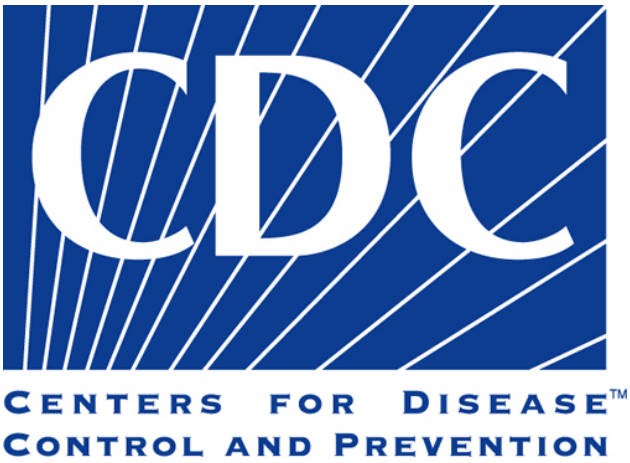


Centers for Disease Control and Prevention

Center for Global Health

Strengthening Laboratory Capacity and Quality for HIV Diagnosis, Care, Treatment, and Monitoring in Malawi under the President's Emergency Plan for AIDS Relief (PEPFAR)

CDC-RFA-GH-24-0097

02/05/2024

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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-24-0097. 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:

Strengthening Laboratory Capacity and Quality for HIV Diagnosis, Care, Treatment, and Monitoring in Malawi under the President's Emergency Plan for AIDS Relief (PEPFAR)

C. Announcement Type: New - Type 1:

This announcement is only for non-research activities supported by CDC. If research is proposed, the application will not be considered. For purposes of this NOFO, research is defined as set forth in 45 CFR 75.2 and, for further clarity, as set forth in 42 CFR 52.2 (see eCFR :: 45 CFR 75.2 -- Definitions and *https://www.gpo.gov/fdsys/pkg/CFR-2007-title42-vol1/pdf/CFR-2007-title42-vol1-sec52-2.pdf*. In addition, for purposes of research involving human subjects and available exceptions for public health activities, please see 45 CFR 46.102(l) (*https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.102#p-46.102(l)*).

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 FY24 NOFO. Applicants should not submit LOIs.

Amendment I: Questions and Answers (Q&A) and Additional Updates

The purpose of this amendment is to include the updates as listed below.

- The amendment includes questions and answers (Q&A) in Section H. Other Information.
- CDC has retired the Risk Assessment Questionnaire Requirement and applicants are no longer required to submit the CDC Risk Questionnaire as part of their NOFO application. CDC continues to conduct the review of risk posed by applicants described in Phase III Review and may ask for additional information prior to the award based on the results of the review. Risk Questionnaires that are submitted will not be included in this risk review.
- In F. Award Administration Information, 2. Administrative and National Policy Requirements, CDC has added AR-38: Health Information Technology (IT) Interoperability to the list of Organization Specific Administrative Requirements.

D. Agency Notice of Funding Opportunity Number:

CDC-RFA-GH-24-0097

E. Assistance Listings Number:

93.067

F. Dates:

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

2. Due Date for Applications:

02/05/2024

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

As Malawi strives to reach HIV epidemic control, there is a need to improve and sustain achievements in the national laboratory systems. Technical assistance (TA) to the Ministry of Health (MOH) will ensure universal diagnostics access and address public health system gaps. For sustainability, MOH's public health laboratory capabilities will be strengthened for governance and ownership, National Reference Laboratories (NRL) capacity will be built for surveillance and outbreak responses, and the HIV laboratory program will be integrated into broader disease areas.

Priorities include scaling up patient-centered approaches to identify and address challenges of low viral load coverage (VLC) and suppression in different age groups and populations, point of care testing (POCT) laboratories for integrated multi-disease tests, and rapid testing continuous quality improvement (RTCQI) to achieve national certification. Other priorities include improving access for advanced HIV disease (AHD) and pre-exposure prophylaxis (PrEP) tests, conducting regular diagnostic network optimization to ensure efficiencies and testing accessibility, increasing utilization of high throughput instruments in conventional molecular laboratories to improve VLC, improving biosafety and waste management, preparing additional laboratories for International Organization for Standardization (ISO) accreditations, and extending the external quality assessment (EQA) program to multiple testing parameters.

a. Eligible Applicants:
Open Competition

b. Funding Instrument Type:
CA (Cooperative Agreement)

c. Approximate Number of Awards
2
The expected number of awards is 1-2.

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:
$8,375,000
The Approximate Total Fiscal Year Funding/Average One Year Award Amount/Approximate Average Award amount for Year 1 is $8,375,000. The expected number of awards is 1-2. 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, 2024

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
According to the Malawi Population-based HIV Impact Assessment 2020-2021, Malawi has made remarkable achievements by attaining 88-98-97 of the UNAIDS 95-95-95 targets towards epidemic control. The country needs to address overall systemic challenges to sustain and

improve gains. Malawi has weak laboratory systems, affecting the quality of testing and patient management. Due to a limited number of health facilities in the country, people living with HIV (PLHIV), including priority populations (PP), have difficulties in accessing diagnostic and treatment monitoring services. The laboratory services are affected by weak infrastructure, slow implementation of quality management systems (QMS), inefficient supply chain systems, and an inadequate number of qualified laboratory workers. VLC has been consistently below 70%, and the gap in children under 5 years of age and other PP is significant. The overall VL test turnaround time (TAT) in conventional molecular laboratories is above 30 days, resulting in delayed patient management. NRL in the Public Health Institute of Malawi (PHIM) does not have adequate capacity to conduct surveillance and respond to emerging and re-emerging diseases that affect PLHIV. Any improved laboratory capacity should be integrated into the general public health response per current PEPFAR guidance.

