# U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



Office of Global Health (OGH)
Office of the Administrator (OA)
Health Resources and Services Administration (HRSA)

# Quality Improvement Solutions for Sustained Epidemic Control Project (QISSEC)

Funding Opportunity Number: HRSA-21-096 Funding Opportunity Type: New Assistance Listings (CFDA) Number: 93.266

# NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2021

Application Due Date: May 7, 2021

Ensure your SAM.gov and Grants.gov registrations and passwords are current immediately!

HRSA will not approve deadline extensions for lack of registration.

Registration in all systems, including SAM.gov and Grants.gov,

may take up to 1 month to complete.

Issuance Date: March 8, 2021

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

#### **EXECUTIVE SUMMARY**

The Health Resources and Services Administration (HRSA), Office of Global Health (OGH) is accepting applications for fiscal year (FY) 2021 to administer the Quality Improvement Solutions for Sustained Epidemic Control Project (QISSEC). The purpose of this project is to facilitate improvements in quality across the HIV care continuum at the site level (defined as the location where persons diagnosed with HIV receive care and treatment) and within the community. The project attempts to improve the effectiveness, efficiency, patient-centeredness, safety, accessibility, and equity of the HIV services in low to middle-income countries (LMIC) as identified by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) program. FY21 PEPFAR priorities recognize quality health services as essential in order to ensure that optimal health outcomes are met on a daily and routine basis. Therefore, all PEPFAR country programs must incorporate explicit quality management (QM) practices, including both quality assurance (QA) and quality improvement (QI) activities into service delivery and partner management. Focused on building the capacity of countries to sustain and spread QI methodologies, improve documentation of efforts and continuously enhance staff knowledge, QISSEC strives to impact the delivery of quality HIV services, improve health outcomes and support HIV/AIDS epidemic control. This Notice of Funding Opportunity (NOFO) will fund two cooperative agreements in support of the PEPFAR focus on the management of evidence-informed interventions for scale-up and spread. The successful applicants will facilitate solutions for long-term change management approaches and sustainability of QA and QI activity.

Funding Opportunity Title:	Quality Improvement Solutions for
	Sustained Epidemic Control Project
Funding Opportunity Number:	HRSA-21-096
Due Date for Applications:	May 7, 2021
Anticipated Total Annual Available	Up to \$20,000,000 funding ceiling
FY 2021 Funding:	
Estimated Number and Type of Award(s):	2 cooperative agreements
Estimated Award Amount:	Up to \$20,000,000 per year subject to the
	availability of appropriated funds
Cost Sharing/Match Required:	No
Period of Performance:	September 30, 2021 through September
	29, 2026 (5 years)

Eligible Applicants:

Domestic or foreign public or non-profit private entities, including schools of medicine, nursing, public health, management and public administration, and academic health centers, community-based organizations, faith-based organizations, and consortia consisting of such organizations, are eligible to apply.

See Section III.1 of this notice of funding

See <u>Section III.1</u> of this notice of funding opportunity (NOFO) for complete eligibility information.

## **Application Guide**

You (the applicant organization/agency) are responsible for reading and complying with the instructions included in HRSA's *SF-424 Application Guide*, available online at <a href="http://www.hrsa.gov/grants/apply/applicationguide/sf424guide.pdf">http://www.hrsa.gov/grants/apply/applicationguide/sf424guide.pdf</a>, except where instructed in this NOFO to do otherwise.

#### **Technical Assistance**

HRSA has scheduled the following technical assistance:

Webinar

Date: Friday, March 19, 2021

Time: 1:00 PM - 2:30 PM EST

Adobe Connect URL Weblink: <a href="https://hrsa.connectsolutions.com/nofo">https://hrsa.connectsolutions.com/nofo</a> pre-application/

Call-In Number: Dial-in: Conference Call 888-730-9136 for all callers (U.S. and international)

Participant passcode 5686097 (U.S. and international)

The webinar will be recorded and should be available for viewing by March 31, 2021. The location of the recording and frequently asked questions (FAQ's) will be discussed during the webinar.

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# I. Program Funding Opportunity Description

# 1. Purpose

This notice announces the opportunity to apply for funding for the Quality Improvement Solutions for Sustained Epidemic Control Project (QISSEC). The purpose of this project is to facilitate improvements in quality across the HIV care continuum at the site level (defined as the location where persons diagnosed with HIV receive care and treatment) and within the community. The project attempts to improve the effectiveness, efficiency, patient-centeredness, safety, accessibility, and equity of the HIV services in low to middle-income countries (LMIC) as identified by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) program.

FY21 PEPFAR priorities recognize quality health services as essential in order to ensure that optimal health outcomes are met on a daily and routine basis. Therefore, all PEPFAR country programs must incorporate explicit quality management (QM) practices, including both quality assurance (QA) and quality improvement (QI) activities into service delivery and partner management.

Focused on building the capacity of countries to sustain and spread QI methodologies, improve documentation of efforts, and continuously enhance staff knowledge, QISSEC strives to impact the delivery of quality HIV services, improve health outcomes, and support HIV/AIDS epidemic control. This Notice of Funding Opportunity (NOFO) will fund two cooperative agreements in support of the PEPFAR focus on the management of evidence-informed interventions for scale-up and spread. The successful applicants will facilitate solutions for long-term change management approaches and sustainability of QA and QI activity.

The QISSEC shall focus on developing innovative strategies to improve the delivery of HIV quality care and treatment for use by facilities that serve the most vulnerable individuals in PEPFAR-supported LMICs. Using quality improvement methodologies, tools, and techniques, the project will identify gaps in service delivery, and develop culturally and medically appropriate, sustainable interventions targeted to PEPFAR-identified vulnerable and key populations.

Over 18 years PEPFAR <a href="https://www.state.gov/pepfar/">https://www.state.gov/pepfar/</a> has evolved to a complex and high impact program, with mature stakeholders and partners showing that epidemic control is indeed possible. It is in this context that HRSA is renewing its commitment to PEPFAR and specifically seeking to fill gaps as well as to bring targeted and innovative solutions to the remaining barriers to epidemic control around the globe. The PEPFAR 2021 Country Operational Plan Guidance for all PEPFAR Countries (<a href="https://www.state.gov/wp-content/uploads/2020/12/PEPFAR-COP21-Guidance-Final.pdf">https://www.state.gov/wp-content/uploads/2020/12/PEPFAR-COP21-Guidance-Final.pdf</a>) suggests all PEPFAR country programs must incorporate explicit quality management practices, including both QA and QI activities, into service delivery and partner management.

#### 2. Background

This program is authorized by Public Law 108-25 (the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003) [22 U.S.C. 7601 *et seq.*], Public Law

110-293 (the Tom Lantos and Henry Hyde United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008), and Public Law 113-56 (PEPFAR Stewardship and Oversight Act of 2013).

Since its inception, PEPFAR has invested over \$85 billion in the global HIV/AIDS response, saving over 18 million lives, preventing millions of HIV infections, and accelerating progress toward controlling the global HIV/AIDS epidemic.

PEPFAR's investments continue to strengthen the systems that drive client-centered and sustainable health care. These investments create a lasting health system for partner countries to confront other current and future health challenges, enhance global health security, and protect America's borders. The HIV/AIDS pandemic constantly evolves in every community and country and PEPFAR continually adapts to address new risk groups, new health challenges, and persistent gaps. (https://www.state.gov/about-us-pepfar/).

Under the leadership of the Office of the U.S. Global AIDS Coordinator (OGAC), as part of the U.S. Government's global HIV response, HRSA has been a significant contributor to PEPFAR's achievements. HRSA's work builds on the agency's domestic and international experience and expertise by improving outcomes along the HIV care continuum for people living with HIV (PLHIV). Domestically, HRSA's programming includes integrations with other bureaus in the agency, such as the HIV/AIDS Bureau (HAB) and the Bureau of Primary Health Care (BHPC). HAB provides a comprehensive system of HIV primary medical care, essential support services, and medications for low-income PLHIV who are uninsured and underserved. More than half of people living with diagnosed HIV in the United States receive services through the Ryan White HIV/AIDS Program each year. That means more than half a million people received services through the program. BHPC oversees the Health Center Program, a national network of health centers that provide comprehensive primary health care services to more than 27 million people nationwide, regardless of a patient's ability to pay, charging for services on a sliding fee scale. These health centers play an important role in "Ending the HIV Epidemic" by serving as a key point of entry for people undiagnosed with HIV. Integrating HIV services into primary care delivery is critical for success, both for health centers and for patients living with HIV. They emphasize coordinated and comprehensive care, and have the ability to manage patients with multiple health care needs.

