

**AMENDMENT I (02/16/2012):**

- i) Page 14 - Deleted \$650,000 from “approximate average year award” and “approximate current fiscal year funding” and replaced with \$6,000,000.*
- ii) Page 14 – Deleted \$87,000,000 from “approximate total project period funding” and replaced with \$91,000,000.*
- iii) Page 15 - Deleted \$2,000,000 from “ceiling of individual award range” and replaced with \$6,000,000*

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**PART 1. OVERVIEW INFORMATION**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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

**Funding Opportunity Title:** Development of a Laboratory Network and Society to Implement a Quality Systems Improvement Program Toward Accreditation and Laboratory Management under the President’s Emergency Plan for AIDS Relief (PEPFAR)

**Announcement Type:** New – Type 1

**Agency Funding Opportunity Number:** CDC-RFA-GH12-1201

**Catalog of Federal Domestic Assistance Number:** 93.067

**Key Dates:**

Application Deadline Date: April 09, 2012 on Grants.gov, 11:59pm Eastern Standard Time.

Measurable objectives of the program will be in alignment with one (or more) of the following performance goal(s):

1. Advancing development of laboratory policies in PEPFAR-supported countries
  - a. Coordinate with Ministries of Health, partner Ministries, and professional laboratory associations to develop evidence-based laboratory policies for two countries by Year 3, four additional countries by Year 4, and six additional countries by Year 5.
2. Advocating for resources to improve laboratories throughout PEPFAR-supported countries
  - a. Establish MOUs with at least two relevant partners that will focus on quality laboratory services improvement by Year 2.
  - b. Develop and implement an African continent-wide strategic communication plan with key stakeholders such as media, patient and civil societies, to promote community participation and awareness by Year 3. If given the opportunity and funding by countries outside Africa, these strategic communication plans should be developed within one year after receiving such funding.
  - c. Identify at least three additional incremental revenue streams to allow the organization to be financially sound and sustainable to support its secretariat and its activities, including financial inflows from individual, institutional and corporate memberships by Year 2 and become fully sustainable by end of project period.
3. Expanding WHO AFRO Stepwise Laboratory Improvement Process Toward Accreditation (SLIPTA) program in multiple PEPFAR-supported countries

- a. Grantee will likely operate as an implementing partner of World Health Organization Regional Office for Africa (WHO AFRO) through a Memorandum of Understanding (MOU). This MOU with WHO AFRO should be established in year 1. In this MOU, the role of the Grantee as the implementer of the WHO AFRO Stepwise Laboratory Improvement Process towards Accreditation (SLIPTA) process shall be clearly articulated. The Grantee should prioritize assessment of current status of the implementation of the accreditation preparedness process in countries, develop a framework, standardize and finalize the checklist for the accreditation process.
  - b. The Grantee should establish a technical advisory group in Year 1 with well defined terms of reference and its members can be drawn from existing organizations like South African National Accreditation System (SANAS), South African Development Community Accreditation Service (SADCAS) and Kenyan Accreditation Service (KENAS). WHO is fully committed to the WHO AFRO SLIPTA process and as such shall remain responsible for the WHO AFRO laboratory quality systems improvement stepwise approach toward accreditation process.
  - c. Beginning in Year 2, the Grantee should provide accreditation-related presentations to Government policy makers on the importance of Quality Management Systems. By Year 2, Grantee should partner with existing External Quality Assessment programs to encourage them to keep EQA charges at modest levels. By Year 2, the grantee should engage partners willing to support the accreditation program.
4. Improving in-service laboratory science education by enhancing the quality of training and increasing access by laboratory professionals
    - a. A comprehensive review of existing regulatory bodies, licensing boards, and medical laboratory science programs should be accomplished by Year 2 and would involve establishing strong partnership with Governments by working with the local societies and regulating bodies, drawing on and reviewing strategic plans, and assessing and taking inventory of regulating bodies, current scope of practice, and medical laboratory science curricula and

training programs. If given the opportunity and funding by countries outside Africa, similar reviews should be conducted in these countries/regions within one year of receiving such funding.

