Issue Date: December 18, 2024

Deadline for Questions: December 27, 2024, 5:00PM EDT

Closing Date and Time for CONCEPT NOTE: January 28, 2025, 5:00PM EDT

Closing Date and Time for FULL APPLICATION: TBD

Subject: Notice of Funding Opportunity (NOFO), Number: 7200AA25RFA00001

Program Title: New Partners Initiative Translational HIV Research for Innovative Vaccines Ecosystem (NPI THRIVE)

Federal Assistance Listing Number: 98.0001

Ladies/Gentlemen:

The United States Agency for International Development (USAID) is seeking applications for cooperative agreements from qualified entities to implement activities under the Translational HIV Research for Innovative Vaccines Ecosystem (NPI THRIVE) Program. NPI-THRIVE is a New Partnerships Initiative (NPI) Activity, meaning it encourages the use of innovative, locally-led approaches with new, nontraditional, and local partners. Eligibility for these awards is not restricted.

USAID intends to award at least two Applicants, at least one for each of the two objectives of this funding opportunity, based on the merit review criteria described in this NOFO and subject to a risk assessment. Parties interested in applying are encouraged to read this NOFO thoroughly to understand the type of program sought, application submission requirements, and selection process.

This funding opportunity is posted on www.grants.gov, and may be amended. It is the Applicant's responsibility to regularly check the website to ensure they have the latest information pertaining to this NOFO and to ensure that the NOFO has been received 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 Helpdesk at 1-800-518-4726 or via email at support@grants.gov for technical assistance.

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 furnished to all potential Applicants through an amendment to this notice posted to www.grants.gov. Please note that applications must be RECEIVED by USAID **before the deadline**. Applicants are highly encouraged to submit their application prior to the deadline to account for any delays in transmission.

English is the official language of all award documents. In the event of inconsistency between any terms of this NOFO and any translation into another language, the English language version will control.

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 Fortson

Administrative Agreement Officer

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SECTION A: BASIC INFORMATION

1. Executive Summary

The overall goal of NPI THRIVE is to accelerate the development of a safe and globally effective HIV vaccine by supporting a collaborative research ecosystem led by scientists and institutions from countries in Africa with high burdens of HIV working in close partnership with leading scientific institutions from other regions. This will be achieved through pursuing two complementary objectives, one focusing on clinical research and the other on preclinical research.

Objective 1 of NPI THRIVE is to utilize collaborative, African-led systems for clinical immunology, virology, bioinformatics, and innovative clinical trials to contribute novel scientific knowledge to accelerate the development of preventive HIV vaccines. This will involve 1) conducting-depth laboratory analyses of immune responses that inform HIV vaccine development; 2) identifying, sequencing, characterizing, and utilizing currently circulating HIV viruses to develop improved reagents and immunogens; 3) storing, managing, sharing, and analyzing data and samples from HIV vaccine-related clinical studies; and 4) accelerating clinical development of HIV immunogens and bnAbs for infant prophylaxis.

Objective 2 of NPI THRIVE is to rapidly advance promising immunogens toward first-in-human studies through strategic partnerships between organizations in African countries, other LMIC, and the US that promote efficient manufacturing, preclinical testing, and scientific innovation. This will involve: 1) manufacturing HIV immunogens affordably, efficiently, and sustainably through partnerships between organizations in African countries, other LMIC, and the US, with staged capacity transfer and co-investment from the private sector over the life-of-project; 2) refining and advancing promising HIV immunogens through the battery of tests and supportive activities needed to enter first-in-human studies, while strengthening related capabilities for preclinical development in Africa; and 3) developing innovative concepts that address key obstacles to eliciting protective bnAb responses through partnerships between academic institutions in African countries and the US.

Eligibility for this NOFO is not restricted. This is a multi-tiered NOFO. Selection under this NOFO will be based on a three-step process, involving: 1) concept paper submission and evaluation; 2) co-creation, including virtual and in-person sessions; and 3) full application submission and evaluation.

This NOFO is issued under USAID's New Partnerships Initiative. NPI leads USAID's work to diversify the Agency's partner base, contributing solutions-oriented support, while serving a pivotal coordination and exchange role with internal and external stakeholders to make USAID a more equitable partner and produce more sustained and locally-led development and humanitarian outcomes. Applicants must apply using one of the three specific NPI partnership approaches described in the NOFO. These include: 1) direct awards to local entities, new and underutilized organizations, or locally-established partners; 2) mentoring

awards, for partners of any type to apply to serve as prime recipients, but requires that at least 50% of the total award amount go to organizations that meet local entity, or regional partner criteria; or 3) partners of any type to serve as Prime recipients as long as Primes meet a minimum of a 1:2 cash leveraging of other public or private sector resources OR the implementation of the activity will significantly strengthen community financing ecosystems.

2. Estimate of Funds Available and Number of Awards Contemplated

USAID intends to award one or two Cooperative Agreements pursuant to this NOFO. Subject to funding availability and at the discretion of the Agency, USAID intends to provide up to $98,500,000 in total USAID funding over a five-year period, including up to $61,500,000 to support activities under Objective 1 and up to $37,000,000 to support activities under Objective 2. The estimated funds available for each year are as follows:

Objective 1				
Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**
$8,500,000	$10,500,000	$13,000,000	$17,000,000	$12,500,000

Objective 2				
Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**
$4,500,000	$6,000,000	$8,000,000	$10,000,000	$8,500,000

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 before September 30th, 2025.

4. Agency Point of Contact

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

Name: Koni Demissie
Title: Agreement Specialist
Email: npithrive@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 Code 935. The work to be conducted under the NPI THRIVE Program will support research conducted within the United States and with global research partners in geographic areas outside of the United States in accordance with Code 935. Additionally, some research and development collaborations may engage institutions and researchers that receive national or government-supported funding, which may be considered partner government entities under ADS 220. 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.

7. Expected Performance Indicators, Targets, Baseline Data, and Data Collection

Program goals and objectives should be responsive to the technical, programmatic, and operational aims of the NPI THRIVE Project as described in Section A.

8. **Intellectual Property**

Intellectual Property is discussed in Mandatory Provision "M7. Title to and Use of Property (December 2014)" for non-US NGOs. In general, awardee(s) may elect to pursue ownership of intellectual property that is developed as a result of an award. In such cases, USAID would typically retain a nonexclusive, non-transferable, royalty-free license to use any such intellectual property. Please see Annex 2 to review the mandatory provision.

SECTION B: ELIGIBILITY

1. Eligible Applicants and NPI Partnering Approaches

Eligibility for this NOFO is not restricted.

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.

Additionally, USAID welcomes applications from organizations that have yet to previously receive financial assistance from USAID.

This NOFO invites applications for one or more awards (cooperative agreements), anticipating making at least one award for each of the two objectives of the NPI THRIVE program. (**Note:** USAID may issue one award to one entity if the entity has submitted proposals for both objectives and the Merit Review Committee finds this entity to provide the strongest proposal for both objectives according to the evaluation criteria in Section F) Interested Applicants may submit no more than one application under this NOFO for Objective 1 and no more than one application for Objective 2. Individual organizations may be sub-partners on multiple applications that address each objective.

Applicants must apply using one of the three specific NPI partnership approaches described below. Note that organizations only need to use one of the three approaches:

1.1. Direct Awards.

Approach #1 focuses on empowering partners with strong local ties to national communities, including marginalized and underserved communities, and relies heavily on these partners during co-creation processes to offer innovative ideas and solutions to the development challenges. Under Approach #1, awards may be issued only to Prime recipients that meet one or more of the definitions below:

A. Local Entities[1]

I. An individual or organization that:

i. Is legally organized under the laws of a country that is receiving assistance from USAID;

ii. Has its principal place of business or operations in a country receiving assistance from USAID;

[1] As defined in Automated Directive System (ADS) Chapter 303.

iii. Is majority-owned by individuals who are citizens or lawful permanent residents of a country receiving assistance from USAID; and
iv. Is managed by a governing body, the majority of whom are citizens or lawful permanent residents of the country receiving assistance from USAID.

B. New and Underutilized Organizations are those that have never received any funding from USAID, or have received less than $25 million cumulatively in direct or indirect awards from USAID over the last five years. Under this approach, nontraditional partners including (but not limited to) local, government, faith-based, diaspora, minority-serving, and volunteer organizations, are encouraged to apply.

Regional partners may also apply for awards under this approach if they also meet the definition of a new and underutilized organization.
Regional Partners are:

I. An individual, a corporation, a nonprofit organization, a government entity, or another body of persons that:

i. Is legally organized under the laws of, and has as its principal place of business in, a country which is part of the same region as a country(ies) it is providing assistance; and
ii. Is providing assistance in one or more countries in the same region where it is legally organized and has its principal place of business.

C. Locally Established Partners (LEPs)

I. A U.S. or international organization that works through locally-led operations and programming models. LEPs:

i. Have maintained continuous operations in-country for at least five years and demonstrate a long-term presence in a country through adherence or alignment to the following:

- Local staff comprise at least 50% of office personnel;
- Maintenance of a dedicated local office;
- Registration with the appropriate local authorities,
- A local bank account; and
- A portfolio of locally implemented programs.

1.2 Mentoring Awards.

Approach #2 allows for partners of any type to serve as prime recipients, but requires that at least 50% of the total award amount go to organizations that meet local entity, or regional partner criteria.

This approach requires prime recipients to provide grants to and engage with local partners to build feedback loops with relevant actors engaged in the development challenge and

serve as mentors to the sub-awardee partners, providing knowledge, learning, monitoring, or capacity strengthening that supports locally determined objectives.

1.3. Nontraditional Financing Partnerships:

Approach #3 allows for partners of any type to serve as Prime recipients as long as Primes meet a minimum of a 1:2 cash leveraging of other public or private sector resources OR the implementation of the activity will significantly strengthen community financing ecosystems. The objective of these awards is to ensure that applications include ideas for maximizing USAID investments by identifying additional resources to support the achievement of development objectives. These awards may also strengthen local philanthropy, support community financing, or develop models that provide sustained funding for local organizations over time.

A. Leverage Awards: NPI seeks to support partnerships with organizations that can leverage private, non-U.S. Government, and/or local funding sources. Organizations of all types can qualify for these awards if they are able to propose and demonstrate commitment of leveraged funds worth a minimum of 50 percent of the total value of the award they seek from USAID. The leveraged funds can include non-Federal grants, contributions from local philanthropic sources and external awards, and/or in-kind contributions of intellectual property and volunteer hours provided by third-party actors. Applicants are encouraged to seek multiple funding sources to reach the 50 percent requirement. The leveraged funds cannot include additional types of in-kind contributions from the awardee.

B. Awards to Strengthen Local Funding Networks: NPI seeks to support approaches that will strengthen local philanthropic organizations' and community-based financing models that have the ability to provide sustained funding over time to local organizations. This model aims to strengthen local philanthropic and community-based financing models to reach common development objectives. Organizations of all types can apply and do not need to propose leveraged funding. At least 25% of the proposed activity must have the objective of leveraging local philanthropic contributions, strengthening philanthropic networks locally, supporting alternative financing methods for local actors, and supporting community-based financing models or similar activities.

2. Cost Sharing

Cost Sharing is not required for this activity.

SECTION C: PROGRAM DESCRIPTION

This funding opportunity is authorized under the Foreign Assistance Act (FAA) of 1961, as amended. The resulting awards will be subject to 2 CFR 200, 2 CFR 700, and 2 CFR 200 Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards. Cost Principles, and Audit Requirements for Federal Awards; and/or Standard Provisions for US and Non-U.S. Organizations; as well as the additional requirements noted in this NOFO.

Note: The term "program" as used in 2 CFR 200 and this NOFO is typically considered by USAID to be an Activity supporting one or more Project(s) pursuant to specific Development Objectives. Please see 2 CFR 700 for the USAID specific definitions of the terms "Activity" and "Project" as used in the USAID context for purposes of planning, design, and implementation of USAID development assistance.

1. Background

New Partnerships Initiative (NPI)

This NOFO is issued under USAID's New Partnerships Initiative. NPI leads USAID's work to diversify the Agency's partner base, contributing solutions-oriented support, while serving a pivotal coordination and exchange role with internal and external stakeholders to make USAID a more equitable partner and produce more sustained and locally-led development and humanitarian outcomes.

NPI advances this mission by diversifying its partner base and changing how the Agency establishes partnerships based on six key principles:

1. Promote local leadership. NPI works with local actors, traditional partners, and nontraditional partners to strengthen local and national systems in ways that advance locally-led development.

2. Improve equity and inclusivity within partner relationships. NPI proactively seeks opportunities to engage local communities more equitably and increase intentional inclusion in operations and programming, particularly for those communities that traditionally have been overlooked and underserved by USAID and other donor agencies—including faith-based organizations (FBOs); marginalized, underserved, and underrepresented communities; and diaspora communities.

3. Demonstrate accountability to constituents. Recognizing that USAID's work is "from the American people" to the people of the world, NPI emphasizes the need to be accountable to all members of the communities in which we work as well as to the American taxpayer.

4. Seek innovative approaches. NPI capitalizes on the full marketplace of ideas and solutions by collaborating with partners from all sectors of society, while developing partnerships that foster mutual accountability and strengthen local capacity.

5. Lower barriers to partnerships. NPI identifies processes, policies, norms, and regulations that prohibit potential partnerships and finds ways to mitigate them while maintaining appropriate safeguards on taxpayer resources.

