

AMENDMENT I (03/29/2012):

*1) Pages 42 – Inserted the following language: Pre-Application Conference Call
CDC Headquarters will conduct a pre-application meeting by conference call on April
12, 2012 from 9 to 10 am EDT. The toll-free phone number is 1-866-581-8651; the
alternate number is 1-203-875-7211 and the participant passcode is 4934171.
Interested applicants should contact Deborah Hamilton (DHAMILTONI@cdc.gov)
regarding recommended discussion questions.*

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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: Technical Assistance Support for the Strengthening of Blood Transfusion Services in Selected Countries Under the President's Emergency Plan for AIDS Relief

Announcement Type: New – Type 1

Agency Funding Opportunity Number: CDC-RFA-GH12-1255

Catalog of Federal Domestic Assistance Number: 93.067

Key Dates:

Application Deadline Date: *May 24, 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. National Blood System

- a. Summarize assessment results and identified gaps, and develop a five year strategic plan with the Ministry of Health National Blood Transfusion Service (MOH/NBTS) to address the gaps with goals and measurable outcomes for the recipient, and technical assistance requirements by the end of Year one (implement the plan in subsequent years).
- b. Assist with the development of a draft legal framework and appropriate legislation governing the National Blood Transfusion Service (NBTS) as an autonomous body with a functional organogram, proposed structure, authority and adequate budget, management team and trained and motivated staff by the end of Year two.
- c. Develop or improve a budgeting and finance system to examine the cost recovery or other sustainable financing, and make recommendations to be implemented by the NBTS by the end of Year three.
- d. Advocate for support and recognition of NBTS as a separate unit with direct financial and budgetary allocation, management team, and the appropriate number of trained staff by the end of six months. By the end of Year two, the NBTS should have all of the tools needed to advocate for these items and the

skills on how to communicate with the respective country government. These tools should include presentations that articulate the points/aspects specific to the country.

2. Infrastructure Development

- a. Summarize the assessment results and develop recommendations to improve the existing infrastructure of the National Blood Transfusion Service within six months of grant award.
- b. Provide assessment of current IT system and five year needs.
 - i. If a new IT system is recommended:
 1. Provide a completed requirements document within first year which includes a technical assistance plan,
 2. Provide language for tender developed within first year, and;
 3. Develop implementation and validation plan within the first year.
- c. Complete a report by facility with identified equipment, supply, training needs, and capacity is completed by the end of Year one.
- d. Complete a status report(s) by region, regional blood collection facility on presence/functional status of required equipment, number of tests done (by category), and inventory stock of required reagents by the end of Year one.
- e. Provide guidance on hardware and software acquisition, installation, and the standardization and specifications of equipment, and procurement of vehicles for mobile collection. All records are available for review by the end of Year one.
- f. Develop guidelines, standard operating procedures (SOPs), and processes based on the recommendations for infrastructure development including regular maintenance, calibration and repair of critical equipment, etc. by the end of Year one.

3. Blood Collection

- a. Develop SOPs, standardized forms, and training materials for donor screening and blood collection by the end of Year one.

- b. Develop a system to increase the annual blood unit collections by the NBTS of 10% per year during each year of the project. By the end of the project period (Year five), the NBTS should provide all of the required blood units to fulfill national demand.
 - c. Map out the current system, enumerate all blood collection sites, and propose a new system (fixed sites, satellite centers, mobiles) that would provide the highest level of quality across the NBTS network (including hard to reach areas) that will enable the country to meet their national blood needs by the end of Year three.
 - d. The number of blood units collected from repeat donors will continue to increase by at least 10% during each year of the project.
 - e. The percentage of Transfusion Transmitted Infections (TTI), including HIV, in units of donated blood will incrementally decrease each year and reach the target set based on the assessment by the end of Year five.
 - f. The percentage of collected blood units processed into components will incrementally increase each year and reach the target set based on the assessment by the end of Year five.
4. Blood Testing and Production of Blood Products
- a. Standard Operating Procedures (SOPs) should be available for review by the end of Year two.
 - b. Appropriate documentation for each step of blood collection, processing, and testing (including test kits and reagents) should be available for review by the end of Year two.
 - c. Development of national and site specific protocols for obtaining, handling and storing, transporting, and distributing blood for use in blood collection facilities should be in place by the end of Year three.
 - d. Development of national and site specific protocols for testing blood for HIV, hepatitis B, hepatitis C, and syphilis should be in place by the end of Year two and implemented in 95% of the sites (match to QA measure) by end of the project.
5. Transfusion and Blood Utilization

