This is an amendment to Funding Opportunity Announcement CDC-RFA-PS10-10119

Pages 4-5: 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.

Page 12 and 39: Anticipated Award Date: **September 30, 2010**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Disease Control and Prevention (CDC)

Quality Management Systems for HIV Rapid Testing, Biological Safety Cabinet Certification Training, and Laboratory Systems in Various African Countries under the President's Emergency Plan for AIDS Relief (PEPFAR)

I. Authorization of Intent

Announcement Type: New

Funding Opportunity Number: CDC-RFA-PS10-10119

Catalog of Federal Domestic Assistance Number: *93.067*

Health Impact Number: 9380

Application Deadline: March 15, 2010

Key Dates:

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 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.

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 initial five year period, 2003 - 2008 is available at the following Internet address: http://www.pepfar.gov.

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.

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 provide training for laboratory workers in the areas of Laboratory Management and Policy, Quality Management Systems,WHO biosafety, and certification of biological safety cabinets. Further, the purpose of this program will be to provide support for the implementation of Laboratory Information Systems in PEPFAR-supported countries.

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

1. Assist in the development of indigenous capacity to meet the PEPFAR II goal of 140,000 trained healthcare workers, in particular:
    a. Personnel having Masters level training in Laboratory Management and Policy (5 persons by beginning of year 3; 5 additional persons for each subsequent year of the agreement (20 total by end of award);
    b. Personnel well versed in WHO biosafety practices(10 persons by beginning of year 2; 10 additional persons for each subsequent year of the agreement (50 total by end of award); and
    c. Personnel capable of certifying biological safety cabinets (5 persons by beginning of year 2, 10 additional persons for each subsequent year of the agreement (45 total by end of award).
2. Implementation of easy-to-use Laboratory Information Systems (LIS):

a. Implementation of LIS in at least three laboratories in year one; and
b. Five additional laboratories in each subsequent year of the agreement (23 total by end of award).

This announcement is intended for non-research activities supported by the Centers for Disease Control and Prevention within HHS (HHS/CDC)**.** If an applicant proposes research activities, HHS/CDC will not review the application. For the definition of "research", please see the HHS/CDC Web site at the following Internet address: http://www.cdc.gov/od/science/regs/hrpp/researchdefinition.htm

II Program Implementation:

Activities:

Partners receiving HHS/CDC funding must place a clear emphasis on developing local indigenous capacity to deliver HIV/AIDS related services in various PEPFAR-supported countries' population and must also coordinate with activities supported by indigenous, international or USG agencies to avoid duplication. Partners receiving HHS/CDC funding must collaborate across program areas whenever appropriate or necessary to improve service delivery.

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

The recipient will implement activities both directly and, where applicable, through sub-grantees; the recipient 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 recipient 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 various PEPFAR-supported countries. The grantee will produce an annual operational plan, which the U.S. Government Emergency Plan team on the ground in Headquarters 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. Develop and administer curriculum for Master level degree in Laboratory Management and Policy in PEPFAR-supported countries in partnership with the Field Epidemilogy and laboratory Training Programs (FELTP)
2. Support PEPFAR-supported countries to expand Quality Management Systems activities in PMTCT and VCT clinic laboratories, leveraging on established collaborations with Ministries of Health through the FELTPs.
3. Support development and implementation of easy to use Laboratory Information Systems in PEPFAR-supported countries
4. Develop and implement a WHO biosafety training program in PEPFAR countries and disseminate the implementation and use through FELTPs
5. Develop and implement an equipment certification program through FELTPs in PEPFAR-supported countries to develop indigenous capacity for proper functioning of equipment

CDC Activities:

The selected applicant (grantee) 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 awardee for briefing 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 recommendation to the process used by the awardee to select key personnel and/or post-award subcontractors and/or subawardees 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 recommendation to the awardee'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 recommendation to the awardee's monitoring-and-evaluation plan, including for compliance with the strategic-information guidance established by the Office of the U.S. Global AIDS Coordinator.
5. Meet on a monthly basis with the awardee to assess monthly expenditures in relation to approved work plan and modify plans, as necessary.

