



June 9, 2011

Reference: Technologies for Health RFA-OAA-11-000009

Subject: Amendment 02

Dear Applicants,

The purpose of Amendment 02 is to provide Q &A's and to address changes to the above referenced solicitation.

Please see the following pages for the changes this Amendment makes to the specific section. Please submit any questions in writing to swatkins@usaid.gov by Wednesday, June 15, 2011 2PM Eastern Standard Time (EST).

Sincerely,

Sonja Watkins

Sonja Watkins
Agreement Specialist
US Agency for International Development
Office of Acquisition and Assistance
M/OAA/GH

cc: Enclosure

Administrative Changes:

- 1) Cover Page “Question Due Date:” delete:

“Thursday, May 12, 2011 at 5:00 PM”

Replace with:

“Wednesday, June 15, 2011 at 2:00 PM”

- 2) Cover Page “Closing Date and Time:” delete:

“Monday, June 6, 2011 at 11:00 AM EST.”

Replace with:

“Monday, June 27, 2011 at 11:00 AM EST.”

- 3) Page 3, delete:

“**DUE DATE** of Monday, June 6, 2011 at 11:00AM EST.”

Replace with:

“Monday, June 27, 2011 at 11:00 AM EST.”

- 4) Page 3, delete:

“**QUESTIONS** submission date of “Thursday, May 12, 2011 at 5:00 PM”

Replace with:

“Wednesday, June 15, 2011 at 2:00 PM EST.”

- 5) Page 4, Table of Contents insert: “Section I. G. Planning and Reporting”

- 6) Page 5, Table of Contents insert: “ANNEX F: Supplemental Registration Information”

- 7) Page 6, Section I. Program Description, B, Background, delete:

“Since 1985, the Technologies for Health project has been a primary USAID initiative allowing for the research and development of some 130 innovative new health

technology leads, 40 of which have either been developed or are currently under development, and at least 26 have been commercialized and are now being used in public health programming around the world.”

Replace with:

“Since 1985, the HealthTech project has been a primary USAID initiative allowing for the research and development of some 130 innovative new health technology leads, 40 of which have either been developed or are currently under development, and at least 26 have been commercialized and are now being used in public health programming around the world.”

- 8) Page #13, Section I. Program Description, D. Agreement Results, delete:

“An important component of this collaborative planning process will be the development and routine updating of Product and Market development and Introduction Plans (DIPs) (discussed in detail in Section I G.2).”

Replace with:

“An important component of this collaborative planning process will be the development and routine updating of Product and Market development and Introduction Plans (DIPs) (discussed in detail in Section I G.1).”

- 9) Page #19, insert: “Section I G. Planning and Reporting” and “Section I G.1, “Collaborative Development and Approval of Product and Market Development and Introduction Plans (DIP), and All Modifications.””

- 10) Page #20, insert: “Section I G.2. Reporting & Evaluation Requirements.”

- 11) Page #21, insert: “Section I G.3. Collaboration.”

- 12) Page #25, Section III, Eligibility Information, A. Eligibility Criteria, a. delete:

“Be a U.S.-based institution, for-profit, non-profit or private voluntary organization or consortium of such organizations registered with USAID, including research organizations, universities, developing countries institutions and partners, and relevant special interest associations.”

Replace with:

“Be a U.S. and Non-U.S. non-governmental institution, for-profit, non-profit or private voluntary organization or consortium of such organizations registered with USAID, including research organizations, universities, developing countries institutions and partners, and relevant special interest associations. Must be able to meet the eligibility criteria in 22 CFR 228 sub-part D.”

- 13) Page #27, Section IV, Application and Submission Instructions, A. Submission Instructions, delete:

“1. RFA Closing Date and Time: Applications shall be submitted on or before 11:00 AM EST on Monday, June 6, 2011.”

Replace with:

“1. RFA Closing Date and Time: Applications shall be submitted on or before 11:00 AM EST on Monday, June 27, 2011.”

