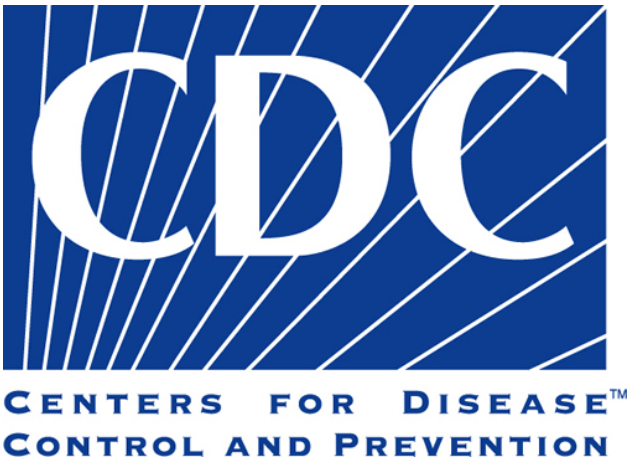

Centers for Disease Control and Prevention

Center for Global Health

Transitioning and Integrating Laboratory Services for High Quality HIV Diagnosis, Care, Treatment, and Monitoring to the Ministry of Health (MOH) to Sustain Achievement of the 95-95-95 Goals in Zambia under PEPFAR

CDC-RFA-GH-23-0010

03/27/2023

Table of Contents

Part I. Overview

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Subscribe" button link to ensure they receive notifications of any changes to CDC-RFA-GH-23-0010. 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:

Transitioning and Integrating Laboratory Services for High Quality HIV Diagnosis, Care, Treatment, and Monitoring to the Ministry of Health (MOH) to Sustain Achievement of the 95-95-95 Goals in Zambia under 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 https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html (See section 45 CFR 46.102(d)).

Applicants should note that a Letter of Intent (LOI) is **not** requested or required as part of the application for this NOFO or for any CDC PEPFAR FY23 NOFO. Applicants should **not** submit LOIs. There may be dates populated in some NOFOs in the LOI fields (1. Due Date for Letter of

Intent (LOI) under Part I. Overview, and a. Letter of Intent Deadline under D. Application and Submission Information), but this is an error CDC is working to fix. These sections should be blank to reflect that LOIs are not requested or required.

Amendment I: Questions and Answers (Q&A) and Application Due Date Extension

The purpose of this amendment is to include questions and answers (Q&A) in Section H. Other Information and to extend the Application Due Date from March 26, 2023 (3/26/2023) to March 27, 2023 (3/27/2023).

D. Agency Notice of Funding Opportunity Number:

CDC-RFA-GH-23-0010

E. Assistance Listings Number:

93.067

F. Dates:

1. Due Date for Letter of Intent (LOI):

2. Due Date for Applications:

03/27/2023

11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.

3. Due Date for Informational Conference Call:

N/A

G. Executive Summary:

1. Summary Paragraph

This NOFO will support the stepwise full transition of PEPFAR-supported laboratory systems and services to the Government of the Republic of Zambia (GRZ). The recipient will provide technical assistance (TA) for further adaptation of the diagnostic system for immediate needs such as outbreaks of novel diseases, additional surveillance system requirements, and new international reporting mechanisms as guided by CDC. By the end of the project period, the recipient should perform a capacity assessment of GRZ to carry out all the laboratory system functions and a cost assessment to fully understand the costs of sustaining the system. Assessments for transition should include: viral load (VL), early infant diagnosis (EID), sample referral, testing and results return systems, laboratory information management systems (LIMS), including: integration with SmartCare, eLABS, and DHIS2, laboratory equipment calibration facilities and systems, external quality assurance (EQA) systems following implementation of ISO 17043, diagnostic equipment maintenance program, courier vehicle replacement, salvage and maintenance program, waste management, backup power systems, rapid test continuous quality improvement (RTCQI) as an activity related to baseline VL, diagnostic network optimization (DNO), laboratory quality management systems (QMS), biosafety and biosecurity program, and laboratory-specific supply chain management and integrated testing including human papillomavirus (HPV) and TB.

a. Eligible Applicants:

Open Competition

b. Funding Instrument Type:

CA (Cooperative Agreement)

c. Approximate Number of Awards

1

d. Total Period of Performance Funding:

$0

The Approximate Project Period of Performance Funding/Estimated Total Funding for the Total 5 year Project Period is None. The Approximate Total Fiscal Year Funding/Average One Year Award Amount/Approximate Average Award amount for years 2-5 will be set at continuation.

e. Average One Year Award Amount:

$9,000,000

The Approximate Total Fiscal Year Funding/Average One Year Award Amount/Approximate Average Award amount for Year 1 is $9,000,000. The expected number of awards is 1. Exact amounts for each award under this NOFO will be determined at the time of award. Applicants are encouraged to apply to the Approximate Total Fiscal Year Funding/Average One Year Award Amount/Approximate Average Award amount.

f. Total Period of Performance Length:

5 year(s)

g. Estimated Award Date:

September 30, 2023

h. Cost Sharing and / or Matching Requirements:

No

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

Part II. Full Text

A. Funding Opportunity Description

1. Background

a. Overview

Over 1.2 million Zambians are now on life-saving anti-retroviral therapy (ART). Monitoring the effectiveness of ART to maintain epidemic control requires full access to laboratory services, a goal now achieved, with substantial partner support. Over the past five years, laboratory systems in Zambia have matured to the point that GRZ is ready for full transition for oversight and

administration. Partner support to date has been essential, but to achieve sustainability and maximum system efficiency, the MOH must be able to focus all resources on program implementation instead of partner management. Until HIV is curable, ART is a life-long requirement. As such, diagnostic support for people living with HIV (PLHIV) is expected to be required for many decades. Full internal funding and administration of laboratory services is the only way that services not only for HIV, but for all public health challenges (endemic and emerging diseases), can be sustained in the long term. The purview of the laboratory services of Zambia effectively starts with patient contact, data collection in requisition forms, initial sample processing, and sample referral, all of which culminates in the diagnostic testing itself. Laboratory responsibility continues through data archival, and results return. All system elements depend on ancillary functions (e.g., equipment calibration, waste management, specialized power requirements, biosafety and biosecurity, and supply chain management). All systems require continuous optimization and quality improvement to keep up with technical and clinical developments, as well as to maintain and improve efficiency. All system elements have benefited from implementing partner support since the inception of PEPFAR. The aim of this NOFO is to support the transition of laboratory services, which is a key element of public health, to GRZ, while also allowing implementation of future needs, activities, or innovation within the laboratory system. The transition will need a capacity assessment of GRZ to perform all the laboratory system functions and a cost assessment to fully understand the costs of sustaining the system. As such, the recipient of this NOFO should maintain continuity of service with prior efforts in the specified sub-areas of laboratory systems capacity building, analyze sustainability costs, and achieve transition of activities to the MOH (depending on GRZ funding commitment). A key outcome of this effort will be to help GRZ clearly define the costs of the system and enable the GRZ laboratory services, and ultimately the MOH to demonstrate the need for continuous budget allocation.

b. Statutory Authorities

This program is authorized under Public Law 108-25 (the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003) [22 U.S.C. 7601, et seq.] and Public Law 110-293 (the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008), and Public Law 113-56 (PEPFAR Stewardship and Oversight Act of 2013).

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 2030

N/A

d. Other National Public Health Priorities and Strategies

Under the leadership of the Office of the U.S. Global AIDS Coordinator (OGAC), as part of PEPFAR, the U.S. Department of Health and Human Services’ Centers for Disease Control and Prevention (HHS/CDC) works in partnership with host country governments 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 in a manner consistent with the purposes of this NOFO. Goals and priorities include the following:

- Reducing the prevention and treatment gaps for adolescent girls and young women (AGYW), children, and key populations (KP);
- Strengthening national and local programmatic, financial, and community leadership;
- Designing new partnerships with key private, public, and multi sector entities that can complement existing programs and expand reach;
- Utilizing the PEPFAR platform for broader disease surveillance and public health programming, consistent with the PEPFAR legislative and funding authority;
- Investing in the scale-up of cutting edge behavioral, and implementation science to bend the curve on new infections;
- 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, use, and share 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 relevant partners. Recipients may be requested to participate in the following programmatic activities:

- Scale-up evidence-based programs to identify and close the major HIV gaps among AGYW, children, and key populations;
- 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, putting our national and local partners in the lead and actively enabling their growth through design of the program at all phases;
- Build sustainability through investments in health systems;
- Enhance health equity and reduce disparities in access to and uptake of HIV services;
- Improve performance metrics, monitoring and evaluation and the quality of related data; and
- Promote research, development, and innovation to develop a body of knowledge, enhance awareness and increase the skills and abilities of stakeholders (research is not supported by this NOFO).

PEPFAR defines national HIV epidemic control as the point at which the number of new infections falls below the declining number of deaths among people living with HIV (PLHIV). This definition of epidemic control does not suggest near-term elimination or eradication of HIV as may be possible with other infectious diseases, but rather suggests a decline of HIV-infected persons in a population, achieved through the reduction of new HIV infections when mortality among PLHIV is steady or declining, consistent with natural aging. Critically, however, a country will not be able to maintain epidemic control if program efforts are not sufficiently sustained and new infections are allowed to rebound or death rates to increase.

In addition to the specific activities listed in the Strategies and Activities section of this NOFO, all CDC PEPFAR cooperative agreements resulting from this NOFO may address the following activities, where and when appropriate, that focus U.S. government resources and activities toward achieving and sustaining the HIV/AIDS epidemic:

- Optimize HIV testing and treatment strategies to reach undiagnosed populations living with HIV, especially young adults, men, and KP. These strategies may include or build upon traditional methods and activities related to outbreak detection, investigation, and response, including efforts to reduce or remove evidenced barriers to services such as stigma and discrimination and inequitable gender norms. Responding to recent infections or ongoing patterns of transmission will be prioritized.
- Focus on prevention among children, adolescents, young adults, and members of vulnerable and key populations.
- Support surveillance activities and programs, along with information systems, that improve understanding of HIV epidemiology, help identify inequities and remaining gaps (e.g., societal impediments to HIV services), and inform future programming.
- Support efforts to maintain quality for laboratory systems and activities, including diagnostics and viral load measurement.
- Actively use epidemiologic, program, and financial/cost data to ensure implementation of high quality, cost-effective programs to improve partner performance and increase epidemiologic impact.
- Support country-led, sustainable programming by working with and implementing activities through local partners, including faith communities and faith-based organizations (FBOs), HIV network organizations and community-based organizations (CBOs) directly servicing communities and populations at-risk and most affected by HIV to build local capacity.
- Strengthen programmatic, financial, and community contributions by partner governments in the HIV/AIDS response.
- Support activities, interventions, and programs (e.g., including those intended to reduce or remove evidenced societal impediments to services such as stigma, discrimination, and inequitable gender norms) to find, treat, and prevent TB among PLHIV and to identify and treat HIV among people infected with TB.
- Support efforts to prevent, detect, respond, and treat infectious and non-infectious diseases that impact PLHIV and populations affected by HIV.

All activities outside of HIV or TB activities will be consistent with the direction set forth in OGAC's Country Operational Plan (COP).

Geographic prioritization may change over the course of the period of performance based on the burden of disease and changing program and PEPFAR priorities.

If the scope of activities to be conducted by the recipient(s) of funds under this NOFO includes work with KP, the recipient(s) will be expected to collaborate with KP organizations in the design and delivery of appropriate optimal and quality HIV services to KP.