6. Meet on a quarterly basis with the awardee to assess quarterly technical and financial progress reports and modify plans as necessary.
7. Meet on an annual basis with the awardee to review annual progress report for each U.S. Government Fiscal Year, 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 awardee 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 awardee on designing and implementing the activities listed above, including, but not limited to the provision of technical assistance to develop program activities, data management and analysis, quality assurance, the presentation and possibly publication of program results and findings, and the management and tracking of finances.
11. 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.

12. Assist the awardee in developing and implementing quality-assurance criteria and procedures.
13. Facilitate in-country planning and review meetings for technical assistance activities.

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.

III. Award Information and Requirements

Type of Award: Cooperative Agreement.

HHS/CDC's involvement in this program is listed in the Activities Section above.

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

Fiscal Year Funds: 2010

Approximate Fiscal Year Funding: $1,000,000.00

Approximate Total Project Period Funding: $10,000,000.00 (This amount is an estimate, and is subject to availability of funds and includes direct costs and indirect costs in the case of domestic grantees.)

Approximate Number of Awards: One

Approximate Average Award: $1,000,000.00 (This amount is for the first 12 month budget period, and includes direct costs and indirect costs in the case of domestic grantees.)

Floor of Individual Award Range: $150,000.00

Ceiling of Individual Award Range: $1,000,000.00 (This ceiling is for the first 12 month budget period and includes direct costs and indirect costs in the case of domestic grantees.)

Anticipated Award Date: **September 30, 2010**

Budget Period Length: 12 Months

Project Period Length: Five Years

Throughout the project period, HHS/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 U.S. Government, through the Emergency Plan review and approval process for Country Operational Plans, managed by the Office of the U.S. Global AIDS Coordinator.

IV. Eligibility Information

IV.1. Eligible applicants

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

- Public nonprofit organizations
- Private nonprofit organizations
- For profit organizations
- Small, minority, women-owned business
- Universities
- Colleges

- Research institutions
- Hospitals
- Community-based organizations
- Faith-based organizations
- Federally recognized Indian tribal organizations
- Alaska Native tribal governments
- Indian tribes
- Tribal Epidemiology centers
- Indian tribal organizations
- Other (specify)
- 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 Marianna 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 letter from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms" when submitting via www.grants.gov.

IV.2. Cost Sharing or Matching

Cost sharing or matching funds are not required for this program. If applicants receive funding from other sources to underwrite the same or similar activities, or anticipate receiving such funding in the next 12 months, they must detail how the disparate streams of financing complement each other.

IV.3. 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 submission requirements.

The successful applicant may be responsible for planning, implementing, and coordinating infrastructure development requirements supporting the primary public health purpose of this FOA.

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.

The Global AIDS Coordinator may waive the above criteria where justified to address the circumstances in a specific case.

* HHS will only implement paragraph 2 (entity) of the definition.

** USAID and its partners are subject to restrictions on parastatal eligibility for USAID funding. See 22 CFR 228.33

Special Requirements:

If the application is incomplete or non-responsive to the special requirements listed in this section, it will not be entered into the review process. The applicant will be notified that the application did not meet submission requirements.

- Late submissions will be considered non-responsive. See section "V.3. Submission Dates and Times" for more information on deadlines.
- 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 U.S. Government funds constituting a grant, loan, or an award.

V. Application Content

V.1. Address to Request Application Package

To apply for this funding opportunity, the application forms package posted in Grants.gov must be used.

Electronic Submission:

HHS/CDC requires applicants to submit applications electronically at www.Grants.gov. The application package can be downloaded from www.Grants.gov. Applicants are able to complete it offline, and then upload and submit the application via the Grants.gov Web site. Email submissions will not be accepted. If an applicant has technical difficulties in Grants.gov, customer service can be reached by email at support@grants.gov, or by phone at 1-800-518-4726 (1-800-518-GRANTS). The Customer Support Center is open 24 hours, 7 days a week.