- a. Assess the presence of national guidelines or standards for the appropriate use of blood and blood products. If none exist, develop them by end of first year. If present, update them to reflect any system upgrades by the end of the first year (e.g. introduction of blood components).
- b. Once there are guidelines/standards in place on the appropriate use of blood and products, train 10% of clinicians and other hospital staff by the end of year one, and identify individuals in country to become trainers. Utilize these clinicians as train-the-trainers (TOT) over the course of the process, use them in year 2 to train an additional 20% of staff, and work with the local training institutions to incorporate this into pre-service training.
- c. Develop a pilot to use as a functioning model for hospital-based transfusion committees and hemovigilance system if none exists by the end of Year one. Use this system to monitor the use of blood, adverse transfusion events and overall patient outcomes.
- d. After the pilot is set up in Year one, develop a TOT system and mentor the NBTS to increase the number of functional committees by 10 % per year.
- e. Sixty percent (60%) of all hospitals receiving blood from the NBTS will provide feedback on utilization by the end of Year three, and 100% by the end of Year five.

6. Monitoring and Evaluation (M&E)

- a. Development and implementation of a viable monitoring and evaluation system including a plan and forms by end of Year one.
- b. Phase this system in by the end of Year two and use data to inform planning by the end of Year three.
- c. Develop a process to facilitate data collection to monitor program progress and blood bank and transfusion service operations by the end of Year three.
- d. A functional system (manual or electronic) information management system will be in place by the end of Year three.

7. Training

- a. Create a training plan for all staff (including new hires) which includes annual task based training, refresher training or mentoring in their appropriate

technical areas (management, finance, human resources, donor recruitment, counseling, retention, blood bank management, good laboratory practice, appropriate blood use, blood components, hemovigilance, data management systems, etc.), with materials developed and TOT identified by the end of year one.

- b. Conduct trainings for 80% of staff and develop TOT in each topic area by end of Year two.
- c. All (100%) staff should receive training in their technical program area by the end of Year three.
- d. By the end of the project all (100%) staff are on a schedule and receive annual training.
- e. Identify key staff and their additional training needs, including on-site mentoring and international training, by the end of Year two.

8. Quality Systems

- a. Advise on the systems for a quality assurance program and assist the country to put the mechanisms in place to be implemented by the NBTS by the end of Year three.
- b. A plan for internal and external quality assurance programs should be in place for all tests by the end of Year four.
- c. Results of internal and external quality assurance programs for all tests should be available for review. Protocols should be in place and corrective action completed by the end of Year five.
- d. The coverage of safe blood provision to facilities engaging in blood transfusion within the NBTS system is collected, handled, and processed in a quality manner. The number of facilities that adhere to quality systems (rapid tests, etc.) will increase to 60% by the end of Year three, and reach 95% by the end of Year five, with a special emphasis on the hard to reach areas within the country.
- e. Establish recommended job descriptions and training/mentoring plans for key personnel (medical director, quality manager) and qualified and trained staff

in each key aspect of the blood transfusion service with clear roles and responsibilities by the end of Year one.

- f. Develop policies and standard operating procedures (SOPs) for specific activities (e.g., blood collection, laboratory screening algorithms, transfusion indications, risk assessment, and risk management) by the end of Year two.
- g. Functional organizational charts based upon current structure/function, and related management structures should be developed, put in place, and tailored to meet the needs of the MOH/NBTS (after MOH approval of the charts and materials) by the end of Year one.

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 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 strengthen the rapid implementation of safe blood programs and precautions against the medical transmission of HIV, thereby ensuring a safe and adequate blood supply as a priority area for the President's Emergency Plan for AIDS Relief (PEPFAR). The purpose of this initiative is to provide expert guidance and technical assistance to the Ministries of Health (MOH) or the National Blood Transfusion Services (NBTS) in selected countries around the world that are impacted and affected by HIV/AIDS for the development and implementation of a national safe blood program with demonstrable and sustainable results. An additional intent is to develop sustained indigenous capacity to continue these programs after the project ends.

