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

Family Planning and Reproductive Health Methods To Address Unmet Need

Round Two Full Solicitation
December 17, 2014

SECTION I: FUNDING OPPORTUNITY DESCRIPTION

Statement of Purpose:

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 sexual 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).

PLEASE NOTE: The specific aims of <u>Round Two</u> of this APS are discussed in more detail in the Program Description.

U.S. Government Frameworks and Regulations:

Awards under this APS will contribute to the Foreign Assistance Program Element 1.7, Family Planning and Reproductive Health, which aims to expand access to high-quality voluntary FP services and information, and RH care. Some awards under this APS also will contribute to the Foreign Assistance Program Element 1.1, HIV/AIDS, which aims to reduce the transmission and impact of HIV/AIDS through support for prevention, care and treatment programs. In addition,

awards under this APS will contribute directly to four of the seven principles of the President's Global Health Initiative: promote women, girls, and gender equality; leverage and strengthen key multilateral organizations, global health partnerships and the private sector; foster strategic coordination and integration; and promote research and innovation.

This APS is issued under the Foreign Assistance Act of 1961, as amended. Awards shall be made in accordance with federal regulations and agency policy. For U.S. non-governmental organizations (NGOs), awards shall be administered according to 22 CFR 226, and OMB Circulars and USAID Standard Provisions will apply (http://www.usaid.gov/policy/ads/300/303maa.pdf); for non-U.S. NGOs, other USAID provisions will apply (http://www.usaid.gov/policy/ads/300/303mab.pdf). Since funding is provided through PRH, all awardees will be expected to comply with USAID regulations governing family planning and reproductive health programs; awardees under Objective 5 will also be expected to comply with USAID regulations governing HIV/AIDS programs, given the expected co-funding from the Office of HIV/AIDS (OHA) for that Objective.

USAID Required Analyses for Environment, Gender and Sustainability:

- *Environmental Analysis:* Per 22 CFR 226.3(a)(7), the Environmental Review (ER) should occur at the earliest time in project design and implementation at which a meaningful review can be undertaken, but in no event later than when previously unidentified subprojects or aspects of projects, programs, or activities are identified and planned. Because the PF/RH Methods APS does not identify the individual projects and activities in sufficient detail to all for a meaningful ER, it will be deferred until the work scopes of final awards are planned and submitted. At that time, the potential awardees will be required to submit appropriate documentation for the ER. The majority of the activities awarded through the FP/RH Methods APS are expected to fall within categorical exclusions. However, because some activities may produce an environmental impact, a negative determination with exclusions covers all likely scenarios and has been approved by the Environmental Officer of USAID's Global Health Bureau.

- *Gender Analysis:* The objectives of the FP/RH Methods APS are aligned closely with the Agency's commitment to gender equality and female empowerment, as outlined in the USAID Gender Equality and Female Empowerment Policy (please refer to: http://transition.usaid.gov/our_work/policy_planning_and_learning/documents/GenderEqualityPolicy.pdf). To this end, awards resulting from the FP/RH Methods APS will incorporate into programming the three overarching goals of the policy: 1) To reduce gender disparities in access to, control over, and benefit from resources, wealth, opportunities, and services; 2) To reduce gender-based violence and mitigate its harmful effect on individuals; and 3) To increase capability of women and girls to realize their rights, determine their life outcomes, and influence decision-making.

- *Sustainability Analysis:* The intent of the FP/RH Methods APS is to bolster sustained public health impact through continued research on new and existing FP methods, as well as maximizing the potential of underutilized methods. While specific research activities of awards resulting from this APS are not expected to be wholly sustainable, the results generated are expected to contribute to the development and refinement of FP methods that

are low cost and appropriate for developing country budgets, and to inform and influence policy and program decisions for the long-term.

General Background and Problem Statement:

For more than 40 years, USAID has played a critical role in advancing contraceptive research and development, and expanding contraceptive availability and use worldwide, helping to increase contraceptive prevalence in USAID-supported countries from an average of 10 percent in 1965 to 37 percent today. Yet despite these impressive gains, unmet need for FP remains persistently high. Currently, 222 million women in sub-Saharan Africa and South Asia would like to delay, space, or limit their next pregnancy, but either do not have access to or do not use contraceptives.[1] This unmet need results in more than 80 million unintended pregnancies and 26 million abortions every year.[2] Method-related reasons account for fully 70 percent of non-use of FP, primarily due to women's concerns about: health risks and side effects (22 percent), low frequency of sex (21 percent), being postpartum or breastfeeding (17 percent), and opposition from partners (10 percent).[3] Thus, expanding the use of new and underutilized FP methods, including non-hormonal barrier and fertility awareness methods, is especially critical in addressing some of these primary reasons for non-use.

