - b) use forced labor in the performance of this award.
2. If HHS/CDC determines that there is a reasonable basis to believe that any private party contractor or subrecipient has violated paragraph 1 of this section or that an employee of the contractor or subrecipient has violated such a prohibition where that the employee's conduct is associated with the performance of this award or may be imputed to the contractor or subrecipient, HHS/CDC may, without penalty, (i) require the Grantee to terminate immediately the contract or subaward in question or (ii) unilaterally terminate this Agreement in accordance with the termination provision.
3. For purposes of this provision, "employee" means an individual who is engaged in the performance in any part of the Project as a direct employee, consultant, or volunteer of any private party contractor or subrecipient.
4. The Applicant must include in all subagreements, including subawards and contracts, a provision prohibiting the conduct described in subsection a by private party subrecipients, contractors, or any of their employees.

- Requirements for Voluntary Family Planning Projects

- (1) A family planning project must comply with the requirements of this paragraph.
- (2) A project is a discrete activity through which a governmental or nongovernmental organization or Public International Organization (PIO) provides family planning services to people and for which funds obligated under this award, or goods or services financed with such funds, are provided under this award, except funds solely for the participation of personnel in short-term, widely attended training conferences or programs.
- (3) Service providers and referral agents in the project must not implement or be subject to quotas or other numerical targets of total number of births, number of family planning acceptors, or acceptors of a particular method of family planning. Quantitative estimates or indicators of the number of births, acceptors, and acceptors of a particular method that are used for the purpose of budgeting, planning, or reporting with respect to the project are not quotas or targets under this paragraph, unless service providers or referral agents in the project are required to achieve the estimates or indicators.
- (4) The project must not include the payment of incentives, bribes, gratuities or financial rewards to (i) any individual in exchange for becoming a family planning acceptor, or (ii) any personnel performing functions under the project for achieving a numerical quota or target of total number of births, number of family planning acceptors, or acceptors of a particular method of contraception. This restriction applies to salaries or payments paid or made to personnel performing functions under the project if the amount of the salary or payment increases or decreases based on a predetermined number of births, number of family planning acceptors, or number of acceptors of a particular method of contraception that the personnel affect or achieve.
- (5) A person must not be denied any right or benefit, including the right of access to participate in any program of general welfare or health care, based on the person's decision not to accept family planning services offered by the project.
- (6) The project must provide family planning acceptors comprehensible information about the health benefits and risks of the method chosen, including

those conditions that might render the use of the method inadvisable and those adverse side effects known to be consequent to the use of the method. This requirement may be satisfied by providing information in accordance with the medical practices and standards and health conditions in the country where the project is conducted through counseling, brochures, posters, or package inserts.

1. The recipient must notify CDC when it learns about an alleged violation in the requirements for voluntary family planning projects described in paragraphs (3), (4), or (5), above.
 2. The recipient must investigate and take appropriate corrective action, if necessary, when it learns about an alleged violation and must notify CDC about violations in a project affecting a number of people over a period of time that indicate there is a systemic problem in the project.
 3. iii) The recipient must provide CDC such additional information about violations as CDC may request.
- Investment Promotion
 1. No funds or other support provided hereunder may be used to provide a financial incentive to a business enterprise currently located in the United States for the purpose of inducing such an enterprise to relocate outside the United States if such incentive or inducement is likely to reduce the number of employees of such business enterprise in the United States because United States production is being replaced by such enterprise outside the United States.
 2. In the event the Applicant requires clarification from HHS/CDC as to whether the activity would be consistent with the limitation set forth above, the Applicant must notify HHS/CDC and provide a detailed description of the proposed activity. The Applicant must not proceed with the activity until advised by HHS/CDC that it may do so.
 3. The Applicant must ensure that its employees and subcontractors

and sub-recipients providing investment promotion services hereunder are made aware of the restrictions set forth in this clause and must include this clause in all subcontracts and other sub-agreements entered into hereunder.

- Worker's Rights

1. No funds or other support provided hereunder may be used for any activity that contributes to the violation of internationally recognized workers rights of workers in the recipient country.
2. In the event the Applicant is requested or wishes to provide assistance in areas that involve workers' rights or the Applicant requires clarification from HHS/CDC as to whether the activity would be consistent with the limitation set forth above, the Applicant must notify HHS/CDC and provide a detailed description of the proposed activity. The Applicant must not proceed with the activity until advised by HHS/CDC that it may do so.
3. The Applicant must ensure that all employees and subcontractors and sub-recipients providing employment-related services hereunder are made aware of the restrictions set forth in this clause and must include this clause in all subcontracts and other sub-agreements entered into hereunder.
4. The term "internationally recognized worker rights" includes-- the right of association; the right to organize and bargain collectively; a prohibition on the use of any form of forced or compulsory labor; a minimum age for the employment of children, and a prohibition on the worst forms of child labor; and acceptable conditions of work with respect to minimum wages, hours of work, and occupational safety and health.

5. The term “worst forms of child labor” means-- all forms of slavery or practices similar to slavery, such as the sale or trafficking of children, debt bondage and serfdom, or forced or compulsory labor, including forced or compulsory recruitment of children for use in armed conflict; the use, procuring, or offering of a child for prostitution, for the production of pornography or for pornographic purposes; the use, procuring, or offering of a child for illicit activities in particular for the production and trafficking of drugs; and work which, by its nature or the circumstances in which it is carried out, is likely to harm the health, safety, or morals of children, as determined by the laws, regulations, or competent authority of the country.

- Contract Insurance Requirement: To the extent that a host government partner enters into contracts expressly approved by the U.S. government, the host country government partner shall ensure that its contractors or subcontractors (a) provide, before commencing performance under any contracts or subcontracts funded under this agreement, such workers' compensation insurance or security as required by HHS/CDC and (b) continue to maintain such insurance until performance is completed. The host country government partner shall insert, in all contracts and subcontracts under this agreement, a clause similar to this clause (including this sentence) imposing upon those contractors and subcontractors the obligation to obtain workers' compensation insurance or security as required by HHS/CDC.
- No funds or other support provided under the award may be used for support to any military or paramilitary force or activity, or for support to any police, prison authority, or other security or law enforcement forces without the prior written consent of HHS/CDC.