HRSA continues to work with host countries and with other key partners to assess the needs of each country and design a customized program of assistance that fits within the host country's strategic plan. PEPFAR guidance changes regularly; therefore recipients will consistently monitor, adapt and align their program activities with current PEPFAR guidelines.

#### II. Award Information

# 1. Type of Application and Award

Type of applications sought: New

HRSA will provide funding in the form of a cooperative agreement. A cooperative agreement is a financial assistance mechanism where substantial involvement is anticipated between HRSA and the recipient during performance of the contemplated project.

#### HRSA program involvement will include:

- Participate in discussions for planning, implementing, and evaluating program activities, including the identification and selection of additional incountry impact partners.
- Assist in the coordination and collaboration among program partners, such as the Office of the U.S. Global AIDS Coordinator and Health Diplomacy (OGAC), other HHS agencies, the USAID, foreign governments, international donors, and other key stakeholders.
- Participate, as appropriate, in planning and producing meetings or workgroups conducted during the period of performance.
- Maintain an ongoing dialogue with the recipients of this cooperative agreement concerning program plans, policies, and other issues that have major implications for any activities under the cooperative agreement.
- Review and provide comments and recommendations for documents, curricula, program plans, budgets, contracts, personnel (including consultants), revisions of work plans, etc., prior to printing, dissemination, or implementation.
- Support the engagement of relevant stakeholders and assist in developing and periodically reviewing the recipients' five-year monitoring and evaluation plan (M&E), ensuring compliance with the strategic information guidance established by OGAC.
- Provide technical assistance, as mutually agreed upon, and revise annually during validation of the first and subsequent annual work plans. This could include expert technical assistance and targeted training activities in specialized areas, such as strategic information, project management, confidential counseling and testing, palliative care, treatment literacy, and adult learning techniques.
- Support access to the expertise of HRSA personnel and other relevant resources to the project.
- Participate in the dissemination of project findings, best practices, and lessons learned across the initiative.

#### The cooperative agreement recipient's responsibilities will include:

- Collaborate closely with HRSA, country governments, in-country U.S.
  Government (USG) teams, and other key stakeholders to gain a greater
  understanding of the identified LMIC's situation, root causes for state fragility,
  short and longer term needs and priorities in order to better mobilize, build
  consensus, and efficiently plan and coordinate successful interventions for the
  highest impact.
- Consult with HRSA and field teams as applicable, to inform HRSA on program progress and barriers encountered, identify activities to be planned jointly, and discuss matters that require HRSA input and approval.
- Implement strategies for facilitating scale-up and sustainability of activities supported under this agreement that include building on and strengthening previous and/or existing efforts by governments, local networks, and institutions that benefit the populations served. Strategies should strengthen indigenous capacity in all aspects of the agreement.

- Develop and execute a final M&E plan within the first six months of the period of performance, in consultation with HRSA and key stakeholders.
- Support the relevant governmental, academic, and regulatory bodies by partnering with local organizations and providing technical support to the government. The partnerships are expected to expand through the period of performance.
- Support health systems strengthening interventions that are grounded in primary health care and universal health coverage principles and capable of responding to diverse and unexpected challenges that might arise in the future.
- Respond to the health needs of the people of the identified LMICs in their unique political, economic, and health system circumstance. Identifying post-conflict, resource-poor, or policy-poor considerations that possess uniquely complicated characteristics will require a customized approach.

#### 2. Summary of Funding

HRSA anticipates a funding ceiling of \$20,000,000 to be available annually to fund two (2) recipients. You may apply for a ceiling amount of up to \$20,000,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. The period of performance is September 30, 2021 through September 29, 2026. Funding beyond the first year is subject to the availability of appropriated funds for QISSEC in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government. HRSA may reduce recipient funding levels beyond the first year if a recipient is unable to fully succeed in achieving the goals listed in the application.

All HRSA awards are subject to the Uniform Administrative Requirements, Cost Principles, and Audit Requirements at 45 CFR part 75.

Grants to foreign organizations and foreign public entities that are 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 8 percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of \$25,000.

# III. Eligibility Information

#### 1. Eligible Applicants

Eligible applicants include domestic or foreign public or non-profit private entities, including schools of medicine, nursing, public health, management and public administration, and academic health centers, community-based organizations, faith-based organizations, and consortia consisting of such eligible organizations.

#### 2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

#### 3. Other

HRSA will consider any application that exceeds the ceiling amount non-responsive and will not consider it for funding under this notice.

HRSA will consider any application that fails to satisfy the deadline requirements referenced in <u>Section IV.4</u> non-responsive and will not consider it for funding under this notice.

HRSA will consider any application that exceeds the page limit referenced <u>Section IV.2</u> non-responsive and will not consider it for funding under this notice.

NOTE: Multiple applications from an organization are not allowable.

If for any reason (including submitting to the wrong funding opportunity number or making corrections/updates) an application is submitted more than once prior to the application due date, HRSA will only accept your **last** validated electronic submission, under the correct funding opportunity number, prior to the Grants.gov application due date as the final and only acceptable application.

# IV. Application and Submission Information

# 1. Address to Request Application Package

HRSA **requires** you to apply electronically. HRSA encourages you to apply through <u>Grants.gov</u> using the SF-424 workspace application package associated with this notice of funding opportunity (NOFO) following the directions provided at <a href="http://www.grants.gov/applicants/apply-for-grants.html">http://www.grants.gov/applicants/apply-for-grants.html</a>.

The NOFO is also known as "Instructions" on Grants.gov. You must provide your email address when reviewing or preparing the workspace application package in order to receive notifications including modifications and/or republications of the NOFO on Grants.gov before its closing date. You will also receive notifications of documents placed in the RELATED DOCUMENTS tab on Grants.gov that may affect the NOFO and your application. Responding to an earlier version of a modified notice may result in a less competitive or ineligible application. *Please note you are ultimately responsible for reviewing the For Applicants page for all information relevant to desired opportunities*.

## 2. Content and Form of Application Submission

Section 4 of HRSA's <u>SF-424 Application Guide</u> provides instructions for the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, and abstract. You must submit the information outlined in the Application Guide in addition to the program-specific information below. You are responsible for reading and complying with the instructions included in HRSA's <u>SF-424 Application Guide</u> except where instructed in the NOFO to do otherwise. You must submit the application in the English language and in the terms of U.S. dollars (45 CFR § 75.111(a)).

See Section 8.5 of the Application Guide for the Application Completeness Checklist.

#### **Application Page Limit**

The total size of all uploaded files may not exceed the equivalent of **80** pages when printed by HRSA. The page limit includes the abstract, project and budget narratives, attachments, and letters of commitment and support required in the *Application Guide* and this NOFO. Standard OMB-approved forms that are included in the workspace application package do not count in the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. We strongly urge you to take appropriate measures to ensure your application does not exceed the specified page limit.

Applications must be complete, within the specified page limit, and validated by Grants.gov under the correct funding opportunity number prior to the deadline to be considered under this notice.

#### Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

- 1) You, on behalf of the applicant organization certify, by submission of your proposal, that neither you nor your principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
- 2) Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. 3321).
- 3) Where you are unable to attest to the statements in this certification, an explanation shall be included in Attachment 11: Other Relevant Documents.

See Section 4.1 viii of HRSA's <u>SF-424 Application Guide</u> for additional information on all certifications.

#### **Program-Specific Instructions**

In addition to application requirements and instructions in Section 4 of HRSA's <u>SF-424</u> <u>Application Guide</u> (including the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, and abstract), include the following:

#### **Project Level Activities**

Given the diversity of PEPFAR funded countries' needs for quality improvement technical assistance, this announcement is not intended to be a prescriptive approach to improving quality but rather requires that you support implementation of innovative, evidence-informed practices. PEPFAR priorities stress the importance of successfully operationalizing a quality management program to support programs with fidelity, scale, and quality. HRSA encourages you to offer ideas and strategies, and to incorporate an inter-professional approach or multidisciplinary team-based approach. The World Health Organization defines inter-professional practice as a collaborative process of communication and decision-making between a multidisciplinary team to influence new knowledge and new skills.

