Issue Date: January 27, 2021
Deadline for Question: February 8, 2021, Time 4 P.M., U.S. Eastern Time
Closing Date: March 28, 2021
Closing Time: 4 Time P.M., U.S. Eastern Time

Subject: Notice of Funding Opportunity (NOFO), Number: 7200AA21RFA00008

Program Title: The Microbicide 2021 Introduction and Access Project

Federal Assistance Listing Number: 7200AA21RFA00008

Ladies/Gentlemen:

The United States Agency for International Development (USAID) is seeking applications for a cooperative agreement from qualified entities to implement the Microbicide 2021 Introduction and Access Project. Eligibility for this award is not restricted.

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

To be eligible for award, the applicant must provide all information as required in this NOFO and meet eligibility standards in Section C of this NOFO. This funding opportunity is posted on www.grants.gov, and may be amended. It is the responsibility of the applicant to regularly check the website to ensure they have the latest information pertaining to this notice of funding opportunity 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.

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 Section D.6.f. The registration process may take many weeks to complete. Therefore, applicants are encouraged to begin registration early in the process.

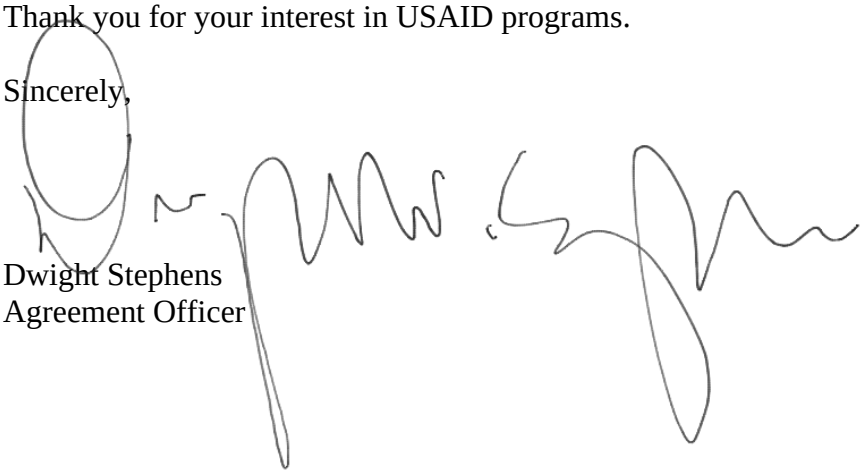
Please send any questions to the point(s) of contact identified in Section D. The deadline for questions is shown above. Please note that applications must be RECEIVED by USAID before the deadline, applicants are highly encouraged to submit their application prior to the deadline to

account for any delays in transmission. 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.

Issuance of this notice of funding opportunity 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,



Dwight Stephens
Agreement Officer

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SECTION A: PROGRAM DESCRIPTION

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

I. Background

As described in the PEPFAR 2020 Annual Report to Congress, PEPFAR supports individuals and national governments to reduce the number of new HIV infections, especially for key and priority populations. As PEPFAR-supported countries transition into epidemic control status, decreasing the absolute number of new HIV infections will be critical. This will be especially paramount for vulnerable populations, including women and more specifically, adolescent girls and young women (AGYW) in sub-Saharan Africa (SSA). According to recent population-based HIV impact assessments (PHIA), HIV incidence for women, especially AGYW, remains disproportionately high in many regions of SSA, with five in six new HIV infections in persons aged 15-19 years occurring in females (UNAIDS 2020). Biological, behavioral, and structural factors may all contribute to this disproportionate rate.

Daily oral pre-exposure prophylaxis (PrEP) using antiretroviral (ARV) pills is currently the only biomedical prevention product for women with regulatory approval other than condoms (including female condoms); however, many women at greatest likelihood for HIV acquisition, like AGYW in SSA, are not able or willing to use oral PrEP for various reasons, including lack of awareness and accessibility, difficulty with daily adherence and side effects, and insufficient opportunity for discreet use, among other barriers. Other HIV prevention products for women are advancing in the development pipeline and achieving significant milestones. The monthly dapivirine vaginal ring (DVR) received a positive scientific opinion from the European Medicines Agency (EMA) in July 2020 and received the World Health Organization's (WHO) pre-qualification in November 2020, which confirms that the ring meets global standards for quality, safety, and efficacy and is an essential step towards in-country regulatory approval. Long-acting cabotegravir (CAB-LA), a bi-monthly injectable ARV has shown significant protection in clinical trials, and alternative oral and injectable formulations are planned for clinical testing as well. Other novel active agents and delivery systems are at earlier stages of research.

USAID, through PEPFAR, has a long and substantial history of supporting the research and development (R&D) of safe and effective microbicides (including both topical and systemic non-vaccine products that women can use to prevent HIV acquisition) and of expanding activities needed to prepare for and expedite the introduction of oral PrEP and new products for HIV prevention as they achieve regulatory approval and become available.

The significant contributions of USAID's Microbicide Program to date are highlighted by 1) the first-ever demonstration, or proof of principle, that an antiretroviral drug, tenofovir, as a vaginal gel, could significantly reduce a woman's risk of HIV infection; 2) research that contributed to

the identification, regulatory approval, and programmatic introduction and rollout of oral PrEP as a key HIV prevention tool; 3) two recent pivotal Phase III clinical trials, supported by USAID and other donors, that indicated the safety and significant efficacy of the DVR as the first long-acting, female-controlled HIV prevention product; 4) early stage studies of CAB-LA; and 5) expansion of product introduction and access through five synergistic projects that comprised the Microbicide Product Introduction Initiative (MPii).

These achievements have been coordinated with the Office of the United States Global AIDS Coordinator (S/GAC), other United States Government (USG) agencies (e.g., NIH, CDC, DoD), other donors and stakeholders (e.g., the Bill & Melinda Gates Foundation, Unitaid, the United Kingdom Foreign, Commonwealth, and Development Office, and the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM), among others), and the pharmaceutical industry to complete critical activities in the research, development, and introduction of HIV prevention products for women, and to create synergies across all research and HIV prevention efforts.

USAID's Microbicide Program aims to bridge gaps and reduce barriers among R&D, regulatory approval, introduction, access, and scale-up of close-to-market products through program research and country engagement activities that identify and address obstacles, gaps, and bottlenecks that delay timely access to new prevention technologies and their resulting impact. Such work requires understanding and addressing key challenges at the global level (e.g., manufacturing and supply chain), national level (e.g., policy and systems), service delivery level (e.g., facility and community scale-up), and individual level (e.g., uptake and adherence, end-user preferences) that impact successful introduction and access.

The USAID Microbicide Program Strategy provides a framework for these and future activities with a Vision in which women, especially AGYW, have access to an optimal selection of HIV prevention products that are safe, effective, acceptable, and affordable, including multipurpose technologies that prevent other sexually transmitted infections (STIs) or unintended pregnancy as well as HIV.

II. Objective of the USAID Microbicide 2021 Introduction and Access Project

The Objective of the Microbicide 2021 Introduction and Access Project is to ensure that women can prevent HIV acquisition by accelerating the introduction and scale-up of biomedical products for HIV prevention, especially those products that are new or for which regulatory approval is imminent, and to expedite their availability, acceptance, uptake, and impact in PEPFAR programs.

To achieve this Objective, the Microbicide 2021 Introduction and Access Project will prioritize support to expedite the introduction of new, innovative, and high-impact HIV prevention products that respond to the needs of women, including AGYW, at greatest likelihood of HIV acquisition, as well as the needs of HIV prevention service delivery programs supported through PEPFAR. These HIV prevention products will need to be reliable and affordable, with attributes that women want, and available at prices that will allow countries to procure and program them without continued donor support. By bridging the gap between regulatory approval and scale-up of such new and existing prevention products and approaches, The Project outcomes are anticipated to

contribute significantly to controlling the HIV epidemic. The Microbicide 2021 Introduction and Access Project will also build on the USAID strategic pillars of respecting American taxpayer investments, advancing national security, and advancing countries on their Journey to Self-Reliance (J2SR).

Achieving the Objective of the Microbicide 2021 Introduction and Access Project will require targeted approaches that effectively address each of the interrelated technical, programmatic, and operational elements identified below.

