USAID
FROM THE AMERICAN PEOPLE

Subject: **Request for Information (RFI)**

Date Issued: **October 11, 2019**

Response Deadline: **November 15, 2019 at 12:00 noon EDT**

Ref: **Annual Program Statement (APS) Number SOL-OAA-A-13-000024**

This is a Request for Information. This is not a Request for Applications (RFA) and is not to be construed as a commitment by the U.S. Government to issue any solicitation or Notice of Funding Opportunity, or ultimately award a contract or assistance agreement on the basis of this RFI, or to pay for any information voluntarily submitted as a result of this request.

USAID posts its competitive business opportunities on www.grants.gov. It is the potential applicant's responsibility to monitor these sites for announcements of new opportunities. Please note that responding to this Request for Information (RFI) will not give any advantage to any organization or individual in any subsequent competition. Responses will not be provided by USAID, this is for informational purposes only. Respondents will not be notified of the result of the review. Responses may be used by USAID without restriction or limitation, therefore proprietary information should not be sent.

This USAID/ Washington's Office of Population and Reproductive Health (PRH) RFI is issued for the purpose to offer the opportunity for interested organizations and individuals to provide information, opinions, and recommendations on approaches on how to address a focused set of family planning/reproductive health (FP/RH) issues. USAID requests that any interested applicant provide comments regarding the draft program description.

Response Deadline: USAID will receive responses November 15, 2019 at 12:00 noon EDT. USAID requests that responses be no more than two (2) pages in length and should focus on addressing the objectives and illustrative results in the Program Description.

RESPONSES SHOULD BE DIRECTED TO: Marcus Moon, (by email only) at mmoon@usaid.gov.

Sincerely,

Alisa Dunn M/OAA/POP
Agreement Officer

Background:

The purpose of this APS is to publicize the United States Government's (USG) plan to fund a limited number of awards through USAID/Washington's Office of Population and Reproductive Health (PRH) to address a focused set of family planning/reproductive health (FP/RH) issues.

The primary aim of the **FP/RH Methods APS** is to support the research, development, and introduction of technologies and approaches that better meet the needs of women and girls as their FP and reproductive health concerns change over time.

The General Objectives of the APS are to:

1. Refine existing FP methods to address method-related reasons for non-use.
2. Respond to product-related issues about currently available FP methods that arise at purchase and/or from the field, and that may affect provider/user perceptions and/or the supply chain.
3. Develop new FP methods that address method-related reasons for non-use, and/or fill gaps in the existing method mix.
4. Conduct research to foster the introduction and uptake of new and/or underutilized woman-initiated methods, particularly non-hormonal barriers, contraceptive vaginal rings, and fertility awareness methods based on knowledge and monitoring of the menstrual cycle.
5. Develop multipurpose prevention technologies (MPTs) that address the simultaneous risks of unintended pregnancy, HIV, and other sexually transmitted infections (STIs) – particularly Herpes Simplex Virus (HSV) and Human Papillomavirus (HPV).

Multiple rounds for this APS aim to meet the overarching purpose mentioned above. **The details and specific aims of Round Four are discussed in the following sections**.

The FP/RH Methods APS builds upon USAID's strategic pillars of respecting American taxpayers' investments, advancing national security, and advancing countries on their journey to self-reliance by supporting the development of reliable and more affordable technologies, particularly those related to fertility and contraception, with attributes that women want and that are available at prices countries will be able to purchase and program without continued donor support.

U.S. Government Frameworks and Regulations

Awards under this APS will contribute to the Foreign Assistance Program Element 1.7, Family Planning (FP) and Reproductive Health (RH), which aims to expand access to high-quality voluntary FP services and information, and RH care. Awards will be made under relevant federal regulations and agency policy. For U.S. Non-governmental organizations, awards must be administered according to 2 CFR 200 and 2 CFR 700, and USAID Standard Provisions will apply. For non U.S. non-governmental organizations, USAID provisions for non U.S. non-government organizations will apply.

A. Round Four Background

Voluntary and informed FP can play an important role in improving the health of women, children, and their families by contributing to healthy timing and spacing of pregnancies. For more than 50 years, USAID has played a critical role in advancing contraceptive research and development, and expanding contraceptive availability and use worldwide. However, the current range of available contraception options does not meet the needs of all women across their life stages. Currently, 214 million women of reproductive age in developing countries would like to delay, space, or limit their next pregnancy, but do not use modern contraceptives. This unmet need contributes to 89 million unintended pregnancies every year. One of the most important and persistent reasons women report for not using contraception is they have concerns about the side effects, health risks or inconvenience of methods, all related to the attributes of the methods currently available. A need remains for new products and technologies that are more acceptable, lower cost, and more easily implemented at scale.

B. Round Four Draft Program Description

The primary aim of the FP/RH Methods APS is to support the research, development, and introduction of technologies and approaches that better meet the needs of women and girls as their reproductive health concerns change over time. Expanding **method choice** is key to achieving all of these goals. GH/PRH defines method choice as *client-centered information, counseling and services that enable more women, youth, men, and couples to decide and freely choose a contraceptive method that best meets their reproductive desires and lifestyle, while balancing other considerations important to choice, correct use, or switching methods.* Our vision for method choice is that a broad range of contraceptive methods is available to meet the varying needs of women, youth, men and couples who wish to prevent pregnancy.