This NOFO aims to continue to assist the MOH in strengthening the laboratory systems and to tackle structural and political barriers. TA should be provided to MOH on the development and implementation of policies and strategic plans. To improve the quality of laboratory services and sustain laboratory accreditation efforts, this NOFO aims to support establishing a national accreditation body and ancillary equipment calibration center. To sustain the preparedness of the national laboratory public health systems and laboratory networks, PHIM capacity should be built with modern technologies, training, and infrastructure.

To ensure accessibility for accurate and timely testing for HIV and TB, this NOFO aims to support laboratories on infrastructure improvement, equipment management, and availability of commodities/reagents, as well as develop workforce capacity and establish appropriate biosafety systems. Integrated and multi-disease testing should be enhanced at POCT and conventional molecular laboratories. VLC should be improved through intensive demand creation and an optimized diagnostic network. Closing equity gaps among PP, providing training to health care workers, transitioning to an all-inclusive pricing service agreement with suppliers, and scaling up the integration of the Electronic Medical Records (EMR) with the Laboratory Information Management System (LIMS) should also be used to improve VLC.

To support patient-centered services, standard and innovative CQI initiatives should be scaled up to all testing laboratories. Efforts should continue to achieve and maintain ISO15189 accreditation for multiple scopes of tests. Stepwise Process for Improving Quality for Point of Care Testing should be rolled out for instrument-based and rapid diagnostics tests. HIV RTCQI should be scaled up to ensure all testing points are certified by the Medical Council of Malawi and enhanced by training test providers using the Extension for Community Health Outcome platform. The EQA program should be maintained and scaled up for VL, Early Infant Diagnosis (EID), TB, AHD, and PrEP tests. To sustain the EQA program, local proficiency panels, production should be strengthened in the NRL.

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 Global Health Security and Diplomacy Bureau (GHSD Bureau), 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 (KPs);
- 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 KPs;
- 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.

Any activities outside of HIV or TB activities will be consistent with the direction set forth in PEPFAR's Five-Year Strategy, PEPFAR's annual Country/Regional Operational Plan (COP/ROP) Guidance, annual COPs/ROPs, or other similar forthcoming strategy, guidance, or planning documents as may be consistent with applicable law.

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.

Any Personally Identifiable Information (PII) collected for continuity of service provision should be managed in a manner that ultimately protects individual-level data to the extent allowed by applicable law.

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.

In its work with partners, CDC seeks to help control HIV epidemics and to achieve and maintain low levels of HIV incidence and mortality. Now and in the future, viable, capable, durable, and successful local partners will play an important role in achieving and sustaining control of national HIV epidemics. To that end, CDC strongly encourages direct applications from local organizations (i.e., institutions located, registered, and managed in the country and/or sub-region where work occurs and led by national of that country and/or sub-region). U.S.-based partners working in international settings also offer unique capabilities and will continue to make important contributions. Partnerships between local organizations and U.S.-based organizations may also offer benefits and are encouraged in such cases.

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

For the past 20 years, PEPFAR, through CDC and CDC-funded implementing partners, has collaborated with the MOH to strengthen Malawi's laboratory systems. PEPFAR has played a significant role in improving access to HIV diagnostics and treatment monitoring services across the 28 districts. This NOFO is expected to continue the progress made under the last NOFO (CDC-RFA-GH19-1910), which should lead to further laboratory system strengthening.

Currently, the country has 14 centrally located conventional molecular and 80 POCT laboratories with multi-disease testing capacities. The conventional molecular laboratories test most (99%) of the VL samples. To provide consistent services, PEPFAR supports training laboratory staff to run tests and deploying trained laboratory technologists and data clerks to enhance testing quality. PEPFAR also supports improving infrastructure for a suitable working environment, providing ancillary equipment, including regular calibration and preventive maintenance, supporting a LIMS for timely result return and data capturing, and supplying reagents and commodities during shortages to minimize service interruptions.

To improve access to HIV and TB tests, the sample referral system is fully funded by PEPFAR. 790 facilities and testing laboratories are networked in a hub and spoke model. To enhance access to testing and to maximize instrument utilization, 65 laboratories with GeneXpert devices provide multiplex testing for EID, TB, targeted VL, HPV, and SARS-CoV-2 tests. To improve VLC, the country has a policy to test VL samples from PP using GeneXpert platforms. To enhance electronic information transfer from anti-retroviral therapy (ART) clinics to hubs and testing molecular laboratories, LIMS and Electronic Medical Records System (EMRS) are being integrated to minimize missing results and the TAT. LIMS is being extended to monitor the overall laboratory stock management from end to end. Laboratories receive training on

appropriate waste management, and innovative liquid and solid waste management is being introduced.

Diagnostics network optimization is being finalized for appropriate resource utilization across the VL, EID, and TB testing cascades. The capacity of each laboratory in the network will be optimized depending on the workload, availability of human resources, and equipment utilization. To create an efficient sample referral system, the distance between sample referring facilities to testing laboratories is being optimized. To increase VLC above 95%, PEPFAR supports data clerks in ART clinics, hubs, and molecular laboratories. Old molecular platforms were replaced with new and high throughput platforms to minimize service interruptions and reduce TATs. To avoid wastage of reagents and supplies, long-lasting backup power was provided to very high VL testing molecular laboratories. Using the gold standard, plasma sample for VL testing is being scaled up to reach up to 70% by the end of 2025.

CQI was provided at all levels of the testing network. 24 laboratories underwent Strengthening Laboratory Management Towards Accreditation (SLMTA) and Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) in preparation for ISO15189 accreditation. 9 laboratories achieved and maintained their ISO15189 accreditation status, and the plan is to prepare additional laboratories, including the NRL, for ISO1518 and ISO17043 accreditations, respectively. HIV RTCQI was rolled out in 775 testing points within 672 facilities. A baseline assessment was conducted using the Stepwise Process for Improving the Quality of HIV RT checklist at the beginning of the enrollment, and 249 of the testing points scored a level 4. Of the 249 testing points, 152 were certified by the Medical Council of Malawi. Enhanced interface between clinical and laboratory services has improved tracking of VL and EID testing progress.