- Conscience Clause: An organization, including a faith-based organization, that is otherwise eligible to receive funds under this agreement for HIV/AIDS prevention, treatment, or care—
 1. Shall not be required, as a condition of receiving such assistance—
 - a) To endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS; or
 - b) To endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection; and
 - c) Shall not be discriminated against in the solicitation or issuance of grants, contracts, or cooperative agreements for refusing to meet any requirement described above.

- Medically Accurate Information About Condoms: Information provided about the use of condoms as part of projects or activities funded under the award must be medically accurate and must include the public health benefits and failure rates of such use.

- Consistent with numerous United Nations Security Council resolutions, including UNSCR 1267 (1999) ([http://www.undemocracy.com/S-RES-1269\(1999\).pdf](http://www.undemocracy.com/S-RES-1269(1999).pdf)), UNSCR 1368 (2001) ([http://www.undemocracy.com/S-RES-1368\(2001\).pdf](http://www.undemocracy.com/S-RES-1368(2001).pdf)), UNSCR 1373 (2001) ([http://www.undemocracy.com/S-RES-1373\(2001\).pdf](http://www.undemocracy.com/S-RES-1373(2001).pdf)), and UNSCR 1989 (2011), both HHS/CDC and the Applicant are firmly committed to the international fight against terrorism, and in particular, against the financing of terrorism. It is the policy of HHS/CDC to seek to ensure that none of its funds are used, directly or indirectly, to provide support to individuals

or entities associated with terrorism. In accordance with this policy, the Applicant agrees to use reasonable efforts to ensure that none of the HHS/CDC funds provided under this Agreement are used to provide support to individuals or entities associated with terrorism, including those identified on the U.S. Department of Treasury Office of Foreign Assets Control Specially Designated Nationals List. This provision must be included in all subagreements, including contracts and subawards, issued under this award.

- Source and Nationality and Other Procurement Restrictions

1. Disbursements will be used exclusively to finance the costs of goods and services required for this Agreement [in accordance with 22 CFR 228, and] having their source and nationality in countries [included in Geographic Code [937 or 935]] OR [identified in subsection 6 below], except as HHS/CDC may otherwise agree in writing and as follows:

(a) Ocean transportation costs must be financed under the Agreement only on vessels under flag registry of [countries included in Code 935] OR [the following countries: LIST. Also see subsection 7 below on use of U.S.-flag vessels.

(b) Any motor vehicles financed under the Agreement will be of United States manufacture, except as HHS/CDC may otherwise agree in writing.

2. The nationality of the contractor providing ocean and air shipping services will be deemed to be the ocean vessel's or aircraft's country of registry at the time of shipment.

3. Provisions concerning restricted and ineligible goods and services may be provided in subsequent written communications between the parties. Special procurement rules apply to agricultural commodities, pharmaceuticals, pesticides, and fertilizer, none of which may be procured without advance written consent of HHS/CDC.

4. Transportation by air of property or persons financed under this agreement will

be on carriers holding United States certification, to the extent service by such carriers is available under the Fly America Act. This requirement may be further described by HHS/CDC in subsequent written communications between the parties.

5. Eligibility Date. No goods or services may be financed under the Agreement which are procured pursuant to orders or contracts firmly placed or entered into prior to the date of this Agreement, except as the Parties may otherwise agree in writing.

6. Eligible countries for procurement: HHS/CDC to identify for specific agreement.

7. Transportation

(a) In addition to the requirements in subsection 1 above, costs of ocean or air transportation and related delivery services may not be financed under this Agreement, if the costs are for transportation under an ocean vessel or air charter which has not received prior HHS/CDC approval.

(b) Unless HHS/CDC determines that privately owned U.S. -flag commercial ocean vessels are not available at fair and reasonable rates for such vessels, or otherwise agrees in writing:

- i. At least fifty percent (50%) of the gross tonnage of all goods (computed separately for dry bulk carriers, dry cargo liners and tankers) financed by HHS/CDC which may be transported on ocean vessels will be transported on privately owned U.S.-flag commercial vessels; and
- ii. At least fifty percent (50%) of the gross freight revenue generated by all shipments financed by HHS/CDC and transported to the territory of the Grantee on dry cargo liners shall be paid to or for the benefit of privately owned U.S.-flag commercial vessels. Compliance with the requirements of (1) and (2) of this subsection must be achieved with respect to both any cargo transported from

U.S. ports and any cargo transported from non-U.S. ports, computed separately.

- HHS/CDC and the Applicant agree to implement the Project in conformance with the regulatory and legal requirements of the Partner Country's environmental legislation and HHS/CDC's environmental policies.

The Applicant is required to create and follow an environmental mitigation plan and report (EMPR) for each thematic area covered by this agreement. The EMPR shall include the following:

- Coversheet;
- Narrative with project specific information, including level of effort;
- Annexes:
 - Environmental Screening Form (Table 1);
 - Identification of Mitigation Plan (Table 2);
 - Environmental Monitoring and Tracking Table (Table 3);
- Photos and Maps, as appropriate.

The EMPR will capture potential environmental impacts and also inform whether a supplemental Initial Environmental Examination (IEE) is required and should be completed and submitted to HHS/CDC.

- All PEPFAR-funded programs or activities must adhere to PEPFAR branding guidance, which includes guidance on the use of the PEPFAR logo and/or written attribution to PEPFAR. PEPFAR branding guidance can be found at <http://www.pepfar.gov/guidance/branding/index.htm>.

The 8% Rule

The 8% rule does not apply to Afghanistan, Brazil, Cameroon, Mali, Senegal, Sierra Leone and the Asia Regional Office, due to the fact that these countries are not required to have a Country Operations Plan (COP) in place. All other countries are required to have a Country Operations Plan (COP) in place.

The President's Emergency Plan for AIDS Relief (PEPFAR) seeks to promote sustainability for programs through the development, use, and strengthening of local partnerships. The diversification of partners also ensures additional robust capacity at the local and national levels.