In pursuit of this vision, **Round Four** of this APS will emphasize research on <u>two</u> specific aims:

1) Refining existing contraceptive methods to address method-related reasons for non-use, including conducting related biomedical and epidemiological studies to inform the understanding of health impacts of contraceptive use.

2) Developing new contraceptive methods that address method-related reasons for non-use, and/or fill gaps in the existing method mix.

Descriptions of each specific aim, and USAID's illustrative research priorities for that aim, are provided below. Under Round Four, USAID is not seeking application where the prime research and development goal is the development of new multipurpose prevention technologies.

Please note that USAID may award up to two cooperative agreements and applicants may respond to one or both aims. Applicants must provide illustrative examples of their capacity to address the aim/s. Partnerships among organizations in the submission of proposals, including by a consortia of partners with diverse but complementary expertise, are strongly encouraged. Partnerships with the private sector are essential to the utilization and scale up of any method or technology. Successful applicants will be required to demonstrate engagement and commitment from the private sector (ex. cost-share, co-funding, or contribution of technical

resources). Partnerships with developing country entities, including pharmaceutical companies are strongly encouraged. Organizations that receive funding through this solicitation should expect to invest in building the institutional capacity of local organizations. This includes capacity to conduct high-quality research, analyze data, and apply the findings to improve programs.

The awardee will be expected to work collaboratively with the USAID project management team in prioritizing specific research activities to be conducted, as well as with other USAID projects and partners conducting research and implementing programs to expand contraceptive method choice. Partnerships will ensure an iterative research and development process that prioritizes not only product development, but also leverages innovative design processes that integrate feedback from clients, providers, development partners, and international stakeholders. Technology refinement concepts should describe the potential and private sector interest in generic product development, including interest in pursuing necessary label changes for refined use of an existing method.

Any FP/RH technologies developed through Round Four of this APS will be expected to meet the following general parameters:

- low cost to manufacture and/or provide, which may include partnerships with generic manufacturers;
- no cold chain storage requirements;
- shelf-life of at least three years under tropical (high heat & humidity) condition; and
- appropriate for provision and use in low resource settings.

Additional ideal product characteristics include:

- potential for provision by lower level care providers and/or administered by the client;
- potential for discreet use; and
- quick return to fertility after cessation of product use.

New awards will aim to develop reliable and more affordable technologies with attributes that women want and that are available at prices countries will be able to afford and program without continued donor support. The award scope includes advancing our understanding of how contraceptives impact a woman's health across her lifespan, while developing new products and technologies that are more acceptable, lower cost, and more easily implemented at scale. Applicants are encouraged to submit applications with proposed work that addresses priority questions across the scope of the award.

C. Round Four Aims

Refining existing contraceptive methods to address method-related reasons for non-use, including conducting related biomedical and epidemiological studies to inform the understanding of health impact from contraceptive use.

Research priorities include, *but are not limited to*:

A. Addressing current and future method-related reasons for non-use or discontinuation (e.g., unacceptable side effects, safety or efficacy concerns, drug-drug interactions); and/or enhancing method-related health benefits (e.g.,reduction in anemia). This also includes supporting the biomedical and epidemiological studies necessary to inform decision-making around health impact of contraceptive use.

B. Modifying or developing new approaches to the administration and/or delivery of existing FP methods that:

1. reduce method-related reasons for discontinuation;
2. enhance other health benefits; and/or
3. improve ease of delivery and/or removal, enable provision by lower level care providers and/or "at-home" self-administration/provision.

C. Partnering with manufacturers to support development of lower-cost commodities or commodities with label changes that provide clients with more favorable product profiles (e.g., lower side effects or extended duration). This may include:

1. Studies to bridge the regulatory gap of late-stage research and development and product introduction;
2. Supporting technology transfers or other necessary preparatory work for production of generic pharmaceuticals; or
3. key post-registration research questions that can lead to safer products and more acceptable, effective, or efficient programming.

Develop <u>new</u> FP methods that address method-related reasons for non-use, and/or fill gaps in the existing method mix.

Research priorities include, *but are not limited to,* the development of:

A. Pericoital "on demand" methods appropriate for women and girls who have infrequent or intermittent sex. Ideal characteristics include at least 90% efficacy; minor to no side effects; no disruption of the menstrual cycle; and potential for discreet use. Systemic or non-gel based pericoitals preferred.

B. Highly effective longer acting methods. Ideal characteristics include at least 95% efficacy; minor to no side effects; little to no disruption of the menstrual cycle; return to fertility within six months; potential for provision by trained lower level care providers; and potential for discreet use.

C. Novel drug delivery systems or formulations that:

- increase acceptability, accessibility, and/or affordability of existing/new products;
- enhance other health benefits;
- allow for a quick return to fertility after cessation of product use; and/or
- enable discreet use or "at-home" self-administration/provision.

USAID-supported new method development will not include direct support for the discovery and/or early development of non-hormonal contraceptive methods or of non-surgical permanent

contraception, despite the pressing need for both types of options in the existing contraceptive methods mix. Other donors prioritize these areas of research.

Results of activities supported through Round Four of the APS will be measured, where relevant, by increased provision and/or use of existing methods due to refinements, and/or reductions in product-related costs; the number of new products advancing through the major phases of development; and the number of new products approved by the US Food and Drug Administration or other stringent regulatory authority. Expected results and benchmarks would be part of the Performance Monitoring Plan required for all cooperative agreement. Please note that all new FP methods supported under Round Four will be required to have a target product profile with clear go/no-go criteria.