- b. A personnel qualifications examination committee should be established by Year 2 and focus on whether passing such an examination would enable an individual to work in any PEPFAR-supported laboratory or whether such a passport approach would encourage resource loss as individuals find employment in the higher paying labs around the continent.
  - c. A guideline document for overseeing and evaluating training and certification of laboratory personnel should be available by Year 3 and review and harmonize Modular in-service and certificate programs, and the issue of transitioning to on-the-job mentoring as a way to upgrade in-service training.
5. Enhancing the interaction between laboratory professionals and clinician through continuing medical education
- a. Improve the communication between clinicians and laboratory professionals by developing Multi-disciplined training curriculum which, ensures the laboratory component forms a prominent part of undergraduate medical training programs and vice-versa, and encourages joint activities in healthcare practice. This training curriculum should be developed and implemented in at least one undergraduate medical training program by Year 2.
  - b. Develop and implement a laboratory error monitoring system focused on improving the quality of diagnosis and ongoing patient care essential to laboratory services in at least 10 laboratories by Year 3.
  - c. Promote standards of quality and appropriate utilization of laboratory sciences for the improvement of health and well-being of communities in Africa and other PEPFAR-supported countries by ensuring at least 100 laboratories are accredited by international standards by Year 4.
  - d. Improve communication and alignment of expectations (e.g., error rates, turnaround times, etc.) between clinicians and laboratory professionals by implementation of a society whose membership includes both laboratorians and clinicians by Year 5

6. Increasing technical capacity and developing platforms for dissemination and communication of laboratory science research
  - a. Promote all types of research and create a directory of research activities and contacts by Year 2.
  - b. Guarantee major communications are translated into English, French, and Portuguese by Year 2.
  - c. Collaborate with key stakeholders and other partners to host a workshop which outlines the broad laboratory research agenda for PEPFAR-supported countries and ensure the appropriate use of data to improve policies, patient care, and surveillance by Year 3.
  - d. Encourage countries to include research and dissemination plans in their laboratory strategic plans. Ensure that at least 5 countries have these plans in place by Year 5.
  - e. Develop communication vehicles, including a journal, professional magazine, internet groups, and local and international meetings. Partner with local, national, and international media to report research findings by Year 5.
  - f. Develop and publish, both online and in print, a scientific research journal by Year 2.
7. Improving access to high quality technical assistance consultants and materials
  - a. Develop a list of consultants and experts that includes their qualifications, areas of expertise, and, if possible, prior performance evaluations by Year 2.
  - b. Develop a monitoring and evaluation system for TA providers, which would include an assessment of the providers' efforts to permanently transfer the technology to the host country by Year 5.
  - c. Work with partners to perform country or regional needs assessment for TA and develop in-country and/or regional TA coordination mechanism in alignment with country's Laboratory Strategic Plan for two countries by Year 3, four additional countries by Year 4, and six additional countries by Year 5.
8. Strengthening public health network capacity
  - a. Assist existing country-level associations to work together and to establish a country-level steering committee (forum) or facilitate establishment of an

association(s) where none exist, for two countries by Year 3, four additional countries by Year 4, and six additional countries by Year 5.

- b. Establish a web portal to support laboratory strengthening initiatives to facilitate group to group and individual communications to support network activities and intra-network collaboration and strengthening and develop database of existing professional associations, information resources, reference documents, key meetings and important trainings and tools by Year 3. The portal should also serve as a tool request clearing house and support development of training templates.
- c. Establish task force to follow up on recommendations and initiate communications with key stakeholders and emphasize successes in strengthening national laboratory systems among national public health laboratories and professional laboratory medical associations through WHO-AFRO Region by Year 2.

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).

#### **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.
- 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.

The purpose of this program is to develop laboratory systems capacity and sustainability, utilizing evidenced-based quality control measures focusing on the following eight

strategic areas: Policy; Advocacy, Communication and Resource Mobilization; Laboratory Accreditation and Quality Management Systems; Laboratory Workforce Development; Laboratory-Clinical Interface; Research Capacity and Publication; Technical Assistance; and Laboratory Strategy and Networks.