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: Scale-up multi-disease and integrated diagnosis and treatment monitoring services across the country **Strategy 2**: Strengthen biosafety, biosecurity, and waste management measures and systems at all levels of laboratory networks **Strategy 3**: Strengthen MOH capacity to coordinate and oversee national diagnostic services **Strategy 4:** Scale-up of CQI in conventional laboratories and POCT services	**Increased adequate use of laboratory equipment in both conventional and POCT sites** **Increased capacity of laboratory staff to conduct genomic sequencing** **Reduced risk of staff to potential hazards and sample contamination by improving physical laboratory infrastructure** **Improved staff skills and workflow of liquid and solid waste management and laboratory biorepository capacity at all levels** **Improved capacity of Health Technical Services Support (HTSS) Department at MOH to coordinate and integrate laboratory systems** **Increased access and uptake of SLMTA/SLIPTA**	**Improved quality, reliability, and timeliness of testing services at all levels of laboratories** **Increased viral suppression coverage** **Improved genomic data analysis and pharmacovigilance** **Improved biosafety, biorepository, biosecurity, and waste management at all levels** **Improved adherence to national laboratory guidelines and standard operating procedures (SOP) at MOH and testing laboratories** **Increased ISO accredited laboratories and nationally certified testing sites**	Reduced HIV transmission, mortality, and morbidity Improved TB case detection and treatment among PLHIV **Improved pathogen detection during outbreak and pandemic responses**

	enrollment and processes **Improved access and uptake of EQA program and national certifications**		

i. Purpose

The purpose of this NOFO is to improve and sustain PEPFAR's laboratory investments through the Malawi MOH. Specifically, produce timely and multi-disease testing services; test 95% of VL, EID, TB, PrEP, and AHD samples and dispatch results on time; optimize the diagnostic network; enhance appropriate biosafety and waste management; obtain ISO15189/ISO17043 accreditations in testing and proficiency panel producing laboratories; enroll PEPFAR priority tests into the EQA program with a 90% pass rate; and expand HIV RTCQI activities for national certification.

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:

- Increased adequate use of laboratory equipment in both conventional and POCT sites
    - Laboratory equipment refers to molecular platforms for multi-disease testing. The adequate use includes human resources capacity, laboratory infrastructure optimization proper equipment, and commodities management.
    - Conventional molecular laboratory refers to laboratories with high throughput molecular platforms with a pre-determined testing capacity. These laboratories are expected to monitor the utilization of each platform according to a pre-specified utilization rate.
- Increased capacity of laboratory staff to conduct genomic sequencing
- Reduced risk of staff to potential hazards and sample contamination by improving physical laboratory infrastructure
    - Physical laboratory infrastructure refers to adequate space, consistent power and water supply, and a conducive working environment**.**
- Improved staff skills and workflow of liquid and solid waste management, and laboratory biorepository capacity at all levels
- Improved capacity of HTSS Department at MOH to coordinate and integrate laboratory systems
    - Health Technical Services Support-Diagnostics (HTSS-D) capacity needs to be built on central coordination and integration of laboratory programs; this will minimize duplication of efforts and improve efficient utilization of limited resources.
- Increased access and uptake of SLMTA/SLIPTA enrollment and processes
    - SLMTA/SLIPTA program is the framework to implement cost-effective and sustainable QMS which leads to ISO accreditation.
- Improved access and uptake of EQA program and national certifications
    - EQA program ensures accuracy and reliability of laboratory results. Proficiency Testing (PT) program is the most common EQA method that provides evidence of laboratory competence to customers and accreditation bodies.
    - POCT platforms are deployed in laboratory and non-laboratory settings. Non-laboratory professionals conduct testing in the non-laboratory settings and appropriate training and quality assurance systems need to be implemented.
    - Laboratories have POCT platforms that are used for multi-disease testing and equipment utilization and TAT need to be monitored based on the pre-specified targets.

Intermediate Outcomes:

- Improved quality, reliability, and timeliness of testing services at all levels of laboratories
- Increased viral suppression coverage
    - All PLHIV are expected to have annual VL samples collected, tested, and results returned to the facility for appropriate patient management.
- Improved genomic data analysis and pharmacovigilance
- Improved biosafety, biorepository, biosecurity, and waste management at all levels
    - Appropriate biosafety equipment, materials, infrastructure, and training need to be in place to reduce exposure of staff, work environment, and community from potentially infectious organisms, toxins, and biological hazards.
    - Standard biorepository system builds capacity to collect, process, and store biological specimens for enhanced surveillance.
    - Appropriate waste management is key at all levels of the laboratory network; this includes proper handling and disposal of solid and liquid waste within and outside a laboratory.
- Improved adherence to national laboratory guidelines and SOP at MOH and testing laboratories
- Increased ISO accredited laboratories and nationally certified testing sites
    - CQI initiatives are stepwise quality improvement approaches to implement QMS in HIV and TB diagnostic services in conventional and POC testing facilities.

Long-Term Outcomes:

- Improved pathogen detection during outbreak and pandemic responses
    - Improved pathogen detection includes laboratories having the appropriate biosafety levels, modern technologies, infrastructure, and well-trained staff.

iii. Strategies and Activities

CDC may require or allow applicants to propose additional related strategies and activities other than those identified in the NOFO to achieve the expected Outcomes.

