RFP NIH-NIAID-DAIDS-01-04

"Simian Vaccine Evaluation Units"

ALL AMENDMENTS TO THIS RFP WILL BE POSTED ON THE NIAID CONTRACTS MANAGEMENT HOME PAGE: HTTP://WWW.NIAID.NIH.GOV/. ALL OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE NIAID WEBSITE FOR ANY POSSIBLE SOLICITATION AMENDMENTS THAT MAY BE ISSUED. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.

Request for Proposal No.:	NIH-NIAID-DAIDS-01-04
OMB #:	0990-0115
Issue Date:	February 23, 2000
Point of Contact:	Grace Bruce gb15w@nih.gov Contracting Officer Contract Management Branch, NIAID, NIH Room 2230, MSC 7612 6700-B Rockledge Drive Bethesda, Maryland 20892-7612
Purchase Authority:	Public Law 92-218 as amended
Small Business Set-Aside:	No, SIC Code 8731
Just In Time:	No
Offer Expiration Date:	Offers shall be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH 2043".
Proposal Due Date:	***May 5, 2000, 4:00 P.M Local Time***

Ladies and Gentlemen:

You are invited to submit a proposal in accordance with the requirements of this RFP. The Government anticipates that up to seven (7) cost reimbursement, completion type contracts will be awarded for a period of five (5) years as a result of this RFP.

The Government reserves the right to make award without discussions. Accordingly, Offerors are advised to submit their best offer and complete proposal information by the closing date of the RFP.

Offerors must submit one copy each of the technical and business proposals ELECTRONICALLY. Please note that the electronic copy of your proposal will need to be submitted in Adobe Acrobat portable document format (PDF). Adequate security for electronic transmission is provided by using a dedicated server with access restricted through passwords. HARDCOPIES OF BOTH THE TECHNICAL AND BUSINESS PROPOSALS MUST BE SUBMITTED IN ACCORDANCE WITH THE INSTRUCTIONS AND TO THE ADDRESS LISTED IN **ATTACHMENT F, PACKAGING AND DELIVERY OF THE PROPOSALS. An official authorized to bind your organization must sign the hardcopy of your proposal.**

See Attachment F for complete details on proposal format and instructions on how to prepare and submit a proposal. All pages of the technical proposal must be numbered sequentially and these numbers must be consistent with the information outlined in the technical proposal Table of Contents.

The attachments included with this electronic RFP package are as follows:

Attachments:

A. **BACKGROUND AND STATEMENT OF WORK**, dated February 23, 2000
B. **REPORTING REQUIREMENTS AND DELIVERABLES**, dated February 23, 2000
C. **EVALUATION FACTORS FOR AWARD**, dated February 23, 2000
D. **SPECIFIC RFP INSTRUCTIONS AND PROVISIONS**, dated February 23, 2000
E. **APPLICABLE RFP REFERENCES**, dated February 23, 2000 **[NOTE: This Attachment contains five (5) other referenced documents that must be retrieved, in whole or in part, in order to submit a proposal**
F. **HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL**, dated February 23, 2000

If you are unable to download any of the applicable documents, please contact Grace A. Bruce, Contracting Officer, by phone, fax or e-mail at the numbers/address listed below.

YOUR ATTENTION IS FURTHER DIRECTED TO THE "PROPOSAL INTENT RESPONSE SHEET" CONTAINED IN ATTACHMENT D OF THIS DOCUMENT. IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE THIS FORM AND RETURN IT TO THIS OFFICE VIA FAX OR E-MAIL ON OR BEFORE MONDAY, APRIL 03, 2000. THE RECEIPT OF THIS FORM IS CRITICAL AS IT CONTAINS INFORMATION ESSENTIAL FOR NIAID'S COORDINATION OF THE ELECTRONIC SUBMISSION OF PROPOSALS.

If your proposal is not received by the Contracting Officer or designee at the place and time specified, then it will be considered late and handled in accordance with the PHS Clause 352.215-10 entitled, "Late Proposals, Modifications of Proposals, and Withdrawals of Proposals."

Questions concerning the solicitation must be furnished in writing. Please contact Grace A. Bruce at (301) 496-0195 or at the Internet electronic mail address gb15w@nih.gov, via fax at (301) 402-0972. Collect calls will **NOT** be accepted.

Sincerely,

Jacqueline C. Holden
Senior Contracting Officer
Contract Management Branch
National Institute of Allergy and Infectious Diseases, NIH

Attachments: A - F

ATTACHMENT A

RFP-NIH-NIAID-DAIDS-01-04
February 23, 2000

BACKGROUND AND STATEMENT OF WORK

BACKGROUND

The National Institute of Allergy and Infectious Diseases (NIAID) supports Simian Vaccine Evaluation Unit (SVEU) contracts for preclinical evaluation of the immunogenicity and efficacy of promising SIV and HIV candidate

vaccines in non-human primates. Studies are conducted at the initiation of NIAID, and vaccines to be evaluated are selected by NIAID.