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

- A. Asia Region (Cambodia, Kazakhstan, Kyrgyzstan, Papua New Guinea, Tajikistan, Turkmenistan, Ukraine, Uzbekistan)
- B. Caribbean Region (Haiti, Dominican Republic, Guyana)
- C. Africa Region – Southern (Angola, Botswana, Lesotho, Malawi, Mozambique, Namibia, South Africa, Swaziland, Zambia, Zimbabwe)
- D. Africa Region – Eastern (Ethiopia, Kenya, Rwanda, South Sudan, Tanzania, Uganda)
- E. Africa Region - West and Central (Cameroon, Cote d’Ivoire, Democratic Republic of Congo, Ghana, Mali, Nigeria)

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

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 the PEPFAR supported countries and must also coordinate with other organizations or United States Government (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. National Blood System
 - a. Conduct an assessment of the status of blood transfusion and blood safety in the country relative to the World Health Organization (WHO) Blood Safety Aide Memoirs or accreditation.
 - b. Assess budget and financing systems and make recommendations regarding program sustainability.
2. Infrastructure Development
 - a. Perform or assist with a situational assessment of the existing infrastructure in terms of needs for a national blood transfusion service, including analysis of blood demand, blood collection, screening, processing and blood banking facilities, capital and consumable needs (e.g., blood collection bags and tubes, laboratory devices and reagents, cold chain equipment, etc.), and information technology (IT) systems necessary to track data on blood donors, blood collections, laboratory results and, where available, hemovigilance.
 - b. Based on the assessment, develop or strengthen policies, plans and systems for preventing stock outs of essential materials and supplies, equipment standardization, waste management, etc.
3. Blood Collection
 - a. Assist with development of generic and site-specific protocols for collecting, handling and storing, transporting, and distributing blood in and from fixed and mobile blood collection facilities. Provide support, as requested, in strengthening the capacity of blood donor recruiters and blood donor counselors at each blood collection site.
 - b. Provide advice in developing and maintaining a system to recruit and retain low risk, voluntary, non-remunerated blood donors (VNRD). This may include, but not be limited to, guidance on the development of telephone or text message-based call-back systems and electronic data systems to manage donor lists.
 - c. Provide technical recommendations or guidance on ways to strengthen blood collection sites. These sites may be integrated with larger healthcare facilities or exist as stand-alone, or mobile sites. Infrastructure recommendations must

be site-specific, based on the location of the facility (e.g., urban or rural), and must include a review of the available or needed logistics systems to support each site.

- d. Provide guidance on effective quality assurance procedures for collecting and storing blood.

4. Blood Testing and Production of Blood Products

- a. Develop generic national and site-specific protocols for all required testing of blood: including for HIV and other relevant transfusion-transmissible pathogens; sero-typing and cross matching following Good Laboratory Practices. All testing algorithms should be based on internationally accepted standards, and include internal and external quality assurance components.
- b. Provide assistance to support the strengthening blood services' capacity to manage blood testing laboratories and build capacity to fractionate blood products from collected units of whole blood. Activities in this area may include, but will not be limited to, assisting in the development or strengthening and implementation of laboratory Standard Operating Procedures (SOPs), testing algorithms, blood production guidelines and SOPs, cold chain systems, electronic record-keeping systems and policies to ensure good manufacturing practices.

5. Transfusion and Blood Utilization

- a. Assist with the development and implementation of national guidelines for the appropriate use of blood and blood products. These guidelines may be developed through a series of national consensus conferences attended by transfusion practitioners and domestic and international transfusion experts.
- b. Provide guidance and advice for the development of hospital-based transfusion committees and hemovigilance systems to monitor the use of blood, adverse transfusion events and overall patient outcomes.