6. Identify new and nontraditional sources of funding. NPI fosters partnerships that leverage non-U.S. government funding sources to enhance local ownership and support effective collaboration across the spectrum of humanitarian and development funders.

USAID's Support for HIV Vaccine Research and Development

The world still needs an HIV vaccine to sustainably control the HIV pandemic. Despite the significant progress in combating HIV and achieving epidemic control, 39.9 million people were living with HIV in 2023 globally. The highest burden of HIV globally occurs in countries in Africa, where 65% of the world's people living with HIV reside. Moreover, 62% of new HIV infections that occurred in these African countries were among women and girls. While new biomedical tools, such as oral and long-acting injectable pre-exposure prophylaxis, offer promise for continuing to reduce HIV incidence, a safe and effective preventive HIV vaccine could enable a more durable, rapid, and cost-effective reduction than would be possible by employing currently available interventions. Considering the profound HIV burden in many African countries, it is critical that HIV vaccine candidates are designed to effectively neutralize viruses circulating in this region.

Recent studies suggest that an HIV vaccine can be effective if it generates robust, broadly neutralizing antibodies (bnAbs) that can block a variety of HIV strains. However, traditional approaches to vaccination have yet to induce bnAbs effectively. The HIV vaccine research field is, therefore, focusing on using a variety of groundbreaking approaches to develop innovative vaccine candidates that have been rationally designed to stimulate the human immune system to produce bnAbs along with complementary T-cell responses. Over the next decade, there will be a need to conduct many small-scale trials to test new HIV vaccine immunogens, iteratively improving them until they generate high enough titers of bnAbs to justify testing them in larger-scale efficacy trials.

USAID has invested in HIV vaccine research and development (R&D) since 2001, gaining a deeper understanding of the global challenges facing the development of a safe, globally effective, preventive HIV vaccine. The Agency's investments so far have centered on strengthening and utilizing the capacity of African scientists and institutions to lead in the design, implementation, and analysis of early-stage HIV vaccine trials and more fully participate in the pre-clinical design of innovative HIV vaccine concepts. Going forward, USAID intends to support the evolving ecosystem for HIV vaccine R&D that encourages African investigators to utilize the skills they have built over these past two decades. In part due to USAID's long-standing support, the scientists in countries most affected by the HIV/AIDS pandemic are well-positioned to design

and test immunogens best suited for their populations. THRIVE is designed to implement, monitor, and evaluate HIV Vaccine R&D programs that elevate local/indigenous leadership and advance gender equality and inclusive development to achieve more effective, equitable, and sustainable outcomes. These principles are central to this NOFO.

As a key PEPFAR implementer, USAID works in concert with the State Department's Bureau of Global Health Security and Diplomacy (GHSD) to shape the strategic and technical direction of its HIV Vaccine R&D Program. The Program is further guided by the Agency's (a) Global Health Research and Development Strategy 2023-2028 and (b) localization vision and approach. In accordance with the Global Health Research and Development Strategy 2023-2028, USAID's HIV Vaccine R&D Program strives to define, design, develop, and deliver new, innovative, and effective products and interventions through a dynamic and iterative process.

The search for a safe, effective, preventive HIV vaccine must be sustainable, cost-effective, and equitable. To achieve this, scientists and institutions in countries most impacted by the HIV/AIDS pandemic must lead in designing and testing vaccine candidates. Accordingly, the HIV Vaccine R&D Program's implementation of the Agency's localization vision and approach involves a gradual transition of resources and leadership from US- to LMIC-based R&D partners to directly implement research programs and lead the way toward a sustainable R&D landscape through robust South-South and triangular collaboration. USAID's collaboration with these partners and their networks, combined with the Agency's extensive field presence and experience in LMIC, make it uniquely positioned to leverage and coordinate across public-sector agencies, private foundations, and private-sector partners.

2. Goals and Objectives

The overall goal of NPI THRIVE is to accelerate the development of a safe and globally effective HIV vaccine through supporting a collaborative research ecosystem led by scientists and institutions from countries in Africa with high burdens of HIV working in close partnership with leading scientific institutions from other regions.

This will be achieved through pursuing two complementary objectives:

Objective 1: To utilize collaborative, African-led systems for clinical immunology, virology, bioinformatics, and innovative clinical trials to contribute novel scientific knowledge to accelerate the development of preventive HIV vaccines.

Objective 2: To rapidly advance promising immunogens toward first in human (FIH) studies through strategic partnerships between organizations in African countries, other LMIC, and the US that promote efficient manufacturing, preclinical testing, and scientific innovation.

3. Geographic Focus

Activities supported under the NPI THRIVE project should predominantly be implemented within

countries in Africa with high burdens of HIV, but they may also be implemented in other low- and middle-income countries with high HIV incidence and/or burden and where strategic opportunities exist. In seeking to meet each of the two results described below, at least 70% of direct costs of the projects should be incurred in African countries (although funding devoted to vaccine manufacturing under Objective 2 may be excluded from the 75% threshold), and no more than 40% of direct costs should be incurred in any one country. For Objective 1, activities should occur in at least four countries in Africa, and for Objective 2, activities should occur in at least two countries in Africa.

4. Technical and Strategic Approach

In responding to Objective 1 or Objective 2, Applicants should propose an approach that utilizes the existing capacity, indigenous scientific talent, and ingenuity across Africa and other LMICs to generate knowledge that advances the HIV vaccine field. Approaches should also intentionally encourage the enhancement of local institutional structures, individual leadership, and relevant partnerships essential to R&D that are capable of outlasting the NPI THRIVE project. The approach should also identify and frame how gender-related considerations will be addressed in the design and implementation of the proposed HIV vaccine R&D.

As applications for Objective 1 and Objective 2 would be submitted separately, the objectives and results under each are described separately below.

A. <u>Objective 1:</u> Utilize collaborative, African-led systems for clinical immunology, virology, bioinformatics, and innovative clinical trials to contribute novel scientific knowledge to accelerate the development of preventive HIV vaccines.

Under Objective 1 of THRIVE, activities will focus on support for clinical HIV vaccine research and development, aiming to achieve the four interrelated results below through a cohesive approach that builds on the connections between them to expand impact.

Result 1.1: In-depth laboratory analyses of immune responses that inform HIV vaccine development are completed in African countries by utilizing existing and enhanced lab capacity expanded via partnerships with US institutions

Many new HIV immunogens designed to elicit broadly neutralizing antibodies (bnAbs) will be tested in clinical trials in the next 5-7 years. To evaluate and refine these immunogens, in-depth analyses of B-cell responses will be needed using a variety of methods, including cell sorting and sequencing, binding antibody multiplex assays (BAMA), neutralization assays, analyses of allelic diversity, surface plasmon resonance (SPR), electron-microscopy-based polyclonal epitope mapping (EMPEM), and other approaches. To achieve Result 1.1, a high priority should be placed upon supporting one or more centers of excellence with advanced B-cell analytic capabilities to probe B-cell immune responses to vaccine immunogens in clinical trials, partnering with a variety of clinical trial sites across Africa and immunogen developers from around the world in a collaborative manner that advances the HIV vaccine field. These advanced capabilities could also

be utilized to probe HIV-associated immune responses from epidemiological or pathogenesis studies if promising opportunities are identified. While a few African laboratories have already established capabilities for sorting and sequencing, BAMA, and neutralization assays, the equipment, facilities, and training for EMPEM and SPR may still need to be fully established. Partnerships with and leveraging of US institutions with such capabilities are encouraged so that even if it is not feasible to establish EMPEM and SPR in Africa with the funding available under the current NOFO, African scientists can be trained by fellowship programs or other means to utilize and interpret them.

Although a relatively lower priority under the NOFO than B-cell analytics, support of laboratories in Africa to conduct analyses of T-cell responses in samples from clinical studies is also encouraged, particularly analyses of CD4/T follicular helper cells, given their importance in influencing B-cell responses. Utilizing the sorting and sequencing capabilities established for B-cell analytics to more deeply probe T-cell responses in existing samples from epidemiological studies of early HIV infection, for example, USAID-funded (IAVI) Protocol C, is also encouraged, as sequencing T cell receptor (TCR) repertoires and better characterizing T cell phenotypes and functions with new technologies could provide essential and fresh insights into determinants of effective T cell responses.

To achieve Result 1.1, support could be considered to strengthen labs at select clinical trial sites in Eastern, Central, and Western African countries so that they have strong capabilities to conduct standard immune endpoint analyses needed for trials and will no longer need to send these samples out to labs in other countries. Such support would need to be prioritized for sites in East, Central, and West Africa that have not been the beneficiaries in the past of extensive USAID-supported HIV vaccine laboratory strengthening, with the selection of sites based upon an objective assessment of where the impact of lab capacity augmentation is likely to be the greatest. Along with this, strengthening capabilities in LMIC outside of Africa to enable them to conduct clinical trials of next-generation HIV vaccine immunogens, including strengthening clinical capabilities to conduct leukapheresis and lymph node fine-needle aspiration and potentially advanced B-cell laboratory analytics, could be considered if there is national government support and scientific rationale. In particular, such support could be considered for countries in Asia such as India, given the very high absolute numbers of HIV infections occurring there, and/or Thailand, given the strong record of HIV vaccine clinical trials in that country. Support could also be provided to improve procurement and management of laboratory commodities in African countries.

Result 1.2: Viruses from early infections are identified, sequenced, characterized, and used to develop improved reagents and immunogens through cost-effective approaches, linking to national programs and leveraging existing samples.

Having up-to-date sequences and phenotypic information for viruses that are representative of new HIV infections currently occurring in countries in Africa and other LMIC with high or increasing incidence or burden is critically important for HIV vaccine and monoclonal antibody research so that reference reagents such as pseudoviruses for neutralization panels are

appropriately reflective of global viral breadth and diversity and to prioritize and design vaccines and antibodies that can be highly effective against a wide range of global isolates. However, current virus panels are not well representative of the most recent viruses circulating in many countries with high incidence and/or burden, especially in countries where non-B and non-C clades predominate. Among African countries in particular, viral phylogeny is widely divergent between viruses in West, Central, East, and Southern Africa, with viral samples from West Africa being the most underrepresented. Moreover, even viruses sampled from countries where subtypes B and C predominate are not systematically representative of the viruses currently circulating in such countries, both because a substantial proportion of the samples were taken many years previously and may provide an overly optimistic picture of neutralization sensitivity, and because many derive from clinical trials that were not designed to sample new infections in a population-based, structured way. Such prevention efficacy trials will likely be less common in the coming decade than in the past, making fewer samples available. Given the costs and limitations of relying on future clinical trials and cohort studies as the primary sources of viral samples from very early infection time points, new approaches are required.

To achieve Result 1.2, a high priority should be placed on implementing cost-effective systematic approaches to enable ongoing identification, sequencing, and characterization of viral samples that are representative at the population level of new infections occurring in LMIC with high and/or rising incidence and/or high burden, and in sub-populations that are at highest risk, including key populations (people who inject drugs, female sex workers, men who have sex with men, transgender persons) and adolescent girls and young women, as well among HIV-exposed infants in countries with high antenatal prevalence. Rather than implementing new and costly epidemiological studies to gather samples, the focus would be better placed on developing sustainable partnerships to leverage existing samples where these are available, including through sequencing existing samples from underrepresented regions and through linking to national recency testing efforts using sequencing to estimate the degree of intraindividual viral variation to refine which viruses are most likely to be very early after initial infection and could be close approximations to transmitted founder viruses. Where feasible, samples from bio-behavioral surveys of key populations could also be employed. In addition to benefiting HIV vaccine design and monoclonal antibody development efforts, such approaches could have a secondary benefit in refining recency testing data by reducing the number of false positives, thereby providing more precise population-based information about where new infections are occurring, which could help to plan future efficacy trials and to feedback useful data to inform national HIV programs. Population-based sequencing data might also be valuable in providing phylogenetic data regarding transmission patterns and networks to some countries that could inform prevention strategies. Although these sequencing efforts could focus on countries in Africa with high burdens of HIV, expanding efforts to identify viruses from key populations in other regions with high burden or increasing incidence, such as Asia and Eastern Europe, is also highly encouraged if valid links can be made to samples from those regions.

Along with developing sustainable approaches to identify and sequence viruses from early time points after initial infection, the widespread sharing of HIV viral sequences is important to assist scientists in efforts to develop a globally effective HIV vaccine. While the sharing of HIV sequences between different countries and partners is occurring, there may be opportunities to

further strengthen this through targeted support for more intentionally coordinated action. Furthermore, the development and sharing of up-to-date viral reference reagents to use in neutralization panels is important, as is the sharing of neutralization data between different scientists around the world. To achieve Result 1.2, activities that enhance such collaboration and sharing are highly encouraged.

Result 1.3. Data and samples from HIV vaccine-related clinical studies are securely stored, managed, shared, and analyzed by African scientists to inform HIV vaccine development using augmented capacity in bioinformatics and artificial intelligence.

Over the last three decades, numerous clinical trials and epidemiologic and immunological studies have been conducted in Africa that are relevant to HIV vaccines. Moreover, many early-phase trials will provide new data in the coming years. Significant potential exists to obtain insights through analyzing immunological and virologic data and samples using new laboratory technologies and bioinformatic tools that have become available, including artificial machine learning/artificial intelligence. However, for these resources to be optimally utilized, intentional and coordinated support to facilitate collaboration is needed.