Current SVEU contractors are (1) Tulane University Regional Primate Research Center (N01-AI-65300), (2) University of Washington Regional Primate Research Center (N01-AI-65302), (3) TSI Mason Laboratories, now Primedica Corporation (N01-AI-65303), (4) Advanced BioScience Laboratories (N01-AI-65314), and (5) Henry M. Jackson Foundation (N01-AI-65301). The SVEUs conduct preliminary studies on new vaccines, conduct larger-scale studies on vaccines that have already demonstrated promise, evaluate the immunogenicity and safety of candidate HIV vaccines (or immunogenicity, safety, and efficacy of SIV vaccines which parallel HIV vaccines in approach) in anticipation of Phase I human clinical trials, and conduct comparative studies on vaccines and/or adjuvants from multiple sources. The SVEUs may also conduct studies with passively administered vaccines. The SVEUs are expected to provide non-human primates for the studies, immunize animals with candidate vaccines, conduct initial assessments of immune responses, challenge the non-human primates with infectious virus, and determine whether or not the animals become infected.

The SVEUs conduct *in vivo* titrations of virus challenge stocks when requested. SVEUs may also conduct microbicide studies in order to evaluate the ability of topically administered microbicides and other antiviral substances to block infection of non-human primates with virus administered vaginally or by other mucosal routes. In addition, in order to maximize the use of resources, animals that have become infected with viruses after a vaccine study, virus titration, or microbicide study may be used for pilot studies with antiviral agents administered alone or in conjunction with a vaccine.

STATEMENT OF WORK

Independently, and not as an agent of the Government, the Contractor shall furnish all services, qualified personnel, materials, equipment, animals, and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the work set forth below.

Specifically, the Contractor shall:

1) **Acquire, house, observe, and maintain animals and record data.**

a) Acquire/provide SIV-free non-human primates and have the capacity to house approximately [*50-300**] animals at one time for vaccine studies, vaccine-related studies, and other specified studies.

***[NOTE #1 TO OFFERORS: The number of non-human primates to be housed by each SVEU will be discussed during negotiations for these contracts. The approximate number of non-human primates to be housed at a SVEU is expected to range from a minimum of approximately 50 per site up to approximately 200-300 per site, depending upon the available capacity of the facility, experience of the Offeror's personnel in conducting vaccine studies, the outcome of the review of proposals, and the needs of the NIAID. Offeror's initial proposal should be based on the number of non-human primates that the Offeror would be able and willing to make available to NIAID for studies to be conducted under this contract.**

For purposes of this proposal, Offerors are requested to submit two budgets: First, Offerors are requested to submit a proposed five year budget covering the number of non-human primates that they would be able and willing to make available to NIAID for studies to be conducted under this contract. In addition, for purposes of providing a uniform basis of comparison for proposals received in response to this RFP, Offerors are requested to prepare a partial second budget presenting only their Year 1 costs to maintain a population of 100 non-human primates for the conduct of vaccine/vaccine-related studies.]

[NOTE #2 TO OFFERORS: If Offerors propose to acquire monkeys from outside sources, primate facilities from which the monkeys will be purchased shall be identified, and past experience in obtaining monkeys from these proposed sources shall be documented. A discussion of quarantine procedures and a description of estimated lead time (from past experience) from placement of the order for purchase of the animals to start of study shall be included. (Outside purchase of the animals is not considered a weakness and will not affect scoring.)

If Offerors propose to acquire monkeys from their own facility, a description of the process for transferring animals onto the SVEU for a study shall be provided.

Primary emphasis will be on rhesus macaques (Macaca mulatta) of Indian origin. This does not preclude the possibility of housing and utilizing other monkey species (e.g. pig-tail macaques [Macaca nemestrina], Chinese rhesus, African green monkey [Cercocebus atys], or cynomolgus monkey [Macaca fascicularis], or baboons), as determined by the Project Officer.]

b) Determine and record the herpes virus B status, the STLV (simian T-cell lymphotrophic virus) status, and the SRV (simian type D retrovirus) status of the animals before initiation of the study. As requested by the Project Officer, determine the MHC type of the monkeys, or ship specimens to a laboratory designated by the Project Officer for such analysis.