- 14) Page #27, Section IV, Applications and Submission Instructions, A. Submission Instructions, delete:

“2. Applicants must download application from grants.gov to submit SF 424A&B and Technical and Cost Application before closing date.”

Replace with:

“2. Applicants must download application package from grants.gov to submit SF 424, SF 424-A & B and Technical and Cost Application before closing date.”

- 15) Page #28, Section IV, Application and Submission Instructions, A. Submission Instructions, delete in its entirety:

“7. An Applicant’s complete application consists of the grants.gov submission and receipt of hard copies.”

- 16) Page #28, Section IV, Application and Submission Instructions, B. General Application Instructions, delete:

“3c. Shall not exceed twenty **(20) pages** excluding documents requested to be provided in an annex (e.g. resumes, references, etc.) and the following (if applicable): Cover page, executive summary, dividers, acronym list and table of contents. **Applications in excess of this limit will not be evaluated.**”

Replace with:

“3c. Shall not exceed twenty-five **(25) pages** excluding documents requested to be provided in an annex (e.g. resumes, references, etc.) and the following (if applicable): Cover page, executive summary, dividers, acronym list and table of contents. **Applications in excess of this limit will not be evaluated.**”

17) Page #28, Section IV, Application and Submission Instructions, B. General Application Instructions, delete:

“3d. Any graphs, charts, exhibits, tables, etc. contained in the body of the technical application shall be numbered and included in the **20** pages limit. The font used in tables and charts may be adjusted as appropriate but should be no smaller than 10 point.”

Replace with:

“3d. Any graphs, charts, exhibits, tables, etc. contained in the body of the technical application shall be numbered and included in the **25** pages limit. The font used in tables and charts may be adjusted as appropriate but should be no smaller than 10 point.”

18) Page #29, Section IV, Application and Submission Instructions, B. General Application Instructions, delete:

“4c. The application must be submitted using SF-424 and SF 424-A “Application for Federal Assistance.” The form is downloadable on USAID’s website at:
http://www.usaid.gov/procurement_bus_opp/procurement/forms/.”

Replace with:

“4c. The application must be submitted using SF-424, SF 424A and SF 424B “Application for Federal Assistance” (see **ANNEX ‘D’**).”

19) Page #29, Section IV, Application and Submission Instructions, C. Technical Application Guidelines, delete:

“Cover Page (1 page – not included in the 20 page limit).”

Replace with:

“Cover Page (1 page – not included in the 25 page limit).”

20) Page #29, Section IV, Application and Submission Instructions, C. Technical Application Guidelines, delete:

“Executive Summary (2 pages – not included in the 20 page limit).”

Replace with:

“Executive Summary (2 pages – not included in the 25 page limit).”

21) Page #29, Section IV. Application Submission Instructions, C. Technical Application Guidelines, delete:

“Technical Application (Maximum 20 pages) – Applicants may choose the number of pages to devote to each section, within the **twenty (20) page limit of the technical application.”**

Replace with:

“Technical Application (Maximum 25 pages) – Applicants may choose the number of pages to devote to each section, within the **twenty-five (25) page limit of the technical application.”**

22) Page #31, Section IV. Application and Submission Information. C. Technical Application Guideline, 2. Key Personnel Qualifications and Staffing Capabilities, delete bullet #5:

“In an Annex, provide the following for key personnel only: Resumes and references (including the name, title/position, telephone and email contact information for each reference) – case of project director, at least one reference should be a developing country work contact.”

Replace with:

“In an Annex, provide the following for key personnel only: Resumes and at least 3 references per position (including the name, title/position, telephone and email contact information for each reference) – case of project director, at least one reference should be a developing country work contact.”

23) Page #36, Section IV. Application and Submission Instructions. C. Technical Application Guidelines, 6. delete:

“Past performance (note: all material to be provided in an annex and does not count toward the 20 page limit).”

Replace with:

“Past performance (note: all material to be provided in an annex and does not count toward the 25 page limit).”

