Centers for Disease Control

Center for Global Health

Supporting HIV-Related Laboratory Networks and Partnerships to Facilitate Laboratory Strengthening and Management Activities for Countries Supported under the President's Emergency Plan for AIDS Relief (PEPFAR)

CDC-RFA-GH18-1805

Application Due Date: 10/16/2017
Supporting HIV-Related Laboratory Networks and Partnerships to Facilitate Laboratory Strengthening and Management Activities for Countries Supported under the President’s Emergency Plan for AIDS Relief (PEPFAR)

CDC-RFA-GH18-1805

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Part I. Overview Information
Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notifications Emails" link to ensure they receive notifications of any changes to CDC-RFA-GH18-1805. Applicants also must provide an e-mail address to www.grants.gov to receive notifications of changes.

A. Federal Agency Name:
Centers for Disease Control and Prevention (CDC) / Agency for Toxic Substances and Disease Registry (ATSDR)

B. Notice of Funding Opportunity (NOFO) Title:
Supporting HIV-Related Laboratory Networks and Partnerships to Facilitate Laboratory Strengthening and Management Activities for Countries Supported under the President's Emergency Plan for AIDS Relief (PEPFAR)

C. Announcement Type: New - Type 1
This announcement is only for non-research activities supported by CDC. If research is proposed, the application will not be considered. For this purpose, research is defined at https://www.gpo.gov/fdsys/pkg/CFR-2007-title42-vol1/pdf/CFR-2007-title42-vol1-sec52-2.pdf. Guidance on how CDC interprets the definition of research in the context of public health can be found at http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf.

D. Agency Notice of Funding Opportunity Number:
CDC-RFA-GH18-1805

E. Catalog of Federal Domestic Assistance (CFDA) Number:
93.067

F. Dates:
1. Due Date for Letter of Intent (LOI): N/A
3. Date for Informational Conference Call:
N/A

G. Executive Summary:
1. Summary Paragraph:
Access to quality assured diagnostics and laboratory services is critical to the effective diagnosis, treatment, and management of HIV and other HIV-related diseases, including TB. Achieving an AIDS-Free Generation and the UNAIDS 90-90-90 targets requires establishment and operationalization of laboratory and diagnostic networks, including strong and sustainable collaborations with partners. To date, PEPFAR-supported laboratory and integrated diagnostic network strengthening efforts have led to improved access to the quality diagnostic and patient monitoring services required to support the HIV clinical cascade. However, work remains to establish and maintain the partnerships and collaborations required to support these efforts. This NOFO will focus on building and strengthening sustainable networks and partnerships to
support laboratory systems, policies, and data use in PEPFAR-supported countries; improving in-service laboratory safety and science competencies through quality training for laboratory professionals; collaborations across partner organizations, laboratory professionals, and clinicians; strengthened public health laboratory and diagnostic network capacity, quality, and functionality; and improved access to high quality and effective technical assistance (TA) resources.

a. **Eligible Applicants:** Open Competition
b. **NOFO Type:** Cooperative Agreement
c. **Approximate Number of Awards:** 4
The expected number of awards is 1-4.
d. **Total Project Period Funding:** $0
The Approximate Project Period Funding/Estimated Total Funding for the Total 5 year Project Period is None. Award ceilings for years 2-5 will be set at continuation.
e. **Average One Year Award Amount:** $3,750,000
f. **Total Project Period Length:** 5
g. **Estimated Award Date:** 04/01/2018
h. **Cost Sharing and / or Matching Requirements:** N
Cost sharing or matching funds are not required for this program. Although there is no statutory match requirement for this NOFO, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

**Part II. Full Text**

**A. Funding Opportunity Description**

**Part II. Full Text**

1. **Background**

a. **Overview**

PEPFAR countries have made progress towards scaling up and increasing access to quality-assured conventional services, including HIV rapid testing, early infant diagnosis (EID), and detection of HIV-associated TB and HIV viral load (VL) monitoring. Further scale up to attain and sustain optimal coverage and universal access to the uninterrupted laboratory and diagnostic services necessary for reaching epidemic control and making measurable progress toward the UNAIDS 90-90-90 fast-track treatment targets will require novel testing technologies and approaches; well-trained and competent laboratory staff; country-specific policies and laboratory strategic plans; and effective collaborations with clinicians and other key stakeholders.

CDC and its partners have made significant strides toward these goals; however, challenges still exist. The December 2, 2016 CDC Morbidity and Mortality Weekly Report noted that while the seven countries reviewed had the capacity to perform VL testing for all patients currently on HIV treatment, the percentage of patients receiving VL testing was <25% in four of the
countries. Noted barriers included weaknesses in sample transport and laboratory workflow; finances and procurement; human resources; equipment maintenance; and laboratory-clinic interface. Other reports indicate that <40% of the patient management decisions in resource-limited countries are based on laboratory test results, compared to 70-80% in other countries. Utilization of laboratory diagnostics varies; however, slow turn-around times, low confidence in the accuracy of lab results, and limited communications between the laboratory and clinical staff are consistently cited as issues.

This NOFO seeks to ensure access to quality-assured HIV-related laboratory and diagnostic services; support Laboratory Quality Management Systems (QMS); strengthen laboratory organizational and workforce capacity; and develop and maintain partnerships. At the end of the project period, laboratorians, clinicians, and patients in PEPFAR-supported countries (may include, but are not limited to: Angola, Cameroon, Caribbean Region, Cote d'Ivoire, Democratic Republic of Congo, Ethiopia, Kenya, Malawi, Mozambique, Nigeria, South Africa, South Sudan, Tanzania, Uganda, Zambia, and Zimbabwe) will have:

- Increased access to quality-assured diagnostics and uninterrupted testing services through efficient laboratory networks in line with appropriate country-specific policies, procedures, and laboratory strategic plans implemented at all levels of the clinical and diagnostic network;
- Increased utilization of QMS and tools such as External Quality Assessment (EQA), the World Health Organization-AFRO (WHO-AFRO) Stepwise Laboratory Improvement Process Toward Accreditation (SLIPTA) and Strengthening Laboratory Management Toward Accreditation (SLMTA) Programs, Rapid Test Quality Improvement Initiative (RTQII), and other Continuous Quality Improvement (CQI) activities leading to increased accuracy, reliability, and use of diagnostic test results, which will in turn lead to enhanced uptake for clinical decision-making and improved clinical outcomes for patients with HIV and HIV/AIDS related infections;
- Strengthened organizational infrastructure with a qualified laboratory workforce that has expertise to support the HIV continuum of care; and
- Effective global, regional, and local partnerships and collaborations with clinicians, technical experts, and other professionals to improve the diagnosis, treatment, and management of people living with HIV (PLHIV) in PEPFAR-supported countries.

b. Statutory Authorities


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. The overarching purpose of this NOFO is to fund activities to prevent or control disease or injury and improve health, or to improve a public health program or service.
**c. Healthy People 2020**

N/A

**d. Other National Public Health Priorities and Strategies**

Under the leadership of the U.S. Global AIDS Coordinator, as part of the President's Emergency Plan, the U.S. Department of Health and Human Services’ Centers for Disease Control and Prevention (HHS/CDC) works with host countries and other key partners to assess the needs of each country and design a customized program of assistance that fits within the host nation's strategic plan and partnership framework.

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

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

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

- Implement a woman- and girl-centered approach;
- Increase impact through strategic coordination and integration;
- Strengthen and leverage key multilateral organizations, global health partnerships and private sector engagement;
- Encourage country ownership and invest in country-led plans;
- Build sustainability through investments in health systems;
- Improve metrics, monitoring and evaluation; and
- Promote research, development and innovation (research is not supported by this NOFO).

This announcement is only for non-research activities supported by CDC. Recipients may not use funds for research. Certain activities that may require human subjects review due to
institutional requirements but that are generally considered not to constitute research (e.g., formative assessments, surveys, disease surveillance, program monitoring and evaluation, field evaluation of diagnostic tests, etc.) may be funded through this mechanism. 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

e. Relevant Work
This NOFO will build on CDC’s previous work and lessons learned which focused on working through collaborations and partnerships with Ministries of Health (MOHs), global, regional, and local partners to strengthen HIV-related diagnostics and laboratory services in PEPFAR-supported countries.

2. CDC Project Description

a. Approach

**Bold** indicates period of performance outcome.
### i. Purpose
The purpose of this NOFO is to support the diagnostic and laboratory capacity, partnerships, and collaborations in PEPFAR-supported countries to address HIV and HIV-related infections.

### ii. Outcomes
Applicants may propose additional related project period outcomes other than those identified in the NOFO.

<table>
<thead>
<tr>
<th>Strategies and Activities</th>
<th>Short-Term Outcomes</th>
<th>Intermediate Outcomes</th>
<th>Long-Term Outcomes</th>
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<tr>
<td>Provide TA, mentoring, training, and human resources development for laboratories to support improved diagnostic procedures, implementation of innovative diagnostic approaches, quality control (QC) and quality assurance (QA)</td>
<td>Increased adherence among staff in laboratory and clinical sites to national and international testing, and guidelines and laboratory quality practices (EQA, SLIPTA, SLMTA, RTQII, and other CQI activities)</td>
<td>Increased implementation of laboratory policies, procedures, and strategic plans at all levels of the laboratory</td>
<td>Improved clinical outcomes, diagnosis, treatment, and management of HIV and related diseases in PEPFAR countries</td>
</tr>
<tr>
<td>Partner with other organizations and subject matter experts (SMEs) to develop and implement laboratory networks, with support for uptake and sustainability of QMS and CQI policies and procedures</td>
<td>Improved implementation of QMS and CQI practices</td>
<td>Increased participation and adoption of laboratory QA practices leading to CQI</td>
<td>Improved laboratory human resource capacity through a well-qualified and stable workforce with expertise to support the laboratory associated components of the HIV continuum of care</td>
</tr>
<tr>
<td>Work with other partners to develop and implement in-service training, mentorship, and increase access to SMEs and technical resources to strengthen laboratory and diagnostic testing processes and systems</td>
<td>Increased knowledge and utilization of innovative diagnostic approaches and QMS tools among laboratory and clinical staff</td>
<td>Increased development of innovative approaches and policies to address laboratory system and laboratory-clinic interface improvements</td>
<td>Improved accuracy and reliability of diagnostic results Decreased frequency and duration of testing interruptions</td>
</tr>
<tr>
<td>Collaborate with other organizations to review systems and processes for improving the laboratory clinical interface</td>
<td>Improved quality of HIV-related diagnostic and clinical testing, treatment, and monitoring at PEPFAR-supported sites</td>
<td>Increased use of diagnostic results for clinical decision making</td>
<td>Improved clinical trust in and reliance on test results for patient management Improved linkages between the diagnostic and clinical activities in PEPFAR-supported countries</td>
</tr>
</tbody>
</table>
Short-Term Outcomes:

- **Increased adherence among staff in laboratory and clinical sites to national and international testing, and guidelines and laboratory quality practices (EQA, SLIPTA, SLMTA, RTQII, and other CQI activities).** This will include:
  - Increased uptake of QMS and CQI tools such as EQA, SLIPTA, SLMTA, RTQII, and other CQI activities
  - Improved processes to identify and increase access to tools and resources for building and supporting human resources capacity through in-service training, mentorships, and access to high quality TA consultants

- **Improved implementation of QMS and CQI practices.** This will include:
  - Increased and improved monitoring of QMS and other CQI activities leading to increased quality and timeliness of diagnostic and patient monitoring tests

- **Increased knowledge and utilization of innovative diagnostic approaches and QMS tools among laboratory and clinical staff.** This will include:
  - Increased access to quality TA to accomplish the NOFO goals through local and regional partnerships
  - Increased development of practical guidance, training materials, and other implementation tools to support laboratory and diagnostic network quality
  - Increased efficient use of laboratory resources to improve the quality of HIV and TB-related diagnostic and clinical testing at PEPFAR-supported sites
  - Increased support for quality diagnostic services and collaborations including the establishment of a Technical Working Group (TWG) representing key stakeholders such as clinicians, technical experts, and other organizations and professionals working to support the diagnosis, treatment, and management of PLHIV in PEPFAR-supported countries
  - Increased development/revision of HIV-related laboratory and diagnostic testing policies and strategic plans
  - Increased development and updates of laboratory policies and strategic/operational plans in PEPFAR-supported countries among MOHs and laboratory regulatory bodies
  - Improved implementation of QMS and CQI practices
  - Increased access to country-specific guidance and policies developed for implementation and adoption of national QMS strategies
  - Increased access to updated standard operating procedures (SOPS), job aids, and other tools to strengthen laboratory quality and capacity for laboratory and clinical staff
  - Increased partnerships between laboratories, MOHs, and other governing bodies to support patient access to quality diagnosticians and timely laboratory results, including systems for real-time monitoring of testing achievements and gaps
  - Increased access to quality in-service training for laboratory professionals in PEPFAR-supported countries
  - Increased capacity through trained, competent, and certified laboratory staff supporting HIV and TB diagnostic technologies
  - Increased establishment of laboratory networks for HIV and HIV-associated diagnostic and patient monitoring tests among PEPFAR-supported countries
o Increased development of capacity building plans by PEPFAR countries to support the institutionalization and sustainability system improvements

**Intermediate Outcomes:**

- **Increased implementation of laboratory policies, procedures, and strategic plans at all levels of the laboratory.** This will include:
  o Increased and maintained laboratory networks with MOHs and other governing bodies working to support patient access to quality diagnostics; increased patient access to timely laboratory results; and real-time monitoring of testing achievements and gaps
  o Increased implementation of comprehensive laboratory policies and strategic plans at all levels of the laboratory network
  o Increased and sustained implementation of capacity building plans to support the institutionalization and sustainability system improvements among PEPFAR-supported countries

- **Increased participation and adoption of laboratory QA practices leading to CQI.** This will include:
  o Increased development of policies to ensure the institutionalization of QMS and procedures among PEPFAR-supported countries
  o Increased development by PEPFAR countries of innovative approaches, processes, and policies to address system improvements to support better lab and clinical integration, including HIV testing turnaround times
  o Sustained participation and engagement of the TWG and other laboratory stakeholders leading adoption of laboratory QMS and CQI policies and practices

- **Increased development of innovative approaches and policies to address laboratory system and laboratory-clinic interface improvements.** This will include:
  o Sustained collaborations and partnerships that ensure access to quality diagnostics for HIV TB and other HIV-associated infections
  o Increased and sustained compliance with the procedures outlined in the laboratory SOPs among all PEPFAR-supported labs implementing QMS activities
  o Improved, established, and fully functional systems and processes that ensure full access for laboratory and clinical professions to tools and resources for building and supporting human resources capacity through in-service training, mentorships, and access to high quality TA consultants
  o Increased accuracy and reliability of diagnostic results and increased use of the results to support clinical decision making
  o Sustained partnerships, collaborations, and strategic communications channels with clinicians, technical experts, and other organizations and professionals working to support the diagnosis, treatment, and management of PLHIV in PEPFAR-supported countries

**Long-Term Outcomes:**

- **Improved laboratory human resource capacity through a well-qualified and stable workforce with expertise to support the laboratory associated components of the**
HIV continuum of care. This will include:
- Improved and sustained strong laboratory organizational and technical infrastructure with a well-trained and qualified laboratory workforce
- Increased initialization of policies and procedures to support QMS and CQI leading to sustainable systems improvements

- Improved linkages between the diagnostic and clinical activities in PEPFAR-supported countries. This will include:
  - Improved, maintained and fully functional laboratory networks with MOHs that have adopted laboratory guidelines, policies, and procedures to support access to quality assured diagnostics
  - Improved accuracy and reliability of diagnostic results leading to increased clinical trust and reliance on test results for patient management
  - Decreased frequency and duration of testing interruptions

iii. Strategies and Activities
Applicants may propose additional related project period activities other than those identified in the NOFO.

