

Amendment Number 01

APS –SOL-OAA-13-000024 FP/RH – UNMET NEED

Questions and Answers

Question 1: Would applicants from South Africa be eligible? Noted in Objective 4 under Research priorities, South Africa is not included as a USAID/PRH priority country.

Answer: Applicants from any country are eligible, provided they meet the eligibility criteria specified on page 12.

Question 2: Is the focus on women and girls only, or could one include engagement with young men, men and male partners?

Answer: Although the focus of Round One is primarily on women and girls, activities to engage men (including young men and male partners) will be considered.

Question 3: Research is heavily emphasized throughout the APS. Is the research component intended to be on a national scale? Or can it be more targeted on a specific population, geographic area (village, district, region), etc.?

Answer: The research approach should be appropriate to the activity being proposed, and thus can be as broad or specific as required.

Question 4: Page 6 of the APS states: “Because other Divisions within PRH, as well as other USG agencies and FP/RH donors, are focused on expanding access to long-acting and permanent methods (LAPMs), Round One of the APS will **instead emphasize** research on the development and introduction of woman-initiated methods that complement and expand upon the primary product- and clinic-based FP methods available in public sector programs”. Under the description of those methods, male and female permanent contraception are mentioned. Are organizations expected to propose or avoid LAPMs for the APS round ending February 28, 2013?

Answer: LAPMs are not a priority of Round One of this APS; however, concept papers with a strong rationale and justification for focusing on LAPMs in order to meet specific research priorities under one or more Objectives will be considered. Please see the answers to Questions 6, 10 and 14 as well.

Question 5: Confirm that competitive bids can focus on just one of the research priorities listed under each objective, or can focus on a combination of priorities from one or more objectives, and do not have to tackle all of the priorities under one objective?

Answer: Yes; concept papers can focus on just one research priority under one Objective, or a combination of research priorities across one or more Objectives. Concept papers do not have to address all of the priorities under one Objective.

Question 6: We understand that LAPMs are not the focus of this APS, but would it be okay to address LAPMs along with other methods that are specifically listed in the APS if that made sense for the research priority?

Answer: Yes. Please see the answers to Questions 4, 10 and 14 as well.

Question 7: Are there any specifics on the length of shelf life required for USAID consideration?

Answer: See pg. 6, para. 2 regarding expectations for general product parameters, including: “shelf-life of at least three years under tropical (high heat & humidity) conditions”.

Question 8: The APS on 4 describes the parameters for an environmental analysis. The text reads “...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...” We have reviewed USAID’s Environmental Compliance Procedures, Title 22, Code of Federal Regulations, Part 216. We would appreciate it if USAID could please clarify “negative determination with exclusions” or give some examples.

Answer: The correct phrase is “negative determination with conditions”. If activities undertaken by a cooperative agreement awarded through this APS are expected to produce medical waste (e.g., disposable injectable devices), or other environmental waste (e.g., as a result of construction), such expectations must be disclosed in the final program description for the cooperative agreement, and the required environmental documentation must be completed and filed.

Question 9: Is \$6M for a win proposal or all worldwide?

Answer: The award ceiling and floor noted on the Synopsis page are incorrect. The award ceiling is actually \$80 million across all awards made in Round One, based on the maximum available funding of \$16 million annually across all five Objectives (see pg. 10) for the maximum period of performance of five years. However, it is highly unlikely that a single concept paper will sufficiently address all of the research priorities in all five Objectives; thus, applicants should project their proposed budget ceilings accordingly. The award floor is actually \$500,000, based on a minimum of \$500,000 for one award with a period of performance of one year. Please see the answers to Questions 26 and 29 as well.

Question 10: On page 7 of the APS, Objective 2 states “Respond to product-related issues about currently available FP methods...” In Round 1, will USAID support funding approaches addressing any currently available LAPM FP methods or is USAID preference solely for women-initiated FP methods (eg. female condom, diaphragm, and rhythm) in Round 1 of this APS?

Answer: USAID will consider concept papers addressing LAPMs as appropriate in response to specific research priorities under one or more Objectives. Please see the answers to Questions 4, 6 and 14 as well.

Question 11: Under Objective 2, will USAID support reduction of product-related costs in the private sector in addition to the stated interest in supporting public sector?

Answer: Yes, provided the activity supports the development of lower cost private markets in one or more PRH priority countries.

Question 12: If you bid on priorities from two or more objectives, how will the funding be allocated when different objectives have different maximum funding levels? Can they be combined in a single proposal and budget?

Answer: Applicants should use the annual funding levels for each Objective as a guide to determine appropriate budget levels for combined priorities across more than one Objective. Please see the answer to Question 16 as well.

Question 13: Is it the expectation that the concept note will identify the specific countries where this funding is awarded? Are only PRH priority countries acceptable?

Answer: The rationale for targeting specific regions, countries or populations should be clear in the concept paper, including any non-PRH priority countries.

Question 14: On page. 6, the RFP reads “...expanding access to long-acting and permanent methods (LAPMs), ... of women-initiated methods that complement and expand upon the primary product- and clinic-based FP methods available in the public sector programs (e.g., oral contraceptives, injectables, implants, IUDs, and male and female permanent contraception).” Please clarify which specific contraceptive methods are considered to be “women-initiated.” Are these “women-initiated” methods the only methods that can be included in concepts submitted for this APS?

Answer: The primary emphasis of Round One of this APS is on research to accelerate the development and introduction of women-initiated methods, particularly fertility awareness methods, barrier methods (e.g., female condoms and diaphragms), and contraceptive vaginal rings. Concept papers focused on other contraceptive methods will be considered in response to specific research priorities. Please see the answers to Questions 4, 6 and 10 as well.