Registering an applicant organization through www.Grants.gov is the first step in submitting applications online. Registration information is located in the "Get Registered" screen of www.Grants.gov. Applicants are required to use this online tool. Please visit www.Grants.gov at least 30 days prior to filing an application to become familiar with the registration and submission processes. Under "Get Registered," the one time registration process will take three to five days to complete. Only the person who

registers the organization on grants.gov can submit the application. This is important to remember if the person who originally registered an organization on grants.gov is no longer working for that particular organization. HHS/CDC suggests submitting electronic applications prior to the closing date so if difficulties are encountered in Grants.gov, a hardcopy of the application can be submitted prior to the deadline.

Foreign organizations must include a NATO Commercial and Governmental Entity (NCAGE) Code to complete their Grants.gov registration. Instructions for obtaining an NCAGE Code may be found at: http://www.cdc.gov/od/pgo/funding/NATO_Commercial_and_Governmental_Entity_12-18-06.doc.

If technical difficulties are encountered in Grants.gov, customer service may be reached by email at support@grants.gov, or by phone 1-800-518-4726 (1-800-518-GRANTS). The Customer Support Center is open from 7:00 a.m. to 9:00 p.m. Eastern Time, Monday through Friday.

V.2. Content and Form of Submission

Application:

A Project Abstract must be submitted with the application forms. All electronic project abstracts must be uploaded in a PDF file format when submitting via Grants.gov. The abstract must be submitted in the following format:

- Maximum of 2-3 paragraphs;
- Font size: 12 point unreduced, Times New Roman;
- Single spaced;
- Paper size: 8.5 by 11 inches (preferred), or generally accepted paper size; and
- Page margin size: One inch.

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. All electronic narratives 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 the 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;
- Paper size: 8.5 by 11 inches (preferred), or generally accepted paper size;
- Page margin size: One inch;

- Number all pages of the application sequentially from page one (Application Face Page) to the end of the application, including charts, figures, tables, and appendices not to exceed the maximum number of pages; and
- If paper application submission is applicable, the application should be printed only on one side of each page and should be held together only by rubber bands or metal clips; not bound in any other way.

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:* Describe the overall goals of the project, and specific objectives that are measurable and time phased, consistent with the objectives and numerical targets of the Emergency Plan and for this Cooperative

Agreement program as provided in the "Purpose" Section at the beginning of this Announcement;

- *Project Outputs:* Be sure to address each of the program objectives listed in the "Purpose" Section of this Announcement. Measures must be specific, objective and quantitative so as to provide meaningful outcome evaluation;
- *Project Contribution to the Goals and Objectives of the Emergency Plan:* Provide specific measures of effectiveness to demonstrate accomplishment of the objectives of this program;
- *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;
- *Performance Measures:* Measures must be specific, objective and quantitative;
- *Timeline* (e.g., GANTT Chart); and
- *Management of Project Funds and Reporting*.

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:

- ***Project Budget Justification:***

  With staffing breakdown and justification, provide a line item budget and a narrative with justification for all requested costs. 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 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;

- ***Curricula vitae*** of current key staff who will work on the activity ;
- ***Job descriptions*** of proposed key positions to be created for the activity ;
- ***Applicant's Corporate Capability Statement***;
- ***Letters of Support*** (5 letters maximum) ;
- ***Evidence of Legal Organizational Structure; and***

If the total amount of appendices includes more than 80 pages, the application will not be considered for review.

The agency or organization is required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access the Dun and Bradstreet website or call 1-866-705-5711.

Guidance that may require the submission of additional documentation with the application is listed in section "VII.2. Administrative and National Policy Requirements."

V.3. Submission Dates and Times

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 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.

Application Deadline Date: March 15, 2010.

Explanation of Deadlines: The HHS/CDC Procurement and Grants Office must receive applications by 11:59 p.m. Eastern Time on the deadline date.

Electronic Submissions:

Applications may be submitted electronically at www.Grants.gov. Applications completed on-line through Grants.gov are considered formally submitted when the applicant organization's Authorizing Organization Representative (AOR) electronically submits the application to www.Grants.gov. Electronic applications will be considered as having met the deadline if the application has been successfully submitted electronically by the applicant organization's AOR to Grants.gov on or before the deadline date and time.