#### You are required to:

- Use a sample of PEPFAR-funded countries to illustrate and identify quality improvement gaps across the HIV care continuum, including, but not limited to: HIV service delivery gaps, adult and pediatric antiretroviral therapy (ART), ART switch confidence, treatment adherence, support of medical case management, retention in care, and viral suppression management. The use of the <u>U.S.</u>
   <u>Centers for Disease Control and Prevention Granular Site Management Tool</u>, and SIMS are effective sources of country data.
- Build communities of learning through implementing various QI activities that
  offer levels of QM, QA, and QI methodologies, tools, and techniques related to
  any of the above-listed or that are newly identified. Communities of learning
  have proven to be effective collaborative models.
- Facilitate rapid scale up and dissemination of interventions that:
  - o Are ministries of health (MOH) and stakeholder vetted
  - o Are targeted and time-limited
  - Extend across country programs, and across distinct technical areas to facilitate the spread of new knowledge
- Assess the impact of implementation on health outcomes through demonstrated plans of monitoring and evaluation, revealing outcome and impact data. You must use the results of the assessment, as presented in an M&E plan, throughout the project to continuously modify interventions for sustainability.

# **Principles of QISSEC**

Integrate the following principles in the overall approach to the QISSEC project:

- HIV care continuum approach
- Integrated design
- Documentation
- Evidence-based QI
- Institutionalization of QI and sustainability
- Evaluation of QI

#### HIV care continuum approach

The <u>HIV care continuum</u> includes the diagnosis of HIV, linkage to HIV medical care, retention in HIV medical care, prescription of ART, and, ultimately, HIV viral suppression.

## Integrated design

HRSA expects that this project will focus on large scale, country-specific activities designed to introduce or expand and enhance modern quality improvement as an integral part of health care. Funding allocations are made to align with PEPFAR priorities, country specific epidemiological information, and other data. Recipient(s) should plan to assist HRSA in preparation for annual portfolio reviews and subsequent funding allocations consistent with program needs and supported by evidence of

impact. QISSEC country programs will generally be designed to be supported by an office established and staffed by the recipient(s) in each host country or within a region. Staff in the field is not an explicit requirement, but consistent support and access to a virtual platform is optimal.

#### **Documentation**

The documentation of QI changes in both quantitative and qualitative indicators will be used to monitor the results of QI activities, how the teams produced these results, and how QI interventions were implemented. For example, the development of a QI knowledge hub provides access to resources and tools in support of dissemination and spread of QI knowledge for replication.

#### Evidence-Informed QI

Evidenced-informed improvement science offers an approach to improving quality that includes the measurement of change in relation to well-defined, appropriate indicators. Specifically, improvement science suggests supporting the testing of changes in health care processes, and then measuring the impact of these changes using indicators that capture the performance of that process or its outcome.

## Institutionalization of QI and Sustainability

The QISSEC seeks to make quality improvement a permanent and an integral part of delivering health services in QISSEC countries. To achieve this goal, the project must build the capacity of host country institutions to carry out effective improvement interventions without external assistance. As a result of this institutionalization, the project will support the development of improvements in health care processes that endure over the long term rather than improvements that depend on external support or on a level of effort that cannot be sustained by the health system of the host country.

#### Evaluation of QI

The central purpose of evaluation under QISSEC is to contribute to the development of more cost effective QI activities that are fully institutionalized and sustainable components of the provision of health services. The primary focus should be on the assessment of implementation through demonstrated plans of monitoring and evaluation, revealing outcome and impact data. These efforts will contribute to improving the design of QI programs and evaluations that measure the impact of QI programs HIV service delivery gaps.

#### i. Project Abstract

See Section 4.1.ix of HRSA's SF-424 Application Guide.

Please include a summary of the proposed activities; a description of the impact of the proposed activities; and indicate the funding amount requested for the period of performance. The project abstract should not exceed one page.

#### ii. Project Narrative

This section provides a comprehensive framework and description of all aspects of the proposed project. It should be succinct, self-explanatory, consistent with forms and attachments, and well organized so that reviewers can understand the proposed project.

Successful applications will contain the information below. Please use the following section headers for the narrative:

- INTRODUCTION -- Corresponds to Section V's Review Criterion #1
  Briefly describe the purpose of the proposed project. Summarize the existing service gaps, design and rationale of the proposed program, and evolving public health considerations. Discuss how the program will engage and collaborate with stakeholders to collectively develop practical, effective, and innovative solutions. Describe your organization's responsibility for carrying out activities and abilities related to the project activities. Describe your organization's role/contribution and that of each potential partner as it relates to priorities identified by PEPFAR for LMICs. Include a discussion that exhibits an expert understanding of the issues related to the activities included in this funding opportunity announcement among the applicant's internal and consulting staff, as well as any partner organizations.
- NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion #1
   Outline the understanding of the needs of diverse LMICs in which you propose to work. Select three sample LMIC PEPFAR-supported countries to discuss the overall state of quality in PEPFAR-supported countries, followed by a description of the specific needs. Provide examples if possible to enhance understanding and address provider compliance with clinical guidelines and other priority areas in the discussion.

The needs assessment should demonstrate a summary of the following:

- A brief description of the sample countries' HIV/AIDS epidemic
- A brief description of leadership and resources available for HIV care and QI activities
- A brief relevant history of QI interventions and identified gaps in QI activities (for example, performance measurement)

Briefly describe your understanding of the contributing factors of incidence and prevalence rates for HIV in the sampled LMIC countries.

Use and cite demographic and epidemiologic data as presented by the sampled countries for the last two quarters. Data sources may include surveillance and epidemiology reports, Ministry of Health reports, and other programmatic data.

Include in the summary a comprehensive understanding of the types of QI activities that support and facilitate sustainable increases of retention in care and viral suppression. Address key challenges and barriers, such as stigma, infrastructure, and the potential impact of social determinants of health. Include specific cultural considerations, linguistic differences, and health literacy skills

essential to build scalable, sustainable efforts.

METHODOLOGY -- Corresponds to Section V's Review Criterion #2

#### **QISSEC Requirements**

# A. Objectives of the Project

The objectives of the QISSEC include four core components:

- 1. Identify Quality Improvement Gaps in the service delivery of HIV care and treatment across the HIV care continuum. You must accomplish this in collaboration with host MOH, stakeholders such as staff directly delivering HIV care and treatment, vulnerable and key populations, and other civil society stakeholders. This objective will establish a clear plan of action that will support facility level capacity and enhancements to infrastructure, while maximizing evidenced-informed quality improvement interventions. This is a core component of the project.
- 2. Implement Quality Improvement Interventions at the site level, using evidence-informed methodologies and best practice approaches that focus on a range of well-defined innovative strategies for HIV service delivery along the HIV care continuum that increase measurable health outcomes (improved retention in care or enhanced viral suppression). Focused on the development of interventions for country-identified gaps in retention in HIV care and treatment and HIV viral suppression, this core component will support communities of learning.
- 3. **Disseminate/Spread Quality Improvement Tools and Resources** that are supportive, rapid and scalable, user-friendly, and replicable at the facility level. "Spread" in this context is defined as the transfer of knowledge beyond the dissemination point. This transfer can be achieved through traditional face-to-face methods or ideally through a cost-effective virtual platform. This core component will facilitate the widespread dissemination of tools and resources, and supports indigenous organizations to sustain the monitoring and implementation of QI programs.
- 4. **Measure and Evaluate the Impact of Activities** that contribute to scalable and sustainable interventions. This core component will demonstrate the appropriateness of identifying the most urgent gaps for quality improvement activities; will highlight the most effective implementation of quality improvement interventions; and acknowledge the most cost-effective and scalable activities for dissemination and spread of quality improvement tools and resources.
  - Propose methods that you will use to achieve the project's objectives, goals, and intended outcomes. Objectives should be specific, measurable, realistic, and achievable within the project period. Clearly relate the project objectives and goals to the program expectations outlined in Section I of this NOFO. Highlight those activities linked to the goals outlined in PEPFAR. Describe your proposed approach for improving access to and the quality of services for HIV, other communicable and non-communicable diseases, and other priority health areas. This section must include a plan for identifying gaps, implementation of interventions, dissemination, spread, and sustainability of efforts.