Technical, Programmatic, and Operational Elements

1. **Establish a "Product Introduction and Access Consortium"** - USAID has a unified vision for the Microbicide 2021 Introduction and Access Project and is committed to dismantling existing programmatic silos and integrating activities, where possible and appropriate. To achieve the Objective of this Project, it will be essential to efficiently support a comprehensive and coordinated portfolio in which multiple parties will be engaged to collaboratively define, prioritize, facilitate, and implement essential tasks, cultivate partnerships, and leverage the technical and financial resources needed to enable successful introduction of and access to existing and imminent HIV prevention products for women in PEPFAR programs. This Project is anticipated to support a consortium of diverse organizations and stakeholders with clear roles and responsibilities to synergistically advance the introduction of new prevention products while proactively addressing the bottlenecks, barriers, and gaps that delay or prevent introduction of and access to these HIV prevention products. The "Product Introduction and Access Consortium," hereafter referred to as the "Consortium," will serve as a facilitator and coordinator for introduction, access, and adoption of biomedical HIV prevention products, technologies, and approaches in PEPFAR programs, and it will further serve as a catalyst for scale-up and sustained use of the same.

   The Consortium will be led by a prime partner that will be responsible for managing all activities under the anticipated award, in close collaboration with USAID, to achieve the Objective. The prime partner will be responsible for bringing in additional partners, as needed, either through formal sub-awards or other forms of collaborative engagement, including partnerships with the private sector that involve co-investment. While the collective capacities of the prime partner and any sub-partner organizations will need to be sufficient to carry out the diverse range of activities that are needed, it will be up to the potential prime partner to propose how such collaborations can most efficiently be structured and managed.

   It is expected that The Consortium will collaborate with relevant stakeholders with diverse expertise, including R&D organizations, in-country PEPFAR international and local implementing partners, host country governments, the private sector, international and local research institutions, national technical working groups responsible for areas related to HIV prevention in partner countries, regulators, academia, multilateral organizations and other donors, community-based organizations, and advocacy groups, among others. Where relevant, product developers, especially nonprofit organizations, will be integral stakeholders and may be included as collaborators/partners to ensure the successful functioning of The Consortium. Key functions of The Consortium will be to identify, develop, and manage strategic

partnerships; leverage partner resources and networks; and assume a leadership, coordination, and convening role to facilitate collaborations across global, regional, national, and local stakeholders. To achieve this, The Consortium will need to engage a wide range of relevant stakeholders, including those with a deep understanding of the technical priorities and the diverse set of activities required for product introduction, ranging from regulatory approval to access and eventual scale-up.

To ensure product availability and access as quickly as possible, The Consortium will engage and work closely with PEPFAR implementing partners and country stakeholders, preparing and positioning new products for expedited programmatic implementation and uptake. The Consortium will need to have the capacity to conduct coordinated, systematic, and comprehensive pre- and post-launch planning that includes country prioritization for product rollout, strategy development, policy development, and implementation planning. In addition, The Consortium will be encouraged to take a collaborative multi-country and multi-stakeholder implementation science approach that outlines a clear process by which policymakers, implementers, beneficiaries, communities, and other interested parties are continuously engaged according to best practices to develop country-led consensus on research priorities, questions, approaches, and activities; to ensure rapid translation of findings to program implementation; and to share learning in communities of practice.

The Consortium will also coordinate and collaborate closely with existing and future USAID-supported projects, including other global, bilateral, and regional projects. Regular and routine communication and coordination will be required with USAID field missions, other donors and stakeholders, and other USAID-supported activities to ensure project transparency, responsive program management, and alignment with USAID's HIV prevention portfolio and broader mission goals. In addition, all activities will integrate programmatic learnings into existing knowledge management systems for cross-program and field learning. When possible, all collaborations will also maximize scarce USG resources by leveraging co-funding among partners, complementing other donor programs, and amplifying economies of scale.

2. **Facilitate a Product Access Advisory Committee (PAAC)** - It is imperative to the success of health interventions that product introduction and access solutions are rapidly identified, designed, executed, and implemented in collaboration with external experts, national governments, communities, local partners and facilities, and end-users. Therefore, in close consultation with USAID, The Consortium will establish a PAAC composed of external experts in the field to provide objective appraisal and strategic technical guidance on portfolio level research activities for the Project. The PAAC will comprise broad representation from the wide array of stakeholders needed to help set priorities, facilitate coordination and collaboration, and optimize resources for product introduction and access. The PAAC membership will be external to both USAID and The Consortium, and it is expected that each PAAC member will provide objective recommendations and feedback relevant to their product introduction and access expertise. Therefore, during the PAAC selection process, USAID and The Consortium will strategically identify potential members with specific expertise along the product development and introduction pathway including R&D, regulatory review and approval, budget and supply chain planning, market access, end-user preferences,

service delivery, and public health program implementation, all with a focus on meeting the needs of low and middle-income countries (LMICs). It is anticipated that the PAAC will appraise the overall progress of the Project either annually or bi-annually (i.e., twice per year).

The primary purpose of the PAAC is to provide technical and programmatic recommendations for USAID consideration in deciding whether to continue, stop, or modify specific introduction and access activities funded by USAID under the Project. This will entail a number of critical functions, including 1) monitoring go/no-go decisions for Project activities; 2) ensuring an objective appraisal of progress with respect to agreed-upon goals and milestones; 3) identifying and evaluating any needs for additional external expertise that would further support introduction and access; 4) considering how project results can be incorporated into ongoing USAID and PEPFAR programming, to the greatest extent possible; 5) evaluating the public health rationale for Project outcomes; 6) identifying areas on the product development and introduction pathway needing attention, clarity, and/or coordination; and 7) anticipating and highlighting other important gaps that need to be addressed. The PAAC input will help USAID to ensure that resources are prioritized for the most critical activities and that research activities move forward in a well-timed, well-coordinated, cost-effective, and impactful manner. The PAAC will not have decision-making authority, which rests solely with USAID and the implementing partner, and the PAAC will not be a performance monitoring structure. PAAC recommendations will not be implemented until approved by USAID to ensure that they are in line with the scope, budget, and other terms of USAID's support to the Project.

3. **Provide Leadership, Collaboration, and Coordination** - Critical to the work of the Microbicide 2021 Introduction and Access Project will be collaboration, coordination, and communication among stakeholders, as these will help to facilitate trust and mutual understanding; reduce redundancy; increase synergy, scalability, and impact; and promote learning and mutual accountability. The Project is intended to be a leader in the field to ensure research is conducted in an effective way, and that successes and challenges are shared to broadly improve health outcomes and policies across LMICs. The Project will, therefore, demonstrate thoughtful coordination, effective communication, and strategic collaboration in all areas of its work, and it will be expected to build and enhance constructive partnerships, as appropriate. The Project will collaborate and coordinate with a wide variety of stakeholders, including national Ministries of Health (MOH) and other relevant government entities; USG partners (S/GAC, NIH, CDC, et al.); other donors and global health partnerships; bilateral and multilateral agencies; academic and research institutions; private sector and philanthropic organizations; and civil society and faith-based organizations, including women's groups and youth-led organizations. Prospective applicants are encouraged to review the USAID Collaborating, Learning, and Adapting (CLA) framework and the CLA toolkit and to ensure their proposed collaborative approaches to implementation are consistent with these documents.

4. **Ensure Complementarity and Integration** - Building on the extensive relationships and history of collaborations that already exist, activities supported through the Project will closely coordinate and collaborate with PEPFAR and USAID-supported global, bilateral, and

regional programs, as well as non-USG donor and country-led programs. Proposed activities should augment existing efforts in PEPFAR partner countries, helping to fill critical gaps in evidence and availability, and assisting country partners to strengthen their own capacity to overcome bottlenecks to impact, scale, and sustainability. Therefore, applicants should clearly outline how their proposed approaches and specific activities would leverage, complement, and link to other investments related to HIV prevention that are currently being implemented or are anticipated in PEPFAR partner countries. This includes investments from PEPFAR, country governments, the private sector, and other donors, such as the GFATM, Unitaid, and private philanthropic foundations/organizations. Applicants should also clearly outline how their approaches and activities complement, build upon, link to, and/or integrate with other USAID Global Health programs and interventions for HIV prevention beyond oral PrEP, as well as for women's health more broadly, especially including voluntary family planning, prevention of STIs, cervical cancer screening, treatment, and prevention, and prevention and mitigation of gender-based violence (GBV), including intimate partner violence (IPV). Applicants are encouraged to evaluate the benefits and drawbacks to such integration in different settings and to support national programs to implement integrated activities that may be optimal in their country context, where feasible and appropriate. In all cases, duplication and inefficiency will be avoided.