Strategy 1: Scale-up multi-disease and integrated diagnosis and treatment monitoring services across the country

- Support expansion of optimized diagnostic capacities across priority diseases that affect PLHIV, including HIV/TB, HPV, SARS-CoV-2, and other emerging diseases through utilization of conventional and POCT platforms
- Support the scale-up of HIV VL and EID coverage through timely testing and return of results
- Enhance VL testing on POCT platforms for PP; pediatrics, key populations, adolescent girls, pregnant and breast-feeding women
- Scale up Creatinine and Hepatitis B testing capacities for PrEP services
- Strengthen the capacity of NRL at PHIM for emerging and re-emerging disease surveillance, investigation, and response

- Improve pathogen genomic sequencing capacity for emerging and re-emerging diseases at NRL

Strategy 2: Strengthen biosafety, biosecurity, and waste management measures and systems at all levels of laboratory networks

- Improve laboratory infrastructure to increase biosafety and appropriate workflow
- Support the scale-up of liquid and solid waste management systems using innovative strategies
- Strengthen and sustain biosecurity and biorepository at all levels of laboratory networks

Strategy 3: Strengthen MOH capacity to coordinate and oversee national diagnostic services

- Develop and implement national laboratory policies, strategies, and guidelines to strengthen HTSS-D capacity
- Expand HTSS-D capacity to monitor supply chain activities
- Support HTSS-D capacity to develop a standardized supportive supervision program to oversee the performance of laboratories and POCT sites
- Ensure district health offices' laboratory activities are aligned with the MOH decentralization strategy so they can conduct supervision, review meetings, mentorship, training, and PT program management
- Advance data collection, analysis, and interpretation at all laboratory network systems for evidence-based decision-making
- Strengthen a tiered, integrated laboratory network to support diagnostics
- Strengthen human resource competencies for efficient service delivery across various levels of the health system
- Strengthen commodity utilization to ensure uninterrupted access to high-quality diagnostic services
- Implement strong monitoring and evaluation system at HTSS-D to optimize the national referral network; this includes improving data capturing, reporting, analyzing, and interpretation systems
- Promote competent, flexible, and efficient workforce at all levels of the laboratory network by building MOH, District and laboratory management staff leadership skills
- Ensure the NRL at PHIM conduct regular evaluation and verification of new and existing test methods; this enhances the capacity of the laboratories to respond to emerging and re-emerging public health threats impacting PLHIV

Strategy 4: Scale-up of CQI in conventional laboratories and POCT services

- Expand SLMTA/SLIPTA and ISO15189 accreditation in conventional molecular laboratories and near POCT facilities
- Support NRL to attain ISO17043 accreditation
- Support MOH to establish a local ISO accreditation body
- Scale up HIV RT and other POCT CQI
- Support the scale up of EQA to HIV, TB, CD4, Hematology, Chemistry, Microbiology and other PEPFAR-supported tests

- Support NRL capacity for local PT panels production e.g., HIV EID, VL, Cryptococcal Antigen screening, Lateral Flow urine TB-Lipoarabinomannan (LF TB-LAM), TB molecular, TB culture, Syphilis RT, Hepatitis, and other tests
- Establish a local laboratory equipment calibration center for ancillary equipment and support its accreditation to ISO17025

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:

The recipient(s) will be expected to collaborate with CDC-funded health system strengthening and service delivery implementing partners, HIV surveillance, EMRS and LIMS, Sample Transport and Human Resource for Health (HRH) partners. In addition, the recipient(s) will be expected to collaborate with the Malawi Department of HIV and Aids and PHIM. These collaborations will ensure capacity building at various levels and enable sustainability. The CDC Malawi country office will assist the recipient(s) in connecting with other partners working in this area and the recipient(s) will be expected to ensure work is not duplicative but complementary and supportive to other work funded by CDC and other partners. The recipient(s) will likely work specifically with CDC Malawi's Health Systems Strengthening Branch, Health Epidemiology and Strategic Information Branch, Health Services Branch, and Grants Management Branch.

b. With organizations not funded by CDC:

The recipient(s) will be expected to collaborate with other PEPFAR United States government (USG) agencies (USAID, Department of Defense, and State Department) that are supporting health system strengthening and HIV/TB service delivery programs.

Additionally, collaboration will be expected with other MOH departments (ex. HTSS-D, Quality Management Department [QMD]); the Global Fund Project Implementation unit (PIU); non-USG supported partners; international organizations implementing laboratory programs; and regulatory bodies including Medical Council of Malawi.

2. Population(s) of Focus

The populations of focus for this NOFO include the general population of men, women, and children in Malawi, as well as PLHIV. Other populations of focus include the MOH HIV Test Services and laboratory staff, and staff in NRL within PHIM.

This NOFO, including funding and eligibility, is not limited based on, and does not discriminate on the basis of race, color, national origin, disability, age, sex (including gender identity, sexual orientation, and pregnancy) or other constitutionally protected statuses.

a. Health Disparities

The goal of health equity is for everyone to have a fair and just opportunity to attain their highest level of health. Achieving this requires focused and ongoing societal efforts to address historical and contemporary injustices; overcome economic, social, and other obstacles to health and healthcare; and eliminate preventable health disparities.

Broadly defined, social determinants of health are non-medical factors that influence health outcomes. They are the conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life. These forces (e.g., racism, climate) and systems include economic policies and systems, development agendas, social norms, social policies, and political systems. See content below and in other sections (e.g., Approach, Collaborations, Populations of Focus) for information on how this specific NOFO affects social determinants of health.

A health disparity is a preventable difference in the burden of disease, injury, violence, or opportunities to achieve optimal health that are experienced by populations that have been socially, economically, geographically, and environmentally disadvantaged. Health disparities are inextricably linked to a complex blend of social determinants that influence which populations are most disproportionately affected by these diseases and conditions.

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 COP/ROP 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:

For Year 1, CDC anticipates an Approximate Total Fiscal Year Funding/Average One Year Award Amount/Approximate Average Award of $8,375,000 with the below listed components:

- Component 1: COP Q1 Targets/Activities;
- Component 2: COP Q2 Targets/Activities;
- Component 3: COP Q3 Targets/Activities;
- Component 4: COP Q4 Targets/Activities;
- Component 5: COP Additional Targets/Activities;
- Component 6: Additional Activities and Emerging Health Issues (buffer component).