- (a) Based on information in the “Program Description” section referenced above, it seems that implants and injectables are not the focus of Round 1 of the APS. However, on p. 7 for Objective 2, section A, the program announcement indicates that harmonizing MEC criteria for progestin-only methods by breastfeeding women is a priority. We assume that this work would relate to implants and injectables. Also, on p. 7 for Objective 1, section A, the RFP references work modifying injectable contraceptives as a priority. Please kindly confirm whether implants and injectables may be included.

Answer: Yes, in response to specific research priorities.

- (b) Likewise, Objective 1, Section D of the RFP references modifying approaches to product administration and/or delivery. Would oral contraceptive pills and injectables qualify for this activity?

Answer: Yes.

- (c) Do existing methods include methods under development such as new female condoms and microbicide rings that include a contraceptive?

Answer: No – under Objective One, “existing methods” are those that are currently available in the public or private sector.

Question 15: What is the earliest possible start date for the performance period?

Answer: October 1, 2013.

Question 16: How will the budget ceiling be determined for the options listed on page 10 that involve more than one specific Objective?

Answer: Concept papers combining research priorities across more than one Objective should use the annual funding levels provided for each Objective as a guide to determine the maximum funding level possible for the combined priorities. Please see the answer to Question 12 as well.

Question 17: As this will be a two-stage process, please clarify:

- (a) What is the expected response time for Concept Paper submissions?

Answer: See Section II Award Information, Period of Performance. Which list the schedule due dates for each Round of Concept Papers.

- (b) What is the anticipated turnaround time for full proposals?

Answer: The turnaround time for full application will be decided by the Agreement Officer, after the initial Concept Paper review.

Question 18: Have not previously been the direct recipient of USAID funds, or part of a cooperative agreement. Is prior experience with a cooperative agreement required or preferred?

Answer: No. Please see Section III Eligibility Information – Eligibility Criteria.

Question 19: In regards to cost sharing, can staff time or other resources given in kind count toward the 10%?

Answer: A cost share minimum of 10% is required for any Cooperative Agreement resulting from this APS. Please refer to ADS 303.3.10 and 22 CFR 226.23 for cost share guidance.

Question 20: Please confirm that it is ok for an organization to submit multiple proposals for different concepts under this APS.

Answer: Yes.

Question 21: Confirm that all countries (like in Asia) are eligible for this APS (page 12)?

Answer: Yes, although activities that benefit PRH priority countries are preferred.

Question 22: What is expected date for implementing the project for won application? And when will expect due date for full application submission?

Answer: The anticipated date for implementing the project is October 1, 2013. The due date for full application submission, will be decided by the Agreement Officer, after the initial Concept Paper review.

Question 23: Does USAID encourage for new local organization for this APS?

Answer: Yes.

Question 24: How many grants does USAID intend to award, and if available, how many applications your office received in the last round of funding, and of those, how many were awarded?

Answer: See Section II, Award Information which states “Pending the availability of funding, USAID anticipates awarding a number of cooperative agreements both within and across the five objectives. Unfortunately, USAID cannot provide information regarding how many applications were received and were awarded.

Question 25: Is the concept note submitted simply by emailing it to the indicated addresses?

Answer: As stated on the cover letter, Concept papers are to be submitted to Franklin Goode at fgoode@usaid.gov and Ms. Alisa Dunn at adunn@usaid.gov.

Question 26: The award ceiling in the synopsis for the solicitation on Grants.gov is listed as \$6,000,000. Also noted the anticipated annual funding levels within and across the five research objectives on p. 10 of the RFP as amounting to a potential \$16,000,000. Further, the RFP states “the ceiling of each agreement will be determined by funds available and activities proposed”.

(a) Is \$16,000,000 the total award ceiling for Round 1?

Answer: No. The award ceiling is actually \$80 million across all awards made in Round One, based on the maximum available funding of \$16 million annually across all five Objectives (see pg. 10) for the maximum period of performance of five years. Please see the answers to Questions 9 and 30 as well.

(b) How many awards does USAID anticipate will be funded under Round 1?

Answer: Zero to five.

(c) Could USAID kindly give guidance for the anticipated budget ceiling per year for an individual project?

Answer: It will depend on the activities and budget proposed, but will not exceed the total annual funding levels per Objective (individually or combined), as described on pg. 10 of the APS.

Question 27: On p. 10 of the RFP, the program description outlines anticipated funding levels in support of the indicated research priorities within and across each of the five objectives. If selected to submit a full proposal, should Offerors provide a detailed budget for each objective?

Answer: Yes, as relevant to the proposed activities that address the respective research priorities of each Objective.

Question 28: Under the Funding section, on page 10 of the APS, USAID indicated budget ceilings for each objective. Please clarify whether the stated ceilings are totals per Objective or totals per individual projects under each Objective?

Answer: The stated ceilings are anticipated annual funding levels per Objective for all research priorities stated under that Objective.

Question 29: The Synopsis of the APS posted on www.grants.gov indicates that the award ceiling for this APS is \$6,000,000. However, this doesn't appear to match the ceilings indicated on page 10 of the APS under Funding, where the total ceiling under each Objective far exceeds \$6,000,000. Can USAID clarify the total ceiling for Round 1 of this APS?

Answer: The award ceiling and floor noted on the Synopsis page are incorrect; the award ceiling is actually \$80 million across all awards made in Round One, based on the maximum available funding of \$16 million annually across all five Objectives (see pg. 10) for the maximum period of performance of five years. (However, it is highly unlikely that a single proposal will sufficiently address all of the research priorities in all five Objectives; thus, applicants should project their proposed budget ceilings accordingly.) The award floor is actually \$500,000, based on a minimum of \$500,000 for one award with a period of performance of one year. Please see the answers to Questions 9 and 26 as well.