5. **Engage Local and New Partners** - The Objective of this Project will also require the engagement of a variety of sub-partners, including local partners and new partners to the greatest extent possible. These partners are envisioned as part of The Consortium in which local partnerships and sub-awards with local non-governmental organizations, civil society, and advocacy organizations will be an integral part of introduction and access research activities to ensure and expand access to new products through the public and private sectors and through community groups. Funding for local and new partners should be structured to strengthen their capacity to implement high-quality programs and research, analyze data, and apply the findings to design and improve programs, as well as to support institutional capabilities such as gender equity, financial and data management, and resource mobilization, while also strengthening technical capacity.

6. **Integrate Gender Considerations** - USAID and PEPFAR policies and strategies emphasize the importance of integrating gender considerations into all development programming, including for HIV. Gender influences the roles, norms, and behaviors that impact access to and utilization of health services – all of which affect the dynamics of the HIV epidemic and the success of HIV prevention, care, and treatment programs and services. Therefore, addressing gender inequalities and harmful gender norms should be a significant part of activities supported through this project. Additionally, gender equitable practices in staffing and local capacity development should be included to further advance gender equality, women's empowerment, and male engagement outcomes.

7. **Leverage Private Sector Engagement** - A clear private sector engagement strategy will be needed with steps to encourage commitments from the private sector (e.g., cost-share, co-funding, contribution of technical resources/commodities), especially commitments that correspond with defined milestones (e.g., product registration in given countries within a certain timeframe, feasible pricing strategies for LMICs, targets for utilization of the product

by a number of individuals). Partnerships with LMIC private-sector entities, including health service and/or pharmaceutical companies are highly encouraged.

8. **Strengthen Sustainability and Self-Reliance** - The sustainability and long-term success of development assistance ultimately requires local ownership and strengthening the capacity of local systems to produce development outcomes at the regional, national, sub-national, and/or community levels, as appropriate. Self-reliance, a country's ability to plan, finance, and implement solutions to solve its own development challenges, requires both local capacity (to efficiently and effectively manage the human, financial, and technical resources it has to meet its public health goals), and commitment (laws, policies, actions, and informal governance mechanisms, such as cultures and norms). Activities supported through this Project should contribute substantially to achieving sustainability and the objectives of USAID's Journey to Self-Reliance (J2SR) approach by advancing the availability of new HIV prevention products for women, especially AGYW in SSA; strengthening and leveraging global health partnerships, including local health systems and the private sector; and encouraging country ownership and leadership, especially in creating access to new health products and services that are needed as part of other sustainable national development initiatives. Relevant activities should be designed to align with the priorities of local actors, leverage local resources, and increase local implementation capacity to sustain results over time. Under PEPFAR, local partners play an integral role as both sub-partners and direct implementers of activities to attain sustained epidemic control.

9. **Increase Knowledge Management and Research Utilization** - A strategy and plan for collecting, reviewing, and disseminating data to ensure timely availability and utilization to inform product introduction strategies is needed. The Project will establish new and/or strengthen existing global HIV prevention communication and knowledge sharing platforms to ensure rapid translation of research findings, maximize synergies, and reduce duplication.

10. **Conduct Product Introduction Research** - Research is needed that identifies and addresses barriers, gaps, and bottlenecks that delay access to new prevention technologies and their resulting impact. Such research includes innovative product access solutions, delivery platforms that respond to the needs of the field and end-users, research translation, mathematical modelling, and key preparedness needs that will improve the "time-to-market" for new prevention products. These research results can then inform and be utilized by national and local policies and programs.

    Implementation science and program evaluations (process, outcome, economic, etc.) may be included and should be embedded within programs with real-time feedback to enable quick and effective adaptation for implementation, with a focus on identifying and implementing the most cost-efficient approaches to scaling up delivery of HIV prevention products to achieve high coverage among the target populations of women in various country contexts. Pilot types of activities that are predominantly limited to testing interventions in only a few sites or small geographic areas should be avoided unless a strong justification is provided of how these will be rapidly translated to scale.

    As new HIV prevention products go to scale in PEPFAR countries, with millions of

beneficiaries expected in the coming years, there is a need to develop feasible and affordable indirect methods (e.g., impact modeling) to evaluate the impact of programs and better understand key areas of potential concern, including (as below) adherence, resistance, and potential risks of GBV, including IPV that might be associated with HIV prevention product use.

10a. Focus on Target Population - USAID is committed to delivering new and improved biomedical HIV prevention products and technologies in PEPFAR programs and ensuring product access for women, particularly for AGYW, who are especially affected by HIV. Primary beneficiary populations for new prevention products under this Project are AGYW and other women, including transgender women, that have high likelihoods of acquiring HIV. Program implementation efforts designed to meet the needs of these populations must overcome numerous obstacles when introducing new products and technologies before sustained public health impact can be achieved. It is critical that the Project is informed by ongoing feedback from the beneficiary populations and other in-country stakeholders to ensure that the intended audiences are being reached in an effective manner.

10b. Prioritize HIV Prevention Products for AGYW and Other Women - Meeting the Objective of this Project will require expanded introduction and access research to address bottlenecks, barriers, obstacles, and gaps that preclude timely access to HIV prevention products including, for example, existing products such as oral PrEP, as well as imminent new prevention products such as the dapivirine vaginal ring, dual-purpose pill, and CAB-LA. Other potential priorities could include topical or systemic prevention products that have advanced through the development pipeline and may be within five years of regulatory approval, such as islatravir, lenacapavir, and possibly some broadly neutralizing antibodies (bNAbs). Communication and close collaboration with R&D partners will be needed to ensure product prioritization for introduction and access activities is up to date, and will be useful to R&D partners to align product development and preferred product characteristics (PPC) with specific LMIC health system, end-user, and program needs.

10c. Increase Product Uptake and Adherence - Research and evaluation are needed for interventions and methodologies that increase and measure product adherence to and effective use of HIV prevention products. Preferred approaches will utilize service delivery program data and build local systems and country capacity to enable cost-effective and sustainable interventions, and to integrate and link such efforts to real-time programmatic monitoring of ARV adherence where such opportunities exist.

10d. Generate and Sustain Demand - As persistence and adherence are major concerns across HIV prevention products, effective product-specific demand creation materials and education and adherence support resources will need to be developed and applied to improve uptake as well as effective and consistent use of products over time. Activities may include technical and implementation support to address demand generation and increase product awareness, acceptance, availability, uptake, and effective use among different population segments. This might include activities such as

conducting end-user studies, developing and testing social and behavior change interventions, and drawing on human-centered design (HCD) and other innovative approaches to inform programmatic strategies and intervention.

10e. Characterize Viral Resistance to ARVs - Research and evaluation are also needed that use objective measures to characterize rates of drug resistance with the use of oral PrEP and other ARV-based products in different real-world settings within national programs. Preferred approaches will also use service delivery program data and build local systems and country capacity to enable cost-effective and sustainable evaluation of relevant factors, and to integrate and link such efforts to monitoring of ARV adherence and resistance where opportunities exist.

10f. Assess and Mitigate Risks of GBV, including IPV, Associated with Using HIV Prevention Products - Implementation of evidence-based tools and interventions to assess and address risks of GBV, including IPV, among women using oral PrEP and other new prevention products is also needed. GBV facilitates HIV transmission by limiting women's ability to negotiate safer sexual practices, disclose HIV status, and access services, including HIV testing services (HTS), PrEP, post-exposure prophylaxis (PEP), and ARV therapy, due to fear of reprisal. Addressing GBV, including IPV, in the context of increasing product options and choice for women is an area of particular importance to ensure no harm is done to those beneficiaries reached and served by the Project.

