U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT

ROUND FOUR CALL FOR CONCEPT PAPERS
UNDER EXISTING
ANNUAL PROGRAM STATEMENT No. SOL-OAA-13-000024

PLEASE NOTE: This is a Round to an existing United States Agency for International Development (USAID) Annual Program Statement (APS). All interested organizations should carefully review both this Round AND the full APS, which can be found here: https://www.grants.gov/web/grants/search-grants.html?keywords=SOL-OAA-13-000024

In Round Four of the Family Planning and Reproductive Health Methods To Address Unmet Need (APS) No. SOL-OAA-13-000024, USAID is requesting the submission of concept papers. USAID anticipates issuing multiple awards under Round Four.

Unless otherwise stated herein, all terms and conditions of the Family Planning and

Reproductive Health Methods To Address Unmet Need (APS) apply.

Issuance Date of Round Four: January 29, 2020

Questions Deadline before the Submission of Round Four Concept Papers: February 4, 2020 at 12:00 pm EST

Deadline for Submission of Concept Papers for Round Four: February 14, 2020 at 12:00 pm EST

Round Four under the Family Planning and Reproductive Health Methods To Address Unmet Need APS

SECTION 1: FUNDING OPPORTUNITY DESCRIPTION

Statement of Purpose:

The purpose of Round Four under the FP/RH Methods 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).

The USG reserves the right to close the APS application process on or before the end date of January 14, 2023 as soon as the research priorities of the five General Objectives have been addressed in final awards, or all available funding has been committed. Organizations are therefore encouraged to apply as soon as possible to be considered for review and to maximize the possibility of available funding.

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 use 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 method availability and use worldwide. However, the current range of available contraception options does not meet the needs of all women across their life. Currently, 214 million women of reproductive age in developing countries would like to delay, space, or limit their pregnancies, but do not use modern contraceptives. One of the most important and persistent reasons women report for not using contraception is 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 which are more acceptable, lower cost, and more easily implemented at scale.

B. Round Four 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 in low resource settings 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 delay, space, or limit their pregnancies. The intention of Round Four is to marshal the technical expertise needed for research and development along with flexibility to support innovation and respond to the most pressing needs of the field.

In pursuit of this vision, **Round Four** will emphasize research on three specific aims:

1) Refinement of existing contraceptive methods, including pharmaceutical, barrier, or fertility awareness-based, to address method-related reasons (e.g., decreasing side effects, increasing effectiveness and efficacy) for non-use. This aim includes conducting related

biomedical and epidemiological studies to better understand the impact of contraceptive method use on health.

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) Development of new contraceptive methods (e.g., new delivery systems, new chemical entity, use of client-collected biomarkers) 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 this specific Round Four announcement, USAID is **not** seeking concept papers where the primary research and development goal is:

- The development of new multipurpose prevention technologies (MPTs), or research on the contraceptive component of an MPT;
- Male contraceptive methods;
- Non-surgical permanent contraception; or
- Digital tools or technologies where the primary goal is to disseminate data that are supported by existing biomedical research. However, funds may support the development of novel biomedical evidence in tandem with the development of a digital tool or technology to support its implementation/dissemination, or where a digital tool can improve the safety and efficacy of a contraceptive method.

USAID recognizes each of the above technical areas is important, but these activities are supported either by other mechanisms across the Agency or by other donors. USAID will continue to monitor the progress of these activities through its donor coordination efforts.

Please note that USAID expects to award one or multiple cooperative agreements and applicants may respond to any combination of aims one and three. Applicants responding to aim two must also include aim one and/or aim three. Applicants will prepare and submit technical and cost for a five-year period and the budget shall not exceed $35 million. However, support for the full five year agreement will be based on successful achievement of milestones, which will be co-developed between USAID and the implementing partners. For example, the initial two years of funding could be used to bring a product with an acceptable target product profile to the point of a Phase 1 clinical trial. If successful, the remaining three year period could support the completion of a Phase 1 clinical trial, including necessary regulatory activities.