- How you, in collaboration with consortium partners, will build and maintain effective strategic partnerships with relevant government agencies, education institutions, regulatory bodies, health management teams, civil society organizations, other USG-funded programs, and other stakeholders to ensure relevant, appropriate, and timely technical assistance.
- How you will ensure that plans are in alignment with identified LMIC's national strategic plans and current PEPFAR priorities.
- How the proposed approach will work to strengthen the interprofessional approach to care and treatment.
- How the proposed approach will ensure up-to-date knowledge and skills in HIV/AIDS, TB, malaria, and other communicable and non-communicable diseases in response to local health priorities, and addresses the specific needs of low-income youth, women, and men, and targeted key populations.
- How strategies for facilitating scale-up and sustainability of activities will include building on and strengthening previous and/or existing efforts by the individual governments, USG, or other donors.
- How choices will be made to balance between immediate impact or longerterm, more sustainable interventions.
- How your experience in the design and management of health management information systems and/or the capacity to assist institutions in using data to inform decisions is a benefit to PEPFAR-supported LMICs.
- How you will maintain consistency with national plans, specific groups or categories of beneficiaries targeted, and mechanisms for coordination with similar activities that are supported by other funding sources.
- How you will develop the process you will use to manage and monitor subrecipients. Describe the subaward process from initiation to approval, with the corresponding timelines. Describe the approach for working collaboratively with other partners including USG, other implementing partners, donors, and Ministries. You must demonstrate a strong capacity to understand, manage, and leverage different types of relationships to implement the QISSEC project.

You must also propose a plan for project sustainability after the period of performance ends. HRSA expects recipients to sustain key elements of their projects (e.g., strategies or services and interventions) which have been effective in improving practices and those that have led to improved outcomes for the target population.

#### WORK PLAN -- Corresponds to Section V's Review Criteria #2 and #4

Describe the activities or steps that you will use to achieve each of the objectives proposed during the entire period of performance in the Methodology section. Discuss how these goals and objectives directly relate to the requirements and expectations of the project requirements outlined in Section 1. Provide a work plan that demonstrates how the outcomes, strategies, activities, timelines, and staffing will take place over the course of the award. Include a detailed work plan for the first year of the project and a high-level plan for the four subsequent years. The work plan should include goals, objectives, and outcomes that are SMART

(specific, measureable, achievable, realistic, and time-measured). Include all aspects of planning, implementation, and evaluation, along with the role of key staff involved in each activity. The work plan must relate to the needs identified in the needs assessment and to the activities described in the project narrative with a minimum of the following;

- Identify the QI intervention for each goal
- Identify the QI activities for each intervention
- Identify the responsible staff to complete or monitor each activity
- Identify the anticipated timeline for activity, intervention and goal completion

The work plan should include as much detail as possible with the understanding that the work plan will be revised after the cooperative agreement is awarded and after initial consultations with HRSA and in-country stakeholders. Include the project's work plan as **Attachment 1**. This section is often best presented and/or summarized in a chart format.

RESOLUTION OF CHALLENGES -- Corresponds to Section V's Review <u>Criterion</u>
 #2

Discuss challenges that you are likely to encounter in designing and implementing the QISSEC activities described in the needs assessment and work plan sections of the narrative, and provide reasonable and actionable solutions to address these barriers. Discuss the strength of your methodology in identifying and responding to these challenges. Discuss approaches that you will use to resolve such challenges.

 EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criteria #3 and #4

You must describe the plan for the program performance evaluation that will contribute to scalable and sustainable interventions. Describe your capacity to monitor program goals and objectives. Describe plans to track and quantify the utilization of tools, systems, and strategies developed. Describe methods and measures that you will use to evaluate the system-level impacts of the overall project and demonstrate the effectiveness of project activities.

Describe how the performance plan will link with expenditure reporting for the proposed project. The plan should also include a well-defined set of yearly milestones for the proposed activities. Such milestones should conform to the proposed timeline described in the work plan. The plan should outline indicators that will demonstrate timely achievement of milestones. Milestones will be reconsidered on an annual basis. The successful recipient, in consultation with HRSA, will work with relevant stakeholders to co-develop the M&E plan.

Describe the methods you plan to use to collect data. Describe current experience, skills, and knowledge, including individuals on staff, materials

published, and previous work of a similar nature. As part of this section, discuss the effectiveness of methods proposed to monitor and evaluate the project and project results, and include any developed evaluation tools as **Attachment 10** (optional).

# ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criterion #5

In this section, provide an organizational description and project organizational chart, an outline of the management and staffing plan, and an outline of key collaborators and partners. Each element is described in more detail below. Include as **Attachment 8** a list of experience with global health grants, cooperative agreements, and/or contracts, source of funding including the name of project director/principal investigator; institution holding the award; grant, cooperative agreement, or contract number; total amount of award; and end date. This may present well in table form.

You must also include as **Attachment 9**, up to three past performance references (required). Consortium partners may provide up to three past performance references from the last three years for contracts, grants and/or cooperative agreements of similar size, scope, and complexity.

# **Project Structure and Project Organizational Chart**

Provide your current mission and structure, scope of current activities, and history of developing and promoting health system strengthening activities. You must demonstrate at least three years of experience successfully implementing health programs in the international setting.

Describe previous projects that reflect the expertise of proposed personnel in working collaboratively with Ministerial, education institutions, regulatory bodies, health management teams, civil society organizations, other USG-funded programs, and stakeholders.

Describe the proposed organizational structure of the international consortium, and the plans for administering, managing, tracking, and coordinating its activities. Describe the consortium's implementing and technical partners' prior experience and performance with USG grants. Describe the necessary processes and systems in place to comply with the requirements identified at 45 CFR Part 75. Describe the estimated percentage of your total organizational budget that funding from this cooperative agreement would comprise.

Provide a project organizational chart as **Attachment 5.** The organizational chart should be a one-page figure that depicts the organizational structure of your consortium, including impact and technical partners, as well as any collaborating entities, and lines of authority for staff.

Note: If the application includes sub-agreements, describe separately your organization's experience with establishing and administering sub-agreements. Management and Staffing Plan

Include as **Attachment 2** the Staffing Plan and Job Descriptions for Key Personnel.

Provide a staffing plan including key personnel and core technical staff, inclusive of a management plan for project implementation. Indicate and justify the FTE proposed for each. Demonstrate responsibilities and lines of authority. The management plan must describe how the project will relate to and respond to HRSA and to in-country USG. You must describe capacity for rapid start-up of the project, including plans for rapidly accessing and deploying key personnel and essential technical staff to support program implementation.

The staffing plan must also indicate staff who are already employed by the organization and the level of effort.

Include biographical sketches, not to exceed two pages in length, for only key personnel on the project as **Attachment 3**. Include a description of the staff experience; knowledge of PEPFAR priorities, and PEPFAR-supported LMICs. If a biographical sketch for an individual not yet hired is included, you must attach a letter of commitment signed by the individual. Describe the qualifications of the Project Director (by training and experience) that demonstrate their ability to lead a project of similar size and scope. Include a description of publications and funded research in the specialty with appropriate academic preparation, clinical expertise, and experience as an educator.

Key personnel, at a minimum, should include:

- Principal Investigator (PI) should possess a clinical/healthcare background degree.
- A Program Director (PD) with fiscal and programmatic authority for the management of the program who will be the contact person for OGH staff. The Program Director should have experience in project management, working with federal grants and cooperative agreements, and have the skills and requirements addressed under the *Organization Information* in Section IV. 2. This position must be responsible for the administration of the cooperative agreement, and 1) provides vision, 2) directs the strategic planning, operations, and capacity, 3) has the technical expertise in quality improvement, 4) supervises key tasks and staff, 5) clearly delineates staff responsibilities and roles, 6) creates the work plan and timelines, and 7) oversees program management.
- A program evaluator with impact evaluation expertise.

Describe your and your consortium partners' resources, and capabilities to support the provision of culturally and linguistically competent training and capacity development services. See the <u>USG National Standards for Culturally and Linguistically Appropriate Services</u>.

#### Key Collaborators and Partners (Letters of Support)

Describe how you will collaborate with key stakeholders. Describe how you will

liaise and coordinate with the partner government(s) as well as with other district and local government partners, USG partners and other stakeholders working across PEPFAR program areas. If you plan to collaborate with other organizations or government agencies for the implementation of the proposed activities, outline the services each such agency or organization will provide. State whether you have any existing relationships with the proposed partner(s) and, if so, include the MOUs in **Attachment 4**.

#### NARRATIVE GUIDANCE

To ensure that you fully address the review criteria, this table provides a crosswalk between the narrative language and where each section falls within the review criteria. Any attachments referenced in a narrative section may be considered during the objective review.