## **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 PEPFAR supported countries and must also coordinate with other organizations 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 *PEPFAR supported countries*. The grantee will produce an annual operational plan, which the U.S. Government Emergency Plan team on the ground in

these countries will review as part of the annual Emergency Plan review-and-approval process managed by the Office of the U.S. Global AIDS Coordinator.

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, 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 for this program are as follows:

1. Policy:
  - a. Contribute to the development of laboratory policy statements by drafting model or template policies that can be adapted by countries as they endeavor to elaborate their own National Laboratory Policy.
2. Advocacy, Communication and Resource Mobilization. Improve quality laboratory services by:
  - a. Establishing MOUs with relevant partners.
  - b. Developing and implementing a strategic communication plan.
  - c. Identifying sustainable revenue streams.
3. Laboratory Accreditation and Quality Management Systems:
  - a. Provide support to WHO and other partners to collaborate in establishing quality management system processes and a step-wise accreditation scheme.
  - b. Address any concerns regarding the stepwise accreditation preparedness process and successful participation in external quality assurance schemes (EQAs), including how to deal with situations in which a laboratory repeatedly fails to meet the requirements of EQAs and/or the accreditation process.

- c. Develop a process whereby the accreditation process can become self-sustaining.
- 4. Laboratory Workforce Development:
  - a. Conduct a comprehensive review of the existing regulating bodies, licensing boards, and medical laboratory science programs in African countries, and if given the opportunity other PEPFAR-supported countries. Develop a curriculum guideline document for national regulatory bodies that takes into account the strengths of these programs as well as their unique contextual concerns.
  - b. An independently functioning ASLM examination committee is needed to develop an exam that scores individuals on their level of competency. Earning a diploma does not guarantee competency.
  - c. Develop a guideline document for overseeing and evaluating in-service training and certification of ongoing career development.
- 5. Laboratory-Clinical interface:
  - a. Ensure that Continuing Medical Laboratory Education (CMLE) is accessible to PEPFAR-supported healthcare community.
  - b. Improve utilization of laboratory services by bridging the knowledge gap.
  - c. Create a cadre of authoritative laboratory scientists.
- 6. Research Capacity and Publication:
  - a. Work with the Laboratory Workforce Development sections of major universities to strengthen scientific training for laboratorians as part of the standard curriculum.
  - b. Provide technical assistance for grant writing to enable African partners and indigenous partners in other PEPFAR-supported countries to compete for funding opportunities related to laboratory medicine.
  - c. Provide technical assistance for manuscript writing. Increase the quality and quantity of basic and operational research published by authors from PEPFAR-supported countries.

- d. Provide technical assistance for protocol writing to increase the quality of scientific protocols developed by African partners, and other indigenous partners in PEPFAR-supported countries.
  - e. Establish and publish a scientific research journal.
7. Technical Assistance:
- a. Provide technical assistance for lab strengthening and capacity building per national laboratory strategic plan and develop technical assistance request tools with an inventory of partners and/or countries with the technical expertise primarily from within PEPFAR-supported countries.
  - b. Work with international institutions, in-country lab professional organizations, or other agencies to develop in-country and/or regional TA coordination mechanisms.
  - c. Technical assistance will include, but not be limited to: biosafety, laboratory information systems, quality assurance, and laboratory services.
8. Laboratory Strategy and Networks:
- a. Establish Forum Steering Committee to unite grantee's activities with existing laboratory networks in Africa and include nominated members from existing laboratory professional associations and public health laboratory networks.
  - b. Support public health laboratory networks strengthen or establish multi-function website/workspace functionality and connectivity for communication among national public health labs with MOH buy-in and international institution advocacy and increase awareness of existing associations within network.
  - c. Engage Ministers of Health and promote country networking of stakeholder ministries, e.g., agriculture, education.

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

**CDC Activities:**

The selected applicant of this funding competition must comply with all HHS/CDC management requirements for meeting participation and progress and financial reporting for this cooperative agreement (See HHS/CDC Activities and Reporting sections below for details), and comply with all policy directives established by the Office of the U.S. Global AIDS Coordinator.

