RFP-NIH-NIAID-DMID-07-06
Amendment No. 1 (Questions & Answers)

This Amendment provides questions submitted by potential offerors and the responses provided by the NIAID. The responses are offered for information only and do not modify or become part of this solicitation. This Amendment may be updated to add any further questions and their related responses. All potential offerors are advised to refer back to this Amendment for additional Q&A.

"Development of Animal Models and Assays for Plague Vaccines"

Amendment No.:	1 (1st Posting)
Amendment Issue Date:	October 10, 2006 (Questions 1 – 8)
Proposal Due Date/Time:	November 16, 2006, at 4:00 P.M., EST
Issued By:	David T. Lisle Contracting Officer OA/DEA/NIAID/NIH/DHHS 6700-B Rockledge Drive, Room 3214, Bethesda, Maryland 20892-7612
Point of Contact:	Dlisle@niaid.nih.gov David T. Lisle, Contracting Officer

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Offerors must acknowledge receipt of the final posting of Amendment #1, on each copy of the proposal submitted. Failure to receive your acknowledgment of this Amendment may result in the rejection of your proposal.

The hour and date specified for receipt of proposals HAS NOT been extended.

THE FOLLOWING PAGES PROVIDE ANSWERS CONCERNING A NUMBER OF INQUIRIES WE HAVE RECEIVED FOR THE ABOVE NUMBERED ACQUISITION:

Question 1 For the small animal models, are different species required? Specifically, can two mouse strains be used, or must two different species be used?

The RFP requests at least one small animal model for pneumonic plague, and at least one small animal model for bubonic plague. As stated in the RFP, animal models must meet the FDA Animal Rule (21 CFR Part 601.90).

Question 2 Is it correct that 2 or more animal models should be developed which could be either small animals or non human primates?

In addition to the animal models addressed in Question 1, the RFP requests at least one nonhuman primate model for pneumonic plague and at least one nonhuman primate model for bubonic plague.

Question 3 For the human samples NIAID plans to provide for the bridging studies, how much sample is to be provided, what type of samples will be provided, and what will be the matrix?

NIAID has the ability to provide samples of various types in reasonable and adequate quantities on an as needed basis. The specific type and amount will be determined by the contract awardee's requirements to complete the Statement of Work and the availability to NIAID. For proposal purposes, offerors are to assume that the NIAID will provide all types and amounts needed by their proposed technical approach at no cost to the offeror.

Question 4 The bridging studies in Task 4.1 appear to be an *in vitro* analysis. Are actual *in vivo* bridging studies to be performed?

The bridging studies described in Task 4 are analyses of in vitro and in vivo data generated in Tasks 1, 2 and 3.

Question 5 When considering the timeline for completing the requested tasks (3 years for base tasks), it appears that large and small animal studies will have to be conducted in parallel to meet the timeline. When considering the risk associated with conducting these studies in parallel, and in deciding the duration of studies, which factor is of greater importance to NIAID – adherence to the contract timeline or a long duration study?

Offerors are asked to provide their best technical approach and best timeline. Proposals will be evaluated using the evaluation criteria outlined in Section M of the RFP.

Question 6 How much time is required for the NIAID Project Officer's review and approval of reports and protocols? This directly affects timeline construction.

It is not possible to project how much time will be required as each report or protocol may require different amounts of effort to achieve an acceptable end product. The NIAID Project Officer's review will be as timely as possible. Offerors should incorporate into their proposal a reasonable review period.

Question 7 How many different vaccines will NIAID provide for use in the tasks? Will a dosing schedule be provided for each vaccine?

Offerors are directed to Attachment 6 – Additional Technical Proposal Instructions, Section 3 – Uniform Budget Assumption, paragraph B., subparagraph 1., which includes the following: "Option 1: efficacy studies shall be performed for both pneumonic and bubonic plague in one small animal model and one NHP model for two vaccine candidates following the procedures and SOPs developed in Tasks 1 and 2." If relevant data associated with the vaccine candidates is available, NIAID will share the data with the contract awardee.