Narrative Section	Review Criteria
Introduction	(1) Need
Needs Assessment	(1) Need
Methodology	(2) Response
Work Plan	(2) Response and (4) Impact
Resolution of Challenges	(2) Response
Evaluation and Technical Support Capacity	(3) Evaluative Measures and (5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities
Budget and Budget Narrative	(6) Support Requested – the budget section should include sufficient justification to allow reviewers to determine the reasonableness of the support requested.

# iii. Budget

See Section 4.1.iv of HRSA's <u>SF-424 Application Guide</u>. Please note: the directions offered in the SF-424 Application Guide may differ from those offered by Grants.gov. Follow the instructions included in the Application Guide and the additional budget instructions provided below. A budget that follows the Application Guide will ensure that, if HRSA selects the application for funding, you will have a well-organized plan and by carefully following the approved plan can avoid audit issues during the implementation phase.

**Reminder:** The Total Project or Program Costs are the total allowable costs (inclusive of direct **and** indirect costs) incurred by the recipient to carry out a HRSA-supported project or activity. Total project or program costs include costs charged to the award and costs borne by the recipient to satisfy a matching or cost-sharing requirement, as applicable.

In addition, the QISSEC program requires the following:

- Provide a program-specific line item budget for each year of the five-year period of performance using the object class categories in the SF-424A. List personnel separately by position title and the name of the individual for each position title, or note if position is vacant. The line item budget for each of the five years is uploaded as an attachment to the application as **Attachment 6**. The budget allocations on the line item must relate to the activities proposed in the project narrative, including the work plan. The line item budget requested for each year must not exceed the total funding ceiling amount. In addition, the amounts requested on the SF-424A and the amounts listed on the line item budget must match.
- Indirect costs on grants awarded to foreign organizations and performed outside of the territorial limits of the United States may be paid to support the costs of compliance with federal requirements at a fixed rate of eight (8) percent of modified total direct costs exclusive of tuition and related fees, direct expenditures for equipment, and sub-awards and contracts under the grant in excess of \$25,000.
- Allocation of multiple indirect cost rates: For institutions of higher education and nonprofits that have indirect costs benefitting major programs disproportionately, indirect rates will vary.

The Consolidated Appropriations Act, 2021 (P.L. 116-260), Division H, § 202 Salary Limitation does **not** apply to this program.

# iv. Budget Narrative

See Section 4.1.v. of HRSA's SF-424 Application Guide.

#### v. Attachments

Provide the following items in the order specified below to complete the content of the application. **Unless otherwise noted, attachments count toward the application page limit.** Indirect cost rate agreements and proof of non-profit status (if applicable) will not count toward the page limit. You must clearly label **each attachment**.

Attachment 1: Work Plan, required

Attach the work plan for the project that includes all information detailed in <u>Section IV.2.ii. Project Narrative</u>. If you will make subawards or expend funds on contracts, describe how your organization will ensure proper documentation of funds.

Attachment 2: Staffing Plan and Job Descriptions for Key Personnel (see Section

1.1. of HRSA's SF-424 Application Guide), required

Keep each job description to one page in length as much as is possible. Include the role, responsibilities, and qualifications of proposed project staff. Also, please include a description of your organization's timekeeping process to ensure that you will comply with the federal standards related to documenting personnel costs.

#### Attachment 3: Biographical Sketches of Key Personnel, required

Include biographical sketches for persons occupying the key positions described in Attachment 2, not to exceed one page in length per person. In the event that a biographical sketch is included for an identified individual you have not yet hired, please include a letter of commitment from that person with the biographical sketch.

Attachment 4: Letters of Support, Letters of Agreement, Memorandum of Understanding, and/or Description(s) of Proposed/Existing Contracts, required

Provide any documents that describe working relationships between your organization and other entities and programs cited in the proposal. Documents that confirm actual or pending contractual or other agreements should clearly describe the roles of the contractors and any deliverable. Letters of support must be dated and specifically indicate a commitment to the project/program (in-kind services, dollars, staff, space, equipment, etc.).

#### Attachment 5: Project Organizational Chart

Provide a one-page figure that depicts the organizational structure of the project.

#### Attachment 6: For Multi-Year Budgets

You must provide a program-specific line item budget for each year of the five-year period of performance using the object class categories in the SF-424A. Personnel must be listed separately by position title and the name of the individual for each position title, or note if position is vacant. In addition, after using columns (1) through (4) of the SF-424A Section B for the first 4 years of the project period, for year 5, include a copy of Section B of the SF-424A as a part of this attachment.

#### Attachment 7: Indirect Cost Rate Allocation Agreement or Plan, if applicable

If you are requesting indirect costs, attach current HHS Negotiated Indirect Cost Rate Agreement.

# Attachment 8: Global Health Federal Grants and/or Cooperative Agreements, required

Provide a table that lists the qualifying global health grants, cooperative agreements, and/or contracts, source of funding; name of project director/principal investigator; institution holding the award; grant, cooperative agreement, or contract number; total amount of award; and end date. The table may include all collaborating institutions listed in this application to meet the requirement.

#### Attachment 9: Past Performance References, required

You must provide up to three past performance references (required). Consortium partners may provide up to three past performance references from the last three years for contracts, grants and/or cooperative agreements of similar size, scope, and complexity (optional).

#### Attachment 10: Evaluation Tools (optional)

Include in this attachment any evaluation tools that you have developed and plan to use for this project.

# Attachments 11-15: Other Relevant Documents (as applicable)

Include here any other documents that are relevant to the application, including additional letters of support. Letters of support must be dated and specifically indicate a commitment to the project/program (in-kind services, dollars, staff, space, equipment, etc.).

# 3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management

You must obtain a valid DUNS number, also known as the Unique Entity Identifier (UEI), and provide that number in the application. In April 2022, the \*DUNS number will be replaced by the UEI, a "new, non-proprietary identifier" requested in, and assigned by, the System for Award Management (SAM.gov). For more details, visit the following pages: Planned UEI Updates in Grant Application Forms and General Service Administration's UEI Update.

You must also register with SAM and continue to maintain active SAM registration with current information at all times during which you have an active federal award or an application or plan under consideration by an agency (unless the applicant is an individual or federal agency that is exempted from those requirements under 2 CFR § 25.110(b) or (c), or has an exception approved by the agency under 2 CFR § 25.110(d)).

If you are chosen as a recipient, HRSA would not make an award until you have complied with all applicable DUNS (or UEI) and SAM requirements and, if you have not fully complied with the requirements by the time HRSA is ready to make an award, you may be deemed not qualified to receive an award and use that determination as the basis for making an award to another applicant.

If you have already completed Grants.gov registration for HRSA or another federal agency, confirm that the registration is still active and that the Authorized Organization Representative (AOR) has been approved.

\*Currently, the Grants.gov registration process requires information in three separate systems:

- Dun and Bradstreet (<a href="http://www.dnb.com/duns-number.html">http://www.dnb.com/duns-number.html</a>)
- System for Award Management (SAM) (https://www.sam.gov)
- Grants.gov (http://www.grants.gov/)

For further details, see Section 3.1 of HRSA's SF-424 Application Guide.

<u>SAM.GOV</u> ALERT: For your SAM.gov registration, you must submit a <u>notarized letter</u> appointing the authorized Entity Administrator. The review process changed for the Federal Assistance community on June 11, 2018.

In accordance with the Federal Government's efforts to reduce reporting burden for recipients of federal financial assistance, the general certification and representation requirements contained in the Standard Form 424B (SF-424B) – Assurances – Non-Construction Programs, and the Standard Form 424D (SF-424D) – Assurances – Construction Programs, have been standardized federal-wide. Effective January 1, 2020, the forms themselves are no longer part of HRSA's application packages and the updated common certification and representation requirements will be stored and maintained within SAM. Organizations or individuals applying for federal financial assistance as of January 1, 2020, must validate the federally required common certifications and representations annually through SAM located at SAM.gov.

If you fail to allow ample time to complete registration with SAM or Grants.gov, you will not be eligible for a deadline extension or waiver of the electronic submission requirement.

#### 4. Submission Dates and Times

#### **Application Due Date**

The due date for applications under this NOFO is May 7, 2021 at 11:59 p.m. ET. HRSA suggests submitting applications to Grants.gov at least **3 calendar days before the deadline** to allow for any unforeseen circumstances. See Section 8.2.5 – Summary of emails from Grants.gov of HRSA's SF-424 Application Guide for additional information.