24) Page #36, Section IV. Application and Submission Instructions. C. Technical Application Guidelines, 6. delete:

“Prime Applicant Past Performance requirement:

As an annex, please complete past performance information (**see form Annex E**) for three (3) past performance references which describe any contracts, grants, cooperative agreements which the applicant organization has implemented involving similar or related programs over the past three years. Please include the following information: name and address of the organization for which the work was performed; name and current telephone number and email address of responsible representative from the organization for which the work was performed; contract/grant name and number (if any), the period of contract/grant performance, annual amount received for each of the last three years and beginning and end dates; brief description of the project/assistance activity and key project accomplishments / results achieved to date. It is recommended that the applicant alert the contacts that their names have been submitted and that they are authorized to provide past performance information when requested.”

Replace with:

“Prime Applicant Past Performance requirement:

As an annex, please complete past performance information for three (3) past performance references which describe any contracts, grants, cooperative agreements which the applicant organization has implemented involving similar or related programs over the past three years. It is recommended that the applicant alert the contacts that their names have been submitted and that they are authorized to provide past performance information when requested (see form **Annex E**).”

25) Page #36, Section IV. Application and Submission Instructions. C. Technical Application Guidelines, 6. delete:

“Sub-awardees/partners Applicant Past Performance requirement:”

Replace with:

“Both Prime Applicant and Sub-awardees/partner Applicant Past Performance requirement:”

26) Page #36, D. Cost/Business Application Guideline, delete :

“1. The Cost/Business Application must be completely separate from the Applicant’s technical application, and submitted by using SF-424 and SF-424A Application for Federal Assistance.” These forms can be found under Annex D or and are downloadable online at

http://www.usaid.gov/our_work/humanitarian_assistance/disaster_assistance/resources/pdf/SF424_cover.pdf and http://www.usaid.gov/in/working_with_us/pdfs/sf424a.pdf .”

Replace with:

“1. The Cost/Business Application must be completely separate from the Applicant’s technical application, and submitted by using SF-424, SF-424A and SF-424B

“Application for Federal Assistance.” These forms can be found under Annex D or and are downloadable online at

http://www.usaid.gov/our_work/humanitarian_assistance/disaster_assistance/resources/pdf/SF424_cover.pdf and http://www.usaid.gov/in/working_with_us/pdfs/sf424a.pdf and http://www.usaid.gov/in/working_with_us/pdfs/sf424b.pdf .”

27) Page #64, delete:

“ANNEX B: REPRESENTATION AND CERTIFICATIONS-U.S. NGO.”

Replace with:

“ANNEX B: REPRESENTATIONS AND CERTIFICATIONS”

28) Page #80, insert: “ANNEX F: SUPPLEMENTAL REGISTRATION INFORMATION”

Pre-Application Questions and Answers submitted before closing time of May 12, 2011 5:00 PM Eastern Standard Time (EST)

Question #1: Is this program a continuation of the Health Technologies Programs previously funded by USAID?

Government Response: As discussed on p. 6-7 of the RFA, this program builds upon previous USAID health research and health technology activities described in the USAID Health Research Report to Congress and in predecessor projects such as HealthTech <http://www.path.org/projects/healthtech.php> . It also emphasizes a new emphasis of health technology development as part of USAID's research to use strategic framework discussed on p. 7-11 of the RFA.

Question #2: Is this RFA only for organizations registered with USAID as previously working with USAID under those Programs (or another program)?

Government Response: The RFA is open for applicants who meet the application requirements as cited in 22 CFR 228 sub-part D. Also refer to "ANNEX F: Supplemental Registration Information" for guidance.

Question #3: Are organizations not currently registered with USAID eligible for expedited registration prior to the RFA closing date?

Government Response: Refer to response addressed in Question #2.

Question #4: Will answers to RFA related questions be posted as they are received or after the Thursday May 12, 2011 Q&A closing date?

Government Response: Questions and Answers (Q&A) will be published on June 9, 2011 on www.grants.gov.