Provide TA, mentoring, training, and human resources development for laboratories to support improved diagnostic procedures, implementation of innovative diagnostic approaches, QC and QA

- Work collaboratively to provide TA, mentoring, and framework documents that support laboratories to develop, implement, and update their strategic plans and other laboratory guidance
- Work with partners to develop and implement country-specific strategies and activities to ensure access to quality diagnostics by strengthening HIV diagnostic testing, laboratory and point of care (POC) diagnostic quality management, and strengthening laboratory networks and information systems, including specific activities and systems to support EID, VL, and POC testing and monitoring
- Work collaboratively with in-county PEPFAR partners and others to establish and maintain laboratory networks to strengthen development and implementation of HIV diagnostic policies and procedures
- Work collaboratively with PEPFAR partners, including regulatory bodies, licensing boards, and medical and laboratory sciences programs to conduct a comprehensive review of the existing medical laboratory training programs and activities and develop and implement a comprehensive and sustainable training strategy that should include:
  - Strategies to increase training opportunities for laboratory staff using multiple methods which may include in-service training, TA, mentorships, and enhanced medical laboratory science curricula and training programs
  - Convening and coordinating with partners to develop, build consensus, and make available training tools and resources to support basic and advanced diagnostic procedures including TA from consultants SMEs, and information through innovative tools such as e-learning, web-based training, and distance learning platforms
  - Strategies for coordinating with universities and other institutions to develop and
implement laboratory training and capacity development activities focused on in-service opportunities, including continuing education programs and opportunities

**Partner with other organizations and SMEs to develop and implement laboratory networks, with support for uptake and sustainability of QMS and CQI policies and procedures**

- Work in collaboration with PEPFAR-supported partners to develop and implement a comprehensive plan to support QMS with specific activities to strengthen and increase uptake of the: WHO-AFRO SLIPTA Program, SLMTA Program, RTQII, other CQI activities
- Collaborate with PEPFAR-supported countries and other partners to develop and implement a capacity building plan to support the scale up, institutionalization, and sustainability of QMS procedures including specific activities to support VL, EID, and POC testing activities
- Collaborate with HIV and TB laboratories and other partners in PEPFAR-supported countries to develop and disseminate framework documents, job aids, and other tools to support laboratory QMS activities to support HIV and TB-related testing
- Work with partners to review current systems and develop innovative approaches, processes, and policies to:
  - Address system improvements to support better lab and clinical integration, including testing turnaround times
  - Increase and sustain participation and adoption of laboratory QA practices leading to CQI
  - Develop, implement, and operationalize country-specific policies and procedures to ensure the institutionalization of QMS and procedures
  - Support development and implementation of capacity building plans to support the institutionalization and sustainability of CQI system improvements
- Work with partners to establish and maintain a TWG structure to provide input to support program development, implementation, and evaluation of the activities outlined in this NOFO. Focus areas for the TWGs should include, but are not limited to:
  - Coordination across the broad laboratory research agenda for PEPFAR-supported countries to ensure the appropriate use and sharing of data to improve policies, patient care, and surveillance
  - Development and support of collaborations with CDC and other partners, including clinicians, that focus on expanded access to quality diagnostics to support the UNAIDS targets and epidemic control

**Work with other partners to develop and implement in-service training, mentorship, and increase access to SMEs and technical resources to strengthen laboratory and diagnostic testing processes and systems**

- Coordinate with partners to establish and maintain a Pan-African TWG with well-defined Terms of Reference and members drawn from partner organizations, including but not limited to WHO, CDC and PEPFAR partners, in-country laboratory, governing organization representatives, clinicians, and others working to support CQI:
- The TWG should collaborate to develop, implement, and monitor a coordinated framework and plan to improve laboratory quality across PEPFAR-supported countries.
- The TWG should work to harmonize tools, training, and approaches to laboratory quality to ensure maximum impact and resources and prevent duplication of efforts.
- The TWG should collaborate regarding indicators and data collection to improve the ability to measure and determine the impact of PEPFAR efforts to support laboratory quality.
- Coordinate with universities and other institutions to develop and implement a multi-disciplinary training curriculum to support incorporation of laboratory sciences into undergraduate medical training program and vice-versa to encourage joint activities in the healthcare practice. This should include:
  - Work with partners to develop and increase access to updated SOPs, job aids, mentorship opportunities, and other tools for laboratory and clinical staff.
  - Develop and implement a personnel qualifications examination program and committee that would ensure a structured, accessible, and sustainable program to establish standards, including a possible examination to review and certify laboratory professionals to work in PEPFAR-supported laboratory sites.
  - Develop and implement a career development track and plan to identify continued growth opportunities for trained and certified laboratory professionals.
  - Develop and implement an evaluation framework and process to oversee the training and certification activities and ensure continued support with documented impact.
- Work collaboratively to improve communication and technical capacity by developing platforms for dissemination and communication of laboratory science research and practice. This should include ensuring that this information is available in English, French, and Portuguese.
- Collaborate with partners to develop and implement a laboratory strategic communications plan with key stakeholders such as media, patients, civil society, PEPFAR agencies, and others to promote laboratory quality and other key initiatives.
- Develop and maintain communications vehicles, including a scientific journal, professional magazine, and internet groups, and work collaboratively with partners to host local, national, and international events to report research, promote professional development, and support collaborations.
- Develop and maintain a directory of consultants, SMEs, and others who are available as collaborators and TA resources. This should include the areas of expertise and qualifications of the providers, along with a TA coordination plan to build in-country and/or regional capacity by transitioning these activities to local or regional providers.
- Establish and maintain a web portal to support laboratory strengthening initiatives, facilitate communications, and disseminate key information. This should include important program updates and the latest developments in laboratory science, discussion forums, training modules, and other resources.

**Review systems and processes for improving the laboratory and clinical interface**
• Collaborate with other organizations to review country-specific systems and identify comprehensive activities and strategies, including TA and mentoring, to build capacity for laboratorians and others to support:
  o Development and implementation of established diagnostic policies, procedures, and strategic plans
  o Innovative diagnostic approaches
  o Diagnostic QC and QA activities
  o Strengthening of diagnostic referral and transport networks
  o Improved reporting systems to support the increased use of the results to support clinical decision making
  o Improved reporting and monitoring and evaluation systems to monitor clinical outcomes for patients receiving HIV and TB-related laboratory tests in PEPFAR-supported countries
  o The establishment and operationalization of sustainable laboratory networks
  o Development of innovative laboratory information systems and visualization tools
• Work with partners to develop and implement a laboratory error monitoring system focused on improving the quality of diagnosis and increasing healthcare provider confidence and use of the results for clinical decision making

In furtherance of the underlying purpose of this announcement, Recipient is expected to provide copies and/or access to all data, software, tools, training materials, guidelines, and systems developed under this NOFO to MOHs and other relevant stakeholders for appropriate use. CDC should be provided access consistent with applicable grants regulations.

1. Collaborations

a. With other CDC programs and CDC-funded organizations:
The recipient(s) will be expected to collaborate with CDC-funded partners to ensure that all activities are developed in collaboration with PEPFAR-supported laboratory partners, including but not limited to WHO, UNAIDS, Africa CDC, and others to ensure synergies across funding activities and to ensure that all activities are consistent with PEPFAR goals and objectives, WHO normative guidance, national laboratory strategic plans, and other key guidance. The recipient(s) will also be expected to collaborate with CDC-funded MOHs or partner Ministries.

b. With organizations not funded by CDC:
The recipient(s) will be expected to work closely with in-country, regional, and global partners and organizations such as U.S Agency for International Development (USAID), Global Fund, and other PEPFAR partners to conduct the activities outlined in the NOFO and to ensure collaboration and synergies across HIV and TB-related diagnostic and clinical activities. In addition, the recipient(s) will be expected to establish and maintain partnerships and collaborations with non CDC-funded MOHs and partner Ministries, professional laboratory associations, SMEs, technical organizations, and other groups to complete the NOFO activities.

2. Target Populations
The activities outlined in this NOFO will contribute to the HIV and TB-related laboratory system and diagnostic networks in PEPFAR-supported countries and are targeted towards laboratorians, clinical staff, and others who are responsible for the development and implementation of appropriate strategies, partnerships, and collaborations required to support the strengthening of HIV and TB-related diagnostics, treatment, and management across the clinical cascade in PEPFAR-supported countries. PEPFAR supported countries may include, but are not limited to: Angola, Cameroon, Caribbean Region, Cote d'Ivoire, Democratic Republic of Congo, Ethiopia, Kenya, Malawi, Mozambique, Nigeria, South Africa, South Sudan, Tanzania, Uganda, Zambia, and Zimbabwe.

a. Health Disparities
N/A

iv. Funding Strategy
N/A

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy
Applicants should allocate 5% of the budget towards monitoring activities, and 3% of the budget towards evaluation activities.

**Performance Measurement:** Are NOFO outputs being achieved and supportive of PEPFAR Performance Measures?

**Targets and performance measures:**

- PEPFAR-supported laboratories either participating in/and not participating in a CQI program to achieve accreditation.
  - Percentage of laboratories with established policies and guidelines to support laboratory quality, including implementation of SLIPTA, SLMTA, RTQII, and other laboratory CQI activities. 30% of the PEPFAR-supported laboratories during the first year with a goal of 80% by the third year is set as a target for this performance measure*.
- PEPFAR-supported laboratories which have been externally audited but do not meet full accreditation standards, and the number which are fully accredited.
  - Percentage of laboratories supported who achieve accreditation or those that have achieved documented progress towards accreditation. 75% is set as a target for PEPFAR-supported laboratories that achieve documented progress towards accreditation annually*.
- PEPFAR-supported laboratories performing any of following tests: HIV Diagnosis, EID, HIV VL, TB Xpert, TB Acid-fast bacillus (AFB) smear, or TB culture. If performing the analytic-specific test, the number of laboratories participating in and passing PT test for the analytic-specific test.
  - Percentage of laboratories supported that conduct HIV Diagnosis, EID, HIV VL, TB Xpert, TB AFB smear, or TB culture participating in and passing PT test for the analytic-specific test. 40% of the PEPFAR-supported laboratories during the
first year with a goal of 80% by the third year is set as a target for this performance measure*. 

- **Frequency of Reporting:** Quarterly and discussed with CDC and partners at least annually 
- **Data Sources:** Program monitoring data, including: proficiency testing, and other laboratory CQI data; workforce surveys and assessments; Laboratory Information Management System (LIMS) data; and clinical records to assess use of VL results for clinical management. 
- **Reporting Format:** Written reports submitted quarterly with annual discussions and summaries for CDC and partners at least annually

- Percentage of laboratory and clinical staff trained annually to increase awareness of HIV and TB-related diagnostic technologies. 25% of the estimated working in PEPFAR-supported laboratories and testing sites is set as a target for the number of laboratory and clinical staff trained annually*. 
  - **Frequency of Reporting:** Quarterly and discussed with CDC and partners at least annually 
  - **Data Sources:** Program monitoring data, workforce surveys and assessments; LIMS data 
  - **Reporting Format:** Written reports submitted quarterly with annual discussions and summaries for CDC and partners at least annually

- Number of laboratories that develop and implement and/or review and update their strategic plans and other laboratory guidance annually. 85% of the PEPFAR-supported laboratories is set as the annual target for this performance measure.* 
  - **Frequency of Reporting:** Quarterly and discussed with CDC and partners at least annually 
  - **Data Sources:** Program monitoring data, LIMS data 
  - **Reporting Format:** Written reports submitted quarterly with annual discussions and summaries for CDC and partners at least annually

- Number of clinicians reporting increased trust in and reliance on test results for patient management. 60% of the estimated clinicians in PEPFAR-supported countries is set as the annual target for this performance measure. 
  - **Frequency of Reporting:** Quarterly and discussed with CDC and partners at least annually 
  - **Data Sources:** Program monitoring data, including: LIMS data; and clinical records to assess use of test results for clinical management 
  - **Reporting Format:** Written reports submitted quarterly with annual discussions and summaries for CDC and partners at least annually
Number of sustainable partnerships, collaborations, and strategic communications channels developed and maintained, including establishment of a TWG representing key stakeholders such as clinicians, technical experts, and other organizations and professionals working to support the diagnosis, treatment, and management of PLHIV in PEPFAR-supported countries.

- 25 is set as the annual number of new TA partnerships with maintenance and utilization of these resources at 80% throughout the NOFO period.
- Quarterly meetings with participation of no less than 70% of the established members convened via teleconference or other technology is set as the annual target for the full TWG Meetings.
- **Frequency of Reporting:** Quarterly and discussed with CDC and partners at least annually
- **Data Sources:** Program monitoring data, LIMS data; TWG meeting reports and action plan updates
- **Reporting Format:** Written reports submitted quarterly with annual discussions and summaries for CDC and partners at least annually

*The established targets will be confirmed within 6 months following award of the NOFO.