Applicants must provide illustrative examples of their capacity to address one or more of the aim/s. Partnerships among organizations in the submission of proposals, including by a consortia of partners with diverse but complementary expertise, are strongly preferred, including partnerships where a larger organization helps to build the capacity of several smaller organizations, consistent with USAID's emphasis on local partner engagement and capacity building. 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 with and/or commitment from the private sector (e.g., cost-share, co-funding, or contribution of technical resources). USAID recognizes additional data on new technologies, including data generated under this award, may strengthen interest from the private sector. Awardees under this

APS without existing private sector interest will be expected to demonstrate a clear private sector engagement strategy that corresponds with clear milestones under this award (e.g., completion of pre-clinical or clinical trial milestones). Partnerships with developing country entities, including pharmaceutical companies are preferred. As noted above, organizations that receive funding through this announcement should expect to invest in, and budget for building the institutional capacity of local organizations, including the integration of gender perspectives in partner institutions. This may include capacity to conduct high-quality research, analyze data, and apply the findings to improve programs.

The final awardee(s) 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 (e.g. human centered design) 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 pharmaceutical commodities developed through Round Four of this APS will be expected to meet the following general parameters:

- Strong safety profile
- Low cost to manufacture, implement 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 the effects of contraceptive methods on woman's health across her lifespan, while developing new products and technologies or refining existing methods that are more acceptable, lower cost, and more easily implemented at scale. Applicants are encouraged to submit concept papers with proposed work that addresses priority questions across the scope of the award.

C. Round Four Aims

1. Refine 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 the impacts of contraceptive method use on health, including necessary safety assessments of contraceptive methods.

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 utilization, delivery, cessation, and/or removal, enable provision by lower level care providers and/or "at-home" self-administration/provision/utilization.

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 (note: this will require substantial evidence of cost-sharing or other donor/ private sector support, where USAID's additive support would ensure a product is able to come to market); or
3. Key post-registration research questions that can lead to safer products and more acceptable, effective, or efficient programming.

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.

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

A. Addressing regulatory, service delivery, and normative issues at the country, regional, or international level about the provision and/or use of new or existing methods, particularly in relation to side effects, safety or efficacy concerns, drug-drug interactions, or integration with other health sectors (HIV/Maternal Child Health);

B. Addressing quality assurance concerns about specific products.

3.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 who have infrequent or intermittent sex. Ideal characteristics include ability to utilize just prior to or after coitus; at

least 90% efficacy; minor to no side effects; no disruption of the menstrual cycle; and potential for discreet use. Systemic, fertility, 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.

As noted above, USAID-supported new method development will not include direct support for the discovery and/or early development of contraceptive methods. Some examples of method development work not supported under this APS include, but are not limited to, discovery of pharmaceutical/biological targets and discovery/screening of candidate compounds/small-molecules. 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 method or product-related costs; the number of new products advancing through the major phases of development; and products approved by the U.S. Food and Drug Administration or other stringent regulatory authority. Expected results and benchmarks would be part of the Performance Monitoring Plan required for any cooperative agreement that would result from a funded proposal through the APS. Please note that all new FP methods supported under Round Four will be required to have a target product or method profile with clear go/no-go criteria that will include cost of goods parameters. This profile, as well as other agreed upon milestones, will be utilized by USAID when considering annual funding for these awards.

SECTION II: AWARD INFORMATION

General Timeframe:

Issuance Date of Round Four: January 29, 2020

Questions Deadline before the Submission of Round Four Concept Papers: February 4, 2020 at 12:00 pm EST

Deadline for Submission of Concept Papers for Round Four: February 14, 2020 at 12:00 pm EST

Issuance of Round Four does not constitute an award or commitment on the part of the USG, nor does it commit the USG to pay for costs incurred in the preparation and submission of a concept paper. Further, the USG reserves the right to reject any or all concept papers received, or to negotiate separately with an applicant, if such an action is considered to be in the interest of the USG.