To achieve this goal, the Office of the Global AIDS Coordinator (OGAC) establishes an annual funding guideline for grants and cooperative agreement planning. Within each annual PEPFAR country budget, OGAC establishes a limit for the total amount of U.S. Government funding for HIV/AIDS activities provided to a single partner organization under all grant and cooperative agreements for that country. **For U.S. Government fiscal year (FY) 2013, the limit is no more than 8 percent of the country's FY 2013 PEPFAR program funding (excluding U.S. Government management and staffing costs), or \$2 million, whichever is greater.** The total amount of funding to a partner organization includes any PEPFAR funding provided to the partner, whether directly as prime partner or indirectly as sub-grantee. In addition, subject to the exclusion for umbrella awards and drug/commodity costs discussed below, all funds provided to a prime partner, even if passed through to sub-partners, are applicable to the limit. PEPFAR funds provided to an organization under contracts are not applied to the 8 percent/\$2 million single partner ceiling. Single-partner funding limits will be determined by PEPFAR after the submission of the COP(s). Exclusions from the 8 percent/\$2 million single-partner ceiling are made for (a) umbrella awards, (b) commodity/drug costs, and (c) Government Ministries and parastatal organizations. A parastatal organization is defined as a fully or partially state-owned corporation or government agency. For umbrella awards, grants officers will determine whether an award is an umbrella for purposes of exception from the cap on an award-by-award basis. Grants or cooperative agreements in which the primary objective is for the organization

to make sub-awards and at least 75 percent of the grant is used for sub-awards, with the remainder of the grant used for administrative expenses and technical assistance to sub-grantees, will be considered umbrella awards and, therefore, exempted from the cap. Agreements that merely include sub-grants as an activity in implementation of the award but do not meet these criteria will not be considered umbrella awards, and the full amount of the award will count against the cap. All commodity/drug costs will be excluded from partners' funding for the purpose of the cap. The remaining portion of awards, including all overhead/management costs, will be counted against the cap.

Applicants should be aware that evaluation of proposals will include an assessment of grant/cooperative agreement award amounts applicable to the applicant by U.S. Government fiscal year in the relevant country. An applicant whose grants or cooperative agreements have already met or exceeded the maximum, annual single-partner limit may submit an application in response to this FOA. However, applicants whose total PEPFAR funding for this country in a U.S. Government fiscal year exceeds the 8 percent/\$2 million single partner ceiling at the time of award decision will be ineligible to receive an award under this FOA unless the U.S. Global AIDS Coordinator approves an exception to the cap. **Applicants must provide in their proposals the dollar value by U.S. Government fiscal year of current grants and cooperative agreements (including sub-grants and sub-agreements) financed by the Emergency Plan, which are for programs in the country(ies) covered by this FOA.** For example, the proposal should state that the applicant has \$_____ in FY 2013 grants and cooperative agreements (for as many fiscal years as applicable) in each country. For additional information concerning this FOA, please contact the Grants Management Officer for this FOA.

Prostitution and Sex Trafficking

The U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons. None of the funds made available under this agreement may be used to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of

palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.

The following definitions apply for purposes of this provision:

- “Commercial sex act” means any sex act on account of which anything of value is given to or received by any person.
- “Prostitution” means procuring or providing any commercial sex act and the “practice of prostitution” has the same meaning.
- “Sex trafficking” means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act.

The Applicant must insert this provision, which is a standard provision, in all subawards or subcontracts. This provision includes express terms and conditions of the award and any violation of it is grounds for unilateral termination of the award by HHS/CDC prior to the end of its term.

Additional Submission Requirements

Electronic Submission

Submit the application electronically by using the forms and instructions posted for this funding opportunity on www.grants.gov (Grants.gov). If access to the Internet is not available or if the applicant encounters difficulty in accessing the forms on-line, contact the HHS/CDC, Procurement and Grant Office, Technical Information Management Section (PGO TIMS) staff at (770) 488-2700 Email: pgotim@cdc.gov Monday-Friday 7:30am -4:30pm for further instruction.

Note: Application submission is not concluded until successful completion of the validation process.

After submission of your application package, applicants will receive a “submission receipt” email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. This validation process may take as long as two (2) business days. Applicants are strongly encouraged check the status of their application to ensure submission of their application package is complete and no submission errors exists. To guarantee that you comply with the application deadline published in the Funding Opportunity Announcement, applicants are also strongly encouraged to allocate additional days prior to the published deadline to file their application. Non-validated applications will not be accepted after the published application deadline date.

In the event that you do not receive a “validation” email within two (2) business days of application submission, please contact www.grants.gov. Refer to the email message generated at the time of application submission for instructions on how to track your application or the Application User Guide, Version 3.0 page 57.

Applications must be submitted electronically at www.grants.gov. Electronic applications will be considered as having met the deadline if the application has been successfully made available to CDC for processing from www.grants.gov on the deadline date. The application package can be downloaded from www.grants.gov. Applicants can complete the application package off-line, and then upload and submit the application via the www.grants.gov website. The applicant must submit all application attachments using a PDF file format when submitting via www.grants.gov. Directions for creating PDF files can be found on the www.grants.gov website. Use of file formats other than PDF may result in the file being unreadable by staff.

Applications submitted through Grants.gov (http://www.grants.gov), are electronically time/date stamped and assigned a tracking number. The AOR will receive an e-mail notice of receipt when www.grants.gov receives the application. The tracking number serves to document submission and initiate the electronic validation process before the application is made available to CDC for processing.

If the applicant encounters technical difficulties with www.grants.gov, the applicant should contact Grants.gov Customer Service. The Grants.gov Contact Center is available 24 hours a day, 7 days a week, with the exception of all Federal Holidays. The Contact Center provides customer service to the applicant community. The extended hours will provide applicants support around the clock, ensuring the best possible customer service is received any time it is needed. You can reach the Grants.gov Support Center at 1-800-518-4726 or by email at support@www.grants.gov. Submissions sent by e-mail, fax, CD's or thumb drives of applications will not be accepted.