10g. Address Supply Chain Research and Support - Targeted implementation support is needed to address product introduction on the supply side, including training, mentoring, and strengthening capacity of health workers, facilities, and health systems in a manner that is well-coordinated with other PEPFAR investments in partner countries. Activities might also include supply chain delivery research and working with PEPFAR country implementing partners to support innovative approaches to expand access and improve product availability at diverse points-of-care, including private and public healthcare systems as well as community level service delivery options.

10h. Support Policy Development - Technical assistance is needed to support development of global and/or country-level policies, guidelines, SOPs, implementation plans, and budgets; strengthening of M&E systems; development of global and country-specific regulatory strategies and plans; expediting of in-country licensing and approvals; planning related to manufacturing and supply chain; demand forecasting; impact modelling; and resource mapping. The Consortium may utilize in-country "policy champions" to expedite policy development/implementation for facilitating timely introduction and adoption of new prevention products.

10i. Expedite Research Translation - Country-specific activities and resources will be needed in collaboration with local partners whose role will be essential for successful implementation and scale-up at the national, community, and user levels. To this end, in-country research studies will be needed with local partners, including leveraging USAID-supported service delivery programs and research infrastructure whenever feasible. The USAID management team will help to facilitate the relationships and processes needed to

optimize results and ensure the most efficient translation of key strategies developed under this Objective into PEPFAR and other relevant health programs.

10j. Understand the Role of Male Partners - Introduction and access activities will also need to identify and respond as needed to the supportive or non-supportive influence of male partners and other family members in the uptake and sustained use of existing and new HIV prevention products by women at risk of HIV infection. Additionally, The Project activities should be synergistic as feasible and appropriate, with USAID/PEPFAR programs for other populations.

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SECTION B: FEDERAL AWARD INFORMATION

1. Estimate of Funds Available and Number of Awards Contemplated

USAID intends to award one Cooperative Agreement pursuant to this notice of funding opportunity. Subject to funding availability and at the discretion of the Agency, USAID intends to provide up to $85 million in total USAID funding over a five-year period.

2. 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 Microbicide Introduction and Access Project as described in Section A.

Start Date and Period of Performance for Federal Awards

The anticipated period of performance is five years. The estimated start date will be upon signature of the Award and is anticipated to be before September 30, 2021.

3. 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). Examples of potential 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 travel, international meetings, research studies/protocols, training and other capacity building efforts, activity locations, and beneficiary populations.
b. Approval of specified Key Personnel and any revisions to Key Personnel
c. Collaborative involvement in the selection of Project Advisory Access Committee members - and USAID/and PEPFAR may also choose to be a Product Access Advisory Committee (PAAC) member
d. Approval of sub-awardee(s) selection and the technical or programmatic provisions of subawards
e. Collaborative involvement in developing research protocols and disseminating results
f. Other monitoring as appropriate, e.g., as described in 22 CFR 226.

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

5. 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 Microbicide 2021 Introduction and Access Project will support introduction and access activities 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 introduction and access collaborations may engage institutions and researchers that receive national or government-supported funding, which may be considered partner government entities under ADS 220.

6. Nature of the Relationship between USAID and the Recipient

The principal purpose of the relationship with the Recipient and under the subject Project is to transfer funds to accomplish a public purpose of support or stimulation of the Microbicide 2021 Introduction and Access Project which is 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.

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SECTION C: ELIGIBILITY INFORMATION

1. Eligible Applicants

Eligibility for this Notice of Funding Opportunity (NOFO) is not restricted.

This NOFO is issued worldwide as a public notice to ensure that all interested and qualified organizations have a fair opportunity to submit applications for funding.

To be eligible to receive a Cooperative Agreement under this NOFO, an organization must be a Non-Federal Entity per 2 CFR 200.69.

The anticipated Cooperative Agreement will be fully competed and competition is unrestricted. U.S. and non-US organizations, non-profit, or for-profit entities may participate under this NOFO. Pursuant to 2 CFR 200.400(g), USAID Standard Provisions for U.S. NGOs and USAID Standard Provisions for Non-U.S. NGOs, it is USAID policy not to award profit under assistance instruments. However, all reasonable, allocable, and allowable expenses, both direct and indirect, which are related to the Project and are in accordance with applicable cost standards, may be paid under the eventual award.

Faith-based and community organizations are eligible to apply. In support of the Agency's interest in fostering broader collaborations and expanding the number and sustainability of new and local partners, USAID welcomes applications from organizations able to foster strategic collaborative partnerships and maximize leveraging of resources. Organizations from countries listed under Geographic Code 935 are eligible under this procurement. Section 310 of USAID's Automated Directives System provides details on this coding: http://inside.usaid.gov/ADS/300/310.pdf

Each Recipient must be a responsible entity. Applicants must have established financial management, monitoring and evaluation processes, internal control systems, and policies and procedures that comply with established U.S. Government standards, laws, and regulations. The successful Applicant will be subject to a risk assessment (Pre-award Survey) by the Agreement Officer (AO). The Agreement Officer may determine if a Pre-Award Survey is required and if so, will establish a formal survey team to conduct an examination that will determine whether the prospective Recipient has the necessary organization, experience, accounting and operational controls, and technical skills – or ability to obtain them – in order to achieve the objectives of the Project. Applications from organizations not meeting these requirements will not be considered for award.

USAID welcomes applications from organizations that have not previously worked with the Agency.

Eligible Applicants include the following:

Non-Governmental Organizations - Qualified and registered U.S. and non-U.S. private non-profit organizations may apply for USAID funding under this NOFO. Foreign government-

owned parastatal organizations from countries that are ineligible for assistance under the Foreign Assistance Act of 1961 (FAA) or related appropriations acts are ineligible for award.

For-Profit Organizations - Qualified U.S. and non-U.S. for-profit organizations may apply for USAID funding under this NOFO. Potential for-profit applicants should note that, pursuant to 22 CFR 226.81, the payment of fee/profit to the prime recipient under grants and Cooperative Agreements is prohibited. Forgone profit does not qualify as cost-sharing or leveraging. However, if a prime recipient has a (sub)-contract with a for-profit organization for the acquisition of goods or services (i.e., if a buyer-seller relationship is created), fee/profit for the (sub)-contractor is authorized. (For additional information, please see Profit Under Assistance, An Additional Help Document for ADS Chapter 303). Non-U.S. for-profit organizations in countries that are ineligible for assistance under the FAA or related appropriations acts are ineligible for award.

Private Voluntary Organizations (PVO) - A local or indigenous PVO, which by definition is a non-U.S. PVO operating in the same foreign country in which it is organized, that is not already registered with USAID is eligible to receive funding, however, such organizations are encouraged to consider registration. In accordance with 22 CFR 203, a U.S. PVO and an International PVO which by definition is a non-U.S. PVO that performs development work in one or more countries other than the country in which it is domiciled, must be registered with USAID to be eligible to receive funding. For more information on registering with USAID as a PVO, please see: https://www.usaid.gov/pvo. FBOs: USAID has published in the Federal Register (Vol.69, No.202/Wednesday, October 20, 2004/Rules and Regulations) on participation by FBOs in agency programs.

New Partners - USAID encourages applications from new partners. Resultant awards to these organizations may be delayed if USAID must undertake necessary pre-award reviews of these organizations to determine their capacity to address the aforementioned objectives and responsibility as discussed above. These organizations should take this into account and plan their implementation dates and activities accordingly.

Local Organizations and Sub-Agreements - Local organizations (lead host-country investigators or institutions) may enter into sub-agreements with technical assistance providers locally or based in other countries including the United States. For applications from local organizations, sub-agreements to non-local (outside of host-country) entities are limited to less than 50% of the entire award, unless a specific justification is provided.

Colleges and Universities - Qualified U.S. and non-U.S. colleges and universities may apply for funding under this NOFO. USG and USAID regulations generally treat colleges and universities as NGOs, rather than governmental organizations; hence, both public and private colleges and universities are eligible. Non-U.S. colleges and universities in countries that are ineligible for assistance under the FAA or related appropriations acts are ineligible.

These eligibility requirements apply to both the principal applicant and to any sub-awardee.

USAID welcomes applications from organizations that have not previously received financial assistance from USAID.