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.

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy

To ensure continuous quality improvement and monitoring of the program at large, CDC expects that the routine performance data is reviewed, cleaned, and used for program management. To this effect, the recipient(s) should hold regular quarterly review meetings to discuss performance and use data in program quality improvement activities.

The recipient(s) 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(s), a minimum of **10%** of funds should be allocated for monitoring

activities and **5%** of funds should be used for evaluation activities. These are estimates for the total funding over the 5-year project.

PERFORMANCE MONITORING

Currently, reporting on PEPFAR monitoring, evaluation, and reporting (MER) indicators is not applicable to the scope of this NOFO, although that is subject to change in future project years. Some custom (non-MER) indicators, targets, and reporting frequencies corresponding to Year 1 to 5 of the NOFO are shown below. The applicant should also propose additional relevant custom 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.

Non-MER: Additional Performance Measures (Custom Indicators)

Applicants should include additional custom performance measures to monitor achievement of outcomes not directly measured by PEPFAR (MER) indicators. These custom indicators should include process and outcome measures directly correlated with the logic model. Below are examples of additional process and outcome measures for the strategies/activities and outcomes previously discussed in the logic model and associated sections.

- District Hub laboratories:
    - Percentage of VL and EID samples logged into EID/VL LIMS, and dispatched to testing laboratories [Target: 98%; Reporting Frequency: Quarterly]
    - Average TAT from sample draw from patient at requesting facility to dispatch to testing laboratories for VL and EID samples [Target: 5 days; Reporting Frequency: Quarterly]
    - Percentage of EID and VL results received from testing laboratories and dispatched to requesting facilities [Target: 100%; Reporting Frequency: Quarterly]
    - Average TAT for VL and EID from result receipt from testing laboratory to dispatch to requesting facilities [Target: 3 days; Reporting Frequency: Quarterly]
- Near POCT GeneXpert laboratories:
    - Percentage of EID and targeted VL samples tested and dispatched with valid results [Target: 95%; Reporting Frequency: Quarterly]
    - Average TAT from sample draw from patient to result dispatch to requesting facility [Target: <7 days; Reporting Frequency: Quarterly]
    - Percentage of instrument utilization at POCT laboratories [Target: 80%; Reporting Frequency: Quarterly]
- POCT m-PIMA sites:
    - Percentage of EID/VL samples tested and released with valid results within the requesting facility [Target: 95%; Reporting Frequency: Quarterly]

    - Average TAT for EID/VL samples from sample draw from infants/patients to result return within the requesting facility [Target: 1 day; Reporting Frequency: Quarterly]

- Conventional Molecular laboratories:
    - Percentage of VL samples tested and dispatched with valid results [Target: 95%; Reporting Frequency: Quarterly]
    - Average TAT for VL samples from sample draw from patient to result dispatch to district hub laboratories [Target: <17 days; Reporting Frequency: Quarterly]
    - Percentage of valid VL results with <1000copies/ml [Target: >90%; Reporting Frequency: Quarterly]
    - Percentage of instrument utilization by high throughput platform [Target: 80%; Reporting Frequency: Quarterly]

- Conventional molecular and POCT laboratories:
    - Number of PEPFAR-supported laboratories having access to liquid and/or solid waste disposal [Target: 80 GeneXpert and 14 high throughput molecular laboratories; Reporting Frequency: Annually]

- Conventional Molecular and POCT laboratories:
    - Amount of liquid and GeneXpert cartridge containing guanidium thiocyanate (GTC) waste disposed [liquid waste 32,000 liters and GeneXpert cartridges 3000-kilogram Target: 90% of waste properly disposed. Reporting Frequency: Annually]

- Laboratory Proficiency Testing and Continuous Quality Improvement:
    - Percentage of laboratory-based testing sites participating in continuous quality improvement (CQI) and proficiency testing (PT) [Target: 100%; Reporting Frequency: Quarterly for the first 2 years then Annually]
    - Percentage of POCT sites participating in CQI and PT [Target: 70%; Reporting Frequency: Quarterly for the first 2 years then Annually]

Data Sources for MER and Custom Indicators: Data sources may include registers, tally sheets, Log sheets, Charts, electronic and paper patient records, quarterly progress reports, surveillance and survey reports, and other program monitoring tools.

Evaluation

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

Sample Evaluation Topics:

- Country capacity in monitoring laboratory processes for quality-assured testing services (Process Evaluation)
- MOH Capacity to improve and sustain Laboratory systems investments and gains to achieve 95-95-95 targets (Outcome Evaluation)

Evaluation Data Sources: Data sources may include registers, tally sheets, Log sheets, Charts, electronic and paper patient records, quarterly progress reports, surveillance and survey reports, 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.

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/ROP. As such, the example evaluation topics listed in this NOFO may be amended based on feedback from the GHSD Bureau during the annual COP/ROP review process.

ii. Applicant Evaluation and Performance Measurement Plan

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

- How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement, including, as applicable to the award, how findings will contribute to reducing or eliminating health disparities and inequities.
- 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).
- How evaluation findings will be disseminated to communities and populations of interest in a manner that is suitable to their needs.
- 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.

Applicants should submit their initial data management plan (DMP) as part of their initial evaluation and performance measurement plan (EPMP). This should include cybersecurity plans and information about how PII will be protected when collected, stored, in transit, and in use. In addition, the initial DMP should include a description about how data will be de-identified in intermediate and final data sets. Finally, where data collected or generated under this award may be sought by PEPFAR or CDC, recipient(s) will be informed about the need to share such information and how to send such information to PEPFAR or CDC.

