USAID
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Issuance Date:	May 25, 2010
Deadline Date for Receipt of Questions:	June 4, 2010, 2010, 3:00 pm ET
Closing Date AND Time for Concept Papers:	May 24, 2011
Round 1:	June 25, 2010, 12:00 noon ET
Round 2:	February 1, 2011, 12:00 noon ET
Submit Concept Papers to:	Ms. Ebony Fultz efultz@usaid.gov

Subject: Annual Program Statement (APS) – APS-OAA-10-000003
APS for Biomedical Research for Reproductive Health

Dear Applicants:

The United States Agency for International Development (USAID) is seeking concept papers from qualified non-U.S., non-Government Organizations (NGOs) and U.S. Organizations for a program titled, "Biomedical Research for Reproductive Health" for funding of Cooperative Agreements.

The objective of the APS is to foster the R&D, regulatory approval, and introduction of:

1. New contraceptive methods that fill specific gaps in the existing method mix;
2. MPTs that are contraceptive, *and*:
   a. Provide protection from HIV, other sexually transmitted infections (STIs), and/or reproductive tract infections (RTIs);
   b. Are appropriate for occasional or intermittent use; and
   c. Provide additional health benefits.

USAID anticipates awarding a selected number of cooperative agreements for the following four aims:

- **Aim 1: *"Seek out innovative approaches to contraception that would fill gaps in the existing method mix"*** USAID anticipates awarding up to two (2) cooperative agreements to organizations active in contraceptive R&D for a period up to five (5) years each. USAID anticipates obligating up to a total maximum of $5 million for all cooperative agreements awarded under this Aim.
- **Aim 2: *"Fast-track late-stage development of Multipurpose Prevention Technologies (MPTs)"*** USAID anticipates awarding up to three (3) cooperative agreements to organizations active in FP/RH-related R&D for a period up to five (5) years each.

USAID anticipates obligating up to a total maximum of $2 million for all cooperative agreements awarded under this Aim.

- **Aim 3:** ***"Facilitate regulatory approval of MPTs"*** USAID anticipates awarding up to two (2) cooperative agreements to organizations active in FP/RH-related R&D and with demonstrated extensive experience in working with either the FDA or another SRA, for a period of up to three (3) years each. USAID anticipates obligating up to a total maximum of $1 million for all cooperative agreements awarded under this Aim.
- **Aim 4:** ***"Foster mid-to late-stage FP/RH product development"*** USAID anticipates awarding up to two (2) cooperative agreements to organizations active in FP/RH-related R&D for a period up to five (5) years each. USAID anticipates obligating up to a total maximum of $5 million for all cooperative agreements awarded under this Aim.

The expected total ceiling for all agreements that are awarded under this APS is $13 million, from a combination of funds from the USAID/Washington's Office of Population and Reproductive Health (PRH), and Office of HIV/AIDS (OHA). The ceiling for each agreement will be determined by funds available and activities proposed. USAID reserves the right to partially fund applications. Applicants are recommended to provide a 10% cost share.

USAID will conduct two rounds of review of the concept papers. The first round will end June 25, 2010 and the second round will end February 1, 2011. Please submit any questions regarding this APS electronically to Ms. Ebony Fultz at efultz@usaid.gov by 3:00 pm ET Friday, June 4, 2010. USAID encourages applicants to apply by the date of the first review because award of applications received on the submission date after the initial first round will be made subject to the availability of funds.

This APS is issued under the authority of the Foreign Assistance Act of 1961, as amended. Awards to U.S. organizations will be in accordance with 22 CFR 226, Mandatory Standard Provisions for U.S. Non-governmental Recipients, and the applicable additional Standard Provisions for U.S. Non-governmental Recipients. The mandatory and other applicable standard provisions for U.S. Non-governmental Recipients are available on the USAID internet site: (http://www.usaid.gov/policy/ads/300/303maa.pdf).