2. Cost Sharing or Matching

All Applicants in response to this NOFO must propose a minimum of 5% cost share in their cost application. Please note that in accordance with ADS 303.3.10.3 "Meeting Cost Sharing Requirements," in the award budget, cost share must be expressed as a dollar figure rather than a percentage to assist in monitoring the amount. A commitment to this level of cost share should be indicated in any Applications that are submitted to USAID. The cost share, whether it will be in-kind or dollars, must have a direct impact on this program, and can come from the Recipient(s) and sub-partners of the awards. Funds used to meet this required cost sharing may be provided directly by the awardee(s); other multilateral, bilateral, and foundation donors; host governments; and local organizations, communities, and private businesses that contribute financially and in-kind to implementation of objectives and activities outlined in the Cooperative Agreement. This may include contribution of staff level of effort, office space, or other facilities or equipment which may be used for the Project, provided by the awardee(s).

Funding from other USG agencies cannot be counted toward cost share.

For detailed guidance on cost sharing in grants and cooperative agreements, please see 2 CFR 200.306 and 2 CFR 700.10

3. Other

This NOFO invites applications for one Award (Cooperative Agreement) addressing the objectives of the Microbicide 2021 Introduction and Access Project. Individuals organizations may be sub-partners on multiple applications but organizations may only submit one application as the prime recipient.

SECTION D: APPLICATION AND SUBMISSION INFORMATION

1. Agency Point of Contact

Adrienne Shade
Agreement Officer
Email: microbicideprogram@usaid.gov

2. Questions and Answers

Questions regarding this NOFO should be submitted in writing to Adrienne Shade, Agreement Officer, via e-mail to the address above, no later than the date and time indicated on the 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.

3. General Content and Form of Application

Preparation of Applications:

Each applicant must furnish the information required by this NOFO. Applications must be submitted in two separate parts: the Technical Application and the Business (Cost) Application. This subsection addresses general content requirements applying to the full application. Please see subsections 5 and 6, below, for information on the content specific to the Technical and Business (Cost) applications. The Technical application must address technical aspects only while the Business (Cost) Application must present the costs, and address risk and other related issues.

Both the Technical and Business (Cost) Applications must include a cover page containing the following information:

- Project Title - Applicants may develop their own project title for this application
- Notice of Funding Opportunity number
- Name of the organization submitting the application
- DUNS number of applicant organization
- Type of organization
- 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);

- Countries where proposed project or activities will be implemented
- 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).

Any erasures or other changes to the application must be initialed 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.

4. Application Submission Procedures

Applications in response to this NOFO must be received no later than the closing date and time indicated on the cover letter, as amended. Late 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.

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

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

After submitting an application electronically, applicants should immediately check their own email to confirm that the attachments were indeed sent. If an applicant discovers an error in transmission, please send the material again and note in the subject line of the email. 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 cannot guarantee their acceptance by the internet server. File size must not exceed 25mbs.

5. Technical Application Format

The technical application should be specific, complete, and presented concisely. The application must demonstrate the applicant's capabilities and expertise with respect to achieving the goals of

this Project. The application should take into account the requirements of the program and merit review criteria found in this NOFO.

The Application must:

i. Be written in English
ii. Provide all supporting documents in English
iii. Be formatted for letter-size paper (8 1⁄2 x 11 inches) with 1-inch margins on all sides
iv. Be consecutively numbered on each page
v. Use Times New Roman 12-point font or larger for text
vi. Use Times New Roman 10-point font or larger for graphics and charts
vii. Not exceed twenty five (25) pages (not including the cover page, table of contents, acronym page, executive summary, and appendices); Pages in excess of this limit will not be considered.

a) Cover Page (See Section D.3 above for requirements - Does not count towards page limit)

b) Table of Contents

Include major sections and page numbering to easily cross-reference and identify merit review criteria (does not count towards page limit).

c) 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.

d) Technical Application

The Technical Application should demonstrate the capabilities and expertise of the proposed prime partner and consortium partners to achieve the Objective of the Microbicide 2021 Introduction and Access Project and take into account the technical evaluation criteria shown in Section E.

i. *Technical Approach:*
    1. Summarize the programmatic background and other evidence to demonstrate a thorough understanding of The Microbicide 2021 Introduction and Access Project Objective. Describe the current state of HIV biomedical prevention research and programs, available and imminent HIV prevention products and technologies, programmatic needs, product introduction and access challenges, knowledge gaps, opportunities, and the overall technical approach to achieving the Objective. Any references cited should be included in Appendix 1.
    2. Present a detailed Program Description proposing sound approaches to address the technical, programmatic, and operational elements identified in the Program Description. Explain how the proposed approaches will achieve the Microbicide 2021 Introduction and Access Project Objective and contribute to HIV epidemic control. Provide an illustrative Product Introduction and Access Plan for one or

more products (no more than three pages - does not count towards the 25 page limit) in appendix (Appendix 2).

3. Justify the proposed Program Description in terms of its responsiveness to specific strategic priorities that will accelerate the sustainable programmatic introduction and availability of existing and new biomedical products for HIV prevention. Explain the overall strategic framework of the proposed approaches.
4. Provide information about existing tools, available data, research results, Applicant experience, or other evidence demonstrating the feasibility of the proposed approaches.
5. Identify milestones and timelines for completing the proposed activities.
6. Define a feasible system to ensure availability and utilization of data, results, and tools for timely programmatic applications.

ii. *Collaborations and Partnerships*:

1. Describe the details of the proposed Consortium, including its structure, composition (both sub-recipients and other partners), and functions; further, explain its technical and programmatic rationale, describe the synergistic roles of partners, and outline its unique strengths and abilities to address the interrelated technical, programmatic, and operational elements identified in the Program Description in order to achieve the Microbicide 2021 Introduction and Access Project Objective.
2. Explain how proposed partnerships will leverage technical and financial resources (including private sector resources); support strengthening and optimal utilization of local partner and LMIC institutional capabilities; collaborate with PEPFAR implementing partners; and coordinate with introduction and access activities supported by other funders. Provide details of how The Consortium will work in close coordination with USAID and PEPFAR.
3. 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 3).

iii. *Staffing and Management Plan:*

1. *Key Personnel:* Positions to be considered as Key Personnel must be identified, their roles defined, and their Level of Effort (LOE) specified. The relevant skills, education, experience, and expertise of individuals proposed as Key Personnel must be described in the context of respective roles and responsibilities. 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. A Project Director must be proposed and will have overall responsibility for 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 Project Director must have strong leadership qualities with depth and breadth in both technical expertise and management experience. At least 80% LOE is recommended for the Project Director position. A Project Manager must also be proposed and will have responsibility for project-wide administrative functions and will require a high level of technical and programmatic knowledge to be effective. At least 80% LOE is recommended for

the Project Manager position. The Applicant may propose up to three additional Key Personnel positions that are considered necessary for project success. For each Key Personnel position and candidate, the Applicant should describe the role and responsibilities, the rationale for the position, and the minimum criteria (qualifications, education, experience) required, and a summary of the proposed candidates' skills and experience. Key Personnel should also include at least one person with extensive research utilization and PEPFAR programming expertise. Resumes for each individual proposed as Key Personnel should be included in an Appendix 4 (no more than three pages per resume, does not count towards the 25 page limit).