Organizations that encounter technical difficulties in using www.grants.gov to submit their application must attempt to overcome those difficulties by contacting the Grants.gov Support Center (1-800-518-4726, support@www.grants.gov). After consulting with the Grants.gov Support Center, if the technical difficulties remain unresolved and electronic submission is not possible to meet the established deadline, organizations may submit a request prior to the application deadline by email to the Grants Management Officer [See Section VII "Agency Contacts"], for permission to submit a paper application. An organization's request for permission must:

- (a) include the Grants.gov case number assigned to the inquiry by the Grants.gov support desk;*
- (b) describe the difficulties that prevented electronic submission and the efforts taken with the Grants.gov Support Center; and*
- (c) be submitted to the GMO/GMS at least 3 calendar days prior to the application deadline.*

Paper applications submitted without prior approval will not be considered.

If a paper application is authorized, the applicant will receive instructions from PGO TIMS to submit the original and two hard copies of the application by mail or express delivery service. A due date will be provided by PGO.

Intergovernmental Review

Executive Order 12372 does not apply to this program.

V. APPLICATION REVIEW INFORMATION

Eligible applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the funding opportunity announcement GH13-1366. Measures of effectiveness must relate to the performance goals stated in the “Purpose” section of this announcement. Measures of effectiveness must be objective, quantitative and measure the intended outcome of the proposed program. The measures of effectiveness must be included in the application and will be an element of the evaluation of the submitted application.

Criteria

Eligible applications will be evaluated against the following criteria:

Ability to Carry Out the Proposal (20 points):

Does the applicant demonstrate the local experience in each country and institutional capacity (both management and technical) to achieve the goals of the project with documented good governance practices? (5 points) Does the applicant have the ability to coordinate and collaborate with existing Emergency Plan partners and other donors, including the Global Fund and other U.S. Government Departments and agencies involved in implementing the President’s Emergency Plan, including the U.S. Agency for International Development? (10 points) Is there evidence of leadership support and evidence of current or past efforts to enhance HIV prevention? Does the applicant have the capacity to reach rural and other underserved populations in each country? Does the organization have the ability to target audiences that frequently fall outside the reach of the traditional media, and in local languages? (5 points) To what extent does the applicant provide letters of support?

Technical and Programmatic Approach (20 points):

Does the application include an overall design strategy, including SMART (specific, measurable, achievable, relevant, and time-bound) objectives and specific time lines, clear monitoring and evaluation procedures, and specific activities for meeting the proposed objectives? (5 points) Does the applicant display knowledge of the strategy, principles and goals of the President's Emergency Plan, and are the proposed activities consistent with and pertinent to that strategy and those principles and goals? (5 points) Does the applicant describe activities that are evidence-based, achievable, and culturally appropriate to achieve the goals of the President's Emergency Plan? (5 points) Does the application propose to build on and complement the current national response in with evidence-based strategies designed to reach underserved populations and meet the goals of the President's Emergency Plan? (5 points) Does the application include reasonable estimates of output targets? (For example, the numbers of sites to be supported, number of clients the program will reach.) To what extent does the applicant propose to work with other organizations? The reviewers will assess the feasibility of the applicant's plan to meet the outcomes, whether the proposed use of funds is efficient, and the extent to which the specific methods described are sensitive to the local culture.

Capacity Building (25 points):

Does the applicant have a proven track record of building the capacity of indigenous systems, organizations and workforce to respond to the epidemic? Does the applicant have relevant experience in using participatory methods, and approaches, in project planning and implementation? Does the applicant describe an adequate and measurable plan to progressively build the capacity of local systems, organizations and workforce to respond to the epidemic? (15 points) If not a local indigenous organization, does the applicant articulate a clear exit strategy which will maximize the legacy of this project in the intervention communities? Does the capacity building plan clearly describe how it will contribute to a) improved quality and geographic coverage of service delivery to achieve the "3,12,12¹" targets of the President's Emergency Plan, and b) (if not a local

¹ The President's Emergency Plan for AIDS Relief (PEPFAR) has called for immediate, comprehensive and evidence based action to turn the tide of global HIV/AIDS. As called for by the PEPFAR Reauthorization Act of 2008, initiative goals over the period of 2009 through 2013 are to treat at least three million HIV infected people with effective combination anti-retroviral therapy (ART); care for twelve

indigenous organization) an evolving role of the prime beneficiary with transfer of critical technical and management competence to local organizations/sites in support of a decentralized response? (10 points)

Monitoring and Evaluation (15 points):

Does the applicant demonstrate the local experience and capability to implement monitoring and rigorous evaluation of the project? Does the applicant describe a monitoring system used to routinely review information and adjust program activities accordingly? Is the monitoring and evaluation plan consistent with the principles of the "Three Ones"²? Does the monitoring plan include indicators developed for each program milestone, and incorporated into the financial and programmatic reports? Are the indicators consistent with the President's Emergency Plan Indicator Guide and other HHS/CDC requirements? Is the system able to generate financial and program reports to show disbursement of funds, and progress towards achieving the numerical objectives of the President's Emergency Plan and HHS/CDC priorities? Does the applicant describe robust approaches to assure and assess the quality of routinely monitored and reported data on progress toward numerical objectives? (10 points) Does the evaluation plan address the components listed specified under the program evaluation section (i.e. evaluation questions, engagement of stakeholders, data sources and methods, results

million HIV infected and affected persons, including five million orphans and vulnerable children; and prevent twelve million infections worldwide.

² The Emergency Plan supports the multi-sectoral national responses in host nations, adapting U.S. support to the individual needs and challenges of each nation where the Emergency Plan is at work. Countries and communities are at different stages of HIV/AIDS response and have unique drivers of HIV, distinctive social and cultural patterns (particularly with regard to the status of women), and different political and economic conditions. Effective interventions must be informed by local circumstances and coordinated with local efforts. In April 2004, OGAC, working with UNAIDS, the World Bank, and the U.K. Department for International Development (DfID), organized and co-chaired a major international conference in Washington for major donors and national partners to consider and adopt key principles for supporting coordinated country-driven action against HIV/AIDS. These principles became known as the "Three Ones": - **one national plan, one national coordinating authority, and one national monitoring and evaluation system** in each of the host countries in which organizations work. Rather than mandating that all contributors do the same things in the same ways, the Three Ones facilitate complementary and efficient action in support of host nations.

dissemination and use)? Is the evaluation plan feasible, ethical, methodologically sound and engage national stakeholders? (5 points) "Applicants must define specific output and outcome indicators in the proposal, and must have realistic targets in line with the targets addressed in the Activities section of this announcement.