To achieve Result 1.3, a high priority should be placed on enhancing the storage of samples and data from past and future studies conducted on the sub-continent and facilitating the sharing of these samples and data within Africa and more widely as there is demand and scientific justification. Cost-effective approaches that build on existing biorepository and cloud-based data warehousing capabilities in one or more countries in Africa are preferred, with an emphasis on providing a service to the entire field that enables scientists to collaborate more effectively, reducing logistical and financial burdens on individual institutions by subsidizing to some degree the costs involved in supporting long-term storage of samples and data from HIV vaccine studies. While some charges for storing HIV samples and data may still be required of individual institutions, to enhance sustainability, approaches are encouraged that leverage funding from the private sector and from other sources that will support the storage and sharing of data and samples related to other diseases and health conditions beyond HIV, resulting in cost-reductions for HIV programs.

To capitalize on these opportunities provided by the samples and data, approaches are encouraged that will also build robust bioinformatics capacity in countries in Africa, which is critically important to handle increasing demands arising from the need to conduct immunological analyses from discovery medicine trials and increasing analysis of data related to identification, sequencing, and characterization of currently circulating HIV strains. This could include capacity among individual African scientists as well as institutional capacity related to computing equipment needed for advanced bioinformatic analyses. In coordination with these efforts, an approach could also be employed to enable African scientists to collaborate across institutions to identify and support promising early and mid-career investigators who can work on projects that involve analyzing the data and samples to inform HIV vaccine development efforts.

Along with the need to store, share, and utilize samples and data, there is a need to enhance capacity across Africa for clinical trial monitoring and the associated database development and data management. Approaches are encouraged that will expand the capacity for African-led clinical trial monitoring, particularly where this can be done more efficiently and at a lower cost than other existing options. Supporting the clinical trial monitoring for HIV vaccine studies in Africa by using this expanded capacity could be an area of focus to reduce the financial and management burden on African institutions implementing trials.

Result 1.4. Clinical development of HIV immunogens and bnAbs for infant prophylaxis is accelerated in Africa through collaborative clinical trial platforms, regulatory engagement, and coordinated support for strategic actions to address key challenges.

Many new HIV immunogens will hopefully become available for Phase I testing within the next 5-10 years, and investigators from countries that HIV highly impacts must play a leading role in the design and implementation of the trials of the immunogens. Additionally, the testing of HIV immunogens in special populations, including infants and people living with HIV (PLHIV), has great potential to advance the development of preventive HIV vaccines. However, navigating the scientific complexities and ethical considerations involved in conducting clinical trials in such populations will require leadership from scientists in Africa and collaboration to guide the field as it moves forward. Along with this, given the need to test multiple immunogens efficiently and in ways that allow for valid comparisons and potentially for future combinations among them, innovation in clinical trial platforms may be required, possibly through approaches that involve a master clinical trial protocol, with a standardized design and procedures, which can still be adapted somewhat if needed for specific immunogens or adjuvants. Moreover, using bnAbs for passive immunization of infants also holds promise, and candidate products may advance into initial proof-of-concept efficacy testing within the next five years. However, for an infant bnAb product to advance through clinical trials and eventually reach licensure, several challenges need to be addressed related to clinical trial design and implementation, product optimization for LMIC, manufacturing strategy, and mobilizing resources from the private sector. Accelerating the development of both vaccine candidates and bnAbs for infant prophylaxis will require African leadership, and coordinated engagement of regulators, bioethicists, and other stakeholders will be important to develop consensus on how to address a variety of complex issues that will be involved in the clinical development of these products.

Under Result 1.4, a high priority should be placed on supporting leadership, collaboration, and collective action by scientists and other stakeholders from African countries with high burdens of HIV, and potentially other LMICs, to prioritize, design, and implement clinical trials and related clinical-stage activities to accelerate HIV vaccine development. Support could also be provided for the clinical trials and other activities to accelerate the development of bnAbs for infant prophylaxis, assuming that a strong public health investment case can continue to be made for how a product can be feasibly developed and scaled up to achieve high public health impact in an era in which long-acting PrEP may become increasingly available for pregnant and lactating people. Partnerships for early-phase HIV vaccine clinical trials that would be led or co-led by African scientists could involve diverse collaborations beyond Africa with scientists in US

academic institutions, not-for-profit organizations, and private sector partners. While resources from the NOFO that contribute to Result 1.4 should primarily be focused on supporting African scientific leadership in advancing the global HIV vaccine enterprise, it may also be strategic to include sites from other LMIC in regions where there is a high burden of HIV and/or high incidence in key populations since it will be important to understand how vaccines that are designed to induce bnAbs perform in populations with different germline repertoires and environmental influences. If countries outside of Africa are included, support could be considered to strengthen capabilities in these countries to enable them to conduct clinical trials of next-generation HIV vaccine immunogens, including strengthening clinical capabilities to conduct leukapheresis and lymph node fine-needle aspiration and potentially advanced B-cell laboratory analytics, if there is national government support, along with scientific rationale and complementary resources to leverage. In particular, such support could be considered for clinical trials in countries in Asia such as India, given the very high absolute numbers of HIV infections occurring there, and/or Thailand, given the strong record of HIV vaccine clinical trials in that country.

Regarding broad priority areas for the types of trials supported under the NOFO, Applicants are especially encouraged to consider including at least one trial among each of two priority populations that have to date been understudied in HIV vaccine trials but which could provide important insights to guide HIV vaccine development. One of these populations is infants and/or children, who typically have a more plastic immune system than adults and who may be able to develop bnAbs more frequently than adults in response to vaccination. A second priority population is PLHIV, in whom immunization experiments may provide unique insights to inform the development of a preventive HIV vaccine. In this regard, several trials are ongoing involving boosting people living with HIV with envelopes to drive antibodies toward broader neutralization, but now that germline targeting immunogens are beginning to show good results in priming responses, new opportunities may emerge to explore a potentially more promising approach involving priming PLHIV with these immunogens and then, through carefully monitored analytical treatment interruptions, identifying HIV envelopes that may drive response toward broad neutralization. Such trials in Africa involving PLHIV who have been primed with germline targeting vaccine immunogens would leverage the viral diversity that exists in PLHIV in Africa and could help identify envelope immunogens that have particularly strong potential for broadening responses in African populations, both for preventive and therapeutic vaccines. Analyses of such trials could also take advantage of the immunological and sequencing capabilities that would be supported under Results 1.1 and 1.2.

Along with trials in PLHIV and infants, which could be relatively small if other promising clinical trial priorities that require more resources are identified by scientists in African countries and other LMIC with high burdens of HIV, Applicants are encouraged to prioritize testing those immunogens that these scientists, in consultation with other global experts, determined to be the most promising. Ideally, this would include at least one that has been developed in some form of partnership between scientists in Africa and the US, which could be an immunogen developed through support under the Objective 2 project described below. Maximizing approaches that leverage funding from other donors and LMIC governments are encouraged.

Efforts are also strongly encouraged to include clinical trial sites outside of South Africa alone and equitably include the most capable clinical trial sites with proven experience conducting complex HIV vaccine trials. This could include support for one or two sites outside of South Africa to participate in larger trials funded primarily by donors other than USAID if such support helped make the population in the trial better representative of the countries with the highest incidence or burden of HIV. Support under the NOFO could also be considered for efforts to stabilize the clinical trial workforce in Africa and for improving infrastructure at clinical trial sites through generators, or internet connectivity (although no new construction would be supported under the NOFO) to help ensure the quality of clinical research executed.

B. <u>Objective 2:</u> To rapidly advance promising immunogens toward first-in-human studies through strategic partnerships between organizations in African countries, other LMIC, and the US that promote efficient manufacturing, preclinical testing, and scientific innovation.

Under Objective 2 of THRIVE, activities will focus on support for preclinical HIV vaccine research and development, aiming to achieve the three interrelated results below through a cohesive approach that builds on the connections between them to expand impact.

Result 2.1 HIV immunogens are manufactured affordably, efficiently and sustainably through partnerships between organizations in Africa, other LMIC, and the US, with staged capacity transfer and co-investment from the private sector over the life-of-project

Although RNA vaccines offer a promising platform to enable innovators to develop new HIV immunogens, only a few RNA-delivered HIV immunogens have yet entered early-phase clinical trials, in part due to bottlenecks to manufacturing them. Given the many immunogens that have shown promising preclinical results and the importance of rapid feedback from trials to iteratively refine immunogens, there is a pressing need to accelerate the process of moving these immunogens into Phase I testing. Having the capability to manufacture RNA-delivered HIV immunogens for early-phase trials in Africa could be particularly valuable for expediting progress and reducing costs over the long run.

To achieve Result 2.1, a high priority should be placed on the manufacturing of promising RNA-delivered immunogens for early-phase HIV vaccine clinical trials in a manner that is flexible and open to immunogens from a variety of innovators from different organizations based in the U.S., Africa, and other LMIC regions. Partnerships with innovators from other countries could also be considered if promising opportunities arise. To minimize the risk of failure, Applicants are encouraged to engage at least one U.S.-based organization that has proven capability to manufacture RNA-delivered HIV envelope immunogens that has successfully entered at least one clinical trial already, and that would be willing to partner with innovators from different organizations to manufacture the most promising immunogens for Phase I trials in a manner that would retain flexibility for the innovators to form partnerships with additional organizations, including private sector companies, to advance these immunogens into further

clinical development if warranted. Through such a collaborative and flexible approach, opportunities may also arise to mix and match different immunogens from various innovators using the same liposomal platform to formulate RNAs.

Along with supporting the manufacturing of some promising immunogen candidates through one or more experienced US-based partners, activities to achieve Result 2.1 would involve tech transfer from the experienced partner(s) to at least one African organization so that by the end of the project, that organization participated in the manufacturing of one or more immunogens for a clinical trial and can manufacture multiple RNA-delivered antigens for future trials. Ideally, an African partner that can manufacture phase I trial material would also be interested in co-investing to bring promising products forward into later phases of development if and when the data warrant it. There may also be potential to leverage resources from governments in Africa that HIV heavily impacts to help support the manufacturing of the most promising HIV immunogens. Companies in other regions such as Asia, Latin America, or Europe that are willing to co-invest could also be considered for support to manufacture HIV immunogens as part of a broader public-private partnership that involves a U.S. organization and an organization in Africa. In addition, although the focus under Objective 2 is on RNA vaccine manufacturing, a backup plan should be considered involving protein immunogens should emerging data on the side-effect profile of RNA-delivered HIV immunogens not be supportive of advancing such immunogens into later phases of product development.

Result 2.2 Promising HIV immunogens are refined and advanced through the battery of tests and supportive activities needed to enter FIH studies as related capabilities for preclinical development in Africa are strengthened.

Along with strengthening manufacturing capabilities, enhancing the capabilities in Africa to advance new immunogens through the full battery of tests and supportive activities needed for entry into FIH studies can increase the efficiency, sustainability, and impact of African countries' contributions to the global HIV vaccine enterprise. Based on an assessment of the needs, the greatest opportunities to accelerate the cost-effective development of candidates, and the potential to leverage other resources, activities to achieve Result 2 might include increasing capabilities for some of the following: preclinical immunogenicity testing; safety and toxicology testing; analytical development; and activities to optimize RNA-delivered immunogens, including construct design, lead selection, and optimization, and formulation of lipid nanoparticles. Investments could be made in laboratory equipment for measuring immune responses or toxicology tests, instruments to produce RNA for more efficient and rapid screening of envelope immunogens, needed staff training, improving/renovating animal facilities, or making facilities GLP-compliant. However, new construction will not be supported with USAID funds under this NOFO. Support could include building specialized capabilities related to animal research that are important for preclinical work on HIV vaccines, such as developing allelic reference databases, assessing bnAb precursors, and/or testing germline-targeting antigens in the potentially lower-cost African Green Monkey model. Protein production capabilities within Africa would also be useful in producing reagents and immunogens, both for preclinical and clinical trials. Therefore, if promising opportunities exist through technology transfer partnerships between U.S.

institutions with needed expertise and African institutions willing to co-invest resources, support could be provided to develop or expand protein production capabilities in Africa.

Given the many different preclinical capabilities required to advance promising preclinical candidates into FIH studies, necessary preclinical activities to advance promising immunogens could take place in the United States, Africa, and/or other countries. However, Applicants are highly encouraged to use some of the preclinical capabilities being developed in Africa under Result 2.2 for at least some of the activities involved in advancing promising immunogens into FIH studies. Where applicable, activities under Result 2.2 should also be coordinated with manufacturing activities under Result 2.1 so that they contribute to advancing one or more promising immunogens into FIH studies.

Result 2.3 Innovative concepts that address key obstacles to eliciting protective bnAb responses are developed and advanced through partnerships between US and African academic institutions, exploring opportunities created by nucleic-acid delivery, controlled-release technologies, and artificial intelligence for structure-based immunogen design.

Result 2.3 will be achieved through scientific collaborations between one or more academic institutions from the Global North with proven expertise in vaccine design and scientists at academic institutions in countries across Africa and potentially in other LMIC regions, including early- and mid-career investigators. Approaches are encouraged that would integrate efforts to strengthen the capacity of these LMIC investigators within the collaborative research projects. Where applicable, partners are encouraged to utilize the preclinical capabilities being enhanced in Africa under Result 2.2, toward the achievement of Result 2.3. Approaches are encouraged that focus on supporting innovative projects that are initially relatively small and address the topics below, with stepwise continuation of the most promising projects depending on how they meet defined benchmarks for tracking progress over 5 years. Ideally, at least one or two innovations supported under Result 2.3 are ready to be advanced into Phase I trials by the end date of the overall cooperative agreement, potentially through manufacturing support provided under activities to achieve Result 2.1. Projects could be supported related to two broad areas described below, one related to design of immunogens to elicit bnAbs and the second related to exploring different delivery platforms and adjuvants in order to improve the durability, magnitude, and diversity of immune responses and/or the feasibility of delivering vaccines in LMIC.

