

**Amendment #4
to RFP-NIH-NIAID-DAIDS-03-13**

"HLA Typing and Epitope Mapping Relative to HIV Vaccine Design"

Amendment to Solicitation No.: NIH-NIAID-DAIDS-03-13

Amendment No.: Four (4)

Amendment Date: October 3, 2002

RFP Issue Date: May 30, 2002

Proposal Due Date: **October 10, 2002 at 4:00 PM Local Time**

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Name and Address of Offeror: To All Offerors

Purpose of Amendment: See below.

The purpose of this amendment is to provide all potential Offerors with an additional clarification resulting from issues raised by potential Offerors and to update the Notes to Offerors accordingly. **The date and time for receipt of proposals is UNCHANGED.**

Question 1:

The answer to question #1 on RFP Amendment #3 states "we would request full length sequencing only on the 50 viral isolates for expansion." The response to question #3 on Amendment #3 states, "Please propose and budget for sequencing 300 isolates." We interpret that as being two different answers to the same question.

Answer 1:

Question # 2, answer #2 in Amendment # 3 states, "Propose and budget for sequencing 300 isolates." So in summary budget for sequencing 300 isolates in total, of which a subset (50) should be expanded to make viral stocks.

The following Notes to Offerors are amended to read as follows. Changes are in bold font.

NOTE #4 TO OFFEROR: A potential source of acquiring specimens shall include, but is not limited to the pool of NIAID grantees funded through the HIV Vaccine Trials Network (the HVTN). For a complete list of sites and principal investigators in the HVTN see <http://www.scharp.org/hvtn/>. A potential site or sites should lie within a related geographic region that is accessible by road or air transportation and does not require overnight transportation of fresh, unfrozen, samples. The Offeror should describe the rationale for site(s) and sample selection, and how the samples shall be delivered to the contract site in a timely manner. The Offeror is strongly

encouraged to perform the immunological and virological assays at the site of sample acquisition or at a central laboratory, to minimize transportation of specimens and shipping difficulties, and also to promote technology transfer to international institutions. The need for the Contractor to supply shipping containers will be minimal and will be limited to foreign suppliers who do not have access to such materials. For purposes of preparing a budget, assume shipping receipt and processing of approximately 500 samples/year. Samples shall include, but are not limited to: fresh whole blood (10-15 ml collected in the presence of anti-coagulant and 10-15 ml collected in the absence of anti-coagulant) or frozen tissues including blood cells, serum and plasma, and frozen virus culture supernatants. **For the performance of the neutralization assays, either serum or plasma works, but experience with existing NIAID programs has taught us that the anticoagulant in tubes used for plasma collection is toxic to cells at concentrations of 1:30 or less. Because most primary isolate neutralization will require serum/plasma concentrations at <1:30 dilution, this could potentially ruin the neutralization assays as well as lead to false positives – the anticoagulant is killing the cells rather than the antibody neutralizing virus. Thus for neutralizing assays performed in this contract, we request use of heat inactivated serum.**

NOTE #9 TO OFFEROR: The Offeror shall describe in detail their technical approaches for evaluating cellular immune responses by providing current SOPs, as well as peer reviewed published papers. These SOPs should include a description of the experimental design (sequence in which various types of studies will be carried out), and a description of the methods to carry out evaluations. A rationale for the design, based on statistical considerations, if appropriate, should be provided as well as a discussion of potential logistical problems and possible solutions. Many of the required reagents are available through the AIDS Research and Reference Repository (operated by McKesson BioServices, 621 Lofstrand Lane, Rockville, MD 20850). For purposes of preparing a budget, the Offeror shall assume that ELISPOT assays will be carried out on 200 samples/year. The Offeror should submit information pertaining to development of new assays, or adaptation of assays for large-scale use, but costs for performing the assays should not be included in the cost estimate. For QA/QC testing of cellular immune assays, the Project Officer will co-ordinate the acquisition and supply of appropriate samples from DAIDS-supported clinical networks. For purposes of preparing a budget, the Offeror shall assume that proficiency testing will occur bi-annually with panels of about 10 coded specimens. **For budget purposes, assume 200 samples/year for ELISPOT assays. For new assays, it notes costs should not be included in the cost estimate for new assays.**

NOTE #14 TO OFFEROR: In the technical proposal, the Offeror shall provide sample protocols together with documentation of their experience in performing these protocols, for example, peer reviewed papers. The Offeror shall assume that virus load measurements will be carried out on 300 specimens/year, virus isolation attempts will be carried out on 200 samples/year, that virus expansions will be required for approximately 50 isolates/year, that HMA analysis will be conducted on 100 isolates/year, and that genetic sequencing will be conducted on 300 isolates/year. **Budget for sequencing 300 isolates in total, of which a subset (50) should be expanded to make viral stocks.**

NOTE #17 TO OFFEROR: The Contractor and all key personnel will be subject to an annual review of performance by an External Advisory Committee, as described under the “Reporting Requirements” section of this RFP. The membership of the external Advisory Committee will be jointly proposed and agreed to by the Contractor and the NIH. The Contractor will convene the External Advisory Committee and will pay travel expenses of the Committee. **Budget for three (3) external advisors; one (1) immunologist, one (1) virologist and one (1) immunogenetics person. Offerors may propose two (2) domestic advisors and one (1) international advisor to average the travel budget and plan on two (2) days of per diem to the host site of the contract.**

Except as provided herein, all terms and conditions of the RFP document NIH-NIAID-DAIDS-03-13 remain unchanged and in full force and effect. Offerors must acknowledge this Amendment #4, by acknowledging receipt of the amendment on each copy of the offer submitted. Failure to receive your acknowledgment of this amendment may result in the rejection of your offer.