Issuance of this APS does not constitute an award commitment on the part of the U.S. Government, nor does it commit the U.S. Government to pay for the costs incurred in the submission of an application. Further, the U.S. Government 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 U.S. Government.

Sincerely,

Alicia Harris
Agreement Officer
M/OAA/GH

Biomedical Research APS Acronym Sheet

AIDS	Auto Immune Deficiency Syndrome
APS	Annual Program Statement
CFR	Code of Federal Regulations
CV	Curriculum Vitae
FDA	Food & Drug Administration
FP	Family Planning
FP/RH	Family Planning/Reproductive Health
GHI	Global Health Initiative
HIV	Human Immunodeficiency Virus
MPT	Multipurpose Prevention Technologies
OHA	Office of HIV/AIDS
OMB	Office of Management and Budget
PM	*post meridiem*
PRH	Population and Reproductive Health
R&D	Research & Development
RH	Reproductive Health
RTI	Reproductive Tract Infection
SRA	Stringent Regulatory Authority
STI	Sexually Transmitted Infections
TEC	Technical Evaluation Committee
US	United States
USAID	United States Agency for International Development
USG	United States Government

Annual Program Statement (APS) Number:
Biomedical Research for Reproductive Health

SECTION I: FUNDING OPPORTUNITY DESCRIPTION

Statement of Purpose: The purpose of the APS is to publicize this United States Government's (USG) plan to fund a limited number of awards through USAID/Washington's Office of Population and Reproductive Health (PRH), and Office of HIV/AIDS (OHA), to address a focused set of family planning/reproductive health (FP/RH) issues. The areas of interest for the APS are listed below. Funds may support the research and development (R&D), regulatory approval, and introduction of new contraceptives that fill existing gaps in the FP method mix, and multipurpose prevention technologies (MPTs) that meet various RH needs of women in low resource settings. The innovative and potentially varied nature of these activities and products, which are united by a theme but not necessarily a common technological platform or programmatic focus, may require a diversity of partners with differing areas of expertise. Thus, the intention of the APS is to marshal the greatest amount of technical expertise for promising product leads and initiatives, while remaining flexible enough to support innovation and respond to the most pressing needs of the field.

The objective of the APS is to foster the R&D, regulatory approval, and introduction of:

1. New contraceptive methods that fill specific gaps in the existing method mix;
2. MPTs that are contraceptive, *and*:
   a. Provide protection from HIV, other sexually transmitted infections (STIs), and/or reproductive tract infections (RTIs);
   b. Are appropriate for occasional or intermittent use; and
   c. Provide additional health benefits.

The specific aims are discussed in more detail in the Program Description.

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; the 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, this APS will address several key focus areas of the President's new *Global Health Initiative* (GHI), including the renewed emphasis on family planning and maternal health, women-centered approaches, research and innovation, and strategic coordination for integrated solutions to global health challenges. (http://www.usaid.gov/our_work/global_health/home/Publications/docs/ghi_consultation_document.pdf)

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 organizations, awards shall be administered according to 22 CFR 226. OMB Circulars and USAID Standard Provisions will apply (http://www.usaid.gov/policy/ads/300/303maa.pdf); for

non-U.S., non-government organizations, USAID provisions for non-government organizations will apply (http://www.usaid.gov/policy/ads/300/303mab.pdf). Since the funding is provided through PRH and OHA, awardee(s) will be expected to comply with USAID regulations governing family planning and reproductive health programs.

Period of performance: The proposed period of performance for this APS will be from October 1, 2010 to September 30, 2015, subject to availability of funds. However, applications may describe activities with a timeframe of no less than one year to no more than five years.