When submission of the application is done electronically through Grants.gov (http://www.grants.gov), the application will be electronically time/date stamped and a tracking number will be assigned, which will serve as receipt of submission. The AOR will receive an e-mail notice of receipt when HHS/CDC receives the application.

V.4. Intergovernmental Review of Applications

Executive Order 12372 does not apply to this program.

V.5. Funding restrictions

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

- Recipients may not use funds for research.
- Recipients may only expend funds for reasonable program purposes, including personnel, travel, supplies, and services, such as contractual.
- 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.
- 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 recipients are subject to audit requirements specified in 45 CFR 74.26(d). A non-Federal audit is required, if during the recipients fiscal year, the recipient expended a total of $500,000.00 or more under one or more HHS awards (as a direct recipient and/or as a sub-recipient). The recipient 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 recipient 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 Recipient 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.

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)** 2010**, the limit is no more than 8 percent of the country's FY** 2010 **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. PEPFAR publishes the single-partner funding limits annually as part of guidance for preparing the Country Operational Plan (COP). U.S. Government Departments and agencies must use the limits in the planning process to develop Requests for Applications (RFAs), Annual Program Statements (APSs), or Funding Opportunity Announcements (FOAs). However, as PEPFAR country budgets are not final at the COP planning stage, the single partner limits remain subject to adjustment. The current limit applicable to this FOA is $1,000,000 for first year, $10,000,000 for the entire project period (8 percent or $2 million, whichever is greater, of the country's PEPFAR program funding). (Grants officers should insert the following sentence if the Department or agency issues the RFA prior to Congressional appropriation and final COP approval: "Please note that the current limit is based on an estimated country budget developed for planning purposes; thus, the limit is also an

estimate and subject to change based on actual appropriations and the final approved country budget.") 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-awardees, 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 2010 grants and cooperative agreements (for as many fiscal years as applicable) in Headquarters-managed cooperative agreements. For additional information concerning this RFA/APS/FOA, please contact the Grants Officer for this RFA/APS/FOA. (Grants officers: Where the statement of work indicates awards will be made as umbrella awards, add the following language to the RFA/APS/FOA): Based on the statement of work for this RFA/APS/FOA, PEPFAR will consider awards hereunder as umbrella awards, and they will be exempt from the single-partner funding limit.

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 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."

VI. Application Review Information

VI.1. Criteria

Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the "Purpose" section of this announcement. Measures must be objective and quantitative and must measure the intended outcome. The measures of effectiveness must be submitted with the application and will be an element of evaluation.

The application will be evaluated against the following criteria:

Ability to Carry Out the Proposal (20 points):

Does the applicant demonstrate the local experience in African countries and institutional capacity (both management and technical) to achieve the goals of the project with documented good governance practices? 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? 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 African countries? 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?

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? 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? 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? Does the applicant have a proven track record in Field Epidemiology and Laboratory like training, particularly with regard to laboratory management and policy training? 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? Does the application include reasonable estimates of outcome 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

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 preexisting relationships with Ministries of Health in any African countries? Does the applicant have preexisting laboratory networks involving the Ministries of Health in any African countries? 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? 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[1]" targets of the President's Emergency Plan, and b) (if not a local 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?

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

Monitoring and Evaluation (15 points):

Does the applicant demonstrate the local experience and capability to implement rigorous monitoring and evaluation of the project? 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? Is the plan to measure outcomes of the intervention, and the manner in which they will be provided, adequate? Is the monitoring and evaluation plan consistent with the principles of the "Three Ones[2]?" Applicants must define specific utput 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.

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[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.

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? 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?

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.

Administration and Management (10 points):

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 or pharmacy management? The grantee must demonstrate an ability to submit quarterly reports in a timely manner to the HHS/CDC office.

Budget (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?