c) House all animals in appropriate biohazard containment facilities, using appropriate biosafety procedures to care for and handle virus-infected animals. Animals may be held in BL-2 biohazard containment until exposure to infectious SIV or a related retrovirus. After exposure, biohazard containment shall be, at a minimum, BL-2 containment using BL-3 practice for animal handlers.

d) Provide care and routine health surveillance for the non-human primates, and record and maintain clinical observations for each animal. The veterinary staff shall perform and record observations, including the animal's health status, any treatments received, and the results of periodic weighing. The Project Officer shall be notified if an animal is ill enough for the veterinarian to recommend euthanization.

e) Perform and document tuberculosis testing of all animals maintained under this Contract on a quarterly basis.

f) Provide for the security and coverage of the animal holding facility 24 hours per day, seven days per week, including at least daily observation of the health status of each animal. Provide a security system to prevent unauthorized entry into the facility.

g) At the termination of a study, the end of the contract, or when requested by the Project Officer: (1) move the animals onto another study, which could include a pilot study of the efficacy of antiviral agents, or a vaccine study in the presence of antiviral agents; (2) euthanize animals according to humane procedures approved by the Contractor's institutional Animal Care and Use Committee; or (3) ship the animals (including virus-infected animals) to another facility, as requested by the Project Officer.

h) Comply with USDA regulations pertaining to primate care and with the "PHS Policy on Humane Care and Use of Laboratory Animals."

2) **Develop a protocol for each study**.

Protocols are to include, but not be limited to, the schedules of immunizations, specimen collection, and virus challenge, and are to be developed in conjunction with the Project Officer, other appropriate NIAID staff, and other collaborators who may be involved in a study, such as those providing vaccines for the study. Obtain final written approval of each study protocol from the Project Officer before initiation of the study. Submit protocols to the Contractor's institutional Animal Care and Use Committee for approval. Amend the protocols during the studies, if necessary, after concurrence of the Project Officer.

3) **According to approved protocols, conduct: vaccine studies; *in vivo* titrations of virus stocks; route of immunization of route of infection studies and other preliminary studies as may be required to carry out a vaccine study; evaluations of the efficacy of passively administered antibodies, microbicides, and other anti-viral substances; or other studies as requested by the Project Officer.**

[NOTE #3 TO OFFEROR: In the proposal, Offeror shall provide descriptions of procedures and safety precautions to be observed during inoculation, blood and tissue collection, shipping of biohazardous samples, disposal of biohazard waste, etc.]

a) Immunize/treat animals with candidate vaccines, adjuvants, microbicides or other anti-viral substances,

etc., using the doses, schedules, and routes indicated in the approved protocols. Inoculation routes shall include one or more of the following: intramuscular, intradermal, subcutaneous, intranasal, intravaginal, intrarectal, intravenous, or other routes designated by the approved protocol. Candidate vaccines, adjuvants, microbicides, etc., will be provided by or through NIAID.

b) Draw blood or obtain other fluids or tissue samples prior to immunization/treatment and from immunized/treated animals, at times and of volumes/quantities specified in the protocols, for immunological assessment and other tests and assays as indicated in the protocols. Specimens to be collected may include, but are not necessarily limited to: sera, mucosal (nasal, vaginal and rectal) secretions/washes, lymphocytes, cerebrospinal fluid, fecal samples, broncho-alveolar lavages, and biopsies of lymph nodes and other organs. Samples shall be processed as specified in the protocols and either assayed at the SVEU, frozen for storage at the SVEU, sent to the NIAID contract Primate Immunology Laboratories located at Harvard University and Duke University, or sent to another appropriate laboratory, as specified by the Project Officer and/or defined in the study protocol.

[NOTE #4 TO OFFEROR: For budgetary purposes, it is anticipated that serum and lymphocytes will be collected, processed, and stored on a biweekly basis from each animal entered into an experimental vaccine protocol. Mucosal samples are anticipated to be collected at least monthly. Procedures for collection of lymph node biopsies are anticipated to be performed on the average of six times per year. For budgetary purposes, Offerors should propose to ship samples once a month to each of the Primate Immunology Laboratories.]

c) Monitor immunized/treated animals for toxicity, and monitor both immunized/treated and virus-challenged animals for general health status (i.e., weight, standard blood and chemistry profiles, opportunistic infections, and other assessments specified in the protocol). Maintain records of this information.

d) Challenge immunized/treated and/or control/naive animals, as requested by the Project Officer, with a specific dilution of a titered stock of virus (SIV, SHIV, HIV-2 or related virus), using doses and routes specified in the protocols. Routes of administration of the challenge virus shall include one of the following: intravenous, intravaginal, intrarectal, or other route specified in the approved protocol. Virus stocks will be provided by or through NIAID.

e) Draw blood or obtain other fluids or tissues from the challenged animals for virus isolation by co-culture, other virological assessment, immunological assessment, and other tests or assays as specified in the protocol or requested by the Project Officer. Conduct biopsies or necropsies as requested by the Project Officer.