**Evaluation Questions**

**Did the PEPFAR-supported countries conduct evaluations and adopt policies to support the uptake of novel HIV and TB diagnostic technologies as a result of this NOFO?**

- **Type of Evaluation:** Outcome Evaluation
- **Data Source:** Program monitoring data and interviews with those adopting policies; VL/EID quarterly monitoring indicators
- **Collection Method:** Document Review
- **Frequency of Collection:** Quarterly and discussed with CDC and partners at least annually
- **Dissemination:** Provide feedback to CDC and other partners to progress and address issues if applicable

**Did the PEPFAR-supported countries develop and implement policies to support HIV and TB CQI as a result of this NOFO, including policies to ensure the expansion and institutionalization of the customized SLMTA mentorship package components and approaches to address HIV laboratories, diagnostic networks, and testing sites.**

- **Type of Evaluation:** Outcome Evaluation
- **Data Source:** Program monitoring data, including: Proficiency testing, CQI, and Site Assessment data
- **Collection Method:** Document review, survey or interviews among those who implemented SLMTA or other CQI activities
- **Frequency of Collection:** Quarterly monitoring data and discussed with CDC and
partners at least annually; annual interviews
- **Dissemination**: Provide feedback to CDC and other partners to progress and address issues if applicable

**Did HIV test result turnaround times decrease as a result of this NOFO?**

- **Type of Evaluation**: Outcome Evaluation
- **Data Source**: Program monitoring data
- **Collection Method**: Document review and interviews with program staff
- **Frequency of Collection**: Quarterly monitoring data and discussions with CDC and partners at least annually; annual interviews
- **Dissemination**: Provide feedback to CDC and other partners to progress and address issues if applicable

**Performance Measurement**

**Performance Measurement**: *Are NOFO outputs being achieved?*

**Targets and performance measures**: Long-Term Outcomes (5th year):

- Improved and maintained accuracy, reliability, and quality of diagnostic results with improved and maintained clinician trust in and reliance on test results for clinical decision making and patient management leading to improved clinical outcomes for HIV and HIV/AIDS related infections/diseases in PEPFAR-supported countries
- Improved and maintained system-wide processes and approaches which have led to improvements to the diagnostic and clinical interface, including specific activities to support HIV diagnostic testing, laboratory and POC diagnostic quality management, and strengthening laboratory networks and systems, including specific activities to support EID, VL, and POC testing
- Improved and maintained support to ensure the full institutionalization and sustainability of system improvements
- Improved linkages between the diagnostic and clinical activities in PEPFAR-supported countries
- Improved laboratory and diagnostic quality with PEPFAR-supported countries maintaining and implementing policies that ensure the institutionalization of QMS and procedures leading to CQI and sustainable systems improvements
- Improved and maintained innovative approaches, processes, and policies to address system improvements that support better laboratory and clinical linkages, including strategies to improve HIV testing turnaround times and reduce testing interruptions
- Improved and sustained strong laboratory organizational and technical infrastructure with a well-trained and qualified laboratory workforce
- Improved, established, and fully functional systems and processes that ensure access to tools and resources for building and supporting human resources capacity through in-service training, mentorships, and access to high quality TA consultants
- Improved, sustained, and fully functional and effective participation and engagement of
the Laboratory TWG and other laboratory stakeholders leading adoption of laboratory QA practices and to CQI

• Improved, sustained, fully functional, and effective collaborations with CDC and other partners that ensure maintained and expanded access to quality diagnostics to support the UNAIDS targets and epidemic control
• Improved, established, and fully functional sustainable partnerships, collaborations, and strategic communications channels with clinicians, technical experts, and other organizations and professionals working to support the diagnosis, treatment, and management of PLHIV in PEPFAR-supported countries

**Monitoring:**

To what extent did PEPFAR-supported countries increase access to and improve the quality of HIV related diagnostics through HIV laboratory networks and systems, especially EID, VL, and POC?

• **Data Source:** Program monitoring data
• **Collection Method:** Document Review
• **Frequency of Collection:** Quarterly and discussed with CDC and partners, including the TWG at least quarterly
• **Dissemination:** Provide feedback to CDC and other partners, including the TWG regarding progress and address issues if applicable; updates published on the website at least annually after Year 2

To what extent did PEPFAR-supported programs develop policies to ensure expansion and institutionalization of QMS policies and approaches to address HIV-related laboratories, diagnostic networks, and testing sites?

• **Data Source:** Program monitoring data
• **Collection Method:** Document Review
• **Frequency of Collection:** Quarterly and discussed with CDC, TWG and other partners at least annually
• **Dissemination:** Provide feedback to CDC, TWG and other partners, regarding progress and to address issues if applicable

To what extent did PEPFAR-supported programs improve and strengthen laboratory organizational and technical infrastructure, including having a well-trained and qualified laboratory workforce?

• **Data Source:** Program monitoring data; program evaluation data
• **Collection Method:** Document review, training, workshop and course pre and post test results
• **Frequency of Collection:** Quarterly and discussed with CDC and the TWG and other partners at least annually
• **Dissemination:** Provide feedback to CDC, TWG, and other partners to discuss progress
and address issues if applicable; share data via website and other publications

To what extent did PEPFAR-supported countries develop and maintain partnerships and communications to support the clinical cascade and achieve epidemic control and strengthen the laboratory/clinical interface?

- **Data Source:** Program monitoring data
- **Collection Method:** Document Review; partner engagement evaluation; website metrics
- **Frequency of Collection:** Quarterly and discussed with CDC and TWG and other partners at least annually
- **Dissemination:** Provide feedback to CDC, TWG, and other partners regarding progress and address issues if applicable

Evaluations are expected to align with national, PEPFAR, and agency priorities and programmatic gaps, and will be reviewed and approved as part of the Country Operating Plan (COP). As such, the evaluation questions listed in this announcement may be amended based on feedback from the Office of the U.S. Global AIDS Coordinator and Health Diplomacy during the annual COP review process.

**ii. Applicant Evaluation and Performance Measurement Plan**

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this NOFO. At a minimum, the plan must describe:

- How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement.
- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, and other relevant data information (e.g., performance measures proposed by the applicant)
- Plans for updating the Data Management Plan (DMP), if applicable, for accuracy throughout the lifecycle of the project. The DMP should provide a description of the data that will be produced using these NOFO funds; access to data; data standards ensuring released data have documentation describing methods of collection, what the data represent, and data limitations; and archival and long-term data preservation plans. For more information about CDC’s policy on the DMP, see [https://www.cdc.gov/grants/additionalrequirements/ar-25.html](https://www.cdc.gov/grants/additionalrequirements/ar-25.html).

Where the applicant chooses to, or is expected to, take on specific evaluation studies, they should be directed to:

- Describe the type of evaluations (i.e., process, outcome, or both).
- Describe key evaluation questions to be addressed by these evaluations.
• Describe other information (e.g., measures, data sources).

Recipients will be required to submit a more detailed Evaluation and Performance Measurement plan, including a DMP, within the first 6 months of award, as described in the Reporting Section of this NOFO.

c. Organizational Capacity of Recipients to Implement the Approach

Applicants should provide the following materials in the appendix that demonstrate organizational capacity to address the requirements of the NOFO and as described in the Project Description:

• **Statement of experience (maximum 3 pages)** describing the applicant’s organizational capacity working in PEPFAR-supported countries to strengthen laboratory capacity.
  o The statement of experience should demonstrate that the organization has experience building diagnostic capacity to address HIV and HIV-related infections in PEPFAR-supported countries (may include, but are not limited to: Angola, Cameroon, Caribbean Region, Cote d'Ivoire, Democratic Republic of Congo, Ethiopia, Kenya, Malawi, Mozambique, Nigeria, South Africa, South Sudan, Tanzania, Uganda, Zambia, and Zimbabwe). The statement should include but not be limited to experience:
    ▪ Supporting the development and implementation of laboratory workforce development programs and activities
    ▪ Supporting of laboratory policies and procedures; improving access to quality diagnostics and the other activities as described in the NOFO
    ▪ Developing and sustaining effective collaborations and partnerships with key organizations and SMEs to complete work as described in this NOFO, including: 1) names of partners and collaborators, and 2) types of activities conducted through the partnership or collaboration

• **Curricula Vitae (CVs)/Resumes** of the key staff who are currently employed and will work on this activity.
  o Job titles may vary depending on the institution practice, but applicants should provide a CV/Resume for the following key staff in line with the organogram:
    ▪ Principal Investigator (PI)
    ▪ Business Official/Chief Operating Officer
    ▪ Program Directors/Program Managers
    ▪ Communications Officer
    ▪ Deputy of Administration/Administrative Officer
    ▪ Director of Science
    ▪ Head of Finance (if different from the business official)
    ▪ Technical Area Advisors/Lead(s)
    ▪ SI and Monitoring and Evaluation (M&E) Advisors/Lead(s)
  o CVs/Resumes should highlight the skills and experience related to carrying out the proposal; professional experience referenced should be recent, e.g., within the last 2-5 years.

• **Job Descriptions** for all positions key to the performance of the award, including
positions applying less than 100% Level of Effort (LOE) on the award.
  o Job Descriptions should be included for (but are not limited to) the positions
    listed above.
  o Page guidance: 1-2 pages per job description

• **Organizational Chart:** Applicants should submit an organizational chart (organogram)
  for the project. Major focus should be on the staffing structure for the proposed activities.

• **Financial Management Statement (maximum 4 pages):**
  o The financial management statement should describe:
    ▪ Experience managing cooperative agreements or grants involving U.S
      Government funds greater than $1,500,000 per annum
    ▪ Systems and procedures used to manage funds
    ▪ Experience supervising consultants and contractors and using sub-grants
      or other systems of sharing resources with community-based
      organizations or smaller non-governmental organizations
    ▪ Procurement procedures and experience managing procurement processes
  o The financial management statement should also include a 1-2 page (included in
    the 4 page maximum) executive summary from a recent business systems
    assessment, audit, or equivalent which included funds from the U.S Government.
    Assessment described should be recent (e.g. within the last 2 years) and contain
    the following information:
      ▪ Name of the institution/firm conducting the assessment or audit
      ▪ Date of the assessment
      ▪ Period that was assessed and project, if applicable
      ▪ Findings of the assessment/audit

Applicants must title these documents in their appendix as follows: “Experience,”
“CVs/Resumes,” “Job Descriptions,” “Organizational Chart,” “Financial Statement” and upload
it at [www.grants.gov](http://www.grants.gov).

d. **Work Plan**

Applicant must include a work plan that demonstrates how the outcomes, strategies, activities,
timelines, and staffing will take place over the course of the award. Applicants must submit a
detailed work plan for the first year of the project and a high level plan for the subsequent years.

e. **CDC Monitoring and Accountability Approach**

Monitoring activities include routine and ongoing communication between CDC and recipients,
site visits, and recipient reporting (including work plans, performance, and financial reporting).
Consistent with applicable grants regulations and policies, CDC expects the following to be
included in post-award monitoring for grants and cooperative agreements:

- Tracking recipient progress in achieving the desired outcomes.
- Ensuring the adequacy of recipient systems that underlie and generate data reports.
- Creating an environment that fosters integrity in program performance and results.

Monitoring may also include the following activities deemed necessary to monitor the award:
• Ensuring that work plans are feasible based on the budget and consistent with the intent of the award.
• Ensuring that recipients are performing at a sufficient level to achieve outcomes within stated timeframes.
• Working with recipients on adjusting the work plan based on achievement of outcomes, evaluation results and changing budgets.
• Monitoring performance measures (both programmatic and financial) to assure satisfactory performance levels.

Monitoring and reporting activities that assist grants management staff (e.g., grants management officers and specialists, and project officers) in the identification, notification, and management of high-risk recipients.

f. CDC Program Support to Recipients (THIS SECTION APPLIES ONLY TO COOPERATIVE AGREEMENTS)

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring. CDC activities for this program include, but are not limited to, the following:

1. Organize an orientation meeting with the recipient 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 recipient to select key personnel and/or post-award subcontractors and/or subrecipients to be involved in the activities performed under this agreement, as part of PEPFAR Country Operational Plan (COP) review and approval process, managed by the OGAC.

3. Review and approve recipient’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 approve the recipient’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 recipient to assess expenditures in relation to approved work plan and modify plans as necessary.

6. Meet on a quarterly basis with the recipient to assess quarterly technical and financial progress reports and modify plans as necessary.

7. Meet on an annual basis with the recipient 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 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 recipient meet U.S. Government financial and reporting requirements approved by the Office of Management and Budget (OMB).

10. Collaborate with the recipient 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 technical assistance or advice on any data collections on 10 or more people that are planned or conducted by the recipient. All such data collections-- where CDC staff will be or are approving, directing, conducting, managing, or owning data-- must undergo OMB project determinations by CDC and may require OMB PRA clearance prior to the start of the project.

12. Provide consultation and scientific and technical assistance based on appropriate HHS/CDC and OGAC documents to promote the use of best practices known at the time.

13. Assist the recipient in developing and implementing quality-assurance criteria and procedures.

14. Facilitate in-country planning and review meetings for technical assistance activities.

15. Provide technical oversight for all activities under this award.

16. Conduct site visits through the Site Improvement through Monitoring System (SIMS), in compliance with PEPFAR requirements, to monitor and evaluate clinical and community service delivery site capacity to provide high-quality HIV/AIDS services in all program areas and 'above-site' capacity to perform supportive or systemic functions, by assessing and scoring key program area elements of site performance and work with the recipient on identified gaps and continuous quality improvement, which might include more thorough data quality or service quality assessments as indicated.

17. Ensure the recipient’s Evaluation and Performance Measurement Plan is aligned with the strategic information guidance established by OGAC and other HHS/CDC requirements, including PEPFAR’s Monitoring Reporting and Evaluation (MER) strategy, PEPFAR’s Evaluation Standards of Practice, and CDC’s Data for Partner Monitoring Program (DFPM).

18. Provide ethical reviews, as necessary, for evaluation activities, including from HHS/CDC headquarters. Evaluations can be process, outcome or impact.

1. Process Evaluation: measures how the intervention was delivered, what worked/did not, differences between the intended population and the population served, and access to the intervention

2. Outcome Evaluation: determines effects of intervention in target population(s) (e.g., change in knowledge, attitudes, behavior, capacity, etc.).


19. Supply the recipient with protocols for related evaluations.
B. Award Information

1. Funding Instrument Type: Cooperative Agreement
   CDC's substantial involvement in this program appears in the CDC Program Support to Awardees Section.

2. Award Mechanism: U2G

3. Fiscal Year: 2018
4. Approximate Total Fiscal Year Funding: $15,000,000
5. Approximate Project Period Funding: $0

This amount is subject to the availability of funds. The Approximate Project Period Funding/Estimated Total Funding for the Total 5 year Project Period is None. Award ceilings for years 2-5 will be set at continuation.

Estimated Total Funding: $0
6. Total Project Period Length: 5 year(s)
7. Expected Number of Awards: 4

The expected number of awards is 1-4.

8. Approximate Average Award: $3,750,000 Per Budget Period

9. Award Ceiling: $15,000,000 Per Budget Period

This amount is subject to the availability of funds.

10. Award Floor: $0 Per Budget Period

 None

11. Estimated Award Date: 04/01/2018
12. Budget Period Length: 12 month(s)

Throughout the project period, CDC will continue the award based on the availability of funds, the 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. The total number of years for which federal support has been approved (project period) will be shown in the “Notice of Award.” This information does not constitute a commitment by the federal government to fund the entire period. The total period of performance comprises the initial competitive segment and any subsequent non-competitive continuation award(s).

13. Direct Assistance

Direct Assistance (DA) is not available through this FOA.

C. Eligibility Information
### 1. Eligible Applicants

**Eligibility Category:** Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility"

**Additional Eligibility Category:**

**Government Organizations:**
- State governments or their bona fide agents (includes the District of Columbia)
- Local governments or their bona fide agents
- Territorial governments or their bona fide agents in 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.
- State controlled institutions of higher education
- American Indian or Alaska Native tribal governments (federally recognized or state-recognized)

**Non-government Organizations:**
- American Indian or Alaska native tribally designated organizations

**Other:**
- Ministries of Health

### 2. Additional Information on Eligibility

This is a fully competitive NOFO. In addition to the entities listed above in the text field entitled “Eligible Applicants,” the following entities are eligible to apply for this NOFO:
- Government Organizations:
  - Political subdivisions of States (in consultation with States)
- Non-government Organizations:
  - Alaska Native health corporations
  - Tribal epidemiology centers
  - Urban Indian health organizations
  - Nonprofit with 501C3 IRS status (other than institution of higher education)
  - Nonprofit without 501C3 IRS status (other than institution of higher education)
  - Research institutions (that will perform activities deemed as non-research)
- Colleges and Universities
- Community-based organizations
- Faith-based organizations
- For-profit organizations (other than small business)
- Hospitals
- Small, minority, and women-owned businesses
- All Other

The award ceiling for this NOFO is $15,000,000. CDC will consider any application requesting an award higher than this amount as nonresponsive and it will receive no further review.

