Issue Date: January 17, 2025

Deadline for Questions: January 31, 2025

Closing Date and Time for CONCEPT NOTE: February 28, 2025, 5:00PM Eastern Standard Time (i.e., local time in Washington, D.C.)

Closing Date and Time for FULL APPLICATION: To be determined

Subject: Notice of Funding Opportunity Number (NOFO), Number: 7200AA25RFA00003

Program Title: Harmonization of systems and services to embed HIV service delivery into primary health care (HARMONIZE)

Federal Assistance Listing Number: 98.001

Greetings,

The United States Agency for International Development (USAID) is seeking applications for a cooperative agreement from qualified entities to implement the Harmonization of systems and services to embed HIV service delivery into primary health care (HARMONIZE) programs. Eligibility for this award is not restricted.

USAID intends to make an award to the applicant(s) who best meets the objectives of this funding opportunity based on the merit review criteria described in this NOFO, subject to a risk assessment. Eligible parties interested in submitting an application are encouraged to read this NOFO thoroughly to understand the type of program sought, application submission requirements, and selection process.

To be eligible for award, the applicant must provide all information as required in this NOFO and meet eligibility standards in Section B of this NOFO. This funding opportunity is posted on www.grants.gov and may be amended. It is the responsibility of the applicant to regularly check the website to ensure they have the latest information pertaining to this NOFO and to ensure that it has been downloaded from the internet in its entirety. USAID bears no responsibility for data errors resulting from transmission or conversion processes. If you have difficulty registering on www.grants.gov or accessing the NOFO, please contact the Grants.gov Support Center by phone at 1-800-518-4726 or by email at support@grants.gov for technical assistance or if you need assistive technology and are unable to access any material on this site.

Unless an exception in 2 CFR 25.110 applies, applicants must comply with 2 CFR 25 requirements to obtain a Unique Entity Identifier (UEI) and register in the System for Award Management (SAM.gov), as applicable. See Section E, Submission Requirements and Deadlines, for more information. The registration process may take many weeks to complete. Therefore, applicants are encouraged to begin registration early.

Please send any questions to the point(s) of contact identified in Section A.4. The deadline for questions is shown above. Responses to questions received prior to the deadline will be available to all potential applicants through an amendment to this notice posted to www.grants.gov.

Issuance of this NOFO does not constitute an award commitment on the part of the Government nor does it commit the Government to pay for any costs incurred in preparation or submission of comments/suggestions or an application. Applications are submitted at the risk of the applicant. All preparation and submission costs are at the applicant's expense.

Thank you for your interest in USAID programs.

Sincerely,

/s/

Elton E. Fortson

Agreement Officer

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SECTION A: BASIC INFORMATION

1. Executive Summary

At the beginning of the President's Emergency Plan for AIDS Relief (PEPFAR) HIV response, an intensive vertical approach to HIV care and treatment was necessary to help countries rapidly scale up services and curb the exploding epidemic. Siloed services are disease-centered (rather than person-centered, which support more comprehensive health needs across a continuum), increase opportunity costs for clients, and present additional challenges for partner countries in financing and managing a health system that meets all health needs for its population. For partner countries to sustain these services, it is necessary to embed them into existing health systems, particularly at the level of primary health care (PHC). This can also result in more tremendous success in closing gaps in 95-95-95 targets and ending AIDS.

Furthermore, the COVID-19 pandemic demonstrated the fragility of countries' health systems and health workforce with the disruption of key HIV treatment and prevention services. It is essential to strengthen the systems needed to prevent and mitigate the increasing occurrence and severity of health threats from emerging infectious disease outbreaks, climate change, or political instability. PEPFAR investments in health systems have contributed to global health security by strengthening the health workforce, laboratory systems, supply chain, infection prevention and control, risk communication, and community engagement. Expanding the reach of HIV health services and systems investments can support the prevention, detection, and response to other health threats.

2. Estimate of Funds Available and Number of Awards Contemplated

USAID intends to award 7200AA25RFA00003 pursuant to this NOFO.

Subject to the availability of funding and at the discretion of the Agency, USAID intends to provide $3 million of seed funding for each year of implementation of this activity. Field support buy-in is anticipated every year for five years for a total of $780 million.

3. Start Date and Period of Performance for Federal Awards

The anticipated period of performance is five years. The estimated start date will be upon signature of the Award and is anticipated to be July 17, 2025.

4. Agency Points of Contact

Name: Elton Fortson
Title: Agreement Officer
Email: nofo_harmonize@usaid.gov

Name: Roxane Wiser
Title: Agreement Specialist
Email: nofo_harmonize@usaid.gov

5. Acquisition and Assistance Ombudsman

The A&A Ombudsman helps ensure equitable treatment of all parties who participate in USAID's acquisition and assistance process. The A&A Ombudsman serves as a resource for all organizations who are doing or wish to do business with USAID. Please visit this page for additional information: https://www.usaid.gov/work-usaid/acquisition-assistance-ombudsman.

The A&A Ombudsman may be contacted via: Ombudsman@usaid.gov

6. Authorized Geographic Code

The geographic code for the procurement of commodities and services under this program is 935, which authorizes grantees to purchase goods and services from any country except prohibited source countries. Except as may be specifically approved in advance by the Agreement Officer, all commodities and services that will be reimbursed by USAID under this award must be from the authorized geographic code specified in this NOFO, and must meet the source and nationality requirements set forth in 22 CFR 228.

SECTION B: ELIGIBILITY

1. Eligible Applicants

Eligibility for this NOFO is not restricted and all potential applicants are eligible. USAID intends to award one cooperative agreement to the applicant(s) who best meets the objectives of this funding opportunity based on the merit review criteria described in this document, subject to a risk assessment. The applicant must meet eligibility standards in Section C of this NOFO. Instructions for responding to this NOFO are included in Section D and E. This NOFO is posted on www.grants.gov and may be amended. Eligible parties interested in submitting an application are encouraged to read this document thoroughly to understand the type of program sought, application submission requirements, and selection process.

USAID welcomes applications from organizations that have not previously received financial assistance from USAID. USAID welcomes applications from local organizations and/or consortiums that include local organizations. USAID defines a "local entity" as an individual, a corporation, a nonprofit organization, or another body of persons that:

1. Is legally organized under the laws of; and
2. Has as its principal place of business or operations in; and
3. Is
    a. majority owned by individuals who are citizens or lawful permanent residents of; and
    b. managed by a governing body the majority of who are citizens or lawful permanent residents of a country receiving assistance.

For purposes of this definition, "majority owned" and "managed by" include, without limitation, beneficiary interests, and the power, either directly or indirectly, whether exercised or exercisable, to control the election, appointment, or tenure of the organization's managers or a majority of the organization's managers or a majority of the organization's governing body by any means.

Faith-based organizations are eligible to apply for federal financial assistance on the same basis as any other organization and are subject to the protections and requirements of Federal law.

Interested and eligible applicants may submit no more than **one** application under this NOFO.

If Partners are included in the application, then for the purposes of the technical and cost application for this NOFO, partners should be grouped into two categories:

Principal consortia partners, which have an intended or proposed role across multiple scopes of work. The intended roles of principal consortia partners should be reflected as

appropriate in the technical approach, the management and staffing approaches, and the cost narrative and budget. Signed letters of intent to collaborate shall be provided in a Technical Application Annex for partners in this category. All principal consortia partners included in the cost application will be considered sub-awardees and may be approved at the time of award if they meet all pre-award requirements AND have a budget tab and narrative included in the cost application.

Resource partners, often regional or country-level organizations, which may have a role in one specific context or specific area of work as required, and do not have a proposed budget in the application. Signed letters of intent to collaborate are NOT required for partners in this category and these partners are not approved as sub-awardees at the time of award. However, the technical and management narratives should still describe how these partners will be selected and utilized as required to successfully achieve the program purpose. Formal consortiums should submit official consortium documentation as described in Section D of this NOFO.

2. Cost Sharing

Cost Sharing is <u>not</u> required for this activity. Though there is not a cost share requirement under this NOFO, if the applicant is including voluntary cost share the applicant should include in the Budget and Budget Narrative: 1) an estimate of the amount of cost-sharing 2) the type of resources committed (e.g., funds, in-kind, etc.) 3) the sources of cost share contributions (e.g., third party contributions from non-Federal entity, applicant organization funds, direct procurement, etc.), and 4) the basis of calculation (e.g., detailed explanation of costs). To complete the SF-424A, components of cost share should be broken down into the same major cost categories described above. Applicants must also submit third-party information such as references, letters of support, or letters of commitment to contribute to cost sharing. Please note that if cost share is included in the application, it will not be evaluated because it is not required or specifically encouraged.

SECTION C: PROGRAM DESCRIPTION

This funding opportunity is authorized under the Foreign Assistance Act (FAA) of 1961, as amended. The resulting award will be subject to 2 CFR 200 – Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, and USAID's supplement, 2 CFR 700, as well as the additional requirements found in Section H.

I. Introduction

Over the past 20 years, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) has made tremendous progress in accelerating the HIV response by expanding treatment coverage and closing the gap in life expectancy for people living with HIV (PLHIV). Through the efforts of PEPFAR, 25 million lives have been saved, 20.1 million men, women, and children are on life-saving treatment, and 5.5 million babies have been born HIV-free. Eight countries (Botswana, Burundi, Eswatini, Lesotho, Malawi, Namibia, Rwanda, Zimbabwe) have reached the UNAIDS 95-95-95 goals (95% of all people living with HIV know their HIV status; 95% of all people with diagnosed HIV infection receive sustained antiretroviral therapy (ART); and 95% of all people receiving ART will have viral suppression) as of 2023, and another nine countries (Cameroon, Ethiopia, Haiti, Kenya, Nigeria, Tanzania, Uganda, Vietnam, Zambia) have reached or are close to reaching the 95-95-95 goals. As a result of COVID-19, global HIV progress has slowed; the latest data collected by UNAIDS show that while new HIV infections fell globally from 2020 to 2021, the drop was only 3.6% —a minor annual reduction since 2016.[1] Preventing new infections, reducing mortality, and improving quality of life are critical to sustaining the gains of the HIV response. Renewed efforts to strengthen countries' health systems will also maintain advances in the HIV response and contribute to global health security goals to prevent, detect, and respond to health threats.

At the beginning of PEPFAR's HIV response, an intensive vertical approach to HIV care and treatment was necessary to help countries rapidly scale up services and curb the exploding epidemic. These vertical approaches are now less critical due to the scale-up and institutionalization of "test and treat"; simplified and effective antiretroviral therapy (ART) regimens; multi-month dispensing and other differentiated service delivery modalities; biomedical prevention approaches (e.g. voluntary medical male circumcision (VMMC), pre-exposure prophylaxis (PrEP), PEP, condoms, and lubricants); and other comprehensive structural programs for adolescent girls and young women and orphans and vulnerable children. Siloed services are disease-centered (rather than person-centered, which support more comprehensive health needs across a continuum), increase opportunity costs for clients, and present additional challenges for partner countries in financing and managing a health system that meets all health needs for its population. For partner countries to sustain these services, it is necessary to embed

[1] In Danger: UNAIDS Global AIDS Update 2022. https://www.unaids.org/sites/default/files/media_asset/2022-global-aids-update_en.pdf. Accessed Oct 30, 2023.

them into existing health systems, particularly at the primary health care (PHC) level. This can also result in more tremendous success in closing gaps in 95-95-95 targets and ending AIDS.[2]

PLHIV face health needs that are becoming more prominent, including those related to sexual and reproductive health, mental health, and noncommunicable diseases (NCDs). Aging PLHIV have an increased prevalence of NCDs, and as the aging population has expanded, providing care for NCDs has become critical to prolonging health span and reducing mortality. Delivering HIV services as part of primary health care can provide non-stigmatizing entry opportunities to reach people at risk for HIV infection with prevention and testing services and support linkage to and continuity of treatment. Transforming PHC to enable the management and delivery of HIV services, encourages greater national ownership and more substantial local capacity for service delivery.

Transforming primary health care to deliver comprehensive HIV services will support delivery of "whole person" care across individuals' life stages and optimize resources for cross-cutting systems investments that address systems bottlenecks, including a strengthened health workforce. PHC is often the first point of contact between PLHIV and the health system, helping ensure people have access to quality health services without financial hardship. It also provides education and support to individuals and communities to help improve their health and prevent illness. PHC systems are the first defense against infectious disease outbreaks and other public health threats. Harmonization of health services can, therefore, bolster the capacity to prevent, detect, and respond to HIV and other health threats.

Global health security (GHS) is the presence of developed and resilient public health systems that can prevent, detect, and respond to health threats wherever they occur. Unfortunately, the COVID-19 pandemic demonstrated the fragility of countries' health systems and health workforce with the disruption of key HIV treatment and prevention services. It is essential to strengthen the systems needed to prevent and mitigate the increasing occurrence and severity of health threats from emerging infectious disease outbreaks, climate change, or political instability. PEPFAR investments in health systems have contributed to global health security by strengthening the health workforce, laboratory systems, supply chain, infection prevention and control, risk communication, and community engagement. Expanding the reach of HIV health services and systems investments can support preventing, detecting, and responding to other health threats.

The goal of the HARMONIZE (Harmonization of systems and services to embed HIV service delivery into primary health care) award is to contribute to sustaining the gains in the HIV response, accelerate the response to close remaining gaps, and enable pandemic preparedness and resilience in the face of other health threats by supporting existing country health systems and primary health care programs to manage and provide HIV prevention, care, and treatment services with other health services.

[2] The path that ends AIDS: UNAIDS Global AIDS Update 2023. https://www.unaids.org/sites/default/files/media_asset/2023-unaids-global-aids-update_en.pdf. Access Oct 30, 2023

Three **broad strategic objectives** will help achieve this goal, which focuses on assisting countries to design, adapt, and deliver high-quality, person-centered routine HIV services as part of general health services offered within the health system, including services delivered both within facilities and in communities.

Strategic Objective 1: Support health facilities and community sites to achieve and maintain sustained epidemic control by embedding HIV and other related services into the existing health system while strengthening PHC systems and services.

Strategic Objective 2: Build local system and governance structure capacity necessary for the design, administration, management, and implementation of essential HIV prevention, care, and treatment services delivered as part of primary health care.

Strategic Objective 3: Strengthen the investment in health services, service delivery programs, and health and surveillance systems to rapidly prevent, detect, and respond to emerging new HIV infections to sustain the HIV response and strengthen the prevention, detection, and response for other health threats.

Section 4 describes these three objectives in greater detail, along with related results and illustrative activities and indicators.

II. PEPFAR and USAID Strategic Alignment

A. Program Background: The U.S. President's Emergency Plan for AIDS Relief (PEPFAR)

Working in over 50 countries for the past 20 years, PEPFAR has saved and improved millions of lives, prevented millions of HIV infections, and changed the course of the global HIV/AIDS epidemic. Today, PEPFAR supports more than 20 million men, women, youth, and children with ART and has provided HIV testing services for 85.5 million people. PEPFAR has enabled more than 5.5 million babies to be born HIV-free to HIV+ women and has provided assistance to more than seven million orphans and vulnerable children and their caregivers. PEPFAR funds the clinical cascade of services, which includes finding people at risk for HIV infection, testing them, referring HIV-negative individuals for HIV prevention services, initiating HIV-infected individuals onto ART, and retaining them on treatment so that they will remain virally suppressed. Delivering the clinical cascade of services at scale provides the basis for attaining and maintaining epidemic control. Epidemic control is the point at which new HIV infections have decreased and fall below the number of all-cause deaths among PLHIV.

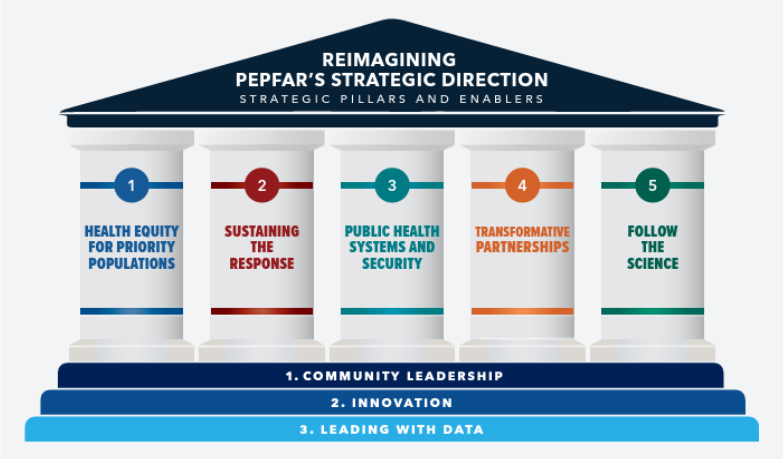
PEPFAR supports partner countries' efforts to achieve epidemic control while also promoting the long-term sustainability of partner countries' HIV/AIDS responses as they assume greater responsibility for controlling the HIV/AIDS epidemic and ensuring

epidemic maintenance thereafter. Epidemic maintenance is defined as a state after epidemic control is achieved, when achievements made along the HIV/AIDS prevention and treatment cascades can be fully controlled, financed, and led by local health systems (inclusive of public, private, and civil society sectors) with little to no involvement by PEPFAR. In alignment with the United Nations Sustainable Development Goals, PEPFAR collaborates with partner countries, multilateral institutions, the private sector, faith groups, and community and civic society organizations to end AIDS as a public health threat. The potential for sustainability, innovation, and scalability is much more significant with the support and collaboration of a broad array of partners, especially capable local partners, including community-based organizations (CBOs) and faith-based organizations (FBOs), academic institutions, private sector, and most importantly, partner governments.

B. PEPFAR's Technical and Strategic Areas of Emphasis

In its five-year strategy, *Reimagining PEPFAR's Strategic Direction*, PEPFAR plans to accelerate the response to end the HIV/AIDS pandemic as a public health threat by 2030 and ensure equitable access while sustainably strengthening public health systems. To accomplish this, PEPFAR focuses on five strategic pillars supporting health equity, sustainability, public health systems, security, partnerships, and science. HARMONIZE will support Strategic Pillar 2, Sustaining the Response, and Strategic Pillar 3, Public Health Systems and Security.

Figure 1: *Reimaging PEPFAR's Strategic Direction: Strategic Pillars and Enablers*



As part of Strategic Pillar 2, Sustaining the Response, PEPFAR highlights the need to work with governments to embed vertical HIV/AIDS programming more efficiently and effectively into the local health service delivery infrastructure. Where possible, PEPFAR will embed HIV programming into strengthened public health systems to manage tuberculosis, high-burden non-communicable diseases, sexual reproductive health, rights, and services, as well as other local health priorities that impact PLHIV – to protect HIV/AIDS gains and strengthen health and economic outcomes. In addition, it will be

critical to design and sustain service delivery models, including differentiated service delivery approaches, that effectively meet the needs of HIV prevention and PLHIV for adult men and women, youth[3], children, and key populations (KP).

In Strategic Pillar 3, Public Health Systems and Security, PEPFAR will continue to strengthen partner country public health systems, pandemic preparedness, and community-led efforts necessary to sustain long-term HIV impact. These efforts can also support epidemic surveillance and deliver effective, efficient, and sustainable health care for PLHIV and program participants. Aligned with the U.S. government and global and regional priorities, these investments will further enhance global health security by not only equipping countries to sustain the impact of HIV but also efficiently strengthening local capacity for preparedness and response to other diseases and outbreaks. As an area of focus, PEPFAR will enhance the capacity of regional and national public health institutions in PEPFAR-supported partner countries by improving their leadership and management in disease surveillance, data collection and management, and laboratory systems to sustain reductions in HIV incidence and strengthen local capacity to protect the HIV/AIDS response gains and for preparedness and response to other diseases and outbreaks.

C. USAID's Policy Framework

USAID's Policy Framework establishes three overarching priorities to drive progress: 1) Confront the greatest challenges of our time; 2) Embrace new partnerships; and 3) Invest in USAID's enduring effectiveness. To confront the greatest challenge of our time, USAID will bolster health security, improve PHC, and reverse the decline in global life expectancy. USAID will work on the ground with countries to help them strengthen global health security and be better prepared for the next pandemic or health emergency. To respond to future disease outbreaks and pandemics, we will continue to reorient our commitment to address emerging global health issues. USAID will go beyond disease programs to expand its impact and investments in PHC systems, such as digital health and primary health workforce which includes community health workers. We will improve coordination across global health programming, including in digital health, and investment in a stronger primary health workforce and community health workers capable of adapting to shifting needs, delivering more comprehensive services that work toward universal health coverage, and ultimately saving more lives. It is with this focus on global health security and strengthening primary health care that ongoing efforts in service delivery in the core HIV programs will end HIV/AIDS as an epidemic threat.

D. USAID/GH Primary Impact

PHC is a whole-of-society approach to effectively organize and strengthen health systems to bring health services closer to communities, including health promotion, prevention, diagnosis, and treatment.[4] PHC is essential to high-performing health systems, delivering

[3] USAID's Youth in Development Policy defines youth as individuals between the ages of 10 and 29.

[4] https://www.who.int/health-topics/primary-health-care#tab=tab_1

effective, affordable, and inclusive care to people when needed. PHC is the most inclusive, equitable, and cost-effective way to achieve universal health coverage (UHC). USAID promotes a mix of public, private and civil society-based primary health systems that lead to more responsive services, lower or equivalent costs, higher standards of quality, greater efficiencies, and broader acceptance by local communities.

Strong PHC systems pave the way for countries to build healthy families, stable communities, productive economies and promote self-reliance. PHC is often the first point of contact between individuals and the health system. It also provides education and support to individuals and communities to help improve their health and prevent illness. By providing preventive and basic curative health care services, PHC helps to reduce the burden of disease on the individual and on the healthcare system, and improve quality of life.

PHC can help reduce healthcare costs with its potential for early detection and treatment of health issues, before they become more serious. Furthermore, strong PHC systems help safeguard national security as the first line of defense against public health threats, infectious disease outbreaks and other events that can overburden health systems. In emergency situations, PHC can provide routine health services, identify and manage emergency cases, prevent disease outbreaks with effective public health measures and play a key role in disease surveillance. A primary health care approach develops resilience within health systems and can advance global health security.[5]

Resilient PHC-oriented health systems, anchored by robust and well-supported health workforces, can improve life expectancy, increase health equity, and respond intuitively to disease outbreaks and emerging health threats. Many USAID-supported services, such as HIV, maternal, neonatal and child health (MNCH), ANC, nutrition, and malaria programs, are delivered as components of PHC. Advancing delivery of essential HIV prevention, care, and treatment services at the PHC level will enable delivery of "whole person" care across individuals' life stages and optimize resources for cross-cutting systems investments that address systems bottlenecks, including a strengthened health workforce.[6]

Primary Impact, USAID's renewed PHC focus, builds more intentional linkages across USAID's current global health programs and initiatives, aiming to demonstrate a model to further strengthen PHC, working in a set of focus countries. By utilizing USAID's global health programs to further strengthen PHC, USAID will have greater alignment and continuity of whole-person care across lifespans. This will better equip country health systems and health workforce to respond to health emergencies and address their population's lifetime health needs.

[5] WHO Technical Brief: Primary Health Care and Health Emergencies. https://www.who.int/docs/default-source/primary-health-care-conference/emergencies.pdf. Accessed Oct 30, 2023.