VI.2. Application Review Process

Applications will be reviewed for completeness and for responsiveness jointly by the Procurement and Grants Office (PGO) and HHS/CDC Global AIDS Program staff.

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 submission requirements.

An objective review panel will evaluate complete and responsive applications according to the criteria listed in the "VI.1. Criteria" section above. All persons who serve on the panel will be external to the U.S. Government Country Program Office. The panel may include both U.S. Federal Government and non-U.S. Federal Government participants.

VI.3. Applications Selection Process

Applications will likely be funded in the order by score and rank determined by the review panel. However, the following *"Funding Preferences"* may affect the funding decision:

1) Applicant has established Field Epidemiology Training Program or Field Epidemiology Laboratory Training Program like Masters level curriculum in Laboratory Management and Policy in Africa

2) Applicant has a proven track record in administering Field Epidemiology/Laboratory Training in laboratory policy management

3) Applicant has proven track record in training of, and providing mentoring support for, Quality Management System principles in laboratories in African countries

4) Applicant has proven track record for providing support for the implementation of Laboratory Information Systems at the national and district level.

5) Applicant has established laboratory-related associations and/or network arrangements with Ministries of Health in various African countries.

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

VI.4. Anticipated Award Announcement Date

The anticipated date for announcing the award is **September 30, 2010**.

VII. Award Administration Information

VII.1. 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 emailed to the program director and a hard copy mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

VII.2. Administrative and National Policy Requirements

Successful applicants must comply with the administrative requirements outlined in 45 CFR Part 74 and 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-7 Executive Order 12372
- AR-8 Public Health System Reporting Requirements
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-14 Accounting System Requirements
- AR-15 Proof of Non-Profit Status
- AR-23 States and Faith-Based Organizations
- AR-24 Health Insurance Portability and Accountability Act Requirements
- AR-25 Release and Sharing of Data

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-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

VII.3. Terms and Conditions

The applicant must provide HHS/CDC with an original, plus two hard copies, of the following reports:

1. Interim progress report, due no less than 90 days before the end of the budget period. The progress report will serve as the non-competing continuation application, and must contain the following elements:
    a. Activities and Objectives for the Current Budget Period;
    b. Financial Progress for the Current Budget Period;
    c. Proposed Activity and Objectives for the New Budget Period Program;
    d. Budget;
    e. Measures of Effectiveness, including progress against the numerical goals of the President's Emergency Plan for AIDS Relief; and
    f. Additional Requested Information;
2. Annual progress report, due 90 days after the end of the budget period. Reports

should include progress against the numerical goals of the President's Emergency Plan for AIDS Relief for Kenya;

3. Financial status report, due no more than 90 days after the end of the budget period; and
4. Final financial FSR and progress reports, due no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management Specialist listed in the "VII. Agency Contacts" section of this announcement.

VIII. Agency Contacts

HHS/CDC encourages inquiries concerning this announcement.

For program technical assistance, contact:

G. David Cross, Co-Project Officer

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

1600 Clifton Road, N.E.

Mailstop G-45

Atlanta, GA 30333

Telephone: 404-718-1004

E-mail: GCross@cdc.gov

OR

Sherry L. Orloff, Co-Project Officer

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

1600 Clifton Road, N.E.

Mailstop G-45

Atlanta, GA 30333

Telephone: 404-639-1533

E-mail: SOrloff@cdc.gov

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

Ina Jee, Grants Management Specialist,

Procurement and Grants Office

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

2920 Brandywine Road, Mail Stop: K-75

Atlanta, GA 30341

Telephone: 770-488-2919

Email: Ijee@cdc.gov

For general questions, contact:

Technical Information Management Section

Procurement and Grants Office

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

2920 Brandywine Road, Mail Stop E-14

Atlanta, GA 30341

Telephone: 770-488-2700

Email: pgotim@cdc.gov

IX. Other Information

Other CDC funding opportunity announcements can be found on the CDC Web site, Internet address: http://www.cdc.gov/od/pgo/funding/FOAs.htm and on the website of the HHS Office of Global Health Affairs, Internet address: www.globalhealth.gov.