6. Monitoring and Evaluation (M&E)

- a. Provide recommendations and guidance on systems for collecting, managing and analyzing data on key programmatic indicators. This will extend to providing advice and guidance on methods and mechanisms for reviewing and adjusting program activities based on monitoring data.
- b. The use of M&E data may include, but will not be limited to:
 - i. Tracking the distribution of blood to evaluate hospitals' use of blood collected and screened by the NBTS (vs. blood collected and screened by the hospital or a private entity)
 - ii. Tracking trends in the prevalence of TTIs in donated blood to adjust donor recruitment practices and/or improve educational materials on ways donors can maintain a healthy lifestyle and reduce their risk of infection with HIV
 - iii. Tracking program costs to develop cost-recovery and other systems to ensure the program's sustainability.

7. Training

- a. Develop a training plan for in-service, pre-service, continuing education, and/or short and long term career development, along with assisting with identification of appropriate venues internally or externally. Topics may include any aspect of blood safety from community mobilization and donor recruitment to blood processing and distribution, logistics, transfusion practices and hemovigilance, or management and supervision.
- b. Develop a training plan including an appropriate lesson plan containing outcomes, objectives and assessment of comprehension or competence, in the case of a procedure. The use of TOT methods with appropriate assessment and supportive supervision to assure quality and sustainability is strongly encouraged.
- c. Provide all technical instructors, trainee guides, and all other training materials such as textbooks, workbooks, manuals, evaluation forms and other documentation tailored to the requested audience and subject matter.
- d. Deliver on-site classroom training or on the job mentoring, or a combination as determined by the country and the particular topic and target audience.

Target audience(s) will depend on the subject matter and may include but not be limited to health care professionals (e.g. physicians, nurses, physician assistants, community health aides, counselors, laboratory technicians, blood donor recruiters and blood service administrators.)

- e. Assist with development or adaptation of curricula and materials to be incorporated into other training scenarios such as pre-service training and continuing education programs.

8. Quality Systems

- a. Support efforts to ensure the overall safety of the transfusion process, from the recruitment of blood donors to the transfusion of blood and blood products and follow-up of the recipients.
- b. Provide technical assistance in the implementation of effective quality systems, covering all aspects of NBTS activities, including quality management, development and implementation of quality standards, effective documentation systems, training of staff and regular quality assessment.
- c. Evaluate the status of the blood safety with regards to quality systems. If one exists, recommend improvements. If none exists, recommend best practices for the creation and implementation of a national quality system.
- d. Provide assistance to MOH/NBTS partners to support the development of external quality control agreements between host governments and internationally accredited laboratories.

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 HHS agencies and the Office of the U.S. Global AIDS Coordinator (OGAC).
2. Review and make recommendations as necessary to the process used by the grantee to select key personnel and/or post-award subcontractors and/or subgrantees to be involved in the activities performed under this agreement, as part of the President's Emergency Plan for Relief (PEPFAR) Country Operational Plan (COP) review and approval process, managed by the OGAC.
3. 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.
4. Review and approve the grantee's monitoring and evaluation plan, including for compliance with the strategic information guidance established by the OGAC.
5. Meet on a regular basis with the grantee to assess expenditures in relation to approved work plan and modify plans as necessary.
6. Meet on a quarterly basis with the grantee to assess quarterly technical and financial progress reports and modify plans as necessary.
7. Meet on an annual basis with the grantee to review annual progress report for each U.S. Government Fiscal Year, and to review annual work plans and budgets for the subsequent year, as part of the PEPFAR review and approval process for COPs, managed by the OGAC.
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, and confidential counseling and testing.

9. Provide in-country administrative support to help the grantee meet U.S. Government financial and reporting requirements approved by the Office of Management and Budget (OMB) under 0920-0428 (Public Health Service Form 5161).
10. Collaborate with the grantee on designing and implementing the activities listed above, including, but not limited to: the provision of technical assistance to develop program activities, 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 OGAC documents to promote the use of best practices known at the time.
12. Assist and mentor the recipient in developing and implementing quality management systems and procedures.
13. Facilitate in-country planning and review meetings for technical assistance activities.
14. Provide technical oversight for all activities under this award.
15. Provide ethical reviews, as necessary, for evaluation activities, including from HHS/CDC headquarters.
16. Supply the grantee 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: \$ 15,000,000

Approximate Total Project Period Funding: \$84,615,000

Approximate Number of Awards: 1-5

Approximate Average Award: \$ 3,000,000

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: \$15,000,000(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: \$16,500,000

Budget Year 3 Ceiling amount: \$18,150,000

Budget Year 4 Ceiling amount: \$19,965,000

Budget Year 5 Ceiling amount: \$15,000,000

Anticipated Award Date: September 30, 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 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.