Understanding of the Problem (10 points):

Does the applicant demonstrate a clear and concise understanding of the current national HIV/AIDS response and the cultural and political context relevant to the programmatic areas targeted? (5 points) Does the applicant display an understanding of the Five-Year Strategy and goals of the President's Emergency Plan? (5 points) To what extent does the applicant justify the need for this program within the target community

Personnel (10 points):

Does the organization employ staff fluent in local languages who will work on this project? Are the staff roles clearly defined? As described, will the staff be sufficient to meet the goals of the proposed project? If not an indigenous organization, does the staff plan adequately involve local individuals and organizations? Are staff involved in this project qualified to perform the tasks described? Curricula vitae provided should include information that they are qualified in the following: management of HIV/AIDS prevention activities, especially confidential, voluntary counseling and testing; and the development of capacity building among and collaboration between Governmental and non-governmental partners.

Budget (SF 424A) and Budget Narrative (Reviewed, but not scored):

Is the itemized budget for conducting the project, along with justification, reasonable and consistent with stated objectives and planned program activities? Is the budget itemized, well justified and consistent with the goals of the President's Emergency Plan for AIDS Relief? If applicable, are there reasonable costs per client reached for both year one and later years of the project?

If the applicants requests indirect costs in the budget, a copy of the indirect cost rate agreement is required. If the indirect cost rate is a provisional rate, the agreement should be less than 12 months of age. The indirect cost rate agreement should be uploaded as a PDF file with “Other Attachment Forms” when submitting via [Www.grants.gov](http://www.grants.gov).

The indirect cost rate agreement does not apply to international applicants.

The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address:

<http://www.cdc.gov/od/pgo/funding/budgetguide.htm>.

Funding Preferences (30 points): In addition to direct consideration of findings from the Objective Review Panel, funding under this award will be subject to several preferences based on programmatic needs and in-country strategic priorities. **Applicants meeting the criteria set forth in these funding preferences will receive additional points beyond the possible total of 100 as follows:**

- Preference will be given to nationally or internationally recognized clinical laboratory societies and/or associations, or laboratory standards development organizations (25 points)
- Preference will be given to organizations with previous experience with assisting in the implementation of a step-wise approach to laboratory accreditation (5 points)

Review and Selection Process

Review

All eligible applications will be initially reviewed for completeness by the Procurement and Grants Office (PGO) staff. In addition, eligible applications will be jointly reviewed for responsiveness by HHS/CDC Division of Global HIV/AIDS and PGO. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified the application did not meet eligibility and/or published submission requirements.

An objective review panel will evaluate complete and responsive applications according to the criteria listed in Section V. Application Review Information, subsection entitled “Criteria.” The panel may include both U.S. Federal Government and non-U.S. Federal Government participants.

Selection

Applications will be funded in order by score and rank determined by the review panel unless funding preferences or other considerations stated in this FOA apply.

In addition, the following factors may affect the funding decision:

- Preference will be given to nationally or internationally recognized clinical laboratory societies and/or associations, or laboratory standards development organizations
- Preference will be given to organizations with previous experience with assisting in the implementation of a step-wise approach to laboratory accreditation

CDC will provide justification for any decision to fund out of rank order.

VI. AWARD ADMINISTRATION INFORMATION

Award Notices

Successful applicants will receive a Notice of Award (NoA) from the CDC Procurement and Grants Office. The NoA shall be the only binding, authorizing document between the recipient and CDC. The NoA will be signed by an authorized Grants Management Officer and e-mailed to the program director. A hard copy of the NoA will be mailed to the recipient fiscal officer identified in the application. Any application awarded in response to this FOA will be subject to the DUNS, CCR Registration and Transparency Act requirements.

Unsuccessful applicants will receive notification of the results of the application review by mail and/or e-mail.

Administrative and National Policy Requirements

Successful applicants must comply with the administrative requirements outlined in 45 Code of Federal Regulations (CFR) Part 74 or Part 92, as appropriate. The following additional requirements apply to this project:

- AR-4 HIV/AIDS Confidentiality Provisions
- AR-5 HIV Program Review Panel Requirements
- AR-6 Patient Care
- AR-8 Public Health System Reporting Requirements
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-12 Lobbying Restrictions
- AR-14 Accounting System Requirements
- AR-15 Proof of Non-Profit Status
- AR-21 Small, Minority, and Women-Owned Business
- AR-23 States and Faith-Based Organizations
- AR-24 Health Insurance Portability and Accountability Act Requirements
- AR-25 Release and Sharing of Data
- AR-26 National Historic Preservation Act of 1966
(Public Law 89-665, 80 Stat. 915)
- AR-27 Conference Disclaimer and Use of Logos
- AR-29 Compliance with E.O. 13513 Federal Leadership on Reducing Text Messaging While Driving, October 1, 2009.
- AR-30 Information Letter 10-006. – Compliance with Section 508 of the Rehabilitation Act of 1973
- AR-32 FY 2012 Enacted General Provisions

Additional information on the requirements can be found on the CDC Web site at the following Internet address: http://www.cdc.gov/od/pgo/funding/Addtl_Reqmnts.htm.

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address:

<http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>

Applicants must include an additional Certifications form from the PHS5161-1 application in the Grants.gov electronic submission only. Applicants should refer to the following Internet address:[http://www.cdc.gov/od/pgo/funding/PHS5161-1-](http://www.cdc.gov/od/pgo/funding/PHS5161-1-Certificates.pdf)

[Certificates.pdf](http://www.cdc.gov/od/pgo/funding/PHS5161-1-Certificates.pdf). Once the applicant has filled out the form, it should be attached to the Grants.gov submission as an Other Attachments Form. CDC Assurances and Certifications can be found on the CDC Web site at the following Internet address:

<http://www.cdc.gov/od/pgo/funding/grants/foamain.shtm>

Reporting

Federal Funding Accountability And Transparency Act Of 2006 (FFATA): Public Law 109-282, the Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single publicly accessible Web site, USASpending.gov. The Web site includes information on each Federal financial assistance award and contract over \$25,000, including such information as:

1. The name of the entity receiving the award
2. The amount of the award
3. Information on the award including transaction type, funding agency, etc.
4. The location of the entity receiving the award
5. A unique identifier of the entity receiving the award; and
6. Names and compensation of highly-compensated officers (as applicable)

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients: 1) information on executive compensation when not already reported through the Central

Contractor Registry; and 2) similar information on all sub-awards/subcontracts/consortiums over \$25,000.