In addition, PEPFAR is committed to protecting children from abuse, exploitation, and neglect in order to decrease their vulnerability to HIV/AIDS. Consistent with underlying authorities, PEPFAR seeks to ensure that children and youth obtaining services through PEPFAR programming are also protected from abuse, exploitation, and neglect in CDC PEPFAR-supported programs.
To that end, because activities to be funded under this NOFO may involve children or personnel coming into contact with children, Recipients of CDC PEPFAR funds agree to ensure compliance with host country and local child welfare and protection legislation or international standards, whichever gives greater protection, and with U.S. law, where applicable. Further, Recipients of CDC PEPFAR funding are strongly encouraged to: 1) have in place policies and procedures that prohibit recipient personnel from engaging in child abuse, exploitation, or neglect; 2) consider child safeguarding in project planning and implementation to determine potential risks to children that are associated with project activities and operations; 3) apply measures to reduce the risk of child abuse, exploitation, or neglect, including, but not limited to, limiting unsupervised interactions with children; prohibiting exposure to pornography; and complying with applicable laws, regulations, or customs regarding the photographing, filming, or other image-generating activities of children; 4) promote child-safe screening procedures for personnel, particularly personnel whose work brings them in direct contact with children; and 5) have a process for ensuring that personnel and others recognize child abuse, exploitation, or neglect, report allegations, investigate and manage allegations, and take appropriate action in response to such allegations. It is also strongly encouraged that Recipients include the above provisions in any applicable code of conduct for its personnel implementing PEPFAR-funded activities.

This NOFO 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: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.102

e. Relevant Work

This NOFO will continue activities that were implemented, and results that have been achieved under previous PEPFAR support through NOFO CDC-RFA-GH18-1824 that scaled-up laboratory systems in Zambia to address barriers to access and uptake of HIV VL testing.

Since implementation of PEPFAR in Zambia, MOH laboratories have been assisted through a variety of general TA and specific programs for laboratory infrastructure development, training, and quality assurance (QA). Prior awards have included support for human resources (HR) (i.e., salaries for staff embedded in provincial health offices (PHO), laboratories, and couriers). For instance, for the courier services many motorcycles and four-wheel vehicles were owned (and directed) by implementing partners; however, currently courier services have been transitioned to the GRZ to support employment, administration, and oversight.

PEPFAR has assisted MOH to establish fully on call sample referral services that are fully integrated into MOH and are program agnostic (referring any sample type). All laboratories offer fully integrated testing services including for HPV and TB at a minimum and there is no restriction on use of facilities or equipment for any public health infectious disease diagnostic need. MOH conducts formal DNO and supply chain management.

The HIV related laboratory services of Zambia are a three-tier system: 1) approximately 3000 health facilities where patient interactions, sampling, and data management occur, 2) approximately 260 “hub” laboratories where near-care testing is performed and further sample processing, as well as temporary storage takes place, and 3) the 24 VL/EID laboratories all of which utilize conventional VL testing platforms and have a full LIMS. There is no lead national reference laboratory, as the system is decentralized. MOH provides central QA oversight over the system, but each VL/EID system is wholly contained and overseen in its day-to-day operations by the given PHO, with most of the responsibility assigned to the provincial biomedical scientist.

Each VL/EID laboratory has a QMS program and is accredited or is on a path to accreditation under ISO 15189 standards. All laboratories conducting VL/EID testing are enrolled in EQA to monitor the quality of testing. Over 123 of the approximately 260 hub laboratories conduct VL/EID testing on either GeneXpert or mPIMA. Hub laboratories are part of a formal national internal certification program. All hub laboratories have a version of a LIMS that ensures that results go into the central data repository and are reported by one or more methods of digital results return. All facilities have access to digital results return method.

Prior work has also capacitated three calibration centers for laboratory equipment and established standards for power backup, biosafety and biosecurity, and waste management. Baseline VL is standard practice and laboratories carry out follow up analysis of samples with clinical leadership to ensure that diagnostic accuracy is re-verified as patients continue treatment.

The above represents the achievements and systems established within the four traditionally CDC-supported provinces- Lusaka, Eastern, Western, and Southern; however, many lessons learned, and best practices have been applied throughout the other six Zambian provinces. This NOFO is intended to facilitate transition of all HIV related laboratory services to GRZ oversight and control. Prior work has assisted MOH in establishing the QA Coordinating Unit (QACU) in

Lusaka, which is responsible for oversight of all clinical and public health laboratory services in Zambia. The QACU is the primary focus of this NOFO.

2. CDC Project Description

a. Approach

Bold indicates period of performance outcome.

Strategies and Activities	Short-Term Outcomes	Intermediate Outcomes	Long-Term Outcomes

Strategy 1: Maintain continuity with prior laboratory strengthening efforts **Strategy 2:** Provide TA (tangible and mentorship) to achieve full system functionality **Strategy 3**: Conduct capacity assessment of laboratory system and determine recurrent costs to maintain laboratory services **Strategy 4**: Stepwise transition of laboratory services and support and subcomponents to MOH implementation and oversight	**Decreased interruptions of diagnostic services throughout the health system** **Improved planning process (HR, program, and financial) to achieve a fully functional laboratory system** **Accelerated implementation of costed laboratory service transition plan** **Increased capacity to identify itemized recurrent costs to maintain laboratory services and systems** **Enhanced financial, technical, and management capacity for GRZ-led laboratory services**	**Increased government technical ability to support and maintain laboratory services and systems** **Improved laboratory capacity to provide sustainable diagnostic services** **Improved MOH ability to self-support laboratory services** **Improved government capacity to independently manage and oversee laboratory services and systems** **Increased cost-effectiveness of laboratory systems management** **Increased GRZ capacity for financing and resource mobilization for laboratory service strengthening**	**Sustained access to essential HIV diagnostics** **Sustained country accountability for achieving planned program results** **Reduced reliance on US Government (USG) funding and partners for laboratory services**

i. Purpose

The purpose of this NOFO is to support quality and sustainable laboratory systems to support diagnosis and care of PLHIV. This NOFO is to strengthen and transfer laboratory administrated services to the MOH and enable the GRZ to define the costs of laboratory systems to support

MOH laboratory budget allocations.

ii. Outcomes

CDC may require or allow applicants to propose additional related project period outcomes other than those identified in the NOFO.

Short-Term Outcomes:

- Decreased interruptions of diagnostic services throughout the health system
- Improved planning process (HR, program, and financial) to achieve a fully functional laboratory system
- Accelerated implementation of costed laboratory service transition plan
- Increased capacity to identify itemized recurrent costs to maintain laboratory services and systems
- Enhanced financial, technical, and management capacity for GRZ-led laboratory services

Intermediate Outcomes:

- Increased government technical ability to support and maintain laboratory services and systems
- Improved laboratory capacity to provide sustainable diagnostic services
- Improved MOH ability to self-support laboratory services
- Improved government capacity to independently manage and oversee laboratory services and systems
- Increased cost-effectiveness of laboratory systems management
- Increased GRZ capacity for financing and resource mobilization for laboratory service strengthening

Long-Term Outcomes:

- Sustained access to essential HIV diagnostics
- Sustained country accountability for achieving planned program results
- Reduced reliance on USG funding and partners for laboratory services

iii. Strategies and Activities

Strategy 1: Maintain continuity with prior laboratory strengthening efforts

- Fund activities and procurement (e.g., supply chain management) to maintain high-quality laboratory system performance (i.e., VL/EID sample referral, testing and results return systems, LIMS (including integration with SmartCare, eLABS, DHIS2 and other systems), waste management, backup power systems, RTCQI as an activity related to baseline VL, diagnostic network optimization, and the biosafety/biosecurity program
- Provide TA to maintain high-quality laboratory system performance (including all sub-systems as noted above)

- Support implementation of QMS mentorship and TA to the MOH QACU to achieve accreditation of all 24 VL laboratories and ensure EQA compliance by all VL/EID testing facilities
- Identify remaining gaps to support laboratory strengthening measures
- Coordinate with MOH laboratory services unit to plan final steps to achieve a system that is functional (e.g., transition strategy with defined action plan)
- Develop a transition strategy that includes an action plan, how the transition process will be monitored, assessed, pivoted as needed to achieve outcomes, support and TA required during transition of organizational systems and governance – keeping up with certifications, financial, and business management as well as procurement and supply chain management
- Develop a transition plan where the MOH can provide/implement integrated, collaborative, and responsive measures for emerging and re-emerging infectious diseases

Strategy 2: Provide TA (tangible and mentorship) to achieve full system functionality

- Fund activities and procurement to address identified remaining gaps in laboratory system (i.e., VL/EID sample referral, testing and results return systems, LIMS including integration with SmartCare, eLABS, DHIS2 and other systems, waste management, backup power systems, RTCQI as an activity related to baseline VL, diagnostic network optimization, biosafety/biosecurity program, and laboratory-specific supply chain management to include integrated testing for HPV and TB at a minimum)
- Provide TA (tangible and mentorship) to address remaining gaps in laboratory system (including all sub-systems as noted above)
    - Tangible TA defined as provision of equipment, supplies, reagents, commodities, or fuel that is mutually agreed as required for laboratory system maintenance and otherwise unfunded

- Assist MOH to fully take on all PEPFAR-supported laboratory systems strengthening activities as agreed upon based on the financial assessments and PEPFAR priorities
- Provide TA for further adaptation of the diagnostic system for immediate needs such as outbreaks of novel disease, additional surveillance system requirements, and new international reporting mechanisms as guided by CDC
- Complete establishment of calibration centers
- Develop diagnostic equipment maintenance program
- Develop financial management plan of calibration centers to support equipment maintenance program and be financially self-sufficient and semi-independent from MOH
- Develop sustainable financial and business systems that will support transition of organizational systems and governance
- Develop a national courier vehicle replacement/salvage/maintenance program
- Assist in establishing a laboratory system that fully provides for diagnostic services
- Assist in implementing domestic production of EQA panels as necessary following implementation of ISO 17043

Strategy 3: Conduct capacity assessment of laboratory system and determine recurrent costs to maintain laboratory services

- Perform desk review and/or need assessments including site-level assessments to determine laboratory capacity and service cost estimates
- Cross check analysis to fully cost out and determine individual recurrent costs of the system by subcomponent
- Identify opportunities for GRZ to apply for and access donor funding for recurrent costs and GRZ's capacity to leverage government resources to ensure sustainability

Strategy 4: Stepwise transition of laboratory services and support and subcomponents to MOH implementation and oversight

- Ensure MOH has essential capacity to assume responsibility for management, oversight, administration, financial accountability of diagnostic network optimization, LIMS management, and all specified laboratory system sub-functions
- Co-manage the laboratory system in an advisory/observational capacity, while reducing participation over time to achieve sole MOH oversight and administration of laboratory services
- Enable MOH to demonstrate capacity for independent oversight and improve cost-effectiveness

In furtherance of the underlying purposes of this NOFO, Recipient is expected to provide copies of and/or access to all data, software, tools, training materials, guidelines, and systems developed under this NOFO to Ministry of Health and other relevant stakeholders, including HHS/CDC, for appropriate use consistent with underlying authorities.