[6] https://www.usaid.gov/news-information/press-releases/dec-13-2022-usaid-announces-400-million-partnership-five-african-nations-accelerate-primary-health-care

USAID has identified five priority domains for its work under Primary Impact. These five priorities reflect strategic, high-impact processes that USAID will focus on through Primary Impact to further the advancement of primary healthcare and drive expected outcomes and results. These priorities will ensure efforts are distinct, non-duplicative, and focused on streamlining USAID funding streams into existing country-driven programs. The five key priorities are as follows:

1. Promote effective models of PHC delivery: USAID's priority will be to implement the most effective models of PHC delivery, including strengthening facility and community-based PHC service delivery, supporting harmonization of services and referrals across health elements, increasing sustainability of healthcare services, improving active community outreach, and enhancing care for the most vulnerable populations.

2. Enhance community engagement and partnership in PHC: USAID believes PHC must be established fully at the community level and be delivered through community ownership using a systems lens and a truly harmonized approach.

3. Optimize quality sub-national and facility management: USAID's focus will be on strengthening financial management and budget systems, and health workforce management capacity and performance at the sub-national level in support of a stronger overall PHC system. Improving these elements at a sub-national level will contribute to greater quality of care as well as equity of access and coverage for country-wide PHC.

4. Boost unified and interoperability of systems: USAID's priority will be to strengthen supply chain systems, health management information systems, and reporting across disease areas to inform decision-making, streamline systems for managers, and enhance the patient experience.

5. Bolster resilient health systems and services: USAID will focus on strengthening linkages between primary healthcare and essential public health functions, and global health security in order to improve overall health system and service resilience, preparedness, and agility for whatever the future holds.

E. USAID's Locally Led Development

USAID's *Locally Led Development* is the process in which local actors – encompassing individuals, communities, networks, organizations, private entities, and governments – set their own agendas, develop solutions, and bring the capacity, leadership, and resources to make those solutions a reality. USAID recognizes that local leadership and ownership are essential for fostering sustainable results across our development and humanitarian assistance work. USAID is catalyzing and facilitating local leadership of development and humanitarian assistance in a variety of ways throughout the design, procurement, management, and measurement of assistance. As part of local leadership,

USAID recognizes that locally-led development is not a single approach, but a range of ways that USAID, its partners, and communities can work together to shift agenda-setting and decision-making power into the hands of local actors.

III. Project Stakeholder

A. Previous/Current Mechanisms

As USAID redesigned central mechanisms for implementation of PEPFAR funding, HARMONIZE builds on components of multiple central mechanisms that will implement activities with HIV/AIDS funding, including:

1) Adolescents and Children, HIV Incidence Reduction, Empowerment and Virus Elimination (ACHIEVE) 4/15/2019 - 12/30/2026: USAID-funded global project to reach and sustain HIV epidemic control among pregnant and breastfeeding women, adolescents, infants, and children. The two primary objectives of the activity are to: (1) Attain and sustain HIV epidemic control among at-risk and hard to reach PBF women, infants, children, and youth, as well as to mitigate the impact of HIV/AIDS and prevent HIV transmission among these populations; and (2) Support the transition of prime funding and implementation to capable local partners.

2) Data for Implementation (Data.FI) 4/15/2019 - 12/15/2025: Data.FI works with a range of stakeholders to support partner governments to further enhance existing health information systems to inform management responses to well-defined gaps in HIV/AIDS programming. This mechanism bolsters data quality, utilizes available data, performs analyses and translates findings in a way that facilitates rapid, efficient implementation, as well as generates information to provide rationales for costs and outcomes for scale-up and maintenance.

3) Meeting Targets and Maintaining Epidemic Control (EpiC) 4/15/2019 - 12/30/2027: Provides HIV/AIDS technical assistance and service delivery and implements programs in over 60 USAID presence and non-presence countries across Africa, Asia, and Latin America and the Caribbean. EpiC helps countries meet or exceed PEPFAR targets for reaching adult, key, and priority populations by finding those who have not yet been identified as positive, linking those who are positive to treatment, and by keeping those on treatment virally suppressed. EpiC works with a range of stakeholders to ensure that partner countries can maintain program gains with appropriately decreasing dependence on PEPFAR/USAID.

4) Reaching Impact, Saturation, and Epidemic Control (RISE) 4/15/2019 - 12/30/2027: Helps meet or exceed PEPFAR targets for reaching at-risk men, women, key populations, and priority populations by finding those who have not

yet been identified as positive, linking those who are positive to treatment, and by keeping those on treatment virally suppressed. This mechanism works with a range of stakeholders to ensure that partner government health systems and partner countries are able to maintain program gains with appropriately decreasing dependence on PEPFAR/USAID. The mechanism also supports the transition of direct funding and implementation to capable local partners.

5) Global Health Risk and Capacity (GHRC) (anticipated): If USAID proceeds with the anticipated GHRC award as planned, it will provide partners and Missions support for sustainably working with local organizations across USAID/Global Health's portfolio, building on the successes and lessons learned from PEPFAR's local partner transition, as well as other localization efforts across the Agency. The award has three primary objectives: a) support USAID Operating Units' engagement with local partners, b) support capacity strengthening of USAID-funded local health partners through technical assistance to individual organizations or government entities, and c) support capacity of USAID funded local health partners through global activities that promote knowledge exchange.
6) Maximizing Options to Advance Informed Choice for HIV Prevention (MOSAIC) 8/15/2021 - 8/14/2026: The MOSAIC award is designed to accelerate introduction and scale-up of new biomedical prevention products and expedite their availability, acceptance, uptake, and impact in PEPFAR programs to help individuals, especially women, prevent HIV and other infectious diseases.

B. New USAID Office of HIV/AIDS Mechanisms

The USAID Global Health Bureau's Office of HIV/AIDS (OHA) will procure new awards to more rapidly reach epidemic control and ensure maintenance while reducing costs to PEPFAR by employing targeted interventions to address key gaps, ensure at-scale programs, and meet goals for transition to local partners. These mechanisms will coordinate and collaborate proactively at the headquarters and field levels to maximize US Government investment and efficiencies and minimize duplication. USAID will provide funds to Missions to better support the use of Annual Program Statements to increase bilateral local partner awards. OHA's future projects are designed to more rapidly reach epidemic control and 95-95-95 goals and ensure maintenance while reducing costs to PEPFAR. All new projects will support countries in directly meeting PEPFAR targets while supporting in-country teams to work with partner governments and local partners to achieve sustainability. OHA's two major new technical projects include: (1) achieving the 95-95-95 goals and sustaining epidemic control for key and priority populations (Accelerate and Sustain), and (2) harmonization of systems and services to embed HIV service delivery into primary health care (HARMONIZE).

The goal of the Accelerate and Sustain activity is to accelerate achievement of the 95-95-95 goals and sustain HIV epidemic control for key and priority populations in

partnership with governments and communities. Targeted populations include adolescents, youth, men, PBFW, children, key populations, and other priority populations. Evidence-based strategies will be used to prevent HIV infection, find, engage, and retain priority and key populations in the clinical cascade, and to provide differentiated service delivery tailored to achieve epidemic control in specific populations with heterogeneous risk. Programming exclusively focused on providing equitable HIV services to specific priority populations, such as key populations and adolescent girls and young women (AGYW), falls within the purview of the Accelerate and Sustain mechanism whereas HARMONIZE's scope is broader, and will focus on ensuring that HIV services are available within primary healthcare for all populations. There will also be OHA support to Missions to better support use of Annual Program Statements to increase bilateral local partner awards. Additionally, all new projects will be based on the current (and future) evidence-based solutions that have been proven effective and are scalable. See "Collaboration and Coordination" below for additional details about the new projects.

IV. Project Goal and Objectives

The goal of HARMONIZE is to contribute to sustaining the gains in the HIV response and enable pandemic preparedness and resilience in the face of other health threats by supporting existing country health systems and primary health care programs to manage and provide HIV prevention, care, and treatment services with other health services.

By building upon a primary health care program's ability to manage and provide HIV prevention, care, and treatment services, we describe the shift from siloed HIV services to those offered as part of or alongside other health services. This approach enables people to receive "a continuum of health promotion, disease prevention, diagnosis, treatment, disease management, rehabilitation, and palliative care services, coordinated across different levels and sites of care within and beyond the health sector, and according to their needs throughout the life course."[7] The main focus is the merging of health services, leading to the co-location and co-scheduling of HIV services with other essential primary healthcare services for the client and coordinated through networks of care. Merging services for marginalized populations (e.g., KPs) may require specialized approaches. Consideration of cross-cutting health systems building blocks (e.g. health workforce, lab, supply chain, HIS) is necessary to support the coordinated delivery of relevant health services across facility and community settings. For example, to support merging HIV with NCD services, service models, workforce, and associated system requirements would need to be configured so that HIV and NCD care can be provided at the same time and in the same place. To ensure harmonization, monitoring tools and medical records for both conditions must be interoperable. Harmonization can take a variety of forms[7], such as:

[7] Goodwin N. Understanding Integrated Care. Int J Integr Care. 2016 Oct 28;16(4):6. doi: 10.5334/ijic.2530. PMID: 28316546; PMCID: PMC5354214.

Horizontal: Care between health services, social services, and other care providers that is based on the development of multi-disciplinary teams and/or care networks that support a specific client group (e.g., for older people with complex needs).

Vertical: Care across primary, community, hospital and tertiary care services manifests in protocol-driven (best practice) care pathways for people with specific diseases (such as COPD and diabetes) and/or care transitions between hospitals and intermediate and community-based care providers.

Sectoral: Care focused within a single sector, such as combining horizontal and vertical coordinated care programs within mental health services through multi-professional teams and networks of primary, community, and secondary care providers.

People-centered: Care between providers, patients and other service users to engage and empower people through health education, shared decision-making, supported self-management, and community engagement.

Whole-system: Care that embraces public health to support both a population-based and person-centered approach to care. This is health care at its most ambitious since it focuses on the multiple needs of whole populations, not just care groups or diseases.

Table 1: HARMONIZE *Results Framework*

Strategic Objective 1: Support health facilities and community sites to achieve and maintain sustained epidemic control by embedding HIV and other related services into the existing health system while strengthening PHC systems and services.

Strategic Objective 2: Build local system and governance structure capacity necessary for the design, administration, management, and implementation of essential HIV prevention, care, and treatment services delivered as part of primary health care.

Strategic Objective 3: Strengthen the investment in health services, service delivery programs, and health and surveillance systems to rapidly prevent, detect, and respond to emerging new HIV infections to sustain the HIV response and strengthen the prevention, detection, and response for other health threats.

GOAL: Contribute to sustaining the gains in the HIV response, accelerate the response to close remaining gaps, and enable pandemic preparedness and resilience in the face of other health threats by supporting existing country health systems and primary health care programs to manage and provide HIV prevention, care, and treatment services with other health services.

Strategic Objective 1: Harmonizing HIV and other related services Support health facilities and community sites to achieve and maintain sustained epidemic control by embedding HIV and other related services into the existing health system while strengthening PHC systems and services. .	**Strategic Objective 2**: **Supporting health systems for harmonization** Build local system and governance structure capacity necessary for the design, administration, management, and implementation of essential HIV prevention, care, and treatment services delivered as part of primary health care.	**Strategic Objective 3: Strengthening global health security** Strengthen the investment in health services, service delivery programs, and health and surveillance systems to rapidly prevent, detect, and respond to emerging new HIV infections to sustain the HIV response and strengthen the prevention, detection, and response for other health threats.
Result 1: Improved harmonization of health services across community and facility settings for people living with HIV and individuals at risk of HIV acquisition or who could benefit from prevention services	**Result 2:** Improved health systems and governance structures for harmonizing HIV services with primary health care	**Result 3**: Improved public health systems to prevent, detect, and respond to HIV and other health threats
IR 1.1:Strengthened delivery of people-centered and simplified HIV services delivered through the local primary health care system, at the community level, and the private sector, while supporting partner governments to achieve and maintain epidemic control.	IR 2.1: Identification of bottlenecks and weaknesses of existing health systems that limit the ability to achieve sustainable epidemic control or harmonized services for clients	IR 3.1: Enhanced fiscal investments in surveillance and accountability to strengthen national systems for monitoring HIV and other diseases effectively.
IR 1.2: Increased implementation of person-centered differentiated service delivery models, through facility and community programs, that address the evolving and various needs of clients	IR 2.2:Improved health system capacity to provide HIV services within primary healthcare settings	IR 3.2:Improved health systems capacity to mitigate the spread of public health threats
IR 1.3 Improved demand and utilization of quality services for HIV positive and individuals at risk of HIV acquisition	IR 2.3 Increased capacity of country-level systems to fund, implement, monitor, and sustain high-quality social and behavior change (SBC) interventions that address harmonization of HIV and PHC health services	IR. 3.3: Increased local organizational capacity and expanded transformative partnerships to maintain, manage, use, and disseminate data and system analytics to inform program interventions in response to emerging health threats
	IR 2.4: Improved coordinated community and facility responses and services that address the holistic needs of people living with HIV and individuals at risk of HIV acquisition	

Strategic Objective 1: Harmonizing HIV and other related services

Support health facilities and community sites to achieve and maintain sustained epidemic control by embedding HIV and other related services into the existing health system while strengthening PHC systems and services.

Embedding HIV services into primary health care can help countries achieve epidemic control and the UNAIDS 95-95-95 goals and ensure that these gains are sustained. This objective is focused on merging HIV services into primary health care services such that stable HIV clients and those at risk for HIV do not need to see a different provider, go to a different building, or attend a different appointment from that of their primary healthcare needs. HARMONIZE should de-silo HIV prevention, care, and treatment services, provide client-centered care instead of disease-centered care, and support the service delivery needs to ensure harmonized care. In settings without a strong primary health care system, comprehensive HIV prevention, diagnosis, care, and treatment services in the community and facility can be embedded into other health services to facilitate providing the skeletal framework for a primary health care system.

A one-size-fits-all approach to embedding HIV prevention, care, and treatment services into primary health care does not exist and is not realistic. Effective strategies under HARMONIZE will be age-appropriate and context-specific, and vary depending on the local epidemic, health system, and population. Engagement of PLHIV, local communities (including KPs and youth), ministries of health, and other relevant line ministries are essential to determining appropriate interventions to facilitate the merging of HIV services with partner government primary health care packages delivered through PHC structures.

Result 1: Improved harmonization of health services across community and facility settings for people living with HIV and individuals at risk of HIV acquisition or who could benefit from prevention services

Intermediate Result 1.1 Strengthened delivery of people-centered and simplified HIV services delivered through the local primary health care system, at the community level, and the private sector while supporting partner governments to achieve and maintain epidemic control.

To strengthen PHC, HIV clinical services need to be embedded with other health services such as MNCH, FP/SRH, TB, NCD, GBV, and mental health (MH), and should be well-coordinated between community and facility settings. This will provide client-centered care instead of disease-centered care. Not all health services can be incorporated into PHC. Depending on the local context, there may be a need to continue to provide specialty care, especially for complicated clients or clients that require unique services. However, to the extent possible, HIV services should be embedded into other existing health programs and services to ensure the sustainability of programs. This may also contribute to a decrease in stigma associated with seeking critical services, such as those associated with access to family planning and HIV prevention, testing, and treatment services.

<u>Illustrative activities</u>

- Support and facilitate alignment between partner government PHC programs and existing PEPFAR HIV programs (prevention, testing, care and treatment) to ensure well-coordinated, client-centered services across facility and community settings.
- Support the delivery of HIV services within the private sector (e.g., decentralized drug distribution) to increase client-centered care, increase additional resources for the HIV response, and increase innovation to improve the efficiency and sustainability of the HIV response.
- Support the coordination of broader health harmonization activities related to HIV services within the country with an emphasis on PHC programs.
- Support linkages and harmonization plans between HIV services and MNCH, FP/SRH, TB, NCD, GBV, MH, and other acute or chronic coinfection and comorbidity outpatient department services to enhance primary health care.
- Facilitate community-based programs that support achieving HIV prevention, care, and treatment desired clinical outcomes and can help reach or maintain the 95-95-95 goals.
- Develop standard operating procedures (SOPs) and update PHC guidelines and materials to include simplified management of uncomplicated HIV infection and provision of combination prevention services (e.g., PrEP, PEP, VMMC, condoms, and lubricants), including differentiated approaches for key and vulnerable populations across both facility and community settings.
- Assess community and facility-based health workers' knowledge, skills, and support needs (including commodities) to provide a comprehensive suite of essential health services, including those for HIV, and develop interventions to address the identified needs. “Essential health services” are defined as the prevention, treatment, and care management services needed or prioritized for a population’s overall health outcomes.
- Support the harmonization of MNCH and HIV services for mothers (including considerations of the unique needs of young moms) and their children, including the screening and treatment of gestational hypertension (HTN) and diabetes mellitus (DM), MH and GBV services, and facilitate community health follow-up activities and psychosocial support.
- Embed routine HIV testing into routine PVT services and other entry points for PBFW.
- Embed early infant diagnostic testing, index testing, and HIV self-testing into well-child and other primary health care visits.
- Embed comprehensive and age-appropriate clinical post-GBV care that meets the expressed needs of survivors. This may include conducting routine or clinical inquiry for violence, providing age-appropriate first-line support [e.g., WHO's Listen, Inquire, Validate, Enhance safety, and Support (LIVES) and LIVES CC approach] to those who disclose experience of violence, and providing or referring survivors to local clinical and/or non-clinical GBV response services.
- Engage recipients of care in the design, implementation, monitoring and evaluation of harmonized services.
- Support and expand harmonization of FP and HIV services for adolescent girls and young women (AGYW) and KPs in facility and community settings.

- Build upon existing, population-specific, community-led services that provide combined HIV, FP, STI, GBV, and other services, as these can and should be a part of PHC.
- Support and appropriately harmonize clinical aspects of laboratory tests assessed for all services provided to community and facility sites to improve quality and access to people-centered lab and diagnostic services.

Intermediate Result 1.2: Increased implementation of person-centered differentiated service delivery models through community and facility programs that address the evolving and various needs of clients

Differentiated service delivery (DSD) simplifies and adapts HIV services across the cascade to reflect the preferences, expectations, and needs of people living with and vulnerable to HIV. HARMONIZE should expand these approaches to include other primary health care services to provide client-centered care while reducing unnecessary burdens on the health system.

Illustrative activities

- Implement DSD models for HIV treatment and prevention with TB, family planning, SRH services, mental health, GBV services, COVID, and treatment of other acute or chronic co-infections and morbidities.
- Scale up high-impact DSD models that meet the health, socio-economic, and psychosocial needs of women, children, youth, and families.
- Expand decentralized drug distribution beyond facility ART programs to routinely include community pick-up points and multi-month dispensing in coordination with other ongoing health needs, including PrEP, HIV self-testing, NCDs, FP, and MH.
- Collaborate with relevant stakeholders to align and bundle other essential medicines (or associated relevant commodities) with multi-month dispensing and decentralized drug delivery activities, thereby increasing return on investment for current existing systems put in place originally just for HIV medications.
- Conduct operational research on differentiated service delivery models that co-deliver HIV services with other health care services and programs.

Intermediate Result 1.3: Improved demand and utilization of quality services for HIV positive and individuals at risk of HIV acquisition.

Activities under this intermediate result will take to scale proven SBC interventions known to improve the quality of services for HIV positive individuals and those at risk. These interventions should address individual-, community-, and facility-level factors (self-efficacy, personal beliefs and attitudes, peer and community relationships, and client-provider interaction), and utilize customized, contextualized, peer-led approaches to identify and address barriers to uptake of services through the use of SBC tactics [e.g. human centered design (HCD), nudges, behavioral insights (BI)].

Illustrative activities

- Carry out formative research to identify emotional drivers and cultural and social barriers to the uptake of services for HIV positive and individuals at risk of HIV acquisition.
- Embed evidence-based SBC approaches in the design and implementation of interventions to improve both quality and the uptake of services.
- Engage recipients of care, including youth, KP, and other marginalized populations, in human centered design (HCD) activities to develop tools and materials to build confidence and agency of clients/PLHIV and improve interpersonal communication with providers at both community and facility.
- Routinely collect clients' feedback to generate insights to be used to reposition services and improve uptake.
- Reduce provider stigma towards HIV positive and individuals at risk of HIV acquisition by creating awareness and empathy to improve confidence.
- Engage critical and relevant community programs to facilitate reduction of stigma and discrimination, while addressing barriers to uptake (attitudes, beliefs, perceptions, biases, and other internal factors) within specific communities where programs exist.
- Deliver community mobilization activities that address harmful gender norms that sanction and perpetuate gender-based violence and violence against children and youth, including activities that reach parents/caregivers, faith and traditional leaders, male partners of AGYW, and other community influencers.
- Mobilize and collaborate with the private sector to bring new skills, innovations, and ideas that enhance services.

Obj. 1 Illustrative Indicators

- Client-reported experience of harmonized service delivery.
    - Number and types of different providers seen at each encounter.
    - Number of different queues the client joined at each clinic visit.
- Percent of PLHIV treated for other chronic conditions (e.g., HTN, DM) at the same encounter.
- Percent of PLHIV provided with other health care services (e.g, FP, SRH, mental health) at the same encounter.
- Percent of clients receiving HIV prevention services (PrEP, VMMC) that are offered and/or provided with other health care services (e.g, FP, SRH, mental health) at the same encounter.
- Percent of clients that receive HIV testing services (HTS) that are screened for an array of other conditions (e.g. TB, COVID, Malaria, diabetes, alcohol and tobacco use, GBV) at the same encounter.
- Percent of clients offered an array of health promotion and prevention services besides HIV prevention (e.g. TB, COVID, malaria, FP, diet & exercise, alcohol and tobacco use, GBV) at the same encounter.
- Percent of PLHIV with other PHC medications delivered at the same time as ART.
- Percent of PLHIV receiving multi-month supplies of ART along with comorbidity medications.
- Number of sites providing FP counseling and/or offered at least three FP methods.

    - Number of PLHIV with a diagnosis of hypertension that is controlled (BP <140/90).
    - Number of PLHIV with a diagnosis of diabetes mellitus that is controlled (further definition of "controlled" to be established).
- Percent of clients screened for violence using clinical or routine enquiry, provided with first-line support, and provided clinical and/or non-clinical care.

Strategic Objective 2: Supporting health systems for harmonization

Build local system and governance structure capacity necessary for the design, administration, management, and implementation of essential HIV prevention, care, and treatment services delivered as part of primary health care.

The health system building blocks, such as human resources, health information systems, laboratory, supply chain, governance, and community structures, must support the harmonization of HIV services with other health care services. Each country will have different health system needs to support the merging of HIV services with primary health care. HARMONIZE should identify these needs and provide the systems interventions that can successfully enable implementation. For example, if an ART clinic were to be embedded into a generalized outpatient clinic that provides primary care, health providers at the outpatient clinic would need to be trained in HIV care (if they are not familiar with how to provide such care), and workload implications would need to be assessed and planned for. Health information systems that the ART and generalized outpatient clinics use to store clinical data and support data analytics would need to be interoperable. Supply chain systems supporting forecasting, quantification, and logistics and ensuring access to ART must be aligned with other systems supporting other commodities' needs for primary health care.

Result 2: Improved health systems and governance structures for harmonizing HIV services with primary health care

Intermediate Result 2.1 Identification of bottlenecks and weaknesses of existing health systems that limit the ability to achieve sustainable epidemic control or harmonized services for clients

Harmonizing essential health services (defined as the prevention, treatment, and care management services needed or prioritized for a population's overall health outcomes) within the health system is a large undertaking. HARMONIZE cannot address all aspects of the health system but should identify the most critical areas needed to support embedding HIV into primary health care.