For the full text of the requirements under the Federal Funding Accountability and Transparency Act of 2006, please review the following website:

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_bills&docid=f:s2590enr.txt.pdf

1. Interim Progress Report: Each funded applicant must provide CDC with an annual Interim Progress Report submitted via www.www.grants.gov. The Interim Progress Report is due no less than 90 days before the end of the budget period. The Interim Progress Report will serve as the non-competing continuation application, and must contain the following elements:

- a. Standard Form (“SF”) 424S Form
- b. SF 424A Budget Information-Non-Construction Programs
- c. Budget Narrative
- d. Indirect Cost Rate Agreement
- e. Project Narrative
- f. Activities and Objectives for the Current Budget Period
- g. Interim Federal Financial Report (SF 425) for the current budget period
- h. Proposed Activity and Objectives for the New Budget Period Program
- i. Budget
- j. Measures of Effectiveness, including progress against the numerical goals of the President's Emergency Plan for AIDS Relief for each country and HHS/CDC guidance
- k. Pipeline Analysis – Expenditures versus budget as identified in work plan, description of challenges, and explanation of unexpected pipeline (high or low).

Additionally, funded applicants must provide CDC with an original, plus two hard copies of the following reports:

2. Programmatic Impact Reporting and Monitoring:
 - A. The recipient is responsible for managing and monitoring each project, program, subaward, function or activity supported through this Agreement. Recipients must monitor subawards to ensure that subrecipients have met the programmatic impact requirements as set forth in the subrecipient's agreement.
 - B. The recipient must submit the original and two copies of annual and quarterly Performance reports. Annual reports must be due 90 calendar days after the award year and quarterly reports must be due 30 days after the reporting period. The final performance reports are due 90 calendar days after the expiration or termination of this Agreement.
 - C. Performance reports must generally contain, for each award, brief information on each of the following:
 - i. A comparison of actual accomplishments with the goals and objectives previously established for the period, including metrics outlined in the monitoring and evaluation plan (section on M&E), any findings of an external entity, or both. Whenever appropriate and the output of programs or projects can be readily quantified, such quantitative data must be included in the reports and be related to cost data for computation of unit costs. Also included should be a brief description of the methods used to assure and assess the quality of the quantitative data, including any remediation taken to improve findings of poor data quality.
 - ii. Reasons why established goals for the performance period were not met, if appropriate.
 - iii. Other pertinent information including, when appropriate, statutory or Congressional reporting requirements, analysis and explanation of cost overruns or high unit costs reported in financial reports.
 - iv. The recipient must immediately notify the awarding agency of developments that have a significant impact on the award-supported activities. Also, recipients must give notification immediately in the case of problems, delays, or adverse conditions which materially impair the ability to meet the

objectives of the award. This notification must include a statement of the action taken or contemplated, and any assistance needed to resolve the situation.

- v. The recipient is required to submit in a timely manner both semi-annual and annual program results for all relevant programmatic indicators in accordance with U.S. government guidance.
3. Financial Reporting Clause (Federal Financial Report – SF-425): The recipient must submit the *Federal Financial Report* (FFR) SF-425 on a quarterly and annual basis. Additional financial information may be requested as required and directed by HHS/CDC. The following reporting period end dates must be used for quarterly reports: March 31st, June 30th, September 30th, or December 31st. Quarterly FFR reports must be submitted no later than 30 days after the end of each reporting period. Annual reports must be submitted no later than 90 days after the end of each reporting period. A final *FFR* must be submitted no later than 90 days after the project or grant period end date at the completion of the award agreement.

Electronic versions of SF-425 can be downloaded into Adobe Acrobat and completed on-line by reviewing,

http://www.whitehouse.gov/sites/default/files/omb/grants/approved_forms/SF-425.pdf (reporting form) and
http://www.whitehouse.gov/sites/default/files/omb/grants/approved_forms/sf-425a.pdf (attachment).

Federal Funding Accountability and Trans[agency (FFATA)

- a. Reporting of first-tier subawards.
 - i. Applicability. Unless you are exempt as provided in paragraph D. of this award term, you must report each action that obligates \$25,000 or more in Federal funds that does not include Recovery funds (as defined in section 1512(a)(2) of the American Recovery

and Reinvestment Act of 2009, Pub. L. 111-5) for a subaward to an entity (see definitions in paragraph E. of this award term).

- ii. Where and when to report.
 - i. You must report each obligating action described in paragraph A.1. of this award term to <http://www.fsrs.gov>.
 - ii. For subaward information, report no later than the end of the month following the month in which the obligation was made. (For example, if the obligation was made on November 7, 2010, the obligation must be reported by no later than December 31, 2010).
- iii. What to report. You must report the information about each obligating action that the submission instructions posted at <http://www.fsrs.gov> specify.

b. Reporting Total Compensation of Recipient Executives.

- i. Applicability and what to report. You must report total compensation for each of your five most highly compensated executives for the preceding completed fiscal year, if –
 - 1. The total Federal funding authorized to date under this award is \$25,000 or more;
 - 2. In the preceding fiscal year, you received –
 - a. 80 percent or more of your annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and

1. In the subrecipient's preceding fiscal year, the subrecipient received-

- a. 80 percent or more of its annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and
- b. \$25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts), and Federal financial assistance subject to the Transparency Act (and subawards); and
- c. The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at <http://www.sec.gov/answers/execomp.htm>).

ii. Where and when to report. You must report subrecipient executive total compensation described in paragraph c.1. of this award term:

- 1. To the recipient.
- 2. By the end of the month following the month during which you make the subaward. For example, if a subaward is obligated on any date during the month of October of a given year (i.e., between October 1 and 31), you must

report any required compensation information of the subrecipient by November 30 of that year.

d. Exemptions

- i. If, in the previous tax year, you had gross income, from all sources, under \$300,000, you are exempt from the requirements to report:
- ii. Subawards, and
- iii. The total compensation of the five most highly compensated executives of any subrecipient.

e. Definitions. For purposes of this award term:

- i. Entity means all of the following, as defined in 2 CFR part 25:
 1. A Governmental organization, which is a State, local government, or Indian tribe;
 2. A foreign public entity;
 3. A domestic or foreign nonprofit organization;
 4. A domestic or foreign for-profit organization;
 5. A Federal agency, but only as a subrecipient under an award or subaward to a non-Federal entity.
- ii. Executive means officers, managing partners, or any other employees in management positions.
- iii. Subaward:
 1. This term means a legal instrument to provide support for the performance of any portion of the substantive project or program for which you received this award and that you as the recipient award to an eligible subrecipient.