1. Collaborations

a. With other CDC projects and CDC-funded organizations:

To achieve the activities of this NOFO, collaboration with the following CDC supported organizations will be essential:

- Organizations engaged in laboratory facility and equipment upgrades and provision of training and services related to VL/EID scale-up
- Organizations involved in provision of training and mentoring for laboratory accreditation
- Organizations that conduct laboratory management and leadership training and support equipment maintenance and calibration training and tools
- MOH, including the PHO to coordinate training, laboratory activities, supervision and TA, staffing, and specimen referral systems.

b. With organizations not funded by CDC:

As needed, the recipient of this award will be expected to collaborate with organizations not funded by CDC, including but not limited to non-government organizations and other PEPFAR agencies and their implementing partners.

2. Target Populations

The target populations for this NOFO include laboratory staff of all cadres and at all levels as well as PLHIV and the general population seeking laboratory health services, including HIV diagnosis, HIV care management and treatment, and EID.

a. Health Disparities

In an effort to assure that activities funded through this NOFO (1) affirm and advance, as appropriate, the role of health equity and an equitable, diverse, and inclusive workforce as core principles, and (2) advance the reduction of stigma and discrimination through the promotion, consistent with applicable laws, of civil and human rights to improve the health outcomes of persons at risk of, or living with, HIV and/or TB infection, CDC PEPFAR awards resulting from this NOFO may address the following activities, where and when appropriate:

- Community involvement in the design, implementation, and monitoring of HIV and TB services.
- Training for implementing partners involved in the design, implementation, and/or monitoring of activities on stigma, discrimination, gender equitable norms, human rights, and community engagement to minimize the likelihood for activities to unintentionally increase stigma and discrimination directed towards PLHIV, people with TB, and other KP.
- Programs to address evidenced health disparities and social barriers (e.g., HIV-related stigma) to HIV and TB services.
- Use of data to monitor disparities and implement strategies to improve access, service use, and outcomes.

iv. Funding Strategy

Applicants to this NOFO are encouraged to apply to the Approximate Total Fiscal Year Funding/Average One Year Award Amount/Approximate Average Award amount. Applications must not exceed this amount.

Component Funding: It is required that all PEPFAR-funded cooperative agreements be formulated for component funding. A component is a discrete set of activities with an associated budget. CDC will use component funding to provide funding for activities proposed in an application that received merit review but were not selected for funding in the initial award (i.e., at the onset of budget period 1) but may be funded at a later point in the budget period as programmatically necessary and as funding becomes available. Please review the following key points about component funding:

- Component funding must be setup at the time of the application. While preparing the application, applicants should review the expectations listed in the NOFO for Year 1 activities and group them under the anticipated components listed below. Only activities

planned for Year 1 should be grouped into components; applicants do not need to group activities in the high-level plan for the subsequent years 2-5 of the award into components. Funding amounts and components for years 2-5 will be determined at continuation.

- Each component must be a discrete set of activities with an associated budget. Distinguishable component budget narratives are required. Setting up components based on time (i.e., quarterly) is an appropriate distinction of activities, provided activities are clearly outlined.
- Applicants should submit the anticipated components on an SF-424A form as part of their application which shows all components for the budget period. The amounts should exactly match what is being requested for funding. Each component has its own approved amount and cannot be funded above the established amount. The combined total of all components must total the requested amount.
- If more than 4 components are proposed, multiple SF-424As will be needed. Applicants may include the first 4 components on one SF-424A form and the remaining components on a second SF-424A form. Applicants may download additional SF-424A forms and upload them as PDFs under "Budget Narrative Attachment Form" or "Other Attachments Form." These should be clearly labeled for easy identification and included in the Table of Contents for the entire submission.
- If possible, applicants are encouraged to submit a separate budget justification for each component, but it is not a requirement. Applicants will not be deemed incomplete if separate budget justifications are not provided with the submission. A separate budget justification will ultimately be required for all components that are funded.
- Any component that is not funded at the time of a new award may be deemed "Approved but Unfunded (ABU)". There is no guarantee that all components will be funded in a budget period as ABU components are subject to the availability of funds and the underlying legal authority for the work.
    - Components may not be awarded in order. All ABU components are eligible to receive funding once (and if) funds become available.
    - If funding becomes available, multiple components can be funded through the same funding action (single NOA).
    - If funding is awarded for an amount less than the ABU component approved amount, it is not possible to fund the difference at a later time. Components can only be funded once.

- If, during the funding confirmation, the Program Office approves a budget that differs from what was submitted at the time of application (reflected in the budget markup), a revised budget may be required in addition to the technical review responses. If required, the revised budget is due within thirty (30) days of the start of the budget period. If required, technical review responses will also be due within thirty (30) days of the start of the budget period and must be submitted separately from revised budget applications. Future funding for ABU components will not be awarded until a revised budget, if required, is submitted and approved by CDC.
- Once components are awarded, funds cannot be redirected between components. However, funds may be redirected within a component between object class categories.

It is critical to ensure accountability, transparency, and programmatic performance of all U.S. taxpayer dollars. When developing the annual work plan, please be advised that the annual Country Operational Plan (COP) guidance requires that CDC take decisive action if an implementing partner is underperforming programmatically during any quarter of a fiscal year.

Applicants are encouraged to consider the following in the development of their budgets and budget narratives:

CDC anticipates an Approximate Total Fiscal Year Funding/Average One Year Award Amount/Approximate Average Award of $9,000,000 with the following components:

- Component 1 - COP23 Q1 Targets/Activities;
- Component 2 - COP23 Q2 Targets/Activities;
- Component 3 - COP23 Q3 Targets/Activities;
- Component 4 - COP23 Q4 Targets/Activities;
- Component 5 - COP23 Additional Targets/Activities;
- Component 6 – Placeholder for Potential Non-PEPFAR Funds (TBD; Other Emerging Public Health Activities)

Applicants must specify a descriptive title for each corresponding column shown on the SF-424A, followed by the total (cumulative) in the column to the far right of the SF-424A. Applicants are encouraged to use the components listed above, but may propose alternative budget components so long as the general component funding guidance is followed.

Funding provided under this NOFO is subject to the availability of funds. The total number of years for which federal support has been programmatically 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. All future year funding will be based on satisfactory programmatic progress and the availability of funds.

Coronavirus Disease 2019 (COVID-19) Funds: A recipient of a grant or cooperative agreement awarded by the Department of Health and Human Services (HHS) with funds made available under the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123); the Coronavirus Aid, Relief, and Economic Security Act, 2020 (the "CARES Act") (P.L. 116-136); the Paycheck Protection Program and Health Care Enhancement Act (P.L. 116-139); the Consolidated Appropriations Act and the Coronavirus Response and Relief Supplement Appropriations Act, 2021 (P.L. 116-260) and/or the American Rescue Plan of 2021 [P.L. 117-2] agrees, as applicable to the award, to: 1) comply with existing and/or future directives and guidance from the Secretary regarding control of the spread of COVID-19; 2) in consultation and coordination with HHS, provide, commensurate with the condition of the individual, COVID-19 patient care regardless of the individual's home jurisdiction and/or appropriate public health measures (e.g., social distancing, home isolation); and 3) assist the United States Government in the implementation and enforcement of federal orders related to quarantine and isolation.

In addition, to the extent applicable, Recipient will comply with Section 18115 of the CARES Act, with respect to the reporting to the HHS Secretary of results of tests intended to detect SARS–CoV–2 or to diagnose a possible case of COVID–19. Such reporting shall be in accordance with guidance and direction from HHS and/or CDC. HHS laboratory reporting guidance is posted at: https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf.

Further, consistent with the full scope of applicable grant regulations (45 C.F.R. 75.322), the purpose of this award, and the underlying funding, the recipient is expected to provide to CDC copies of and/or access to COVID-19 data collected with these funds, including but not limited to data related to COVID-19 testing. CDC will specify in further guidance and directives what is encompassed by this requirement.

This award is contingent upon agreement by the recipient to comply with existing and future guidance from the HHS Secretary regarding control of the spread of COVID-19. In addition, recipient is expected to flow down these terms to any subaward, to the extent applicable to activities set out in such subaward.

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy

CDC expects that routine performance data is reviewed, cleaned, and used for program management. To this effect, the recipient should hold regular review meetings to discuss performance and use data in program quality improvement activities.

The recipient should allocate funds made available under this NOFO for both evaluation activities and performance monitoring. While the final funding amount will be agreed upon by both CDC and the recipient, a minimum of 4% of funds should be allocated for monitoring activities and 5% of funds used for evaluation activities. These are estimates for the total funding over the 5-year project.

PERFORMANCE MONITORING
Some anticipated PEPFAR (MER) and non-MER indicators, targets, and reporting frequencies corresponding to Year 1 of the NOFO are shown below. Applicants should also propose any additional relevant PEPFAR MER and non-MER indicators as part of their initial Evaluation and Performance Measurement Strategy.

Applicants should note that these may be adjusted or new targets and indicators may be identified in subsequent years based on implementation of HIV/AIDS epidemic control strategies and program priorities. Any gaps or unmet needs not fulfilled in the first year may affect the targets of the subsequent years.

Unless otherwise indicated, the reporting periods for MER indicators will mirror the PEPFAR MER indicator reporting frequency (quarterly, semi-annually, and annually). Additional information regarding MER reporting is included in the MER Guidance and resource materials, available at the following link (copy/paste into web browser to access):

https://datim.zendesk.com/hc/en-us/articles/360000084446-MER-Indicator-Reference-Guides.

PEPFAR MER Process and Outcome Measures:

- **LAB_PTCQI**: Number of PEPFAR-supported laboratory-based testing and/or Point-of-Care Testing (POCT) sites engaged in continuous quality Improvement (CQI) and proficiency testing (PT) activities. [Target: Not Assigned; Reporting Frequency: Annually]
- **Viral Load Test Coverage**: Percentage of patients eligible for viral load testing who have received a viral load test. Definition: TX_PVLS denominator / TX_CURR (from 2 quarters prior). [Target > 95%; Reporting Frequency: Quarterly]
    - (Note, TX_PVLS is the percentage of ART patients with a suppressed viral load (VL) result (<1000 copies/ml) documented in the medical or laboratory records/laboratory information systems (LIS) within the past 12 months)

Non-MER Additional Performance Measures:

- Number of VL and EID tests conducted in the supported laboratories [Target: 1,300,000; Reporting Frequency: Annual]
- Proportion of 123 laboratories performing POCT VL and EID passing EQA and 24 laboratories performing "conventional" VL and EID passing EQA [Target: 100%; Reporting Frequency: Semi-Annual]
- Proportion of 24 laboratories maintaining or achieving ISO 15189 accreditation [Target: 100%; Reporting Frequency: Annual]
- Proportion of VL laboratories processing VL liquid waste in accordance with MOH guidelines [Target: 100%; Reporting Frequency: Monthly]
- Proportion of requests for assistance supported [Target: 100%; Reporting Frequency: Annually]
- Proportion of pipettors and centrifuges used in VL laboratories calibrated within Zambia [Target: 100%; Reporting Frequency: Quarterly]
- Proportion of high throughput VL/EID laboratories passing EQA [Target: 100%; Reporting Frequency: Semi-Annual]
- Proportion of PEPFAR-supported hub laboratories performing GeneXpert VL and EID passing EQA [Target: 100%; Reporting Frequency: Semi-Annual]
- Proportion of EID and priority VL results returned within 24 hrs [Target: 95%; Reporting Frequency: Weekly]
- Proportion of routine VL results returned within 14 days [Target: 95%; Reporting Frequency: Weekly]
- Proportion of results on file by SmartCare report or TDB matching with DISA [Target: 99%; Reporting Frequency: Monthly]
- Number of QA units achieving ISO 17043 accreditation [Target: 11; Reporting Frequency: Annually]
- Proportion of new machine placements based on DNO [Target: 100%; Reporting Frequency: Annually]
- Proportion of hub laboratories certified [Target: 80%; Reporting Frequency: Annually]

- Proportion of laboratories compliant with policy [Target: 95%; Reporting Frequency: Quarterly]
- Proportion of laboratories with power backup [Target: 100%; Reporting Frequency: Quarterly]
- Proportion of laboratories with no stock out [Target: 100%; Reporting Frequency: Annually]
- Proportion of courier systems with internally managed programs [Target: 100%; Reporting Frequency: Annually]
- Proportion of financial management and internal control gaps addressed by the partner [Target: 90%; Reporting Frequency: Quarterly]
- Proportion of accurate quarterly financial master tracker reports submitted on time [Target: 100%; Reporting Frequency: Annually]
- Proportion of cooperative agreement officials that have a workplan and annual review in place [Target: 100%; Reporting Frequency: Annually]

Data Sources for MER and Custom Indicators: Data sources may include interviews with MOH chief of laboratory services and QACU staff, CoAg reports, registers, tally sheets, electronic and paper patient records, quarterly progress reports, surveillance and survey reports, laboratory reports, mentorship and assessment reports and records from Laboratory Quality Officers and other program monitoring tools.

