Amendment #1 to RFP-NIH-NIAID-DAIDS-06-15

"Simian Vaccine Evaluation Units (SVEUs)"

Amendment to Solicitation No.:	**RFP-NIH-NIAID-DAIDS-06-15**
Amendment No.:	**1**
Amendment Date:	**June 23, 2005 Questions/Answers 1-8** **July 20, 2005 Question/Answer 9**
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Issued By:	**Jacqueline C. Holden** **Contracting Officer** **NIH/NIAID** **Contract Management Program** **6700-B Rockledge Drive** **Room 3214, MSC 7612** **Bethesda, Maryland 20892-7612**
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Name and Address of Offeror:	**To All Offerors**

THIS AMENDMENT PROVIDES QUESTIONS SUBMITTED BY OFFERORS AND THE RESPONSES PROVIDED BY THE NIAID PROJECT OFFICER AND CONTRACTING OFFICER. THE RESPONSES ARE OFFERED FOR INFORMATION ONLY AND DO NOT MODIFY OR BECOME PART OF THIS SOLICITATION. ANY FURTHER QUESTIONS AND THEIR RELATED RESPONSES WILL BE ADDED TO THIS AMENDMENT AT LEAST WEEKLY. ALL OFFERORS SHOULD REFER BACK TO THIS AMENDMENT #1 FOR ADDITIONAL QUESTIONS AND RESPONSES.

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

Question 1.

Our general experience in similar competitions is that the successful bidder is responsible for any transition costs incurred to transfer project elements from the former contractor to the new contractor. However, the tenor of the RFP, namely Note #29 to Offerers, seems

to allot the responsibility for moving specimens and animals to the incumbent rather than the successful bidder. Our question is, should this proposal estimate any costs for the "Initial Transition" (e.g., transportation) and/or should the proposal project any costs for the "Final Transition" (e.g., transportation)?

Answer 1:

Currently, the plan is for the incumbent to arrange for and cover the costs associated with the transfer of specimens and animals to the new contractor.

Question 2.

It is our understanding that some of the protocols to be run by this contract will be with outside investigators and commercial organizations. The data generated during these projects may be restricted by these groups through negotiated contracting arrangements or material transfer agreements. In General Instructions section of the RFP Item #29, the Sharing of Research Data is indicated as applicable. The Confidentiality of Information attachment to the statement of work places restrictions on information sharing. Should the data generated on projects involving a third party be part of our data sharing plan or should it be treated separately in an individually negotiated plan?

Answer 2:

Because the SVEU contractors are required to maintain the confidentiality of study information and reagents, it becomes the responsibility of the vaccine collaborator to publish (in collaboration with the SVEU contractor) the results of the study and to make relevant reagents available. So in this case, I would think that the Sharing of Research Data is not the responsibility of the SVEU contractor.

In the case of reagents developed under the contract, such as viral stocks, the SVEU contractor's Sharing of Research Data plan may be one in which these reagents are sent to investigators when requested by the NIAID Project Officer, but the SVEU contractor will not be authorized to send the reagents without prior approval from the Project Officer.

Question 3:

Please specify the maximum and minimum limits, if any, on the level of effort (FTE) that may be proposed to complete the work for the each of the following personnel categories: Principal Investigator, the Study Coordinator, Data Entry staff, veterinarians, technical/scientific staff, and animal care staff.

Answer 3:

The level of effort for each position should be based upon the estimated level of effort needed to support vaccine studies in the proposed number of animals. There is no pre-set

lower and upper limit.

Question 4:

Please specify the maximum and minimum number of non-human primates as well as the species and virus-infection status of non-human primates which could be required to be moved from one currently funded SVEU site to a newly funded SVEU site as outlined in the 'Initiation Plan'. In addition, please specify whether transcontinental shipment of non-human primates could be required. The appropriate, accurate costs for an 'Initiation Plan' can not be budgeted without this specific information.

Answer 4:

A newly funded SVEU contractor will not be expected to bear the cost of the transportation of animals from a previous contractor. The expenses for this will be covered by the out-going SVEU contractor.