With regard to the first broad area of designing improved immunogens to elicit bnAb responses, given the relatively large amount of attention that has been devoted to the CD4 binding site, projects are encouraged to focus on eliciting bnAb responses to other viral sites of vulnerability than the CD4 binding site. Applicants are encouraged to initially support at least 3 small projects that explore different strategies to elicit bnAbs: 1) germline targeting and/or lineage-based approaches; 2) immuno-focusing or minimal epitope approaches; and 3) mosaic nanoparticle displays. As part of these projects, investments are also encouraged in strengthening capabilities related to artificial intelligence/machine learning and structure-based immunogen design,

including through fellowships or other collaborations between academic institutions in the U.S. and Africa. Because there have already been important preclinical successes in priming bnAb responses to several different viral targets, projects are encouraged that focus on driving already primed responses further toward bnAbs or addressing important gaps to make priming more effective, for example, by reducing off-target responses. Regarding strategy 3, mosaic nanoparticle displays, this refers to approaches that present multiple variants of an antigenic target on a single particle to immune cells, which has shown promise in eliciting improved antibody responses to the influenza virus. With the advent of RNA vaccines, which make it possible to express many different variants of HIV envelope protein on a single particle or cell, and with the increasing availability of different full-length envelope constructs, it is now more feasible to test approaches that co-express multiple different envelope constructs on a given particle or cell to understand if these can successfully focus responses on conserved epitopes. Comparing immune responses to a mosaic display on one particle to approaches that express different envelopes on distinct particles administered simultaneously or sequentially could also provide useful insights to inform HIV vaccine design.

Concerning the second broad area related to improving the durability, magnitude, and diversity of immune responses and/or the feasibility of delivering vaccines in LMIC, projects are encouraged that would focus on the following: 1) adjuvants that could be delivered along with RNA vaccines; 2) sustained-release delivery technologies; and 3) comparison of different approaches for delivering antigens via different nucleic acid platforms. If good opportunities exist, these different strategies could be explored in conjunction with some of the bnAb-inducing strategies noted above. Regarding adjuvants delivered to improve response to RNA vaccines, these could include molecular adjuvants that are RNAs co-packaged with the immunogen (for example, CD40-ligand RNA co-packaged with env immunogens) and/or adjuvants that are mixed within the liposomal component of RNA vaccines or that are given alongside them. Regarding sustained and/or pulsatile release technologies, strategies could be considered that would make it more feasible to administer complex immunization regimens involving various envelope immunogens at different time points, and/or that may improve the magnitude of the immune response, and/or that may increase elicitation of antibodies to subdominant epitopes that may be important for neutralization. Projects are encouraged to focus on sustained or controlled release technologies that have already shown some preclinical potential for administering antigens for HIV and/or other diseases and which could potentially be practical and cost-effective for administration in LMIC. Regarding the comparison of different nucleic acid delivery approaches, projects are encouraged that would compare responses to standard RNA vaccines in liposomes, to self-amplifying RNA in liposomes, and also to DNA in liposomes (but not naked DNA), as some data indicate that liposomes increase the delivery efficiency of DNA and have an adjuvant effect which can substantially enhance responses.

5. Substantial Involvement

In the implementation of any Cooperative Agreement resulting from this NOFO, USAID may have an appropriate level of substantial involvement based on the programmatic requirements of the award (ADS 303.3.11). Areas of substantial involvement include the following.

a. Approval of implementation plans and monitoring, evaluation, and learning (MEL) plans, usually annually; the implementation plans will include planned activities for the respective year, planned expenditures, knowledge management plans, planned events, international meetings, research studies/protocols, training and other capacity building efforts, activity locations, and beneficiary populations;

b. Approval of press releases wherein USAID is cited, e.g., staff quotes, etc.;

c. Approval of specified Key Personnel and any revisions to Key Personnel;

d. Collaborative involvement in the selection of a Scientific Advisory Group (SAG) - and USAID and PEPFAR may also choose to be a SAG member;

e. Approval of sub-awardee(s) or contract selection and the technical or programmatic provisions of subawards, as well as any revisions in the statement of work and/or total approved budget;

f. Collaborative involvement in developing research protocols and disseminating results;

g. Enforcing inclusive development across all funded activities to ensure that all people are included and can participate fully in and benefit equally from USAID development efforts;

h. Agency monitoring to permit specific kinds of direction or redirection of the work because of the interrelationships with other projects or activities;

i. Other monitoring as appropriate, e.g., as described in 2 CFR 200;

j. Agency Authority to Halt a Construction Activity;

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

SECTION D: APPLICATION CONTENT AND FORMAT

1. General Content and Form of Application

Preparation of Concept Notes and Applications:

Each Applicant must furnish the information required by this NOFO. Concept Papers are to be submitted in Phase 1 as described in Section D.2a below. However, the full applications in Phase 3 (see Section D.2c below) must be submitted in two separate parts: the Technical Application and the Business Application. This subsection addresses general content requirements applying to both concept notes and the full application. Please see subsections 2 and 3, below, for information on the content specific to the Technical and Business Applications.

The Concept Paper, the Technical Application, and the Business Applications must each include a cover page containing the following information:

- 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.
- Each Cover Page for the Concept Note and for the Full Application should also indicate what Objective of the NOFO it is responding to (Objective 1 or Objective 2). If an Applicant wants to apply for both Objectives, it should submit separate Concept Papers and Applications for each Objective.

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 choose to 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 for **all** stages:

- 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 Concept Note, 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 Concept Note and Technical Application must be a searchable and editable Word or PDF format as appropriate.

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

For Full Application ONLY:

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.

- The estimated start date identified in Section B of this NOFO must be used in the cost application.

- 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 must review, understand, and comply with all aspects of this NOFO. **Failure to do so may be considered as being non-responsive and may be evaluated accordingly**.
Applicants should retain a copy of the application and all enclosures for their records.

2. Application Process and Submission Instructions

This is a multi-tiered NOFO in accordance with ADS 303.3.6.1(c). Selection under this NOFO will be based on a three-step process:

Phase 1 - CONCEPT PAPER: Applicants must first submit a concept paper for review. All concept papers will be evaluated according to merit review criteria laid out in Section E of this NOFO.

Phase 2 - CO-CREATION: USAID will invite selected Applicant(s) to enter a period of co-

creation, in which they will collaborate on and refine approach(es) with one another and USAID.

Phase 3 - FULL APPLICATION: USAID will invite selected Applicants who have completed the co-creation phase to submit a full application. Full applications will be evaluated according to the merit review criteria laid out in Section E of this NOFO.

a. PHASE 1 - CONCEPT PAPER

Submission Instructions:

Applications must be submitted by email before the deadline to the addresses under Section A.4 Agency Point of Contact. Email submissions must include the NOFO number and Applicant's name in the subject line heading.

The concept paper must **not** exceed seven (7) pages, not including the cover page, using guidance provided under Section D.3. With the exception of the Accountability and Feedback Plan (see below), additional documentation, such as annexes, charts and graphs that exceed the seven pages will **not** be reviewed. The concept paper should be in either PDF or Microsoft Word format (.docx).

i. Cover Page (1 page, not counted toward the 7-page limit) - See Section D.1 above for format.

ii. Technical (7 pages) - The Concept paper must describe the Applicant's understanding and approach to achieving either Objective 1 or Objective 2 of NPI THRIVE as described in Section A and address all Results described under "Technical and Strategic Approach" (Section A, Subsection 4). 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.

iii. Annex 1 - Accountability and Feedback Plan: Applicants must submit an Accountability and Feedback Plan that details how feedback on the prime partner is collected and acted upon to advance equitable implementation and partnerships, collecting feedback from sub-partners, resource partners, beneficiaries, local leaders, communities, etc. These should be no longer than two pages. Further instructions can be found in Annex 5 of this NOFO.

iv. Annex 2 - Eligibility Certification Form: Applicants are required to include an eligibility certification form with their concept paper noting what type of NPI Partnership Approach they are using and certifying that it is applicable to their organization. Please see Annex 6 of this NOFO for the form.

b. PHASE 2: CO-CREATION

Successful Applicants at the initial concept paper phase will be invited to engage in a co-creation process with USAID as follows.

Phase 2a: VIRTUAL CO-CREATION WORKSHOP: The first phase of the co-creation process will be two virtual workshops, one for Objective 1 and one for Objective 2. Workshops will take place in mid-March, 2025, from 8 AM to 12 PM EST to which all successful Applicants of concept papers for a given objective will be invited. For each successful concept paper, up to 2 representatives of the prime organization applying can attend. Applicants will also be given the option if they so desire to propose bringing with them 1-2 representatives each from any other organizations who possess technical knowledge of the subject matter, were instrumental in drafting the concept paper, and are included as subpartners on their concept note. Please note that once USAID is given the number of proposed attendees by each prime Applicant, if there are more than 50 total from all organizations, prime Applicants may be asked to reduce their number of proposed attendees. In choosing who should attend from their respective organizations, Applicants should prioritize staff that have technical and scientific knowledge relevant to HIV vaccine R&D, rather than staff whose main responsibilities relate to business development, human resources, or other non-technical areas. The co-creation process may create opportunities for new partnerships between various organizations, and therefore USAID recommends that Applicants consider avoiding entering into binding agreements with potential subpartners ahead of the co-creation process so that there will be maximum flexibility in developing collaborations during the workshop.

The week prior to the virtual co-creation workshop, USAID will also offer an optional 2-hour pre-workshop orientation call during which the co-creation process will be explained and applicants will have the opportunity to ask any questions they may have about the process.

The goal of a co-creation workshop would be to explore and validate key challenges and problems in HIV vaccine R&D, and then jointly to develop promising solutions or adapt and expand upon existing solutions. USAID envisions the initial product of the workshop to be a draft framework from each Applicant or group of Applicants that has decided to work together for how they plan to address the objective in the NOFO.

Day 1: **USAID presentation** will provide an overview of key challenges and priorities it sees related to Objective 1 of the NOFO, share about USAID's existing support for HIV vaccine R&D projects, and identify general strengths, weaknesses, and gaps it noted from the concept papers.

Note: **USAID will NOT** discuss any specific details of what individual Applicants proposed in their concept notes during this evaluation period.

Applicant presentations for Objective 1 - Each Applicant will then each be allotted equal time to present their organization's capabilities and what they see as the key challenges and opportunities related to Objective 1. At their discretion, Applicants will have the option of also sharing specifics about existing solutions, approaches, or activities from their concept papers. These may be discussed and further developed in the workshop with the larger group, but workshop thinking, and possible eventual full applications, will not be limited to these ideas.

At the end of the first half-day, USAID and the Applicants will then begin to discuss together

possible solutions for how to address identified gaps and challenges.

Day 2: After a brief summary of the prior day's discussion, other donors and companies involved in HIV vaccine R&D activities related to Objective 1 will briefly share about their relevant priorities and capabilities to address. Participants in the co-creation workshop will then break into 4 subgroups to discuss specific challenges and solutions relating to achieving the 4 results under Objective 1, before reporting back to the larger group. By the end of the half-day, each subgroup and the larger group will also determine if there are any next steps they need to take over the next 4 weeks to continue to resolve key issues before making a draft presentation of their framework(s) to USAID in 4 weeks time.

Day 3: USAID presentation will provide an overview of key challenges and priorities it sees related to Objective 2 of the NOFO, share about USAID's existing support for HIV vaccine R&D projects related to Objective 2, and identify general strengths, weaknesses, and gaps it noted from the concept papers.

Note: USAID will NOT discuss any specific details of what individual Applicants proposed in their concept notes during this evaluation period.

Applicant presentations for Objective 2 - Each Applicant will then each be allotted equal time to present their organization's capabilities and what they see as the key challenges and opportunities related to Objective 2. At their discretion, Applicants will have the option of also sharing specifics about existing solutions, approaches, or activities from their concept papers. These may be discussed and further developed in the workshop with the larger group, but workshop thinking, and possible eventual full applications, will not be limited to these ideas.

Day 4: After a summary of the prior day's discussion, other donors and companies involved in HIV vaccine R&D activities related to Objective 2 will share about their relevant priorities and capabilities to address. Participants in the co-creation workshop will then break into 3 subgroups to discuss specific challenges and solutions relating to achieving the 3 results under Objective 2, before reporting back to the larger group. By the end of the half-day, each subgroup and the larger group will also determine if there are any next steps they need to take over the next 4 weeks to continue to resolve key issues before making a draft presentation of their framework(s) to USAID in 4 weeks time. By the end of the half-day, each subgroup will also determine

Two-week break: Applicants will be provided the opportunity to discuss possible collaborations with one another, including possibly forming new consortia, to support proposed solutions and activities. They will also be encouraged to reach out to other potential collaborators and resource partners. USAID will be available during this period to actively participate in technical discussions and answer any questions as needed.