#### 5. Intergovernmental Review

QISSEC is not a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

See Section 4.1 ii of HRSA's SF-424 Application Guide for additional information.

#### 6. Funding Restrictions

You may request funding for a period of performance of up to five (5) years, at no more than \$20,000,000 per year (inclusive of direct **and** indirect costs). This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds in a timely manner. Awards to support projects beyond the first budget

year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

The General Provisions in Division H of the Consolidated Appropriations Act, 2021 (P.L. 116-260) do **not** apply to this program.

You cannot use funds under this notice for the following purposes:

- Research
- Construction
- Travel, per diem, hotel expenses, meals, conference fees, or other conference costs for any member of a foreign government's delegation to an international conference sponsored by a multilateral organization, as defined below, unless approved by HRSA in writing.

In addition, please note the following:

- Consistent with numerous United Nations Security Council resolutions, including UNSCR 1267 (1999), UNSCR 1368 (2001), UNSCR 1373 (2001), UNSCR 1989 (2011), and UNSCR 2253 (2015) (<a href="https://www.un.org/sc/suborg/en/sanctions/unsc-consolidated-list">https://www.un.org/sc/suborg/en/sanctions/unsc-consolidated-list</a>), both HRSA and the recipient are firmly committed to the international fight against terrorism, and in particular, against the financing of terrorism. Funds may not be 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 HRSA funds provided under this award are used to provide support to individuals or entities associated with terrorism, including those identified on the United States Department of Treasury Office of Foreign Assets Control Specially Designated Nationals List (<a href="https://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx">https://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx</a>). This provision must be included in all subagreements, including contracts and subawards, issued under this award.
- 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 HRSA.
- Funds may not be used, directly or indirectly, to provide support to individuals or entities
  designated for United Nations Security Council sanctions. In accordance with the policy, the
  recipient agrees to use reasonable efforts to ensure that none of the funds provided under
  this award are used to provide support ofindividuals or entities designated for UN Security
  Council Sanctions (compendium of Security Council Targeted Sanctions Lists at:
  <a href="https://www.un.org/sc/suborg/en/sanctions/un-sc-consolidated-list">https://www.un.org/sc/suborg/en/sanctions/un-sc-consolidated-list</a>). This provision must be included
  in all subagreements, including contracts and subawards, issued under this award.
- No funds or other support provided hereunder may be used for any activity that contributes to the violation of internationally recognized worker rights 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 HRSA as to whether the activity would be consistent with the limitation set forth above, the recipient must notify HRSA and provide a detailed description of the proposed activity. The recipient must not proceed with the activity until advised by HRSA that it may do so. The recipient must ensure that all employees and subcontractors and subrecipients providing employment- related services hereunder are made aware of the restrictions set forth in this clause and must include this clause in all subcontracts and other sub- agreements entered into hereunder. The term "internationally recognized worker rights" includes the right of association; the right to organize and bargain collectively; a prohibition on the use of any form of forced or compulsory labor; a minimum age for the employment of children, and a prohibition on the worst forms of child labor; and acceptable conditions of work with respect to minimum wages, hours of work, and occupational safety and health. The term "worst forms of child labor" means all forms of slavery or practices similar to slavery, such as the sale or trafficking of children, debt bondage and 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 laws and regulations.

HRSA reserves the right to terminate this award or take other appropriate measures if the recipient or a key individual of the recipient is found to have been convicted of a narcotics offense or to have been engaged in drug trafficking as defined in 22 CFR Part 140.

- The Applicant agrees not to disburse, or sign documents committing the Applicant to disburse funds to a subrecipient designated by HRSA until advised by HRSA that: 1) any United States Government review of the subrecipient and its key individuals has been completed; 2) any related certifications have been obtained; and 3) the assistance to the subrecipient has been approved.
- The Applicant shall insert the following clause, or its substance, in its agreement with its subrecipient: The Applicant reserves the right to terminate this Agreement or take other appropriate measures if the [subrecipient] or a key individual of the [subrecipient] 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.
- An organization, including a faith-based organization, that is otherwise eligible to receive funds under this award for HIV/AIDS prevention, treatment, or care—
  - 1) Shall not be required, as a condition of receiving such assistance
    - (a) To endorse or utilize a multi-sectoral or comprehensive approach to combating HIV/AIDS; or
    - (b) 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 in paragraph (a) above.
- 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.
- 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.
- 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 HRSA as to whether the activity would be consistent with the limitation set forth above, the recipient must notify HRSA and provide a detailed description of the proposed activity. The recipient must not proceed with the activity until advised by HRSA that it may do so.
  - The recipient must ensure that its employees and subcontractors and subrecipients providing investment promotion services hereunder are made aware of the restrictions set forth in this clause and must include this clause in all subcontracts and other sub-agreements entered into hereunder.
- No funds made available under this award may be used for needle exchange programs.
- Trafficking in Persons Provision:
  - No recipient or subrecipient under this Agreement that is a private entity may, during the period of time that the award is in effect:
    - Engage in trafficking in persons, as defined in the Protocol to Prevent, Suppress, and Punish Trafficking in Persons, especially Women and Children, supplementing the UN Convention against Transnational Organized Crime;
    - Procure any sex act on account of which anything of value is given to or received by any person; or
    - Use forced labor in the performance of this award.
  - o If HRSA determines that there is a reasonable basis to believe that any private party recipient or subrecipient has violated the above or that an employee of the recipient or subrecipient has violated such a prohibition where the employee's conduct is associated with the performance of the award or may be imputed to the recipient or subrecipient, HRSA may, without penalty, 1) require the recipient to terminate immediately the contract or subaward in question or 2) 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 recipient or subrecipient.
  - The Applicant must include in all subagreements, including subawards and contracts, a provision prohibiting the conduct described above by private party subrecipients, contractors, or any of their employees.

You are required to have the necessary policies, procedures, and financial controls in place to ensure that your organization complies with all legal requirements and restrictions applicable to the receipt of federal funding including statutory restrictions on use of funds for lobbying, executive salaries, gun control, abortion, etc. Like those for all other applicable grants requirements, the effectiveness of these policies, procedures, and controls is subject to audit.

All program income generated as a result of awarded funds must be used for approved project-related activities. The program income alternative applied to the award(s) under the program will be the addition/additive alternative. You can find post-award requirements for program income at 45 CFR § 75.307.

# V. Application ReviewInformation

#### 1. Review Criteria

HRSA has procedures for assessing the technical merit of applications to provide for an objective review and to assist you in understanding the standards against which your application will be reviewed. HRSA has critical indicators for each review criterion to assist you in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation.

These criteria are the basis upon which the reviewers will evaluate and score the merit of the application. The entire proposal will be considered during objective review.

Review criteria are used to review and rank applications. The QISSEC program has six (6) review criteria. See the review criteria outlined below with specific detail and scoring points.

Criterion 1: NEED (10 points) – Corresponds to Section IV's Introduction and <u>Needs</u>
Assessment sections of the Narrative.

The extent to which the applicant demonstrates an understanding of the problem and associated factors contributing to the problem.

- The extent to which the application describes the problem and associated contributing factors to the problem.
- The extent to which the applicant demonstrates understanding of the HIV epidemic service delivery gaps and related quality improvement programs appropriate to respond to the needs.
- Strength and clarity of the applicant's ability to conduct a feasible and timely needs assessment for the identified PEPFAR-supported LMICs. The extent to which the planned assessment is clear, efficient and well organized, supplementing existing solutions, and necessary for project implementation. The quality of the described methodology to assess and address country and facility needs.

- The extent to which the applicant describes a specific plan that includes a
  rationale and expected results of the improvement activity, documents the
  activities that will be carried out by process improvement teams to develop and
  test changes, and provides a strategy for the sustainability of improved work
  processes, institutionalization of QI, and for the spread/scaling up of any
  improved practices.
- The extent to which the application describes flexible and feasible responses to challenges likely to be encountered in project implementation.

Criterion 2: RESPONSE (30 points) – Corresponds to Section IV's <u>Methodology</u>, <u>Work Plan</u>, and <u>Resolution of Challenges</u>.

The extent to which the proposed project responds to the "Purpose" included in the program description. The strength of the proposed goals and objectives and their relationship to the identified project. The extent to which the activities (scientific or other) described in the application are capable of addressing the problem and attaining the project objectives.