EVALUATION
The evaluation topics below are examples of areas that the recipient may be expected to answer through process or outcome evaluation(s). Applicants should include at least 1, but no more than 3 potential evaluation questions. Recipients will be expected to conduct a mid-term and/or end-year evaluation.

Sample Evaluation Topics:

- Country ownership of laboratory system improvement process to support HIV and VL testing (Process/Outcome Evaluation)
- Data quality monitoring for VL coverage of general adult HIV, PBF women and EID testing at facility level (Process Evaluation)

Evaluation Data Sources: Data sources may include registers, tally sheets, electronic and paper patient records, partner progress reports, focus groups, in-depth interviews, surveys, and other program monitoring tools.

Dissemination of Evaluation Results: Dissemination channels may include local and international conferences and forum abstract presentations, conference poster displays, manuscripts, bulletins, reports, presentations to technical working groups and stakeholder meetings, and other approved products in print and electronic media. The primary intended users of evaluation results and findings will be the wider program stakeholders. All evaluation reports will be publicly available on PEPFAR resource sites. CDC and stakeholders will use overall evaluation findings during the five-year NOFO period to share and implement key recommendations to strengthen program implementation and effectiveness, sustainability, and

continued program improvement upon completion of the award.

Recipients should plan to conduct an economic evaluation or costing analysis during the COP or program review processes once during the award project period to determine:

- Cost and/or unit costs, and cost drivers of interventions or activities
- Cost-effectiveness of interventions or activities

Recipients will receive advance notice and guidance about conducting this activity and how to allocate funds to conduct a cost analysis or economic evaluation.

Evaluations and strategy should align with national, PEPFAR, and agency requirements and priorities, and will be reviewed and may require approval as part of the COP. As such, the example evaluation topics listed in this NOFO may be amended based on feedback from OGAC 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 the 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) as new pertinent information becomes available. If applicable, throughout the lifecycle of the project. Updates to DMP should be provided in annual progress reports. 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/additional-requirements/ar-25.html.

Where the applicant chooses to, or is expected to, take on specific evaluation studies, the applicant 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, if applicable, 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 must provide supporting documentation to show evidence of their organizational capacity to implement the approach. Documentation supporting this element must be submitted in the appendix, be clearly labeled, and be easily identifiable. Applicants must submit the following materials in their appendix:

- Statement of Experience demonstrating organizational capacity to address the requirements of the NOFO and specifically in the following areas:
    - Capacity in sub-Saharan Africa and specifically in Zambia to maintain and enhance integrated laboratory systems, building on the foundation of the PEPFAR supported VL/EID diagnostic system, leading to full local government oversight and management
    - Experience establishing and managing national level laboratory QMS including laboratory data management, EQA, waste management, biosafety/biosecurity, supply chain management, power backup system management, laboratory equipment maintenance, courier system management, and DNO
    - Experience in financial and programmatic management of laboratory systems, including fiscal planning/system cost assessments
    - Experience working with MOH and other partner supported laboratory systems to integrate and harmonize laboratory systems under the auspices of the National Laboratory Strategic Plan
- CVs/Resumes for key personnel (at the applicant's discretion, but may include Principal Investigator, Business Official, monitoring and evaluation expert, laboratory financial management expert, laboratory logistics expert, diagnostics technical expert)
- Job Descriptions for key personnel
    - Should include information on qualifications/experience on the following: laboratory system financial management, QMS, and laboratory technical service delivery
    - Should demonstrate organizational HR capacity to lead transition and hand over of previously partner-supported program-specific laboratory systems for sustainable integrated laboratory systems
        - Relevant technical specialties include laboratory QMS, business operations and systems engineering.
- Organizational Chart
- Financial Management Statement that describes the following:
    - Systems and procedures used to manage funds
    - Procurement procedures
    - Previous experience managing budgets greater than $6,000,000

Applicants must title these documents in their appendix as follows: “Experience,” “CVs/Resumes,” “Job Descriptions,” “Organizational Chart,” “Financial Statement” and include in the Table of Contents.

d. Work Plan

Applicants must include a work plan within the Project Narrative that demonstrates how the outcomes, strategies, activities, monitoring, evaluation, 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

If funded, a cooperative agreement, as defined by the Federal Grant and Cooperative Agreement Act of 1977 (P.L. 95-224, 31 USC 6301 et seq.), will be used as the funding mechanism to award funds. CDC will have substantial programmatic involvement after the award is made. Substantial involvement is in addition to all post-award monitoring, technical assistance, and performance reviews undertaken in the normal course of stewardship of federal funds and is not intended to gain stricter controls. CDC may coordinate, facilitate, collaborate, and/or intervene to programmatically effectuate performance under the award, consistent with applicable law, regulations, and the terms of this NOFO. The substantial involvement responsibilities

enumerated in this NOFO and any additional substantial involvement responsibilities will be used to support the purposes of this NOFO.

Under a cooperative agreement, CDC is responsible for normal oversight and monitoring activities. Examples of normal oversight and monitoring activities are listed below:

1. Organize an orientation meeting with the recipient for a briefing on applicable U.S. Government, HHS/CDC, and 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 OGAC.
2. Review and approve recipient's annual work plan and detailed budget, as part of the PEPFAR COP review and approval process, managed by OGAC.
3. Review and approve the recipient's monitoring and evaluation plan, including for compliance with the strategic information guidance established by OGAC.
4. Meet on a regular basis with the recipient to assess expenditures in relation to approved work plan and modify plans as necessary.
5. Meet on a quarterly basis with the recipient to assess quarterly technical and financial progress reports and modify plans as necessary.
6. 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 COP review and approval process, managed by OGAC.
7. Provide technical oversight for all activities under this award.

Above and beyond the normal oversight and monitoring examples, CDC's substantial involvement includes, but is not limited to, the following activities:

1. Involvement in the review and selection of key personnel and/or post-award sub-contractors and/or sub-recipients to be involved in the activities performed under this agreement. This is solely limited to reviewing and making recommendations as necessary to the process used by the recipient to select key personnel and/or post-award sub-contractors and/or sub-recipients to be involved in the activities performed under this agreement, as part of the PEPFAR COP review and approval process, managed by OGAC.
2. Provide technical assistance, as mutually agreed upon or as may be necessary based on performance and revise annually work plans in concert with the recipient during validation of the first and subsequent annual work plans. This could include providing expert technical assistance and targeted training activities in specialized areas, such as strategic information, project management, and confidential counseling and testing.
3. Provide appropriate 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).
4. 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.

5. Provide technical assistance or advice on any data collections on 10 or more people that are planned or conducted by the recipient. Data collections funded under this award, in particular 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 Paperwork Reduction Act of 1995 (PRA) clearance prior to the start of the project.
6. Provide continuous 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.
7. Assist the recipient in developing and implementing quality-assurance criteria and procedures.
8. Facilitate and/or participate in in-country planning and review meetings for technical assistance activities.
9. 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 collaborating strategically with the recipient on identified gaps and continuous quality improvement, which might include more thorough data quality or service quality assessments as indicated.
10. Coordinate with the recipient to 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, Evaluation, and Reporting (MER) strategy, PEPFAR's Evaluation Standards of Practice (ESoP), and CDC's Data for Partner Monitoring Program (DFPM).
11. Provide ethical reviews in order to direct and/or facilitate desired changes, as necessary, for evaluation activities, including from HHS/CDC headquarters. Evaluations can be process, outcome, or economic.
    A. Process Evaluation: measures how the intervention was delivered, what worked/did not, differences between the intended population and the population served, and access to the intervention.
    B. Outcome Evaluation: determines effects of intervention in target population(s) (e.g., change in knowledge, attitudes, behavior, capacity, etc.).
    C. Economic Evaluation: justifies the investment, and determines the efficiency and economic impact of interventions.
12. Supply the recipient with protocols for related evaluations.

As described in current COP guidance, quarterly performance thresholds should be monitored throughout the year. In addition to CDC's substantial involvement, the agency will conduct normal oversight and monitoring activities to effectuate program performance. Underperformance in achieving established programmatic targets may result in corrective action being taken as outlined in current COP guidance. Corrective action may include the implementation of a Target Improvement Plan (TIP) and/or a Corrective Action Plan (CAP) to assist recipients with meeting established programmatic targets.

The agency will assess recipients' level of effort, including any preventative action taken, and any extenuating circumstances internal and external to the recipient when considering a TIP and/or CAP. Be advised that any changes made to the COP guidance related to substantial involvement and the monitoring of quarterly and annual performance PEPFAR targets will become effective and implemented in accordance with the revised/new COP guidance. These changes may impact the agency's substantial involvement and/or how it ensures the achievement of recipients' quarterly and annual PEPFAR targets.

The use of a TIP and/or CAP does not replace or reduce recipient's requirement to comply with Federal regulations promulgated in 45 CFR § 75.371. If a recipient fails to comply with Federal statutes, regulations or the terms and conditions of its cooperative agreement, CDC or the pass-through entity may impose additional conditions, as described in 45 CFR § 75.207. If CDC or the pass-through entity determines that noncompliance cannot be remedied by imposing additional conditions, CDC or the pass-through entity may take one or more actions legally available.

B. Award Information

1. Funding Instrument Type:

CA (Cooperative Agreement)

CDC's substantial involvement in this program appears in the CDC Program Support to Recipients Section.

2. Award Mechanism:

U2G -Global HIV/AIDS Non-Research Cooperative Agreements

3. Fiscal Year:

2023

4. Approximate Total Fiscal Year Funding:

$9,000,000

5. Total Period of Performance Funding:

$0

This amount is subject to the availability of funds.

The Approximate Project Period of Performance Funding/Estimated Total Funding for the Total 5 year Project Period is None. The Approximate Total Fiscal Year Funding/Average One Year Award Amount/Approximate Average Award amount for years 2-5 will be set at continuation.