Late submissions will be determined non-responsive unless a request for extension is approved following the procedure outlined in “Other Submission Requirements, Paper Submission”. Please see “Application and Submission Information,” “Submission Dates and Times” for the application deadline date. Please also see, “Other Submission Requirements” for information on technical difficulties and paper submission. All requests to submit a paper application must be received at least three calendar days prior to the application deadline.

### 3. Justification for Less than Maximum Competition

N/A

### 4. Cost Sharing or Matching

Cost Sharing / Matching Requirement: No

Cost sharing or matching funds are not required for this program. Although there is no statutory match requirement for this NOFO, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

### 5. Maintenance of Effort

Maintenance of effort is not required for this program.

### D. Application and Submission Information

#### 1. Required Registrations

An organization must be registered at the three following locations before it can submit an application for funding at [www.grants.gov](http://www.grants.gov).
a. **Data Universal Numbering System:**
All applicant organizations must obtain a Data Universal Numbering System (DUNS) number. A DUNS number is a unique nine-digit identification number provided by Dun & Bradstreet (D&B). It will be used as the Universal Identifier when applying for federal awards or cooperative agreements.
The applicant organization may request a DUNS number by telephone at 1-866-705-5711 (toll free) or internet at [http://fedgov.dnb.com/webform/displayHomePage.do](http://fedgov.dnb.com/webform/displayHomePage.do). The DUNS number will be provided at no charge.
If funds are awarded to an applicant organization that includes sub-recipients, those sub-recipients must provide their DUNS numbers before accepting any funds.

b. **System for Award Management (SAM):**
The SAM is the primary registrant database for the federal government and the repository into which an entity must submit information required to conduct business as a recipient. All applicant organizations must register with SAM, and will be assigned a SAM number. All information relevant to the SAM number must be current at all times during which the applicant has an application under consideration for funding by CDC. If an award is made, the SAM information must be maintained until a final financial report is submitted or the final payment is received, whichever is later. The SAM registration process can require 10 or more business days, and registration must be renewed annually. Additional information about registration procedures may be found at [www.SAM.gov](http://www.SAM.gov).

c. **Grants.gov:**
The first step in submitting an application online is registering your organization at [www.grants.gov](http://www.grants.gov), the official HHS E-grant Web site. Registration information is located at the “Get Registered” option at [www.grants.gov](http://www.grants.gov).
All applicant organizations must register at [www.grants.gov](http://www.grants.gov). The one-time registration process usually takes not more than five days to complete. Applicants should start the registration process as early as possible.

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<th>Step</th>
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| 1    | Data Universal Number System (DUNS) | 1. Click on [http://fedgov.dnb.com/webform](http://fedgov.dnb.com/webform)  
2. Select Begin DUNS search/request process  
3. Select your country or territory and follow the instructions to obtain your DUNS 9-digit #  
4. Request appropriate staff member(s) to obtain DUNS number, verify & update information under DUNS number | 1-2 Business Days | To confirm that you have been issued a new DUNS number check online at ([http://fedgov.dnb.com/webform](http://fedgov.dnb.com/webform)) or call 1-866-705-5711 |
| 2    | System for | 1. Retrieve organizations | 3-5 Business | For SAM |
2. Request Application Package

Applicants may access the application package at www.grants.gov.

3. Application Package

Applicants must download the SF-424, Application for Federal Assistance, package associated with this notice of funding opportunity at www.grants.gov. If Internet access is not available, or if the online forms cannot be accessed, applicants may call the CDC OGS staff at 770-488-2700 or e-mail OGS ogstims@cdc.gov for assistance. Persons with hearing loss may access CDC telecommunications at TTY 1-888-232-6348.

4. Submission Dates and Times

If the application is not submitted by the deadline published in the NOFO, it will not be processed. Office of Grants Services (OGS) personnel will notify the applicant that their application did not meet the deadline. The applicant must receive pre-approval to submit a paper application (see Other Submission Requirements section for additional details). If the applicant is authorized to submit a paper application, it must be received by the deadline provided by OGS.
a. Letter of Intent Deadline (must be emailed or postmarked by)
Due Date for Letter of Intent: N/A

b. Application Deadline
Due Date for Applications: 10/16/2017, 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov. If Grants.gov is inoperable and cannot receive applications, and circumstances preclude advance notification of an extension, then applications must be submitted by the first business day on which grants.gov operations resume.

Date for Information Conference Call
N/A

5. CDC Assurances and Certifications
All applicants are required to sign and submit “Assurances and Certifications” documents indicated at http://wwwn.cdc.gov/grantassurances/(S(mj444mxct51Inrv1hljijmaa))/Homepage.aspx. Applicants may follow either of the following processes:

- Complete the applicable assurances and certifications with each application submission, name the file “Assurances and Certifications” and upload it as a PDF file with at www.grants.gov
- Complete the applicable assurances and certifications and submit them directly to CDC on an annual basis at http://wwwn.cdc.gov/grantassurances/(S(mj444mxct51Inrv1hljijmaa))/Homepage.aspx

Assurances and certifications submitted directly to CDC will be kept on file for one year and will apply to all applications submitted to CDC by the applicant within one year of the submission date.

Duplication of Efforts
Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual’s time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual’s effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award.
Report Submission: The applicant must upload the report in Grants.gov under “Other Attachment Forms.” The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap.”

6. Content and Form of Application Submission
Applicants are required to include all of the following documents with their application package at www.grants.gov.

7. Letter of Intent
LOI is not requested or required as part of the application for this NOFO.

8. Table of Contents
(There is no page limit. The table of contents is not included in the project narrative page limit.): The applicant must provide, as a separate attachment, the “Table of Contents” for the entire submission package. Provide a detailed table of contents for the entire submission package that includes all of the documents in the application and headings in the "Project Narrative" section. Name the file "Table of Contents" and upload it as a PDF file under "Other Attachment Forms" at www.grants.gov.

9. Project Abstract Summary
(Maximum 1 page)
A project abstract is included on the mandatory documents list and must be submitted at www.grants.gov. The project abstract must be a self-contained, brief summary of the proposed project including the purpose and outcomes. This summary must not include any proprietary or confidential information. Applicants must enter the summary in the "Project Abstract Summary" text box at www.grants.gov.

10. Project Narrative
(Unless specified in the "H. Other Information" section, maximum of 20 pages, single spaced, 12 point font, 1-inch margins, number all pages. This includes the work plan. Content beyond the specified page number will not be reviewed.)
Applicants must submit a Project Narrative with the application forms. Applicants must name this file “Project Narrative” and upload it at www.grants.gov. The Project Narrative must include all of the following headings (including subheadings): Background, Approach, Applicant Evaluation and Performance Measurement Plan, Organizational Capacity of Applicants to Implement the Approach, and Work Plan. The Project Narrative must be succinct, self-explanatory, and in the order outlined in this section. It must address outcomes and activities to be conducted over the entire period of performance as identified in the CDC Project Description section. Applicants should use the federal plain language guidelines and Clear Communication Index to respond to this Notice of Funding Opportunity. Note that recipients should also use these tools when creating public communication materials supported by this NOFO. Failure to follow the guidance and format may negatively impact scoring of the
a. Background
Applicants must provide a description of relevant background information that includes the context of the problem (See CDC Background).

b. Approach

i. Purpose
Applicants must describe in 2-3 sentences specifically how their application will address the public health problem as described in the CDC Background section.

ii. Outcomes
Applicants must clearly identify the outcomes they expect to achieve by the end of the project period, as identified in the logic model in the Approach section of the CDC Project Description. Outcomes are the results that the program intends to achieve and usually indicate the intended direction of change (e.g., increase, decrease).

iii. Strategies and Activities
Applicants must provide a clear and concise description of the strategies and activities they will use to achieve the period of performance outcomes. Applicants must select existing evidence-based strategies that meet their needs, or describe in the Applicant Evaluation and Performance Measurement Plan how these strategies will be evaluated over the course of the project period. See the Strategies and Activities section of the CDC Project Description.

1. Collaborations
Applicants must describe how they will collaborate with programs and organizations either internal or external to CDC. Applicants must address the Collaboration requirements as described in the CDC Project Description.

2. Target Populations and Health Disparities
Applicants must describe the specific target population(s) in their jurisdiction and explain how such a target will achieve the goals of the award and/or alleviate health disparities. The applicants must also address how they will include specific populations that can benefit from the program that is described in the Approach section. Applicants must address the Target Populations and Health Disparities requirements as described in the CDC Project Description.

c. Applicant Evaluation and Performance Measurement Plan
Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this NOFO. At a minimum, the plan must describe:
• How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement. The Paperwork Reduction Act of 1995 (PRA): Applicants are advised that any activities involving information collections (e.g., surveys, questionnaires, applications, audits, data requests, reporting, recordkeeping and disclosure requirements) from 10 or more individuals or non-Federal entities, including State and local governmental agencies, and funded or sponsored by the Federal Government are subject to review and approval by the Office of Management and Budget. For further information about CDC’s requirements under PRA see http://www.hhs.gov/ocio/policy/collection/.
• How key program partners will participate in the evaluation and performance measurement planning processes.
• Available data sources, feasibility of collecting appropriate evaluation and performance data, data management plan (DMP), and other relevant data information (e.g., performance measures proposed by the applicant).

Where the applicant chooses to, or is expected to, take on specific evaluation studies, they should be directed to:

• Describe the type of evaluations (i.e., process, outcome, or both).
• Describe key evaluation questions to be addressed by these evaluations.
• Describe other information (e.g., measures, data sources).

Recipients will be required to submit a more detailed Evaluation and Performance Measurement plan (including the DMP elements) within the first 6 months of award, as described in the Reporting Section of this NOFO.

d. Organizational Capacity of Applicants to Implement the Approach

Applicants must address the organizational capacity requirements as described in the CDC Project Description.

Applicants must title these documents in their appendix as follows: “Experience,” “CVs/Resumes,” “Job Descriptions,” “Organizational Chart,” “Financial Statement” and upload it at www.grants.gov.

11. Work Plan

(Included in the Project Narrative’s page limit)

Applicants must prepare a work plan consistent with the CDC Project Description Work Plan section. The work plan integrates and delineates more specifically how the recipient plans to carry out achieving the period of performance outcomes, strategies and activities, evaluation and performance measurement.

12. Budget Narrative
Applicants must submit an itemized budget narrative. When developing the budget narrative, applicants must consider whether the proposed budget is reasonable and consistent with the purpose, outcomes, and program strategy outlined in the project narrative. The budget must include:

- Salaries and wages
- Fringe benefits
- Consultant costs
- Equipment
- Supplies
- Travel
- Other categories
- Contractual costs
- Total Direct costs
- Total Indirect costs

Indirect costs could include the cost of collecting, managing, sharing and preserving data. Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.

If applicable and consistent with the cited statutory authority for this announcement, applicant entities may use funds for activities as they relate to the intent of this NOFO to meet national standards or seek health department accreditation through the Public Health Accreditation Board (see: http://www.phaboard.org). Applicant entities to whom this provision applies include state, local, territorial governments (including 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), or their bona fide agents, political subdivisions of states (in consultation with states), federally recognized or state-recognized American Indian or Alaska Native tribal governments, and American Indian or Alaska Native tribally designated organizations. Activities include those that enable a public health organization to deliver public health services such as activities that ensure a capable and qualified workforce, up-to-date information systems, and the capability to assess and respond to public health needs. Use of these funds must focus on achieving a minimum of one national standard that supports the intent of the NOFO. Proposed activities must be included in the budget narrative and must indicate which standards will be addressed.

Applicants must name this file “Budget Narrative” and upload it as a PDF file at www.grants.gov. If requesting indirect costs in the budget, a copy of the indirect cost-rate agreement is required. If the indirect costs are requested, include a copy of the current negotiated federal indirect cost rate agreement or a cost allocation plan approval letter for those Recipients under such a plan. Applicants must name this file “Indirect Cost Rate” and upload it at www.grants.gov.
13. Funds Tracking
Proper fiscal oversight is critical to maintaining public trust in the stewardship of federal funds. Effective October 1, 2013, a new HHS policy on subaccounts requires the CDC to set up payment subaccounts within the Payment Management System (PMS) for all new grant awards. Funds awarded in support of approved activities and drawdown instructions will be identified on the Notice of Award in a newly established PMS subaccount (P subaccount). Recipients will be required to draw down funds from award-specific accounts in the PMS. Ultimately, the subaccounts will provide recipients and CDC a more detailed and precise understanding of financial transactions. The successful applicant will be required to track funds by P-accounts/sub accounts for each project/cooperative agreement awarded. Applicants are encouraged to demonstrate a record of fiscal responsibility and the ability to provide sufficient and effective oversight. Financial management systems must meet the requirements as described 2 CFR 200 which include, but are not limited to, the following:

- Records that identify adequately the source and application of funds for federally-funded activities.
- Effective control over, and accountability for, all funds, property, and other assets.
- Comparison of expenditures with budget amounts for each Federal award.
- Written procedures to implement payment requirements.
- Written procedures for determining cost allowability.
- Written procedures for financial reporting and monitoring.

14. Intergovernmental Review

Executive Order 12372 does not apply to this program.

15. Pilot Program for Enhancement of Employee Whistleblower Protections
Pilot Program for Enhancement of Employee Whistleblower Protections: All applicants will be subject to a term and condition that applies the terms of 48 Code of Federal Regulations (CFR) section 3.908 to the award and requires that recipients inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC’s Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient’s submitting author
must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient’s submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.

The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

### 17. Funding Restrictions

Restrictions that must be considered while planning the programs and writing the budget are:

- Recipients may not use funds for research.
- Recipients may not use funds for clinical care except as allowed by law.
- Recipients may use funds only for reasonable program purposes, including personnel, travel, supplies, and services.
- Generally, recipients may not use funds to purchase furniture or equipment. Any such proposed spending must be clearly identified in the budget.
- Reimbursement of pre-award costs generally is not allowed, unless the CDC provides written approval to the recipient.
- Other than for normal and recognized executive-legislative relationships, no funds may be used for:
  - publicity or propaganda purposes, for the preparation, distribution, or use of any material designed to support or defeat the enactment of legislation before any legislative body
  - the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before any legislative body
- See [Additional Requirement (AR) 12](#) for detailed guidance on this prohibition and [additional guidance on lobbying for CDC recipients](#).
- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project outcomes and not merely serve as a conduit for an award to another party or provider who is ineligible.
- In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs
that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability (https://www.cdc.gov/grants/additionalrequirements/ar-35.html).

- Indirect costs on grants awarded to foreign organizations and foreign public entities, and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization. Indirect costs will not be reimbursed under grants to foreign organizations, international organizations, and foreign components of grants to domestic organizations (does not affect indirect cost reimbursement to the domestic entity for domestic activities).
- 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 recipients for currency exchange fluctuations through the issuance of supplemental awards.