2. *Other Staffing*: List and describe other staffing proposed with LOE, name of individuals, and their institutional affiliation (whenever possible), and roles and responsibilities as part of the overall staffing plan. A staffing matrix with position titles, names of proposed individuals, roles, LOE, and institutional affiliation should be included in an appendix (Appendix 5) (no more than three pages, does not count towards the 25 page limit).
3. *Management Plan:* Describe a functional management plan for the proposed Consortium, including sub-award structures; partnership coordination; technical, financial, and administrative management and oversight; oversight of design, development, and implementation of pre-clinical and clinical research; and integration of capacity strengthening activities. Include a detailed organogram in an appendix (Appendix 6) (no more than 3 pages, does not count towards the 25 page limit) with an explanation of the proposed staffing and management relationship required to implement the Technical Approach.

iv. *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 be submitted in an appendix (Appendix 7; no more than four pages , does not count towards the 25 page limit) with specific timelines, indicators, and benchmarks for monitoring, evaluating, and learning the progress of the proposed activities in achieving the expected results, outcomes, and impacts. Gender considerations, capacity strengthening targets, and USAID CLA principles should be reflected in the proposed MEL plan.

v. *Appendices*: The appendices must include the following items:
   1. References for relevant work cited
   2. Provide an illustrative Product Introduction and Access Plan for one or more products (no more than three pages) outlining tasks and timelines with milestones and decision points
   3. Sub-recipient Letters of Intent specifying respective roles and stating commitment to participate in The Consortium (no more than one page per organization)
   4. Resumes for all Key Personnel (no more than three pages each) with signed letters of commitment for all Key Personnel
   5. Staffing Matrix and Organizational Chart including staff skills by technical area, institutional affiliation, and geographic location (no more than three pages)

6. Management Plan for The Consortium, indicating roles and responsibilities (no more than three pages)
7. MEL Plan, with timeline of milestones from the beginning to the completion of the proposed activity, including all deliverables. (no more than four pages)

6. Business (Cost) Application Format

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

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

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

a) Cover Page (See Section D.3 above for requirements)

b) SF 424 Form(s)

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

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

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

c) Required Certifications and Assurances

The applicant must complete the following documents and submit a signed copy with their application:

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

d) Budget and Budget Narrative

The Budget must be submitted as one unprotected Excel file (MS Office 2000 or later versions) with visible formulas and references and must be broken out by project year, including itemization of the federal and non-federal (cost share) amount. Files must not contain any hidden or otherwise inaccessible cells. Budgets with hidden cells lengthen the cost analysis time required to make award, and may result in a rejection of the cost application. The Budget Narrative must contain sufficient detail to allow USAID to understand the proposed costs. The applicant must ensure the budgeted costs address any additional requirements identified in Section F, such as Branding and Marking. The Budget Narrative must be thorough, including sources for costs to support USAID's determination that the proposed costs are fair and reasonable.

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

- Summary Budget, inclusive of all program costs (federal and non-federal), broken out by major budget category and by year for activities implemented by the applicant and any potential sub-applicants for the entire period of the program. See Section H, Annex 1 for Summary Budget Template
- Detailed Budget, including a breakdown by year, sufficient to allow the Agency to determine that the costs represent a realistic and efficient use of funding to implement the applicant's program and are allowable in accordance with the cost principles found in 2 CFR 200 Subpart E.
- Detailed Budgets for each sub-recipient, for all federal funding and cost share, broken out by budget category and by year, for the entire implementation period of the project.

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

1) Salaries and Allowances – Must be proposed consistent with 2 CFR 200.430 Compensation - Personal Services. The applicant's budget must include position title, salary rate, level of effort, and salary escalation factors for each position. Allowances, when proposed, must be broken down by specific type and by position. Applicants must explain all assumptions in the Budget Narrative. The Budget Narrative must demonstrate that the proposed compensation is reasonable for the services rendered and consistent with what is paid for similar work in other activities of the applicant. Applicants must provide their established written policies on personnel compensation. If the applicant's written policies do not address a specific element of compensation that is being proposed, the Budget Narrative must describe the rationale used and supporting market research.

2) Fringe Benefits – (if applicable) If the applicant has a fringe benefit rate approved by an agency of the U.S. Government, the applicant must use such rate and provide evidence of its approval. If an applicant does not have a fringe benefit rate approved, the applicant must propose a rate and explain how the applicant determined the rate. In this case, the Budget Narrative must include a detailed breakdown of all items of fringe benefits (e.g., superannuation, gratuity, etc.) and the costs of each, expressed in U.S. dollars and as a percentage of salaries.

3) Travel and Transportation – Provide details to explain the purpose of the trips, the number of trips, the origin and destination, the number of individuals traveling, and the duration of the trips. Per Diem and associated travel costs must be based on the applicant's normal travel policies. When appropriate please provide supporting documentation as an attachment, such as company travel policy, and explain assumptions in the Budget Narrative.

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

5) Subawards – Specify the budget for the portion of the program to be passed through to any subrecipients. See 2 CFR 200 for assistance in determining whether the sub-tier entity is a subrecipient or contractor. The subrecipient budgets must align with the same requirements as the applicant's budget, including those related to fringe and indirect costs.

6) Construction – Not Applicable

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

8) Indirect Costs – Applicants must indicate whether they are proposing indirect costs or will charge all costs directly. In order to better understand indirect costs please see Subpart E of 2 CFR 200. The application must identify which approach they are requesting and provide the applicable supporting information. Below are the most commonly used Indirect Cost Rate methods:

   <u>Method 1 - Direct Charge Only</u>
   Eligibility: Any applicant
   Initial Application Requirements: See above on direct costs

Method 2 - Negotiated Indirect Cost Rate Agreement (NICRA)
Eligibility: Any applicant with a NICRA issued by a USG Agency must use that NICRA
Initial Application Requirements: If the applicant has a current NICRA, submit your approved NICRA and the associated disclosed practices. If your NICRA was issued by an Agency other than USAID, provide the contact information for the approving Agency. Additionally, at the Agency's discretion, a provisional rate may be set forth in the award subject to audit and finalization. See USAID's Indirect Cost Rate Guide for Non Profit Organizations for further guidance.

Method 3 - De minimis rate of 10% of modified total direct costs (MTDC)
Eligibility: Any applicant that does not have a current NICRA
Initial Application Requirements: Costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as a non-Federal entity chooses to negotiate an indirect rate, which the non-Federal entity may apply to do at any time. The applicant must describe which cost elements it charges indirectly vs. directly. See 2 CFR 200 for further information.

Method 4 - Indirect Costs Charged As A Fixed Amount
Eligibility: Non U.S. non-profit organizations without a NICRA may request, but approval is at the discretion of the AO

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

- Total costs incurred by the organization for the previous fiscal year and estimates for the current year.
- Indirect costs (common costs that benefit the day-to-day operations of the organization, including categories such as salaries and expenses of executive officers, personnel administration, and accounting, or that benefit and are identifiable to more than one program or activity, such as depreciation, rental costs, operations and maintenance of facilities, and telephone expenses) for the previous fiscal year and estimates for the current year
- Proposed method for prorating the indirect costs equitably and consistently across all programs and activities of using a base that measures the benefits of that particular cost to each program or activity to which the cost applies.

If the applicant does not have an approved NICRA and does not elect to utilize the 10% de minimis rate, the Agreement Officer will provide further instructions and may request additional supporting information, including financial statements and audits, should the application still be under consideration after the merit review. USAID is under no obligation to approve the applicant's requested method.

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

e) Prior Approvals in accordance with 2 CFR 200.407:

Inclusion of an item of cost in the detailed application budget does not satisfy any requirements for prior approval by the Agency. If the applicant would like the award to reflect approval of any cost elements for which prior written approval is specifically required for allowability, the applicant must specify and justify that cost. See 2 CFR 200.407 for information regarding which cost elements require prior written approval.

f) Approval of Subawards

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

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

g) Dun and Bradstreet and SAM Requirements

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

1. Provide a valid DUNS number for the applicant and all proposed sub-recipients;

2. Be registered in SAM before submitting its application. SAM is streamlining processes, eliminating the need to enter the same data multiple times, and consolidating hosting to make the process of doing business with the government more efficient (www.beta.sam.gov).
3. Continue to maintain an active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by a Federal awarding agency.

The registration process may take many weeks to complete. Therefore, applicants are encouraged to begin the process early. If an applicant has not fully complied with the requirements above by the time USAID is ready to make an award, USAID may determine that the applicant is not qualified to receive an award and use that determination as a basis for making an award to another applicant.

DUNS number: http://fedgov.dnb.com/webform
SAM registration: http://www.beta.sam.gov

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

h) History of Performance

The applicant must provide information regarding its recent history of performance for all its cost-reimbursement contracts, grants, or cooperative agreements involving similar or related programs, not to exceed 10 years, as follows:

- Name of the Awarding Organization;
- Award Number;
- Activity Title;
- A brief description of the activity;
- Period of Performance;
- Award Amount;
- Reports and findings from any audits performed in the last 2 years; and
- Name of at least two (2) updated professional contacts who most directly observed the work at the organization for which the service was performed with complete current contact information including telephone number, and e-mail address for each proposed individual.