Estimated Total Funding:

$0

6. Total Period of Performance Length:

5 year(s)

year(s)

7. Expected Number of Awards:

1

8. Approximate Average Award:

$9,000,000

Per Budget Period

The Approximate Total Fiscal Year Funding/Average One Year Award Amount/Approximate Average Award amount for Year 1 is $9,000,000. The expected number of awards is 1. Exact amounts for each award under this NOFO will be determined at the time of award. Applicants are encouraged to apply to the Approximate Total Fiscal Year Funding/Average One Year Award Amount/Approximate Average Award amount.

9. Award Ceiling:

$0

Per Budget Period

This amount is subject to the availability of funds.

The Award Ceiling is None. Please refer to the Approximate Total Fiscal Year Funding, Average One Year Award Amount, and Approximate Average Award for the anticipated total funding amount for Year 1. This amount is approximate and is subject to the availability of funds.

10. Award Floor:

$0

Per Budget Period

None

11. Estimated Award Date:

September 30, 2023

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 NOFO.

If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

C. Eligibility Information

1. Eligible Applicants

Eligibility Category:
99 (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 and eligibility is unrestricted, meaning any and all types of organizations and entities are eligible to apply.

In addition, as may be required by host country laws, applicant is expected to comply with and document that it has satisfied all regulatory requirements of their governing entities that could otherwise compromise the integrity and resources provided by this program or make the conduct of expected activities under this award unable to be performed. Applicants must also meet the criteria established in CDC’s pre-award risk assessment to be eligible to receive funds under this NOFO.

The Approximate Total Fiscal Year Funding/Average One Year Award Amount/Approximate Average Award amount for this NOFO is $9,000,000. CDC will consider any application requesting an award higher than this amount as non-responsive 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” and “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.

NEW THIS YEAR: CDC reserves the right to determine an application non-responsive as part of the Phase I review if the application does not respond to and falls outside the published scope of the NOFO as set out in the Background and CDC Project Description sub-sections within the Funding Opportunity Description section of this NOFO.

NEW THIS YEAR: CDC reserves the right to determine an application non-responsive if the Project Narrative file exceeds the 20-page limit. Although not required, the following four administrative materials may be included in the Project Narrative file and will not count toward the 20-page limit: 1) Table of Contents, 2) Cover or Title Page, 3) Non-Disclosure Statement, and 4) Acronym or Abbreviation List. All other content included in the Project Narrative file will count toward the 20-page limit.

CDC will provide justification for any application that is determined non-responsive, including a description of why it was considered to be out of the published NOFO scope, if applicable. Non-responsive applications will not advance to Phase II review.

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 no statutory matching requirement for this NOFO exists, 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.

PLEASE NOTE: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission (SF-424, field 8c). The UEI is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and Grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov- Finding the UEI.

a. Unique Entity Identifier (UEI):

All applicant organizations must obtain a Unique Entity Identifier (UEI) number by registering in SAM.gov prior to submitting an application. A UEI number is a unique twelve-digit identification number assigned to the registering organization.

If funds are awarded to an applicant organization that includes sub-recipients, those sub-recipients must provide their UEI 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 and a Unique Entity Identifier (UEI). 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 SAM.gov and the SAM.gov Knowledge Base.

c. Grants.gov:

The first step in submitting an application online is registering your organization at www.grants.gov, the official HHS E-grant Web site. Registration information is located at the "Applicant Registration" option at www.grants.gov.

All applicant organizations must register at 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.

Step	System	Requirements	Duration	Follow Up
1	System for Award	1. Go to SAM.gov and designate an E-Biz POC (You will need to have an active SAM account before you can register on	3-5 Business Days but up to 2 weeks and must be renewed once a year	For SAM Customer Service Contact https://

	Management (SAM)	grants.gov). The UEI is generated as part of your registration.		fsd.gov/ fsd-gov/ home.do Calls: 866-606-8220
2	Grants.gov	1. Set up an individual account in Grants.gov using organization's new UEI number to become an Authorized Organization Representative (AOR) 2. Once the account is set up the E-BIZ POC will be notified via email 3. Log into grants.gov using the password the E-BIZ POC received and create new password 4. This authorizes the AOR to submit applications on behalf of the organization	It takes one day (after you enter the EBiz POC name and EBiz POC email in SAM) to receive a UEI (SAM) which will allow you to register with Grants.gov and apply for federal funding.	Register early! Applicants can register within minutes.

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.

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)

b. Application Deadline

Due Date for Applications 03/27/2023

03/27/2023

11:59 pm U.S. Eastern 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.

Due Date for Information Conference Call

N/A

5. Pre-Award Assessments

Risk Assessment Questionnaire Requirement

CDC is required to conduct pre-award risk assessments to determine the risk an applicant poses to meeting federal programmatic and administrative requirements by taking into account issues such as financial instability, insufficient management systems, non-compliance with award conditions, the charging of unallowable costs, and inexperience. The risk assessment will include an evaluation of the applicant's CDC Risk Questionnaire, located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, as well as a review of the applicant's history in all available systems; including OMB-designated repositories of government-wide eligibility and financial integrity systems (see 45 CFR 75.205(a)), and other sources of historical information. These systems include, but are not limited to: FAPIIS (https://www.fapiis.gov/), including past performance on federal contracts as per Duncan Hunter National Defense Authorization Act of 2009; Do Not Pay list; and System for Award Management (SAM) exclusions.

CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-1132 annually. This questionnaire, which is located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, along with supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. If your organization has completed CDC's Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization representative to include the original submission date, organization's EIN and UEI.

When uploading supporting documentation for the Risk Questionnaire into this application package, clearly label the documents for easy identification of the type of documentation. For example, a copy of Procurement policy submitted in response to the questionnaire may be labeled using the following format: Risk Questionnaire Supporting Documents _ Procurement Policy.

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. Applicants do **not** need to submit an LOI.

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

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 application.

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.

The Project Narrative must include a heading titled Organizational Capacity of Applicants to Implement the Approach, under which applicants should include a brief description of their organizational capacity.

A list of materials specific to this NOFO that must be submitted in the appendix is included in Part II Section 2. A. 2 c. Organizational Capacity of Recipients to Implement the Approach. Additional instructions on appendix submittal requirements can be found in Section H Other Information.

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.

Vital records data, including births and deaths, are used to inform public health program and policy decisions. If applicable and consistent with the cited statutory authority for this NOFO, applicant entities are encouraged to collaborate with and support their jurisdiction's vital records office (VRO) to improve vital records data timeliness, quality and access, and to advance public health goals. Recipients may, for example, use funds to support efforts to build VRO capacity through partnerships; provide technical and/or financial assistance to improve vital records timeliness, quality or access; or support vital records improvement efforts, as approved by CDC.

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 45 CFR 75 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. 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.

15. Copyright Interests Provisions

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.

16. 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.

Indirect Costs
Indirect costs on grants awarded to foreign organizations and foreign public entities are only available as provided by 45 CFR 75.414. All requests for indirect costs must be submitted in the budget. 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
HHS/CDC will assess the applicant's systems required to manage the activities supported with funds provided under this NOFO. Should an award be made, it is expressly conditioned upon that assessment, as well as any measures, mitigation, or means by which the applicant has or will address any vulnerabilities or weaknesses found in the assessment. The applicant 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 any resulting 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
Conference costs and fees for any member of a foreign government's delegation to an international conference sponsored by a multilateral organization under this award may not be

used without express written approval of the Grants Management Officer/Grants Management Specialist and the CDC project officer.

- Definitions:
    - 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.
    - 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.
    - 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:
    - 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 precluded.

Prostitution and Sex Trafficking

A standard term and condition of award will be included in the final notice of award; all recipients 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.

Trafficking in Persons Provision

- No contractor or sub-recipient 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 sub-recipient has violated paragraph 1 of this section or that an employee of the contractor or sub-recipient 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 sub-recipient, HHS/CDC may, without penalty, (i) require the Recipient to terminate immediately the contract or sub-award 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 sub-recipient.
- The recipient must include in all sub-agreements, including sub-awards and contracts, a provision prohibiting the conduct described in sub-section a by private party sub-recipients, 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 Recipient agrees not to disburse, or sign documents committing the Recipient 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 Recipient shall insert the following clause, or its substance, in its agreement with the Designated Sub-recipient:
    - The Recipient 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), UNSCR 1368 (2001), UNSCR 1373 (2001), and UNSCR 1989 (2011) (available by search at the following link: http://unscr.com/en/resolutions), both HHS/CDC and the Recipient 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 Recipient 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 sub-agreements, including contracts and sub-awards, 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 recipient 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 (see e.g. https://www.un.org/securitycouncil/sanctions/information). 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 Recipient is requested or wishes to provide assistance in areas that involve workers' rights or the Recipient requires clarification from HHS/CDC as to whether the activity would be consistent with the limitation set forth above, the Recipient must notify HHS/CDC and provide a detailed description of the proposed activity. The

Recipient must not proceed with the activity until advised by HHS/CDC that it may do so.

- The Recipient must ensure that all employees and sub-contractors 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 sub-contracts 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 serfdom, or forced or compulsory labor, including forced or compulsory recruitment of children for use in armed conflict; the use, procuring, or offering of a child for prostitution, for the production of pornography or for pornographic purposes; the use, procuring, or offering of a child for illicit activities in particular for the production and trafficking of drugs; and work which, by its nature or the circumstances in which it is carried out, is likely to harm the health, safety, or morals of children, as determined by the laws, regulations, or competent authority of the country.

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 Recipient requires clarification from HHS/CDC as to whether the activity would be consistent with the limitation set forth above, the Recipient must notify HHS/CDC and provide a detailed description of the proposed activity. The Recipient must not proceed with the activity until advised by HHS/CDC that it may do so.
- The Recipient must ensure that its employees and sub-contractors 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 sub-contracts 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 sub-contractors (a) provide, before commencing performance under any contracts or sub-contracts 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 sub-contracts under this agreement,

a clause similar to this clause (including this sentence) imposing upon those contractors and sub-contractors 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 source and nationality restrictions as provided in 22 CFR 228, and having their source and nationality in countries as listed in Geographic Code 937 or 935 or as HHS/CDC may otherwise agree in writing.

Environmental Impact Statement
HHS/CDC and the Recipient 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 Recipient is required to create and follow an environmental mitigation plan and report (EMPR) for each thematic area covered by this agreement. 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 the HHS/CDC. The Recipient will need to discuss this requirement with the Grants Management Officer/Grants Management Specialist.

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-GH-23-0010."

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 https://www.state.gov/reports-pepfar/. This guidance does not govern the use of the HHS and/or CDC logo; express written permission via a license must be obtained prior to the use of the HHS and/or CDC logo separate from the PEPFAR brand. The use of the CDC or HHS logo is addressed in the CDC Non-Research Terms and Conditions (page 11): https://www.cdc.gov/grants/documents/General-Terms-and-Conditions-Non-Research-Awards.pdf.

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.

Project Officer prior approval is also required for registration fees for virtual scientific conference attendance for IPs with accepted oral posters or oral abstracts for presentations that give clear attribution to PEPFAR, which may be authorized if funds are available. Please note that use of cooperative agreement funds to attend scientific conferences by non-presenters and non-oral poster presenters is not authorized, except by Partner Government Officials with approval of the PEPFAR Deputy Principals.

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.