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 for a briefing on applicable U.S. Government, HHS/CDC, and President's Emergency Plan for AIDS Relief (PEPFAR) expectations, regulations and key management requirements, as well as report formats and contents. The orientation could include meetings with staff from WHO AFRO.
2. Review and approve the grantee's annual work plan and detailed budget, as part of the PEPFAR COP review and approval process, managed by the OGAC.
3. Review and approve the grantee's monitoring and evaluation plan for laboratories, including for compliance with the strategic information guidance established by the OGAC.
4. Conduct conference calls on a regular basis with the grantee to assess expenditures in relation to approved work plan and modify plans as necessary.
5. Conduct a site visit to the corporate office of the grantee on an annual basis for the purpose of reviewing the annual progress report for each U.S. Government Fiscal Year, and reviewing annual work plans.
6. 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 laboratory quality management systems, strategic information, and project management.
7. 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 for laboratory capacity development and

sustainability, data management and analysis, laboratory quality assurance, the presentation and possibly publication of program results and findings, and the management and tracking of finances.

8. Provide consultation and scientific and technical assistance based on appropriate HHS/CDC and OGAC documents to promote the use of best practices known at the time.
9. Assist and mentor the recipient in developing and implementing laboratory quality management systems and procedures.
10. Facilitate in-country planning and review meetings for technical assistance activities.
11. Provide technical oversight for all activities under this award.
12. Provide ethical reviews, as necessary, for evaluation activities, including from HHS/CDC headquarters
13. Supply the awardee with protocols for related evaluations.

## **II. AWARD INFORMATION**

**Type of Award:** Cooperative Agreement.

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

**Fiscal Year Funds:** 2012

**Approximate Current Fiscal Year Funding:** \$ 6,000,000

**Approximate Total Project Period Funding:** \$ 91,000,000 (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.)

**Approximate Number of Awards:** 1

**Approximate Average Award:** \$ 6,000,000

**Floor of Individual Award Range:** none

**Budget Year 2 Floor amount:** none

**Budget Year 3 Floor amount:** none

**Budget Year 4 Floor amount:** none

**Budget Year 5 Floor amount:** none

**Ceiling of Individual Award Range: \$6,000,000** (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.)

**Budget Year 2 Ceiling amount:** \$10,000,000

**Budget Year 3 Ceiling amount:** \$20,000,000

**Budget Year 4 Ceiling amount:** \$25,000,000

**Budget Year 5 Ceiling amount:** \$30,000,000

**Anticipated Award Date:** September 2012

**Budget Period Length:** 12 months

**Project Period Length:** 5 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. Ceiling amounts in budget years 02-05 include additional funds for anticipated scale-up of existing activities.

*Note: Applicants should only apply for the first budget period funding taking into consideration the first budget period floor and the first budget period ceiling.*

### **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
- Other (specify)

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](http://www.grants.gov).

PEPFAR Local Partner definition:

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 within that country:

(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 least 51% for FY 2009-10; 66% for FY 2011-12; and 75% for FY 2013 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 51% for FY 2009-10; 66% for FY 2011-12; and 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 51% for FY 2009-10; 66% for FY 2011-12; and 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 51% for FY 2009-10; 66% for FY 2011-12; and 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.

Host 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 board may rest 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 Registrations**

Registering your organization through [www.Grants.gov](http://www.Grants.gov), the official agency-wide 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](http://www.Grants.gov). Please visit [www.Grants.gov](http://www.Grants.gov) at least 30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The “one-time” registration process will take three to five days to complete. However, the Grants.gov registration process also requires that you register your organization with the Central Contractor Registry (CCR) and DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) which will require up to at least 4 weeks to complete registration in its entirety. The CCR registration can require an additional two weeks to complete. You are required to maintain a current registration in CCR. CCR registration must be renewed annually.

### **Central Contractor Registration and Universal Identifier Requirements**

Foreign entities only: Prior to registering for CCR, please follow the Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code:  
[http://www.dlis.dla.mil/Forms/Form\\_AC135.asp](http://www.dlis.dla.mil/Forms/Form_AC135.asp).