Day 5: Each group that forms to address Objective 1 or Objective 2 will present a draft framework to USAID for how they would address the objectives of the NOFO and USAID would provide comments and suggestions for the Applicants to consider to strengthen the

framework.

Applicants would then be given four weeks (30 calendar days) to finalize their frameworks and flesh out their specific plans in greater detail, including selection/identification of a prime. This will also provide adequate time for USAID and potential partners to make travel arrangements for the in-person meeting.

Phase 2b: IN-PERSON CO-CREATION MEETING

During the second phase of the co-creation, USAID staff will meet separately with each group of Applicants/consortium for each Objective for 1-2 days at a location TBD, preferably in Africa, and occurring in the last week in April, 2025. The locations will be selected relative to the Applicants and with a view toward minimizing travel costs and travel distances to the extent possible. Applicants will present their specific plans and USAID can provide feedback on these plans or answer other questions as needed.

The desired outcome of this second phase will be a strong draft program description from each Applicant/consortium for the full application phase, as well as quantitative and/or qualitative indicators or performance milestones. This draft program description will then be revised by the Applicant as they finalize the program description to submit as part of their technical application according to the instructions for the program description section described in Section D4.c.i.4 below.

Applicants would then be given 28 calendar days to develop and submit their full applications.

NOTE:

i. **None of USAID's communication during the co-creation process should be interpreted as a commitment to making an award of USAID funding**.

ii. **Until full applications are submitted, the Applicant may identify and include potential additional technical partners and/or potential resource partners. All additional sub-partners may be included as part of a subsequent full application if there is an agreement to do so between the potential sub-partner, the original concept paper Applicant, and USAID, but this is not guaranteed. Discussions with potential resource partners may continue throughout the process and during implementation.**

c. PHASE 3: FULL APPLICATION

After the co-creation phase, the Applicant(s) or consortium who presented to USAID the draft program description in accordance with the NOFO will then be able to submit a full application according to the instructions below.

Note: USAID may **NOT** award to an Applicant unless the Applicant has complied with all applicable unique entity identifier and System for Award Management (SAM) requirements

detailed in this section D in subsection of C. Cost Application #7 SAM Requirements on page 26.

The full application consists of (a) Technical Application and (b) Cost Application and should be submitted separately to the email addresses listed above under Section A.4 Agency Point of Contact by the deadline noted at cover page of this NOFO. 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:

"SUBJECT: NPI THRIVE [organization name], Cost Application, Part 1 of 2"

Instructions for technical applications for Objective 1 and 2 of the NOFO are described separately below:

i. Technical Application for Objective 1 (not to exceed 25 pages)

The Application must also contain the following sections:

1. **Cover Page:** See Section D.1 above for specific information that should be included on the cover page.

2. **Table of Contents:** Include major sections and page numbering to easily cross-reference (does not count towards page limit).

3. **Executive Summary:** (Two pages - Does not count towards page limit**)** The Executive Summary must provide a high-level overview of key elements of the Technical Application.

4. **Program Description**: This section should summarize how the proposed project would achieve The NPI THRIVE Project Objective 1. It should be divided up into the following sections: a) Technical Approach; b) Collaborations and Capabilities; and c) Staffing and Management Plan. The sections should cover the specific elements below:

   a. *Technical Approach:*

      i. Describe the current state of HIV vaccine research programs, with a focus on clinical HIV vaccine research, including knowledge gaps and opportunities. Include an overview of current challenges related to accelerating the clinical development of promising candidate immunogens and monoclonal antibodies for infant prophylaxis. Describe key barriers that the field needs to overcome to increase efficiency and impact of clinical HIV vaccine research in the current landscape to advance the field more rapidly to an effective HIV vaccine. Any references cited should be included in Appendix 1.

      ii. Describe sound approaches and specific activities that will address the technical, programmatic, and operational element to achieve the NPI THRIVE Project Objective 1,

including activities related to clinical immunology,; viral identification and characterization,; storing, sharing, and analyzing data and samples; and accelerating the clinical development of promising immunogens and potentially antibodies for infant prophylaxis. This should include providing specific examples of what activities will be supported and, describing why these would be expected to provide practically useful information to advance HIV vaccine science. Provide a feasible plan and timeline for completing proposed activities including any clinical studies over the five-year project timeline. Please also explain how investigators in African countries and potentially other LMIC will play a lead in the conceptualization of clinical immunology and virology experiments and activities, clinical study designs, protocol development, and analyzing and disseminating the results.

iii. Justify the proposed technical approach in terms of its responsiveness to specific strategic priorities that will accelerate the progress toward a safe and effective HIV vaccine. Explain why the proposed activities are important for advancing the HIV vaccine field.

iv. Provide information about existing tools, available data, research results, Applicant experience, or other evidence demonstrating the feasibility of the proposed approaches. This should include any scientific data that supports the proposed activities as well as examples of related studies or research that have been carried out by one or more partners involved.

v. Define feasible systems to ensure the availability and utilization of data, results, and tools for timely application to HIV vaccine research and development. This should include systems that enable preclinical and clinical data to be securely shared and analyzed by scientific partners, as well as systems for storing and sharing biological samples.

vi. Explain how the approach will create opportunities for promising scientists in African countries and other LMICs and augment the capabilities of scientific institutions in African countries and other LMIC.

b. *Collaborations and Capabilities*:

i. Describe the details of the proposed technical, scientific, and programmatic collaborations, including their structure, composition (both sub-recipients and other partners), and functions; further, explain the technical, scientific, and programmatic rationale, describe the synergistic roles of partners, and outline their unique strengths and abilities to address the interrelated technical, programmatic, and operational elements identified in the Program Description in order to achieve the NPI THRIVE Project Objective.

ii. Explain how proposed partnerships will leverage technical and financial resources (including any private sector resources), support strengthening and optimal utilization

of local partner and LMIC institutional capabilities, and coordinate with HIV vaccine research and development supported by other funders.

iii. Provide evidence of capabilities of the prime partner and/or any relevant subpartners to conduct state-of-the-art early-stage human clinical trials of candidate HIV vaccines at international standard, including providing examples of studies that they have performed that require similar capabilities to what is being proposed in the application.

iv. Provide evidence of capabilities to conduct in-depth characterizations of adaptive immune responses from human samples, without sending samples from the studies to high-income countries. This should include capabilities to perform detailed analyses of B-cell repertoires for any proposed studies related to germline targeting; capabilities to assess functional T-cell and innate immune responses; and the ability to do mucosal sampling of vaccine-induced immune responses where this is indicated. provide evidence of capabilities to employ viral sequencing to inform HIV vaccine development and specific examples of how this would be employed to advance HIV science.

v. Describe any collaborative approaches to strengthen biobanking and sample sharing between institutions and to utilize existing cloud-based and innovative data systems to enhance scientific collaboration, and explain how capabilities in bioinformatics and related fields would be strengthened.

vi. Explain how opportunities for local investigators and scientists to utilize data and samples to inform HIV vaccine research will be supported through partnerships with academic institutions in LMIC, the United States, and other countries (if relevant)

vii. Follow policies and guiding documents of USAID's New Partnerships Initiative (see Section I of this NOFO) and ensure principles are closely aligned with those outlined in the Research Fairness Initiative (see RFI for more details)

viii. Include any letters of commitment from sub-recipients or other collaborative agreements in an appendix (no more than one page per organization, does not count towards the 25 page limit) (Appendix 2).

c. *Staffing and Management Plan:*

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.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 Key Personnel are considered to be essential to the work. For this award, Key Personnel must include at least a Program Director, Clinical Director, Program Coordinator, Senior M&E Advisor, and Operations and Finance Director

	Position	Name
1	Program Director	
2	Clinical Director	
3	Program Coordinator	
4	Senior M&E Advisor	
5	African Operations Manager	

Key Personnel positions and candidates require USAID approval, as noted in the substantial involvement provision, and should represent individual experience and expertise that is essential to successfully achieve the Project Objective.

The Applicant must identify each Key Personnel and provide a summary of the proposed candidate's skills and experience, define their roles and responsibilities, justify the need for each position for three additional Key Personnel positions, specify the minimum criteria (qualifications, education, experience) required, and specify the Level of Effort (LOE). The relevant skills, education, experience, and expertise of individuals proposed as Key Personnel must be described in the context of respective roles and responsibilities. The Applicant will include resumes for each individual proposed as Key Personnel (no more than three pages per resume).

i. **Program Director:** The Program Director will have overall responsibility for the coordination of all Project activities and staff, be responsible for technical leadership and administrative oversight of the Project, and serve as the principal institutional liaison to USAID. The Program Director must have strong leadership qualities with depth and breadth in both technical expertise and management experience. At least

70% LOE is recommended for the Program Director position, although the first year could require somewhat less when fewer research activities are being implemented.

ii. **Clinical Director:** A Clinical Director must be proposed and will have responsibility for overseeing clinical trials and other clinical studies implemented during the project. The Clinical Director will exercise leadership to ensure collaboration between technical leaders involved in implementing clinical research funded directly through the project and other non-USAID sources. At least 60% LOE is recommended for the Clinical Director Position, although the first year could require less when fewer research activities are being implemented.

iii. **Program Coordinator** The Program Coordinator will have a key role in coordinating with USAID, ensuring all requirements related to work-planning and reporting are met, and facilitating effective and equitable partnerships between the prime and different partners in the United States, African countries, and other LMICs. This leadership position will require a high level of programmatic knowledge and administrative skills to be effective. 100% LOE is recommended for the Program Coordinator., although the first year could require somewhat less when fewer research activities are being implemented.

iv. **Senior M&E Advisor** - The Senior M&E Advisor will oversee the development and implementation of the monitoring and evaluation plan of the project, working to ensure that the quality of data collected, assisting the project in implementing collaboration, learning, and adapting (CLA) activities, leading the development of reports to USAID, and supporting monitoring of the Accountability and Feedback Plan and other work to ensure research fairness and equity. At least 80% LOE is recommended for the Senior M&E Advisor, although the first year could require less when fewer research activities are being implemented.

v. **African Operations Manager** – The African Operation Manager must be based in Africa and will oversee administrative and financial aspects related to implementation of activities across Africa.. At least 70% LOE is recommended for the Africa Operations Manager, although the first year could require somewhat less when fewer research activities are being implemented.

d. *Appendices*: The appendices do not count with page limit and must include the following items at the very least:

i. Appendix 1 - References for relevant work cited (please provide at least 10 but no more than 50 relevant references)

ii. Appendix 2 - *Monitoring, Evaluation, and Learning (MEL) Plan:* To track progress, promote learning, strengthen adaptive programming, and identify course corrections, Applicants must present a robust Theory of Change (ToC) which is reflected in a Project MEL plan and incorporate regular reporting on strategic indicators designed to measure and monitor progress and impact. The proposed MEL Plan should include

specific timelines, gender equity considerations, capacity strengthening targets, indicators, milestones, and benchmarks for monitoring, evaluating, and learning the progress of the proposed activities in achieving the expected results, outcomes, and impacts. (No more than four pages)

iii. Appendix 3 - *Sub-recipient Letters of Intent* specifying respective roles and stating commitment to participate (no more than one page per organization)

iv. Appendix 4- *Resumes for all Key Personnel* (no more than three pages each) with signed letters of commitment for all Key Personnel

v. Appendix 5-*Staffing Matrix and Organizational Chart* including staff skills by technical area, institutional affiliation, and geographic location (no more than three pages)

vi. Appendix 6- *Management Plan* for the proposed project, indicating roles and responsibilities (no more than three pages)

vii. Appendix 7 - *Performance History* - The Applicant must submit a list with the Applicant's (maximum of five) most relevant contracts, grants, or cooperative agreements involving similar or related programs. The reference information for these awards must include the performance location, award number (if available), a brief description of the work performed, results achieved, and a point of contact with current telephone numbers and email addresses. (Use Annex 4 Template)

USAID reserves the right to obtain past performance information from other sources including those not named in the applications.

ii. Technical Application for Objective 2 (not to exceed 25 pages)

The Application must also contain the following sections:

1. **Cover Page:** See Section D.1 above for specific information that should be included on the cover page.

2. **Table of Contents:** Include major sections and page numbering to easily cross-reference (does not count towards page limit).

3. **Executive Summary:** (Two pages - Does not count towards page limit**)** The Executive Summary must provide a high-level overview of key elements of the Technical Application.