**Public Financial Management Clause**

- The Parties acknowledge that HHS/CDC has assessed the recipient’s systems required to manage the activities supported with US Government funds under this Agreement and that this Agreement is expressly conditioned upon that assessment, as well as any measures, mitigation or means by which the recipient has or will address the vulnerabilities or weaknesses, if any, found in that assessment. The recipient agrees to take the necessary action(s) to address the recommendations or requirements of the assessment as agreed separately in writing with HHS/CDC in accordance with an action plan to be jointly developed to address such recommendations or as otherwise contained in this agreement.

**Conscience Clause**

An organization, including a faith-based organization, that is otherwise eligible to receive funds under this agreement for HIV/AIDS prevention, treatment, or care—

- Shall not be required, as a condition of receiving such assistance—
- To endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS; or
- To endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection; and
• Shall not be discriminated against in the solicitation or issuance of grants, contracts, or cooperative agreements for refusing to meet any requirement described above.

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

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

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

Needle Exchange
• No funds made available under this award may be used for needle exchange programs.

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

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

**Prostitution and Sex Trafficking**

- A standard term and condition of award will be included in the final notice of award; all applicants will be subject to a term and condition that none of the funds made available under this award may be used to promote or advocate the legalization or practice of prostitution or sex trafficking. In addition, non-U.S. nongovernmental organizations will also be subject to an additional term and condition requiring the organization’s opposition to the practices of prostitution and sex trafficking. Any enforcement of this provision is subject to courts’ orders in Alliance for Open Society International v. USAID (See, e.g., S.D.N.Y. 05 Civ. 8209, Orders filed on January 30, 2015 and June 6, 2017, granting permanent injunction).

**Trafficking in Persons Provision**

- No contractor or subrecipient under this Agreement that is a private entity may, during the period of time that the award is in effect:
  - engage in trafficking in persons, as defined in the Protocol to Prevent, Suppress, and Punish Trafficking in Persons, especially Women and Children, supplementing the UN Convention against Transnational Organized Crime;
  - procure any sex act on account of which anything of value is given to or received by any person; or
  - use forced labor in the performance of this award.
- If HHS/CDC determines that there is a reasonable basis to believe that any private party contractor or subrecipient has violated paragraph 1 of this section or that an employee of the contractor or subrecipient has violated such a prohibition where that the employee’s conduct is associated with the performance of this award or may be imputed to the contractor or subrecipient, HHS/CDC may, without penalty, (i) require the Recipient to terminate immediately the contract or subaward in question or (ii) unilaterally terminate this Agreement in accordance with the termination provision.
- For purposes of this provision, “employee” means an individual who is engaged in the performance in any part of the Project as a direct employee, consultant, or volunteer of any private party contractor or subrecipient.
- The Applicant must include in all subagreements, including subawards and contracts, a provision prohibiting the conduct described in subsection a by private party subrecipients, contractors, or any of their employees.
Prohibition on Assistance to Drug Traffickers

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

Financing of Terrorism

- Consistent with numerous United Nations Security Council resolutions, including UNSCR 1267 (1999) (http://www.undemocracy.com/S-RES-1267(1999).pdf), UNSCR 1368 (2001) (http://www.undemocracy.com/S-RES-1368(2001).pdf), UNSCR 1373 (2001) (http://www.undemocracy.com/S-RES-1373(2001).pdf), and UNSCR 1989 (2011), both HHS/CDC and the Applicant are firmly committed to the international fight against terrorism, and in particular, against the financing of terrorism. It is the policy of HHS/CDC to seek to ensure that none of its funds are used, directly or indirectly, to provide support to individuals or entities associated with terrorism. In accordance with this policy, the Applicant agrees to use reasonable efforts to ensure that none of the HHS/CDC funds provided under this Agreement are used to provide support to individuals or entities associated with terrorism, including those identified on the U.S. Department of Treasury Office of Foreign Assets Control Specially Designated Nationals List. This provision must be included in all subagreements, including contracts and subawards, issued under this award.

Restriction on Assistance for Military or Paramilitary Purposes or for Police and Prisons

- No funds or other support provided under the award may be used for support to any military or paramilitary force or activity, or for support to any police, prison authority, or other security or law enforcement forces without the prior written consent of HHS/CDC.

UN Security Council Sanctions List

- It is the policy of HHS/CDC to seek to ensure that none of its funds are used, directly or indirectly, to provide support to individuals or entities designated for United Nations
Security Council sanctions. In accordance with this policy, the applicant agrees to use reasonable efforts to ensure that none of the funds provided under this grant are used to provide support of individuals or entities designated for UN Security Council sanctions (compendium of Security Council Targeted Sanctions Lists at: http://www.un.org/sc/committees/list_compend.shtml). This provision must be included in all sub-agreements, including contracts and sub-awards, issued under this award.

Worker’s Rights

- No funds or other support provided hereunder may be used for any activity that contributes to the violation of internationally recognized workers’ rights of workers in the recipient country.
- In the event the Applicant is requested or wishes to provide assistance in areas that involve workers’ rights or the Applicant requires clarification from HHS/CDC as to whether the activity would be consistent with the limitation set forth above, the Applicant must notify HHS/CDC and provide a detailed description of the proposed activity. The Applicant must not proceed with the activity until advised by HHS/CDC that it may do so.
- The Applicant must ensure that all employees and subcontractors and sub-recipients providing employment-related services hereunder are made aware of the restrictions set forth in this clause and must include this clause in all subcontracts and other sub-agreements entered into hereunder.
- The term “internationally recognized worker rights” includes-- the right of association; the right to organize and bargain collectively; a prohibition on the use of any form of forced or compulsory labor; a minimum age for the employment of children, and a prohibition on the worst forms of child labor; and acceptable conditions of work with respect to minimum wages, hours of work, and occupational safety and health.
- The term “worst forms of child labor” means-- all forms of slavery or practices similar to slavery, such as the sale or trafficking of children, debt bondage and servitude, or forced or compulsory labor, including forced or compulsory recruitment of children for use in armed conflict; the use, procuring, or offering of a child for prostitution, for the production of pornography or for pornographic purposes; the use, procuring, or offering of a child for illicit activities in particular for the production and trafficking of drugs; and work which, by its nature or the circumstances in which it is carried out, is likely to harm the health, safety, or morals of children, as determined by the laws, regulations, or competent authority of the country.

Investment Promotion

- No funds or other support provided hereunder may be used to provide a financial incentive to a business enterprise currently located in the United States for the purpose of inducing such an enterprise to relocate outside the United States if such incentive or inducement is likely to reduce the number of employees of such business enterprise in the United States because United States production is being replaced by such enterprise outside the United States.
- In the event the Applicant requires clarification from HHS/CDC as to whether the
activity would be consistent with the limitation set forth above, the Applicant must notify HHS/CDC and provide a detailed description of the proposed activity. The Applicant must not proceed with the activity until advised by HHS/CDC that it may do so.

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

**Contract Insurance Requirement**

- To the extent that a host government partner enters into contracts expressly approved by the U.S. government, the host country government partner shall ensure that its contractors or subcontractors (a) provide, before commencing performance under any contracts or subcontracts funded under this agreement, such workers’ compensation insurance or security as required by HHS/CDC and (b) continue to maintain such insurance until performance is completed. The host country government partner shall insert, in all contracts and subcontracts under this agreement, a clause similar to this clause (including this sentence) imposing upon those contractors and subcontractors the obligation to obtain workers’ compensation insurance or security as required by HHS/CDC.

**Source and Nationality and Other Procurement Restrictions**

- Disbursements will be used exclusively to finance the costs of goods and services required for this Agreement [in accordance with 22 CFR 228, and] having their source and nationality in countries [included in Geographic Code [937 or 935]] OR [identified in subsection 6 below], except as HHS/CDC may otherwise agree in writing and as follows:
  - Ocean transportation costs must be financed under the Agreement only on vessels under flag registry of [countries included in Code 935] OR [the following countries: LIST. Also see subsection 7 below on use of U.S.-flag vessels.
  - Any motor vehicles financed under the Agreement will be of United States manufacture, except as HHS/CDC may otherwise agree in writing.
- The nationality of the contractor providing ocean and air shipping services will be deemed to be the ocean vessel's or aircraft's country of registry at the time of shipment.
- Provisions concerning restricted and ineligible goods and services may be provided in subsequent written communications between the parties. Special procurement rules apply to agricultural commodities, pharmaceuticals, pesticides, and fertilizer, none of which may be procured without advance written consent of HHS/CDC.
- Transportation by air of property or persons financed under this agreement will be on carriers holding United States certification to the extent service by such carriers is available under the Fly America Act. This requirement may be further described by HHS/CDC in subsequent written communications between the parties.
- Eligibility Date. No goods or services may be financed under the Agreement which are procured pursuant to orders or contracts firmly placed or entered into prior to the date of
this Agreement, except as the Parties may otherwise agree in writing.
• Eligible countries for procurement: HHS/CDC to identify for specific agreement.
• Transportation
  o In addition to the requirements in subsection 1 above, costs of ocean or air transportation and related delivery services may not be financed under this Agreement, if the costs are for transportation under an ocean vessel or air charter which has not received prior HHS/CDC approval.
  o Unless HHS/CDC determines that privately owned U.S.-flag commercial ocean vessels are not available at fair and reasonable rates for such vessels, or otherwise agrees in writing:
    ▪ At least fifty percent (50%) of the gross tonnage of all goods (computed separately for dry bulk carriers, dry cargo liners and tankers) financed by HHS/CDC which may be transported on ocean vessels will be transported on privately owned U.S.-flag commercial vessels; and
    ▪ At least fifty percent (50%) of the gross freight revenue generated by all shipments financed by HHS/CDC and transported to the territory of the Recipient on dry cargo liners shall be paid to or for the benefit of privately owned U.S.-flag commercial vessels. Compliance with the requirements of (1) and (2) of this subsection must be achieved with respect to both any cargo transported from U.S. ports and any cargo transported from non-U.S. ports, computed separately.

Environmental Impact Statement

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

• The Applicant is required to create and follow an environmental mitigation plan and report (EMPR) for each thematic area covered by this agreement. The EMPR shall include the following:
  o Coversheet;
  o Narrative with project specific information, including level of effort;
  o Annexes:
    ▪ Environmental Screening Form (Table 1);
    ▪ Identification of Mitigation Plan (Table 2);
    ▪ Environmental Monitoring and Tracking Table (Table 3);
    ▪ Photos and Maps, as appropriate.
• The EMPR will capture potential environmental impacts and also inform whether a supplemental Initial Environmental Examination (IEE) is required and should be completed and submitted to HHS/CDC.

Attribution to PEPFAR

• All PEPFAR-related accepted abstracts presented by implementing partners during any conference (regardless of conference/meeting size) must be attributed to PEPFAR. All posters must include the PEPFAR logo as well as the following language: “This research
has been supported by the President’s Emergency Plan for AIDS Relief (PEPFAR) through HHS/CDC under the terms of CDC-RFA-GH18-1805.”

PEPFAR Branding

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

Using PEPFAR funds for Implementing Partners (IPs) and Partner Government Officials

IPs are required to notify their Project Officer immediately upon abstract acceptance. Once accepted, IPs are required to submit a written justification to their Project Officer stating the rationale for seeking support to attend the conference. IPs with accepted oral posters or oral abstracts for presentations that give clear attribution to PEPFAR may be authorized to use PEPFAR funds for travel providing that funds are available for travel. Funds for travel must be drawn from an existing agreement with the IP and not from PEPFAR country program management and operations budget. IPs must obtain prior approval from their respective Project Officer for participation and on availability and use of funds.

PEPFAR partner government officials who wish to attend any large conference using PEPFAR funds must submit requests to the Project Officer, who will work with this PEPFAR Coordination office in-country, or to the designated PEPFAR Point of Contact in countries without Coordinators. Final decisions will be made in collaboration with the PEPFAR Deputy Principals and responses will be circulated to Post.

Requirements for Voluntary Family Planning Projects

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

- (5) A person must not be denied any right or benefit, including the right of access to participate in any program of general welfare or health care, based on the person’s decision not to accept family planning services offered by the project.

- The project must provide family planning acceptors comprehensible information about the health benefits and risks of the method chosen, including those conditions that might render the use of the method inadvisable and those adverse side effects known to be consequent to the use of the method. This requirement may be satisfied by providing information in accordance with the medical practices and standards and health conditions in the country where the project is conducted through counseling, brochures, posters, or package inserts.
  - The recipient must notify CDC when it learns about an alleged violation in the requirements for voluntary family planning projects described in paragraphs (3), (4), or (5), above.
  - The recipient must investigate and take appropriate corrective action, if necessary, when it learns about an alleged violation and must notify CDC about violations in a project affecting a number of people over a period of time that indicate there is a systemic problem in the project.
  - The recipient must provide CDC such additional information about violations as CDC may request.

**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) 2018, the limit is no more than 8 percent of the country’s FY2018 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-recipient. 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-recipients, 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 NOFO. 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 NOFO 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 NOFO. For example, the proposal should state that the applicant has $_________ in FY2018 grants and cooperative agreements (for as many fiscal years as applicable) in the country(ies) covered by this NOFO. For additional information concerning this NOFO, please contact the Grants Management Officer for this NOFO.

The 8% rule does not apply to Brazil, Cameroon, Mali, Senegal, Sierra Leone, Central America Regional Office, or the Asia Regional Office because these countries are not required to have a Country Operations Plan (COP) in place.

Monitoring and Evaluation Section (SIMS)

- HHS/CDC or its designee will also undertake monitoring and evaluation of the defined activities within the agreement. The recipient must ensure reasonable access by HHS/CDC or its designee to all necessary sites, documentation, individuals and information to monitor, evaluate and verify the appropriate implementation the Activities and use of HHS/CDC funding under this Agreement, must require a provision to this effect in all sub-awards or contracts financed by funds under this Agreement. Where applicable, this includes support for, and response to, activities associated with the Site Improvement through Monitoring System.

Monitoring Reporting and Evaluation

- CDC programs must ensure that recipient’s Evaluation and Performance Measurement Plan is aligned with the strategic information guidance established by OGAC and other HHS/CDC requirements, including PEPFAR’s Monitoring Reporting and Evaluation (MER) strategy and CDC’s Data for Partner Monitoring Program (DFPM). All
evaluations conducted with PEPFAR funds must submit an evaluation report following the format included in Appendix C of PEPFAR Evaluation Standards of Practice http://www.pepfar.gov/documents/organization/247074.pdf.

Human Subjects Restrictions for PEPFAR Awards

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.

Data collection protocols required for release of human subjects funding restrictions must be submitted to the DGHT 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 Recipient has not been granted an exception to the deadlines specified above.

18. Data Management Plan

As identified in the Evaluation and Performance Measurement section, applications involving data collection must include a Data Management Plan (DMP) as part of their evaluation and performance measurement plan. The DMP is the applicant’s assurance of the quality of the public health data through the data’s lifecycle and plans to deposit data in a repository to preserve and to make the data accessible in a timely manner. See web link for additional information:

https://www.cdc.gov/grants/additionalrequirements/ar-25.html

19. Other Submission Requirements

a. Electronic Submission: Applications must be submitted electronically at www.grants.gov. The application package can be downloaded at www.grants.gov. Applicants can complete the application package off-line and submit the application by uploading it at www.grants.gov. All application attachments must be submitted using a PDF file format. Directions for creating PDF files can be found at www.grants.gov. File formats other than PDF may not be readable by OGS Technical Information Management Section (TIMS) staff.