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 grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an

AOR should complete the **US D&B D-U-N-S Number Request Form** or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number.

Additionally, all applicant organizations must register in the Central Contractor Registry (CCR) and maintain the registration 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. CCR 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 a recipient. Additional information about registration procedures may be found at the CCR internet site at [www.ccr.gov](http://www.ccr.gov).

If an award is granted, the grantee organization must notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the grantee organization.

### **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 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 80 pages, 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.

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.

#### **IV. Application and Submission Information**

##### **Submission Dates and Times**

This announcement is the definitive guide on LOI and application content, submission, and deadline. 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:** April 09, 2012 on Grants.gov, 11:59pm Eastern Standard Time. ON GRANTS.GOV, 11:59pm Eastern Standard Time.

Applicants must download the SF424 application package associated with this funding opportunity from [Grants.gov](http://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](mailto: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 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](mailto: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 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 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 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 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.

**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 project budget justification must be included as a separate attachment of the application, not to be counted in the narrative page limit.

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 80 pages and can only contain information related to the following:**

- *Curricula vitae* of current key staff who will work on the activity, including the Board Director, the Chief Executive Officer, and the Chief Financial Officer
- *Job descriptions* of proposed key positions to be created for the activity, including the Board Director, the Chief Executive Officer, the Chief Financial Officer, the Communication Officer, and the Deputy of Administration
- *Applicant's Corporate Capability Statement;*
- *Letters of Support* (5 letters maximum): Ministries of Health (at least 3 countries), WHO AFRO, professional laboratory boards and/or associations, and clinician boards and/or associations
- *Evidence of Legal Organizational Structure Organizational Chart delineating roles and responsibilities; 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.

Additional information submitted via 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.
- 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.

- Needle Exchange – No funds appropriated under this Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.
- 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. 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.
- Foreign grantees are subject to audit requirements specified in 45 CFR 74.26(d). A non-Federal audit is required, if during the grantees fiscal year, the grantee expended a total of \$500,000.00 or more under one or more HHS awards (as a

direct grantee and/or as a sub-grantee). The grantee either may have (1) A financial related audit (as defined in the Government Auditing Standards, GPO stock #020-000-00-265-4) of a particular award in accordance with Government Auditing Standards, in those case where the grantee receives awards under only one HHS program; or, if awards are received under multiple HHS programs, a financial related audit of all HHS awards in accordance with Government Auditing Standards; or (2) An audit that meets the requirements contained in OMB Circular A-133.

- A fiscal Grantee Capability Assessment may be required, prior to or post award, in order to review the applicant's business management and fiscal capabilities regarding the handling of U.S. Federal funds.
- ADS 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.

### **The 8% Rule**

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) 2012, the limit is no more than 8 percent of the country's FY 2012**

**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 RFA/APS/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 RFA/APS/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 RFA/APS/FOA.** For example, the proposal should state that the applicant has \$\_\_\_\_\_ in FY 2012 grants and cooperative agreements (for as many fiscal years as applicable) in a PEPFAR supported country (be specific). For additional information concerning this RFA/APS/FOA, please contact the Grants Officer for this RFA/APS/FOA.

### **Prostitution and Related Activities**

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.

Any entity that receives, directly or indirectly, U.S. Government funds in connection with this document (“recipient”) cannot use such U.S. Government funds 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. A recipient that is otherwise eligible to receive funds in connection with this document to prevent, treat, or monitor HIV/AIDS shall not be required to endorse or utilize a multisectoral approach to combating HIV/AIDS, or to endorse, utilize, or participate in a prevention method or treatment program to which the recipient has a religious or moral objection. Any information provided by recipients about the use of condoms as part of projects or activities that are funded in connection with this document shall be medically accurate and shall include the public health benefits and failure rates of such use.

In addition, any recipient must have a policy explicitly opposing prostitution and sex trafficking. The preceding sentence shall not apply to any “exempt organizations” (defined as the Global Fund to Fight AIDS, Tuberculosis and Malaria, the World Health Organization and its six Regional Offices, the International AIDS Vaccine Initiative or to any United Nations agency).