Illustrative activities

- Conduct landscape analysis of the existing health system and HIV services and programs provided in consultation with the government and other stakeholders to determine needs for embedding HIV into PHC.
- Identify health systems requirements for harmonization of HIV and PHC services, including health workforce capacity and management, quality assurance, health information systems, access to services, laboratory services, and supply chain, delivered

through the local primary health care system and other community-based support services.

Intermediate Result 2.2 Improved health system capacity to provide HIV services within primary health care settings

HARMONIZE should consider the various building blocks of the health system (leadership and governance, health workforce, health information systems, laboratory, and supply chain) that need to be strengthened to support service alignment and coordination. These health systems strengthening activities should complement the service delivery activities in Strategic Objective 1.

Illustrative activities

- Support necessary policy changes and coordination of central governance structures (and potential realignment) to ensure harmonization of HIV and health services that can be cascaded to the lowest-tier health facilities, community systems, and structures.
- Support forecasting, supply planning, supply chain logistics, and stock management of health commodities beyond those for HIV to include other essential medications and diagnostics (i.e., HTN, including gestational HTN, and DM medications and supplies) for NCDs, family planning, COVID, sexually transmitted infections, VMMC, post-GBV care, and other community programming and PHC needs.
- Harmonize HIV regulatory, procurement, and supply chain systems, such as electronic logistics information systems, with other systems for managing other essential PHC commodities.
- Build upon PEPFAR-supported laboratory systems for HIV detection and management to strengthen laboratory services that enhance primary health care.
- Support laboratory diagnostic work across disease states, including health threats (e.g., TB, HPV, HIV/EID, COVID).
- Harmonize data and information, reduce fragmentation and duplication and increase interoperability of HIV-specific digital systems with other diseases.
- Harmonize client health records systems and other HIV monitoring and evaluation tools and databases into the local health records and information systems to eliminate disease-specific systems and records, promote client-centered data systems and monitoring, and reduce the data entry burden.
- Align the PEPFAR-supported health workforce (facility-based and community-based) with the local health workforce structure in collaboration with relevant line ministries (e.g., finance and planning).
- Support a nationwide HRIS and health workforce strategic plan that includes an equitably distributed and sustainable health workforce for HIV service delivery needs.
- Upskill the PEPFAR-supported health workforce to provide other PHC services (e.g., MNCH, including gestational HTN, SRH, TB, FP, COVID, NCD, MH, GBV, and community care & support) as a bridge towards a multidisciplinary health workforce that can provide comprehensive and harmonized services.

- Build the capacity of health and social service workers in facility and community settings to co-deliver prevention, screening, treatment, and adherence services for HIV as part of PHC protocols.
- Update curricula and training requirements for health worker pre-service (and in-service where feasible) education and scopes of work to harmonize HIV and primary healthcare-related services.
- Provide KP sensitivity/KP competency in pre-and in-service training.
- Provide stigma and discrimination reduction and empathy competency in pre-and in-service training.
- Strengthen WHO health systems' building blocks (service delivery, health workforce, access to medicines, financing, leadership/governance, and health information systems) to support a youth-responsive health system.
- Provide in-service training and support changes to staffing models for government healthcare workers (HCWs) delivering PHC services to also provide HIV prevention and treatment services (with appropriate referral for complex cases/AHD as well as referral to community-based support where required).
- Review indicators across primary health and HIV services with national-level stakeholders to identify key HIV indicators for reporting and evaluating the quality of enhanced HIV service delivery across facility and community settings.
- Embed HIV into existing PHC QA/QI activities and build capacity for HIV monitoring and evaluation and supportive supervision across facility and community settings.
- Support the development of a health and social service workforce that advances women, nonbinary, and gender minorities' leadership opportunities and fosters a safe work environment with fair remuneration and non-discrimination.
- Support the development and/or maintenance of robust gender-sensitive data systems that utilize measures and metrics of gender equality, gender-based violence, and structural barriers (e.g., beliefs/perceptions of gender roles and equality and experiences of stigma and discrimination) to improve planning, delivery, and monitoring of HIV and PHC services.

Intermediate Result 2.3 Increased capacity of country-level systems to fund, implement, monitor, and sustain high-quality SBC interventions that address harmonization of HIV and PHC services

HARMONIZE should support partner governments in strengthening their commitment to SBC programming. This can be achieved by bridging the capacity of local organizations, including women, youth, and KP-led organizations, and country-level systems in SBC through funding, managing, and initiating SBC programs; ensuring the alignment of SBC efforts in multi-sectoral programming, and engaging private sector actors in solving SBC-related public health and development challenges.

<u>Illustrative activities</u>

- Increase the capacity of public systems to include the monitoring and evaluation of SBC interventions, including randomized impact evaluations and cost-effectiveness evaluations, as a core component of any harmonized public health program.
- Increase partnerships with local behavioral scientists and behavioral science organizations (HCD, marketing, behavioral economics, and insights) to support the design of SBC interventions and the training of government counterparts.
- Incorporate meaningful youth engagement across programming to ensure youth's needs, perspectives, and abilities are thoughtfully incorporated in SBC interventions.

Intermediate Result 2.4: Improved coordinated community and facility responses and services that address the holistic needs of people living with HIV and individuals at risk of HIV acquisition

Community engagement is a critical component of primary healthcare. Coordination of community-facility programming incorporated into governance structures ensures comprehensive, locally led primary health services that are delivered more efficiently. Health systems should establish effective referral systems between health facilities and community structures.

Illustrative activities

- Support community-facility operational linkages and functional referrals for comprehensive people-centered care and support for all PLHIV within a stigma-free, empowering, and enabling environment, focusing on meaningful involvement of the PLHIV community.
- Embed HIV services into the local community structures for general health promotion, prevention, and detection and intentionally merged HIV services with relevant programming from other line ministries outside health, such as social welfare, education, youth and women affairs, and finance.
- Train and support community health workers to provide health services for HIV, NCDs, COVID, nutrition, substance abuse, malaria, mental health, and essential social services.
- Expand community models to engage and build demand among PBFW, with attention to the unique needs of young PBFW, who may not be attending facilities for HIV prevention and testing services.
- Ensure coordination and referrals between clinical and community-based support services for children, youth, and families to support adherence, including case conferencing.
- Engaging the HIV community to determine local needs and aspirations, promote health and reduce health inequalities, improve service design and quality of care, and strengthen local accountability frameworks for services rendered.
- Strengthen community health systems in alignment with existing clinical programs.
- Improve the quality of HIV community services by fostering stronger connections between clinics and community health services, enhancing social accountability, strengthening community health workforces, and incorporating clinical support services as appropriate for the country context.

- Collaborate with relevant stakeholders to establish a harmonized system and formal remuneration for community health workers and implement coordinated HIV services with other disease programs and services.
- Conduct advocacy to engage with related national agencies to professionalize the cadre of community health workers to support HIV services aligned with general health services.

Obj. 2 Illustrative Indicators

- Guidelines or SOPs developed and implemented for a formal national system for community-facility bi-directional referral and linkage.
- Guidelines or SOPs developed and implemented for a formal referral system between various levels of the health care system.
- Number of subnational and facility levels providing commodity storage, distribution, and supply/inventory management with a streamlined supply chain for HIV and other PHC-related commodities.
- Completion of referral loop (% referrals which received back referral in the previous X months).
- Number of PEPFAR-supported HCWs who received/completed non-HIV training [e.g., FP, TB, GBV first-line support (LIVES), GBV clinical care].
- Number of health workers trained and supported to provide harmonized health services, including for HIV.
- Number of health facilities with laboratory sample transport mechanisms that include samples for other chronic conditions, health threats, and primary healthcare needs.
- Number of laboratories that include other health threats and primary healthcare needs as applicable to the country context.
- Number of health facilities that meet quality standards for harmonized care.
- Number/percentage of clients with disparate/non-interoperable health records or systems that are consolidated or reduced.
- Number of service providers who are providing HIV care and treatment services alongside other chronic disease management services (e.g., HTN, TB, COVID, DM).
- Number of "ART-only" clinics that closed and transferred clients to primary health care sites or converted to a primary care site that provides care beyond HIV.
- Percent of PLHIV who tested HIV positive outside the facility in community settings and were successfully linked into care and treatment.
- Percent of PLHIV who want and are receiving adherence support services at the community level.

Strategic Objective 3: Strengthening global health security

Strengthen the investment in health services, service delivery programs, and health and surveillance systems to rapidly prevent, detect, and respond to emerging new HIV infections to sustain the HIV response and strengthen the prevention, detection, and response for other health threats.

PHC systems are the first defense against infectious disease outbreaks and other public health threats. Transforming PHC to include the delivery of HIV services can, therefore, bolster the capacity to prevent, detect, and respond to HIV and other health threats. Programs supporting the prevention, diagnosis, care, and treatment of PLHIV have established a public health system that can strengthen other emerging health threats. This objective will take the laboratory detection networks, surveillance and data use analytics, health workforce, and supply chain systems built for HIV programming and extend them to other health threats to support a robust global health security system. For example, HIV programs that have developed strong risk communication and community engagement can be aligned or embedded into security systems to limit the spread of other health threats by generating demand and supporting rapid detection and referral.

Result 3: Improved public health systems to prevent, detect, and respond to HIV and other health threats

Intermediate Result 3.1: Enhanced fiscal investments in surveillance and accountability to strengthen national systems for monitoring HIV and other diseases effectively.

An effective disease surveillance system is essential to detecting health threats to respond quickly. Strengthening surveillance systems can improve HIV detection and help maintain the gains in HIV epidemic control.

Illustrative activities

- Capacitate National Public Health Institutes to lead HIV/AIDS routine population-level surveillance and survey efforts to build national capacity to conduct surveillance for HIV and other public health threats.
- Support a comprehensive public health surveillance system to detect HIV and other potential events of concern for public health security.
- Support national capacity to analyze and link data between the different levels of the early warning system.

Intermediate Result 3.2: Improved health systems capacity to mitigate the spread of public health threats

Embedding HIV programs into global health security systems can strengthen the response to HIV and other health threats. These systems investments include the health workforce, community structures, supply chain, and laboratory systems.

Illustrative activities

- Capacitate a multisectoral workforce, including youth, to prevent, detect, and respond to public health threats, including infection prevention and control, risk communication and community engagement, occupational health safety and security, and emergency response protocols to ensure continuity of HIV and other primary health care related services.

- Support laboratory diagnostics on common platforms across disease states, including health threats (e.g., TB, HPV, HIV/EID, COVID).
- Support infection prevention and control, occupational health, prevention and surveillance for health care acquired infections (HCAIs), and safe environments in health facilities for HIV/TB and other HCAIs.
- Capacitate public health communications systems to effectively engage the public through media, social media, mass awareness campaigns, health promotion, social mobilization, and stakeholder engagement in the prevention, care, and treatment of HIV and other public health threats.
- Harmonize the diagnostic pathways and supply chain systems to ensure the availability of commodities for rapid identification and treatment of health threats.
- Support comprehensive management of respiratory infections at PHC sites, including COVID-19 Test to Treat initiatives, to enable rapid diagnostics and treatment delivery where available.
- Support systems to prevent disruptions of essential medical services during a health threat.
- Support and harmonize service delivery models for vaccine administration for pediatrics and adults.

Intermediate Result 3.3: Increased local organizational capacity and expanded transformative partnerships to maintain, manage, use, and disseminate data and system analytics to inform program interventions in response to emerging health threats

Systems to generate and analyze data are needed to respond to health threats quickly. Healthcare workers and local partners should be capacitated to produce, utilize, and disseminate data for an effective response.

Illustrative activities

- Capacitate health care workers, including youth, in data analytics for disease surveillance and outbreak investigations.
- Capacitate local partners to support surveillance to collect, maintain, manage, use, and disseminate data on emerging public health threats.
- Strengthen partnerships with local, national, and international organizations within the country to expand funding and build upon existing surveillance systems for developing, managing, and utilizing data to address emerging public health threats.

Obj. 3 Illustrative Indicators

- Increase Joint External Evaluation International Health Regulations (IHR) scores in specific technical areas.
- Number of laboratories that include other health threats and primary healthcare needs as applicable to the country context.
- Percentage of facilities with staff trained in infection and prevention control protocols.
- Percentage of facilities with an IPC focal person.
- Percentage of facilities with staff trained (or protocols) in the prevention of and response

to HCAIs.

- Establishment of national risk communication systems (eg, national strategy, national and subnational coordination committees or programs) that applies to/inclusive of multiple disease threats, including HIV.
- Establishment of an early warning system and active surveillance of HIV and other health threats.
- Establishment of a routine system for adult vaccinations at the PHC level.
- Number of healthcare workers trained to prevent, detect, and respond to public health threats (e.g., outbreak response, emergency management).
- Percentage of local/service providers trained in different categories such as data collection, management, and analysis using a scorecard of the different emerging threats to be monitored in the local/national context.
- Percentage of strategic surveillance systems and data utilized to identify or notify any threats.
- Number of analytical products in the form of profiles, reports or fact sheets disseminated to the public and relevant stakeholders in a defined period of time (annual usually).

V. Strategic Areas of Emphasis

A. Gender Equality and Gender-Based Violence (GBV) Considerations

Gender inequity and inequality, discrimination, and violence continue to pose significant barriers to reaching and sustaining HIV epidemic control. Through its global health investments, USAID seeks to address the root causes of inequality and promote a healthier and more equitable world to achieve three key goals: 1) Advance gender equality and end gender-based violence, which is essential to sustain health outcomes and create a healthier and more equitable world for all people; 2) Promote the human rights of women and men, girls and boys, LGBTIQ+ and those of other gender identities – of all ages and abilities – so that they may utilize quality health services; practice healthy behaviors and build equitable relationships at home and in the community; exercise their rights; and live free from violence, stigma, and discrimination; and 3) Build strong and resilient health and social service workforces and systems that are responsive to the needs of diverse populations.

Gender inequality impedes the effectiveness of HIV prevention, testing, care, and treatment programs and services. While gender inequities and inequalities manifest themselves in different ways across the HIV clinical cascade, they are fundamentally rooted in socio-cultural norms that endorse inequitable power and decision-making, acceptance of the use of violence – particularly by men, stigma, and discrimination, and social constructions of gendered identity that shape what is considered acceptable and what is not. Gender influences the roles, norms, and behaviors that impact access to and utilization of health services – all of which affect the dynamics of the HIV epidemic and the success of prevention, care, and treatment programs and services. GBV facilitates HIV transmission by limiting one's ability to negotiate safe sexual practices, disclose HIV status, and access services, including HTS, PrEP, PEP, and ART, due to fear of reprisal. Biomedical prevention and treatment interventions alone do not address the

underlying behavioral and structural drivers of the epidemic. Addressing gender inequalities and harmful gender norms and preventing and responding to GBV are essential to controlling the epidemic and reaching 95-95-95 goals.

PEPFAR and USAID policies and strategies emphasize the importance of incorporating gender considerations into HIV programming to positively impact the epidemic and address underlying structural and behavioral drivers, including gender inequalities and gender-based violence (GBV). PEPFAR's Country Operational Plan Guidance outlines key technical priorities and approaches for implementing gender and GBV considerations into HIV prevention, care, and treatment programming, including addressing harmful gender norms and inequities; overcoming gender-specific barriers to prevention, care, and treatment interventions; creating opportunities for economic empowerment and education; shaping a supportive legal and policy environment; overcoming stigma and discrimination; and preventing and responding to GBV. USAID has articulated these priorities in its Advancing Gender Equality and Preventing & Responding to Gender-Based Violence to Achieve Sustained HIV Epidemic Control strategy. In addition, the USAID Gender Equality and Women's Empowerment Policy and the U.S. Strategy to Prevent and Respond to Gender-Based Violence Globally detail technical priorities and institutional requirements for addressing gender inequalities and GBV in USAID programs and services.

Throughout the life of the project, HARMONIZE will be expected to close gaps in access to and utilization of HIV and other health services; address structural gender inequities and inequalities, including preventing and responding to gender-based violence, stigma, and discrimination; and support an enabling environment through policies and systems that foster health equity and equality. HARMONIZE will be expected to monitor and use sex- and age-disaggregated program data, as well as other routine and custom indicators data sources. The awardee(s) will utilize appropriate and feasible methods for data collection (disaggregated by sex, age, and KP status as appropriate), tracking, verification, analysis, and reporting, including attention to differential impacts by sex and age, and make needed adjustments to the project to address harmful gender norms and prevent and respond to gender-based violence.

B. Sustainability

The sustainability and long-term success of development assistance ultimately require local ownership and strengthening the capacity of local systems to produce development outcomes at the regional, national, subnational, or community levels, as appropriate. USAID assistance should be designed to align with the priorities of local actors, utilize local resources, and increase local implementation to sustain results over time.

PEPFAR's commitment to achieving and maintaining epidemic control relies on strategic, sustainable improvements in the local systems through which HIV/AIDS prevention and control activities are implemented. Meeting PEPFAR's target of 70% of funding to local partners is a significant step toward increasing local implementation of PEPFAR programming. HARMONIZE should aim to strengthen the role of local partners in the implementation of HIV/AIDS

programming. PEPFAR's definition of a local partner can be found here. [Note the PEPFAR definition of Local Partner differs from USAID's definition under Local Solutions.]

PEPFAR has identified 15 critical elements for sustainability in the Sustainability Index and Dashboard, which provides a guiding framework for measuring progress towards sustainability. For the activities under this agreement, USAID/OHA has focused on several specific priorities for enhancing sustainability over the next five years. Activities under this project will advance country systems towards achieving and maintaining epidemic control by targeting specific improvements in key, system-level domains essential for sustainability. For the activities under this agreement, USAID/OHA has focused on governance and leadership, service delivery, and strategic information. HARMONIZE will identify specific improvements in one or more of these domains that will be achieved throughout the project and connect project activities to advances in system-level sustainability. While sustainability is a long-term agenda, HARMONIZE should identify one or more specific aspects of sustainability that will be measurably strengthened and improved as a result of project activities. HARMONIZE should also plan for and explain how these targeted improvements will be maintained beyond the life of the program.

C. Collaboration and Coordination

Coordination, communication, and collaboration among stakeholders facilitate trust and mutual understanding, reduce redundancy, increase synergy, scalability, and impact, and promote learning and mutual accountability. This project intends to be a leader in the field to ensure that activities are implemented effectively and that successes and challenges are shared to improve health outcomes and policies broadly. HARMONIZE must demonstrate thoughtful coordination, effective communication, and strategic collaboration in all areas of work. The project is expected to build and enhance constructive partnerships, as appropriate. The project will collaborate and coordinate with a wide variety of stakeholders, including country Ministries of Health (MOH) and other relevant government entities; USG partners, such as the U.S. State Department's Bureau of Global Health Security and Diplomacy (GHSD) and the Centers for Disease Control and Prevention (CDC); global health partnerships, such as UN Agencies and The Global Fund to Fight AIDS, TB, and Malaria; other bilateral and multilateral agencies; academic and research institutions; private sector and philanthropic organizations; and faith-based and civil society organizations.

The project will collaborate with other USAID mechanisms, including but not limited to Accelerate and Sustain, local partners, and USAID digital health and data-related mechanisms. Collaborations will support the implementation of creative approaches to cost-effective and timely data collection and use while strengthening technical capacity and service delivery in the field. The anticipated coordination among projects is expected to be extensive and may include, but is not limited to, quarterly meetings among project leadership, coordinated work plans, and in-country coordination between projects and the Mission, which may include sharing office space and staff and joint project activities when appropriate.

D. Safeguarding

USAID is committed to protecting program participants from all forms of abuse, unethical behavior, and misconduct. These actions, when identified, must be safely and proactively addressed in a manner that is survivor-centered, trauma-informed, and respects the rights and needs of program participants. HARMONIZE will demonstrate its commitment to safeguarding program participants and upholding zero tolerance for all forms of abuse, unethical behavior, misconduct (i.e., sexual, physical, emotional, or financial abuse; coercion; exploitation; or neglect) or discrimination based on sexual orientation, race, ethnicity, religion, disability, age, or gender. The project will protect and promote program participants' health and human rights, confidentiality, safety, and security. HARMONIZE will also ensure that all services and programs are delivered in a non-discriminatory and non-coercive manner, with safeguards to prevent and respond to abuse, unethical behavior, and misconduct. Additionally, the project will establish systems to hold staff accountable for adhering to these principles.

E. **Inclusion of People with Disabilities**

HARMONIZE should include targeted approaches to ensure routine HIV prevention, care, and treatment services are accessible for people living with disabilities. Disabilities may include vision impairment, deaf or hard of hearing, mental health conditions, intellectual disability, acquired brain injury, autism spectrum disorder, and physical disability. HARMONIZE is encouraged to work with Ministries of Health, other Ministries, and Government colleagues in collaboration with local Disabled People's Organizations, advocates, partners, and community actors to assess and regularly improve efforts to design HIV and other health services and interventions that remove barriers for PLHIV with disabilities. Linkages should also be provided for clients with disabilities who may need access to screening and referral services. Where possible, HARMONIZE should strengthen links to USAID, PEPFAR, and non-funded PEPFAR rehabilitation services to enable people living with HIV and who have disabilities to remain virally suppressed and improve their quality of life. In addition, they should identify and promote ways in which people with disabilities can prevent new HIV infection (and consider how these efforts may be linked to other prevention work. HARMONIZE may also work to increase human resources processes to recruit and retain employees with disabilities and track data on clients and staff with disabilities.

F. Meaningful Youth Engagement

USAID's Youth in Development Policy aims to increase the meaningful participation of youth within their communities, schools, organizations, economies, peer groups, and families, enhancing their skills, providing opportunities, and fostering healthy relationships so they may build on their collective leadership. Through HARMONIZE, we aim to strengthen meaningful youth engagement across all activities to ensure youth have better access to information and services, actively participate, are respected, and their ideas, perspectives, and skills are included in decision-making processes. Additionally, we seek to ensure local and national systems better serve them through more coordinated and effective services, practices, and policies embodying positive youth development principles.

VI. Transition Awards

HARMONIZE's scope includes financial, technical, and organizational capacity building of local organizations. For Missions that want HARMONIZE to support transition awards, HARMONIZE will be the initial award in a transition award process. HARMONIZE will provide local subrecipient(s) capacity building so they can become prime recipients of follow-on transition awards. Transition awards require the prime implementing partner (also referred to as the initial award partner) to: 1) identify a high-capacity local subrecipient(s) in collaboration with the USAID mission; 2) provide any necessary capacity building and/or conduct any necessary assessments, such as a pre-award audit; and 3) track the progress of the subrecipient(s) towards meeting agreed upon criteria for a transition award so that the Mission can transition funding from the prime implementing partner to the local subrecipient under a new bilateral award without competition. The transition period will depend on the capacity of the subrecipient and Mission planning. Additional information about transition awards is included below under Section C, IX, "Substantial Involvement."

VII. Crisis Modifiers

When a crisis occurs, the default should be to request USAID permission for adjustments within scope that exceed a 10 percent line item change pursuant to 2 Code of Federal Regulations (CFR) 200.308(e).

However, there may be cases where HARMONIZE may employ crisis modifiers to respond to evolving programmatic considerations that require a high degree of flexibility to allow for interventions in response to emergencies and disasters that inhibit the achievement of programmatic goals. A crisis modifier may be used when emergency response is required or when events such as humanitarian emergencies, drought, climate change, unstable security environments, and challenges to safety and security threaten programmatic achievements. A core programming consideration is supporting civil society organizations (CSOs), program participants, and implementing partners, particularly those led by and serving key and priority populations. For priority populations, particularly key populations, many of whom may engage in behavior criminalized by partner governments and stigmatized by communities, crisis response

may be needed to protect individuals, their families, and community organizations' physical, mental, and material safety.