#### Methodology (15 points)

- The extent to which the application provides an overall strategy that is clearly related to the program objectives, goals, and expectations as outlined in the NOFO.
- The extent to which the application clearly articulates a comprehensive plan with specific, measurable, realistic, and achievable outcomes on how project objectives will be achieved. The extent to which the application describes the process of quality improvement through a virtual platform and dissemination of technical assistance to additional communities, districts, and stakeholders throughout the host country.
- The extent to which the application describes scale-up, dissemination, and spread of activities that include strengthening previous and/or existing efforts by the host country government, USG, or other stakeholders.
- The extent to which the application proposes a plan for promoting sustainability through the development of an appropriate plan to transition QI decision-making and interventions to indigenous country stakeholders.

#### Work Plan (10 points)

- The extent to which the application provides a detailed first year work plan that demonstrates the ability to reach stated program objectives within the required time of performance.
- The extent to which the application highlights activities focused at the facility level and targeted towards retention in HIV care and treatment and achievement of viral suppression.

 The extent to which the application describes how the proposed goals, objectives, and outcomes will be achieved through a SMART plan (specific, measureable, achievable, realistic, and time-measured).

#### Resolution of Challenges (5 points)

The extent to which the application describes the challenges likely to be encountered in designing and implementing the activities outlined in the needs assessment and work plan sections of the narrative.

- The extent to which the application describes activities/approaches/methodologies for identifying, addressing, and resolving challenges.
- The extent to which the application describes the effectiveness of implementing proposed methodologies in past projects.
- The extent to which the applicant describes their ability to resolve effectively the challenges in similar work plans.

# Criterion 3: EVALUATIVE MEASURES (15 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity

The extent to which the application describes the method proposed to monitor and evaluate the project results. Evidence that the evaluative measures will be able to assess: 1) to what extent the program objectives have been met, and 2) to what extent these can be attributed to the project.

- The extent to which the application describes the proposed methods to monitor and evaluate the progress of the funded project and present results of the evidence-informed interventions.
- Strength and clarity of the applicant's ability to incorporate baseline and performance measures that demonstrate progress towards identified goals and align with country-specific PEPFAR goals.
- The extent to which the applicant demonstrates a proposed strategy to collect, analyze, and track data to measure process and impact (quantitative and qualitative)/outcomes, and describes a plan indicating how data will be used to inform project development and implementation.
- The extent to which the applicant demonstrates the in-country experience and capability to implement performance monitoring and evaluation of the project.
- The extent to which the application describes how the performance plan will link with expenditure reporting.
- The extent to which the application clearly articulates the role of key program partners in the evaluation and performance measurement planning processes.

Criterion 4: IMPACT (10 points) – Corresponds to Section IV's <u>Work Plan</u> and Section IV's <u>Evaluation and Technical Support Capacity</u>.

The extent to which the proposed project has a public health impact and the project will be effective, if funded. This may include: the effectiveness of plans for dissemination of project results, the impact (quantitative and qualitative) results may have on the community or target population, the extent to which project results may be scaled up in scope, the degree to which the project activities are replicable, and the sustainability of the program beyond the federal funding.

- The extent to which the application describes the feasibility and effectiveness of plans for dissemination of project results.
- The extent to which the application demonstrates how the project activities are replicable and sustainable after the project period ends, and the extent of the proposed sustainability plan.
- The extent to which the applicant articulates likely challenges to be encountered in sustaining the program, and the extent and feasibility of the proposed approaches to resolving such challenges.

Criterion 5: RESOURCES/CAPABILITIES (25 points) – Corresponds to Section IV's <u>Evaluation and Technical Support Capacity</u>, <u>Organizational Information</u>, <u>Budget</u> and <u>Budget Justification Narrative</u>, and **Attachments 5-8**.

The extent to which project personnel are qualified by training and/or experience to implement and carry out the project. The capabilities of the applicant organization and the quality and availability of facilities and personnel to fulfill the needs and requirements of the proposed project.

Organizational Experience and Project Organization Chart (10 points)

- The extent to which the applicant demonstrates the capability of the organization and its commitment to fulfilling the terms of the cooperative agreement.
- The extent to which the application describes the experience, skills, and knowledge of the organization to implement the evaluation activities reflective of the project activities, including individuals on staff, materials published, and previous work of a similar nature.
- The extent to which the application describes how the proposed staffing plan (Attachment 2) and project organizational chart (Attachment 5) are sufficiently organized to meet the needs of the proposed activities; including evidence that the staffing plan includes adequate personnel with allocated time and effort to successfully implement all of the project activities. The extent to which the application describes current organizational structure, proposed staff, consortium partners, and scope of current activities that contribute to the applicant's ability to conduct the proposed program and meet the QISSEC expectations and requirements.

#### Management and Staffing Plan (5 points)

- The extent to which the application describes the qualifications of the identified Project Director (by training and experience) to support their ability to lead a project of similar size and scope; the extent to which competence is appropriately demonstrated (e.g., publications, funded research) in the specialty with appropriate academic preparation, clinical expertise, and experience as an educator.
- The extent to which the application describes **key project personnel**, qualified by training and/or experience to implement the project.

# Administrative and Fiscal Oversight (5 points)

- Strength and clarity of the plan that outlines the roles, responsibilities, and functions of the applicant and each consortium partner, including how each partner contributes to the ability of the consortium to conduct the project requirements and meet project expectations.
- The extent to which the application proposes processes for providing oversight and technical assistance for subrecipient and contractor services.
- The extent to which the applicant demonstrates the capacity to fiscally manage a USG-funded program, including the capacity to develop a standardized method to manage, execute in a timely manner, and monitor contracts and subcontracts.

# Key Collaborations (5 points)

- The extent to which the applicant demonstrates a strong capacity to successfully build, manage, leverage, and engage in various types of partnerships.
- The extent to which the application demonstrates the organization's ability to collaborate with HRSA, in-country USG, and other key stakeholders.
- The extent to which the applicant provides Letters of Agreement and MOUs (Attachment 4) to demonstrate sufficient and necessary support for the proposed project.
- The extent to which the application describes past performance and references to demonstrate the organizations' capacity to successfully carry out the proposed program.

Criterion 6: SUPPORT REQUESTED (10 points) – Corresponds to Section IV's <u>Budget</u> and <u>Budget Narrative</u>.

The reasonableness of the proposed budget for each year of the period of performance in relation to the objectives, and the anticipated results.

- The extent to which the proposed budget demonstrates reasonableness for each year of the period of performance in relation to the objectives, the complexity of the activities, and the anticipated results.
- The extent to which the proposed budget and budget narrative demonstrate the applicant's costs in relation to executing the work plan.

The extent to which the applicant's narrative describes and justifies each line item in relation to the goals and objectives of the program; and comparability across budget documents.

#### 2. Review and Selection Process

The objective review process provides an objective evaluation to the individuals responsible for making award decisions. The highest ranked applications receive consideration for award within available funding ranges. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below. See Section 5.3 of HRSA's SF-424 Application Guide for more details.

#### 3. Assessment of Risk and other Pre-Award Activities

HRSA may elect not to fund applicants with management or financial instability that directly relates to the organization's ability to implement statutory, regulatory or other requirements (45 CFR § 75.205).

HRSA reviews applications receiving a favorable objective review for other considerations that include past performance, as applicable, cost analysis of the project/program budget, assessment of your management systems, ensuring continued applicant eligibility, and compliance with any public policy requirements, including those requiring just-in-time submissions. HRSA may ask you to submit additional programmatic or administrative information (such as an updated budget or "other support" information) or to undertake certain activities (such as negotiation of an indirect cost rate) in anticipation of an award. However, even at this point in the process, such requests do not guarantee that HRSA will make an award. Following review of all applicable information, HRSA's approving and business management officials will determine whether HRSA can make an award, if special conditions are required, and what level of funding is appropriate.

Award decisions are discretionary and are not subject to appeal to any HRSA or HHS official or board.

Effective January 1, 2016, HRSA is required to review and consider any information about your organization that is in the Federal Awardee Performance and Integrity Information System (FAPIIS). You may review and comment on any information about your organization that a federal awarding agency previously entered. HRSA will consider any of your comments, in addition to other information in FAPIIS in making a judgment about your organization's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed as described in 45 CFR § 75.205 HHS Awarding Agency Review of Risk Posed by Applicants.