The following definition applies for purposes of this clause:

- Sex trafficking means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act. 22 U.S.C. § 7102(9).

All recipients must insert provisions implementing the applicable parts of this section, “Prostitution and Related Activities,” in all subagreements under this award. These provisions must be express terms and conditions of the subagreement, must acknowledge that compliance with this section, “Prostitution and Related Activities,” is a prerequisite to receipt and expenditure of U.S. government funds in connection with this document, and must acknowledge that any violation of the provisions shall be grounds for unilateral termination of the agreement prior to the end of its term. Recipients must agree that HHS may, at any reasonable time, inspect the documents and materials maintained or prepared by the recipient in the usual course of its operations that relate to the organization’s compliance with this section, “Prostitution and Related Activities.”

All prime recipients that receive U.S. Government funds (“prime recipients”) in connection with this document must certify compliance prior to actual receipt of such funds in a written statement that makes reference to this document (e.g., “[Prime recipient's name] certifies compliance with the section, ‘Prostitution and Related Activities.’”) addressed to the agency’s grants officer. Such certifications by prime recipients are prerequisites to the payment of any U.S. Government funds in connection with this document.

Recipients' compliance with this section, "Prostitution and Related Activities," is an express term and condition of receiving U.S. Government funds in connection with this document, and any violation of it shall be grounds for unilateral termination by HHS of the agreement with HHS in connection with this document prior to the end of its term. The recipient shall refund to HHS the entire amount furnished in connection with this document in the event HHS determines the recipient has not complied with this section, "Prostitution and Related Activities."

*Any enforcement of this clause is subject to Alliance for Open Society International v. USAID, 05 Civ. 8209 (S.D.N.Y., orders filed on June 29, 2006 and August 8, 2008) (orders gaining preliminary injunction) for the term of the Orders.*

*The List of the members of GHC and InterAction is found at:*

*[http://www.usaid.gov/business/business\\_opportunities/cib/pdf/GlobalHealthMemberlist.pdf](http://www.usaid.gov/business/business_opportunities/cib/pdf/GlobalHealthMemberlist.pdf)*

## **Additional Submission Requirements**

### **Electronic Submission**

Submit the application electronically by using the forms and instructions posted for this funding opportunity on [www.Grants.gov](http://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 7:30am -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](http://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](http://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 Grants.gov on the deadline date. The application package can be downloaded from [www.Grants.gov](http://www.Grants.gov). Applicants can complete the application package off-line, and then upload and submit the application via the Grants.gov Web site. The applicant must submit all application attachments using a PDF file format when submitting via Grants.gov. Directions for creating PDF files can be found on the Grants.gov Web site. 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 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 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](mailto:support@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](http://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@grants.gov](mailto:support@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 GMO/GMS [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, (b) describe the difficulties that prevented electronic submission and the efforts taken with the Grants.gov Support Center (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.***

***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.***

## **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 GH12-1201. 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 PEPFAR-supported countries 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) Does the organization have the ability to target audiences that frequently fall outside the reach of the traditional media, and in local languages? To what extent does the applicant provide letters of support? (5 points)*

**Technical and Programmatic Approach (20 points):**

*Does the application include an overall design strategy, including measurable 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, realistic, achievable, measurable and culturally appropriate to achieve the goals of the President's Emergency Plan? (5 points) Does the application include reasonable estimates of outcome targets? (For example, the numbers of laboratories to be supported.) To what extent does the applicant propose to work with other organizations? (5 points) The reviewers will assess the feasibility of the applicant's plan to meet the target goals, 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 (15 points):**

*Does the applicant have a proven track record of building the capacity of indigenous organizations and individuals? 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 organizations and of target beneficiaries to respond to the epidemic? (10 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 "3,12,12<sup>1</sup>" targets of the President's Emergency Plan, and b) (if not a local indigenous*

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<sup>1</sup> 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

*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? (5 points)*

**Monitoring and Evaluation (15 points):**

*Does the applicant demonstrate the local experience and capability to implement rigorous monitoring and evaluation of the project? (5 points) Does the applicant describe a system for reviewing and adjusting program activities based on monitoring information obtained by using innovative, participatory methods and standard approaches? Does the 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? 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? (10 points) Applicants must define specific output and outcome indicators must be defined 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? To what extent does the applicant justify the need for this program within the target community (5 points)?*

**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*

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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.