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 describing the organization's experience working in relevant program areas including laboratory QMS. Experience should be recent e.g. within the previous 5-7 years. Each example should include:
    - Title of program/project
    - List the role of the applicant's organization (prime recipient, sub-recipient, consortium member, etc.)
    - Approximate duration of program/project (years or months)
    - Project budget (in US dollars) and funding source(s)
    - Size of population served
    - Geographic focus/region
    - Project goals and targets and achievements accomplished solely by the applicant in addition to overall accomplishments made by the consortium or other recipients against these goals and targets
- The Experience Statement should demonstrate organizational capacity to address the requirements of the NOFO, specifically in the following areas:
    - Experience in rapid scale-up of testing in EID, VL, TB, Cervical cancer (HPV), and Hepatitis, SARS-CoV-2
    - Experience working within PEPFAR environment/USG funding
    - Experience working with Sub-Saharan region Host Government MOH including district and local facilities

    - Experience in transitioning PEPFAR programs to local partners and government in sub-Saharan Africa

- CVs/Resumes for key personnel (at the applicant's discretion but may include Principal Investigator [PI] or Technical Director, Country Director, Business Official (Finance Lead), Monitoring and Evaluation Lead, Procurement Lead, etc.)
- Job descriptions for key personnel
- Organizational chart
- Financial Management Statement that describes the following:
    - Financial Management and procedure manual
    - Procurement policy and procedures manual
    - Previous experience managing annual budgets greater than $5,000,000

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 the GHSD Bureau.
2. Review and approve recipient's annual work plan and detailed budget, as part of the PEPFAR COP/ROP review and approval process, managed by the GHSD Bureau.
3. Review and approve the recipient's monitoring and evaluation plan, including for compliance with the strategic information guidance established by the GHSD Bureau.
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/ROP review and approval process, managed by the GHSD Bureau.
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/ROP review and approval process, managed by the GHSD Bureau.

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 GHSD Bureau 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 an approved Quality Assessment System and/or Site Improvement through Monitoring System (SIMS), in compliance with PEPFAR requirements, to monitor 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 (EPMP) is aligned with the strategic information guidance established by the GHSD Bureau 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. In addition to these categories, all evaluations should be classified in terms of their Cooperative Agreement-level. The term Cooperative Agreement-level evaluation is used to denote a small-scale evaluation study attached to a specific Cooperative Agreement of which the overall goal is to examine implementation fidelity and/or effectiveness of a specific activity under a Cooperative Agreement or of the entire Cooperative Agreement. Each Cooperative Agreement is required to have at

least one evaluation executed over the course of funding. CDC will provide guidance to the recipient, including how to allocate funds and conduct evaluation activities. The evaluation can be one of the following:

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: determines cost and/or unit costs, cost drivers, as well as cost-effectiveness, efficiency, factors influencing economic behavior and choices, and economic impact of interventions or activities to justify the investment.

12. Supply the recipient with protocols for related evaluations.

As described in current COP/ROP 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/ROP 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/ROP 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/ROP 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:
2024

4. Approximate Total Fiscal Year Funding:
$8,375,000

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)

7. Expected Number of Awards:
2
The expected number of awards is 1-2.

8. Approximate Average Award:

$8,375,000
Per Budget Period

The Approximate Total Fiscal Year Funding/Average One Year Award Amount/Approximate Average Award amount for Year 1 is $8,375,000. The expected number of awards is 1-2. 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, 2024

12. Budget Period Length:
12 month(s)

Throughout the period of performance, 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 (period of performance) 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 in CDC's review of risk posed by applicants 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 $8,375,000. 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.

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 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. It is the responsibility of applicants to double-check for formatting issues that occur upon upload during application submission. If a formatting problem causes a 20-page narrative to exceed 20-pages, the application will be deemed non-responsive for exceeding 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 Management (SAM)	1. Go to SAM.gov and create an Electronic Business Point of Contact (EBiz POC). You will need to have an active SAM account before you can register on grants.gov). The UEI is generated as part of your registration.	7-10 Business Days but may take longer and must be renewed once a year	For SAM Customer Service Contact https://fsd.gov/fsd-gov/home.do Calls: 866-606-8220
2	Grants.gov	1. Set up an account in Grants.gov, then add a profile by adding the organization's new UEI number. 2. The EBiz POC can designate user roles, including Authorized Organization Representative (AOR). 3. AOR is authorized to submit applications on behalf of the organization in their workspace.	Allow at least one business 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. Additional information about applying for CDC grants and cooperative agreements can be found here: https://www.cdc.gov/grants/applying/pre-award.html

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

Number Of Days from Publication 76

02/05/2024
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, Word, or Excel file format 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 period of performance, 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 period of performance. 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. Population(s) of Focus and Health Disparities

Applicants must describe the specific population(s) of focus in their jurisdiction and explain how to 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 Population(s) of Focus and Health Disparities requirements as described in the CDC Project Description, including (as applicable to this award) how to address health disparities in the design and implementation of the proposed program activities.

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 https://www.cdc.gov/os/integrity/reducepublicburden/index.htm.
- 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.

Applicants should submit their initial data management plan (DMP) as part of their initial evaluation and performance measurement plan (EPMP). This should include cybersecurity plans and information about how PII will be protected when collected, stored, in transit, and in use. In addition, the initial DMP should include a description about how data will be de-identified in intermediate and final data sets. Finally, where data collected or generated under this award may

be sought by PEPFAR or CDC, recipient(s) will be informed about the need to share such information and how to send such information to PEPFAR or CDC.

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 or reaccreditation 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 essential public health services and ensure foundational capabilities are in place, such as activities that ensure a capable and qualified workforce, strengthen information systems and organizational competencies, build attention to equity, and advance 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 can upload it as a PDF, Word, or Excel file format 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. Employee Whistleblower Rights and Protections

Employee Whistleblower Rights and Protections: All recipients of an award under this NOFO will be subject to a term and condition that applies the requirements set out in 41 U.S.C. § 4712, “Enhancement of contractor protection from reprisal for disclosure of certain information” and 48 Code of Federal Regulations (CFR) section 3.9 to the award, which includes a requirement that recipients and subrecipients inform employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. § 4712. For more information see: https://oig.hhs.gov/fraud/whistleblower/.