Applications must be submitted electronically by using the forms and instructions posted for this notice of funding opportunity at www.grants.gov.

If Internet access is not available or if the forms cannot be accessed online, applicants may contact the OGS TIMS staff at 770- 488-2700 or by e-mail at ogstims@cdc.gov. Monday
through Friday, 7:30 a.m.–4:30 p.m., except federal holidays. Electronic applications will be considered successful if they are available to OGS TIMS staff for processing from www.grants.gov on the deadline date.

b. Tracking Number: Applications submitted through www.grants.gov are time/date stamped electronically and assigned a tracking number. The applicant’s Authorized Organization Representative (AOR) will be sent an e-mail notice of receipt when www.grants.gov receives the application. The tracking number documents that the application has been submitted and initiates the required electronic validation process before the application is made available to CDC.

c. Validation Process: Application submission is not concluded until the validation process is completed successfully. After the application package is submitted, the applicant will receive a “submission receipt” e-mail generated by www.grants.gov. A second e-mail message to applicants will then be generated by www.grants.gov that will either validate or reject the submitted application package. This validation process may take as long as two business days. Applicants are strongly encouraged to check the status of their application to ensure that submission of their package has been completed and no submission errors have occurred. Applicants also are strongly encouraged to allocate ample time for filing to guarantee that their application can be submitted and validated by the deadline published in the NOFO. Non-validated applications will not be accepted after the published application deadline date.

If you do not receive a “validation” e-mail within two business days of application submission, please contact www.grants.gov. For instructions on how to track your application, refer to the e-mail message generated at the time of application submission or the Grants.gov Online User Guide.

d. Technical Difficulties: If technical difficulties are encountered at www.grants.gov, applicants should contact Customer Service at www.grants.gov. The www.grants.gov Contact Center is available 24 hours a day, 7 days a week, except federal holidays. The Contact Center is available by phone at 1-800-518-4726 or by e-mail at support@grants.gov. Application submissions sent by e-mail or fax, or on CDs or thumb drives will not be accepted. Please note that www.grants.gov is managed by HHS.

e. Paper Submission: If technical difficulties are encountered at www.grants.gov, applicants should call the www.grants.gov Contact Center at 1-800-518-4726 or e-mail them at support@grants.gov for assistance. After consulting with the Contact Center, if the technical difficulties remain unresolved and electronic submission is not possible, applicants may e-mail CDC GMO/GMS, before the deadline, and request permission to submit a paper application. Such requests are handled on a case-by-case basis. An applicant’s request for permission to submit a paper application must:

1. Include the www.grants.gov case number assigned to the inquiry
2. Describe the difficulties that prevent electronic submission and the efforts taken with
the www.grants.gov Contact Center to submit electronically; and
3. Be received via e-mail to the GMS/GMO listed below at least three calendar days before the application deadline. Paper applications submitted without prior approval will not be considered.

If a paper application is authorized, OGS will advise the applicant of specific instructions for submitting the application (e.g., original and two hard copies of the application by U.S. mail or express delivery service).

### E. Review and Selection Process

#### 1. Review and Selection Process: Applications will be reviewed in three phases

**a. Phase 1 Review**

All applications will be initially reviewed for eligibility and completeness by CDC Office of Grants Services. Complete applications will be reviewed for responsiveness by the Grants Management Officials and Program Officials. Non-responsive applications will not advance to Phase II review. Applicants will be notified that their applications did not meet eligibility and/or published submission requirements.

**b. Phase II Review**

A review panel will evaluate complete, eligible applications in accordance with the criteria below.

i. **Approach**
   - Evaluation and Performance Measurement
   - Applicant’s Organizational Capacity to Implement the Approach

Not more than thirty days after the Phase II review is completed, applicants will be notified electronically if their application does not meet eligibility or published submission requirements.

<table>
<thead>
<tr>
<th>i. Approach</th>
<th>Maximum Points:35</th>
</tr>
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</table>

- How well does the application outline an overall strategy with measurable timelines and specific activities for meeting the proposed programmatic outcomes? Specifically, does the plan clearly outline activities to: 1) increase access to quality diagnostic services through strong, efficient laboratory networks and development and utilization of policies, procedures, and laboratory strategic plans at all levels of the laboratory network; and 2) increase utilization of QMS systems and tools such as EQA, SLIPTA, SLMTA, RTQII, and other CQI activities with increased accuracy and reliability of diagnostic results leading to increased use for clinical decision making and improved clinical outcomes for HIV and HIV-related infections/diseases in PEPFAR-supported countries? (10 points)
- To what extent does the applicant clearly describe and outline strategies and activities focused on strengthening laboratory organizational and technical infrastructure through a well-trained and qualified laboratory workforce and increased human resources
capacity leading to a qualified laboratory workforce with the expertise necessary to support the HIV continuum of care? (5 points)

- To what extent does the proposal include clear plans and strategies to coordinate and collaborate with existing PEPFAR partners, including MOH officials and other donors including the Global Fund, USAID, and other U.S. Government Departments and agencies? (5 points)
- To what extent does the applicant clearly outline a plan to increase partnerships, collaborations, and strategic communications with clinicians, technical experts and other professionals to strengthen the laboratory clinical interface and improve diagnosis, treatment, and management of PLHIV in PEPFAR-supported countries? (5 points)
- To what extent is the applicant’s planned approach feasible to meet the target goals, including whether the proposed use of funds is efficient, and the extent to which the specific methods described are sensitive to the local cultures in PEPFAR-supported countries? (5 points)
- To what extent does the proposal reflect organizational experience building the capacity of indigenous organizations in PEPFAR-supported countries, including an adequate and measurable plan to progressively build the capacity of local organizations to respond to the epidemic, and specifically to build local laboratory capacity? If not a local indigenous organization, does the applicant articulate a clear exit strategy which will maximize the legacy of this project in the target populations and countries? Does the applicant clearly outline an evolving role for local partners which includes the transfer of critical technical and management competence to local organizations? (5 points)

### ii. Evaluation and Performance Measurement

- Maximum Points: 25

- To what extent does the applicant demonstrate the PEPFAR country level experience and capability to implement performance monitoring of the project? (5 points)
- To what extent does the applicant demonstrate the PEPFAR country level experience and capability to implement rigorous evaluation of the project? (5 points)
- To what extent does the evaluation and performance measurement plan appropriately address the components specified in the NOFO (i.e., key evaluation questions, types of evaluations to be conducted, performance measures (i.e., indicators), how often performance measures must be reported, how the evaluation data will be used to demonstrate the value of the interventions, and how results will be disseminated)? (10 points)
- To what extent 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? (5 points)

### iii. Applicant's Organizational Capacity to Implement the Approach

- Maximum Points: 40

- How well does the applicant demonstrate a history working to strengthen laboratory programs in PEPFAR-supported countries (may include, but not limited to: Angola, Cameroon, Caribbean Region, Cote d'Ivoire, Democratic Republic of Congo, Ethiopia, Kenya, Malawi, Mozambique, Nigeria, South Africa, South Sudan, Tanzania, Uganda,
Zambia, and Zimbabwe)? Does the documentation provided clearly demonstrate that the organization has experience working in PEPFAR-supported countries, including but not limited to those listed above? (10 points)

- To what extent do the appendix materials demonstrate the experience and qualifications to achieve the following: 1) ensure access to quality diagnostics by strengthening HIV diagnostic testing though strengthening laboratory networks and systems, including country-specific laboratory policies and strategic plans with specific activities to support EID, VL, and POC laboratory testing; 2) support Laboratory QMS through the SLIPTA and SLMTA Programs, and increased uptake of the RTQII and other CQI activities; 3) strengthen laboratory organizational and technical infrastructure through a well-trained and qualified laboratory workforce and increased human resources capacity through in-service training, mentorships, and access to high quality TA consultants and information; and 4) develop and maintain partnerships and communications to support the clinical cascade and achieve epidemic control and strengthen the laboratory/clinical interface? (10 points)

- To what extent does the applicant clearly document experience in building strong administration and management systems to support 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, as documented by CVs/Resumes or other appendix materials, sufficient to ensure speedy implementation of the project? To what extent does the applicant have a proven track record managing budgets in excess of $1,500,000 per annum, supervising consultants and contractors, and using sub-grants or other systems of sharing resources with community-based organizations or smaller non-governmental organizations? (10 points)

- To what extent does the applicant document a clear and concise understanding of the current PEPFAR HIV priorities and response in the area of diagnostics, and to what extent does the applicant propose to build and complement the current response? How well does the applicant clearly document and propose sufficient staff to meet the goals of the proposed project, specifically staff with experience supporting and building networks for strong diagnostic capacity to address HIV in PEPFAR-supported countries? (10 points)

**Budget**

**Budget (reviewed 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?

**c. Phase III Review**

In addition, the following factors also may affect the funding decision: Funding Preferences
Funding Preferences (15 points):

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

Funding Preference 1: Preference to local and indigenous organizations.

Deliverable 1: Letter from the PI clearly demonstrating how the organization meets the published criteria of a PEPFAR local partner

Label for Deliverable 1: Local Partner preference

Each funding preference deliverable must be submitted as part of the appendix, clearly named using the label for the deliverable above, and uploaded as a PDF file at www.grants.gov. Funding preference points will not be awarded to applicants who do not provide the required deliverable for the applicable funding preference. Funding preference points will not be awarded to applicants who fail to label the supporting documentation as required to certify the deliverable for the funding preference.

Applications will be funded in order by score and rank determined by the review panel unless funding preferences or other considerations stated in this NOFO apply. Final selection and approval of activities will be prioritized in collaboration with CDC. After completion of the Phase II Review, applicants are placed in rank order based on their overall score from the objective review panel and funding preference if applicable. In the event two or more applicants are tied for top ranked, CDC will conduct a further review of the applicants tied for highest rank. CDC will deem the applicant with the highest overall score in the Approach section as top ranked. In the event there is still a tie, CDC will move to the Applicant’s Organizational Capacity Section to Implement the Approach and will deem the applicant with the highest overall score in that section as top ranked. CDC will provide justification for any decision to fund out of rank order.

Review of risk posed by applicants.

Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.

In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Recipient Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR
§75.207. CDC’s framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this Notice of Funding Opportunity.

In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:
(1) Financial stability;
(2) Quality of management systems and ability to meet the management standards prescribed in this part;
(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
(4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and
(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

2. Announcement and Anticipated Award Dates
The anticipated announcement date is February 2018. The award date will be April 1, 2018.

F. Award Administration Information

1. Award Notices
Recipients will receive an electronic copy of the Notice of Award (NOA) from CDC OGS. The NOA shall be the only binding, authorizing document between the recipient and CDC. The NOA will be signed by an authorized GMO and emailed to the Recipient Business Officer listed in application and the Program Director.

Any applicant awarded funds in response to this Notice of Funding Opportunity will be subject to the DUNS, SAM Registration, and Federal Funding Accountability And Transparency Act Of 2006 (FFATA) requirements.

Unsuccessful applicants will receive notification of these results by e-mail with delivery receipt or by U.S. mail.
2. Administrative and National Policy Requirements


The following administrative requirements apply to this project:

Generally applicable administrative requirements (ARs):

- AR-10: Smoke-Free Workplace
- AR-12: Lobbying Restrictions
- AR-14: Accounting System Requirements
- AR-16: Security Clearance Requirement
- AR-21: Small, Minority, And Women-owned Business
- AR-24: Health Insurance Portability and Accountability Act
- AR-25: Release and Sharing of Data
- AR-26: National Historic Preservation Act of 1966
- AR-29: Compliance with EO13513, “Federal Leadership on Reducing Text Messaging while Driving,” October 1, 2009
- AR-30: Compliance with Section 508 of the Rehabilitation Act of 1973
- AR-33: Plain Writing Act of 2010, P.L. 111-274
- AR-34: Affordable Care Act, P.L. 111-148

ARs applicable to Center for Global Health Assistance Awards:

- AR-35: Protecting Life in Global Health Assistance

ARs applicable to HIV/AIDS Awards:

- AR-5: HIV Program Review Panel
- AR-6: Patient Care

Organization Specific ARs:

- AR-8: Public Health System Reporting (Community-based non-governmental organizations)
- AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities
- AR-15: Proof of Non-profit Status (Non-profit organizations)
- AR 23: Compliance with 45 C.F.R. Part 87 (Faith-based organizations)

Potentially Applicable Public Policy Requirements

- False or Misleading Information
• Taxes: Certification of Filing and Payment of Taxes
• Fly America Act/ U.S. Flag Air Carriers
• National Environmental Policy Act

If applicable, award recipients will be required to submit an electronic version of the final, peer-reviewed manuscript of any work developed under this award upon acceptance for publication. Additional information will be provided in the award terms.

For more information on the CFR visit http://www.access.gpo.gov/nara/cfr/cfr-table-search.html

### 3. Reporting

Reporting provides continuous program monitoring and identifies successes and challenges that recipients encounter throughout the project period. Also, reporting is a requirement for recipients who want to apply for yearly continuation of funding. Reporting helps CDC and recipients because it:

- Helps target support to recipients;
- Provides CDC with periodic data to monitor recipient progress toward meeting the Notice of Funding Opportunity outcomes and overall performance;
- Allows CDC to track performance measures and evaluation findings for continuous quality and program improvement throughout the period of performance and to determine applicability of evidence-based approaches to different populations, settings, and contexts; and
- Enables CDC to assess the overall effectiveness and influence of the NOFO.

The table below summarizes required and optional reports. All required reports must be sent electronically to GMS listed in the “Agency Contacts” section of the NOFO copying the CDC Project Officer.

<table>
<thead>
<tr>
<th>Report</th>
<th>When?</th>
<th>Required?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recipient Evaluation and Performance Measurement Plan</td>
<td>6 months into award</td>
<td>Yes</td>
</tr>
<tr>
<td>Annual Performance Report (APR)</td>
<td>120 days before end of budget period. Serves as yearly continuation application.</td>
<td>Yes</td>
</tr>
<tr>
<td>Performance Measure Reporting</td>
<td>Annual reports due 90 calendar days after the award year and quarterly reports due 30 days after the reporting period</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Audit, Books, and Records</strong></td>
<td>When applicable, within 30 days of completion of the audit and no later than nine months after the end of the period under audit</td>
<td>Yes, as applicable</td>
</tr>
<tr>
<td><strong>Reporting of Foreign Taxes</strong></td>
<td>Quarterly reports due April 15, July 15, October 15, and January 15</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Expenditure Analysis</strong></td>
<td>Annually, in conjunction with the PEPFAR Annual Progress Report at the completion of the USG fiscal year</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Federal Financial Reporting Forms</strong></td>
<td>90 days after end of calendar quarter in which budget period ends</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Final Performance and Financial Report</strong></td>
<td>90 days after end of project period.</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Payment Management System (PMS) Reporting</strong></td>
<td>Quarterly reports due July 30, 2018; October 30, 2018; January 30, 2019, April 30, 2019</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**a. Recipient Evaluation and Performance Measurement Plan (required)**

With support from CDC, recipients must elaborate on their initial applicant evaluation and performance measurement plan. This plan must be no more than 20 pages; recipients must submit the plan 6 months into the award. HHS/CDC will review and approve the recipient’s monitoring and evaluation plan to ensure that it is appropriate for the activities to be undertaken as part of the agreement, for compliance with the monitoring and evaluation guidance established by HHS/CDC, or other guidance otherwise applicable to this Agreement.