Background and Program Description: Funding from PRH supports the Foreign Assistance FP/RH Program Element, which aims to expand access to high-quality voluntary FP services and information, and RH care. Funding from OHA supports the Foreign Assistance HIV/AIDS Program Element, which aims to reduce the transmission and impact of HIV/AIDS through support for prevention, care and treatment programs. Despite considerable advances over the last two decades in these two major areas of health, much work remains to be done in preventing unintended pregnancies, and addressing the high prevalence of STIs (especially HIV), in low resource settings. Additionally, populations at risk for unintended pregnancies and STIs struggle with other health challenges, including malnutrition, other infectious diseases, and poor maternal and child health. These factors underscore the fundamental need for the research, development and promotion of new contraceptive methods that fill specific gaps in the existing method mix, and MPTs that can prevent unintended pregnancy as well as HIV/STIs and RTIs, all in order to broaden acceptance and use.

Given the aims of the Foreign Assistance FP/RH and HIV/AIDS Program Elements, funding from PRH and OHA will support the primary objective of this APS: *to solicit strategic approaches that meet existing FP/RH needs, with the priority being those close to regulatory approval.* To be clear, the APS is not soliciting for discovery, screening, preclinical, or early clinical R&D of new leads; the intent is to foster mid-stage and late-stage product development where the payoff of regulatory approval and introduction could be likely within five years. The APS will intentionally build upon USAID's active collaborations with other USG agencies and donors to ensure support for various aspects of the R&D pathway for new contraceptives and MPTs. To facilitate a strategic collaboration across various aspects of the R&D pathway, this APS will focus on the following four aims:

1. **Seek out innovative approaches to contraception that would fill gaps in the existing method mix.** Such approaches may include, but are not limited to:
    a) new birth spacing/limiting methods that last 1-3 years
    b) non-hormonal methods
    c) novel hormonal methods
    d) non-surgical sterilization
    e) improvements to existing methods that would:
        i. reduce or eliminate dependency on clinical service delivery
        ii. ensure effectiveness when used only occasionally or intermittently

2. **Fast-track late-stage development of MPTs.** Support further testing of late-stage and/or already approved products that:
    a) are contraceptive *and* have the potential to protect against HIV, other STIs and/or RTIs
    b) prevent HIV, other STIs, and/or RTIs, *and* have the potential to prevent pregnancy (e.g., products developed for HIV/STI/RTI prevention that may have demonstrated contraceptive effects earlier in the R&D pathway)
3. **Facilitate regulatory approval of MPTs.** Support collaboration with the US Food & Drug Administration (FDA) and/or other stringent regulatory authority (SRA) to:
    a) develop appropriate strategies and testing algorithms for the expedited approval of MPTs
    b) foster the hybridized approval of products that fall across two regulatory domains (e.g., devices and drugs)
    c) identify gap-filling preclinical and bridging studies deemed necessary for eventual approval of a MPT
4. **Foster mid- to late-stage FP/RH product development.** Support further testing of promising compounds and delivery methods that exhibit high contraceptive effectiveness, *and*:
    a) protect against HIV, other STIs, and/or RTIs
    b) are effective when used only occasionally or intermittently
    c) confer additional health benefits

Results of activities supported through the APS will be measured by the number of new products approved by the FDA or other SRA; the number of approved products successfully introduced in pilot studies; the number of piloted products included in FP/RH service delivery programs; and the uptake of product use over time (an indication of their acceptability and cost-effectiveness). Expected results and benchmarks would be part of the Performance Management Plan required for any cooperative agreement that would result from a funded proposal through the APS.

SECTION II: AWARD INFORMATION

Funding: Pending the availability of funding, USAID anticipates awarding a selected number of cooperative agreements for the four aims described above:

Aim 1: *Seek out innovative approaches to contraception that would fill gaps in the existing method mix.* USAID anticipates awarding up to two (2) cooperative agreements to organizations active in contraceptive R&D for a period of up to five (5) years each. For each award, USAID anticipates obligating up to a total maximum of $5 million.

Aim 2: *Fast-track late-stage development of MPTs.* USAID anticipates awarding up to three (3) cooperative agreements to organizations active in FP/RH-related R&D for a period of up to five (5) years each. For each award, USAID anticipates obligating up to a total maximum of $2 million.