HRSA will report to FAPIIS a determination that an applicant is not qualified (45 CFR § 75.212).

#### VI. Award Administration Information

#### 1. Award Notices

HRSA will issue the Notice of Award (NOA) prior to the start date of September 30, 2021. See Section 5.4 of HRSA's *SF-424 Application Guide* for additional information.

## 2. Administrative and National Policy Requirements

See Section 2.1 of HRSA's SF-424 Application Guide.

#### Requirements of Subawards

The terms and conditions in the NOA apply directly to the recipient of HRSA funds. The recipient is accountable for the performance of the project, program, or activity; the appropriate expenditure of funds under the award by all parties; and all other obligations of the recipient, as cited in the NOA. In general, the requirements that apply to the recipient, including public policy requirements, also apply to subrecipients under awards. See 45 CFR § 75.101 Applicability for more details.

#### **Data Rights**

All publications developed or purchased with funds awarded under this notice must be consistent with the requirements of the program. Pursuant to 45 CFR § 75.322(b), the recipient owns the copyright for materials that it develops under an award issued pursuant to this notice, and HHS reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use those materials for federal purposes, and to authorize others to do so. In addition, pursuant to 45 CFR § 75.322(d), the Federal Government has the right to obtain, reproduce, publish, or otherwise use data produced under this award and has the right to authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes, e.g., to make it available in government-sponsored databases for use by others. If applicable, the specific scope of HRSA rights with respect to a particular federally supported effort will be addressed in the NOA. Data and copyright-protected works developed by a subrecipient also are subject to the Federal Government's data rights.

#### **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-United States 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.

NOTE: Any enforcement of this provision is subject to courts' orders in Alliance for Open Society International v. USAID (See, e.g., S.D.N.Y. 05 Civ. 8209, Orders filed on January 30, 2015 and June 6, 2017, granting permanent injunction).

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. You can find PEPFAR branding guidance at <a href="http://www.pepfar.gov/reports/guidance/branding/index.htm">http://www.pepfar.gov/reports/guidance/branding/index.htm</a>.

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.

#### 3. Reporting

Award recipients must comply with Section 6 of HRSA's <u>SF-424 Application Guide</u> and the following reporting and review activities:

- 1) **Progress Report**(s). The recipient must submit a progress report to HRSA on an **annual** basis. Further information will be available in the NOA.
- 2) **Integrity and Performance Reporting.** The NOA will contain a provision for integrity and performance reporting in <u>FAPIIS</u>, as required in <u>45 CFR</u> part 75 Appendix XII.
- 3) Non-Competing Continuation Progress Report
  - a. Annual Work Plan
  - b. Budget Documents

# 4) Semi-Annual Progress Reports

The report shall describe progress made during the reporting period and assess overall progress to that date. The reports shall also describe the accomplishments of the recipient and the progress made during the past reporting period and shall include information on all activities, both ongoing and completed during that reporting period. The progress reports shall highlight any issues or problems that are affecting the delivery or timing of services provided by the recipient. The reports will include financial information on the expense incurred, available funding for the remainder of the activity, and any variances from planned expenditures.

#### 5) **PEPFAR Performance Reports**

The recipient will be required to prepare and submit performance reports that reflect detailed data on achievements and targets as identified by PEPFAR guidance. See PEPFAR below.

#### 6) Monitoring and Evaluation Plan

The M&E plan should be developed and submitted as a prior approval as outlined in the notice of award to include the data collection plan which discusses the data flow, collection tools, baseline data collection, and data quality assessments; discussion of the monitoring plan which includes how progress to targets will be measured, a trends analysis, work plan review, periodic stakeholder meetings, and evaluation plan; and data dissemination which includes a discussion about the donor reports, stakeholder meetings, international meetings, networking, and research publications. In those instances when the recipient works to enhance health care workers skills, the M&E plan should include methods for measuring improvement of skills.

#### 7) Quarterly PEPFAR Obligation and Outlays Reports

The recipient will submit to HRSA a quarterly financial report within 20 days after the end of the USG's first fiscal year quarter, and quarterly thereafter. The recipient must provide the quarterly financial reports in summary and by cost category and contain at a minimum:

- Total funds awarded to date by HRSA;
- Total funds previously reported as expended by recipient by the main line items:
- Total funds expended in the current quarter by the recipient by the main line items;
- Total un-liquidated obligations by main line items; and
- Unobligated balance of HRSA funds.

# 8) PEPFAR Reporting Requirements

Progress towards achieving the anticipated results must be tracked by outcomes and outputs. Progress towards targets should be disaggregated by year, country, and other factors as outlined in the applicant's Monitoring and Evaluation Plan. PEPFAR reporting requirements include MER, SIMS, quarterly and annual reports.

#### 9) PEPFAR Monitoring, Evaluation, and Reporting (MER):

- The recipient's Evaluation and Performance Measurement Plan must align with the strategic information guidance established by the Office of the U.S. Global AIDS Coordinator (OGAC) and other HRSA requirements, including PEPFAR's MER strategy (<a href="https://www.state.gov/wp-content/uploads/2019/10/PEPFAR-MER-Indicator-Reference-Guide-Version-2.4-FY20.pdf">https://www.state.gov/wp-content/uploads/2019/10/PEPFAR-MER-Indicator-Reference-Guide-Version-2.4-FY20.pdf</a>).
- Quarterly MER data is submitted by recipient into DATIM

## 10) Site Improvement through Monitoring System (SIMS):

• SIMS is a PEPFAR site visit performed by the U.S. Government to increase accountability and monitoring. HRSA or its designee will undertake monitoring and evaluation of the defined activities within the agreement. The recipient must ensure reasonable access by HRSA or its designee to all necessary sites, documentation, individuals and information to monitor, evaluate and verify the appropriate implementation of activities and use of HRSA funding under this cooperative agreement, and must require a provision to this effect in all subawards or contracts financed by funds under this award.

Please note that the OMB revisions to Guidance for Grants and Agreements termination provisions located at <u>2 CFR § 200.340 - Termination</u> apply to all federal awards effective August 13, 2020.

# VII. Agency Contacts

You may request additional information and/or technical assistance regarding business, administrative, or fiscal issues related to this NOFO by contacting:

Sola Dada
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10SWH03
Rockville, MD 20857

Telephone: (301) 443-0195 Email: ODada@hrsa.gov

You may request additional information regarding the overall program issues and/or technical assistance related to this NOFO by contacting:

Tracey Gantt, MSN, RN, PHNA-BC, Nurse Consultant

Attn: HRSA/OGH/OA

5600 Fishers Lane, Room 9N-35

Rockville, MD 20857 Telephone: (301) 443-1219

Email: tgantt@hrsa.gov

You may need assistance when working online to submit your application forms electronically. Always obtain a case number when calling for support. For assistance

with submitting the application in Grants.gov, contact Grants.gov 24 hours a day, 7 days a week, excluding federal holidays at:

Grants.gov Contact Center

Telephone: 1-800-518-4726 (International Callers, please dial 606-545-5035)

Email: <a href="mailto:support@grants.gov">support@grants.gov</a>

Self-Service Knowledge Base: <a href="https://grants-portal.psc.gov/Welcome.aspx?pt=Grants">https://grants-portal.psc.gov/Welcome.aspx?pt=Grants</a>

Successful applicants/recipients may need assistance when working online to submit information and reports electronically through HRSA's Electronic Handbooks (EHBs). For assistance with submitting information in HRSA's EHBs, contact the HRSA Contact Center, Monday–Friday, 8 a.m. to 8 p.m. ET, excluding federal holidays at:

HRSA Contact Center Telephone: (877) 464-4772

TTY: (877) 897-9910

Web: http://www.hrsa.gov/about/contact/ehbhelp.aspx

#### VIII. Other Information

#### **Technical Assistance**

HRSA has scheduled the following technical assistance: Webinar

Date: March 19, 2021

Time: 1:00 PM - 2:30 PM EST

Adobe Connect URL Weblink: https://hrsa.connectsolutions.com/nofo\_pre-application/

Call-In Number: Dial-in: Conference Call 888-730-9136 for all callers (U.S. and international)

Participant passcode 5686097 (U.S. and international)

The webinar will be recorded and should be available for viewing by March 31, 2021. The location of the recording and frequently asked questions (FAQ's) will be discussed during the webinar.

#### Tips for Writing a Strong Application

See Section 4.7 of HRSA's SF-424 Application Guide.