Recipient Evaluation and Performance Measurement Plan (required): This plan should provide additional detail on the following:

**Performance Measurement**

- Performance measures and targets
- The frequency that performance data are to be collected.
- How performance data will be reported.
- How quality of performance data will be assured.
- How performance measurement will yield findings to demonstrate progress towards achieving NOFO goals (e.g., reaching target populations or achieving expected outcomes).
- Dissemination channels and audiences.
- Other information requested as determined by the CDC program.
Evaluation

• The types of evaluations to be conducted (e.g. process or outcome evaluations).
• The frequency that evaluations will be conducted.
• How evaluation reports will be published on a publically available website.
• How evaluation findings will be used to ensure continuous quality and program improvement.
• How evaluation will yield findings to demonstrate the value of the NOFO (e.g., effect on improving public health outcomes, effectiveness of NOFO, cost-effectiveness or cost-benefit).
• Dissemination channels and audiences.

HHS/CDC or its designee will also undertake monitoring and evaluation of the defined activities within the agreement. The recipient must ensure reasonable access by HHS/CDC or its designee to all necessary sites, documentation, individuals and information to monitor, evaluate and verify the appropriate implementation the activities and use of HHS/CDC funding under this Agreement.

b. Annual Performance Report (APR) (required)

The recipient must submit the APR via [www.Grantsolutions.gov](http://www.Grantsolutions.gov) no later than 120 days prior to the end of the budget period. This report must not exceed 45 pages excluding administrative reporting. Attachments are not allowed, but web links are allowed. This report must include the following:

- **Performance Measures:** Recipients must report on performance measures for each budget period and update measures, if needed.
- **Evaluation Results:** Recipients must report evaluation results for the work completed to date (including findings from process or outcome evaluations).
- **Work Plan:** Recipients must update work plan each budget period to reflect any changes in period of performance outcomes, activities, timeline, etc.
- **Successes**
  - Recipients must report progress on completing activities and progress towards achieving the period of performance outcomes described in the logic model and work plan.
  - Recipients must describe any additional successes (e.g. identified through evaluation results or lessons learned) achieved in the past year.
  - Recipients must describe success stories.
- **Challenges**
  - Recipients must describe any challenges that hindered or might hinder their ability to complete the work plan activities and achieve the period of performance outcomes.
  - Recipients must describe any additional challenges (e.g., identified through evaluation results or lessons learned) encountered in the past year.
- **CDC Program Support to Recipients**
  - Recipients must describe how CDC could help them overcome challenges to complete activities in the work plan and achieving period of performance.
• **Administrative Reporting** (No page limit)
  o SF-424A Budget Information-Non-Construction Programs.
  o Budget Narrative – Must use the format outlined in "Content and Form of Application Submission, Budget Narrative" section.
  o Indirect Cost Rate Agreement.


c. **Performance Measure Reporting (optional)**
CDC programs may require more frequent reporting of performance measures than annually in the APR. If this is the case, CDC programs must specify reporting frequency, data fields, and format for recipients at the beginning of the award period.

The recipient is responsible for managing and monitoring each project, program, subaward, function or activity supported through this Agreement. Recipients must monitor subawards to ensure that subrecipients have met the programmatic impact requirements as set forth in the subrecipient’s agreement.

Performance reports must contain, for each award, brief information on each of the following:

- A comparison of actual accomplishments with the goals and objectives previously established for the period, including metrics outlined in the monitoring and evaluation plan any findings of an external entity, or both.
- Reasons why established goals for the performance period were not met, if appropriate.
- Other pertinent information including, when appropriate, statutory or Congressional reporting requirements, analysis and explanation of cost overruns or high unit costs reported in financial reports.
- The recipient must immediately notify the awarding agency of developments that have a significant impact on or adverse conditions which materially impair the award-supported activities.
- The Quarterly Pipeline Analysis report must contain expenditures versus budget as identified in work plan, description of challenges, and explanation of unexpected pipeline (high or low). The Pipeline Analysis report must contain the project period, award amount to date, outlay or liquidated amount to date, and the balance of the pipeline, or the award amount to date less the outlay.

The recipient must submit the original and two copies of annual and quarterly Performance reports and quarterly pipeline analysis. Annual reports must be due 90 calendar days after the award year and quarterly reports must be due 30 days after the reporting period. The final performance reports are due 90 calendar days after the expiration or termination of this Agreement.

Additionally, the following terms apply to all performance measure and evaluation plans and reports:
CDC programs must ensure that recipient’s Evaluation and Performance Measurement Plan is aligned with the strategic information guidance established by OGAC and other HHS/CDC requirements, including PEPFAR’s Monitoring Reporting and Evaluation (MER) strategy, PEPFAR’s Evaluation Standards of Practice, and CDC’s Data for Partner Monitoring Program (DFPM).

The recipient must ensure reasonable access by HHS/CDC or its designee to all necessary sites, documentation, individuals and information to monitor, evaluate and verify the appropriate implementation the Activities and use of HHS/CDC funding under this Agreement, must require a provision to this effect in all sub-awards or contracts financed by funds under this Agreement. Where applicable, this includes support for, and response to, activities associated with the Site Improvement through Monitoring System and implementation of Data and Service Quality Assessments.

The recipient is required to submit in a timely manner all program results for all relevant programmatic indicators in accordance with U.S. government guidance. All evaluation reports (with or without CDC authors) must adhere to the PEPFAR evaluation standard of practice and must be published on a publically available Internet website, upon approval from CDC offices.

**Audit, Books, and Records Clause (required):**

A. Reports and Information. The recipient must furnish HHS/CDC accounting records and such other information and reports relating to the Agreement as HHS/CDC may reasonably request.

B. The Recipient Agreement Books and Records. The recipient must maintain accounting books, records, documents and other evidence relating to the Agreement, adequate to show, without limitation, all costs incurred by the recipient, the receipt and use of goods and services acquired by the recipient, agreed-upon cost sharing requirements, the nature and extent of solicitations of prospective suppliers of goods and services acquired by the recipient, the basis of award of recipient contracts and orders, and the overall progress of the Agreement toward completion ("Agreement books and records"). The recipient must maintain Agreement books and records in accordance with generally accepted accounting principles prevailing in the United States, or at the recipient’s option, with approval by HHS/CDC, other accounting principles, such as those (1) prescribed by the International Accounting Standards Committee (an affiliate of the International Federation of Accountants), or (2) prevailing in the country of the recipient. Agreement books and records must be maintained for at least three years after the date of last disbursement by HHS/CDC or for such longer period, if any, required to resolve any litigation, claims or audit findings.

C. Partner Government Audit. If $300,000 or more of US Government funds are expended by the recipient in its fiscal year under the Agreement, the recipient must have financial audits made of the expenditures in accordance with the following terms, except as the Parties may otherwise agree in writing:

i. The recipient must use its Supreme Audit Institution (SAI), if the SAI is approved by HHS/CDC, or select an independent auditor to perform the audit in accordance with the guidelines issued by HHS/CDC.

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

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

i. "Covered" sub-recipient is one who expends $300,000 or more in its fiscal year in "US Government awards" (i.e. as recipients of US Government cost reimbursable contracts, grants or cooperative agreements).

ii. The plan must describe the methodology to be used by the recipient to satisfy its audit responsibilities for covered sub-recipients. The recipient may satisfy such audit responsibilities by relying on independent audits of the sub-recipients; expanding the scope of the independent financial audit of the recipient to encompass testing of sub-recipients' accounts; or a combination of these procedures.

iii. The plan must identify the funds made available to sub-recipients that will be covered by audits conducted in accordance with audit provisions that satisfy the recipient’s audit responsibilities.

iv. The recipient must ensure that covered sub-recipients under direct contracts or agreements with the recipient take appropriate and timely corrective actions; consider whether sub-recipients' audits necessitate adjustment of its own records; and require each such sub-recipient to permit independent auditors to have access to records and financial statements as necessary.

E. Audit Reports. The recipient must furnish or cause to be furnished to HHS/CDC an audit report for each audit arranged for by the recipient in accordance with this Section within 30 days after completion of the audit and no later than nine months after the end of the period under audit.

F. Cost of Audits. Subject to HHS/CDC approval in writing, costs of audits performed in accordance with the terms of this Section may be budgeted for, and charged to, the Agreement so long as such costs are allowable, allocable, and reasonable as defined in the Cost Allowability section of this Agreement.

G. Audit by HHS/CDC. HHS/CDC retains the right to perform the audits required under this Agreement on behalf of the recipient conduct a financial review, or otherwise ensure accountability of organizations expending US Government funds regardless of the audit requirement.

H. Opportunity to Audit or Inspect. The recipient must afford authorized representatives of HHS/CDC the opportunity at all reasonable times to audit or inspect activities financed under the Agreement, the utilization of goods and services financed by HHS/CDC, and books, records and other documents relating to the Agreement.

I. Sub-recipient Books and Records. The recipient will incorporate paragraphs (A), (B), (D),
(E), (F), (G) and (H) of this provision into all sub-agreements with non-U.S. organizations which meet the $300,000 threshold of paragraph (C) of this provision. Sub-agreements with non-U.S. organizations, which do not meet the $300,000 threshold, must, at a minimum, incorporate paragraphs (G) and (H) of this provision. Sub-agreements with U.S. organizations must state that the U.S. organization is subject to the audit requirements contained in 2 CFR 200 and 45 CFR 75.

**Expenditure Analysis (required):**

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

d. **Federal Financial Reporting (FFR) (required)**

The annual FFR form (SF-425) is required and must be submitted 90 days after the end of the budget period. The report must include only those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds, and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System’s (PMS) cash transaction data. Failure to submit the required information by the due date may adversely affect the future funding of the project. If the information cannot be provided by the due date, recipients are required to submit a letter of explanation to OGS and include the date by which the Grants Officer will receive information.

e. **Final Performance and Financial Report (required)**

This report is due 90 days after the end of the period of performance. CDC programs must indicate that this report should not exceed 40 pages. This report covers the entire period of performance and can include information previously reported in APRs. At a minimum, this report must include the following:

- Performance Measures – Recipients must report final performance data for all process and outcome performance measures.
- Evaluation Results – Recipients must report final evaluation results for the period of performance for any evaluations conducted.
- Impact/Results/Success Stories – Recipients must use their performance measure results and their evaluation findings to describe the effects or results of the work completed over the project period, and can include some success stories.
- A final Data Management Plan that includes the location of the data collected during the funded period, for example, repository name and link data set(s)
- Additional forms as described in the Notice of Award (e.g., Equipment Inventory Report, Final Invention Statement).

### 4. Federal Funding Accountability and Transparency Act of 2006 (FFATA)
Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252 requires full disclosure of all entities and organizations receiving Federal funds including awards, contracts, loans, other assistance, and payments through a single publicly accessible Web site, http://www.USASpending.gov. 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 applicants: 1) information on executive compensation when not already reported through the SAM, and 2) similar information on all sub-awards/subcontracts/consortiums over $25,000. For the full text of the requirements under the FFATA and HHS guidelines, go to:


5. Reporting of Foreign Taxes (International/Foreign projects only)

A. Valued Added Tax (VAT) and Customs Duties – Customs and import duties, consular fees, customs surtax, valued added taxes, and other related charges are hereby authorized as an allowable cost for costs incurred for non-host governmental entities operating where no applicable tax exemption exists. This waiver does not apply to countries where a bilateral agreement (or similar legal document) is already in place providing applicable tax exemptions and it is not applicable to Ministries of Health. Successful applicants will receive information on VAT requirements via their Notice of Award.

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

1) Annual Report: The recipient must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 – September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the recipient did not pay any taxes during the reporting period.]

2) Quarterly Report: The recipient must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.

3) Terms: For purposes of this clause:
   “Commodity” means any material, article, supplies, goods, or equipment;
“Foreign government” includes any foreign government entity; “Foreign taxes” means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.

4) Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in which you are carrying out the activities associated with this cooperative agreement. In countries where there is no CDC office, send reports to VATreporting@cdc.gov.

5) Contents of Reports: The reports must contain:
   a. recipient name;
   b. contact name with phone, fax, and e-mail;
   c. agreement number(s) if reporting by agreement(s);
   d. reporting period;
   e. amount of foreign taxes assessed by each foreign government;
   f. amount of any foreign taxes reimbursed by each foreign government;
   g. amount of foreign taxes unreimbursed by each foreign government.

6) Subagreements. The recipient must include this reporting requirement in all applicable subgrants and other subagreements.

**G. Agency Contacts**

CDC encourages inquiries concerning this notice of funding opportunity.

**Program Office Contact**

For **programmatic technical assistance**, contact:

Theresa NeSmith, Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention
1600 Clifton Road, Mailstop G-45
Telephone: (404) 639-8435
Email: tbn8@cdc.gov

**Grants Staff Contact**

For **financial, awards management, or budget assistance**, contact:

Dionne Bounds, Grants Management Specialist
Department of Health and Human Services
Office of Grants Services
2920 Brandywine Road, MS K75
Atlanta, GA 30341
Telephone: (770) 488-2082
Email: vhv5@cdc.gov

For assistance with submission difficulties related to www.grants.gov, contact the Contact Center by phone at 1-800-518-4726.
Hours of Operation: 24 hours a day, 7 days a week, except on federal holidays.

For all other submission questions, contact:
Technical Information Management Section
Department of Health and Human Services
CDC Office of Financial Resources
Office of Grants Services
2920 Brandywine Road, MS E-14
Atlanta, GA 30341
Telephone: 770-488-2700
E-mail: ogstims@cdc.gov

CDC Telecommunications for persons with hearing loss is available at: TTY 1-888-232-6348

H. Other Information

Following is a list of acceptable attachments applicants can upload as PDF files as part of their application at www.grants.gov. Applicants may not attach documents other than those listed; if other documents are attached, applications will not be reviewed.

- Project Abstract
- Project Narrative
- Budget Narrative
- CDC Assurances and Certifications
- Report on Programmatic, Budgetary and Commitment Overlap
- Table of Contents for Entire Submission

For international NOFOs:

- SF424
- SF424A
- Funding Preference Deliverables

The appendices will not be counted toward the project narrative page limit. The total amount of appendices must not exceed 90 pages. Any pages after page 90 of the appendix will not be considered for review. The following documents must be included in the application appendices:

- Please refer to “Organizational Capacity of Recipients to Implement the
Approach” for specific requirements in this NOFO.

- **Letters of Commitment**, if applicable
- **Negotiated Indirect Cost Rate Agreement**, if applicable
- **Non-profit organization IRS status forms**, if applicable
- **Funding Preference deliverables**: See “Phase III Review,” as applicable
  - If applying for the funding preference for local partner, the applicant must submit documentation to self-certify how the applicant meets the “PEPFAR local partner definition” listed in the Glossary Section of this NOFO. The applicant must label the supporting documentation as “Local Partner Preference” and must clearly identify which criteria under paragraph 1, 2, or 3 their organization meets, and provide sufficient documentation to certify how their organization meets that criterion. Funding preference points will not be awarded to applicants who do not provide and/or label the supporting documentation required to meet the PEPFAR Local Partner definition.