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 anti-lobbying restrictions 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. Cost increases for fluctuations in exchange rates are allowable costs subject to the availability of funding. Prior approval of exchange rate fluctuations is required only when the change results in the need for additional Federal funding, or the increased costs result in the need to significantly reduce the scope of the project.

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-24-0097."

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

- (1) A family planning project must comply with the requirements of this paragraph.
- (2) 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

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 Data Quality Assessments and Quality Assurance Activities, including but not limited to 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 GHSD Bureau 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 Stewardship and Oversight Accountability Act, which states all completed PEPFAR evaluation reports must be maintained and made available via a website of the implementing agency within 90 days after the completion of the evaluation (Foreign Aid Transparency and Accountability Act of 2016 (FATAA). In accordance with FATAA requirements, the PEPFAR approach to dissemination of evaluation results is twofold: internal dissemination within the PEPFAR community, and external, public release of results (postembargo period, as applicable). A cleared final evaluation report detailing adherence to all evaluation standards on the CDC agency's publicly accessible website within 90 days of completion. https://help.datim.org/hc/en-us/article_attachments/13797449520148/PEPFAR_evaluation_standards_of_practice_v3.1.2_Jan25.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. Application attachments can be submitted using PDF, Word, or Excel file formats. 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 review the Applicants section on www.grants.gov.

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:** 40

To what extent does the proposal reflect a clear understanding of the HIV epidemic in Malawi and the gaps in laboratory services while providing well-constructed strategies to address the identified gaps? (**10 points**)

To what extent does the applicant propose scaling up and improving HIV/TB diagnosis, treatment monitoring, AHD and PrEP testing services to ensure efficient and timely laboratory service delivery? (**15 points**)

How well does the applicant propose to build MOH's Laboratory HRH capacity and QMS to achieve ISO accreditation, and to establish and sustain national integrated laboratory diagnostics in resource-constrained settings? (**10 points**)

How well does the applicant demonstrate a communication plan to engage key stakeholders (i.e., USG, government of Malawi)? **(5 points)**

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

How well does the applicant describe the timeframe, key stakeholders, indicator definitions, and evaluation questions when considering: the initial project evaluation, how each factor will be

measured, and how the findings will be disseminated? To what extent are the proposed indicators and evaluation questions appropriate given the objectives of the NOFO? **(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:** 35

To what extent are the proposed key personnel qualified and experienced with a track record of successfully implementing prior PEPFAR projects with similar scope and scale in Malawi or Sub-Saharan Africa? **(5 points)**

To what extent is the management structure and proposed key personnel qualifications and experience for the project sufficient for the administration and management of the proposed activities? (**5 points**)

How well does the applicant demonstrate past experience (in their financial management statement and experience statement) their ability to manage program resources; provide internal controls; prepare reports; audit expenditures; and produce, collect, and analyze performance data? **(15 points)**

To what extent does the applicant have the existing infrastructure in Malawi, or ability to set up the necessary infrastructure within 3 months of award, to be able to smoothly deliver comprehensive laboratory services on a large scale? **(10 points)**

Budget **Maximum Points:** 0

Budget (Reviewed Not Scored)

Is the budget itemized, well justified, reasonable, and consistent with stated objectives, planned program activities, and PEPFAR goals? 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 (15 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 sub-region served by the PEPFAR program with which the individual	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:

is or may become involved, and a sole proprietorship must be owned by such an individual; or	• 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 sub-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; and **(3)** where an entity has a Board of Directors, at least 51% of the members of	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 evidence of the organization's incorporation or legal organization in the country or sub-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 sub-region;

the Board must also be citizens or lawfully admitted permanent residents of such country; or	• 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 through a board of directors, similar to private corporations.	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.

CDC intends to fund applications 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. In the event there is still a tie, CDC will move to the

Evaluation and Performance Measurement section 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 2024. The award date will be September 30, 2024.

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

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
- AR-38: Health Information Technology (IT) Interoperability

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.

If you receive an award, you must follow all applicable nondiscrimination laws. You agree to this when you register in SAM.gov. You must also submit an Assurance of Compliance (HHS-690). To learn more, see the HHS Office for Civil Rights website.

3. Reporting

Reporting provides continuous program monitoring and identifies successes and challenges that recipients encounter throughout the period of performance. 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

HRH Inventory Reporting	Annually, in conjunction with the PEPFAR Annual Progress Report at the completion of the USG fiscal year.	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 specific 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 the GHSD Bureau 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 their expenditures, as defined by the PEPFAR Financial Classification guidance. Specifically, completion of PEPFAR Program Expenditures (Form DS-4213, approved by OMB 1405-0208, or the relevant OMB-approved format) will be required at the conclusion of the USG fiscal year, in addition to the requirements as outlined as part of the PEPFAR's Monitoring, Evaluation, and Reporting (MER) strategy.

Beginning September 30, 2021, as a term of the award, prime recipients are also required to report expenditure data for their sub-recipients. The full Expenditure Reporting template (Form DS-4213, approved under OMB 1405-0208) was previously completed by prime recipients and only included prime recipient expenditures. Separate submission of prime recipient and sub-recipient expenditures is now required, with all data reported through their prime partner. Sub-recipients with a fiscal year spend of under $25,000 will have a simplified template for expenditure reporting.