4. **Program Description**: This section should summarize how the proposed project would achieve The NPI THRIVE Project Objective 2. It should be divided up into the following sections: a) Technical Approach; b) Collaborations and Capabilities; and c) Staffing and Management Plan. The sections should cover the specific elements below:

   a. *Technical Approach:*

i. Describe the current state of HIV vaccine research and development programs, including knowledge gaps and opportunities, with a focus on preclinical HIV vaccine research and specifically on approaches to generate broadly neutralizing antibody (bnAb) responses with adequate breadth, magnitude, and durability. Please also discuss challenges and opportunities related to improving the efficiency of preclinical research, accelerating the rate of progress of preclinical research, and ensuring equitable inclusion of scientists and institutions in African countries and other LMICs in preclinical HIV vaccine research. Any references cited should be included in Appendix 1.

ii. Describe sound approaches and specific activities that will address the technical, programmatic, and operational elements to achieve the NPI THRIVE Project Objective 2. This should include providing specific examples of a few potential vaccine candidates that could be manufactured and why these would be important to advance the field, what preclinical activities will be undertaken to advance promising immunogens and why these are being prioritized, and what specific innovative scientific collaborative projects involving African and US investigators are being proposed to respond to the suggested topics under Result 2.3. Please also explain what capacity augmentation and tech transfer activities are being proposed related to manufacturing and preclinical research in African countries, why these are being prioritized, and how these will be implemented in a staged or stepwise fashion, if relevant.

iii. Justify the proposed technical approach in terms of its responsiveness to specific strategic priorities that will accelerate the progress toward a safe and effective HIV vaccine. Explain why the proposed activities are important for advancing the HIV vaccine field.

iv. Provide information about existing tools, available data, research results, Applicant experience, or other evidence demonstrating the feasibility of the proposed approaches. This should include any scientific data that supports the proposed activities as well as examples of related studies or research that have been carried out by one or more partners involved.

v. Define feasible systems to ensure the availability and utilization of data, results, and tools for timely application to HIV vaccine research and development. This should include systems that enable preclinical and clinical data to be securely shared and analyzed by scientific partners and also systems for storing and sharing biological samples.

vi. Explain how proposed innovations would be tested in animal models, including, where relevant, how immune-correlates of vaccine-induced protection would be analyzed. Animal models might include non-human primates or small animals.

vii. Explain how the approach will create opportunities for promising scientists in African countries and other LMICs and augment the capabilities of scientific institutions across African countries and other LMICs.

2. *Collaborations and Capabilities*:

    a. Describe the details of the proposed technical, scientific, and programmatic collaborations, including their structure, composition (both sub-recipients and other partners), and functions; further, explain the technical, scientific, and programmatic rationale, describe the synergistic roles of partners, and outline their unique strengths and abilities to address the interrelated technical, programmatic, and operational elements identified in the Program Description in order to achieve NPI THRIVE Project Objective 2.

    b. Explain how proposed partnerships will leverage technical and financial resources (including any private sector resources), support strengthening and optimal utilization of local partner and LMIC institutional capabilities, and coordinate with HIV vaccine research and development supported by other funders.

    c. Provide evidence of the capabilities of the prime partner and/or any relevant subpartners to support the manufacturing of HIV envelope immunogens delivered via RNA, including providing examples of such immunogens that relevant partners have manufactured that have been tested in human trials.

    d. Provide evidence of the capabilities of the prime partner and/or any relevant subpartners to support advanced promising immunogens through the battery of tests and supportive activities needed to enter FIH studies.

    e. Provide evidence of capabilities to support the development of innovative preclinical concepts related to design and testing immunogens to elicit bnAbs, adjuvants, sustained or controlled release technologies, and comparison of different nucleic acid delivery platforms (RNA in liposome, self-amplifying RNA in liposomes, and DNA in liposomes).

    f. Provide evidence of mentoring and capacity building capabilities that will improve the ability of investigators and scientists in LMIC to conduct innovative preclinical research in partnership with investigators in the United States, and other countries (if relevant).

    g. Follow policies and guiding documents of USAID's New Partnerships Initiative (see Section D of this NOFO) and ensure principles are closely aligned with those outlined in the Research Fairness Initiative (see RFI for more details).

    h. Include any letters of commitment from sub-recipient or other collaborative agreements in an appendix (no more than one page per organization, does not count towards the 25 page limit) (Appendix 2).

3. *Staffing and Management Plan:*

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; and oversight of design, development, and implementation. 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 that lists and describes Key Personnel and other staffing proposed with LOE, names 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 the Appendix for more information.

Key Personnel: The Key Personnel are considered to be essential to the work. For this award, Key Personnel must include at least a Program Director, Clinical Director, Program Coordinator, Senior M&E Advisor, and Operations and Finance Director

	Position	Name
1	Program Director	
2	Deputy Director	
3	Senior Manufacturing Advisor	
4	Senior Preclinical Innovation Advisor	
5	Other TBD	

Key Personnel positions and candidates require USAID approval, as noted in the substantial involvement provision, and should represent individual experience and expertise that is essential to successfully achieve the Project Objective.

The Applicant must identify each Key Personnel and provide a summary of the proposed candidate's skills and experience, define their roles and responsibilities, justify the need for each position for three additional Key Personnel positions, specify the minimum criteria (qualifications, education, experience) required, and specify the Level of Effort (LOE) . The relevant skills, education, experience, and expertise of individuals proposed as Key Personnel must be described in the context of respective roles and responsibilities. The Applicant will include resumes for each individual proposed as Key Personnel (no more than three pages per resume).

a. **Program Director:** The Program Director will have overall responsibility for the coordination of all Project activities and staff, be responsible for technical leadership and administrative oversight of the Project, and serve as the principal institutional liaison to USAID. The Program Director must have strong leadership qualities with depth and breadth in both technical expertise and management experience. At least 25% LOE is recommended for the Program Director position.

b. **Deputy Director** – The Deputy Director will oversee administrative and financial aspects related to the implementation of the project. The Deputy Director will work to ensure all requirements related to work-planning and reporting are met, and facilitate effective and equitable partnerships between the prime and different partners in the United States, African countries, and other LMIC. At least 75% LOE is recommended for the Deputy Director for Operations.

c. **Senior Manufacturing Advisor:** The Senior Manufacturing Advisor will have responsibility for overseeing manufacturing activities implemented during the project. At least 30% LOE is recommended for the Senior Manufacturing Advisor

d. **Senior Preclinical Innovation Advisor:** The Senior Preclinical Innovation Advisor will exercise technical leadership in all areas related to preclinical development and scientific innovation that do not relate to manufacturing. At least 30% LOE is recommended for the Program Coordinator.

e. **Other TBD**: The Applicant may propose an additional Key Personnel position if desired.

4. *Appendices*: The appendices do not count with page limit and must include the following items at the very least:

a. Appendix 1 - References for relevant work cited (please provide at least 10 but no more than 50 relevant references)

b. Appendix 2 - *Monitoring, Evaluation, and Learning (MEL) Plan:* To track progress, promote learning, strengthen adaptive programming, and identify course corrections, Applicants must present a robust Theory of Change (ToC) which is reflected in a Project MEL plan and incorporate regular reporting on strategic indicators designed to measure and monitor progress and impact. The proposed MEL Plan should include specific timelines, gender equity considerations, capacity strengthening targets, indicators, milestones, and benchmarks for monitoring, evaluating, and learning the progress of the proposed activities in achieving the expected results, outcomes, and impacts. (No more than four pages). The MEL Plan should also include an Accountability and Feedback Plan which details how feedback on the prime partner is collected and acted upon to advance equitable implementation and partnerships, collecting feedback from sub-partners, resource partners, beneficiaries, local leaders, communities, etc. The Accountability and

Feedback Plan should be no longer than two pages and further instructions can be found in Annex 5.

c. Appendix 3 - *Sub-recipient Letters of Intent* specifying respective roles and stating commitment to participate (no more than one page per organization)

d. Appendix 4- *Resumes for all Key Personnel* (no more than three pages each) with signed letters of commitment for all Key Personnel

e. Appendix 5-*Staffing Matrix and Organizational Chart* including staff skills by technical area, institutional affiliation, and geographic location (no more than three pages)

f. Appendix 6- *Management Plan* for the proposed project, indicating roles and responsibilities (no more than three pages)

g. Appendix 7 - *Performance History* - The Applicant must submit a list with the Applicant's (maximum of five) most relevant contracts, grants, or cooperative agreements involving similar or related programs. The reference information for these awards must include the performance location, award number (if available), a brief description of the work performed, results achieved, and a point of contact with current telephone numbers and email addresses. (Use Annex 4 Template)

USAID reserves the right to obtain past performance information from other sources including those not named in the applications.

3. 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 (See Section D.1 above for requirements)
- 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 upon request by the AO at the stage when an award anticipated to be made:

(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) if applicable, 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 break down 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) 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.*

8) 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.

9) Program Income - Please refer to Section H.4

10) Cost Sharing – 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, 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. [*Consider including the following, as appropriate:]*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.

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 three 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 3 years ; and
- 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 will be asked to provide a Branding Strategy and Marking Plan to be evaluated and approved by the Agreement Officer and incorporated into any resulting award. This should **NOT** be submitted with the initial application

8.1 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 the 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.

(END OF PRE-AWARD TERM)

8.2. Marking Plan – Assistance (October 2024)

a. Applicants recommended for an assistance award must submit and negotiate a "Marking Plan," detailing the public communications, commodities, 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 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 of 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. If the Applicant receives an assistance award, 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. See 2 CFR 200.331 for assistance in determining whether a sub-tier entity is a subrecipient or contractor.

Construction is not authorized under this award.

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

Except as may be specifically approved in advance by the AO, all commodities and services that will be reimbursed by USAID under this award must be from the authorized geographic code specified in Section B.4 of this NOFO and must meet the source and nationality requirements set forth in 22 CFR 228.

h) Conscience Clause

CONSCIENCE CLAUSE IMPLEMENTATION (ASSISTANCE) – PRE-AWARD TERM (February 2012)

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

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

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

(ii) or to endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection; and

2) 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)(1) above.

(b) An Applicant who believes that this solicitation contains provisions or requirements that would require it to endorse or use an approach or participate in an activity to which it has a religious or moral objection must so notify the cognizant Agreement Officer in accordance with the Mandatory Standard Provision titled “Notices” as soon as possible, and in any event not later than 15 calendar days before the deadline for submission of applications under this solicitation. The Applicant must advise which activity(ies) it could not implement and the nature of the religious or moral objection.

(c) In responding to the solicitation, an Applicant with a religious or moral objection may compete for any funding opportunity as a prime partner, or as a leader or member of a consortium that comes together to compete for an award. Alternatively, such Applicant may limit its application to those activities it can undertake and must indicate in its submission the activity(ies) it has excluded based on religious or moral objection. The offeror’s proposal will be evaluated based on the activities for which a proposal is submitted, and will not be evaluated favorably or unfavorably due to the absence of a proposal addressing the activity(ies) to which it objected and which it thus omitted. In addition to the notification in paragraph (b) above, the Applicant must meet the submission date provided for in the solicitation.

(END OF PRE-AWARD TERM)

i) Conflict of Interest Pre-Award Term

a. Personal Conflict of Interest

i. An actual or appearance of a conflict of interest exists when an Applicant organization or an employee 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 may compromise, or have the appearance of compromising, the obligations and duties of a USAID employee or recipient employee.

ii. 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."

k) Other Supporting/Required Documentation

Applicants are required to include an eligibility certification form with their concept paper noting what type of NPI Partnership Approach they are using and certifying that it is applicable to their organization. Please see Annex 6 of this NOFO for the form.

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SECTION E: SUBMISSION REQUIREMENTS AND DEADLINES

1. Questions and Answers

Applicants must submit questions regarding this NOFO, if any, by email to the points of contact noted in Section A.4 of the NOFO 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

Concept papers and full applications in response to this NOFO must be received **no later** than the closing date and time indicated on the cover letter. Late concept notes or applications will be considered only if the AO determines it is in the best interest of the USG. Applicants must retain proof of timely delivery in the form of system-generated documentation of delivery receipt date and time/confirmation from the receiving office. Additionally, Applicants should retain a copy of the application and all enclosures for their records.

Concept papers and 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 a concept paper or 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.

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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 will be evaluated accordingly.

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 Paper; and (b) set the standard against which all Concept Papers will be evaluated.

A. Merit Review for Concept Papers 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.

Merit Review Criteria #1: Technical Approach

The extent to which the Concept Paper is responsive to Objective 1 of the NOFO, including clearly articulating the most up-to-date current and anticipated strategic research/programmatic needs and technical priorities related to clinical HIV vaccine research and development and adequately describing feasible and innovative approaches that the Applicant will take to addressing identified gaps to advance the field of HIV vaccine research in areas related to clinical immunology, clinical virology, storing and sharing samples and data, and advancing clinical development of promising HIV vaccine candidates and monoclonal antibodies for infant prophylaxis.

Merit Review Criteria #2: Capabilities and Collaborations

The extent to which the structure, composition, and rationale for the proposed collaborations and partnerships are appropriate for achieving the results for the Objective as described in the Technical Approach; including capabilities of the various partners and the proposed partnership structure and composition as broadly described in the Concept Paper. The extent to which the Applicant's AFP identifies issues and sources relevant to the proposed approaches that need to be tracked to identify a) potential contributions to inequity, discrimination, or stigma and b) opportunities to advance equity

Merit Review Criteria #3: Locally Led Development and Capacity Strengthening

The extent to which the Applicant's technical approach contributes to locally-led development.as articulated by USAID's locally-led development factsheet. The extent to

which capacity strengthening activities are appropriate, impactful, and responsive to the principles of the LCS Policy and contribute to Objective 1 of the NOFO.

B. Merit Review for Concept Papers for Objective 2

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.

Merit Review Criteria #1: Technical Approach

The extent to which the Concept Paper is responsive to the relevant Objective 2 of the NOFO, including clearly articulating the most up-to-date current and anticipated strategic research/programmatic needs and technical priorities related to preclinical HIV vaccine research and development and adequately describing feasible and innovative approaches that the Applicant will take to addressing identified gaps to advance the field of HIV vaccine research in areas related to manufacturing of immunogens for clinical trials, accelerating the preclinical development of promising immunogens, and testing Innovative preclinical concepts that address key obstacles to eliciting protective bnAb responses.