When a crisis occurs, USAID will determine on a case-by-case basis whether the use of the crisis modifier is appropriate. Crisis modifiers are subject to funding availability and must be approved prior to deployment at the discretion of USAID. Partners should not assume that additional funding will be made available. If USAID determines a crisis modifier is appropriate, the AO and the AOR will ask HARMONIZE to document the rationale for the use of the crisis modifier and develop an action plan and budget for the work proposed. The AO and AOR must approve the action plan and budget and confirm that funds are available and appropriate to fund the proposed crisis modifier scope. If approved by the AO and AOR, the "crisis modifier" cost line item will allow the release of separate, rapid response funds to the recipient for immediate activities to address emergencies, as detailed in the action plan.

Budget proposals must include a set-aside line item for the crisis modifier should additional resources be made available to USAID for that purpose.

VIII. Project Monitoring and Evaluation

In line with PEPFAR monitoring and evaluation (M&E) requirements, all implementing partners must develop an intensive M&E plan. A robust monitoring and M&E plan is a critical component of this project because it will allow implementers to track the performance, effectiveness, and impact of HIV activities. Partner work plans will vary between countries based on the health system landscape, requiring different activities to align services effectively. Therefore, at the country level, indicators will be tailored. Illustrative indicators have been provided based on each objective of the results framework above. HARMONIZE will track routine custom and some MER indicators (input, output, outcome, and impact) relevant to the scope and human resources in health and financial data to enable costing and financial analyses. The proposed M&E of the project should include, at a minimum, appropriate PEPFAR MER indicators as they relate to the merging of HIV and PHC services and the following core indicators as they are likely to apply to all countries:

- Percent of PLHIV provided with other health care services (e.g., FP, SRH, HTN, DM, mental health) at the same encounter.
- Percent of clients that receive HTS that are screened for an array of other conditions (e.g., TB, COVID, malaria, diabetes, alcohol and tobacco use, GBV) at the same encounter.
- Client-reported experience of comprehensive service delivery.
    - Number and types of different providers seen at each encounter.
    - Number of different queues the client joined at each clinic visit.
- Percent of clients offered an array of health promotion and prevention services besides HIV prevention (e.g., TB, COVID, malaria, FP, diet & exercise, alcohol and tobacco use, GBV) at the same encounter.
- Number of service providers who are providing HIV care and treatment services alongside other chronic disease management services (e.g., HTN, TB, COVID, DM).

- Number of “ART-only” clinics that closed and transferred clients to primary health care sites or converted to a primary care site that provides care beyond HIV.
- Percentage of facilities with staff trained (or protocols) in prevention of and response to HCAI.
    - Establishment of an early warning system and active surveillance of HIV and other health threats.
- Number of healthcare workers trained to prevent, detect, and respond to public health threats (e.g., outbreak response, emergency management).

In addition, the project will report on tailored indicators to communicate progress made by project activities.

AORs and Activity Managers will review annual work plans and reports, including detailed M&E plans and results, to ensure that programming properly targets the right health system activities for harmonization. Partners on the ground and USAID Mission and Washington employees will regularly review the data to collaboratively identify the most cost-effective interventions and approaches, what interventions promote the greatest sustainability and determine the most cost and time-efficient way the project can contribute towards harmonization and maintaining epidemic control. This project will remain flexible and adapt to meet the needs of the current and changing geopolitical context on a country-by-country basis.

In addition to the reporting requirements articulated above, implementing partners are expected to report on all non-routine data generated with the support of USAID PEPFAR funding, including all surveys/surveillance, research, and evaluation activities (SRE) to meet USAID OHA-specific reporting requirements. The reporting parameters, data elements, and standard reporting time points (e.g., quarterly, semi-annually, and annually) will be provided by the AOR and will aim to capture and facilitate the use of interim results through existing program and policy decision-making processes.

IX. Substantial Involvement

It is understood and agreed that USAID will be substantially involved during the performance of this Agreement as outlined below:

1. Approval of annual work plans (implementation plans), which include planned activities and budgets.
2. Approval of specified key personnel. Key personnel which require approval under this award are described in section A. Before replacing the individual(s) currently in these positions, the Recipient must notify the AO and the AOR reasonably in advance and submit written justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. Requests for approval of Key Personnel must include (a) written justification, (b) a CV in English, and (c) justification of the salary proposed. As appropriate, any related changes to the agreement budget or sub-award arrangements must be included in the request for approval of key personnel. No replacement may be made by the Recipient without the written approval of the AO.

3. Approval of monitoring, evaluation, and learning (MEL) plans, usually annually.
4. Collaborative involvement in selecting advisory committee members, if the program will establish an advisory committee that provides advice to the Recipient. USAID may participate as a member of this committee. Advisory committees must only deal with programmatic or technical issues, not routine administrative matters.
5. Approval of sub-awardee(s) or contract selection, the technical or programmatic provisions of subawards, and any revisions in the statement of work and/or total approved budget.
6. Agency monitoring to permit specific kinds of direction or redirection of the work because of the interrelationships with other projects or activities.
7. Other monitoring as appropriate, e.g., as described in 2 CFR 200.
8. Agency authority to immediately halt a construction activity. The AO may immediately halt a construction activity if identified specifications are not met.
9. Agency and Recipient Collaboration on Transition Award(s). As appropriate, feasible, and as requested by bureaus, independent offices, or missions, the initial award resulting from this NOFO will seek to transition direct USAID or other donor funding to local organizations that were sub-awardees on the initial award or that are approved as sub-awardees during implementation. While USAID intends to make transition awards to qualified local subrecipients to accomplish the results described in Section A, there is no guarantee that the Agency will make a transition award. Decisions related to issuing a transition award and the selection of transition award Recipients are solely within USAID's discretion.

A transition award is an assistance award to a local entity or locally established partner (collectively referred to as local subrecipients) that is or has been a subrecipient under a USAID assistance award. A transition award can only be made when the following conditions have been met:

1. The Recipient of the transition award is a local subrecipient that has not previously received a direct award from USAID;
2. The initial award required the Recipient to strengthen the capacity of the local subrecipient(s) to become more capable of receiving a direct award from USAID or other donors and
3. The initial award Recipient recommended the local subrecipient for a potential transition award based on explicit criteria contained in the initial award.

The terms "transition award," "local entity," and "locally established partner" are defined in ADS 303.6 – DEFINITIONS.

If a bureau, independent office, or mission indicates an intent to make a transition award as part of its buy-in to this initial award, the Recipient must provide local subrecipients a subaward to carry out a distinct portion of the work in the award's program description. (For example, within a field support-funded scope of work under this award, the Recipient may provide funding to a local subrecipient to design and implement a specific component of the harmonization activities. The expectation is that the subrecipient will subsequently receive a transition award to sustain

or expand these efforts in future years.) Like all Recipient and subrecipient relationships, the Recipient is required to monitor the local subrecipient and is ultimately responsible for the local subrecipient's work (see 2 CFR 200.331). The award must also include appropriate mechanisms to avoid, eliminate, mitigate, and reduce potential or actual conflict of interests, separate funds and accounts, and additional award oversight to ensure proper segregation of roles and funds resulting from an entity being a subrecipient under the same award. After the Recipient identifies the local subrecipient(s) to USAID as having met the initial award capacity development criteria, the Agreement Officer (AO), in consultation with the Agreement Officer's Representative (AOR), may make the transition award consistent with the requirements in Section 5 of ADS Reference 303mbb.

Prior to recommending a local subrecipient to USAID, the Recipient must demonstrate that the local subrecipient has met the following criteria:

1. Has the necessary staff with the technical knowledge, skills, and experience to carry out harmonization activities.
2. Has demonstrated an ability to maintain relationships with stakeholders.
3. Has proficiency in financial management systems and internal controls.
4. Has demonstrated management experience.
5. Has the ability to use relevant IT systems or software needed to accomplish the HARMONIZE activity, which is the basis of the transition award.
6. Has the ability to monitor its own program performance in a cost-effective and efficient manner.
7. Is registered in all applicable USG systems (for example, System for Award Management).
8. Can meet any other pre-award requirements, including the risk assessment, as defined by the AO.

The Recipient is responsible for strengthening the local subrecipient's capacity and tracking progress toward meeting the criteria for a transition award. To assist in this effort, the Recipient will conduct a baseline capacity assessment when any subaward is made to a potential transition award Recipient, with a follow-up assessment before recommending the local subrecipient for a transition award. The content of the baseline capacity assessment will include the areas that the Recipient anticipates being needed by the subrecipient and areas of capacity that the subrecipient itself identifies as necessary for its further strengthening. USAID strongly encourages the Recipient to consider local organizations and institutions for subawards independently of any determination that they meet the criteria for a transition award in the future. For example, the Recipient may select a local organization that has previously worked with USAID as a sub-awardee, even though this organization would not be eligible for a transition award and invite them to participate in capacity-strengthening activities. The option to use transition awards is just one strategy for promoting localization.

USAID Mission concurrence will be required for in-country activities.

X. Key Staffing/Key Personnel

USAID's support to the selected applicant's program will include funding from Missions via field support and central funds. Therefore, it is critical that this project utilize a staffing structure that can not only meet technical objectives but also remain adaptive and flexible to meet the needs that arise at both central and field levels. The rapid start-up will be critical to ensure continuity of services, and the project must provide timely responses to requests from USAID/Washington and USAID Missions.

The HARMONIZE project will have expertise in or access to specialists in the range of technical areas outlined in the NOFO, specifically Section A: Program Description. Five key personnel have been proposed that demonstrate the optimal mix of technical personnel considered necessary for global leadership and country support. Table 2 includes the positions and related qualifications.

Applicants must include CVs for all five key personnel positions as part of the application. Each key personnel position requires USAID approval, as noted in the substantial involvement provisions. All key personnel must demonstrate strong project and personnel management skills, innovation and flexibility in technical practice and/or management, the ability to network and collaborate effectively with a wide range of stakeholders, and strong communication skills. USAID strongly desires the diversity of institutional, technical, and geographic experience across key personnel and other senior project staff. Accordingly, if the prime partner proposes to include sub-partners in its application, the partners' staff should be assigned roles and positions that match the prime applicant's vision of the partners' intended contributions to the achievement of the project's purpose. Individually and collectively, proposed key personnel must show evidence of strong skills for building collaborative relationships with donors, partner governments, and local and international health and development implementers.

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Table 2: *Key Personnel Positions and Qualifications*

Position	**Qualifications**
Project Director	The Project Director will be responsible for coordinating all project activities and staff. They will be responsible for technical leadership and administrative oversight of the program and will serve as the principal institutional liaison to USAID. The PD must have strong leadership qualities and depth and breadth of technical and management expertise. The required attributes of the Project Director are: a senior manager with a degree in public health, social sciences, international development, or a related field and at least 10 years of experience with a master's degree or 12 years of experience with a bachelor's degree and experience leading, managing and implementing large-scale international or national PEPFAR-funded HIV/AIDS prevention, care, and treatment programs in developing countries. Supervisory experience and HR and program management experience required.

Senior HIV Advisor	The Senior HIV Advisor reports directly to the Project Director and provides technical leadership to support incorporating vertical HIV programming into PHC. They will have deep knowledge of HIV service delivery and at least 10 years of experience designing, managing, and/or implementing HIV prevention, care, and treatment programs. The incumbent will also have experience and expertise in one or more areas: health systems strengthening, linking facility and community services, differentiated service delivery, quality improvement, and monitoring and evaluation.
Senior Health Systems Strengthening Advisor	The Senior Health Systems Strengthening Advisor reports to the Project Director and provides technical leadership to support strengthening health systems for incorporating HIV services into PHC. They will have at least ten years of experience managing and implementing public health programs with an emphasis on health systems strengthening. In addition to HIV/AIDS, the incumbent will have technical knowledge in one or more of the following areas: family planning, maternal/child health, malaria, tuberculosis, public health service delivery programs and systems in developing countries, resource-challenged settings, and/or complex environments.
Senior Health Services Delivery Advisor	The Senior Health Services Delivery Advisor reports to the Project Director and provides thought leadership related to comprehensive health service delivery. They will have at least 10 years of experience and expertise in primary health care delivery at facilities and communities, monitoring and evaluation, quality improvement, and developing client-centered, equitable health implementation approaches. Experience in one or more of the following health areas in addition to HIV is required: MNCH, FP/SRH, TB, NCD, GBV, MH, Malaria, and Nutrition.
Senior Social and Behavior Change Advisor	The Senior Social and Behavior Change Advisor will report to the Project Director and provide strategic direction and leadership to strengthen SBC and SBC monitoring, evaluation, and research capacity. They will have at least 10 years of experience and expertise in human-centered design, marketing, SBC, and behavioral economics and demonstrated ability and experience in designing, implementing, and evaluating SBC programs. Experience in one or more health areas is required: HIV, MNCH, FP/SRH, TB, NCD, GBV, MH, Malaria, and Nutrition.
Senior Global Health Security Advisor	The Senior Global Health Security Advisor will report to the Project Director and ensure the successful implementation of global health security-related activities under HARMONIZE. The incumbent will have 10 years of progressive experience in infectious diseases programming. Experience providing technical oversight, managing, designing, and implementing infectious diseases programs with a focus on surveillance of emerging infectious diseases is required.

Emerging Leaders

In recognition of USAID's dedication to meaningful youth engagement across all programming, the Applicant/Offeror is encouraged to include an **Emerging Leaders Program** as part of project implementation in which youth will be hired as emerging leaders into jobs, fellowships, and/or paid internships within the project or directly linked to specific job or remunerated internship opportunities outside the project (such as with partner government or private sector providers). Emerging Leaders are defined as those with less than two years of financially compensated experience yet demonstrate potential for advancing the work activities and bringing in diverse youth perspectives. The inclusion of Emerging Leaders in USAID programming has multiple rationales, including but not limited to support for localization and sustainability; strengthening the capacity of youth in public health and human resources for health, which strengthens the health systems for decades to come; and supporting economic opportunities for youth as a protective factor against poverty and HIV. While implementation details would be determined at the country-activity level in alignment with national youth definitions and policies, applicants are encouraged to include this approach and consider networks and pathways that might be used to support it.

SECTION D: APPLICATION CONTENT AND FORMAT

1. General Content and Form of Application

PLEASE NOTE

THIS APPLICATION IS A TWO-STEP PROCESS. ALL ELIGIBLE APPLICANTS MUST SUBMIT A CONCEPT NOTE TO BE CONSIDERED. IT IS ONLY AFTER EVALUATION OF THE CONCEPT NOTE WILL APPLICANTS BE INVITED TO SUBMIT A FULL APPLICATION. DO NOT SUBMIT A FULL APPLICATION UNLESS REQUESTED.

Concept notes and full applications in response to this NOFO must be submitted no later than the closing dates and times indicated on the cover letter or as stated in an amendment to this NOFO if issued. Late concept notes and applications will be considered only if the Agreement Officer determines it is in the best interest of the USG. Applicants should retain proof of timely delivery through system-generated documentation of the delivery receipt date and time. Concept notes and full applications must be submitted by email to **efortson@usaid.gov, cc, rwiser@usaid.gov,** and email submissions must include the NOFO number and applicant's name in the subject line heading.

Concept Note Format

Preparation of Concept Notes

The concept note must be specific, complete, presented concisely and written in English. The papers should demonstrate the Applicant's capabilities and expertise with respect to achieving the objectives.

The concept note must not exceed six (6) pages, using Calibri 12-point font, on (the electronic equivalent of) standard 8.5" x 11" sized paper, and single spaced with no less than one inch margins and pages numbered consecutively. Any pages submitted beyond the seven page limit will not be evaluated. Additional documentation, such as annexes, charts and graphs that exceed the seven pages will not be reviewed. The concept note should be in either PDF or Microsoft Word format (.docx).

Concept Notes must be developed using the following format:

1. Cover Page (1 Page)
    a. Include the NOFO Number, the organization's name, type of organization (for-profit, non-profit, university, etc.), a main point of contact's name, title, telephone, and e-mail. Describe the organization's capability and expertise, especially with regard to prior experience working with local stakeholders, including governments, communities, and private sector partners, organizational capacity, and technical expertise. **Please indicate if the applicant DOES NOT want**

to have its concept note posted to USAID's cloud platform for sharing purposes. Please note that if an applicant states it does not wish to share its application, it will NOT be provided access to review the other concept notes that pass.

2. Technical (5 pages)
    a. Present your approach and the planned activities to achieving the HARMONIZE objectives as described in Section C.
    b. Describe realistic and context-appropriate strategies for embedding HIV services with primary health services.
    c. Propose clear methodologies and models for reducing vertical HIV programs.
    d. Describe strategies to strengthen capacity for local systems and workforce development in areas like governance, administration, and community engagement.
    e. Propose robust methods to enhance health infrastructure, such as health information systems, supply chains, and workforce training in order to support harmonization of HIV and PHC services.
    f. Provide a clear pathway for sustainability beyond the project's lifespan, including partnerships and funding transitions.
    g. Describe person-centered approaches in service delivery, particularly for marginalized and high-risk groups.
    h. Present a comprehensive monitoring and evaluation framework that includes relevant indicators for measuring harmonization, capacity building, and health outcomes (maximum 1 page).

Merit Review Criteria for <u>Concept Notes</u>

1. Technical Soundness and Feasibility of Approach
    a. Harmonization Strategies: How well does the applicant describe realistic, context-appropriate strategies for embedding HIV services into primary health care? Are the approaches tailored to specific local contexts?
    b. Methodologies for HIV Program Reduction: Does the concept note propose clear methodologies to reduce the siloed nature of HIV programs? Are the suggested models feasible and adaptable?
    c. Sustainability and Local Systems Capacity: Does the applicant present robust strategies for strengthening local systems and workforce capacity, including governance, administration, and community engagement, to support long-term sustainability?
2. Innovation and Relevance of Service Delivery Models
    a. Service Delivery Models: Are the proposed models for unifying health infrastructure (health information systems, supply chains, etc.) innovative and well-suited to the project's needs?
    b. Person-Centered Approaches: Does the applicant clearly outline person-centered approaches, particularly for marginalized and high-risk groups? How well does the concept address the unique needs of these populations?

    c. Adaptability to Evolving Health Needs: Are the models flexible enough to adapt to evolving health needs, pandemic preparedness, and resilience-building?
3. Monitoring and Evaluation (M&E) Framework
    a. Indicators for Success: Are the proposed indicators relevant, measurable, and aligned with the HARMONIZE project's objectives and goals?
    b. Comprehensive M&E Plan: Does the applicant present a thorough framework for tracking alignment, capacity building, and health outcomes?
    c. Continuous Improvement: Does the applicant include mechanisms for data use and analysis to drive ongoing program improvement and responsiveness to health threats?
4. Capability and Expertise of Applicant
    a. Experience and Knowledge: Does the concept note demonstrate the applicant's expertise in coordinating health services and managing large-scale public health programs?
    b. Organizational Capacity: Does the applicant showcase organizational capacity to implement the project goals effectively, including a history of similar successful initiatives?
    c. Capacity for Partnership and Collaboration: Does the applicant outline strategies for working with local stakeholders, including governments, communities, and private sector partners?
5. Clarity, Organization, and Conciseness of Presentation
    a. Adherence to Format Requirements: Does the concept note adhere to the six-page limit, font, and formatting guidelines?
    b. Organization and Structure: Is the concept note well-organized, with logical flow and clear subheadings aligned with the required format?
    c. Clarity of Language and Conciseness: Is the content clear, concise, and free of jargon? Is it written in English and easy to understand?

A Merit Review Committee will review the **Concept Notes** according to the criteria in this Section. The purpose of this review is to ensure that prospective partners bring appropriate capabilities, experiences, and potential contributions to the implementation of activities supporting the strategic objectives of this NOFO. The Agreement Officer will determine the final selection of the successful **Concept Notes**. These applicants will then be invited to submit a full application. **DO NOT SUBMIT A FULL APPLICATION UNLESS REQUESTED.**

Full Technical Application Format

PLEASE NOTE

THIS APPLICATION IS A TWO-STEP PROCESS. ALL ELIGIBLE APPLICANTS MUST SUBMIT A CONCEPT NOTE TO BE CONSIDERED. IT IS ONLY AFTER EVALUATION OF THE CONCEPT NOTE WILL APPLICANTS BE INVITED TO SUBMIT A FULL APPLICATION. DO NOT SUBMIT A FULL APPLICATION UNLESS REQUESTED.

Preparation of Applications

Each applicant must furnish the information required by this NOFO. Applications must be submitted in two separate parts: the Technical Application and the Business Application. This subsection addresses general content requirements applying to the full application. Please see subsections 2 and 3 below for information on the content specific to the Technical and Business Applications. The Technical Application must address technical (e.g., programmatic) aspects only, while the Business Application must present the budget and budget narrative, address risk, and include required standard forms and certifications.

Any erasures or other changes to the application must be initiated by the person signing the application. Applications signed by an agent on behalf of the applicant must be accompanied by evidence of that agent's authority unless that evidence has been previously furnished to the issuing office.

Applicants may submit a cover letter in addition to the cover pages, but it will serve only as a transmittal letter to the Agreement Officer. The cover letter will not be reviewed as part of the merit review criteria. Applications must comply with the following:

- USAID will not review any pages in excess of the page limits noted in the subsequent sections. Please ensure that applications comply with the page limitations.
- Unless otherwise noted, the Technical and Business Applications and all supporting documents must be submitted in English.
- Use standard 8 ½" x 11", single sided, single-spaced, 12 point Calibri font, 1" margins, left justification and headers and/or footers on each page including consecutive page numbers, date of submission, and applicant's name.
- 10 point font can be used for graphs and charts. Tables, however, must comply with the 12 point Calibri requirement.
- Submitted via Microsoft Word or PDF formats, except budget files which must be submitted in Microsoft Excel.
- The estimated start date identified in Section A of this NOFO must be used in the Business Application.
- The Technical Application must be a searchable and editable Word or PDF format as appropriate.
- The Budget (submitted as part of the Business Application) must include an Excel spreadsheet with all cells unlocked and no hidden formulas or sheets. A PDF version of the Excel spreadsheet may be submitted in addition to the Excel version at the applicant's discretion, however, the official Budget submission is the unlocked Excel version.

Applicants should retain a copy of the Technical and Budget Applications and all enclosures for their records.

The technical application should be specific, complete, presented concisely, and demonstrate the applicant's capabilities and expertise with respect to achieving the results of this program. The technical application must take into account Section C: Program Description and Section F: Application Review Information of this NOFO.

The page limit for the technical application, including the executive summary, is 30 pages. Any figures and tables within the technical application itself must fit within the page limit. The cover page, table of contents, acronym list, and annexes are excluded from the overall page limits.

Follow the outline and order of the technical merit review criteria provided in Section E, and as specified below. A complete application consists of the following:

(a) Cover Page (1 page, not included in page limit)

(b) Table of Contents (not included in the page limit)

(c) Acronym List (not included in the page limit)

(d) Executive Summary (1-2 pages, included in the page limit)

(e) Technical Approach - Factor 1 (14 pages maximum)

(f) Management and Institutional Capabilities - Factor 2 (9 pages maximum)

(g) Staffing Approach and Key Personnel - Factor 3 (5 pages maximum)

(h) Annexes (not included in overall page limit):

1. Consortium-Wide Organogram
2. CVs/Resumes of Proposed Key Personnel & References (no more than 3 pages per proposed Key Personnel)
3. Signed Letters of Intent to Collaborate from Each Principal Consortia Partner
4. Staffing Roster
5. List of Potential Resource Partners (if proposed)
6. Activity Start-Up Plan (no more than 7 pages)
7. Illustrative Activity MERL Plan

(a) Cover Page (1 page, not included in page limit)

The cover letter should include the following:

- Name of the organization(s) submitting the application.