Aim 3: *Facilitate regulatory approval of MPTs.* USAID anticipates awarding up to two (2) cooperative agreements to organizations active in FP/RH-related R&D and with demonstrated extensive experience in working with either the FDA or another SRA, for a period of up to three (3) years each. For each award, USAID anticipates obligating up to a total maximum of $1 million.
Aim 4: *Foster mid- to late-stage FP/RH product development.* USAID anticipates awarding up to two (2) cooperative agreements to organizations active in FP/RH-related R&D for a period of up to five (5) years each. For each award, USAID anticipates obligating up to a total maximum of $5 million.

The expected total ceiling for all agreements that are awarded under this APS is $13 million, from a combination of funds from Population and Reproductive Health (PRH), and Office of HIV/AIDS (OHA). The ceiling for each agreement will be determined by funds available and activities proposed. USAID reserves the right to partially fund applications.

This APS will remain open from May 26, 2010 to May 25, 2011. USAID will conduct two rounds of review of the concept papers. The first round will end on June 25, 2010 and the second round will end on February 1, 2011. Please submit any questions regarding this APS electronically to Ms. Ebony Fultz at efultz@usaid.gov by 3:00pm Eastern Time, June 4, 2010. USAID encourages applicants to apply by the date of the first review because award of applications received on the submission date after the initial first round will be made subject to the availability of funds.

However, as soon as the maximum number of qualified concept papers are received (as specified above), or all available funding has been committed, the USG reserves the right to close the APS application process on or before the end date of May 17, 2011. 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 U.S. Government, nor does it commit the U.S. Government to pay for costs incurred in the preparation and submission of a concept paper or an application.

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. The emphasis on specific areas of expertise may differ for each aim under this APS. The actual number of awards under this APS is subject to the availability of funds and the viability of concept papers received. Accordingly, USAID reserves the right to make multiple cooperative agreements, or no awards at all, through this APS.

SECTION III: ELIGIBILITY INFORMATION

Eligibility Criteria: To qualify for funding, organizations must have either a long-standing history and/or demonstrated expertise in FP/RH-related R&D.

SECTION IV: APPLICATION AND SUBMISSION INFORMATION

A. 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 a full application, which will offer the applicant an opportunity to explain their technical approach in more detail. This section provides information on preparing concept papers and full applications.

B. Concept Paper and Application Criteria

Short Technical Concept Papers should not exceed five (5) pages (not including the cover sheet, summary budget, or attachments); any submissions OVER 5 PAGES WILL NOT BE EVALUATED. Concept Papers must be written in English, using Times New Roman, 12 point font on standard 8 ½" x 11" paper, single spaced with each page numbered consecutively, and no less than 1-inch margins on all sides.

Cover sheet [one (1) page]:
The Cover sheet must include APS number APS-OAA-10-000003, the name of the primary applicant, a list of proposed sub-grantees (if any), and the title of the application. In addition, the Cover sheet should provide a contact person for the primary applicant including the individual's name, title or position within the organization, mailing address, e-mail address, and telephone/fax numbers. Applicants should also clearly state whether the identified contact person has the authority to negotiate on behalf of the applicant, and, if not, the contact information for the appropriate person with authority to negotiate should also be listed.

Narrative [five (5) pages]:

1. Strategy: A description of the Aim(s) 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, and including a brief discussion of planned research design and methodologies.
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, and the expertise of proposed key personnel.

Summary Budget [one (1) page]:
The summary budget should clearly identify the major costs by line items, such as personnel, travel, training, commodities, etc. Cost sharing of at least 10% is expected. Please provide information on your cost share as part of the budget.

Reference Materials and Annexes [not more than four (4) pages]
Applicants may provide the CVs of Key Personnel, and brochures or other previously prepared material that describe the applicant's organization, operating history, membership, and management structure.

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