Merit Review Criteria #2: Capabilities and Collaborations

The extent to which the structure, composition, and rationale for the proposed collaborations and partnerships are appropriate for achieving the results for the Objective as described in the Technical Approach; including the capabilities of the various partners and the proposed partnership structure and composition as broadly described in the Concept Paper. The extent to which the Applicant's AFP identifies issues and sources relevant to the proposed approaches that need to be tracked to identify a) potential contributions to inequity, discrimination, or stigma and b) opportunities to advance equity.

Merit Review Criteria #3: Locally Led Development and Capacity Strengthening

The extent to which the Applicant's technical approach contributes to locally-led development as articulated by USAID's locally-led development factsheet. The extent to which capacity strengthening activities are appropriate and responsive to the principles of the LCS Policy and contribute to Objective 2 of the NOFO.

C. Merit Review for the Full Application 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.

Merit Review Criteria #1: Technical Approach

- The extent to which the Application responds to Objective 1 of the NOFO, including clearly articulating the most up-to-date current and anticipated strategic needs and technical priorities related to clinical HIV vaccine research and development and providing a detailed description of the innovative technical approach and related activities that the Applicant will undertake to address identified gaps to advance the field toward a safe and effective vaccine.

- The extent to which the Application provides a strong scientific rationale for the proposed activities; identifies clear milestones and timelines for the proposed activities; describes existing tools, available data, research results, or other evidence that supports the feasibility of completing the proposed activities; and describes a practical system to ensure availability and utilization of data, results, and tools for timely application to HIV vaccine research and development.

- The extent to which the approach creates opportunities for multi-year extended support for promising African scientists. The extent to which the approach identifies and frames gender-related considerations that need to be addressed in HIV vaccine research.

- The extent to which the Application proposes a clear approach and plan for monitoring, evaluation, and learning (MEL), guided by a robust Theory of Change (ToC), that will enable the project to track progress, promote learning, strengthen adaptive programming, and identify course corrections where needed. The extent to which the MEL plan includes appropriate specific, measurable, and attainable indicators, benchmarks, and timelines for monitoring, evaluating, and learning the progress of the proposed activities in achieving the expected results, outcomes, and impacts.

Merit Review Criteria #2: Capabilities and Collaborations

- The extent to which the proposed collaborations and partnerships from scientific, technical, and programmatic perspectives are appropriate for achieving the results for the Objective 1 as specified in the Technical Approach, including describing the details of the proposed collaborations, including their structure, composition (both sub-recipients and other partners), and functions; explaining the technical and programmatic rationale for proposed collaborations, describing the synergistic roles of partners; explaining how proposed partnerships will leverage technical and financial resources from LMIC institutions, the private sector, and other donors, as applicable.

- The extent to which the Application provides evidence of the capabilities of partners to lead state-of-the-art early-stage human clinical trials of candidate HIV vaccines at international standards.

- The extent to which the Application provides evidence of the capabilities of partners to conduct complex human immunological testing needed to inform HIV vaccine development, including necessary B-cell analytics.

- The extent to which the Application provides evidence of the capabilities of partners to identify, sequence, and characterize viruses circulating in LMIC

- The extent to which the Application provides evidence of the capabilities of partners to support the storing, sharing, and utilization within Africa of relevant samples and data to inform HIV vaccine research and development.

- The extent to which the Application provides evidence of necessary gender-related technical capacity to assess how gender-related considerations are being integrated and implemented within the project.

Merit Review Criteria #3: Locally Led Development and Capacity Strengthening

- The extent to which the Applicant's technical approach demonstrates a strong understanding of local challenges and opportunities and outline specific activities that will contributes to locally-led development as articulated by USAID's locally led development factsheet.
- The extent to which the Applicant explicitly applies principles of the LCS Policy and outlines capacity strengthening activities that are appropriate and contribute to Objective 1 of the NOFO. This includes the degree to which the Applicant demonstrates its understanding of the local system; the extent to which Applicants provide a diverse, appropriate, and innovative array of approaches and tools to address the needs of actors that have diverse levels of capacity; and describes its approach to collaboratively measuring capacity strengthening with partner organizations.

Merit Review Criteria #4: Staffing and Management Plan

- The extent to which Key Personnel and Other Staffing are clearly identified; their roles and level of effort are defined; and their education, skills, experience, and expertise are identified and described in a manner that is appropriate and adequate for the proposed activities under the relevant Objective.

- The extent to which the proposed management plan demonstrates the ability to implement the Technical Approach efficiently and effectively, including clearly describing and justifying sub-award structures; partnership coordination; technical, financial, and administrative management and oversight; and oversight of design, development, and implementation of the proposed research.

- The extent to which the Applicant's AFP identifies issues and sources relevant to the proposed approaches that need to be tracked to identify a) potential

contributions to inequity, discrimination, or stigma and b) opportunities to advance equity

Merit Review Criteria #5: Past Performance

- The extent to which the Applicant's past performance as measured by appropriate references provided to USAID supports the Applicant's capabilities to complete effectively the activities that are described in the Application.

C. Merit Review for the Full Application for Objective 2

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.

Merit Review Criteria #1: Technical Approach

- The extent to which the Application responds to Objective 2 of the NOFO, including clearly articulating the most up-to-date current and anticipated strategic needs and technical priorities related to preclinical HIV vaccine research and development and providing a detailed description of the innovative technical approach and related activities that the Applicant will undertake to address identified gaps to advance the field toward a safe and effective vaccine.

- The extent to which the Application provides a strong scientific rationale for the proposed activities; identifies clear milestones and timelines for the proposed activities; describes existing tools, available data, research results, or other evidence that supports the feasibility of completing the proposed activities; and describes a practical system to ensure availability and utilization of data, results, and tools for timely application to HIV vaccine research and development.

- The extent to which the approach creates opportunities for multi-year extended support for promising African scientists. The extent to which the approach addresses gender equity. The extent to which the approach identifies and frames gender-related considerations that need to be addressed in HIV vaccine research.

- The extent to which the Application proposes a clear approach and plan for monitoring, evaluation, and learning (MEL), guided by a robust Theory of Change (ToC), that will enable the project to track progress, promote learning, strengthen adaptive programming, and identify course corrections where needed. The extent to which the MEL plan includes appropriate specific, measurable, and attainable indicators, benchmarks, and timelines for monitoring, evaluating, and learning the progress of the proposed activities in achieving the expected results, outcomes, and impacts.

Merit Review Criteria #2: Capabilities and Collaborations

- The extent to which the proposed collaborations and partnerships from scientific, technical, and programmatic perspectives are appropriate for achieving the results for Objective 1 as specified in the Technical Approach, including describing the details of the proposed collaborations, including their structure, composition (both sub-recipients and other partners), and functions; explaining the technical and programmatic rationale for proposed collaborations, describing the synergistic roles of partners; explaining how proposed partnerships will leverage technical and financial resources from LMIC institutions, the private sector, and other donors, as applicable.

- The extent to which the Application provides evidence of the capabilities of partners to manufacture candidate HIV vaccines for FIH studies and describes feasible approaches for transferring some of these capabilities to one or more partners in Africa.

- The extent to which the Application provides evidence of the capabilities of partners to conduct necessary preclinical testing of immunogens to advance them into FIH studies and describes feasible approaches for transferring some of these capabilities to one or more partners in Africa.

- The extent to which the Application provides evidence of the capabilities of partners to develop and advance innovative preclinical concepts that address key obstacles to eliciting protective bnAb responses

- The extent to which the Application provides evidence of necessary gender-related technical capacity to assess how gender-related considerations are being integrated and implemented within the project.

Merit Review Criteria #3: Locally Led Development and Capacity Strengthening

- The extent to which the Applicant's technical approach demonstrates a strong understanding of local challenges and opportunities and outline specific activities that will contribute to locally-led development as articulated by USAID's locally led development factsheet.

- The extent to which the Applicant explicitly applies principles of the LCS Policy and outlines capacity strengthening activities that are appropriate and contribute to Objective 1 of the NOFO. This includes the degree to which the Applicant demonstrates an understanding of the local system; the extent to which Applicants provide a diverse, appropriate, and innovative array of approaches and tools to address the needs of actors that have diverse levels of capacity; and

describes its approach to collaboratively measuring capacity strengthening with partner organizations.

Merit Review Criteria #4: Staffing and Management Plan

- The extent to which Key Personnel and Other Staffing are clearly identified; their roles and level of effort are defined; and their education, skills, experience, and expertise are identified and described in a manner that is appropriate and adequate for the proposed activities under the relevant Objective.

- The extent to which the proposed management plan demonstrates the ability to implement the Technical Approach efficiently and effectively, including clearly describing and justifying sub-award structures; partnership coordination; technical, financial, and administrative management and oversight; and oversight of design, development, and implementation of the proposed research.

- The extent to which the Applicant's AFP identifies issues and sources relevant to the proposed approaches that need to be tracked to identify a) potential contributions to inequity, discrimination, or stigma and b) opportunities to advance equity.

Merit Review Criteria #5: Past Performance

- The extent to which the Applicant's past performance as measured by appropriate references provided to USAID supports the Applicant's capabilities to complete effectively the activities that are described in the Application.

3. Review and Selection Process

All concept notes/applications received by the deadlines stated on the cover page and as revised via amendment of the NOFO will be reviewed for eligibility and compliance with the instructions for submission prior to evaluation against the criteria listed in this section. The AO will then forward those concept notes/applications that are complete and comply with the instructions to the Merit Review/Selection Committees. The Merit Review/Selection Committees will conduct a review of the concept notes/full applications. The Business Application will be reviewed by the Agreement Officer.

USAID will not provide feedback on concept notes that do not pass. USAID does not anticipate providing feedback to those Applicants that pass; however, it reserves the right to provide written feedback. Should such feedback be provided, it will be provided to all Applicants that pass. Concept notes/applications will be reviewed and evaluated in accordance with the criteria listed below.

Following the review of the Full Application, the Merit Review/Selection Committee will share with the AO their recommendations. The Apparently Successful Applicant(s) may be asked to provide more clarification about their application as well as possibly a presentation.

The AO will work with the Merit Review/Selection Committee in the final review, negotiation and drafting the award. The AO will make the final decision and award the instrument(s).

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.

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.

a) Business Application Review

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 the simplified acquisition threshold, 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.}

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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 Applicants 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 within 14 days of the Agreement Officer's selection.

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.

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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. Reporting Requirements

The awardee(s) will adhere to all reporting requirements listed below. All reports as required under Substantial Involvement shall be submitted by the due date for approval of the USAID AOR. Additional reports requiring review and clearances, when necessary, are listed under each requirement. Awardee(s) will consult with the AOR on the format and expected content of reports prior to submission.

- **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.

In addition, for Non-US Non-governmental Organizations financial reporting requirements will be in accordance with Standard Provisions for Non-U.S. Non-governmental Organizations.

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.

- **Performance Reporting**

  The awardee(s) will submit reports to the USAID as described below. The exact format for preparation of and timing for submission of all reports will be determined in collaboration with USAID.

  1. Annual WorkPlan - The awardee(s) will prepare annual implementation and progress plans on a schedule and according to a format established by USAID, to be submitted to USAID for approval.

  2. Monitoring and Evaluation Plan

  3. Periodic Performance Reports - The Recipient(s) will submit quarterly and annual performance reports to USAID. These reports will include a summary of activities and key achievements, description of progress and actual achievements as well as any issues that are affecting the timing of the activities.

  4. Final Report - As USAID requires, 90 days after the completion date of an agreement, the awardee(s) shall submit a final report. See 22 CFR 226.51.

  5. Ad Hoc Reporting - The awardee(s) will provide to the AOR any cost data, schedules, and progress or results reports requested that are relevant to approval, design, implementation, and monitoring of results to satisfy Agency reporting requirements.

4. Program Income

If the successful Applicant(s) is/are an NGO, any program income generated under the award(s) will be added to USAID funding (and any cost-sharing that may be provided) and used for program purposes. However, pursuant to 22 CFR 226.82, if the successful Applicant(s) is/are a for-profit organization, any program income generated under the award(s) will be deducted from the total program cost to determine the amount of USAID funding. Program income will be subject to 22 CFR 226.24 for U.S. NGOs or the standard provision entitled —Program Income for non-U.S. NGOs.

Please note that USAID's procurement rules do not apply to awards to Public International Organizations (PIOs) unless USAID is the sole contributor to a trust fund established by the PIO. If USAID is the sole contributor, the same rules, as prescribed in subparagraph (a) above for NGOs, will apply. For PIOs, any program income generated under the award(s) will be added to USAID funding (and any non-USAID funding that may be provided) and used for program purposes.

5. Environmental Compliance

Environmental Compliance background information is found at: https://www.usaid.gov/environmental-procedures.

An environmental analysis and programmatic IEE prepared for the NPI-THRIVE program prior to the obligation of funding. The THRIVE implementing partner(s) shall be responsible for implementing all IEE conditions pertaining to interventions to be funded under this award(s). In consultation with the BEO, the AOR will oversee the implementation of the requirements in the IEE/EA. If there are multiple awards with different IPs, each IP will prepare an Environmental Mitigation and Monitoring Plan (EMMP) in coordination with the AOR and approved by the GH BEO before major programmatic implementation begins.

6. Other Requirements

- **USAID Disability Policy Assistance:** The objectives of the USAID Disability Policy are to 1) enhance the attainment of United States foreign assistance program goals by promoting the participation and equalization of opportunities of individuals with disabilities in USAID policy, country and sector strategies, activity designs and implementation; 2) increase awareness of issues of people with disabilities both within USAID programs and in host countries; 3) engage other USG agencies, host country counterparts, governments, implementing organizations and other donors in fostering a climate of nondiscrimination against people with disabilities; and 4) support international advocacy for people with disabilities.