Any additional information submitted via [www.grants.gov](http://www.grants.gov) must be uploaded in a PDF file format, and should be clearly labeled (i.e.: Organizational Chart should be named “organizational chart”).

**Page Limitations**

- Applicants must abide by the page number limitation listed in Section D, #10 Project Narrative. Any pages submitted beyond the number of pages listed for the project narrative will not be reviewed.
- Applicants must abide by the submission requirements for the project narrative and appendix. Materials required in the project narrative submitted in the appendix will not be reviewed. Materials submitted in the appendix that are not requested in the NOFO will not be reviewed.
- If the total amount of appendices includes more than 90 pages, any pages after page 90 of the appendix will not be considered for review. For this purpose, all appendices must have page numbers and must be clearly identified in the Table of Contents as appendices. All applications will be initially reviewed for completeness by CDC OGS staff.

**Amendments, Questions and Answers (Q&As)**

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

All changes, updates, and amendments to the NOFO will be posted to [www.grants.gov](http://www.grants.gov) following the approval of CDC.

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

Other CDC funding opportunity announcements can be found on Grants.gov website, at the following internet address: [http://www.grants.gov](http://www.grants.gov).
I. Glossary

**Activities:** The actual events or actions that take place as a part of the program.

**Administrative and National Policy Requirements, Additional Requirements (ARs):** Administrative requirements found in 45 CFR Part 75 and other requirements mandated by statute or CDC policy. All ARs are listed in the Template for CDC programs. CDC programs must indicate which ARs are relevant to the NOFO; recipients must comply with the ARs listed in the NOFO. To view brief descriptions of relevant provisions, see [http://www.cdc.gov/grants/additional_requirements/index.html](http://www.cdc.gov/grants/additional_requirements/index.html). Note that 2 CFR 200 supersedes the administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).

**Approved but Unfunded:** Approved but unfunded refers to applications recommended for approval during the objective review process; however, they were not recommended for funding by the program office and/or the grants management office.

**Award:** Financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements (e.g., cooperative agreements) in the form of money, or property in lieu of money, by the federal government to an eligible applicant.

**Budget Period or Budget Year:** The duration of each individual funding period within the project period. Traditionally, budget periods are 12 months or 1 year.

**Carryover:** Unobligated federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried over to another budget period to cover allowable costs of that budget period either as an offset or additional authorization. Obligated but liquidated funds are not considered carryover.

**Catalog of Federal Domestic Assistance (CFDA):** A government-wide compendium published by the General Services Administration (available on-line in searchable format as well as in printable format as a .pdf file) that describes domestic assistance programs administered by the Federal Government.

**CFDA Number:** A unique number assigned to each program and NOFO throughout its lifecycle that enables data and funding tracking and transparency.

**CDC Assurances and Certifications:** Standard government-wide grant application forms.

**Competing Continuation Award:** A financial assistance mechanism that adds funds to a grant and adds one or more budget periods to the previously established period of performance (i.e., extends the “life” of the award).

**Continuous Quality Improvement:** A system that seeks to improve the provision of services with an emphasis on future results.

**Contracts:** An award instrument used to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the Federal Government.

**Cooperative Agreement:** A financial assistance award with the same kind of interagency relationship as a grant except that it provides for substantial involvement by the federal agency funding the award. Substantial involvement means that the recipient can expect federal programmatic collaboration or participation in carrying out the effort under the award.

**Cost Sharing or Matching:** Refers to program costs not borne by the Federal Government but by the recipients. It may include the value of allowable third-party, in-kind contributions, as well as expenditures by the recipient.

**Direct Assistance:** A financial assistance mechanism, which must be specifically authorized by statute, whereby goods or services are provided to recipients in lieu of cash. DA generally
involves the assignment of federal personnel or the provision of equipment or supplies, such as vaccines. DA is primarily used to support payroll and travel expenses of CDC employees assigned to state, tribal, local, and territorial (STLT) health agencies that are recipients of grants and cooperative agreements. Most legislative authorities that provide financial assistance to STLT health agencies allow for the use of DA. [http://www.cdc.gov/grants/additionalrequirements/index.html](http://www.cdc.gov/grants/additionalrequirements/index.html).

**DUNS:** The Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is a nine-digit number assigned by Dun and Bradstreet Information Services. When applying for Federal awards or cooperative agreements, all applicant organizations must obtain a DUNS number as the Universal Identifier. DUNS number assignment is free. If requested by telephone, a DUNS number will be provided immediately at no charge. If requested via the Internet, obtaining a DUNS number may take one to two days at no charge. If an organization does not know its DUNS number or needs to register for one, visit Dun & Bradstreet at [http://fedgov.dnb.com/webform/displayHomePage.do](http://fedgov.dnb.com/webform/displayHomePage.do).

**Evaluation (program evaluation):** The systematic collection of information about the activities, characteristics, and outcomes of programs (which may include interventions, policies, and specific projects) to make judgments about that program, improve program effectiveness, and/or inform decisions about future program development.

**Evaluation Plan:** A written document describing the overall approach that will be used to guide an evaluation, including why the evaluation is being conducted, how the findings will likely be used, and the design and data collection sources and methods. The plan specifies what will be done, how it will be done, who will do it, and when it will be done. The NOFO evaluation plan is used to describe how the recipient and/or CDC will determine whether activities are implemented appropriately and outcomes are achieved.

**Federal Funding Accountability and Transparency Act of 2006 (FFATA):** Requires that information about federal awards, including awards, contracts, loans, and other assistance and payments, be available to the public on a single website at [www.USAspending.gov](http://www.USAspending.gov).

**Fiscal Year:** The year for which budget dollars are allocated annually. The federal fiscal year starts October 1 and ends September 30.

**Grant:** A legal instrument used by the federal government to transfer anything of value to a recipient for public support or stimulation authorized by statute. Financial assistance may be money or property. The definition does not include a federal procurement subject to the Federal Acquisition Regulation; technical assistance (which provides services instead of money); or assistance in the form of revenue sharing, loans, loan guarantees, interest subsidies, insurance, or direct payments of any kind to a person or persons. The main difference between a grant and a cooperative agreement is that in a grant there is no anticipated substantial programmatic involvement by the federal government under the award.

**Grants.gov:** A "storefront" web portal for electronic data collection (forms and reports) for federal grant-making agencies at [www.grants.gov](http://www.grants.gov).

**Grants Management Officer (GMO):** The individual designated to serve as the HHS official responsible for the business management aspects of a particular grant(s) or cooperative agreement(s). The GMO serves as the counterpart to the business officer of the recipient organization. In this capacity, the GMO is responsible for all business management matters associated with the review, negotiation, award, and administration of grants and interprets grants administration policies and provisions. The GMO works closely with the program or project officer who is responsible for the scientific, technical, and programmatic aspects of the
grant.

**Grants Management Specialist (GMS):** A federal staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with regulations and guidelines, negotiating grants, providing consultation and technical assistance to recipients, post-award administration and closing out grants.

**Health Disparities:** Differences in health outcomes and their determinants among segments of the population as defined by social, demographic, environmental, or geographic category.

**Health Equity:** Striving for the highest possible standard of health for all people and giving special attention to the needs of those at greatest risk of poor health, based on social conditions.

**Health Inequities:** Systematic, unfair, and avoidable differences in health outcomes and their determinants between segments of the population, such as by socioeconomic status (SES), demographics, or geography.

**Healthy People 2020:** National health objectives aimed at improving the health of all Americans by encouraging collaboration across sectors, guiding people toward making informed health decisions, and measuring the effects of prevention activities.

**Inclusion:** Both the meaningful involvement of a community’s members in all stages of the program process and the maximum involvement of the target population that the intervention will benefit. Inclusion ensures that the views, perspectives, and needs of affected communities, care providers, and key partners are considered.

**Indirect Costs:** Costs that are incurred for common or joint objectives and not readily and specifically identifiable with a particular sponsored project, program, or activity; nevertheless, these costs are necessary to the operations of the organization. For example, the costs of operating and maintaining facilities, depreciation, and administrative salaries generally are considered indirect costs.

**Intergovernmental Review:** Executive Order 12372 governs applications subject to Intergovernmental Review of Federal Programs. This order sets up a system for state and local governmental review of proposed federal assistance applications. Contact the state single point of contact (SPOC) to alert the SPOC to prospective applications and to receive instructions on the State’s process. Visit the following web address to get the current SPOC list: [http://www.whitehouse.gov/omb/grants_spoc/](http://www.whitehouse.gov/omb/grants_spoc/).

**Letter of Intent (LOI):** A preliminary, non-binding indication of an organization’s intent to submit an application.

**Lobbying:** Direct lobbying includes any attempt to influence legislation, appropriations, regulations, administrative actions, executive orders (legislation or other orders), or other similar deliberations at any level of government through communication that directly expresses a view on proposed or pending legislation or other orders, and which is directed to staff members or other employees of a legislative body, government officials, or employees who participate in formulating legislation or other orders. Grass roots lobbying includes efforts directed at inducing or encouraging members of the public to contact their elected representatives at the federal, state, or local levels to urge support of, or opposition to, proposed or pending legislative proposals.

**Logic Model:** A visual representation showing the sequence of related events connecting the activities of a program with the programs’ desired outcomes and results.

**Maintenance of Effort:** A requirement contained in authorizing legislation, or applicable
regulations that a recipient must agree to contribute and maintain a specified level of financial effort from its own resources or other non-government sources to be eligible to receive federal grant funds. This requirement is typically given in terms of meeting a previous base-year dollar amount.

**Memorandum of Understanding (MOU) or Memorandum of Agreement (MOA):** Document that describes a bilateral or multilateral agreement between parties expressing a convergence of will between the parties, indicating an intended common line of action. It is often used in cases where the parties either do not imply a legal commitment or cannot create a legally enforceable agreement.

**Nonprofit Organization:** Any corporation, trust, association, cooperative, or other organization that is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; is not organized for profit; and uses net proceeds to maintain, improve, or expand the operations of the organization. Nonprofit organizations include institutions of higher educations, hospitals, and tribal organizations (that is, Indian entities other than federally recognized Indian tribal governments).

**Notice of Award (NoA):** The official document, signed (or the electronic equivalent of signature) by a Grants Management Officer that: (1) notifies the recipient of the award of a grant; (2) contains or references all the terms and conditions of the grant and Federal funding limits and obligations; and (3) provides the documentary basis for recording the obligation of Federal funds in the HHS accounting system.

**Objective Review:** A process that involves the thorough and consistent examination of applications based on an unbiased evaluation of scientific or technical merit or other relevant aspects of the proposal. The review is intended to provide advice to the persons responsible for making award decisions.

**Outcome:** The results of program operations or activities; the effects triggered by the program. For example, increased knowledge, changed attitudes or beliefs, reduced tobacco use, reduced morbidity and mortality.

**Performance Measurement:** The ongoing monitoring and reporting of program accomplishments, particularly progress toward pre-established goals, typically conducted by program or agency management. Performance measurement may address the type or level of program activities conducted (process), the direct products and services delivered by a program (outputs), or the results of those products and services (outcomes). A “program” may be any activity, project, function, or policy that has an identifiable purpose or set of objectives.

**Period of performance –formerly known as the project period - :** The time during which the recipient may incur obligations to carry out the work authorized under the Federal award. The start and end dates of the period of performance must be included in the Federal award.

**Period of Performance Outcome:** An outcome that will occur by the end of the NOFO’s funding period

**Plain Writing Act of 2010:** The Plain Writing Act of 2010 requires that federal agencies use clear communication that the public can understand and use. NOFOs must be written in clear, consistent language so that any reader can understand expectations and intended outcomes of the funded program. CDC programs should use NOFO plain writing tips when writing NOFOs.

**Program Strategies:** Strategies are groupings of related activities, usually expressed as general headers (e.g., Partnerships, Assessment, Policy) or as brief statements (e.g., Form partnerships, Conduct assessments, Formulate policies).

**Program Official:** Person responsible for developing the NOFO; can be either a project officer,
program manager, branch chief, division leader, policy official, center leader, or similar staff member.

Public Health Accreditation Board (PHAB): A nonprofit organization that works to promote and protect the health of the public by advancing the quality and performance of public health departments in the U.S. through national public health department accreditation [http://www.phaboard.org](http://www.phaboard.org).

Social Determinants of Health: Conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.

Statute: An act of the legislature; a particular law enacted and established by the will of the legislative department of government, expressed with the requisite formalities. In foreign or civil law any particular municipal law or usage, though resting for its authority on judicial decisions, or the practice of nations.

Statutory Authority: Authority provided by legal statute that establishes a federal financial assistance program or award.

System for Award Management (SAM): The primary vendor database for the U.S. federal government. SAM validates applicant information and electronically shares secure and encrypted data with federal agencies' finance offices to facilitate paperless payments through Electronic Funds Transfer (EFT). SAM stores organizational information, allowing [www.grants.gov](http://www.grants.gov) to verify identity and pre-fill organizational information on grant applications.

Technical Assistance: Advice, assistance, or training pertaining to program development, implementation, maintenance, or evaluation that is provided by the funding agency.

Work Plan: The summary of period of performance outcomes, strategies and activities, personnel and/or partners who will complete the activities, and the timeline for completion. The work plan will outline the details of all necessary activities that will be supported through the approved budget.

### NOFO-specific Glossary and Acronyms

**PEPFAR Local Partner Definition**

To be considered eligible as a local partner under this Funding Opportunity Announcement, the applicant must submit supporting documentation demonstrating how their organization meets one of the three criteria listed below under the “PEPFAR Local Partner definition.” The supporting documentation must be included in the Appendices of the application and must be labeled as “Eligibility Documentation for PEPFAR Local Partner Definition.” Applicants that do not provide and/or label the supporting documentation required to meet the PEPFAR Local Partner definition above will not be considered eligible for review.

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

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

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

b) must be at 75% for FY2018 beneficially owned by individuals who are citizens or lawfully admitted permanent residents of that same country, per sub-paragraph (2)(a), or by other corporations, partnerships or other arrangements that are local partners under this paragraph or paragraph (3);

c) at least 75% for FY2018 of the entity’s staff (senior, mid-level, support) must be citizens or lawfully admitted permanent residents of that same country, per sub-paragraph (2)(a), and at least 75% for FY2018 of the entity’s senior staff (i.e., managerial and professional personnel) must be citizens or lawfully admitted permanent residents of such country; and

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

(3) a joint venture, unincorporated association, consortium, or other arrangement in which at least 75% for FY2018 of the funding under the PEPFAR award is or will be provided to members who are local partners under the criteria in paragraphs (1) or (2) above, and a local partner is designated as the managing member of the organization. Partner government ministries (e.g., Ministry of Health), sub-units of government ministries, and parastatal organizations in the country served by the PEPFAR program are considered local partners. A parastatal organization is defined as a fully or partially government-owned or government-funded organization. Such enterprises may function through a board of directors, similar to private corporations. However, ultimate control over the organization rests with the government.

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