If the applicant encountered problems on any of the referenced Awards, 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.

i) 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

j) 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 will not be 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.

k) Conscience Clause

CONSCIENCE CLAUSE IMPLEMENTATION (ASSISTANCE) – SOLICITATION PROVISION." [Further guidance is found in AAPD 14-04, Section 2.D.]

l) 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.

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SECTION E: APPLICATION REVIEW INFORMATION

1. Review and Selection Process

The review process under this NOFO has the following steps:

1. Application. All interested organizations must submit an Application in English through **microbicideprogram@usaid.gov**. GH/OHA is unable to review Applications written in any other language.

2. Application Review. Each Application receives a thorough technical review from a panel of USAID staff.

3. Agreement Officer Determination. The review panel will share recommendations with the AO for further review and to inform award instrument negotiation and finalization. During this process, the Apparently Successful Applicant(s) and the Bureau for Global Health, Office of HIV and AIDS can further refine the technical approach, general resource requirements, and management control of the project under the guidance of the AO.

4. Request for Additional Information. If necessary, the Apparently Successful Applicant and GH/OHA may also work with partners identified by the Decision Panel, to provide additional information on the approach. The Apparently Successful Applicant may also be asked to provide more information about its technical approach, capacity, management and organization, past performance, and budget, as well as certifications and representations, or other information, as needed.

5. Final Review and Negotiation. The AO, in conjunction with GH/OHA, will engage in final review, negotiation, and determinations of award, responsibility, and cost reasonableness, and will craft an award with the Apparently Successful Applicant.

6. Award. The USAID AO will award the instrument. See Section F below for more information.

2. Technical Application Evaluation Criteria

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

A presentation regarding the proposed activities may be required prior to award.

The technical evaluation criteria are outlined below for the Microbicide 2021 Introduction and Access Project.

1. Technical Approach

The extent to which the Applicant is responsive to the Objective of the NOFO, including clearly articulating the most up-to-date current and anticipated strategic research/programmatic needs and priorities related to HIV prevention products and adequately describing approaches to addressing identified gaps; the extent to which the Applicant is responsive to technical priorities and provides a feasible, appropriate, and flexible MEL plan.

2. Collaborations and Partnerships

The extent to which the structure, composition, and rationale for the proposed collaborations and partnerships from scientific, technical, and programmatic perspectives are appropriate for achieving the results for the Objective as specified in the Technical Approach; including the consortium structure and composition.

3. Staffing and Management Plan

The extent to which Key Personnel and Other Staffing are clearly identified and their roles and LOE are defined; the extent to which the education, skills, experience, and expertise identified and described are appropriate and adequate for the proposed activities under the Objective. The extent to which the proposed management plan demonstrates the ability to feasibly and effectively implement the Technical Approach.

3. Cost Application Review

The Agency will evaluate the cost application of the applicant(s) under consideration for an award as a result of the merit criteria review to determine whether the costs are allowable in accordance with the cost principles found in 2 CFR 200 Subpart E.

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.

Proposed cost share, if provided, will be reviewed for compliance with the standards set forth in 2 CFR 200.306, 2 CFR 700.10, and the Standard Provision "Cost Sharing (Matching)" for U.S. entities, or the Standard Provision "Cost Share" for non-U.S. entities.

The AO will perform a risk assessment (2 CFR 200.206). The AO may determine that a pre-award survey is required to inform the risk assessment in determining whether the prospective recipient 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).

SECTION F: FEDERAL AWARD ADMINISTRATION INFORMATION

1. Federal 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, potential applicants are hereby notified of these requirements and conditions for the award.

2. Administrative & National Policy Requirements

The resulting award from this NOFO will be administered in accordance with the following policies and regulations.

For US organizations: ADS 303, 2 CFR 700, 2 CFR 200, and Standard Provisions for U.S. Non-governmental organizations.

For Non US organizations: Standard Provisions for Non-U.S. Non-governmental Organizations.

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:**

  Financial reporting requirements will be in accordance with 22 CFR 226. Instructions for submitting the SF-425 will be provided.

- **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 Implementation Plan - 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 the USAID for approval.
  2. 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.
  3. Ad Hoc Reporting - The awardee(s) will provide to the AOR any cost data, schedules, and progress or results reports requested which 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 a 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: http://www.usaid.gov/our_work/environment/compliance. Information on how USAID ensures environmental soundness and compliance in design and implementation when required by 22 CFR 216 determination (ADS 204) is found at: http://www.usaid.gov/who-we-are/agency-policy/series-200.

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. The full text of the policy paper can be found on the USAID website (www.usaid.gov).

  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‖ (http://www.usaid.gov/policy/ads/200/200mbe.pdf).

SECTION G: FEDERAL AWARDING AGENCY CONTACT(S)

For any questions regarding this NOFO, contact **microbicideprogram@usaid.gov**. If an application is awarded, the AO will appoint an Agreement Officer's Representative (AOR) at that time to provide technical and administrative oversight of the specific award.

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SECTION H: 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.

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 purpose, should mark the cover page with the following:

> "This application includes data that must not be duplicated, used, or disclosed – 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."

ANNEX 1 - SUMMARY BUDGET TEMPLATE

Please see attached.

ANNEX 2 - STANDARD PROVISIONS

(Note: the full text of these provisions may be found at: https://www.usaid.gov/ads/policy/300/303maa and https://www.usaid.gov/ads/policy/300/303mab). The actual Standard Provisions included in the award will be dependent on the organization that is selected. The award will include the latest Mandatory Provisions for either U.S. or non-U.S. Nongovernmental organizations**.** The award will also contain the following "required as applicable" Standard Provisions:

Please note that the resulting award will include all standard provisions (both mandatory and required as applicable) in full text.

REQUIRED AS APPLICABLE STANDARD PROVISIONS FOR U.S. NONGOVERNMENTAL ORGANIZATIONS

Required	Not Required	Standard Provision
TBD		RAA1. NEGOTIATED INDIRECT COST RATES - PREDETERMINED (NOVEMBER 2020)
		RAA2. NEGOTIATED INDIRECT COST RATES - PROVISIONAL (Nonprofit) (NOVEMBER 2020)
		RAA3. NEGOTIATED INDIRECT COST RATE - PROVISIONAL (Profit) (DECEMBER 2014)
		RAA4. INDIRECT COSTS – DE MINIMIS RATE (NOVEMBER 2020)
TBD		RAA5. EXCHANGE VISITORS AND PARTICIPANT TRAINING (JUNE 2012)
X		RAA6. VOLUNTARY POPULATION PLANNING ACTIVITIES – SUPPLEMENTAL REQUIREMENTS (JANUARY 2009)
TBD		RAA7. PROTECTION OF THE INDIVIDUAL AS A RESEARCH SUBJECT (APRIL 1998)
	X	RAA8. CARE OF LABORATORY ANIMALS (MARCH 2004)
	X	RAA9. TITLE TO AND CARE OF PROPERTY (COOPERATING COUNTRY TITLE) (NOVEMBER 1985)
X		RAA10. COST SHARING (MATCHING) (FEBRUARY 2012)
TBD		RAA11. PROHIBITION OF ASSISTANCE TO DRUG TRAFFICKERS (JUNE 1999)
	X	RAA12. INVESTMENT PROMOTION (NOVEMBER 2003)
X		RAA13. REPORTING HOST GOVERNMENT TAXES (DECEMBER 2014)
X		RAA14. FOREIGN GOVERNMENT DELEGATIONS TO INTERNATIONAL CONFERENCES (JUNE 2012)
X		RAA15. CONSCIENCE CLAUSE IMPLEMENTATION (ASSISTANCE) (FEBRUARY 2012)
X		RAA16. CONDOMS (ASSISTANCE) (SEPTEMBER 2014)
X		RAA17. PROHIBITION ON THE PROMOTION OR ADVOCACY OF THE LEGALIZATION OR PRACTICE OF PROSTITUTION OR SEX TRAFFICKING (ASSISTANCE) (SEPTEMBER 2014)
X		RAA18. USAID DISABILITY POLICY - ASSISTANCE (DECEMBER 2004)