Question 5

Please specify the rationale for the requirement of transporting SIV-infected nonhuman primates from one SVEU site to another. To our knowledge it is not legal to ship non-human primates know to be infected with lentiviruses (i.e. HIV, SIV or SHIV) by any U. S. commercial carrier. The costs for private transport of virus-infected primates are extremely high; liability insurance, security personnel, and regular veterinary supervision in additional to routine animal care are essential for private transport of virus-infected primates adding substantial costs. In addition, the mandatory quarantine holding of virus-infected animals at the secondary SVEU site after transport would delay ability to use animals and further increase costs. Finally, most non-human primates infected with virulent lentiviruses have variable onset of disease that is exacerbated by stress; thus, the unavoidable transport and quarantine time and stress could compromise the health of animals and thus the outcome of any experimental protocol. Overall, it would be economically counter-productive and scientifically unsound as well as a public safety risk to transport virus-infected, non-human primates from one SVEU site to another.

Answer 5:

These are all valid points, but do not need to be the concern of a new SVEU contractor, since any transportation will be arranged and paid for by the out-going contractor.

Question 6:

Please specify whether any or all aspects of studies outlined in the statement of work will require or may use Good Laboratory Procedures (GLP) which requires Quality Assurance personnel with expertise and training in GLP performance of non-human primate studies.

Answer 6:

There is no expectation of a requirement for GLP performance of nonhuman primate studies under the SVEU contracts.

Question 7:

Please clarify if the offeror may specify the number of non-human primates to be provided in any given year of the contract by age, gender, Major Histocompatibility Complex (MHC) genotype or haplotype, geographic origin and species.

Answer 7:

In the proposal, the Offeror should specify the variety of animals available to the Offeror from institutional breeding facilities or outside purchase. After the contract is awarded and the SVEU contractor is requested to conduct studies, the species, age, gender, MHC, etc. of the animals to use for each study will be determined by the requirements of the study and the availability of nonhuman primates to the SVEU contractor. The Offeror is not required to know in advance what animals will be needed. If, however, an Offeror wishes to propose to provide only newborn macaques for specialized studies (for example), that is acceptable. Or an Offeror may indicate that newborns macaques can be made available for studies as needed, and juveniles and adults can also be provided for studies. In either case, the maximum number of animals that the Offeror is willing and able to house at any given time should be specified. The budget would reflect the initial purchase of the animals and a yearly replacement of a portion of the animals (keeping in mind that most vaccine studies have been taking a year or more to conduct).

Question 8:

Please clarify what types of equipment (e.g. ultralow freezers, liquid nitrogen tanks for storage of non-human primate blood and tissue samples, sample bar-coding and tracking systems) that are required to complete the studies specified in the statement of work may be proposed for purchase.

Answer 8:

Offerors are requested to list existing equipment that would be available for use in SVEU contract studies. In addition, Offerors may request, with justification, the purchase of additional equipment that would be needed for the conduct of the studies, storage of samples, etc.

Question 9:

Under Note #9 to Offerers (budget) the RFP states "Secondly, for purposes of providing a uniform basis of comparison among proposals, offerors are requested to prepare a partial

second budget presenting only their Year 1 costs to maintain a population of 100 nonhuman primates for the conduct of vaccine/vaccine-related studies." We assume that maintenance costs for 100 NHP's would include only those associated with routine housing and care of animals, e.g., feeding and care, physical exams and associated testing to monitor health, costs for environmental enhancement, etc., and would not include cost associated with experimental manipulations required for vaccines, in vivo virus titrations or microbicide studies (note #12 to offerers). Therefore, specific costs described in notes to offerers, e.g., (#14) collection. processing and storage of serum and lymphocytes, biopsies, phenotyping, necropsies, (#15) infections and collections of plasma, serum and lymphocytes, (#17 and 19) ELISA and Western blot assays, (#18 and 20) confirmation of viral RNA and DNA loads in tissues, virus isolations, in vitro virus titrations, (#25) entry of study protocols and data into databases, would not be included in this partial second budget. Are these assumption correct?

Answer 9:

The rationale behind having a separate, "dummy", budget for one year with 100 monkeys was so that costs could be more accurately compared among Offerors. Therefore, it was intended to be an example of the costs that an Offeror would charge to conduct studies with 100 monkeys. While it is impossible to exactly calculate the costs, since we did not give them a sample protocol to "conduct", they should include costs for animal immunization (we can postulate 5 immunizations per animal), sample collection and processing, assays that the SVEU would routinely conduct, etc. It is perfectly valid for Offerors who will be proposing to provide more than 100 animals to base this "dummy" budget upon their real budget, with adjustments of costs such as animal caretakers, where there might be an economy of scale.