- Identification and signature of the primary contact person (by name, title, organization, mailing address, telephone number and email address) and the identification of the alternate contact person (by name, title, organization, mailing address, telephone number and email address).
- Program name
- Notice of Funding Opportunity number
- Name of any proposed sub-recipients or partnerships (identify if any of the organizations are local organizations, per USAID's definition of 'local entity' under ADS 303.

(b) Table of Contents (not included in the page limit)

Include major sections and page numbering to easily cross-reference and identify merit review criteria.

(c) Acronym List (not included in the page limit)

Include all acronyms used in the application.

(d) Executive Summary (1-2 pages, included in the page limit)

This section must provide a succinct summary of the application as a whole and should contain the information the applicant believes best represents its proposed project. This may include an overview of the proposed technical approach, expertise, experience of the prime applicant and its proposed partners/subawardees, overall project management approach, and technical/managerial resources to achieve the proposed project.

(e) Technical Approach - Factor 1 (14 page maximum)

Provide a technical narrative outlining your understanding and approach to achieving the strategic objectives and results listed in the Program Description in Section A of the RFA. The approach must be feasible, innovative, and contribute to sustainability. The applicant must describe the technical expertise and capabilities of the proposed applicant, and consortium members and/or sub-awardees, if any.

<u>Overall Technical Understanding and Approach</u>

- Describe how your proposed approach contributes towards accomplishing the strategic objectives and results presented in this funding opportunity, focusing on what is technically and politically feasible within five years of the program.
- Describe your approach to achieving all relevant IRs inclusive of any proposed components specific to this NOFO and the proposed technical approach over the life of the five-year project.

- Articulate your proposed activities to accomplish the strategic objectives and results presented in the Funding Opportunity Description, focusing on what is technically and politically feasible within the five years of the program. You should not merely repeat what is already described in the program description but describe how you and your resources propose to achieve the program purpose and results, detailing the results to be achieved and methodologies employed.
- Describe how you will support the incorporation of HIV services at the PHC level, including the use of existing data and efforts to enhance measurement and learning, with a focus on the program goal, strategic objectives, results, and IRs described in Section A of this NOFO.
- Describe your proposed approach to global, regional, and local partnerships and collaboration to ensure IRs are met.
- Articulate how you might adapt and tailor approaches for different contextual needs, such as: working towards sustainability of interventions that are age-appropriate and context specific and vary depending on the local epidemic, health system, and by population.

<u>Monitoring, Evaluation, Research and Learning and Knowledge Management</u>

Demonstrate how monitoring, evaluation, research, and learning (MERL) and knowledge management (KM) will be incorporated throughout implementation. This section should provide an overview of the MERL and KM activities incorporated in the proposed technical approach, focusing on a) ensuring timely evidence use and adaptive management within the program, b) supporting and aligning with country monitoring and evaluation priorities, and c) enhancing the delivery of HIV services at the PHC level.

- Describe key priorities and potential challenges in measurement and evaluation of global and country-level project results and provide examples of how those challenges might be overcome within program activities.

- Describe key learning questions, approaches, and priorities to drive program MERL and KM, including rapid and timely methods for incorporating and applying program learning to strengthen program adaptation, enhance the incorporation of HIV services into primary healthcare programs , and support effective knowledge generation, synthesis, dissemination, and utilization. Describe how data and knowledge will be developed, analyzed and applied.

- Provide an illustrative Activity MERL Plan (as an annex, not included in the page count) for the proposed project, to describe the monitoring, evaluation, research and learning metrics, approaches, and strategies across core- and field support-funded activities, including how both quantitative and qualitative MERL will be incorporated in different types of implementation contexts, and how performance will be measured.

(f) Management and Institutional Capabilities - Factor 2 (9 page maximum)

Provide an overview of the management approach in response to this NOFO. Provide a management approach consistent with the complexity of the proposed technical approach, addressing the ability to manage a) overall operations; b) global and regional implementation approaches or collaborations; c) country or technical area-specific approaches aligned with Mission buy-ins; d) potential capacity strengthening of local organizations; and d) partnerships with local organizations or groups, each bringing a particular set of experiences and expertise that would contribute to the accomplishment of the activities undertaken, and the strategic objectives and results within this NOFO. The overview should include the management process for responding to timely central investments or Mission buy-ins. You should highlight those areas of program management *not* discussed in other sections. A draft startup plan will be an annex to this section (described below).

Activity Start-Up Plan (Annex, 7 pages maximum)

Provide an effective and feasible approach for mobilizing and staffing the project over the initial two months following award at both country and global levels. This plan must:

- Describe a schedule and plan for mobilizing the project over the initial two months following award, including but not limited to timely availability of staff, submission of required work plans and documents, plan for collaboration with USAID teams, and other factors.
- Indicate how you will be able to rapidly prepare for and initiate timely activities across at least three country contexts during the immediate months after award (assuming funding availability) while simultaneously addressing general program start-up needs.
- Incorporate principles of flexibility and adaptive management as appropriate.

Management Plan and Organizational Chart

This narrative section must detail a management structure and approach that ensures the efficient use of resources, effective and adaptive management, strong technical implementation, and high-quality administrative and financial support. You must explain the management structure presented in the consortium-wide organogram.

- Describe the proposed principal consortia partners and justification for their selection. The justification should include how they will contribute to achieving the activity's purpose and results and successfully implementing the proposed technical approach. Describe the agreed-upon roles and responsibilities of these partners in executing the proposed technical approach.
- Any formal arrangements for a consortium and with partner organizations and subawardees must be indicated.
- Describe strategies for ensuring effective and optimal use of all proposed principal and resource partners while maximizing the cohesion of overall project

activities and collaboration. Include a feasible and concise plan for effective coordination and technical engagement among all partners. This should incorporate and engage subrecipients as partners in the design and implementation of activities, including through co-creation of scopes of work with partners to the extent feasible.

- Describe strategies for providing oversight and support as the Applicant to proposed partners/subawardees. Describe internal management and operational plans and approaches for new and local partner capacity-building, as appropriate.
- Describe internal management strategies for ensuring effective communication and collaboration, including how you will develop clear lines of communication between activity staff, partners, and USAID. While USAID does not have or aspire to legal relationships with subrecipients, where appropriate and feasible, partners should be present when USAID is interacting with the prime.
- Describe your operational approaches for assurance of timely and accurate management, disbursement, and reporting of multiple funding streams. Demonstrate experience in critical capacities, including management of operations across various stakeholders, operating units, and financial streams, including managing federal award funding across multiple funding streams and buy-ins.

<u>Institutional and Consortium Capabilities</u>

Through the narrative and experiences described, provide information on the following:

- The institutional capabilities of your organization and any proposed principal consortia partners, including the array of technical skills or characteristics in prime and/or in the consortia, and how these combined capabilities will effectively and efficiently support the achievement of HARMONIZE's purpose and IRs and the proposed technical approach.

- Your relevant experiences within the last five years in implementing comprehensive programs of similar size and scope in LMICs, including:

  1) The name, award number, and dollar value of any relevant awards.

  2) The role of the applicant (prime or subawardee) in those awards.

  3) The relevancy of any such experiences to this proposed activity.

  4) In those experiences, how the applicant worked to ensure quality of implementation (including consistency in meeting goals and targets) and technical expertise; maintained schedule (including timeliness of performance) and cost control; and managed business relations, partnership development, management of sub-awards, and working with new/local partners.

- Your relevant experience in forming strong collaborative partnerships with a range of donors, implementing partners, governments, and partner country organizations, among others; and
- A summary of the relevant experiences of the proposed principal consortia partners for the last five years, including:

  1) Their past roles (prime or subawardee) in relevant awards.

  2) The relevancy of their experiences to this proposed activity.

  3) That their technical (and managerial, if relevant) contributions were to the results achieved in those activities.

Consortium-Wide Organogram (Annex)

Include one consortium-wide organogram (as an Annex) with a visual representation of the structure and relationships across your organization as the prime, principal consortia partners, and/or resource partners proposed. The organogram should indicate proposed roles and responsibilities, lines of authority, and reporting within the project, including technical and administrative duties.

- If proposed, include as an annex the list of potential resource partners.

(g) Staffing Approach and Key Personnel (3 pages maximum)

The Technical Application should describe a functional management plan for the proposed project, including sub-award structures; partnership coordination; technical, financial, and administrative management and oversight; oversight of design, development, and implementation of pre-clinical and clinical research.The Applicant will provide a detailed organogram (no more than 3 pages) in the Appendix with an explanation of the proposed and management relationship required to implement the Technical Approach. Additionally, this should also include a staffing plan which lists and describes Key Personnel and other staffing proposed with LOE, name of individuals, and their institutional affiliation (whenever possible), and roles and responsibilities. The Applicant will provide a staffing matrix in the Appendix with position titles, names of proposed individuals, roles, LOE, and institutional affiliation (no more than three pages). Please see Appendix for more information.

Key Personnel

The applicant may propose up to five total key personnel positions, but the following four are considered essential:

- The **Project Director** will be responsible for coordinating all project activities and staff. They will be responsible for technical leadership and administrative oversight of the program and will serve as the principal institutional liaison to USAID. The PD must have strong leadership qualities and depth and breadth of technical and management expertise. The required attributes of the Project Director are: a senior manager with a degree in public health, social sciences, international development, or a related field and at least 10 years of experience with a master's degree or 12 years of experience with a bachelor's degree and experience leading, managing and implementing large-scale international or national PEPFAR-funded HIV/AIDS prevention, care, and treatment programs in developing countries. Supervisory experience and HR and program management experience required. Management experience with a USG cooperative agreement is preferred. Strong interpersonal, writing, and oral presentation skills in English are also required.
- The **Senior HIV Advisor** reports directly to the Project Director and provides technical leadership to support incorporating vertical HIV programming into PHC. They will have deep knowledge of HIV service delivery and at least 10 years of experience designing, managing, and/or implementing HIV prevention, care, and treatment programs. The incumbent will also have experience and expertise in one or more areas: health systems strengthening, linking facility and community services, differentiated service delivery, quality improvement, and monitoring and evaluation.
- The **Senior Health Systems Strengthening Advisor** reports to the Project Director and provides technical leadership to support strengthening health systems for incorporating HIV services into PHC. They will have at least ten years of experience managing and implementing public health programs with an emphasis on health systems strengthening. In addition to HIV/AIDS, the incumbent will have technical knowledge in one or more of the following areas: family planning, maternal/child health, malaria, tuberculosis, public health service delivery programs and systems in developing countries, resource-challenged settings, and/or complex environments.
- The **Senior Health Services Delivery Advisor** reports to the Project Director and provides thought leadership related to comprehensive health service delivery. They will have at least 10 years of experience and expertise in primary health care delivery at facilities and communities, monitoring and evaluation, quality improvement, and developing client-centered, equitable health implementation approaches. Experience in one or more of the following health areas in addition to HIV is required: MNCH, FP/SRH, TB, NCD, GBV, MH, Malaria, and Nutrition.
- The **Senior Social and Behavior Change Advisor** will report to the Project Director and provide strategic direction and leadership to strengthen SBC and SBC monitoring, evaluation, and research capacity. They will have at least 10 years of experience and expertise in human-centered design, marketing, SBC, and behavioral economics and demonstrated ability and experience in designing,

implementing, and evaluating SBC programs. Experience in one or more health areas is required: HIV, MNCH, FP/SRH, TB, NCD, GBV, MH, Malaria, and Nutrition.

- The **Senior Global Health Security Advisor** will report to the Project Director and ensure the successful implementation of global health security-related activities under HARMONIZE. The incumbent will have 10 years of progressive experience in infectious diseases programming. Experience providing technical oversight, managing, designing, and implementing infectious diseases programs with a focus on surveillance of emerging infectious diseases is required.

In this narrative section, you must:

- Identify key personnel by name and position.
- Summarize key personnel qualifications, including, but not limited to, institutional, management, technical, and geographic skills, experience, and education.
- Describe how key personnel, in total, complement each other to achieve project objectives, including across the diversity of their combined institutional, management, technical, and geographic experience. Diversity of institutional, technical, management, and geographic experience across key personnel and other senior project staff is strongly encouraged by USAID.
- Include brief statements of major duties for each of the key personnel proposed.
- Demonstrate, collectively across the key personnel, strong project and personnel management skills, innovation, flexibility in technical practice and/or management, the ability to network and collaborate effectively with a wide range of stakeholders, and strong communication skills.

Please note that USAID reserves the right to verify the expertise and attributes of proposed staff, in part through previous performance and references provided in the technical application, and through contact of references other than those provided in the application. USAID reserves the right to contact references other than those identified in the application.

In the Technical Application Annexes, you must include a signed letter of intent from each proposed key personnel stating that they are:

1) Available within one month of project start-up and

2) Will participate for at least two (2) years post-award. Additionally, CVs/Resumes for each of the key personnel must be included in the Technical Application Annexes, and the Annexes must include at least three references for each key personnel.

(h) Technical Application Annexes (not included in the overall 30-page limit)

- Consortium-Wide Organogram.

- CVs/Resumes of Proposed Key Personnel & References (no more than 3 pages per proposed Key Personnel). Letters of intent for key personnel may be included beyond the 3-page limit for the CVs and references.
- Signed Letters of Intent to Collaborate from Each Principal Consortia Partner
- Staffing Roster.
- List of Potential Resource Partners (if proposed).
- Activity Start-Up Plan (no more than 7 pages).
- Illustrative Activity MERL Plan.

2. Business Application Format

The Business Application must be submitted separately from the Technical Application. While no page limit exists for the full Business application, applicants are encouraged to be as concise as possible while still providing the necessary details. The Business Application must reflect the entire period of performance, all costs associated with activities included in the technical application (including those to be financed by cost share, or any other non-Federal funding source), and include the required and completed SF-424 Standard Forms. Applicants should ensure that any required supporting documentation identified in the Budget and Budget Narrative instructions below is included in an annex.

Prior to award, applicants may be required to submit additional documentation deemed necessary for the Agreement Officer to assess the applicant's risk in accordance with 2 CFR 200.206. Applicants should not submit any additional information with their initial application.

The Business Application must contain the following sections:

- Cover Page
  The cover letter should include the following:

  - Name of the organization(s) submitting the application.
  - Identification and signature of the primary contact person (by name, title, organization, mailing address, telephone number, and email address) and the identification of the alternate contact person (by name, title, organization, mailing address, telephone number, and email address).
  - Program name.
  - Notice of Funding Opportunity number.
  - Name of any proposed sub-recipients or partnerships (identify if any of the organizations are local organizations, per USAID's definition of 'local entity' under ADS 303.
  - SF 424 Application and Budget Form.

The applicant must sign and submit the following forms from the Standard Form (SF) 424 series. Standard Forms and their accompanying instructions can be accessed electronically at https://www.grants.gov/forms/forms-repository/sf-424-family (use the "Grants.gov" forms). This includes the submission of the:

- Application for Federal Assistance (SF-424).
- Budget Information for Non-Construction Programs (SF-424A).

Applicants should carefully review the official Grants.gov instructions for completing each Standard Form. Failure to accurately complete these forms could result in the rejection of the application.

a) Required Certifications and Assurances

The applicant must complete the following documents and submit a signed copy with their application OR upon request by the AO:

(1) "Certifications, Assurances, Representations, and Other Statements of the Recipient" ADS 303mav document found at https://www.usaid.gov/ads/policy/300/303mav

(2) Assurances for Non-Construction Programs (SF-424B) found at https://www.grants.gov/forms/forms-repository/sf-424-family (use the "Grants.gov" form)

(3) Certificate of Compliance: If applicable, U.S. NGOs may submit a copy of the Certificate of Compliance if the organization's systems have been certified by USAID/Washington's Office of Acquisition and Assistance (M/OAA).

b) Budget and Budget Narrative

The Budget must be submitted as one unprotected Excel file (MS Office 2000 or later versions) with visible formulas and references and must be broken out by program year, including itemization of the federal and non-federal (e.g., cost share, matching, or leverage) amounts. Files must not contain any hidden or otherwise inaccessible cells. Budgets with hidden cells lengthen the cost analysis time required to make an award and may result in a rejection of the Business Application.

The Budget Narrative must be submitted as a separate Word of PDF file and must contain sufficient detail to allow USAID to understand the proposed costs. The applicant must ensure the budgeted costs address all programmatic and administrative activities described in the Technical Application and specifically address any additional requirements identified in the solicitation (e.g., Branding and Marking, PSEA compliance, etc.). The Budget Narrative must be thorough, including sources, descriptions, and

rationales for costs to support USAID's determination that the proposed costs are reasonable, allocable, and allowable in accordance with the Cost Principles in 2 CFR 200, Subpart E. Applicants should ensure the Budget and Budget Narrative are consistent with and reflect all activities included in the Technical Application.

The Budget must include the following worksheets or tabs, and contents, at a minimum:

- Summary Budget, inclusive of all program costs (federal and non-federal), broken out by major budget category and by year for the entire period of the program. The Summary Budget should reflect all proposed activities to be implemented by the applicant and any potential subrecipients and should facilitate completion of the SF-424A (i.e., the Summary Budget and SF 424A major budget categories must match). See Annex 1 for Summary Budget Template.
- Detailed Budget, including a breakdown of each major budget category by year for the entire period of the program, sufficient to allow the Agency to determine that the costs accurately reflect the proposed program activities and represent a realistic and efficient use of funding.
- Detailed Budgets for each subrecipient, inclusive of all program costs (federal and non-federal), broken out by major budget category and by year for the entire period of the program,

The Detailed Budget must contain the following major budget categories and information, at a minimum:

1) Personnel – Costs of employee salaries and wages must be proposed consistent with 2 CFR 200.430 Compensation - Personal Services and the applicant's established policies and practices for similar work. The applicant's Budget must include position title, base salary rate, level of effort, and salary escalation factors for each position. The AO may request an apparently successful applicant's established written policies on personnel compensation. Applicants must explain all assumptions in the Budget Narrative. If the applicant's written policies do not address a specific element of compensation that is being proposed, the Budget Narrative must describe the rationale used and supporting market research. *Applicants should not include the personnel costs of consultants, contractors, or subrecipients under this category*.

2) Fringe Benefits – Costs of employee fringe benefits must be proposed consistent with 2 CFR 200.431 Compensation - Fringe Benefits, as required by applicable law, and in accordance with the applicant's established policies and practices. Fringe benefits include allowances and services provided by employers to their employees in addition to regular salaries and wages (e.g., paid leave, health insurance, retirement, etc.). The applicant's Budget and Budget Narrative must include a detailed breakdown of all proposed fringe benefits along with a description of how costs are calculated (e.g., as a percentage of salary, as a per-person expense, etc.). *Only fringe benefits that will be recovered as direct costs should be included in this category;*

applicants with a negotiated indirect cost rate agreement (NICRA) that includes a fringe benefit rate must include indirect fringe costs under the "Indirect Charges" category.

3) Travel – Travel and transportation costs must be proposed consistent with 2 CFR 200.475 Travel Costs and in accordance with the applicant's established policies and practices. Travel costs may include program-related transportation, lodging, or subsistence for applicant employees (e.g., flights, hotels, per diem, etc.). The applicant's Budget must breakdown individual travel costs and the Budget Narrative must provide details to explain the travel costs (e.g., purpose and number of trips, mode of transportation, the origin and destination, the number of individuals traveling, the duration of the trips, estimated unit costs, etc. The AO may request an apparently successful applicant to provide supporting documentation (e.g., company travel policy, quotation, etc.).

4) Equipment - Costs must be proposed consistent with the definitions of equipment, capital assets, and personal property (tangible) in 2 CFR 200.1, with 2 CFR 200.313 Equipment and 200.439 Equipment and Other Capital Expenditures, and with the applicant's established accounting practices (e.g., capitalization level for financial statement purposes). The applicant's Budget must provide a breakdown of individual equipment costs, including type, quantity, and unit cost. The Budget Narrative must include information on models/specifications, the purpose of the equipment, and the basis for the quantity and cost estimates. The Budget Narrative must support the necessity of any equipment purchase in light of such factors as: rental costs of comparable equipment, if any; market conditions in the area; alternatives available; and the type, life expectancy, condition, and value of the equipment.

5) Supplies - Costs must be proposed consistent with the definitions of supplies and personal property (tangible) in 2 CFR 200.1 and the applicant's established accounting practices. Supplies are defined as all tangible personal property other than those described in the definition of equipment. The applicant's Budget must provide a breakdown of individual supplies, including type, quantity, and unit cost. The Budget Narrative must include information on specifications, the purpose of the supplies, and the basis for the quantity and cost estimates. The Budget Narrative must support the necessity and reasonableness of any supply purchases.

6) Contractual – Costs in this category must include all contracts (except those for individual consultants and those already included under "Equipment," "Supplies," or "Construction") and all subawards. This includes rental and lease agreements for equipment or real property. See 2 CFR 200.331 for assistance regarding subrecipient and contractor determinations. Contractor and subrecipient budgets should reflect the same major budget categories and include budget narratives with the same required information as detailed in this Budget and Budget Narrative section of the Business Application Format instructions. *Applicants should not include the costs for*

individual consultants in this category; consultant costs should be included under "Other".

7) Construction – Limited construction activities are authorized under this award to facilitate the potential colocation and alignment of services. This may include structural modifications, such as removing or adding walls, to create an environment that supports the incorporation of HIV services within the broader health system. Additionally, infrastructure improvements, such as upgrades to primary mechanical, electrical, or other building systems, may be necessary to enhance functionality and efficiency. No construction activities other than those explicitly approved by the Agreement Officer on a case-by-case basis may be performed as part of the cooperative agreement.

8) Other – Applicants should include any other direct costs associated with the proposed program that are not already captured under another cost category (e.g., costs related to individual consultants, report publication/printing costs, training/event/activity costs, staff development, or administrative expenses not recovered via "Indirect Charges"). The applicant's Budget must provide a breakdown of all other expenses in this category, including type, quantity, and unit cost. The Budget Narrative must provide supporting information on the rationale and reasonableness for each proposed expense and the basis for the proposed quantity and unit cost estimates. *For applicants electing to recover all administrative costs directly (i.e., to follow "Method 1" described below to allocate a portion of shared "overhead" or "indirect" costs directly to the program), these cost elements must be itemized under this category and the applicant must explain the allocation basis for each.*

9) Indirect Charges – Applicants must include all indirect costs under this category. Applicants may recover indirect costs via one of the Methods listed below, depending on applicant preference, eligibility, and the approval of the AO. The applicant must identify the selected Method and reflect this in the Budget and Budget Narrative, providing the applicable supporting information, as required. For more information on indirect costs and cost recovery, see **2 CFR 200 Subpart E** and refer to USAID's Indirect Cost Rate Guide for Non Profit Organizations for further guidance. Options for indirect cost recovery include:

- Method 1 - Direct Charge Only (i.e., direct cost allocation)
  Eligibility: Any applicant that does not have or intend to propose a NICRA (see Method 2) or use a de minimis rate on U.S. Federal awards (Method 3).

  Application Requirements: **All costs must be reflected under the "Other" cost category**. See the instructions above on how to reflect allocated "administrative/indirect" costs in the Budget and what supporting information must be provided as part of the Budget Narrative.