Monitoring and Evaluation Section (SIMS)
HHS/CDC or its designee will also undertake monitoring and evaluation of the defined activities within this award. 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 of the activities conducted under the award and use of HHS/CDC funding under this award and 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, Evaluation, and Reporting (MER) strategy and CDC's Data for Partner Monitoring Program (DFPM). All evaluations conducted with PEPFAR funds must adhere to planning and reporting requirements as outlined in the PEPFAR ESoP including posting a final evaluation report detailing adherence to all evaluation standards on a publicly accessible website within 90 days of completion. https://datim.zendesk.com/hc/en-us/article_attachments/360040023292/PEPFAR_evaluation_standards_of_practice_v3.1_October_2019.pdf.

Restrictions Pending Review of Proposed Data Collections for PEPFAR Awards
In an effort to ensure that data collections under this award comply with applicable legal and regulatory requirements (e.g., human subjects and Paperwork Reduction Act requirements), 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 (e.g., scientific conference abstracts or presentations, journal articles, or other published reports) will require project descriptions or, where appropriate, protocols for technical review and review of institutional human subjects protection considerations by CDC. Submissions and review will be conducted through a designated CDC system, i.e., the Study Tracking and Reporting System (STARS), accessed by CDC personnel. Funds for implementing these activities will be restricted until all necessary institutional reviews and approvals to initiate the activities have been obtained. Funds for preparatory activities (e.g., protocol development, training, equipment, reagents, and site preparation) may be available prior to project approval by CDC. To facilitate the availability of

such funding, the budget and narrative should clarify which activities are preparatory.

CDC STARS project approvals 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 CDC STARS project 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.

Reference materials are available to recipients to assist with project submission and approval requirements by contacting the awarding CDC country office. Applicants to this NOFO may also request these materials by sending an email request to pepfarfoas@cdc.gov.

17. Data Management Plan

As identified in the Evaluation and Performance Measurement section, applications involving data collection or generation must include a Data Management Plan (DMP) as part of their evaluation and performance measurement plan unless CDC has stated that CDC will take on the responsibility of creating the DMP. The DMP describes plans for assurance of the quality of the public health data through the data's lifecycle and plans to deposit the 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/additional-requirements/ar-25.html.

18. Other Submission Requirements

a. Electronic Submission:

Applications must be submitted electronically by using the forms and instructions posted for this notice of funding opportunity at www.grants.gov. Applicants can complete the application package using Workspace, which allows forms to be filled out online or offline. All application attachments must be submitted using a PDF file format. Instructions and training for using Workspace can be found at www.grants.gov under the "Workspace Overview" option.

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.

https:// www.grants.gov/help/html/help/index.htm? callingApp=custom#t= Get_Started%2FGet_Started. htm

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 via email.

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
ii. Evaluation and Performance Measurement
iii. 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

i. Approach **Maximum Points:** 30

How well does the application provide evidence-based strategies that demonstrate an understanding of the current laboratory system and are designed to meet the goals of the transition of laboratory services to the QACU? **(10 points)**

To what extent does the application show an implementable plan to assess the organizational capacity and financial needs for the transition of oversight and management of existing laboratory systems to the GRZ? **(10 points)**

How well does the applicant plan for country ownership of all aspects of the laboratory system, enabling value-adds/further integration of the PEPFAR - supported VL/EID focused laboratory system for other needs? **(10 points)**

ii. Evaluation and Performance Measurement **Maximum Points:** 25

How well does the applicant describe an initial project evaluation strategy that includes timeframe, key stakeholders, evaluation questions, how these will be measured, and how findings will be disseminated? **(15 points)**

To what extent does the applicant describe a system for reviewing and adjusting program activities based on performance monitoring and evaluation findings? **(10 points)**

iii. Applicant's Organizational Capacity to Implement the Approach **Maximum Points:** 45

How well does the applicant have established infrastructure and relevant experience in Zambia to immediately assist the GRZ to integrate, refine, and transition all aspects of laboratory

services? **(20 points)**

To what extent is staff involved in this project qualified to perform the tasks described? (CVs/Resumes provided should include information that they are qualified in the following: laboratory system financial management, QMS and laboratory technical service delivery) **(25 points)**

Budget **Maximum Points:** 0

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 PEPFAR? 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

Applicants to this NOFO will be scored based on direct consideration of findings from the Objective Review Panel and, as applicable, responsiveness to the funding preference listed below. Applicants meeting the criteria set forth in this funding preference will receive additional points beyond the possible total of 100 as follows:

PEPFAR Local Partner Funding Preference (10 points)

Applicants must submit supporting documentation and a narrative letter by and through an authorized representative on the organization's official letterhead as a separate attachment from the Project Narrative and Appendices and labeled as "Local Partner Preference" to be considered to receive the Phase III Local Partner Funding Preference points under this NOFO. This documentation should be submitted as a separate attachment from the Appendix file and does not count toward the 90-page limit for the Appendix. This documentation must demonstrate how the prime applicant organization meets at least one of the three criteria listed below under the "PEPFAR Local Partner definition" at the time of application. The full PEPFAR Local Partner Definition, along with sub-regional groupings, can be found in the Glossary section of the NOFO. Funding preference points do not apply to sub-recipients/partners or consortium members.

For each of the criteria listed below, a description of the supporting documentation is provided. Applicants that do not provide labeled supporting documentation to meet the PEPFAR Local Partner definition below will not be considered for, nor receive, the Funding Preference points as noted under Phase III Review. Applicants must meet the requirements of the local partner definition at the time of application submission in order to be eligible for funding preference points. Funding preference points will not be awarded on a scale for partially meeting the definition.

Applicants may choose to submit one supporting document to demonstrate how the applicant meets multiple portions of the definition. If one document is submitted to address multiple portions, it must be clearly noted in the accompanying narrative letter from the authorized representative what the document is addressing.

Any supporting documentation not submitted in English must be described in the accompanying narrative letter from the authorized representative. Submissions may be verified for accuracy.

PEPFAR Local Partner Definition/Eligibility by Criteria	**Supporting Documentation (to be labeled as "Local Partner Preference")**
Individual An individual must be a citizen or lawfully admitted permanent resident of and have his/her principal place of business in the country or region 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	Authorized representative must provide the following documents, plus a letter describing how the documents support that the organization meets the definition under Paragraph (1) of the PEPFAR Local Partner Definition: • Evidence of principal place of business (i.e., certificate of registration/incorporation in country, contact information including physical address, etc.) • If applicant is a sole proprietorship, applicant must provide evidence that the owner of the sole proprietorship meets the requirements above, along with evidence of such ownership (e.g., certificate of registration, organization, or incorporation).
PEPFAR Local Partner Definition/Eligibility by Criteria	**Supporting Documentation (to be labeled as "Local Partner Preference")**
Entity other than a sole proprietorship (such as, a corporation or not-for-profit) must meet all three areas of eligibility: **(1) EITHER** 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 involved **OR** must exist in the region where the entity's funded	Applicants other than sole proprietorships, by and through an authorized representative, must provide the following supporting documents plus a letter on the organization's official letterhead describing how these documents support that the organization meets all three areas of eligibility under this criterion of the PEPFAR Local Partner Definition: • For eligibility area (1), the supporting documentation may include but is not limited to: official documentation from a national or sub-national government issuing organization providing valid

PEPFAR programs are implemented; **(2) EITHER** must be at 75% beneficially owned at the time of application by individuals who are citizens or lawfully admitted permanent residents of that same country, **OR** at least 75% of the entity's staff (senior, mid-level, support) at the time of application must be citizens or lawfully admitted permanent residents of that same country; and **(3)** 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	evidence of the organization's incorporation or legal organization in the country or region and the principal place of business (i.e., certificate of registration, organization, or incorporation). In addition to describing how these documents support eligibility area (1), the supporting letter must include a statement confirming that the organization is incorporated or legally organized under the laws of, and has its principal place of business in, the country or region; • For eligibility area (2), the supporting documentation may include but is not limited to: o evidence of organization and, where appropriate, ownership; a list of the individual officers and/or owners with corresponding titles and roles; and, the citizenship/permanent resident status of each individual officer and/or owner(s). In addition to describing how these documents support eligibility area (2), the letter must include a statement confirming that the entity is at least 75% beneficially owned at the time of application by individuals who are citizens or lawfully admitted permanent residents of that same country (including an exact percentage); OR o a statement within the letter that certifies that at least 75% of the entity's full staff at the time of application are citizens or lawfully admitted permanent residents of the country and that the entity has records to substantiate this if it becomes necessary. The letter must also include a statement providing

	calculations of the exact percentages of full staff who are citizens or lawfully admitted permanent residents of the country; • For eligibility area (3): o If the entity does not have a Board of Directors: the letter must include a statement indicating that the entity does not have a Board of Directors o If the entity does have a Board of Directors: a list of the members of the Board of Directors denoting each Board Member's name and corresponding citizenship or permanent residency status in country. In addition to describing how these documents support eligibility area (3), the letter must include a statement indicating the entity has a Board of Directors, and noting the exact percentage of members of the Board that are citizens or lawfully admitted permanent residents of the country to demonstrate that it is at least 51%
PEPFAR Local Partner Definition/Eligibility by Criteria	**Supporting Documentation (to be labeled as "Local Partner Preference")**
Government Ministries and Parastatals 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 may be fully or partially government-owned or government-funded organization. Such enterprises may function	Principal Investigator (PI) must provide documentation depicting the organization's relationship with the government (e.g., an organizational chart, legislation, statute, or charter), as well as a letter describing how the organization is a partner government ministry, sub-unit of government ministry, or parastatal organization in country, and describing the government's partial ownership of the entity.

through a board of directors, similar to private corporations.	

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. 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.

Any statements of performance submitted by applicants in response to this NOFO will be assessed for accuracy. In the event past performance described is not aligned with actual performance as documented in an official federal agency report (Corrective Action Plan, Site Improvement Plan, Data for Accountability, Transparency and Impact Monitoring (DATIM) target reporting, or similar), CDC would consider any inaccuracies in determination of ranking.

False statements or claims and misrepresentation or mischaracterization of any information in connection to the application, if funded, may result in legal enforcement action, up to and including termination, as authorized by law.

Applicants should note that in furtherance of the activities and priorities of the PEPFAR program, CDC reserves the right to fund applications 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

Applicants will receive notification of their application status by the end of August 2023. The award date will be September 30, 2023.

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 annual 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.

2. Administrative and National Policy Requirements

Recipients must comply with the administrative and public policy requirements outlined in 45 CFR Part 75 and the HHS Grants Policy Statement, as appropriate.

Brief descriptions of relevant provisions are available at https://www.cdc.gov/grants/additional-requirements/index.html.

The HHS Grants Policy Statement is available at http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.

The following administrative requirements apply to this project:
Generally applicable administrative requirements (ARs):

- AR-9: Paperwork Reduction Act Requirements
- AR-10: Smoke-Free Workplace Requirements
- AR-11: Healthy People 2030
- 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 Requirements
- AR-25: Data Management and Access
- 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-31: Research Definition
- AR-34: Accessibility Provisions and Non-Discrimination Requirements are incorporated into CDC General Terms and Conditions
- AR-37: Prohibition on certain telecommunications and video surveillance services or equipment for all awards issued on or after August 13, 2020

ARs applicable to HIV/AIDS Awards:

- AR-4: HIV/AIDS Confidentiality Provisions
- AR-5: HIV Program Review Panel Requirements
- AR-6: Patient Care

Organization Specific ARs:

- AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities
- AR 23: Compliance with 45 CFR Part 87

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.