The unintended pregnancies and short birth intervals that result from unmet need for FP also have a direct effect on maternal and child health.[4] Each year, 450,000 women in developing countries die from complications related to pregnancy and childbirth, and an additional 15 to 20 million women suffer debilitating consequences from pregnancy.[5] Annually, four million newborns die in the first four weeks of life, accounting for 40 percent of all deaths among children under the age of five, and short birth intervals are significantly associated with adverse perinatal outcomes.[6, 7] Thus, ensuring access to a range of safe, effective and acceptable FP options for women will do much to reduce the global public health burden of unintended pregnancies, and the resulting incidence of abortion, maternal morbidity and mortality, and infant mortality.

There is also a great need for woman-initiated methods that prevent HIV and other STIs. Each year in sub-Saharan Africa and South Asia, nearly one million women die from HIV/AIDS and cervical cancer, caused by HPV.[8] Prevention options exclusively for women are currently limited to the female condom, which has lagged in promotion efforts since its development in 1993—despite its potential as both an effective HIV prevention intervention and a dual protection method. The development of MPTs that could address the simultaneous risks of unintended pregnancy, HIV and other STIs has the potential to dramatically improve the sexual and reproductive health of women and girls worldwide.

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[1] Guttmacher Institute. 2012. *Adding it up: Costs and benefits of contraceptive services*
[2] Ibid.
[3] Guttmacher Institute. 2011. *Contraceptive Technologies: Responding to women's needs*
[4] USAID 2010. *MNCH Fact Sheet.*
[5] Ibid.
[6] Ibid.
[7] Conde-Agudelo A, Rosas-Burnudez A, Kafury-Goeta, AC. Birth spacing and risk of adverse perinatal outcomes: A meta-analysis. *JAMA.* 2006;295(15):1809-1823.
[8] WHO, 2012. *Global prevalence and incidence of selected curable sexually transmitted infections – 2008: Overview and estimates.*

Round Two 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 sexual and reproductive health concerns change over time. This primary aim contributes directly to achieving the FP2020 goal of reaching 120 million additional FP users by 2020[9]; meeting 75 percent of demand for FP with modern contraception by 2030; and USAID's top health priorities of ending preventable child and maternal deaths (EPCMD), and achieving an AIDS-free generation (AFG).

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:

- By 2020, more women, youth, men and couples in USAID's 24 priority countries[10] and the Ouagadougou Partnership countries[11] who wish to prevent pregnancy are using their preferred method of contraception; and
- By 2030, 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 Two** of this APS will emphasize research on three specific aims:

1) Refining existing contraceptive methods
2) Responding to product-related issues about existing contraceptive methods
3) Developing new contraceptive methods

Descriptions of each specific aim, and USAID's illustrative research priorities for that aim, are provided below. *Applicants are encouraged to suggest additional areas of research that would fulfill the objectives of each particular aim, and contribute to the goal of FP2020, the Agency's two health priorities of EPCMD and AFG, and the strategic objective of PRH to advance and support voluntary family planning and reproductive health programs worldwide.*

Please note that USAID anticipates awarding only ONE cooperative agreement that will encompass all three aims. Applicants should thus provide illustrative examples of their capacity to address all three aims, and their action plan for responding to new issues and opportunities that arise from the field or the FP/RH research community. The intention of Round Two 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. *Thus, partnerships amongst organizations in the submission of proposals are strongly encouraged.* The final awardee will be expected to work collaboratively with the USAID project management

[9] http://www.familyplanning2020.org/
[10] Afghanistan, Bangladesh, DR Congo, Ethiopia, Ghana, Haiti, India, Kenya, Liberia, Madagascar, Malawi, Mali, Mozambique, Nepal, Nigeria Pakistan Philippines, Rwanda, Senegal, Sudan, Tanzania, Uganda Yemen, and Zambia.
[11] Benin, Burkina Faso, Cote d'Ivoire, Guinea, Mali, Mauritania, Niger, Senegal, and Togo.