Question #5: Can this grant be applied for the implementation of the Electronic Health Records (EHR) on hospitals. If not, are there any other grants available for it?

Government Response: Please see RFA for application requirements. Electronic Health Records are not a current focus area of this grant solicitation.

Question #6: How do I get my administration to update their institution's registration at CCR if they have no clue of the username or password?

Government Response: Please see RFA "Annex F: Supplemental Registration Information- Organization Registration Checklist" for guidance.

Question #7: We would like clarification the Product & Market Development and Introduction Plans (DIPs) on page 13 of the Instruction Manual. Section G.2 referenced is missing from the RFA. Please clarify.

Government Response: Reference to Section I G.2 was removed in error in the initial RFA. The Product & Market Development and Introduction Plans (DIPs) is currently referenced on page #13 Section G.1 and on page #19.

Question #8: Is the case study length included in the 20 page limit for the application?

Government Response: Yes, however the total length of the technical application has been extended to 25 pages.

Question #9: Is this RFA for implementation in India?

Government Response: Potentially yes. However, the final decision for sites for implementation will be determined post award.

Question #10: What types of projects have been funded by this program in the past and who have been the past awardees?

Government Response: Please refer to response to Question 1. Also, further information on prior research and product development activities are described in the USAID Research reports to Congress. See <http://www.harpnet.org/index.html>

Question #11: We discovered this RFA on May 11, 2011, and noticing the closing date of June 6, 2011, we would like to know if we can receive a 1-2 week extension to this closing date to allow us time to prepare our application?

Government Response: The response deadline has been extended to Monday, June 27, 2011 11:00 AM EST.

Question #12: Is the Technology for Health Program a continuous program through which there may expect more RFAs posted in the future?

Government Response: The successful recipient of this cooperative agreement will be expected to develop a competitive sub-award program as noted on p. 17 under IR 2.2 - “Crosscutting activity: Develop a sub-grants program.”

Question #13: Could you provide some further clarification on the eligibility criteria? We were not sure how to interpret them as there is first a requirement for a “US-based institution”, but later a mention of “research organizations, universities, developing country institutions and partners...”.

Government Response: Section III- Eligibility Information, A. Eligibility Criteria, (a) now reads: “Be a U.S. or Non-U.S. non-governmental institution, for-profit, non-profit or private voluntary organization or consortium of such organizations registered with USAID, including research organizations, universities, developing countries institutions and partners, and relevant special interest associations. Must be able to meet the eligibility criteria in 22 CFR 228 sub-part D.”

Question #14: Would an organization with 501(c)3 status in the United States be eligible, if offices are outside the United States? How can we determine whether we are “registered with USAID”?

Government Response: Please refer to RFA “Annex F: Supplemental Registration Information- Organization Registration Checklist” for guidance.

Question #15: To ensure competitiveness and the opportunity for USAID to receive more responsive proposals that can achieve the desired results (through possibly two awards), we respectfully request that USAID consider extending the closing date on the RFA.

Government Response: The deadline has been extended Monday, June 27, 2011 11:00 AM EST.

Question #16: On p. 13 USAID references “at least 10 promising new technologies identified” and “five health technologies introduced”; would this be split if there are two awards or is USAID requesting for 10 and 5 to be produced for each award?

Government Response: If there are two awards the number of technologies identified and introduced would be split between the two awards; however this is subject to negotiation during the initial development of a project work plan and the Product and Market Development Introduction Plans.

Question #17: On page 75, Annex D, the SF-424B is listed as one of the SF-424 forms, in addition to SF-424 and SF-424A. On page 33, D.1 only SF-424 and SF-424A are mentioned. Do we need to complete SF-424B or not?

Government Response: Yes, all applicants must complete SF-424B. Section IV.D.1 “Cost/Business Application Guidelines,” currently on page #36, has been corrected.