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, 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. Please visit 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.

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.

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.

- 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: *May 24, 2012* [ON GRANTS.GOV](https://www.grants.gov), 11:59pm Eastern Standard Time.

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

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

Content and Form of Application Submission

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

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

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

Letter of Intent (LOI):

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

A Project Abstract must be completed in the 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: A one page biographical summary of all key personnel that documents their education, training and demonstrated experience in the field of blood safety, with specific capability in the monitoring, evaluation and management of national blood services in resource-limited settings is required. This latter experience should include exposure to, and familiarity with WHO recommendations and guidelines on blood transfusion services in resource-limited settings. Key personnel must be fluent in English with excellent written and oral communication skills. Depending on the Region, fluency in country specific official languages (French, Portuguese, Russian, etc.) is also required.
- ***Job descriptions*** of proposed key positions to be created for the activity: A one page job descriptions of the Principal Investigator, Project Director, Financial Manager, and Program Coordinator are required.
 - ***Applicant's Corporate Capability Statement;***
 - ***Evidence of Legal Organizational Chart delineating roles and responsibilities of key personnel; 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.
- Associate Director for Science (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

Additional Submission Requirements

Electronic Submission

Submit the application electronically by using the forms and instructions posted for this funding opportunity on 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. Refer to the email message generated at the time of application submission for instructions on how to track your application or the Application User Guide, Version 3.0 page 57.

Applications must be submitted electronically at www.Grants.gov. Electronic applications will be considered as having met the deadline if the application has been successfully made available to CDC for processing from Grants.gov on the deadline date. The application package can be downloaded from www.Grants.gov. Applicants can complete the application package off-line, and then upload and submit the application via the 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. Submissions sent by e-mail, fax, CD's or thumb drives of applications will not be accepted.

Organizations that encounter technical difficulties in using www.Grants.gov to submit their application must attempt to overcome those difficulties by contacting the Grants.gov Support Center (1-800-518-4726, support@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 GH12-1255. 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 (15 points):

Does the applicant have the relevant blood safety experience, resources and institutional capacity (both management and technical) to guide or assist in the development of blood safety policies, systems and structures consistent with WHO guidelines and blood safety and other accreditation bodies to ensure the safety, quality, accessibility and timely availability of blood and blood products to meet the needs of all patients who require transfusion, including: (1) conduct assessments of blood center infrastructure and systems, including buildings, equipment, blood safety information data management and supplies (5 points); (2) 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 (5 points); and (3) demonstrate leadership support and provide evidence of current or past efforts to enhance blood transfusion safety consistent with WHO guidelines and blood safety and other accreditation bodies in resource limited settings (5 points)?

Technical and Programmatic Approach (15 points):

Does the application include: (1) knowledge of the strategy, principles and goals of the President's Emergency Plan, and proposed activities that are consistent with and pertinent to that strategy, principles and goals (5 points); (2) an overall design strategy including realistic estimates of outcome targets (the numbers of sites to be supported, number of clients the program will reach), measurable objectives and time lines, clear monitoring and evaluation procedures, and specific activities that are evidence based, achievable, and culturally appropriate (5 points); (3) a plan to build on and complement the current national response with evidence-based strategies designed to reach underserved populations and meet the goals of the President's Emergency Plan (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.

Training and Capacity Development (10 points):

Does the applicant have a proven track record and relevant experience in building the capacity of Ministries of Health and National Blood Transfusion Services in the area of blood transfusion safety including the transfer of critical technical and management competence, including: (1) developing a comprehensive training program using participatory methods and approaches (mentoring, technical support, twinning and networking) in the basic principles and practices of blood banking and transfusion medicine (5 points); and (2) developing an adequate and measurable plan to progressively contribute to an improved quality and geographic coverage of service delivery to achieve the "3,12,12"¹ targets of the President's Emergency Plan (5 points).

Monitoring and Evaluation (15 points):

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.