Please submit any questions and concept papers electronically to Marcus Moon at mmoon@usaid.gov and LaVietra Shannon at lshannon@usaid.gov.

Funding:

USAID anticipates awarding two cooperative agreements or more that respond to any combination of aims one and three. Applicants responding to aim two must also include aim one and/or aim three. Budget must reflect costs over the timeframe of the potential maximum period of performance over the five-year period of performance, tentatively June 2020 to May 2025, contingent on the availability of funding.

Concept Paper Evaluation Criteria

A Technical Evaluation Committee (TEC) will evaluate the concept papers and score each applicant based on the general criteria outlined below, recognizing that the emphasis on specific areas of expertise will likely differ across the three Aims in Round Four of this APS, and the potential uniqueness of each applicant's action plan for responding to new issues and opportunities that arise from the field or the FP/RH research community.

Evaluation Criteria:

- Technical Understanding and Approach (50%)
- Staffing and Management (25%)
- Organizational Capability (15%)
- Past Performance (10%)

SECTION III: ELIGIBILITY INFORMATION

Eligibility Criteria:

To qualify for funding, organizations must: (1) be US organizations or non-US organizations registered and working in USAID priority countries; and (2) have expertise in research and development. Relevancy of experience will be determined by USAID.

Round Four is being issued worldwide as a public notice to ensure that all interested and qualified organizations have a fair opportunity to submit applications for funding. Eligible

organizations include registered U.S. and non-U.S. private non-governmental organizations, non-profit organizations and for-profit organizations willing to forego profit. Non-eligible entities include other USG agencies and departments. All applicants must be legally recognized organizational entities under applicable law.

SECTION IV: APPLICATION AND SUBMISSION INFORMATION

Overview:

Concept papers received under this APS will be reviewed based on full and open competition, and in accordance with the procedures and selection criteria identified herein. At this time, we are only requesting concept papers. Competition under this APS will consist of a two-step process where applicants first submit a concept paper for an initial competitive review. All concept papers received will be evaluated by a USAID TEC for responsiveness to the specifications outlined in these guidelines. Applicants successful in the concept paper stage will then be requested by USAID to submit full applications that details their application in more detail. Instructions for full applications will be provided at that time.

Concept Paper Format:

Organizations that wish to be considered for funding must submit a concept paper written in English, using standard letter paper size, Times New Roman 12-point font, and 1-inch margins. The concept paper cannot exceed five (5) pages (not including the cover sheet and summary budget). The narrative must include:

1. Strategy: An explanation of the problems to be addressed, the expected goals to be achieved, and a short description of the approach to be used to achieve the goals.
2. Activity Description: A summary of activities that will be undertaken in this program, including a brief discussion of planned research design and methodologies, and a timeline of major milestones anticipated over the course of the proposed work. If applicable, provide a product development plan that identifies critical milestones and go/no-go decision points.
3. Project Monitoring and Evaluation: An outline of expected results, outcomes and impact, potential indicators and mechanisms proposed for monitoring progress.
4. Technical/Administrative Capabilities: A description of the applicant's technical and administrative experience and capabilities in the proposed research area, including expertise of proposed key personnel. If collaborations are proposed, include a description of how the partners will complement each other.

Summary Budget:

The concept paper must include a separate one-page summary budget that clearly identifies the major costs by line items (such as personnel, travel, training, commodities, etc.), over the proposed project's five-year timeframe. The budget presented should commensurate to the number of aims addressed.

Cost Sharing:

A cost share minimum of 10% is required for any Cooperative Agreement resulting from this APS. Applicants should provide their cost share information as part of the budget. Cost share can include cash or in-kind contributions, and will be determined subject to the requirements of 2 CFR 200.306.

An award under Round Four is subject to the availability of funds and the viability of applications received. Accordingly, USAID reserves the right to award multiple, one cooperative agreement, or none at all, through Round Four of this APS.

If an applicant is successful in the concept paper stage, USAID will request the submission of a full application, in line with content and format to be provided in greater detail by the Agreement Officer at that time.