- Method 2 - Negotiated Indirect Cost Rate Agreement (NICRA)
  Eligibility: Any applicant with a NICRA issued by a USG Agency or any applicant intending to propose NICRA rate(s) for use under this (and all other) Federal awards.
    - Applicants with a current NICRA must apply those rate(s) or provide a formal letter explaining the use of lower rates (see Appendix V of USAID's Indirect Cost Rate Guide for Non Profit Organizations for a sample letter).
    - Applicants intending to negotiate a NICRA must be able to demonstrate adequate financial and administrative systems, policies, and practices (see Sections 2-3 of USAID's Indirect Cost Rate Guide for Non Profit Organizations for more information on requirements, process, and timelines).

  Application Requirements: Applicants with a current NICRA must include a copy as an annex to the Budget Narrative. If the NICRA was issued by an Agency other than USAID, provide the contact information for the approving Agency. Applicants intending to negotiate a NICRA must include proposed provisional rate(s) in the Budget and must submit an initial indirect cost rate proposal to support proposed rates. Note: Applicants should carefully review USAID's Indirect Cost Rate Guide for Non Profit Organizations to ensure they meet eligibility requirements, can provide all required supporting documentation for a NICRA, and understand the timeline and steps in the process.

- Method 3 - De minimis rate of up to 15 percent of modified total direct costs (MTDC)
  Eligibility: Any applicant, except applicants with a NICRA

  Application Requirements: Applicants may determine the appropriate rate up to the 15 percent limit. The de minimis rate does not require documentation to justify its use and may be used indefinitely. Organizations electing to use the de minimis rate must ensure the same rate (up to 15 percent) is used for all Federal awards until and unless the organization chooses to apply for a NICRA. The applicant must describe in the Budget Narrative which cost elements it will charge directly vs. indirectly and reflect this in the budget. Costs must be consistently charged as either direct or indirect costs and may not be double charged or inconsistently charged as both. See 2 CFR 200 for further information.

- Method 4 - Indirect Costs Charged as a Fixed Amount
  Eligibility: Non-U.S. nonprofit organizations without a NICRA electing not to use direct cost allocation (Method 1) or the de minimis rate (Method 3)

  Application Requirements: Applicants must provide the proposed fixed amount and a supporting worksheet that includes the following:

- Total costs (i.e., direct and indirect) incurred by the organization for the previous fiscal year and estimates for the current year.
- Total indirect costs incurred (e.g., costs necessary for the day-to-day operations of the organization that were not recovered directly as cost line items under awards) for the previous fiscal year and estimates for the current year. Review USAID's Indirect Cost Rate Guide for Non Profit Organizations for more information on indirect costs.
- Proposed method for prorating total estimated indirect costs equitably and consistently across all programs and activities. This includes describing the allocation base for each indirect cost element that reasonably corresponds to the benefits of that particular cost element to each program or activity. Review USAID's Indirect Cost Rate Guide for Non Profit Organizations for more information on approaches to allocating indirect costs equitably across multiple programs/cost objectives.

If the applicant does not have a NICRA and requests to use Method 2 (NICRA) or Method 4 (Fixed Amount), the Agreement Officer will provide further instructions and may request additional supporting information, including financial statements and audits, should the application still be under consideration after the merit review.

c) Prior Approvals in accordance with 2 CFR 200.407

Cost principles specifically require Agency written prior approval for certain items of cost. For these items, simply including the item in the detailed budget does not satisfy the requirement for Agency prior approval. To request that such an item be approved in an award, the applicant must include an explicit request for its approval in the Budget Narrative.. Note that any such approval is at the Agreement Officer's discretion and such approval may not be granted at the time of award. See 2 CFR 200.407 for information regarding which cost elements require prior written approval.

d) Approval of Subaward Activities

The applicant must submit the following information for each subaward that it wishes to have approved at the time of award:

- Name of prospective subrecipient organization
- Subrecipient organization's UEI, unless exempted under 2 CFR 25.110 (see Section E – Submission Requirements and Deadline for more information).
- Confirmation that the subrecipient does not have active exclusions in the System for Award Management (www.SAM.gov)
- Confirmation that the subrecipient does not appear on the U.S. Treasury Department's Office of Foreign Assets Control (OFAC) Specially Designated Nationals (SDN) and Blocked Persons list (https://sanctionslist.ofac.treas.gov/Home/SdnList)

- Confirmation that the subrecipient is not listed in the United Nations Security Council Consolidated list (https://main.un.org/securitycouncil/en/content/un-sc-consolidated-list)
- Confirmation that the applicant has completed a risk assessment of the subrecipient, in accordance with 2 CFR 200.332(c); including any negative findings as a result of the risk assessment and the applicant's plan for mitigation.

e) History of Performance

The applicant must provide information regarding its recent history of performance for all its cost-reimbursement or fixed price contracts, grants, or cooperative agreements, including any fixed amount awards involving similar or related programs, not to exceed five years, as follows:

- Name of the awarding organization (e.g., funder)
- Award number, if any
- Activity title
- A brief description of the activity
- Period of performance (e.g., start and end dates)
- Award amount
- Reports and findings from any audits performed in the last five years
- Names and contact information (including current telephone number and e-mail address) of at least two (2) professional contacts who most directly observed the work performed.

If the applicant encountered problems when implementing any of the awards listed, it may provide a short explanation and the corrective action taken. The applicant should not provide general information on its performance. USAID reserves the right to obtain relevant information concerning an applicant's history of performance from any sources and may consider such information in its review of the applicant's risk. The Agency may request additional information and conduct a pre-award survey if it determines that it is necessary to inform the risk assessment.

f) Branding Strategy & Marking Plan

The apparently successful Applicant is required to comply (and ensure compliance by partners) with USAID's branding and marking requirements set forth in 2 CFR 700.16 and ADS 320. These regulations and provisions include the requirement for the apparently successful Applicant to submit a Branding Strategy/Marking Plan (BS/MP) for pre-award review, negotiation, and approval by the AO. Under these regulations and provisions, the BS/MP does not need to be submitted until the Applicant is notified by the AO that it is the apparently successful Applicant and is requested to submit the BS/MP by a time specified by the AO.

Thus, the initial application is not required to include a BS/MP. Nevertheless, Applicants are encouraged, but are not required, to submit their BS/MP with their initial cost/business applications. Applicants who choose not to include their BS/MP with their initial cost/business application will not be penalized during the evaluation process, but should be aware that, if the Applicant is the apparently successful Applicant, the Applicant will be required to submit an acceptable BS/MP as a prerequisite for any resulting award. This would delay any such award, pending receipt, review, and, if necessary, negotiation of the Applicant's BS/MP. Moreover, because USAID's branding and marking requirements have cost implications, such costs must be included in the detailed budget even if the Applicant does not submit its BS/MP with the initial cost/business application.

Failure to submit or negotiate a BS/MP within the time specified by the AO may make the Apparently Successful Applicant ineligible for award. The AO shall review for adequacy the proposed BS/MP, and will negotiate, approve, and include the BS/MP in the award.

1. Branding Strategy – Assistance (October 2024)

A. Applicants recommended for an assistance award must submit and negotiate a "Branding Strategy," describing how the program, project, or activity is named and positioned, and how it is promoted and communicated to beneficiaries and host country citizens.

B. The request for a Branding Strategy, by the Agreement Officer from the applicant, confers no rights to the applicant and constitutes no USAID commitment to an award.

C. If the Notice of Funding Opportunity indicates that the apparently successful applicant may submit a Branding Strategy after the award is made, the resultant award will include a special award condition indicating the required submission date. If the Notice of Funding Opportunity requires submission before award, failure to submit and negotiate a Branding Strategy within the specified time frame will make the applicant ineligible for the award.

D. The applicant must include all estimated costs associated with branding and marking USAID programs, such as plaques, stickers, banners, press events, materials, and so forth, in the budget portion of the application. These costs are subject to the revision and negotiation with the Agreement Officer and will be incorporated into the Total Estimated Amount of the grant, cooperative agreement or other assistance instrument.

E. The Branding Strategy must include, at a minimum, all of the following:

(1) All estimated costs associated with branding and marking USAID programs, such as plaques, stickers, banners, press events, materials, and so forth.

(2) The intended name of the program, project, or activity.

(i) USAID requires the applicant to use the "USAID Identity," comprised of the USAID logo and brandmark, with the tagline "from the American people" as found on the USAID Web site at http://www.usaid.gov/branding, unless the Notice of Funding Opportunity states that the USAID Administrator (or delegate) has approved the use of an additional or substitute logo, seal, or tagline.

(ii) USAID prefers local language translations of the phrase "made possible by (or with) the generous support of the American People" next to the USAID Identity when acknowledging contributions.

(iii) It is acceptable to cobrand the title with the USAID Identity and the
applicant's identity.

(iv) If branding in the above manner is inappropriate or not possible, the
applicant must explain how USAID's involvement will be showcased during publicity for the program or project.

(v) USAID prefers to fund projects that do not have a separate logo or
identity that competes with the USAID Identity. If there is a plan to develop a separate logo to consistently identify this program, the applicant must attach a copy of the proposed logos. The Notice of Funding Opportunity will state if an Administrator (or delegate) approved the use of an additional or substitute logo, seal, or tagline.

(3) The intended primary and secondary audiences for this project or program, including direct beneficiaries and any special target segments.

(4) Planned communication or program materials used to explain or market the program to beneficiaries that:

(i) Describe the main program message.

(ii) Provide plans for training materials, posters, pamphlets, public service announcements, billboards, Web sites, and so forth, as appropriate.

(iii) Provide any plans to announce and promote publicly this program or project to host country citizens, such as media releases, press conferences, public events, and so forth. Applicants must incorporate the USAID Identity and the message, "USAID is from the American People."

(iv) Provide any additional ideas to increase awareness that the American people support this project or program.

(5) Information on any direct involvement from host-country government or ministry, including any planned acknowledgement of the host-country government.

(6) Any other groups whose logo or identity the applicant will use on program materials and related materials. Indicate if they are a donor or why they will be visibly acknowledged, and if they will receive the same prominence as USAID.

F. The Agreement Officer will review the Branding Strategy to ensure the above information is adequately included and consistent with the stated objectives of the award, the applicant's cost data submissions, and the performance plan.

G. The Branding Strategy will be included in and made part of the resulting grant or cooperative agreement.

2. Marking Plan – Assistance (October 2024)

A. Applicants recommended for an assistance award must submit and negotiate a "Marking Plan," detailing the public communications, commodities, and program materials, and other items that will visibly bear the "USAID Identity," which comprises of the USAID logo and brandmark, with the tagline "from the American people." The USAID Identity is the official marking for the Agency and is found on the USAID Web site at http://www.usaid.gov/branding. The Notice of Funding Opportunity will state if an Administrator (or delegate) approved the use of an additional or substitute logo, seal, or tagline.

B. The request for a Marking Plan, by the Agreement Officer from the applicant, confers no rights to the applicant and constitutes no USAID commitment to an award.

C. If the Notice of Funding Opportunity indicates that the apparently successful applicant may submit a Marking Plan after the award is made, the resultant award will include a special award condition indicating the required submission date. If the Notice of Funding Opportunity requires submission before award, failure to submit and negotiate a Marking Plan within the specified timeframe will make the applicant ineligible for the award.

D. The applicant must include all estimated costs associated with branding and marking USAID programs, such as plaques, stickers, banners, press events, materials, and so forth, in the budget portion of the application. These costs are subject to the revision and negotiation with the Agreement Officer and will be incorporated into the Total Estimated Amount of the grant, cooperative agreement or other assistance instrument.

E. The Marking Plan must include all of the following:

(1) A description of the public communications, commodities, and program materials that the applicant plans to produce and which will bear the USAID Identity as part of the award, including:

(i) Program, project, or activity sites funded by USAID, including visible infrastructure projects or other sites physical in nature;

(ii) Technical assistance, studies, reports, papers, publications, audio-visual productions, public service announcements, Web sites/Internet activities, promotional, informational, media, or communications products funded by USAID;

(iii) Commodities, equipment, supplies, and other materials funded by USAID, including commodities or equipment provided under humanitarian assistance or disaster relief programs; and

(iv) It is acceptable to cobrand the title with the USAID Identity and the applicant's identity.

(v) Events financed by USAID, such as training courses, conferences, seminars, exhibitions, fairs, workshops, press conferences and other public activities. If the USAID Identity cannot be displayed, the

recipient is encouraged to otherwise acknowledge USAID and the support of the American people.

(2) A table on the program deliverables with the following details:

(i) The program deliverables that the applicant plans to mark with the USAID Identity;

(ii) The type of marking and what materials the applicant will use to mark the program deliverables;

(iii) When in the performance period the applicant will mark the program deliverables, and where the applicant will place the marking;

(iv) What program deliverables the applicant does not plan to mark with the USAID Identity, and

(v) The rationale for not marking program deliverables.

(3) Any requests for an exemption from USAID marking requirements, and an explanation of why the exemption would apply. The applicant may request an exemption if USAID marking requirements would:

(i) Compromise the intrinsic independence or neutrality of a program or materials where independence or neutrality is an inherent aspect of the program and materials. The applicant must identify the USAID Development Objective, Interim Result, or program goal furthered by an appearance of neutrality, or state why an aspect of the award is presumptively neutral. Identify by category or deliverable item, examples of material for which an exemption is sought.

(ii) Diminish the credibility of audits, reports, analyses, studies, or policy recommendations whose data or findings must be seen as independent. The applicant must explain why each particular deliverable must be seen as credible.

(iii) Undercut host-country government “ownership” of constitutions, laws, regulations, policies, studies, assessments, reports, publications, surveys or audits, public service announcements, or other communications. The applicant must explain why each particular item or product is better positioned as a host-country government item or product.

(iv) Impair the functionality of an item. The applicant must explain how marking the item or commodity would impair its functionality.

(v) Incur substantial costs or be impractical. The applicant must explain why marking would not be cost beneficial or practical.

(vi) Offend local cultural or social norms, or be considered inappropriate. The applicant must identify the relevant norm, and explain why marking would violate that norm or otherwise be inappropriate.

(vii) Conflict with international law. The applicant must identify the applicable international law violated by the marking.

F. The Agreement Officer will consider the Marking Plan's adequacy and reasonableness and will approve or disapprove any exemption requests. The Marking Plan will be reviewed to ensure the above information is adequately included and consistent with the stated objectives of the award, the applicant's cost data submissions, and the performance plan.

G. The Marking Plan, including any approved exemptions, will be included in and made part of the resulting grant or cooperative agreement, and will apply for the term of the award unless provided otherwise.

g) Funding Restrictions

Profit is not allowable for recipients or subrecipients under this award.

Limiting construction activities is authorized under this award to facilitate the potential colocation and alignment of services. This may include structural modifications, such as removing or adding walls, to create an environment that supports the incorporation of HIV services within the broader health system. Additionally, infrastructure improvements, such as upgrades to primary mechanical, electrical, or other building systems, may be necessary to enhance functionality and efficiency. No construction activities other than those explicitly approved under the agreement may be performed as part of the cooperative agreement.

USAID will not allow the reimbursement of pre-award costs under this award without the explicit written approval of the Agreement Officer.

h) Conscience Clause

CONSCIENCE CLAUSE IMPLEMENTATION (ASSISTANCE) (FEBRUARY 2012)

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

(a) Shall not be required, as a condition of receiving such assistance—

(1) To endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS; or

(2) 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

(b) 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.

Condoms (Assistance) (September 2014)

Information provided about the use of condoms as part of projects or activities that are funded under this agreement shall be medically accurate and shall include the public health benefits and failure rates of such use and shall be consistent with USAID's fact sheet entitled "USAID HIV/STI Prevention and Condoms". This fact sheet may be accessed at:

http://www.usaid.gov/sites/default/files/documents/1864/condomfactsheet.pdf

The prime Recipient must flow this provision down in all subawards, procurement contracts, or subcontracts for HIV/AIDS activities.

Prohibition on the Promotion or Advocacy of the Legalization or Practice of Prostitution or Sex Trafficking (Assistance) (September 2014)

(a) The U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons. None of the funds made available under this agreement may be used to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post- exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.

(b)(1) Except as provided in (b)(2), by accepting this award or any subaward, a nongovernmental organization or public international organization awardee/subawardee agrees that it is opposed to the practices of prostitution and sex trafficking.

(b)(2) The following organizations are exempt from (b)(1): (i) the Global Fund to Fight AIDS, Tuberculosis and Malaria; the World Health Organization; the International AIDS Vaccine Initiative; and any United Nations agency. (ii) U.S. non-governmental organization Recipients/subrecipients and contractors/subcontractors. (iii) Non-U.S. contractors and subcontractors if the contract or subcontract is for commercial items and services as defined in FAR 2.101, such as pharmaceuticals, medical supplies, logistics support, data management, and freight forwarding.

(b)(3) Notwithstanding section (b)(2)(iii), not exempt from (b)(1) are non-U.S. Recipients, subrecipients, contractors, and subcontractors that implement HIV/AIDS programs under this assistance award, any subaward, or procurement contract or subcontract by:

(i) Providing supplies or services directly to the final populations receiving

such supplies or services in partner countries;

(ii) Providing technical assistance and training directly to partner country individuals or entities on the provision of supplies or services to the final populations receiving such supplies and services; or

(iii) Providing the types of services listed in FAR 37.203(b)(1)-(6) that involve giving advice about substantive policies of a Recipient, giving advice regarding the activities referenced in (i) and (ii), or making decisions or functioning in a Recipient's chain of command (e.g., providing managerial or supervisory services approving financial transactions, personnel actions).

(c) The following definitions apply for purposes of this provision:

"Commercial sex act" means any sex act on account of which anything of value is given to or received by any person.

"Prostitution" means procuring or providing any commercial sex act and the "practice of prostitution" has the same meaning.

"Sex trafficking" means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act (22 U.S.C. 7102(9)).

(d) The Recipient must insert this provision, which is a standard provision, in all subawards, procurement contracts or subcontracts for HIV/AIDS activities.

(e) This provision includes express terms and conditions of the award and any violation of it shall be grounds for unilateral termination of the award by USAID prior to the end of its term.

i) Conflict of Interest Pre-Award Term (October 2024)

a. Personal Conflict of Interest

1. An actual or appearance of a conflict of interest exists when an applicant organization or an employee, officer, agent, board member of the organization has a relationship with an Agency official involved in the competitive award decision-making process that could affect that Agency official's impartiality. The term "conflict of interest" includes situations in which financial or other personal considerations or interest may compromise, or have the appearance of compromising, the obligations and duties of a USAID employee or applicant or recipient employee.

2. The applicant must provide conflict of interest disclosures when it submits an SF-424. Should the applicant discover a previously undisclosed conflict of interest after submitting the application, the applicant must disclose the conflict of interest to the AO no later than ten (10) calendar days following discovery.

b. Organizational Conflict of Interest

The applicant must notify USAID of any actual or potential conflict of interest that they are aware of that may provide the applicant with an unfair competitive advantage in competing for this financial assistance award. Examples of an unfair competitive advantage include but are not limited to situations in which an applicant or the applicant's employee gained access to non-public information regarding a federal assistance funding opportunity, or an applicant or applicant's employee was substantially involved in the preparation of a federal assistance funding opportunity. USAID will promptly take appropriate action upon receiving any such notification from the applicant.

j) Applications with Proprietary Data

Applicants who include data that they do not want disclosed to the public for any purpose or used by the U.S. Government except for evaluation, should mark the cover page with the following:

"This application includes data that must not be disclosed, duplicated or used – in whole or in part – for any purpose other than to evaluate this application. If, however, an award is made as a result of – or in connection with – the submission of this data, the U.S. Government will have the right to duplicate, use, or disclose the data to the extent provided in the resulting award. This restriction does not limit the U.S. Government's right to use information contained in this data if it is obtained from

another source without restriction. The data subject to this restriction are contained in sheets {insert sheet numbers}."

Additionally, the applicant must mark each sheet of data it wishes to restrict with the following:

"Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this application."

SECTION E: SUBMISSION REQUIREMENTS AND DEADLINES

1. Questions and Answers

Applicants must submit questions regarding this NOFO, if any, to the HARMONIZE Team (nofo_harmonize@usaid.gov) no later than the date and time indicated on the NOFO cover letter, as amended. Any information given to a prospective applicant concerning this NOFO will be furnished promptly to all other prospective applicants as an amendment to this NOFO, if that information is necessary in submitting applications or if the lack of it would be prejudicial to any other prospective applicant.

2. Submission Requirements

Applications in response to this NOFO must be submitted no later than the closing date and time indicated on the cover letter, as amended. Late applications will not be reviewed nor considered ***OR*** may be considered at the discretion of the Agreement Officer. Applicants must retain proof of timely delivery in the form of system generated documentation of delivery receipt date and time **OR** confirmation from the receiving office/certified mail receipt. Additionally, applicants should retain a copy of the application and all enclosures for their records.

Email submission:
Applications must be submitted by email to *Insert email address*. Email submissions must include the NOFO number and applicant's name in the subject line heading. In addition, for an application sent by multiple emails, the subject line must also indicate whether the email relates to the technical or cost application, and the desired sequence of the emails and their attachments (e.g. "No. 1 of 4", etc.). For example, if your cost application is being sent in two emails, the first email should have a subject line that states: "[NOFO number], [organization name], Cost Application, Part 1 of 2".

USAID's preference is that the technical application and the cost application each be submitted as consolidated email attachments, e.g. that you consolidate the various parts of a technical application into a single document before sending it. If this is not possible, please provide instructions on how to collate the attachments. USAID will not be responsible for errors in compiling electronic applications if no instructions are provided or are unclear.

After submitting an application electronically, applicants should immediately check their own email to confirm that the attachments were indeed sent. If an applicant discovers an error in transmission, please send the material again and note in the subject line of the email or indicate in the file name if submitted via grants.gov that it is a "corrected" submission. Do not send the same email more than once unless there has been a change, and if so, please note that it is a "corrected" email.

Applicants are reminded that email is NOT instantaneous, and in some cases delays of several hours occur from transmission to receipt. Therefore, applicants are requested to send the application in sufficient time ahead of the deadline. For this NOFO, the initial point of entry to the government infrastructure is the USAID mail server.

There may be a problem with the receipt of *.zip files due to anti-virus software. Therefore, applicants are discouraged from sending files in this format as USAID*/Insert Mission/Office* cannot guarantee their acceptance by the internet server. File size must not exceed *Insert max file size*.

3. Unique Entity Identifier (UEI) and SAM.gov Registration

Each applicant, that does not have an exemption under 2 CFR 25.110, is required to:

(1) Be registered in SAM.gov before submitting an application.
(2) Maintain a current and active registration in SAM.gov at all times during which it has an active Federal award as a recipient or an application under consideration by USAID. The applicant or recipient must review and update its information in SAM.gov annually from the date of initial registration or subsequent updates to ensure it is current, accurate, and complete. If applicable, this includes identifying the applicant's or recipient's immediate and highest-level owner and subsidiaries, as well as providing information on all predecessors that have received a Federal award or contract within the last three years; and
(3) Include its UEI in each application it submits to USAID. A UEI is a unique, alpha-numeric 12-character identifier issued and maintained by SAM.gov that verifies the existence of an entity globally. The UEI is the official government-wide identifier used for Federal awards.

The SAM registration process may take many weeks to complete. Therefore, applicants are encouraged to begin the process early. If an applicant is unable to obtain a UEI and complete SAM registration before submitting an application, the applicant may request an exemption in accordance with the instructions below. If an applicant has not fully complied with the requirements above by the time USAID is ready to make an award, USAID may determine that the applicant is not qualified to receive an award and use that determination as a basis for making an award to another applicant. Applicants can find additional resources for obtaining a UEI and registering in SAM on a blog post on WorkwithUSAID.gov.