Does the applicant describe or demonstrate: (1) the relevant experience and capability to implement rigorous monitoring and evaluation of the project (5 points); (2) a system for reviewing and adjusting blood safety indicators and activities based on information for each program milestone that are obtained by using innovative, participatory methods and standard approaches, and that are consistent with the President's Emergency Plan Indicator Guide (5 points); and (3) a system that is able to generate financial and program reports to show indicators developed, disbursement of funds, and progress towards achieving the numerical objectives of the President's Emergency Plan and the principles of the "Three Ones"² (5 points). Applicants must define specific output and outcome indicators in the proposal, and must have realistic targets in line with the targets addressed in the Activities section of this announcement.

Blood Collection (15 points):

Does the applicant: (1) demonstrate a clear and concise understanding of the current national HIV/AIDS response and the cultural and political context relevant to the strengthening of the national blood transfusion services based on voluntary non-remunerated regular blood donation (5 points); (2) have the resources to guide or assist in the development of blood collection facilities, including the development of blood donor recruitment networks (5 points); and (3) propose a plan to guide or assist in the development of blood collection facilities, including the development of blood donor recruitment networks that are reasonable within the target community (5 points).

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.

Transfusion and Blood Utilization (10 points):

Does the applicant have the relevant experience, resources and technical capacity to: (1) develop scientific and evidence-based guidance on the safety, quality, availability and use of blood and blood products including national blood systems, blood transfusion practice guidelines, and blood utilization review programs (5 points); and (2) strengthening the capacity and quality of national blood systems and improving clinical transfusion practices (5 points).

Processing of Donated Blood (10 points):

Does the applicant have the relevant experience, resources and technical capacity to guide or assist in the rigorous screening of all donated blood required to ensure the safety of the blood supply, including: (1) development and implementation of a national strategy for the screening of all donated blood for transfusion-transmissible infections (TTI), using the most appropriate and effective assays to test for HIV, hepatitis B and C, syphilis; and training of blood transfusion service laboratory technical staff in all aspects of blood screening and processing including blood grouping, compatibility testing, component preparation and storage and transportation of blood products (5 points); and (2) maintenance of quality assurance systems and good laboratory practice, including the use of standard operating procedures and protocols, in all aspects of blood screening and processing; the procurement, supply, central storage and distribution of reagents and materials to ensure continuity in testing at all sites; the maintenance of an effective blood cold chain for the storage and transportation of blood and blood products (5 points).

Administration and Management (10 points):

Does the applicant provide a clear plan for: (1) the administration and management (including appropriately trained personnel fluent in the local language) of the proposed activities, resources of the program, collection and analysis of performance data, preparation of reports, monitoring and evaluating activities, program audits, and a management structure for the project that is sufficient to ensure speedy implementation of program activities (5 points); and (2) have a proven track record in managing large laboratory and IT system budgets, managing transparent and competitive procurement

processes, supervising consultants and contractors, and providing technical assistance in blood safety (5 points)? The grantee must demonstrate an ability to submit quarterly or semi-annual 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>.

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.

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

Pre-Application Conference Call

CDC Headquarters will conduct a pre-application meeting by conference call on April 12, 2012 from 9 to 10 am EDT. The toll-free phone number is 1-866-581-8651; the alternate number is 1-203-875-7211 and the participant passcode is 4934171.

Interested applicants should contact Deborah Hamilton (DHAMILTONI@cdc.gov) regarding recommended discussion questions.

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-20 Conference Support
- 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.

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

Each funded applicant must provide CDC with an annual Interim Progress Report submitted via 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 for PEPFAR supported country.

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 30 days after submission of the Final Performance and Financial Status Reports, and, 30 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:

Deborah Hamilton, Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention
1600 Clifton Road, N.E.
Mailstop E-39

Atlanta, GA
Telephone: 404-718-8690
E-mail: DHAMILTON1@cdc.gov

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

Dionne Bounds, Grants Management Specialist
Department of Health and Human Services
CDC Procurement and Grants Office
2920 Brandywine Road, MS: K-75
Atlanta, GA 30341
Telephone: 770-488-2082
E-mail: vhv5@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

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

VIII. Other Information

Amendments, Questions and Answers (Q&As)

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

Other CDC funding opportunity announcements can be found on Grants.gov Web site,

Internet address: <http://www.grants.gov>.