2. The term does not include your procurement of property and services needed to carry out the project or program (for further explanation, see Sec. ____ .210 of the attachment to OMB Circular A-133, Audits of States, Local Governments, and Non-Profit Organizations).
3. A subaward may be provided through any legal agreement, including an agreement that you or a subrecipient considers a contract.

iv. Subrecipient means an entity that:

1. Receives a subaward from you (the recipient) under this award; and
2. Is accountable to you for the use of the Federal funds provided by the subaward.

v. Total compensation means the cash and noncash dollar value earned by the executive during the recipient's or subrecipient's preceding fiscal year and includes the following (for more information see 17 CFR 229.402(c)(2)):

1. Salary and bonus.
2. Awards of stock, stock options, and stock appreciation rights. Use the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year in accordance with the Statement of Financial Accounting Standards No. 123 (Revised 2004) (FAS 123R), Shared Based Payments.
3. Earnings for services under non-equity incentive plans. This does not include group life, health, hospitalization or medical reimbursement plans that do not discriminate in

favor of executives, and are available generally to all salaried employees.

4. Change in pension value. This is the change in present value of defined benefit and actuarial pension plans.
5. Above-market earnings on deferred compensation which is not tax-qualified.
6. Other compensation, if the aggregate value of all such other compensation (e.g. severance, termination payments, value of life insurance paid on behalf of the employee, perquisites or property) for the executive exceeds \$10,000.

4. Monitoring and Evaluation:

- A. The recipient must submit a monitoring and evaluation plan for approval, and carry out monitoring and evaluation activities in accordance with the approved monitoring and evaluation plan. HHS/CDC will review and approve the recipient's monitoring and evaluation plan to ensure that it is appropriate for the activities to be undertaken as part of the agreement, for compliance with the monitoring and evaluation guidance established by HHS/CDC or other guidance otherwise applicable to this Agreement.
- B. HHS/CDC or its designee will also undertake monitoring and evaluation of the defined activities within the agreement. The recipient must ensure reasonable access by HHS/CDC or its designee to all necessary sites, documentation, individuals and information to monitor, evaluate and verify the appropriate implementation the Activities and use of HHS/CDC funding under this Agreement, must require a provision to this effect in all sub-awards or contracts financed by funds under this Agreement. Where applicable, this includes support for, and response to, activities associated with the Site Monitoring System and implementation of Data and Service Quality Assessments.

5. Expenditure Analysis: Recipients of PEPFAR funds are required to report annually on program expenditures. Specifically, annual completion of PEPFAR Program Expenditures (Form DS-4213, approved by OMB 1405-0208, or the relevant OMB-approved format) will be required in conjunction with the PEPFAR Annual Progress Report at the completion of the USG fiscal year.

6. Audit, Books and Records Clause:
 - A. Reports and Information. The recipient must furnish HHS/CDC accounting records and such other information and reports relating to the Agreement as HHS/CDC may reasonably request.
 - B. The Recipient Agreement Books and Records. The recipient must maintain accounting books, records, documents and other evidence relating to the Agreement, adequate to show, without limitation, all costs incurred by the recipient, the receipt and use of goods and services acquired by the recipient, agreed-upon cost sharing requirements, the nature and extent of solicitations of prospective suppliers of goods and services acquired by the recipient, the basis of award of recipient contracts and orders, and the overall progress of the Agreement toward completion ("Agreement books and records"). The recipient must maintain Agreement books and records in accordance with generally accepted accounting principles prevailing in the United States, or at the recipient's option, with approval by HHS/CDC, other accounting principles, such as those (1) prescribed by the International Accounting Standards Committee (an affiliate of the International Federation of Accountants), or (2) prevailing in the country of the recipient. Agreement books and records must be maintained for at least three years after the date of last disbursement by HHS/CDC or for such longer period, if any, required to resolve any litigation, claims or audit findings.
 - C. Partner Government Audit. If \$300,000 or more of US Government funds are expended by the recipient in its fiscal year under the Agreement, the recipient must have financial audits made of the expenditures in accordance with the following terms, except as the Parties may otherwise agree in writing:
 - i. The recipient must use its Supreme Audit Institution (SAI), if the SAI is

approved by HHS/CDC, or select an independent auditor to perform the audit in accordance with the guidelines issued by HHS/CDC.

- ii. The audit must determine whether the receipt and expenditure of the funds provided under the Agreement are presented in accordance with generally accepted accounting principles agreed to in Section 2 above and whether the recipient has complied with the terms of the Agreement. Each audit must be submitted to HHS/CDC no later than nine months after the close of the recipient's year under audit.

D. Sub-recipient Audits. The recipient, except as the Parties may otherwise agree in writing, must ensure that "covered" sub-recipients, as defined below, are audited, and submit to HHS/CDC, no later than the end of the recipient's year under audit, in form and substance satisfactory to HHS/CDC, a plan for the audit of the expenditures of "covered" sub-recipients, as defined below, that receive funds under this Agreement pursuant to a direct contract or agreement with the recipient.