Note: First-tier subrecipients (i.e., direct subrecipients) must obtain a UEI in order to receive a subaward, but are not required to complete full SAM registration.

Requests for UEI/SAM exemptions: An applicant may include in its application (or separately in writing to the Agreement Officer) a request to be exempted from the above UEI and/or SAM registration requirements, if the criteria for one of the exceptions in 2 CFR 25.110 apply. The applicant may be required to submit additional justification or information in

support of the request for an exemption. In certain cases where an exemption is approved, the selected applicant may still be required to obtain a UEI and/or register in SAM.gov within thirty (30) days after receiving the award.

SECTION F: APPLICATION REVIEW INFORMATION

1. Responsiveness Review

Applicants must review, understand, and comply with all aspects of this NOFO. Failure to comply with the NOFO may be considered as being non-responsive and may be evaluated accordingly.

PLEASE NOTE

THIS APPLICATION IS A TWO-STEP PROCESS. ALL ELIGIBLE APPLICANTS MUST SUBMIT A CONCEPT NOTE TO BE CONSIDERED. IT IS ONLY AFTER EVALUATION OF THE CONCEPT NOTE WILL APPLICANTS BE INVITED TO SUBMIT A FULL APPLICATION. PLEASE REFER TO SECTION D FOR MERIT REVIEW CRITERIA FOR THE CONCEPT NOTES. DO NOT SUBMIT A FULL APPLICATION UNLESS REQUESTED.

2. Merit Review Criteria

The merit review criteria described here are tailored to the requirements of this NOFO. Applicants should note that these criteria serve to: (a) identify the significant matters which the applicants must address in their Concept Note; and (b) set the standard against which all Concept Note will be evaluated.

A. Merit Review for Concept Note for Objective 1

USAID will conduct a merit review of all applications received that comply with the instructions in this NOFO. Applications will be reviewed and evaluated in accordance with the following criteria shown in descending order of importance.

Technical Application Criteria

Applications received by the Selection Committee will be evaluated using an adjectival rating against each evaluation criterion. The criteria listed below are presented in descending order of importance by major category. Where subcriteria exist, these are also presented in descending order of importance in relation to the major criterion under which they appear, and will be used when establishing the overall rating for the major criterion and sub criterion. An overall rating of the application will be determined using the adjectival ratings, and the relative importance of the evaluation criteria.

The following criteria **(listed in descending order of importance)** will be used to evaluate the full applications:

1. Technical Design

Sub-criteria 1: **Technical Approach**

- The extent to which the applicant provides a detailed analysis of the primary challenges in embedding HIV and other services within the existing health system while strengthening PHC. This includes addressing gaps in health systems needs, proposing locally-led interventions, and contributing to sustained epidemic control while enhancing global health security to rapidly prevent, detect, and respond to new HIV infections and other infectious disease-related health threats in PEPFAR-supported countries. The analysis should align with the project goal, expected results and intermediate results, and strategic areas of emphasis in Section C of this NOFO.

- The degree to which the application clearly outlines innovative strategies, creative partnerships, and opportunities for collaboration with key stakeholders (including community actors and local partners, and other donors) needed to achieve HARMONIZE goals. The applicant should detail their approach to building on existing resources and complementing ongoing programs that support the alignment of services.

- The extent to which the applicant demonstrates how the implementation approach will support country-driven processes that identify country-specific needs and enhance community capacity and resilience, and ensure partner country ownership. The approach should outline important criteria for addressing country-specific challenges and capitalizing on opportunities, as well as key technical considerations to meet specific needs.

- The extent to which the applicant explicitly describes its approach for identifying and strengthening inclusive development. This includes the degree to which the applicant demonstrates its understanding of the challenges facing communities in PEPFAR countries, its ability to tailor support based on local and national needs, and its strategy for overcoming barriers to ensure successful achievement of the transition award goals.

Sub-Criteria 2: **Data Review Responses**

- The degree to which the applicant's responses reflect appropriate interventions to achieve results based on the proposed approaches and if they are strategic, sustainable, equitable, evidence-based, innovative, measurable, feasible, and represent an efficient and effective use of resources.

- The extent to which the applicant identifies potential challenges and risks and outlines strategies to address them, as well as how it will support country ownership and maximize the technical expertise of the proposed local partners and stakeholders.

- The degree to which the applicant's responses demonstrate the appropriate selection and use of indicators, project monitoring approaches, and data collection methods to achieve activity objectives.

Sub-Criteria 3: **Performance Monitoring, Evaluation, and Learning**

- The extent to which the applicant presents a clear Performance Monitoring, Evaluation, and Learning approach, with the appropriate selection and use of custom indicators and required PEPFAR indicators for the HARMONIZE objectives. The approach identifies the data collection method, source, and frequency of collection for all indicators across core and field support-funded activities.

- The extent to which the applicant details how it will successfully meet all PEPFAR and USAID reporting and monitoring and evaluation requirements, as well as the strength of the strategy for ensuring routine attention to results, data review and use, and methods for addressing poor performance.

2. Management and Staffing Approach

Sub-Criteria 1: **Management and Staffing Plans**

- The extent to which the application demonstrates that the applicant and its sub-partners possess the necessary technical expertise to achieve the expected results of HARMONIZE as outlined in Section A, especially with regard to reaching and sustaining epidemic control. This includes how the applicant will manage and implement activities to ensure cohesion across overall project efforts and coordination with other projects and stakeholders supporting the goal of incorporating HIV services and systems investments into the existing health system.

- The degree to which the application describes an effective management and administrative structure for multi-country implementation, and a realistic plan for technical and financial management, including efficiencies, cost-effectiveness, and budgetary responsiveness to program results in overall project management.

- The extent to which the staffing pattern, number and type of positions, and organizational arrangements (e.g., consortium, sub-awardees) proposed are responsive to the management and technical requirements of the HARMONIZE NOFO, including capacity building of local subrecipients, with an optimal configuration for efficiency, flexibility, cost containment, and use of expertise.

- The degree to which the applicant demonstrates the ability to recruit local partner country staff, consultants, and/or specialists in order to build partner country capacities and reduce costs.

Sub-Criteria 2: **Utilization of Small Businesses and/or MSIs and/or FBOs**

- The extent to which the applicant proposes to utilize the above referenced organizations.

3. Key Personnel

- The extent to which the proposed Key Personnel position(s) align with the proposed technical and management approach.
- The extent to which the Project Director and other proposed Key Personnel meet or exceed the minimum requirements in Section D.
- The extent to which the professional references support the candidate's ability to successfully accomplish the requirements of the position.

4. Institutional Capacity

- Prior experience with large-scale projects spanning multiple regions and involving numerous stakeholders and the capacity to successfully manage and implement multi-million-dollar projects
- Extent to which the applicant is proficient in donor regulations, financial reporting, and risk management, ensuring that all funding is utilized efficiently and responsibly.
- Extent to which the applicant employs a robust monitoring and evaluation framework, ensuring continuous tracking of program outcomes and financial expenditures.
- Strong internal infrastructure to handle substantial awards with the highest level of accountability, efficiency, and impact.

4. History of Performance

- Past performance will be evaluated on: 1) How well an applicant performed, and 2) Relevancy and recency of work performed under a similar program.

3. Review and Selection Process

The merit review criteria prescribed above are tailored to the requirements of this particular NOFO. Applicants should note that these criteria serve to: (a) identify the significant matters which the applicants should address in their applications, and (b) set the standard against which all applications will be evaluated.

Technical and other factors will be evaluated relative to each other, as described here and prescribed in Section D, Application Content and Format. A USAID Merit Review Committee (MRC) will conduct a merit review of all applications received that comply with the instructions in this NOFO and make the recommendation on which should be considered for award. The Business Application will be reviewed by the Agreement Officer.

A Merit Review Committee will review **the full applications** according to the criteria in this Section. The purpose of this review is to ensure that prospective partners bring appropriate capabilities, experiences, and potential contributions to the implementation of activities supporting the strategic objectives of this NOFO. The final selection of the successful

application will be determined by the AO.

As a result of this process, USAID intends to select the apparently successful applicant based upon the application submission. Once the selection is made, USAID may address any concerns to the selected applicant for resolution. However, USAID reserves the right to negotiate with all applicants prior to selection of the successful applicant if in the best interest of the U.S. Government.

If USAID and the apparently successful applicant cannot come to a mutual understanding during the course of discussions, or if the apparently successful applicant is unable to provide satisfactory Technical and Business Applications, or does not meet deadlines for submissions, or presents an unacceptable risk as a result of the risk assessment, then the Agreement Officer may designate the next highest-evaluated applicant as the apparently successful applicant. This decision is at the sole discretion of the Agreement Officer. The Agreement Officer's decision regarding funding of an award is final and not subject to review.

The Agreement Officer will make the final determination whether the award will be made to the applicant. Award may be made with or without a request for clarifications/additional detail on an application.

The **Chair of the Merit Review Committee** will ensure the success of the evaluation process. Key responsibilities include:

1. **Leading the Evaluation Process**: The Chair organizes and manages the evaluation of proposals, ensuring that all members of the MRC follow the established evaluation criteria and timelines. They ensure the process is fair and transparent.
2. **Coordination and Communication**: The Chair coordinates meetings and discussions among MRC members, facilitating open communication and resolving any disagreements regarding proposal assessments. They serve as the main point of contact between the MRC and other stakeholders (such as Agreement Officer)
3. **Documenting the Evaluation**: The Chair oversees the documentation of the evaluation process, including compiling evaluation reports, ensuring that scores and justifications are well-documented, and that the final report reflects the consensus of the MRC.
4. **Ensuring Objectivity and Compliance**: The Chair ensures that all MRC members remain objective and unbiased during the evaluation. They are responsible for enforcing conflict-of-interest rules and ensuring that evaluation procedures comply with the merit review criteria as outlined above.
5. **Final Recommendations**: After the evaluation is complete, the Chair presents the MRC's recommendations to the decision-making authority, ensuring that the evaluation outcome is clearly communicated and supported by the evaluation criteria.

a) Business Application Review

The Business (Cost) Application must be submitted separately from the Technical Application. While no page limit exists for the Business Application, applicants are encouraged to be as concise as possible while still providing the necessary details. The Business (Cost) application must illustrate the entire period of performance, using the budget format shown in the SF-424A.

Prior to award, applicants may be required to submit additional documentation deemed necessary for the Agreement Officer to assess the applicant's risk in accordance with 2 CFR 200.206. Applicants should not submit any additional information with their initial application.

The Cost Application must contain the following sections (which are further elaborated below this listing with the letters for each requirement):

1) **Cover Page** should include the NOFO number, the organization's name, a main point of contact at the organization along with their contact information, and name of any proposed sub-recipients or partnerships (if applicable).

2) **SF 424 Form(s)**: The applicant must sign and submit the cost application using the SF-424 series. Standard Forms can be accessed electronically at www.grants.gov or using the following links:

Instructions for SF-424	http://www.grants.gov/web/grants/form-instructions/sf-424-instructions.html
Application for Federal Assistance (SF-424)	https://www.grants.gov/web/grants/forms/sf-424-family.html
Instructions for SF-424A	http://www.grants.gov/web/grants/form-instructions/sf-424a-instructions.html
Budget Information (SF-424A)	https://www.grants.gov/web/grants/forms/sf-424-family.html
Instructions for SF-424B	http://www.grants.gov/web/grants/form-instructions/sf-424b-instructions.html
Assurances (SF-424B)	https://www.grants.gov/web/grants/forms/sf-424-family.html

Failure to accurately complete these forms could result in the rejection of the application.

3) **Required Certifications and Assurances**: The applicant must complete the following documents and submit a signed copy with their application:

a) "Certifications, Assurances, Representations, and Other Statements of the Recipient" ADS 303mav document found at http://www.usaid.gov/sites/default/files/documents/1868/303mav.pdf
b) Assurances for Non-Construction Programs (SF-424B)
c) Certificate of Compliance: Submit a copy of your Certificate of Compliance if your organization's systems have been certified by USAID/Washington's Office of Acquisition and Assistance (M/OAA).

4) Budget and Budget Narrative:

The Budget must be submitted as one unprotected Excel file (MS Office 2000 or later versions) with visible formulas and references and must be broken out by project year, including itemization of the federal and non-federal (cost share) amount. Files must not contain any hidden or otherwise inaccessible cells. Budgets with hidden cells lengthen the cost analysis time required to make award and may result in a rejection of the cost application.

The Budget Narrative must be submitted in Word or PDF and contain all assumptions and sufficient detail to allow USAID to understand the proposed costs. The Applicant must ensure the budgeted costs address any additional requirements identified in Section F, such as Branding and Marking. The Budget Narrative must be thorough, including sources for costs to support USAID's determination that the proposed costs are fair and reasonable.

The Budget (see Annex 1 Budget Template) must include the following worksheets or tabs, and contents, at a minimum:

- Summary Budget, inclusive of all program costs (federal and non-federal), broken out by major budget category and by year for activities implemented by the Applicant and any potential sub-Applicants for the entire period of the program.

- Detailed Budget, including a breakdown by year, sufficient to allow the Agency to determine that the costs represent a realistic and efficient use of funding to implement the Applicant's program and are allowable in accordance with the cost principles found in 2 CFR 200 Subpart E.

- Detailed Budgets for each sub-recipient, for all federal funding and cost share, broken out by budget category and by year, for the entire implementation period of the project.

The Detailed Budget and Budget Narrative must contain the following budget categories and information, at a minimum:

a) **Salaries and Allowances** – Must be proposed consistent with 2 CFR 200.430 Compensation - Personal Services. The applicant's budget must include position

title, salary rate, level of effort, and salary escalation factors for each position. Allowances, when proposed, must be broken down by specific type and by position.

Applicants must explain all assumptions in the Budget Narrative. The Budget Narrative must demonstrate that the proposed compensation is reasonable for the services rendered and consistent with what is paid for similar work in other activities of the applicant. Applicants must provide their established written policies on personnel compensation. If the applicant's written policies do not address a specific element of compensation that is being proposed, the Budget Narrative must describe the rationale used and support market research.

b) **Fringe Benefits –** (if applicable) If the Applicant has a fringe benefit rate approved by an agency of the U.S. Government, the applicant must use such rate and provide evidence of its approval. If an applicant does not have a fringe benefit rate approved, the applicant must list each fringe benefit (e.g. superannuation / defined benefit and defined contribution plans, gratuity, medical insurance, etc.). In this case, the Budget Narrative must provide a brief description of each fringe benefit and the costs of each, expressed in U.S. dollars and as a percentage of salaries (if applicable).

c) **Travel and Transportation** – Provide details to explain the purpose of the trips, the number of trips, the origin and destination, the number of individuals traveling, and the duration of the trips. Travel costs (e.g. airfare, per diem and associated travel costs) must be based on the Applicant's normal travel policies. The Applicant should explain assumptions in the budget narrative and when appropriate provide supporting documentation as an attachment, such as company travel policy. Airfare costs exceeding the unrestricted economy class fare will not be reimbursed unless there is a medically documented need for reasonable accommodation. Similarly, travel-related allowances - such as lodging, meals, incidental expenses, and total per diem - will not be reimbursed if they exceed the U.S. Department of State Standardized Regulations (DSSR) maximums, unless extraordinary circumstances are thoroughly documented.

d) **Equipment and Supplies** – Must include information on estimated types of equipment/supplies, models and the cost per unit and quantity. The Budget Narrative must include the purpose of the equipment and supplies and the basis for the estimates. The Budget Narrative must support the necessity of any rental costs and reasonableness in light of such factors as: rental costs of comparable property, if any; market conditions in the area; alternatives available; and the type, life expectancy, condition, and value of the property leased.

e) **Subawards –** Any goods and services being procured will be done through a **contract** mechanism.

Any activities to be implemented will be done through **subrecipient**. For further explanation - please see 2 CFR 200 for subrecipient and contractor.

The Applicant should provide a separate budget and budget narrative for each proposed subaward. The subaward budget and budget narrative must align with the same requirements as the applicant's budget and budget narrative, including those related to fringe and indirect costs.

f) **Other Direct Costs** – This may include other costs not elsewhere specified, such as report preparation costs, passports and visas fees, medical exams and inoculations, as well as any other miscellaneous costs which directly benefit the program proposed by the applicant. The applicant should indicate the subject, venue and duration of any proposed conferences and seminars, and their relationship to the objectives of the program, along with estimates of costs. Otherwise, the narrative should be minimal.

g) **Indirect Costs** – Applicants must indicate whether they are proposing indirect costs or will charge all costs directly. In order to better understand indirect costs please see Subpart E of 2 CFR 200.414. The application must identify which approach they are requesting and provide the applicable supporting information. Below are the most commonly used Indirect Cost Rate methods:

Method 1 - Direct Charge Only

Eligibility: Any applicant

Initial Application Requirements: See above on direct costs

Method 2 - Negotiated Indirect Cost Rate Agreement (NICRA)

Eligibility: Any applicant with a NICRA issued by a USG Agency must use that NICRA.

Initial Application Requirements: If the applicant has a current NICRA, submit your approved NICRA and the associated disclosed practices. If your NICRA was issued by an Agency other than USAID, provide the contact information for the approving Agency. Additionally, at the Agency's discretion, a provisional rate may be set forth in the award subject to audit and finalization. See USAID's Indirect Cost Rate Guide for Non Profit Organizations for further guidance.

Method 3 - De minimis rate of 15% of modified total direct costs (MTDC)

Eligibility: Any applicant that does not have a current NICRA

Initial Application Requirements: Costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged

as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as a non-Federal entity chooses to negotiate an indirect rate, which the non-Federal entity may apply to do at any time. The applicant must describe which cost elements it charges indirectly vs. directly. See 2 CFR 200 for further information.

Method 4 - Indirect Costs Charged As A Fixed Amount

Eligibility: Non U.S. non-profit organizations without a NICRA may request, but approval is at the discretion of the AO.

Initial Application Requirements: Provide the proposed fixed amount and a worksheet that includes the following:

- Total costs incurred by the organization for the previous fiscal year and estimates for the current year.
- Indirect costs (common costs that benefit the day-to-day operations of the organization, including categories such as salaries and expenses of executive officers, personnel administration, and accounting, or that benefit and are identifiable to more than one program or activity, such as depreciation, rental costs, operations and maintenance of facilities, and telephone expenses) for the previous fiscal year and estimates for the current year.
- Proposed method for prorating the indirect costs equitably and consistently across all programs and activities of using a base that measures the benefits of that particular cost to each program or activity to which the cost applies.
- If the applicant does not have an approved NICRA and does not elect to utilize the 15% de minimis rate, the Agreement Officer will provide further instructions and may request additional supporting information, including financial statements and audits, should the application still be under consideration after the merit review. USAID is under no obligation to approve the applicant's requested method.

h) **Cost Sharing** (if applicable) – The applicant should estimate the amount of cost-sharing resources to be provided over the life of the agreement and specify the sources of such resources, and the basis of calculation in the budget narrative. Applicants should also provide a breakdown of the cost share (financial and in-kind contributions) of all organizations involved in implementing the resulting award.

5) Prior Approvals in accordance with 2 CFR 200.407:

Inclusion of an item of cost in the detailed application budget does not satisfy any requirements for prior approval by the Agency. If the applicant would like the award to reflect approval of any cost elements for which prior written approval is specifically

required for allowability, the applicant must specify and justify that cost. See 2 CFR 200.407 for information regarding which cost elements require prior written approval.

6) Approval of Subawards

The applicant must submit information for all subawards that it wishes to have approved at the time of award. For each proposed subaward the applicant must provide the following:

- Name of organization
- Unique Entity Identifier (UEI) Number
- Confirmation that the subrecipient does not appear on the Treasury Department's Office of Foreign Assets Control (OFAC) list
- Confirmation that the subrecipient does not have active exclusions in the System for Award Management (SAM)
- Confirmation that the subrecipient is not listed in the United Nations Security Council designation list, i.e., confirmation that the subrecipient is not suspended or debarred
- Confirmation that the applicant has completed a risk assessment of the subrecipient, in accordance with 2 CFR 200.332(b)
- Any negative findings as a result of the risk assessment and the applicant's plan for mitigation.
- Documentation on the process of how subawards were selected and how their cost was evaluated.

7) SAM Requirements

USAID may **not** award to an applicant unless the applicant has complied with all applicable unique entity identifier (UEI) and System for Award Management (SAM) requirements. Each applicant (unless the applicant is an individual or Federal awarding agency that is exempted from requirements under 2 CFR 25.110(b) or (c), or has an exception approved by the Federal awarding agency under 2 CFR 25.110(d)) is required to:

1. Provide a valid Unique Entity ID number for the applicant and all proposed sub-recipients.

2. Be registered in SAM before submitting its application. SAM is streamlining processes, eliminating the need to enter the same data multiple times, and consolidating hosting to make the process of doing business with the government more efficient.

3. Continue to maintain an active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by a Federal awarding agency.

The registration process may take many weeks to complete. Therefore, applicants are encouraged to begin the process early. If an applicant has not fully complied with the requirements above by the time USAID is ready to make an award, USAID may determine that the

applicant is not qualified to receive an award and use that determination as a basis for making an award to another applicant.

Unique Entity ID and SAM registration: https://sam.gov

http://www.sam.gov

Non-U.S. applicants can find additional resources for registering in SAM, including a Quick Start Guide and a video on how to obtain an NCAGE code, on https://sam.gov/content/home, navigate to Help, then to International Registrants.

The Agency will evaluate the Business Application of the applicant(s) under consideration for an award as a result of the merit criteria review. As part of the review of the Business Application, the Agency will review the budget and budget narrative to determine whether the costs are allowable in accordance with the cost principles found in 2 CFR 200 Subpart E and accurately reflect the proposed activities in the Technical Application.

The Agency will also consider: (1) the extent of the applicant's understanding of the financial aspects of the program and the applicant's ability to perform the activities within the amount requested; (2) whether the applicant's plans will achieve the program objectives with reasonable economy and efficiency; and (3) whether any special conditions relating to costs should be included in the award.

When the NOFO includes a cost share requirement, USAID will review the Business Application for compliance with the standards set forth in 2 CFR 200.306, 2 CFR 700.10, and the Standard Provision "Cost Sharing."

4. Risk Review

The Agreement Officer will perform a risk assessment (2 CFR 200.206) of the apparently successful applicant. The Agreement Officer may determine that a pre-award survey is required to inform the risk assessment in determining whether the applicant has the necessary organizational, experience, accounting and operational controls, financial resources, and technical skills – or ability to obtain them – in order to achieve the objectives of the program and comply with the terms and conditions of the award. Depending on the result of the risk assessment, the AO will decide to execute the award, not execute the award, or award with "specific conditions" (2 CFR 200.208).

Before making an award with a total amount of USAID share greater than $500,000, USAID must review and consider any information about the applicant that is in the responsibility/qualification records available in SAM.gov (see 41 U.S.C. 2313). An applicant can review and comment on any information in the responsibility/qualification records available in SAM.gov. USAID will consider any comments by the applicant in determining whether the applicant is qualified for an award.

SECTION G: AWARD NOTICES

Award of the agreement contemplated by this NOFO cannot be made until funds have been appropriated, allocated and committed through internal USAID procedures. While USAID anticipates that these procedures will be successfully completed, applicants are hereby notified of these requirements and conditions for the award. Notice of Federal award signed by the Agreement Officer is the official document that obligates funds, and will be provided to the authorized official of the selected applicant by electronic means as identified in the application. The Agreement Officer is the only individual who may legally commit the U.S. Government to the expenditure of public funds.

Unsuccessful applicants will be notified by electronic means once the award is announced.