Prime recipients should implement this requirement by providing their sub-recipients with the PEPFAR financial classification intervention categorization associated with their funding. Expenditure data requirements should also be part of any agreement entered between a prime and sub-recipient that are using PEPFAR awarded funding. When reporting expenditures in a separate template, sub-recipients should be reminded to use the PEPFAR Financial Classification Guide and provide full cost category detail for each intervention on their expenditures, unless they expend less than $25,000 in a fiscal year. Sub-recipients with expenditures of less than $25,000 in a fiscal year will have a simplified template that does not require reporting by cost category and only by intervention. Prime recipients are expected to collect expenditure data from sub-recipients, ensure accuracy, and the correct use of the PEPFAR Financial Classification Guide for both prime and subrecipient data, and submit all data in line with the Expenditure Reporting timelines. All data should be uploaded or entered into the PEPFAR data collection system (DATIM).

Human Resources for Health (HRH) Inventory

In the COP/ROP 2023 Guidance, the GHSD Bureau outlines critical activities country and regional teams should take to account for and align their HRH investments to achieve program goals and UNAIDS targets. The guidance states that the "PEPFAR HRH Inventory is a critical tool for transparency around PEPFAR's health worker investments. It should be used to identify gaps in the health workforce, as well as misalignments." Pages 62 – 64 of the COP/ROP 2023 guidance, Section 3.1.3.1, Human Resources for Health, lists prioritized HRH activities. The HRH Inventory replaces the HRH_CURR MER indicator and is reported along with other Q4 APR indicators in DATIM. GHSD requests all partners, prime and sub, to report their HRH investments into DATIM using the HRH Inventory template. Therefore, consistent with GHSD Bureau guidance, all individuals proposed to be supported using funds under this NOFO, once awarded, are expected to report employment information for their PEPFAR-supported HRH investments per the timeline and requirements of the GHSD Bureau or the CDC Global Health Center, including but not limited to, as outlined in the annual HRH Inventory survey: gender, employment title, compensation (salary, fringe and non-monetary), percent of effort, and work location. Variables and reporting timelines may change based on GHSD Bureau requirements. Individuals paid using the negotiated indirect cost agreement (NICRA) are not required to be reported.

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 period of performance, 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 $30,000.

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:
Howard

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

Address:
NICO House

P.O. Box 30016

Lilongwe 3, Malawi

Telephone:
N/A

Email:
hak5@cdc.gov

Grants Staff Contact

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

First Name:
Sharon

Last Name:
Cassell
Grants Management Specialist
Department of Health and Human Services
Office of Grants Services

Address:
2939 Flowers Road, MS TV1

Atlanta, GA 30341

Telephone:
770.488.2703

Email:
zpr0@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 application attachments that can be submitted using PDF, Word, or Excel file formats 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.
- **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.
- **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.It is the responsibility of applicants to double-check for formatting issues that occur upon upload during application submission. If a formatting problem causes a 20-page narrative to exceed 20-pages, the application will be deemed non-responsive for exceeding 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

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 calendar days after the publication date in www.grants.gov. Questions received more than 15 calendar 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 Additional Updates

The purpose of this amendment is to include the updates as listed below.

- The amendment includes questions and answers (Q&A) in Section H. Other Information.

- CDC has retired the Risk Assessment Questionnaire Requirement and applicants are no longer required to submit the CDC Risk Questionnaire as part of their NOFO application. CDC continues to conduct the review of risk posed by applicants described in Phase III Review and may ask for additional information prior to the award based on the results of the review. Risk Questionnaires that are submitted will not be included in this risk review.
- In F. Award Administration Information, 2. Administrative and National Policy Requirements, CDC has added AR-38: Health Information Technology (IT) Interoperability to the list of Organization Specific Administrative Requirements

1. The Funding Strategy outlined in the NOFO (pages 16 – 18) states that "all PEPFAR-funded cooperative agreements be formulated for component funding" and that "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….". The total funding for year one is indicated on page 18 as $8,375,000 with Components 1 – 6 listed; however, we note that the year 1 budget has not been broken down by the listed components. Please advise if there is COP-approved budget amount (Components 1-4) that we should be working with since the total year one funding of $8,375,000 includes 'Component 5: COP Additional Targets/Activities' and 'Component 6: Additional Activities and Emerging Health Issues (buffer component)'.
    - At this time, COP-approved budget amounts are not finalized. Applicants should prepare a year 1 budget of up to $8,375,000 addressing the expectations listed in the NOFO, and group them under Components 1-6. Components 5 and 6 are buffer components in the event that additional funding becomes available or additional components are needed to address COP priorities; at this time, there are no confirmed activities or budget amounts for these components. Components 5 and 6 do not need to be as detailed but should still be included in the SF-424A along with a proposed budget amount and at least a high-level budget justification (ex. "to be finalized if funding becomes available").

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 period of performance. 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.

Community engagement: The process of working collaboratively with and through groups of people to improve the health of the community and its members. Community engagement often involves partnerships and coalitions that help mobilize resources and influence systems, improve relationships among partners, and serve as catalysts for changing policies, programs, and practices.

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.

Equity: The consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment (from Executive Order 13985).

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: Preventable differences in the burden of disease, injury, violence, or opportunities to achieve optimal health that are experienced by populations that have been socially, economically, geographically, and environmentally disadvantaged.

Health Equity: The state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving this requires focused and ongoing societal efforts to address historical and contemporary injustices; overcome economic, social, and other obstacles to health and healthcare; and eliminate preventable health disparities.

Health Inequities: Particular types of health disparities that stem from unfair and unjust systems, policies, and practices and limit access to the opportunities and resources needed to live the healthiest life possible.

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: The act of creating environments in which any individual or group can be and feel welcomed, respected, supported, and valued to fully participate. An inclusive and welcoming climate embraces differences and offers respect in words and actions for all people.

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 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.

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).

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: The non-medical factors that influence health outcomes. The conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life. These forces (e.g., racism, climate) and systems include economic policies and systems, development agendas, social norms, social policies, and political systems. https://www.cdc.gov/about/sdoh/index.html

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 at the time of application demonstrating their organization meets at least one of the three criteria described below.

In the local partner 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 sub-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 sub-region where the entity's funded PEPFAR programs are implemented
2	either	must be at least 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