- i. "Covered" sub-recipient is one who expends \$300,000 or more in its fiscal year in "US Government awards" (i.e. as recipients of US Government cost reimbursable contracts, grants or cooperative agreements).
- ii. The plan must describe the methodology to be used by the recipient to satisfy its audit responsibilities for covered sub-recipients. The recipient may satisfy such audit responsibilities by relying on independent audits of the sub-recipients; expanding the scope of the independent financial audit of the recipient to encompass testing of sub-recipients' accounts; or a combination of these procedures.
- iii. The plan must identify the funds made available to sub-recipients that will be covered by audits conducted in accordance with audit provisions that satisfy the recipient's audit responsibilities.
- iv. The recipient must ensure that covered sub-recipients under direct contracts or agreements with the recipient take appropriate and timely corrective actions; consider whether sub-recipients' audits necessitate

adjustment of its own records; and require each such sub-recipient to permit independent auditors to have access to records and financial statements as necessary.

- E. Audit Reports. The recipient must furnish or cause to be furnished to HHS/CDC an audit report for each audit arranged for by the recipient in accordance with this Section within 30 days after completion of the audit and no later than nine months after the end of the period under audit.
- F. Cost of Audits. Subject to HHS/CDC approval in writing, costs of audits performed in accordance with the terms of this Section may be budgeted for, and charged to, the Agreement so long as such costs are allowable, allocable, and reasonable as defined in the Cost Allowability section of this Agreement.
- G. Audit by HHS/CDC. HHS/CDC retains the right to perform the audits required under this Agreement on behalf of the recipient conduct a financial review, or otherwise ensure accountability of organizations expending US Government funds regardless of the audit requirement.
- H. Opportunity to Audit or Inspect. The recipient must afford authorized representatives of HHS/CDC the opportunity at all reasonable times to audit or inspect activities financed under the Agreement, the utilization of goods and services financed by HHS/CDC, and books, records and other documents relating to the Agreement.
- I. Sub-recipient Books and Records. The recipient will incorporate paragraphs (1), (2), (4), (5), (6), (7) and (8) of this provision into all sub-agreements with non-U.S. organizations which meet the \$300,000 threshold of paragraph (3) of this provision. Sub-agreements with non-U.S. organizations, which do not meet the \$300,000 threshold, must, at a minimum, incorporate paragraphs (7) and (8) of this provision. Sub-agreements with U.S. organizations must state that the U.S. organization is subject to the audit requirements contained in OMB Circular A-133.

7. Reporting of Foreign Taxes

a. Valued Added Tax (VAT) and Customs Duties – Customs and import duties, consular fees, customs surtax, valued added taxes, and other related charges are hereby authorized as an allowable cost for costs incurred from the effective date of September 13, 2012 until September 12, 2013. This waiver does not apply to countries where a bilateral agreement (or similar legal document) is already in place providing applicable tax exemptions and it is not applicable to Ministries of Health.

b. The U.S. Department of State requires that agencies collect and report information on the amount of taxes assessed, reimbursed and not reimbursed by a foreign government against commodities financed with funds appropriated by the U.S. Department of State, Foreign Operations and Related Programs Appropriations Act (SFOAA) (“United States foreign assistance funds”). Outlined below are the specifics of this requirement:

- a) Annual Report. The grantee must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 – September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the grantee did not pay any taxes during the reporting period.]
- b) Quarterly Report. The grantee must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.
- c) Terms: For purposes of this clause:
 - i. “Commodity” means any material, article, supplies, goods, or equipment;

- ii. “Foreign government” includes any foreign government entity;
 - iii. “Foreign taxes” means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.
 - d) Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in which you are carrying out the activities associated with this cooperative agreement. In countries where there is no CDC office, send reports to VATreporting@cdc.gov.
 - e) Contents of Reports. The reports must contain:
 - i. grantee name;
 - ii. contact name with phone, fax, and e-mail;
 - iii. agreement number(s) if reporting by agreement(s);
 - iv. reporting period;
 - v. amount of foreign taxes assessed by each foreign government;
 - vi. amount of any foreign taxes reimbursed by each foreign government;
 - vii. amount of foreign taxes unreimbursed by each foreign government.
 - f) Subagreements. The grantee must include this reporting requirement in all applicable subgrants and other subagreements.
8. Final performance and Federal Financial Reports - Due no more than 90 days after the end of the project period.

These reports must be submitted to the attention of the Grants Management Specialist listed in the Section VIII below entitled “Agency Contacts”.

For additional information on reporting requirements, visit the CDC website at: http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm.

Human Subjects Restrictions

Data collection protocols required for release of human subjects funding restrictions must be submitted to the DGHA Science Office within 6 months of notification of such restrictions, but no later than the end of the first budget year. Requests for exceptions to these deadlines will need to be submitted in writing to the Grants Management Officer.

All protocol approvals should be obtained no later than the end of the subsequent budget period after the award or continuation has been made, provided that the Grantee has not been granted an exception to the deadlines specified above.

VII. AGENCY CONTACTS

CDC encourages inquiries concerning this announcement.

For programmatic technical assistance, contact:

David Cross, Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS: G-45
Atlanta, GA 30333
Telephone: 404-718-1004
E-mail: gcross@cdc.gov

For financial, grants management, or budget assistance, contact:

Kyle Jessop, Grants Management Specialist
Department of Health and Human Services
CDC Procurement and Grants Office
2920 Brandywine Road, MS: K-75
Atlanta, GA 30341
Telephone: 770-488-3160
E-mail: kjessop@cdc.gov

For assistance with **submission difficulties**, contact:

Www.grants.gov Contact Center Phone: 1-800-518-4726.

Hours of Operation: 24 hours a day, 7 days a week. Closed on Federal holidays.

For **submission** questions, contact:

Technical Information Management Section

Department of Health and Human Services

CDC Procurement and Grants Office

2920 Brandywine Road, MS E-14

Atlanta, GA 30341

Telephone: 770-488-2700

Email: pgotim@cdc.gov

CDC Telecommunications for the hearing impaired or disabled is available at: TTY 770-488-2783.

VIII. Other Information

Amendments, Questions and Answers (Q&As)

Applicants must submit their Q&As, if any, to the Project Officer listed under the Agency Contacts Section of this announcement no later than 15 days after the publication date in www.grants.gov. All amendment and Q&As will be published in www.grants.gov following the approval of CDC.

For additional information on reporting requirements, visit the CDC website at:

http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm.

Other CDC funding opportunity announcements can be found on Grants.gov website, at the following internet address: <http://www.grants.gov>.