The full text of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, 45 CFR 75, can be found at: https://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS will be required to complete an HHS Assurance of Compliance form (HHS 690) in which you agree, as a condition of receiving the grant, to administer your programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, age, sex and disability, and agreeing to comply with federal conscience laws, where applicable. This includes ensuring that entities take meaningful steps to provide meaningful access to persons with limited English proficiency; and ensuring effective communication with persons with disabilities. Where applicable, Title XI and Section 1557 prohibit discrimination on the basis of sexual orientation, and gender identity. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider- obligations/index.html and https://www.hhs.gov/civil-rights/for- individuals/nondiscrimination/index.html.

- For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.
- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.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.

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

Access to Records: Access to records pertinent to this Federal award are governed by the provisions of 45 CFR 75.364 and the terms of this award. Of particular note, HHS, the HHS awarding agency, Inspectors General, the Comptroller General of the United States, and the pass-through entity, or any of their authorized representatives, must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts. The right also includes timely and reasonable access to the non-Federal entity's personnel for the purpose of interview and discussion related to such documents.

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 publicly 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 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 outcomes.
- **Administrative Reporting** (No page limit)
    - SF-424A Budget Information-Non-Construction Programs.
    - Budget Narrative – Must use the format outlined in "Content and Form of Application Submission, Budget Narrative" section.
    - Indirect Cost Rate Agreement.

The recipients must submit the Annual Performance Report via www.Grantsolutions.gov no later than 120 days prior to the end of the budget period.

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.

Performance Measure Reporting (required):

If funded, the recipient is responsible for managing and monitoring each project, program, sub-award, function or activity supported through awarded funds. Recipients must monitor sub-awards to ensure that sub-recipients have met the programmatic impact requirements as set forth in the sub-recipient'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, and planned action steps to be taken to meet established goals.
- 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 an award.

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, Evaluation, and Reporting (MER) strategy, PEPFAR's ESoP, 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 of activities funded under this award and use of HHS/CDC funding should an award be made available and must require a provision to this effect in all sub-awards or contracts financed by PEPFAR resources. 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 ESoP and must be published on a publicly 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.

Beginning September 30, 2021, as a term of the award, prime recipients are required to collect expenditure data on a completed Expenditure Reporting template from their sub-recipients with FY2023 expenditures greater than $25,000. The full Expenditure Reporting template (Form DS-4213, approved under OMB 1405-0208) was previously completed by prime recipients only. This form will now be required to be completed by prime recipients and by sub-recipients, who will report through their prime recipient partner. This expenditure reporting is in addition to and in conjunction with the PEPFAR Annual Progress Report required at the completion of the USG fiscal year.

As noted, prime recipients are only required to collect this information from sub-recipients with fiscal year expenditures greater than $25,000. Prime recipients should implement this requirement by providing a template to each of these sub-recipients as part of any agreement entered into between the prime and the sub-recipient using award funds. When reporting expenditures in a separate template, sub-recipients should be reminded to provide full cost category detail on their expenditures, in addition to the program area and beneficiary information. Prime recipients are expected to collect the completed Expenditure Reporting templates from impacted sub-recipients and upload them into the DATIM system in line with the annual Expenditure Reporting timeline.

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 through the Payment Management System (PMS). 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)
The Final Performance Report is due 90 days after the end of the period of performance. The Final FFR is due 90 days after the end of the period of performance and must be submitted through the Payment Management System (PMS). 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:

- https://www.gpo.gov/fdsys/pkg/PLAW-109publ282/pdf/PLAW-109publ282.pdf,
- https://www. fsrs.gov/documents /ffata_legislation_ 110_252.pdf
- http://www.hhs.gov/grants/grants/grants-policies-regulations/index.html#FFATA.

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.

6. Termination

CDC may impose other enforcement actions in accordance with 45 CFR 75.371- Remedies for Noncompliance, as appropriate.

The Federal award may be terminated in whole or in part as follows:

(1) By the HHS awarding agency or pass-through entity, if the non-Federal entity fails to comply with the terms and conditions of the award;

(2) By the HHS awarding agency or pass-through entity for cause;

(3) By the HHS awarding agency or pass-through entity with the consent of the non-Federal entity, in which case the two parties must agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated; or

(4) By the non-Federal entity upon sending to the HHS awarding agency or pass-through entity written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the HHS awarding agency or pass-through entity determines in the case of partial termination that the reduced or modified portion of the Federal award or subaward will not accomplish the purposes for which the Federal award was made, the HHS awarding agency or pass-through entity may terminate the Federal award in its entirety.

G. Agency Contacts

CDC encourages inquiries concerning this notice of funding opportunity.

Program Office Contact

For programmatic technical assistance, contact:

First Name:
Thomas
Last Name:
Stevens
Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention

Address:
CDC Zambia

Telephone:
N/A

Email:
tks3@cdc.gov

Grants Staff Contact

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

First Name:
Shicann
Last Name:
Phillips
Grants Management Specialist
Department of Health and Human Services
Office of Grants Services

Address:
2939 Flowers Road, MS TV1
Atlanta, GA 30341

Telephone:
770.488.2809

Email:
ibq7@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.

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
- Report on Programmatic, Budgetary and Commitment Overlap
- Table of Contents for Entire Submission

For international NOFOs:

- SF424
- SF424A
- Funding Preference Deliverables

Optional attachments, as determined by CDC programs:

General Requirements

- All application materials must be submitted in English. Materials in languages other than English will not be reviewed.
- Application materials must be submitted in 12 point font. This includes tables, graphics, and charts.
- **NEW THIS YEAR: CDC reserves the right to determine an application non-responsive as part of the Phase I review if the application does not respond to and falls outside the published scope of the NOFO as set out in the Background and CDC Project Description sub-sections within the Funding Opportunity Description section of this NOFO. CDC will provide justification for any application that is determined non-responsive, including a description of why it was considered to be**

out of the published NOFO scope, if applicable. Non-responsive applications will not advance to Phase II review.

Project Narrative Requirements

- Applicants must abide by the requirements listed in Section D, #10 Project Narrative which states that the Project Narrative file must be a maximum of 20 pages, single spaced, 12 point font, 1-inch margins, number all pages.
- **NEW THIS YEAR: CDC reserves the right to determine an application non-responsive if the Project Narrative file exceeds the 20-page limit.** Although not required, the following four administrative materials may be included in the Project Narrative file and will not count toward the 20-page limit: 1) Table of Contents, 2) Cover or Title Page, 3) Non-Disclosure Statement, and 4) Acronym or Abbreviation List. All other content included in the Project Narrative file will count toward the 20-page limit. **CDC will provide justification for any application that is determined non-responsive.**

Appendix Requirements

Applicants must abide by the following requirements for the Appendix:

- **There is a 90-page limit for the Appendix file.** Any pages after the 90-page limit will not be reviewed.
- The Appendix file must be single spaced, 12 point font, 1-inch margins, number all pages. Any information submitted as part of the Appendix must be uploaded in a single PDF file, must be clearly labeled with page numbers, and be clearly identified in the application table of contents.
- Applicants must submit and clearly label the following items in the Appendix file: "Experience," "CVs/Resumes," "Job Descriptions," "Organizational Chart," "Financial Statement", as found in the "Organizational Capacity of Recipients to Implement the Approach" section.
- In addition to the above listed materials requested in the Appendix, the following are not required but may also be included and will count toward the 90-page limit:
    - Letters of Commitment, if applicable. Applicants may submit letters of commitment from proposed sub-partners or consortium members. If including letters of commitment, the applicant must submit a list or table outlining all letters of commitment included in the application. The list must include the organization name and its role in the project (i.e., consortium member, sub-partner, etc.). If a list or table is not included, the letters of commitment will not be reviewed. Letters of commitment refer to statements of active financial involvement in the project. Letters of commitment are different from letters of support. Letters of support are not requested and will not be reviewed.
    - Negotiated Indirect Cost Rate Agreement, if applicable
    - Non-profit organization IRS status forms, if applicable
    - Any additional materials at the applicant's discretion submitted in accordance with NOFO instructions

- The Pre-Award Risk Assessment Questionnaire and required documentation should be submitted as a clearly labeled separate attachment from the Appendix file. This does not count toward the 90-page limit for the Appendix.

PEPFAR Local Partner Funding Preference Requirements

- **PEPFAR Local Partner Funding Preference supporting documentation:** See "Phase III Review," as applicable. ***If applying for the PEPFAR Local Partner Funding Preference,***
    - Applicants must submit supporting documentation and a narrative letter by and through an authorized representative on the organization's official letterhead as a separate attachment from the Project Narrative and Appendices and labeled as "Local Partner Preference" to be considered to receive the Phase III Local Partner Funding Preference points under this NOFO. This documentation should be submitted as a separate attachment from the Appendix file and does not count toward the 90-page limit for the Appendix. This documentation must demonstrate how the prime applicant organization meets at least one of the three criteria listed under the "PEPFAR Local Partner definition" at the time of application. The full PEPFAR Local Partner Definition, along with sub-regional groupings, can be found in the Glossary section of the NOFO. Funding preference points do not apply to sub-recipients/partners or consortium members. For each of the criteria, a description of the supporting documentation is provided in the table under "Phase III Review." Applicants that do not provide labeled supporting documentation to meet the PEPFAR Local Partner definition will not be considered for, nor receive, the Funding Preference points as noted under "Phase III Review". Applicants must meet the requirements of the local partner definition at the time of application submission in order to be eligible for funding preference points. Funding preference points will not be awarded on a scale for partially meeting the definition.
    - Applicants may choose to submit one supporting document to demonstrate how the applicant meets multiple portions of the definition. If one document is submitted to address multiple portions, it must be clearly noted in the accompanying narrative letter from the authorized representative what the document is addressing.
    - Any supporting documentation not submitted in English must be described in the accompanying narrative letter from the authorized representative. Submissions may be verified for accuracy.

Amendments, Questions and Answers (Q&As)

Applicants must submit their Q&As, if any, by email to pepfarfoas@cdc.gov and to the Project Officer listed under the Agency Contacts Section of this NOFO no later than 15 days after the publication date in www.grants.gov. Questions received more than 15 days after the NOFO is published on www.grants.gov will not be considered and a response will not be provided.

All changes, updates, and amendments to the NOFO will be posted to www.grants.gov following the approval of CDC.

Amendment I: Questions and Answers (Q&A) and Application Due Date Extension

The purpose of this amendment is to include questions and answers (Q&A) in Section H. Other Information and to extend the Application Due Date from March 26, 2023 (3/26/2023) to March 27, 2023 (3/27/2023).

1. The way the NOFO PDF file has been formatted prevents the search or copy/paste functions from working. Could CDC please reformat the file to enable these functions, so it is searchable and more reader-friendly?

- There may be some NOFOs uploaded under the "Related Documents" tab of www.grants.gov with the search and copy/paste functions disabled, but this is an error CDC is working to fix. In the meantime, applicants may also access the NOFO document by clicking on the "Package" tab of the opportunity on www.grants.gov, clicking the "Preview" button under the "Actions" column of the Opportunity Package, and then clicking on the "Download Instructions" button. This should allow applicants to download the full NOFO PDF document with the search and copy/paste functions enabled.

2. Does an organization with a regional office in East Africa as well as a local office in Zambia qualify under the PEPFAR Local Partner Definition?