*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: laboratory management, laboratory systems development, laboratory network development, laboratory accreditation, external quality assurance of laboratories, and the development of capacity building among and collaboration between Governmental and non-governmental partners.(10 points)*

**Administration and Management (10 points):**

*Is the Board of Directors of the applicant representative of the following: public health research institutions; national laboratory institutes; international laboratory technical agencies, academic institutions, and the private sector? Does the applicant provide a clear plan for the administration and management of the proposed activities, and to manage the resources of the program, prepare reports, monitor and evaluate activities, audit expenditures and produce collect and analyze performance data? Is the management structure for the project sufficient to ensure speedy implementation of the project? If appropriate, does the applicant have a proven track record in managing large laboratory budgets; running transparent and competitive procurement processes; supervising consultants and contractors; using subgrants or other systems of sharing resources with community based organizations, faith based organizations or smaller non-governmental organizations; and providing technical assistance in laboratory management? (10 points)The grantee must demonstrate an ability to submit quarterly reports in a timely manner to the HHS/CDC office.*

**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 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):**

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.

- Preference to local and indigenous African organizations. See lines 474 – 513 for local partner definition. (20 points)
- Preference to organizations that focus on local indigenous partners, such as MOHs, professional laboratory/clinician organizations based in Africa (5 points)
- Preference to organizations whose primary focus relates to highlighting and improving Laboratory Medicine in PEPFAR-supported countries (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 the FOA apply. In addition, the following factors may affect the funding decision: preference to local and indigenous African organizations, preference to organizations that focus on local indigenous partners, such as MOHs, professional laboratory/clinician organizations based in Africa, and preference to organizations whose primary focus relates to highlighting and improving Laboratory Medicine in PEPFAR-supported countries.

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-16 Security Clearance Requirement
- 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

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](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>

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

Each funded applicant must provide CDC with an annual Interim Progress Report submitted via [www.grants.gov](http://www.grants.gov):

1. 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 Financial Status Report (SF-269) 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 in the participating PEPFAR countries; and
  - 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. Quarterly Progress Reports – In addition to the Interim Progress Report and the Final performance and Financial Status Reports, quarterly reports are required 90 days after submission of the Final Performance and Financial Status Reports, and, 90 days after submission of the Interim Progress Report. Reports shall include:

- a. Activities and Objectives for the current quarter;
- b. Financial progress for the current quarter; and
3. Financial Status Report (SF 269) - An annual progress report, due no more than 90 days after the end of the budget period.
4. Final performance and Financial Status Reports - Due no more than 90 days after the end of the project period.

\*Disclaimer: As of February 1, 2011, current Financial Status Report (FSR) requirements will be obsolete. Existing practices will be updated to reflect changes for implementation of the new Federal Financial Reporting (FFR) requirements.

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

### **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

Centers for Disease Control and Prevention  
1600 Clifton Road, N.E.  
Mailstop G-45  
Atlanta, GA  
Telephone: 404-718-1004  
E-mail: GCROSS@cdc.gov

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

Arthur Lusby, Grants Management Specialist  
Department of Health and Human Services  
CDC Procurement and Grants Office  
2920 Brandywine Road, MS: K-75  
Atlanta, GA 30341  
Telephone: 770-488-2865  
E-mail: ALusby@cdc.gov

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

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](mailto: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](http://www.grants.gov). All amendment and Q&As will be published in [grants.gov](http://grants.gov) following the approval of CDC. No amendments or Q&As will be accepted past the due date.

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

[http://www.cdc.gov/od/pgo/funding/grants/additional\\_req.shtm](http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm).

Other CDC funding opportunity announcements can be found on Grants.gov Web site, Internet address: <http://www.grants.gov>.