Pre-award costs are only allowed when specifically included in the award terms, or otherwise approved in writing by the Agreement Officer. Without such written authorization, any costs incurred for application development or program performance prior to an award period of performance start date are at the applicant's own risk; do not assume that the AO will approve them as pre-award costs in the award.

SECTION H: POST-AWARD REQUIREMENTS AND ADMINISTRATION

1. Administrative & National Policy Requirements

The resulting award from this NOFO will be administered in accordance with the following:

For U.S. organizations: 2 CFR 700, 2 CFR 200, and Standard Provisions for U.S. Non-governmental Organizations.

For Non-U.S. organizations: 2 CFR 200 Subpart E and Standard Provisions for Non-U.S. Non-governmental Organizations.

For Fixed Amount Awards: Standard Provisions for Fixed Amount Awards

See Annex 2, for a list of the **Standard Provisions** that will be applicable to awards resulting from this NOFO.

2. Nature of the Relationship between USAID and the Recipient

The principal purpose of the relationship between USAID and the recipient is to transfer funds to accomplish a public purpose of support or stimulation of the program, as authorized by Federal statute. The successful recipient will be responsible for ensuring the achievement of the program objectives and the efficient and effective administration of the award through the application of sound management practices. The recipient will assume responsibility for administering Federal funds in a manner consistent with underlying agreements, program objectives, and the terms and conditions of the Federal award.

3. Post-Award Co-Creation

Co-creation is STRONGLY ENCOURAGED for the development of every annual work plan in each country of operation and can take place virtually and/or in-person.

Co-creation is an intentional design approach which aims to foster innovative problem-solving approaches through a participatory process. The goal of co-creation is to jointly produce a mutually valued outcome and is distinct from other collaborative or participatory practices because it involves sharing power and/or decision making. Co-creation is transparent, time-limited and organized. It can be used to address a specific problem, challenge, question or to gain further insight on a topic of interest. Co-creation focuses on generating a specific outcome.

Co-creation should involve collaborative, non-adversarial engagement between the implementing partner and relevant in-country stakeholder partners, allowing for open dialogue to focus on developing actionable solutions tailored to program goals.

Co-creation can and should extend beyond a single event, embedding itself into relevant phases such as inception, work planning, and strategic planning. This ensures comprehensive stakeholder engagement throughout the process and allows for iterative feedback and adaptation based on participant insights.

Meetings are essential to ensure alignment, engagement, and productive collaboration among stakeholders. A typical multi-stakeholder co-creation workshop should span at least two days to allow for deep reflection and discussion. For virtual settings, workshops are best limited to four-hour sessions each day, often spread over multiple days to avoid fatigue. A pre-workshop meeting is recommended about one week before the main event to set expectations, clarify objectives, and address any participant questions. Throughout the workshop, time should be dedicated to defining the objectives, facilitating trust-building, and enabling interactive sessions to maintain engagement. Additionally, follow-up calls about a week after the workshop provide a valuable opportunity to discuss key takeaways, address any further questions, and plan next steps.

Co-creation exercises are typically conducted by trained facilitators who ensure productive collaboration among participants. Professional facilitators are often recommended, especially external facilitators with experience in managing complex discussions and balancing power dynamics. Facilitators guide activities, keep discussions focused, and create an environment that encourages all voices to be heard, accommodating diverse perspectives and styles of communication. In some cases, internal USAID staff trained in facilitation may take on this role, particularly if budget or timing constraints apply. Additionally, technical USAID staff may participate as equal partners or subject-matter experts rather than facilitators, contributing expertise while maintaining an inclusive and collaborative atmosphere.

Stakeholder diversity is crucial in co-creation. This includes the Agreement Officer's Representative (AOR) / Alternate AOR, USAID technical staff, implementing partners, relevant government agencies, and civil society representatives. These participants should be selected to bring varied perspectives that can enrich the co-creation outcomes.

Co-creation should be a time-bound process, conducted at least once yearly before work plan submissions or as needed in response to specific program developments. Holding regular but strategically spaced co-creation sessions minimizes disruptions to technical work while allowing sustained, meaningful engagement among partners.

Post-co-creation, a comprehensive report should document the insights and strategies agreed upon by participants, providing a roadmap for program implementation. This report should also include metrics for tracking the impact of co-created strategies, setting a basis for continued refinement and stakeholder alignment as the program progresses.

4. Reporting Requirements

- **Financial Reporting:**

For awards other than fixed amount awards, the Standard Form 425 (SF-425) must be submitted via electronic format to the U.S. Department of Health and Human Services (DHHS) via https://pms.psc.gov/. The Recipient must also submit a copy of SF-425 to the Agreement Officer and Agreement Officer's Representative. Electronic copies of the SF-425, along with instructions, can be found at https://www.grants.gov/forms/forms-repository/post-award-reporting-forms. The SF-425 must be submitted with a supplement that provides expenditure information by each Operating Unit and funding stream that is obligated.

Quarterly Financial Report: Quarterly Financial Reports shall be due within 30 days following the end of each quarter corresponding to USAID's fiscal year from October 1 through September 30.

Final Financial Report: The Final Financial Report shall be due within 120 days following the expiration of the award. Financial Reports shall be in accordance with 2 CFR 700.

If the AO determines that an award will be a fixed amount award, financial reporting will not be required; however, the resultant award may specify that recipients submit certain Standard Forms to request an advance payment, if any.

- **Performance Reporting**

(A) Semi-Annual and Annual Performance Reports

The recipient must submit semi-annual performance reports, unless the recipient is notified by the AOR that more frequent reporting (up to quarterly) is required. The performance reports must be submitted each year as follows:

- A mid-term performance report covering the first six months of each twelve month reporting period. These reports must be submitted within 30 calendar days after the end of the first six months of the twelve-month reporting period, or in accordance with AOR instruction.
- An annual performance report covering the entire twelve-month reporting period. These reports must be submitted within 30 calendar days after the end of the twelve-month reporting period, or in accordance with AOR instruction.

Performance reports must contain the following information:

- An executive summary that highlights progress and achievements, as well as obstacles in implementation.
- Progress towards objectives for the period, including progress towards

meeting established program performance indicators, benchmarks and targets and, if established goals were not met, reasons why.

- Analysis and explanation of any costs that deviate from the budget (recipients must immediately notify USAID of developments that have a significant impact on award supported activities).
- Discussion of any problems, delays, or adverse conditions, if encountered, which may materially impair the ability to meet the award objectives. These notifications must include a statement of the action taken or contemplated and any assistance needed to resolve the situation.
- A gender section reporting on related gender activities and achievements.
- An environmental compliance section reporting on related environmental compliance activities and any issues encountered.
- Success stories and photographs (if available). Photographs should comply with guidance provided in the USAID Graphics Standards Manual and should list information on each photo's subject and location.
- Descriptions of all media coverage received (if applicable), including press clippings, links, etc. as appropriate.
- Additional content, formatting, and entry into an electronic database may be requested by the AOR.

(B) Annual Implementation Plan

The recipient will prepare an Annual Implementation Plan (workplan) in accordance with the schedule and format shared by the AOR. It will be submitted to the AOR for approval as outlined under Substantial Involvement provisions. The recipient will submit the country-specific portion draft workplan to the Activity Manager (AM) at the relevant USAID Mission(s) for concurrence prior to seeking approval from the AOR. Depending on the date of award, the first and final year's workplans may cover more or less than twelve calendar months, as agreed upon with the AOR.

The due date for draft workplans may vary depending on GHSD requirements. For the first year, it is anticipated the workplans will be due no later than May 1st, and final workplans will be due no later than September 30th, subject to additional direction from the AOR.

(C) Management Review

USAID may require quarterly management reviews to assess program directions, determine achievement of the prior quarter's work plans, examine major management and implementation issues, and to make recommendations for any program changes. This review may incorporate programmatic and management questions, which may require written responses, as communicated by the AOR. This review and responses may form the basis for a management review discussion between the recipient, the AOR and other relevant USAID staff. Other OHA projects may be included in the review to enhance partner

coordination, collaboration, and joint work planning processes.

(D) Annual PEPFAR Expenditure Reporting

Recipients of PEPFAR funds must report on program expenditures and associated human resources for health data. Specifically, recipients must use the form PEPFAR Program Expenditures (DS-4213 OMB 1405-0208) and the PEPFAR Human Resources for Health template as a part of completing the PEPFAR Annual Progress Report at the end of each USG fiscal year (September 30).

5. Environmental Compliance

The Foreign Assistance Act of 1961, as amended, Section 117 requires that the impact of USAID's activities on the environment be considered and that USAID include environmental sustainability as a central consideration in designing and carrying out its development programs. This mandate is codified in Federal Regulations (22 CFR 216) and in USAID's Automated Directives System (ADS) Parts 201.5.10g and 204 (http://www.usaid.gov/policy/ADS/200/), which, in part, require that the potential environmental impacts of USAID-financed activities are identified prior to a final decision to proceed and that appropriate environmental safeguards are adopted for all activities. Environmental compliance obligations under these regulations and procedures are specified in the following paragraphs of this NOFO.

In addition, the recipient must comply with host country environmental regulations unless otherwise directed in writing by USAID. In case of conflict between host country and USAID regulations, the latter shall govern.

No activity funded under this cooperative agreement will be implemented unless an environmental threshold determination, as defined by 22 CFR 216, has been reached for that activity, as documented in a Request for Categorical Exclusion (RCE), Initial Environmental Examination (IEE), or Environmental Assessment (EA) duly signed by the Bureau Environmental Officer (BEO). (Hereinafter, such documents are described as "approved Regulation 216 environmental documentation.")

An Initial Environmental Examination (IEE) has been prepared for this NOFO (see attachment). The IEE covers activities expected to be implemented under this cooperative agreement. USAID has determined that a **Negative Determination with conditions** applies to one or more of the proposed activities. This indicates that if these activities are implemented subject to the specified conditions, they are expected to have no significant adverse effect on the environment. The recipient shall be responsible for implementing all IEE conditions pertaining to activities to be funded under this award.

As part of its initial Work Plan, and all Annual Work Plans thereafter, the recipient, in collaboration with the USAID Cognizant Technical Officer and Mission Environmental Officer

or Bureau Environmental Officer, as appropriate, shall review all ongoing and planned activities under this cooperative agreement to determine if they are within the scope of the approved Regulation 216 environmental documentation.

Any ongoing activities found to be outside the scope of the approved Regulation 216 environmental documentation shall be halted until an amendment to the documentation is submitted and written approval is received from USAID.

When the approved Regulation 216 documentation is (1) an IEE that contains one or more Negative Determinations with conditions and/or (2) an EA, the recipient shall:

I. Unless the approved Regulation 216 documentation contains a complete environmental mitigation and monitoring plan (EMMP) or a project mitigation and monitoring (M&M) plan, the recipient shall prepare an EMMP or M&M Plan describing how the recipient will, in specific terms, implement all IEE and/or EA conditions that apply to proposed project activities within the scope of the award. The EMMP or M&M plan shall include monitoring the implementation of the conditions and their effectiveness.
II. Integrate a completed EMMP or M&M Plan into the initial work plan.
III. Integrate an EMMP or M&M Plan into subsequent Annual Work Plans, making any necessary adjustments to activity implementation in order to minimize adverse impacts to the environment.

6. Other Requirements

Close-out Plans

Three months prior to the completion of country-level activities and/or the award end date, the recipient must submit a close-out plan for the specific country and/or award.

Final Report

90 days after the completion date of this award, the recipient must submit a final report. The final report will include an executive summary of the recipient's achievement of results; a description of the recipient's activities and attainment of objectives and sub-objectives by country and/or region, as appropriate; analysis of the significance of these activities; and overall project impact.

Ad Hoc Reporting

The recipient will provide the AOR with any cost data, work plans, schedules, and progress or results reports requested that are relevant to the approval, design, implementation, and monitoring of results to satisfy Agency reporting requirements.

Additional PEPFAR reporting required by the U.S. Department of State's Global Health

Security and Diplomacy (GHSD) Bureau

The recipient must submit any additional program and/or fiscal-related data collected from PEPFAR-related programming in accordance with federal regulations and/or Agency requirements.

SECTION I: OTHER INFORMATION

USAID reserves the right to fund any or none of the applications submitted. The Agreement Officer is the only individual who may legally commit the Government to the expenditure of public funds. Any award and subsequent incremental funding will be subject to the availability of funds and continued relevance to Agency programming.

Subject to Agreement Officer approval and proper use of funds, there may be construction-related activities anticipated for small to medium facility modifications to support service delivery. These activities may include renovations, repairs and upgrades. To support the construction work, activities may include other forms of non-clinical technical assistance for minor engineering support to make sure that the systems are set up and maintained, and the right valves / connectors / etc. are available (procured if necessary) to ensure functionality. The specific construction activities, and the countries and facilities in which they will occur, will be determined on a case-by-case basis. No construction-related activities other than those explicitly approved in advance on a case-by-case basis by the Agreement Officer may be performed.

The recipient must submit the following for USAID review and approval:

1. Architecture and Engineering (A&E) firm qualifications using the SF 330 along with the proposed contract with the A&E firm;

2. Design/Construction Documents which include the technical specifications, drawings, and cost estimate.

ADS 303maw_082923 "USAID Implementation of Construction Activities" limits construction to $750,000 per site and $10,000,000 per award.

ADS 303maa_100124 Standard Provisions for US Non-Governmental Organizations states:

M22. LIMITING CONSTRUCTION ACTIVITIES (AUGUST 2023)

(a) Construction is not eligible for reimbursement under this award unless specifically identified in paragraph (d) below.

(b) Definitions:

(1) “Construction” means —construction, alteration, or repair (including dredging and excavation) of buildings, structures, or other real property and includes, without limitation, improvements, renovation, alteration and refurbishment. The term includes, without limitation, roads, power plants, buildings, bridges, water treatment facilities, and vertical structures. The term does not include emplacement and removal of prefabricated structures and humanitarian shelters that are designed and constructed to be readily moved, erected, disassembled, stored, and reused (i.e., “relocatable buildings”), unless the emplacement and removal of the relocatable building requires site preparation work that otherwise meets the definition of construction.

(2) “Improvements, renovation, alteration and refurbishment” means – any betterment or change to an existing property to allow its continued or more efficient use within its designed purpose (renovation), or for the use of a different purpose or function (alteration). Improvements also include improvements to or upgrading of primary mechanical, electrical, or other building systems. “Improvements, renovation, alteration, and refurbishment” does NOT include non-structural, cosmetic work, including painting, floor covering, wall coverings, window replacement that does not include changing the size of the window opening, replacement of plumbing or conduits that does not affect structural elements, and non-load bearing walls or fixtures (e.g., shelves, signs, lighting, etc.). It also does NOT include repairs used in humanitarian assistance which constitute minor fixes to physical elements of a currently serviceable structure, if those repairs do not significantly impact or change the primary mechanical, electrical, or structural elements of the real property.

(c) Agreement Officers will not approve any subawards or procurements by recipients for construction activities that are not listed in paragraph (d) below. USAID will reimburse allowable costs for only the construction activities listed in this provision not to exceed the amount specified in the construction line item of the award budget. The recipient must receive prior written approval from the AO to transfer funds allotted for construction activities to other cost categories, or vice versa, with the exception of increases or decreases directly associated with currency fluctuations.

(d) Description

[Type of construction and location(s)]

(e) The recipient must include this provision in all subawards and contracts and make vendors providing services under this award and subrecipients aware of the restrictions of this provision.

ANNEX 1 - SUMMARY BUDGET TEMPLATE

Applicants should submit a summary budget and a detailed budget using this budget template.

Cost Element	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Salaries and Wages						
Fringe Benefits						
Travel						
Equipment						
Supplies						
Contractual (Subawards)						
Other Direct Costs						
Total Direct Costs						
Total Indirect Costs						
Total						

ANNEX 2 - STANDARD PROVISIONS

The selected applicant will be required to comply with USAID's standard provisions. The standard provisions included in the resultant award will be dependent on the organization that is selected or, in the case of a fixed amount award, the type of award.

The full text of these provisions may be found on USAID's website here:

- Standard Provisions for U.S. Nongovernmental Organizations: https://www.usaid.gov/ads/policy/300/303maa,
- Standard Provisions for non-U.S. Nongovernmental Organizations: https://www.usaid.gov/ads/policy/300/303mab, and
- Standard Provisions for Fixed Amount Awards: https://www.usaid.gov/ads/policy/300/303mat.

The resultant award will include the full text of current Mandatory Standard Provisions and the Required As Applicable Standard Provisions. **The required as applicable standard provisions will be required if checked below.**

Required as Applicable Standard Provisions for U.S. Nongovernmental Organizations

Required	Not Required	REQUIRED AS APPLICABLE STANDARD PROVISIONS U.S. NGOs
Determined at award		RAA1. Negotiated Indirect Cost Rates – Predetermined (August 2024)
Determined at award		RAA2. Negotiated Indirect Cost Rates – Nonprofit Provisional & Final (August 2024)
Determined at award		RAA3. Negotiated Indirect Cost Rate – For-Profit Provisional & Final (August 2024)
Determined at award		RAA4. Indirect Costs – De Minimis Rate (August 2024)
		RAA5. Reserved
		RAA6. Voluntary Population Planning Activities – Supplemental Requirements (January 2009)
		RAA7. Protection of the Individual As A Research Subject (April 1998)
		RAA8. Care of Laboratory Animals (March 2004)
		RAA9. Title to and Care of Property (Cooperating Country Title) (August 2024)
		RAA10. Cost Sharing (August 2024)
		RAA11. Prohibition of Assistance to Drug Traffickers (June 1999)
		RAA12. Investment Promotion (December 2022)
		RAA13. Reporting Partner Government Taxes (December 2022)
		RAA14. Foreign Government Delegations to International Conferences (June 2012)
		RAA15. Conscience Clause Implementation (Assistance) (February 2012)
		RAA16. Condoms (Assistance) (September 2014)

Required	Not Required	REQUIRED AS APPLICABLE STANDARD PROVISIONS U.S. NGOs
		RAA17. Prohibition on the Promotion or Advocacy of the Legalization or Practice of Prostitution or Sex Trafficking (Assistance) (September 2014)
		RAA18. Reserved
		RAA19. Standards for Accessibility for the Disabled in USAID Assistance Awards Involving Construction (September 2004)
		RAA20. Statement for Implementers of Anti-Trafficking Activities on Lack of Support for Prostitution (June 2012)
		RAA21. Eligibility of Subrecipients of Anti-Trafficking Funds (June 2012)
		RAA22. Prohibition on the Use of Anti-Trafficking Funds to Promote, Support, or Advocate for the Legalization or Practice of Prostitution (June 2012)
		RAA23. Reserved
		RAA24. Reporting Subawards and Executive Compensation (August 2024)
		RAA25. Patent Reporting Procedures (December 2022)
		RAA26. Access to USAID Facilities and USAID's Information Systems (August 2013)
		RAA27. Contract Provision for DBA Insurance under Recipient Procurements (December 2022)
		RAA28. Reserved
		RAA29. Reserved
		RAA30. Program Income (August 2024)
		RAA31. Never Contract with the Enemy (August 2024)

Required as Applicable Standard Provisions for Non-U.S. Nongovernmental Organizations

Required	Not Required	REQUIRED AS APPLICABLE STANDARD PROVISIONS Non-U.S. NGOs
Determined at award		RAA1. Advance Payment and Refunds (August 2024)
Determined at award		RAA2. Reimbursement Payment and Refunds (August 2024)
Determined at award		RAA3. Indirect Costs – Negotiated Indirect Cost Rates Provisional & Final (August 2024)
Determined at award		RAA4. Indirect Costs – Charged As A Fixed Amount (Nonprofit) (August 2024)
Determined at award		RAA5. Indirect Costs – De Minimis Rate (August 2024)
		RAA6. Reserved
		RAA7. Reporting Subawards and Executive Compensation (August 2024)
		RAA8. Subawards (August 2024)
		RAA9. Travel and International Air Transportation (December 2014)
		RAA10. Ocean Shipment of Goods (June 2012)

Required	Not Required	REQUIRED AS APPLICABLE STANDARD PROVISIONS Non-U.S. NGOs
		RAA11. Reporting Partner Government Taxes (December 2022)
		RAA12. Patent Rights (December 2022)
		RAA13. Reserved
		RAA14. Investment Promotion (December 2022)
		RAA15. Cost Sharing (August 2024)
		RAA16. Program Income (August 2024)
		RAA17. Foreign Government Delegations to International Conferences (June 2012)
		RAA18. Standards for Accessibility for the Disabled In USAID Assistance Awards Involving Construction (September 2004)
		RAA19. Protection of Human Research Subjects (June 2012)
		RAA20. Statement for Implementers of Anti-Trafficking Activities on Lack of Support for Prostitution (June 2012)
		RAA21. Eligibility of Subrecipients of Anti-Trafficking Funds (June 2012)
		RAA22. Prohibition on the Use of Anti-Trafficking Funds to Promote, Support, or Advocate for the Legalization or Practice of Prostitution (June 2012)
		RAA23. Voluntary Population Planning Activities – Supplemental Requirements (January 2009)
		RAA24. Conscience Clause Implementation (Assistance) (February 2012)
		RAA25. Condoms (Assistance) (September 2014)
		RAA26. Prohibition on the Promotion or Advocacy of the Legalization or Practice of Prostitution or Sex Trafficking (Assistance) (September 2014)
		RAA27. Limitation on Subawards to Non-Local Entities (July 2014)
		RAA28. Contract Provision for DBA Insurance Under Recipient Procurements (December 2022)
		RAA29. Reserved
		RAA30. Reserved
		RAA31. Never Contract with the Enemy (August 2024)

ANNEX 3 - ABBREVIATIONS AND ACRONYMS

ACHIEVE – Adolescents and Children, HIV Incidence Reduction, Empowerment and Virus Elimination
AGYW – Adolescent Girls and Young Women
AOR – Agreement Officer's Representative
ART – Antiretroviral Therapy
BI – Behavioral Insights
BP – Blood Pressure
CBOs – Community-Based Organizations
COPD – Chronic Obstructive Pulmonary Disease
COVID – Coronavirus Disease
DM – Diabetes Mellitus
DSD – Differentiated Service Delivery
EID – Early Infant Diagnosis
EpiC – Meeting Targets and Maintaining Epidemic Control
FBOs – Faith-Based Organizations
FP – Family Planning
GBV – Gender-Based Violence
GHRC – Global Health Risk and Capacity
HARMONIZE –Harmonization of systems and services to embed HIV service delivery into primary health care
HCAIs – Healthcare-Associated Infections
HCD – Human-Centered Design
HCW – Healthcare Worker
HIS – Health Information Systems
HTN – Hypertension
IR – Intermediate Result
KP – Key Populations
LMICs – Low- and Middle-Income Countries
MER – Monitoring, Evaluation, and Reporting
MH – Mental Health
MNCH – Maternal, Neonatal, and Child Health
NCDs – Noncommunicable Diseases
PEPFAR – President’s Emergency Plan for AIDS Relief
PHC – Primary Health Care
PLHIV – People Living with HIV
PVT – Prevention of Vertical Transmission
QA/QI – Quality Assurance/Quality Improvement
RISE – Reaching Impact, Saturation, and Epidemic Control
SBC – Social and Behavior Change
SOPs – Standard Operating Procedures
SRH – Sexual and Reproductive Health
TB – Tuberculosis

UNAIDS – Joint United Nations Programme on HIV/AIDS
USAID – United States Agency for International Development
VMMC – Voluntary Medical Male Circumcision
WHO – World Health Organization