- Applicants must follow the instructions provided under section E. Review and Selection Process, c. Phase III Review; H. Other Information, PEPFAR Local Partner Funding Preference Requirements; and I. Glossary, NOFO-specific Glossary and Acronyms to ensure the required supporting documentation is correctly submitted to be considered to receive the 10-point Phase III PEPFAR Local Partner Funding Preference points under this NOFO. Only applicants fully meeting the definition and able to provide the required supporting documentation at the time of application submission are eligible to receive the funding preference points; funding preference points will not be awarded on a scale for partially meeting the definition.
- The PEPFAR Local Partner definition is provided in I. Glossary, NOFO-specific Glossary and Acronyms and contains a table with relevant sub-regional groupings copied from the COP22 Guidance. Zambia is in the Southern Africa sub-region, along with Angola, Botswana, Bouvet Island, Eswatini, Lesotho, Malawi, Mayotte, Mozambique, Namibia, Reunion, Saint Helena, South Africa, and Zimbabwe.

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 .https://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.

Assistance Listings: A government-wide collection of federal programs, projects, services, and activities that provide assistance or benefits to the American public.

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

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.

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. https://www.cdc.gov/grants/additional-requirements/index.html.

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.

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.

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 2030: 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.

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.

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 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.

UEI: The Unique Entity Identifier (UEI) number is a twelve-digit number assigned by SAM.gov. When applying for Federal awards or cooperative agreements, all applicant organizations must obtain a UEI number as the Universal Identifier. UEI number assignment is free. If an organization does not know its UEI number or needs to register for one, visit www.sam.gov.

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:

Under PEPFAR, a “local partner” may be an individual, a sole proprietorship, or an entity. However, to be considered a local partner, the applicant must submit supporting documentation demonstrating their organization meets at least one of the three criteria listed below at the time of application.

In the below definition, a region is defined as one of the 2020 State Department/ ForeignAssistance.gov Sub Regional groupings (e.g., Southern Africa, Central Africa, Central America, etc.), which are shown in the table below. The PEPFAR Local Partner definition, including sub-regional groupings, can be found at this link: https://www.state.gov/wp-content/uploads/2022/02/COP22-Guidance-Final_508-Compliant-3.pdf (see pages 104-106).

Individual

An individual must be a citizen or lawfully admitted permanent resident of and have his/her principal place of business in the country or region 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

Entity other than a sole proprietorship (such as, a corporation or not-for-profit) must meet all three areas of eligibility:		
1	either	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 involved;
	or	must exist in the region where the entity's funded PEPFAR programs are implemented
2	either	must be at 75% beneficially owned at the time of application by individuals who are citizens or lawfully admitted permanent residents of that same country;
	or	at least 75% of the entity's staff (senior, mid-level, support) at the time of application must be citizens or lawfully admitted permanent residents of that same country;
3		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

Government Ministries and Parastatals
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 may be fully or partially government-owned or government-funded organization. Such enterprises may function through a board of directors, similar to private corporations.

Sub-Regional Groupings

East Asia & Pacific	**Europe & Eurasia**	**Middle East & North Africa**
East Asia	**Central Europe & Baltic States**	**Gulf States**
China	Bulgaria	Bahrain
Hong Kong	Czechia	Iran
Japan	Estonia	Iraq
Macau	Hungary	Kuwait
Mongolia	Latvia	Oman
North Korea	Lithuania	Qatar
South Korea	Poland	Saudi Arabia

Taiwan	Romania	United Arab Emirates
	Slovakia	Yemen
Oceania	Slovenia	
American Samoa		**Israel & Palestinian Territories**
Australia	**Eurasia**	Israel
Christmas Island	Armenia	West Bank and Gaza
Cocos (Keeling) Islands	Azerbaijan	
Cook Islands	Belarus	**Levant**
Federated States of Micronesia	Georgia	Jordan
Fiji	Moldova	Lebanon
French Polynesia	Russia	Syria
Guam	Ukraine	
Kiribati		**North Africa**
Nauru	**South-Central Europe**	Algeria
New Caledonia	Albania	Egypt
New Zealand	Bosnia and Herzegovina	Libya
Niue	Croatia	Morocco
Norfolk Island	Kosovo	North Africa
Northern Mariana Islands	Montenegro	Tunisia
Oceania	North Macedonia	
Palau	Serbia	
Papua New Guinea		
Pitcairn Islands	**Southern Europe**	
Samoa	Cyprus	
Solomon Islands	Greece	
Timor-Leste	Turkey	
Tokelau		
Tonga	**Western Europe**	
Tuvalu	Andorra	
Vanuatu	Austria	
Wallis and Futuna	Belgium	
	Bermuda	
Southeast Asia	Denmark	
Brunei	Faroe Islands	
Burma	Finland	
Cambodia	France	

Indonesia	Germany	
Laos	Gibraltar	
Malaysia	Greenland	
Philippines	Guernsey	
Singapore	Holy See	
Thailand	Iceland	
Vietnam	Ireland	
	Isle of Man	
	Italy	
	Jan Mayen	
	Jersey	
	Liechtenstein	
	Luxembourg	
	Malta	
	Monaco	
	Netherlands	
	Norway	
	Portugal	
	San Marino	
	Spain	
	Svalbard	
	Sweden	
	Switzerland	
	United Kingdom	

South & Central Asia	**Sub-Saharan Africa**	**Western Hemisphere**
Afghanistan/Pakistan	**Central Africa**	**Caribbean**
Afghanistan	Burundi	Anguilla
Pakistan	Cameroon	Antigua and Barbuda
	Central African Republic	Aruba
Central Asia	Chad	Barbados
Kazakhstan	Congo (Brazzaville)	British Virgin Islands
Kyrgyzstan	Congo (Kinshasa)	Cayman Islands
Tajikistan	Equatorial Guinea	Cuba
Turkmenistan	Gabon	Curacao

Uzbekistan	Madagascar	Dominica
	Rwanda	Dominican Republic
South Asia	Sao Tome and Principe	Grenada
Bangladesh		Guadeloupe
Bhutan	**East Africa**	Guyana
British Indian Ocean Territory	Comoros	Haiti
French Southern and Antarctic Lands	Djibouti	Jamaica
Heard Island and McDonald Islands	Eritrea	Martinique
India	Ethiopia	Montserrat
Maldives	Kenya	Puerto Rico
Nepal	Mauritius	Saint Barthelemy
Sri Lanka	Seychelles	Saint Kitts and Nevis
	Somalia	Saint Lucia
	South Sudan	Saint Martin
	Sudan	Saint Vincent and the Grenadines
	Tanzania	Sint Maarten
	Uganda	Suriname
		The Bahamas
	Southern Africa	Trinidad and Tobago
	Angola	Turks and Caicos Islands
	Botswana	U.S. Virgin Islands
	Bouvet Island	
	Eswatini	**Central America**
	Lesotho	Belize
	Malawi	Costa Rica
	Mayotte	El Salvador
	Mozambique	Guatemala
	Namibia	Honduras
	Reunion	Nicaragua
	Saint Helena	Panama
	South Africa	
	Zambia	**North America**
	Zimbabwe	Canada
		Mexico
	West Africa	Saint Pierre and Miquelon

	Benin	United States
	Burkina Faso	
	Cabo Verde	**South America**
	Cote d'Ivoire	Argentina
	Ghana	Bolivia
	Guinea	Brazil
	Guinea-Bissau	Chile
	Liberia	Colombia
	Mali	Ecuador
	Mauritania	Falkland Islands (Islas Malvinas)
	Niger	French Guiana
	Nigeria	Paraguay
	Senegal	Peru
	Sierra Leone	South America
	The Gambia	South Georgia and the South Sandwich Islands
	Togo	Uruguay
	Western Sahara	Venezuela

Synopsis

CDC-RFA-GH-23-0010

Transitioning and Integrating Laboratory Services for High Quality HIV Diagnosis, Care, Treatment, and Monitoring to the Ministry of Health (MOH) to Sustain Achievement of the 95-95-95 Goals in Zambia under PEPFAR

General Information

Summary

Submit Initial Draft
10/25/2022
Document Type
Initial
Record Status
Active
FOA FY Processing Year
2023
Fiscal Year
2023
Program Funding Type
Discretionary
Funding Activity Category
HL - Health
Affordable Care Act (ACA)
No
Funding Instrument Type
CA (Cooperative Agreement)
Directed Announcement
No

Administrative Policies

Global
Yes
Non-Competing
No
Non-Competing Description
Single Source Justification (4,000 character limit)
Limited Competition
No
Additional Disqualification Factors

No

FOA History

New Opportunity

Yes

Previously Published Fiscal Year

Previously Published Funding Opportunity Number

Information Collection

Expected Number of Applications

10

Award Information

Cost Sharing / Matching Requirement

No

Percentage of Cost Sharing / Matching Requirement

0

Expected Number of Awards

1

Estimated FY Funding

$9,000,000

Estimated Total Funding

$0

Estimated Award Ceiling

$0

Per Budget Period

Estimated Award Floor

$0

Per Budget Period

Length of Project Periods

60-month project period with five 12-month budget periods

Length of Project Periods Explanation of Other

Project Period | Expected Duration in Months

60

Project Type

Non-Research

Eligibility Information

Eligibility Category

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

Additional Information on Eligibility (2,500 character limit):

Key Dates

Submit Initial Draft
10/25/2022

Estimated Post Date
02/24/2023

Estimated Application Due Date
April 25, 2023

Application Due Date Explanation
Electronically submitted applications must be submitted no later than 11:59 pm ET on the listed application due date.

Estimated Award Date
September 30, 2023

Estimated Project Start Date
09/30/2023

Estimated Project End Date
09/29/2028

Grants.gov Archive Date
05/25/2023

Forecast Grants.gov Archive Date
05/25/2023

Additional Information

Statutory Authority
This program is authorized under Public Law 108-25 (the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003) [22 U.S.C. 7601, et seq.] and Public Law 110-293 (the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008), and Public Law 113-56 (PEPFAR Stewardship and Oversight Act of 2013).

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.

Description (Grants.gov/Forecast) (18,000 character limit)
The Award Ceiling for Year 1 is 0 (none). CDC anticipates an Approximate Total Fiscal Year Funding amount of $9,000,000 for Year 1, subject to the availability of funds.

This NOFO will support the stepwise full transition of PEPFAR-supported laboratory systems and services to the Government of the Republic of Zambia (GRZ). The recipient will provide technical assistance (TA) for further adaptation of the diagnostic system for immediate needs such as outbreaks of novel diseases, additional surveillance system requirements, and new

international reporting mechanisms as guided by CDC. By the end of the project period, the recipient should perform a capacity assessment of GRZ to carry out all the laboratory system functions and a cost assessment to fully understand the costs of sustaining the system. Assessments for transition should include: viral load (VL), early infant diagnosis (EID), sample referral, testing and results return systems, laboratory information management systems (LIMS), including: integration with SmartCare, eLABS, and DHIS2, laboratory equipment calibration facilities and systems, external quality assurance (EQA) systems following implementation of ISO 17043, diagnostic equipment maintenance program, courier vehicle replacement, salvage and maintenance program, waste management, backup power systems, rapid test continuous quality improvement (RTCQI) as an activity related to baseline VL, diagnostic network optimization (DNO), laboratory quality management systems (QMS), biosafety and biosecurity program, and laboratory-specific supply chain management and integrated testing including human papillomavirus (HPV) and TB.

Grantor Contact Name

Emily Dale

Grantor Contact Phone

(404) 639-8880

Grantor Email Address

pepfarfoas@cdc.gov

Grantor Email Description

pepfarfoas@cdc.gov

Link to Additional Information