  USAID therefore requires that the awardee(s) not discriminate against people with disabilities in the implementation of USAID-funded programs and that it makes every effort to comply with the objectives of the USAID Disability Policy in performing the program under this grant or CoAg. To that end and to the extent it can accomplish this goal within the scope of the program objectives, the awardee(s) must demonstrate a comprehensive and consistent approach for including men, women, and children with disabilities.

- **Protection of Human Subjects in Research Supported by USAID:** All awardee(s) are responsible for safeguarding the rights and welfare of human subjects involved in research supported by USAID and must comply with the Common Federal Policy for the Protection of Human Subjects as found in Part 225 of Title 22 of the Code of Federal

Regulations (22 CFR 225). Additional guidance is available in the ADS 200 Mandatory Reference, —Protection of Human Subjects in Research Supported by USAID.

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.

As a NOFO issued under USAID's New Partnerships Initiative (NPI) projects that are awarded will adhere to the following NPI policies and guiding documents.

1. Locally Led Development

Although NPI retains the ability to partner with all types of organizations, including US-based, international, and local, an overriding objective of the localization initiative is to foster greater locally-led development (LLD). USAID defines LLD as 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. As the LLD Spectrum makes clear, local leadership is not about simply awarding funds directly to local actors; USAID empowers local leadership when it comes alongside initiatives that originate in and are managed by partner country actors. Local actors' credibility, accountability, and long-range time perspective are essential for success in achieving sustainable development. LLD 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.

2. Local Capacity Strengthening (LCS)

Since a key objective of NPI programming is to foster locally-led development, it follows that capacity strengthening support provided through NPI awards should similarly be strategic, inclusive, and locally led, in line with the Agency's LCS Policy. Capacity strengthening allows local organizations to better serve their communities, respond more effectively in crisis situations, develop specialized sectoral expertise, mobilize resources, influence policy, and move beyond the need for donor funding.

Through the LCS Policy USAID is committing to a unified, cohesive, and systemic approach in which USAID collaborates with local partners to:

- Define their own vision for success;
- Strengthen their ability to be effective and relevant actors within their local communities and contexts;
- Elevate local ownership to sustain development results.

3. Inclusive Development

NPI is committed to advance inclusive development as described in Inclusive Development: Additional Help for ADS 201. USAID promotes a nondiscriminatory, inclusive, equitable, and integrated development approach that ensures that all people have access to a country's services, opportunities, and legal protections, and are able to take part in their societies. This approach requires a concerted effort to include those who face discrimination, marginalization, underrepresentation, and/or have been made vulnerable. These intentional and proactive efforts ensure that all individuals are fully included and can actively participate in and benefit from development processes and activities with the goal of achieving equal outcomes for all.

4. Refinement Period

NPI encourages the use of a post-award Refinement Period , when useful, to facilitate the award process with new partners. During a Refinement Period the Recipient and USAID with support as needed from NPI, can further refine and adapt the activity design, technical approaches, and theory of change (TOC) to improve the impact and sustainability of results. Refinement Periods can also be used to identify subpartners, pilot implementation arrangements, strengthen capacity, address Special Award Conditions, or otherwise prepare for full scale implementation.

USAID anticipates the initial Refinement Period Phase for cooperative agreement made under the NPI THRIVE Program will last from 3-4 months. This timeframe will be defined at the discretion of the Office of Acquisition and Assistance during the time the award is made. During the Refinement Period, prime partners will be expected to be engaged in developing a detailed Year 1 workplan and in finalizing any subawards that need to be made to begin implementation of the core activities of the project. In addition, prime partners may be expected to lead or carry out a number of other tasks, including:

- Pre-implementation analysis that addresses evidence and knowledge gaps and strengthens understanding of local context
- Refining the Theory of Change (TOC) and implementation plans (including with other Mission partners in the areas of engagement); and
- Preparation for implementation through hiring, staff training, and procurement of goods and services
- Developing systems or processes to meet special award conditions.
- Meaningful community engagement to enable two-way feedback and participation around the planned activity, interventions and refinement period, and ensure mutual accountability, including in decision making processes.
- Participatory stakeholder engagement for strengthened local partnerships, capacity development, and coordination;
- Collaborating and planning with relevant USAID Mission or Operating Unit activities to receive concurrence for activities and to identify areas for strategic collaboration, effectively layer and leverage other USAID programming, and create lines of communication with other activities;

5. Accountability and Feedback

The NPI recognizes that relationships characterized by equity and accountability within USAID's partner ecosystem—particularly between established and local partners—better empower local populations to take the lead in achieving their own development or humanitarian objectives. Consequently, NPI requires international implementing partners using mentorship or leverage awards to develop Accountability and Feedback Plans (AFPs) within their AMELPs. All prime recipients of awards under this NOFO will be expected to develop and maintain an AFP that fosters accountability between USAID, the prime, sub-awardees, and affected population. Further, AFPs contribute towards USAID's Locally Led Program Indicator

While collecting information from populations engaged with and affected by development work is common practice, the AFP builds on legislative and ADS requirements for participant feedback, inclusive development, and Collaborating, Learning, and Adapting (CLA) principles by encouraging implementing partners to seek information from a broader selection of sources and emphasizes equity as a topic of inquiry.

Accountability and feedback planning is rooted in the recognition that USAID and its implementing partner(s) need input from activity participants, sub-contractors, and the greater community for more effective programming and identifying avenues for adaptive activity implementation. Soliciting and incorporating a diversity of perspectives in the implementation process is valuable: it helps elevate community priorities and ensures they are centered in implementation and adaptation. Furthermore, involving activity participants in key decision-making processes can increase trust and cooperation, build community support for the activity, mobilize local leadership and skills, reduce complaints, and increase efficiency by reducing waste and losses.

6. Do No Harm (DNH)

Throughout a Concept Note (and subsequent application), an Applicant should reflect thoughtful consideration of any risks that could result by bringing together conflicting parties and should provide sufficient explanation of how it will establish and monitor appropriate safeguards to avoid intensifying any conflict or creating harmful situations for participants.

DNH should not be an isolated discussion in a Concept Note or subsequent application; Applicants should address it holistically, especially throughout a longer technical application, if the organization receives an invitation to move forward from a Concept Note submitted under this APS.

Where relevant, Applicants should analyze the impact of planned activities with regard to how they may affect local tensions, points of conflict, or post-conflict environments. It is not satisfactory to simply indicate the program will "DNH."

Applicants should also describe how they plan to monitor (perhaps through indicators) and adapt their DNH strategies and approaches to ensure DNH throughout all stages of design, implementation, and monitoring and evaluation.

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ANNEX 1 - SUMMARY BUDGET TEMPLATE

Please see **attached Annex 1- Summary Budget Template**

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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.**

Guidance: The AO should review the prescriptions for each required as applicable provision and check ("X") whether it will apply to the anticipated award. If this cannot be determined at the NOFO stage, type "determined at award" (similar to the indirect cost rate provisions). As a reminder, the AO must include the full text of all mandatory and required as applicable standard provisions in the award document. If the award will be a fixed amount award or use the simplified grant format, substitute these provisions with the provisions relevant to that award type, see ADS 303mat and ADS 303mbx, respectively.

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)

Required	Not Required	REQUIRED AS APPLICABLE STANDARD PROVISIONS U.S. NGOs
		RAA11. Prohibition of Assistance to Drug Traffickers (June 1999)
		RAA12. Investment Promotion (December 2022)
		RAA13. Reporting Host 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)
		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)

Required	Not Required	REQUIRED AS APPLICABLE STANDARD PROVISIONS Non-U.S. NGOs
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)
		RAA11. Reporting Host 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

ADS Automated Directives System
AIDS Acquired Immune Deficiency Syndrome
AO Agreement Officer
AOR Agreement Officer's Representative
bnAb/s Broadly Neutralizing Antibody/Antibodies
CFR Code of Federal Regulations
FAA Foreign Assistance Act of 1961
FBO Faith-Based Organization
FDA Food and Drug Administration GH Bureau for Global Health
FIH First in Human
HIV Human Immunodeficiency Virus
THRIVE Translational HIV Research for Innovative Vaccines Ecosystem
IEE Initial Environmental Examination
LGBTQI+ Lesbian, gay, bisexual, transgender, queer or questioning, intersex, plus
LMIC Low and Middle-Income Country
MEL Monitoring, Evaluation and Learning
NGO Non-Governmental Organization**NIH** National Institutes of Health
NICRA Negotiated Indirect Cost Rate Agreement
NOFO Notice of Funding Opportunity
NPI New Partnerships Initiative
OHA Office of HIV and AIDS
PEPFAR President's Emergency Plan for AIDS Relief
PAC Product Advisory Committee
PVO Private Voluntary Organizations
RNA Ribonucleic Acid
R&D Research and Development
RFI Research Fairness Initiative
SAM System for Award Management
USAID United States Agency for International Development
USG United States Government
UNAIDS The Joint United Nations Programme on HIV/AIDS

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ANNEX 4 PAST PERFORMANCE INFORMATION (PPI)

1. AWARD NUMBER (IF USAID AWARD**):**
2. CONTRACTOR/RECIPIENT (NAME AND ADDRESS):
3. TYPE OF AWARD:
4. COMPLEXITY OF WORK: DIFFICULT _____ ROUTINE _____
5. DESCRIPTION, LOCATION, AND RELEVANCY OF WORK:
6. DOLLAR VALUE OF WORK: $_____STATUS: ACTIVE_____COMPLETED_____
7. DATE OF AWARD:_____
8. TYPE AND EXTENT OF SUBAWARDS:
9. NAME, ADDRESS, TELEPHONE NUMBER, AND E-MAIL ADDRESS OF THE AWARDING CONTRACTING/AGREEMENT OFFICER AND CONTRACTING/AGREEMENT OFFICER'S REPRESENTATIVE (OR IF NOT APPLICABLE, TWO OTHER INDIVIDUALS THAT CLOSELY OBSERVED THE WORK):

ANNEX 5 – ACCOUNTABILITY AND FEEDBACK PLAN GUIDANCE

Applicants should explain how they will incorporate accountability and feedback mechanisms by submitting a plan or framework that is specific to the interventions included in the application**.** All NPI awards are encouraged to include AFPs to collect feedback broadly from constituents. Additional instructions can be found in the Accountability and Feedback Plan Guidance document. This is a requirement for concept Paper stage, after which the accountability plan should be integrated into MEL Plans for the full application phase Primes must submit the plan or framework as an annex, not to exceed two pages, and describe:

<table>
<tr><td colspan="3">Key Elements of Accountability and Feedback Plans</td></tr>
<tr><td colspan="3">• How and how often you will collect feedback from each relevant stakeholder group
• What are you trying to learn from each group? (See below)
• How you will communicate back to them (closing the loop: communicating what you’re doing with this feedback)
• How will you develop and track implementation of recommendations derived from feedback?</td></tr>
<tr><td>Sub-Awardee</td><td>Marginalized Populations</td><td>All</td></tr>
<tr><td>• How subaward partners will be incorporated into the process of implementing accountability and feedback measures
• What the key issue areas are that you will track through sub-awardee feedback to advance equity and inclusion in implementation</td><td>• What the key groups of affected populations are
• What the key issue areas are that you will track through marginalized population feedback to advance equity and inclusion in implementation and reduce harm to marginalized and underrepresented populations</td><td>• Perception of outcomes
• Suggestions for improving implementation</td></tr>
</table>

ANNEX 6: ELIGIBILITY CERTIFICATION FORM

Please check the appropriate box to certify eligibility for the type of partner that applies:

- (For Partners Applying as New Partner) We certify that, in line with the criteria enumerated in Section III, Sub-Section A, our organization has not received any direct or indirect funding from USAID over the last five (5) years.

- (For Partners Applying as an Underutilized Partner) We certify that, in line with the criteria enumerated in Section III, Sub-Section A, our organization has not received more than $25 million in direct or indirect funding from USAID over the last five (5) years.

- (For Partners Applying as a Local Entity Partner) We certify that, in line with the criteria enumerated in Section III, Sub-Section A, our organization adheres with following: a) is legally organized under the laws of a country that is receiving assistance from USAID; b) has its principal place of business or operations in a country receiving assistance from USAID; c) is majority-owned by individuals who are citizens or lawful permanent residents of a country receiving assistance from USAID; and d) is managed by a governing body, the majority of whom are citizens or lawful permanent residents of the country receiving USAID assistance.

- (For Partners Applying as a Locally Established Partner) We certify that, in line with the criteria enumerated in Section III, Sub-Section A, our organization has a) maintained continuous operations in-country for at least five years and materially demonstrated a long-term presence in the country of activity performance; and b) is locally led in such a way that local citizens are able to exercise the power to control by any means, the election, appointment, or tenure of the organization's managers or a majority of the organization's governing body.

- (For Partners Applying for a Mentorship Award) We certify that, in line with the criteria enumerated in Section III, Sub-Section A, our organization, will subaward a minimum 50% of our award to local or regional partners and provide capacity building support as defined by the relevant Addendum in consultation with the local/locally established partners.

- (For Partners Applying as Leverage) We certify that, in line with the criteria enumerated in Section III, Sub-Section A, our organization can demonstrate 50% of award value of this proposal using non-federal funds.