Question #18: On page 33, D.3 the RFA states: “If the Applicant proposes to charge any training costs to the USG as part of any proposed cooperative agreement, it must clearly identify them.” Is this instruction referring to the Standard Provision for U.S.,

Nongovernmental recipients B. 17 Participant Training? Or does it refer to other forms of training included in our budget?

Government Response: The “Participant Training” standard provision as it relates to this inquiry in reference to U.S. and Non-governmental recipients is not applicable to training costs noted on page 33 of initial RFA (now reflected on page 37 of amended RFA posted June 9, 2011).

Question #19: Section IV.A. item #7 of the RFA states, “An Applicant’s complete application consists of the grants.gov submission and receipt of hard copies.” Below in the General Instructions on page 24, the RFA states that we need to submit hard copies and a CD-ROM, but is silent on any submission to grants.gov. Can you clarify? Are we required to submit the technical proposal and/or the cost proposal also via grants.gov?

Government Response: Submission to grants.gov is not a requirement for this RFA.

Question #20: Section IV.B. item #8 of the RFA states, “Applicants may only submit documents to be included in the Annex as requested in the RFA directions below.” Please confirm that the technical application annex can contain only the following: key personnel resumes, key personnel references, key personnel letters of commitment, 3 past performance reports – short form.

Government Response: Yes.

Question #21: In Section IV.C.2, the key personnel qualifications are listed and references for these positions are requested to be in the annex. How many references should we have for each position?

Government Response: A minimum of three (3) references should be provided per person.

Question #22: Can we provide both a staffing matrix and one-paragraph biographical statements for proposed staff in the annex?

Government Response: Yes.

Question #23: Is it acceptable to have the full-time key personnel budgeted across both federal share and cost share to reach the 100% LOE?

Government Response: Yes, as long as it is an allowable cost share per ADS regulations.

Question #24: In the cost application, are we required to have separate budget detail for the 75-85% that is Washington funded, and the 15-25% that will be mission funded?

Government Response: Yes.

Question # 25: A tremendous number of health technologies in the pipeline and also in field trials in developing countries - mobile tech uses, misoprostol, maternal mortality, and others. We would like to collaborate with others on this. Any suggestions for collaborators?

Government Response: Prospective applicants are encouraged to identify partners through review of publications, reports by funding agencies, and direct communication with other organizations.

Question # 26: There are number of objectives that you have defined on page # 10 and also listed opportunities for health technology development (Annex A, page # 62). Obviously, no one would be doing all those things. My question is- Can we just pick one or two projects that we are good at and then co-ordinate several or some of them with other qualified sub-contractors (partners) by selecting ourselves without requiring going through competitive / bidding process since the time is short for elaborative process to file the application?

Government Response: A strong application should discuss the applicant's comparative managerial, technical, and institutional capacities to achieve the results outlined in this RFA. This includes the types of expertise to be provided by the lead applicant and through sub-recipients, whether named in the proposal or accessed through the competitive sub-grants. Applicants are strongly encouraged to carefully review the application instructions in Section IV.A as well as the evaluation criteria in Section V.

Question # 27: Are we correct to state, it is our understanding that you seem to be implying, ultimately you would like to see TWO teams co-ordinate TWO Grants (Each for \$25 million) and cover as many projects as possible with the given amount in Three to Five year period?

Government Response: USAID seeks to establish up to two five-year competitive awarded cooperative agreements. Successful applicant(s) would be expected to collaborate with USAID as well as other partners.

Question # 28: "Cost share minimum of 5% of the USAID- funded or obligated amount projected up to the maximum ceiling for the recipient award". Question - Does this mean if there are TEN different projects and as many partners, each one has to share 5% of the individual project cost or just one partner could put up 5% of the total project cost share?

Government Response: It is up to the applicant to propose what would make sense. USAID does not specify how a successful applicant will meet cost-share requirements.

Question #29: "Local Lab capabilities": Question – Or you referring to follow up 'use and care' needs re implementing and monitoring a given product (drug)?

Government Response: Supporting manufacturing capabilities to accomplish goals of IR 1.2.