TBD		RAA19. STANDARDS FOR ACCESSIBILITY FOR THE DISABLED IN USAID ASSISTANCE AWARDS INVOLVING CONSTRUCTION (SEPTEMBER 2004)
TBD		RAA20. STATEMENT FOR IMPLEMENTERS OF ANTI-TRAFFICKING ACTIVITIES ON LACK OF SUPPORT FOR PROSTITUTION (JUNE 2012)
TBD		RAA21. ELIGIBILITY OF SUBRECIPIENTS OF ANTI-TRAFFICKING FUNDS (JUNE 2012)
	X	RAA22. PROHIBITION ON THE USE OF ANTI-TRAFFICKING FUNDS TO PROMOTE, SUPPORT, OR ADVOCATE FOR THE LEGALIZATION OR PRACTICE OF PROSTITUTION (JUNE 2012)
X		RAA23. UNIVERSAL IDENTIFIER AND SYSTEM FOR AWARD MANAGEMENT (NOVEMBER 2020)
X		RAA24. REPORTING SUBAWARDS AND EXECUTIVE COMPENSATION (NOVEMBER 2020)
X		RAA25. PATENT REPORTING PROCEDURES (NOVEMBER 2020)
TBD		RAA26. ACCESS TO USAID FACILITIES AND USAID'S INFORMATION SYSTEMS (AUGUST 2013)
X		RAA27. CONTRACT PROVISION FOR DBA INSURANCE UNDER RECIPIENT PROCUREMENTS (DECEMBER 2014)
X		RAA28. AWARD TERM AND CONDITION FOR RECIPIENT INTEGRITY AND PERFORMANCE MATTERS (April 2016)
X		RAA29. PROTECTING LIFE IN GLOBAL HEALTH ASSISTANCE (NOVEMBER 2020)
TBD		RAA30. PROGRAM INCOME (AUGUST 2020)
X		RAA31. NEVER CONTRACT WITH THE ENEMY (NOVEMBER 2020)

REQUIRED AS APPLICABLE STANDARD PROVISIONS FOR NON-U.S. NONGOVERNMENTAL ORGANIZATIONS

Required	Not Required	Standard Provision
TBD		RAA1. ADVANCE PAYMENT AND REFUNDS (NOVEMBER 2020)
		RAA2. REIMBURSEMENT PAYMENT AND REFUNDS (DECEMBER 2014)
TBD		RAA3. INDIRECT COSTS – NEGOTIATED INDIRECT COST RATE AGREEMENT (NICRA) (NOVEMBER 2020)
		RAA4. INDIRECT COSTS – CHARGED AS A FIXED AMOUNT (NONPROFIT) (JUNE 2012)
		RAA5. INDIRECT COSTS – DE MINIMIS RATE (NOVEMBER 2020)
TBD		RAA6. UNIVERSAL IDENTIFIER AND SYSTEM OF AWARD MANAGEMENT (NOVEMBER 2020)
X		RAA7. REPORTING SUBAWARDS AND EXECUTIVE COMPENSATION (NOVEMBER 2020)
X		RAA8. SUBAWARDS (DECEMBER 2014)
X		RAA9. TRAVEL AND INTERNATIONAL AIR TRANSPORTATION (DECEMBER 2014)
X		RAA10. OCEAN SHIPMENT OF GOODS (JUNE 2012)
X		RAA11. REPORTING HOST GOVERNMENT TAXES (JUNE 2012)
X		RAA12. PATENT RIGHTS (JUNE 2012)
X		RAA13. EXCHANGE VISITORS AND PARTICIPANT TRAINING (JUNE 2012)

	X	RAA14. INVESTMENT PROMOTION (NOVEMBER 2003)
X		RAA 15. COST SHARE (JUNE 2012)
TBD		RAA16. PROGRAM INCOME (AUGUST 2020)
TBD		RAA17. FOREIGN GOVERNMENT DELEGATIONS TO INTERNATIONAL CONFERENCES (JUNE 2012)
TBD		RAA18. STANDARDS FOR ACCESSIBILITY FOR THE DISABLED IN USAID ASSISTANCE AWARDS INVOLVING CONSTRUCTION (SEPTEMBER 2004)
X		RAA19. PROTECTION OF HUMAN RESEARCH SUBJECTS (JUNE 2012)
TBD		RAA20. STATEMENT FOR IMPLEMENTERS OF ANTI-TRAFFICKING ACTIVITIES ON LACK OF SUPPORT FOR PROSTITUTION (JUNE 2012)
TBD		RAA21. ELIGIBILITY OF SUBRECIPIENTS OF ANTI-TRAFFICKING FUNDS (JUNE 2012)
	X	RAA22. PROHIBITION ON THE USE OF ANTI-TRAFFICKING FUNDS TO PROMOTE, SUPPORT, OR ADVOCATE FOR THE LEGALIZATION OR PRACTICE OF PROSTITUTION (JUNE 2012)
X		RAA23. VOLUNTARY POPULATION PLANNING ACTIVITIES – SUPPLEMENTAL REQUIREMENTS (JANUARY 2009)
X		RAA24. CONSCIENCE CLAUSE IMPLEMENTATION (ASSISTANCE) (FEBRUARY 2012)
X		RAA25. CONDOMS (ASSISTANCE) (SEPTEMBER 2014)
X		RAA26. PROHIBITION ON THE PROMOTION OR ADVOCACY OF THE LEGALIZATION OR PRACTICE OF PROSTITUTION OR SEX TRAFFICKING(ASSISTANCE) (SEPTEMBER 2014)
	X	RAA27. LIMITATION ON SUBAWARDS TO NON-LOCAL ENTITIES (JULY 2014)
X		RAA28. CONTRACT PROVISION FOR DBA INSURANCE UNDER RECIPIENT PROCUREMENTS (DECEMBER 2014)
X		RAA29. CONTRACT AWARD TERM AND CONDITION FOR RECIPIENT INTEGRITY AND PERFORMANCE MATTERS (April 2016)
X		RAA30. PROTECTING LIFE IN GLOBAL HEALTH ASSISTANCE (NOVEMBER 2020)
X		RAA31. NEVER CONTRACT WITH THE ENEMY (NOVEMBER 2020)

ANNEX 3 - ABBREVIATIONS AND ACRONYMS

ADS Automated Directives System
AGYW Adolescent Girls and Young Women
AIDS Acquired Immune Deficiency Syndrome
AM Mission Activity Manager
AO Agreement Officer
AOR Agreement Officer's Representative
API Active Pharmaceutical Ingredients

ART Antiretroviral Therapy
ARV Antiretroviral
CAB-LA Long-Acting Cabotegravir
CBO Community Based Organization
CFR Code of Federal Regulations
COP Country Operational Plan
DVR Dapivirine Vaginal Ring
EA Environmental Assessment
EMMP Environmental Mitigation Monitoring Plan
EMMR Environmental Mitigation Monitoring Report
FAA Foreign Assistance Act of 1961
FBO Faith Based Organization
FDA Food and Drug Administration
GBV Gender-Based Violence
GH Bureau for Global Health
HIV Human Immunodeficiency Virus
HTS HIV Testing Services
IEE Initial Environmental Examination
IP Implementing Partner
IPV Intimate Partner Violence
IND Investigational New Drug
J2SR Journey to Self-Reliance
LMIC Low and Middle-Income Country
MEL Monitoring, Evaluation and Learning
NICRA Negotiated Indirect Cost Rate Agreement
MPii Microbicide Product Introduction Initiative
NOFO Notice of Funding Opportunity
NGO Non-Governmental Organization
OCA Organizational Capacity Assessment
OHA Office of HIV and AIDS
OHS Office of Health Systems
OMB Office of Management and Budget
PAAC Product Access Advisory Committee
PEA Programmatic Environmental Assessment
PEP Post-Exposure Prophylaxis
PEPFAR President's Emergency Plan for AIDS Relief

PHIA Population-based HIV impact assessment
PrEP HIV Pre-exposure Prophylaxis
PRH Office of Population and Reproductive Health
PVO Private Voluntary Organizations
R&D Research and Development
RCE Request for Categorical Exclusion
SAM System for Award Management
SC Selection Committee
STAB Scientific and Technology Advisory Board
SOPs Standard Operating Procedures

SSA Sub-Saharan Africa
STI Sexually Transmitted Infections
ToR Terms of Reference
ToC Theory of Change
USAID United States Agency for International Development
USG United States Government

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