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.

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

- low cost to manufacture and/or provide
- no cold chain storage requirements
- shelf-life of at least three years under tropical (high heat & humidity) conditions
- appropriate for provision and use in low resource settings

Additional ideal product characteristics include:

- potential for provision by lower level care providers
- potential for discreet use without partner knowledge

Expectations on ideal characteristics for specific types of technologies are provided in the relevant section below.

Round Two Specific Aims:

Aim 1: Refine existing FP methods to address method-related reasons for non-use.
(Total estimated annual minimum obligation of $1.5 million, maximum of $4.0 million, contingent on availability of funds.)

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).

B. Modifying or developing new approaches to the administration and/or delivery of existing FP methods that:
   i. reduce method-related reasons for discontinuation;
   ii. enhance other health benefits; and/or
   iii. enable provision by lower level care providers and/or "at-home" self-administration/provision.

Aim 2: Respond to product-related issues about currently available FP methods that arise at purchase by USAID and/or from the field, and that may affect provider/user perceptions and/or the supply chain.
(Total estimated annual minimum obligation of $0.5 million, maximum of $1.0 million, contingent on availability of funds.)

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

A. Addressing regulatory 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, or drug-drug interactions;

B. Addressing quality assurance concerns about specific products.

Aim 3: Develop <u>new</u> FP methods that address method-related reasons for non-use, and/or fill gaps in the existing method mix.
(Total estimated annual minimum obligation of $1.0 million, maximum of $3.0 million, contingent on availability of funds.)

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.

B. Highly effective methods that last between one to two years. 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. Nonsurgical permanent contraceptive methods for women and men. Ideal characteristics include at least 99% efficacy with one treatment/application; no permanent side effects; and potential for provision by any trained health care provider.

D. Novel drug delivery systems or formulations that:
   i. increase acceptability, accessibility, and/or affordability of existing/new products;
   ii. enhance other health benefits; and/or
   iii. enable discreet use or "at-home" self-administration/provision.

Measurement and Evaluation of Results:

Results of activities supported through <u>Round Two</u> 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, and/or changes in normative guidelines and regulations in USAID PRH priority countries; 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 (FDA) 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.

SECTION II: AWARD INFORMATION

General Timeframe:

This APS will remain open until January 14, 2023. USAID will review concept papers on a biennial basis, with subsequent Rounds addressing new priorities within some or all of the five General Objectives, based on the needs and priorities of USAID.

The schedule of due dates for each Round of Concept Papers is:

Round Two: **February 27, 2015**
Round Three: **February 28, 2017**

The need for additional rounds of concept paper submissions after February 28, 2017 will be determined at a later date.

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.

Issuance of this APS 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 or an application. Further, the USG reserves the right to reject any or all applications 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 regarding Round Two of this APS electronically to Terry Vann Ellis at tellis@usaid.gov by 5:00pm Eastern Time, January 7, 2015.

Funding for Round Two:

USAID anticipates awarding ONE cooperative agreement that encompasses all three specific aims described above. Budget must reflect costs over the timeframe of the potential maximum period of performance from October 1, 2015 to September 30, 2023. Contingent on the availability of funding, USAID anticipates obligating **$3 million to $8 million annually** over eight fiscal years (FY15-FY22) to support research that addresses the three specific Aims of Round Two.

Criteria for Award Selection:

A Technical Evaluation Committee (TEC) will evaluate the concept papers and applications, 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 Two 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.

General Evaluation Criteria:

- Technical Understanding and Approach (50%)
- Staffing and Management (15%)
- Organizational Capability (20%)
- Past Performance (15%)

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

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, development and/or introduction. Relevancy of experience will be determined by USAID.

This APS is 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 and applications received under this APS will be reviewed based on full and open competition, and in accordance with the procedures and selection criteria identified herein. 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 explain their proposals in more detail.

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, summary budget, or appendices). 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 application must include a 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 eight-year timeframe.

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 22 CFR 226.23.

Reference Materials and Appendices:

Applicants must provide key references for relevant work, and summary resumes of key personnel. Applicants may provide previously prepared material that describes the applicant's organization, operating history, membership and management structure. The reference materials and appendices should not exceed five (5) pages.

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.