Question # 30: “Knowledge of manufacturing quality control & quality assurance capabilities”: Question – Are they required to manufacture products in the host country?

Government Response: No, but if local manufacturing is deemed appropriate, a successful applicant should have capabilities to assess a manufacturer’s quality control and quality assurance capabilities.

Question #31 : “International Intellectual property rights”: Question – Do you want us to make sure that the host country would not claim property or patent rights and thus make it difficult to transfer technology for other countries before we file the application?

Government Response: Understanding of expertise in international intellectual property rights, patent policy and implementation, regulatory approvals, and licensing systems will be needed to facilitate scale up of technologies.

Question #32: – Are we required to present the individual experts name and their expertise in the application?

Government Response: Within the constraints of the RFA page limit please provide sufficient detail to present a competitive application.

Question #33: “Promote Technology Transfer”: Question - Is it enough to state our willingness to transfer the technology or required to go through the whole process before the application is filed?

Government Response: This RFA is soliciting expertise for a technology development and introduction project and not a specific technology.

Question #34: “Key Personnel”: Question – Is it enough to present the qualifications they have / would have or required to make a commitment to specific personnel?

Government Response: Greater detail will make an application more competitive.

Question #35: “Program Administrator”: Question – Does he really require MBA or enough professional experience to coordinate the various partners product development and research activities?

Government Response: Please see requirements listed in Section IV-C.2(c) “Key Personnel & Staffing Qualifications,” which states “Graduate degree in public administration, Business Administration (MBA) or equivalent combination/blend of training experience”

Question #36: “Amount of private sector funds leveraged to support technology development”: Question - Are we required to document it or present an estimated amount?

Government Response: This question may be referring to a performance indicator listed in Section IV-C.4. A successful applicant will be expected to report on these indicators during the life of the cooperative agreement.

Questions #37: “Integrated National Health Information System”: Question- If the host country does not have it and it is not critical to the project, are we required to propose it?

Government Response: Although not required, historically successful applicants engage host country partners.

Question #38: “M-Health Technologies”: Question: if we propose a pilot project (example: remote fetal and maternal monitoring using Tele-health medical devices), how many months are we required (One year is enough?) to monitor and how many patients (100 to 200 patients)? Can we pay for the whole pilot project out of Grant money? Should we have an outsider validate? Is he / she required to be identified before the application is filed? Can we also pay for specialty Prenatal, Fetal and post natal neonatal monitoring EMR (Electronic Medical Record) as part of the Pilot project?

Government Response: Please propose what makes sense in responding to the objectives of the project.

Question #39: Can we also monitor Gestational Diabetes (or related complications) as part of the pilot project using Tele health devices? (To have a complete assessment of reduction of maternal and child morbidity or mortality.)

Government Response: Please propose what makes sense in responding to the objectives of the project.

Question #40: U.S based, foreign multinational pharmaceutical company with extensive research involvement is eligible to participate, as one of the partners or as a principal sponsor / recipient?

Government Response: Refer to Section III.A of RFA which states: “To be eligible for the Cooperative Agreement under this RFA, an organization must:

- a) Be a U.S. or Non-U.S. non-governmental institution, for-profit, non-profit or private voluntary organization or consortium of such organizations registered with USAID, including research organizations, universities, developing countries institutions and partners, and relevant special interest associations. Must be able to meet the eligibility criteria in 22 CFR 228 sub-part D.”
- b) Agree to work with and hire individuals who have the technical expertise to contribute to the accomplishment of the RFA's objective and results.
- c) Have managerial, technical, and institutional capacities to achieve the results outlined in this RFA.”

Question #41: In reference to the following statement, “Consortium of such organizations registered with USAID”, are all of the participant organizations required or just the “recipient” organization to register with USAID? If we did not register in the past, is there a deadline to register and what is the procedure to do so?

Government Response: Please refer to RFA “Annex F: Supplemental Registration Information- Organization Registration Checklist” for guidance.