Amendment #1 (Questions and Answers and Revision to Section L) to RFP-NIH-NIAID-DMID-05-22

"Tularemia Vaccine Development Team"

Amendment to Solicitation No.:	NIH-NIAID-DMID-05-22
Amendment No.:	1 (3rd posting)
Amendment Date:	August 5, 2004; October 7, 2004;October 22, 2004
RFP Issue Date:	July 13, 2004
Issued By:	Elizabeth J. Osinski Contracting Officer DHHS/NIH/NIAID Contract Management Program 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, Maryland 20892-7612
Point of Contact:	Elizabeth Osinski, Contracting Officer
Name and Address of Offeror:	To All Offerors

This amendment revises the numbering in Section L. – INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS and also includes answers to questions received on this solicitation.

RFP NIH-NIAID-DMID-05-22 has been re-posted in its entirety in order to correct the numbering in Section L. – INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS. All other provisions of this solicitation are unchanged.

The above referenced solicitation is hereby amended as follows to respond to questions presented by recipients of this RFP. The responses are offered for information only. This Amendment will be updated to add any further questions and their related responses. All potential offerors are advised to refer back to this Amendment #1 for additional Questions and Answers.

Question 1. It appears that one does not need current Good Manufacturing Practices (cGMP) material to complete the milestones requested. Is this true?

Yes, this is true. No cGMP material is required, and no human clinical trials are included in the scope of work. Prototype vaccine for animal use, bacterial strains and possibly other reagents can be made available to the awardee through NIAID's Biodefense Reagent Repository. Offerors, however, are directed to Note 1.c. of this RFP which states that work plans, schedules and task-linked budgets shall be proposed for all activities contained in the proposal. In other words, you should include in your cost proposal, everything that is necessary to complete the statement of work.

Question 2. We had questions regarding whether there could be discovery associated with the immunoassays and development of surrogates of immunity or rather is it expected that offerors employ standard assays that are currently used to develop a surrogate profile in a Good Laboratory Practices (GLP) fashion?

Discovery and development of immunoassays is expected, but any advantage that can be gained by adapting existing assays is encouraged. The ultimate goal is validated assays using qualified reagents and cGLPs, so keeping this in mind during development will reduce cost and timelines, and enhance overall product development.

Question 3. Is the association with a company required for the vaccine discovery portion?

Any combination of participants that can meet the requirements stated in the RFP will be considered. You are encouraged to put together the best team possible.

Question 4, There appears to be conflicting instructions for the cost data required for the Business Proposal. The applicable items contained in Section L – Instructions, Conditions, and Notices to Offerors under Paragraph IV. Business Proposal Instructions on Page 23 of the RFP references both Item 59: Information Other than Cost or Pricing Data and Item 61: Cost or Pricing Data. Item 59 requires data sufficient to determine price reasonableness and Item 61 requires cost and pricing data as part of the proposal. Please clarify which Item is applicable in order to prepare a responsive Business Proposal for the referenced RFP.

Amendment 2 has been issued to the RFP to clarify this issue. This RFP does require the submission of Cost or Pricing Data in the Business Proposal.

Question 5. Will letters of intent and limited cost and background on each of the subcontractors incorporated into a prime contractor's original proposal be sufficient? Note 6- Project Structure of the RFP states that proposed subcontractors require the same proposal information as the prime, including cost detail. It goes on to state "(refer to Section L. Business Proposal Instructions item (6) Subcontractors). We do not find an "Item (6) Subcontractors" element in section L. We do however find an "Item 68(10) Subcontractors" within Section L on the website link. Can you please clarify this issue and the desired level of detail necessary for proposed subcontractors cost detail etc?

Letters of intent and limited cost and background on each of the subcontractors are not sufficient. Item 68(10)(f) of the RFP states that a complete cost proposal should be provided in the Business Proposal for each subcontractor in the same format as the offeror's cost proposal. Amendment #3 to the RFP is correcting Item 6 Subcontractors to read Section L. Business Proposal Instructions, Item 68(10) Subcontractors. This was an error in the RFP.

Question 6. Reference RFP-NIH-NIAID-DMID-05-22, Notes to Offerors, Note #6

The Government requests that subcontractors identified in the Technical Proposal require the same information required of the Prime Contractor such as technical approach, knowledge, methods, facilities, experience, personnel qualifications, and work to be performed. Cost details shall be provided for all subcontractors in the same detail as required for the prime Contractor. Is it the Government's intent that Offerors weave this information, where applicable, into their Technical and Business Proposal or is it the Government's intent that major subcontractors address each of these items separately from the Offeror's Technical and Business Proposal?

This question is being answered in two parts. First, for cost that is required in the Technical Proposal, offerors are directed to Page 15 of the RFP, SECTION J – LIST OF ATTACHMENTS. In this section, the cost

information that is required in your technical proposal is listed. This is Direct Cost information only and instructions are on this form entitled, "Technical Proposal Cost Information/Summary of Labor and Direct Costs." This is required for both the Prime and subcontractors in the technical proposal. The website is http://www.niaid.nih.gov/contract/ref.htm and this form is under RFP FORMS AND ATTACHMENTS.

For the other part of this question, offerors must decide how to best present the subcontractors' technical approach, knowledge, methods, facilities, experience, personnel qualifications in the technical proposal. As long as all the required information is included, this decision is left to prospective offerors.

Question 7. Should offerors include projects that will actually generate new vaccine candidates rather than just test ones already out there?

Yes, offerors should include projects that will actually generate new vaccine candidates. Item 4. on page 5 of the RFP addresses this question.

Question 8. Page 15 of the RFP provides form/format for "Breakdown of Proposed Estimated Costs (plus fee) and Labor Hours." With the complexity of costing structure and systems, is it acceptable to alter these forms/format as long as we provide the detail requested or does it have to be submitted exactly as shown?

Yes, it is acceptable to alter these forms as long as the detail requested is provided. Also, your attention is directed to the requirement for the Business Proposal to include two separate sets of Excel Speadsheets, one by Milestone and the other by annual contract year.

- Except as provided herein, all terms and conditions of this RFP remain unchanged and in full force and effect.
- The hour and date specified for receipt of offers REMAINS: **December 1, 2004, 4:00 PM, EST**.
- Offerors must acknowledge receipt of this Amendment #1, on each copy of the proposal submitted.

Failure to receive your acknowledgment of this amendment may result in the rejection of your offer.

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