[NOTE #5 TO OFFERORS: For budgetary purposes, it is anticipated that serum and lymphocytes will be collected and processed six times in the first month following virus challenge, then on a biweekly basis from each animal for the next six months. Procedures for collection of lymph node biopsies are anticipated to be performed on the average of six times per year. For budgetary purposes, Offerors should propose to ship samples once a month to each of the Primate Immunology Laboratories. For purposes of cost estimates, Offerors should estimate the cost of 20 necropsies per year.]

f) Provide data and information from the studies to the Project Officer when requested, and, at the request of the Project Officer, provide experimental results (reported on an individual animal basis) to a Data Collection and Analysis Unit and/or to the Project Officer in a format to be specified by the Project Officer.

4) **Conduct *in vitro* laboratory immunologic and virologic assays:**

All analyses of material obtained after virus challenge shall be performed in a BL-2 or BL2/BL3 biohazard containment laboratory by trained personnel.

[NOTE #6 TO OFFERORS: Offerors shall provide a floor plan and description of laboratory space to be used. List equipment available for use. Include a description of the biosafety procedures that are in place or that will be developed.]

(a) Assess the immunological responses of immunized animals and of challenged/infected animals.

Perform immunologic analyses of specimens from animals as specified in study protocols, before and/or after challenge with SIV or SHIV. Specifically, detect and/or titer antibodies to SIV, HIV, or SHIV, to specific SIV and/or HIV antigens, or to other antigens as specified in the approved protocol or requested by the Project Officer, and conduct other assays of immunological response as specified in the protocol or requested by the Project Officer. Include appropriate controls and provide quality control of assays. Conduct studies to compare assays with other SVEUs as requested by the Project Officer.

[NOTE #7 to OFFERORS: Offerors shall demonstrate the capability to conduct ELISA assays and immunoblotting (Western blot) assays. Offerors shall propose to conduct one or more additional assays to assess immunological responses, such as antigen-specific proliferation; antigen-specific cytokine or chemokine-release or synthesis by fresh or cultured cells, using assays for protein or mRNA; CD8+ T cell-mediated virus suppressor acitivity; detection of mucosal IgA antibodies; virus neutralization assays; immunoprecipitation assays; immunofluorescence assays; antibody affinity assays; MHC tetramer-peptide binding assays; CTL assays, etc. Offerors may demonstrate capability using SIV or HIV systems.

For purposes of this proposal, Offerors shall propose to conduct ELISA assays on 12 serum samples per year per monkey, and Western blot on 12 samples per year per monkey. Offerors proposing to conduct other assays, in addition, shall budget for performing 100 of each type of proposed assay per year.]

(b) Assess the virological status of challenged animals to confirm protection or infection.

Perform virologic analyses of specimens from animals as specified in the study protocols, before (baseline) and at multiple times after challenge with SIV, SHIV, or HIV. Include appropriate controls and provide quality control of assays. Conduct studies to compare assays with other SVEU contractors as requested by the Project Officer.

[NOTE # 8 TO OFFERORS: Offerors shall demonstrate the capability to conduct virus isolation to assess the virological status of challenged animals. In addition, Offerors shall demonstrate the capability to conduct assays to measure plasma levels of viral RNA in challenged animals, or to propose subcontracts to conduct the assays. Offerors shall also propose to conduct at least one additional assay to detect the presence of virus, such as the measurement of viral nucleic acids (RNA or DNA) in cells of the animals by PCR (polymerase chain reaction).

For purposes of this proposal, Offerors shall propose to conduct virus isolation by co-cultivation with appropriate target cells on an average of 10 samples per year per monkey. For purposes of cost estimates for this proposal, Offerors proposing to conduct plasma virus RNA assays should assume that they will conduct 30 assays per year per monkey. Offerors proposing to conduct other assays should assume that they will conduct assays on 5 samples per year per monkey.]

5) **Store and maintain inventory of titered virus stocks and candidate vaccines supplied by the Project Officer; store and maintain inventory of animal specimens collected during the course of the studies conducted under this contract.**

a) Provide for appropriate storage at -20°C and -80°C, with monitoring of storage conditions by automatic temperature alarm to guarantee continuous proper storage.

b) Ship specimens (plasma, serum, cells, etc.) to investigators as designated by the Project Officer.

[NOTE #9 TO OFFERORS: For purposes of this proposal, Offerors should estimate the cost of 12 shipments per year to Boston, MA, and 12 shipments per year to Durham, NC.]

c) Use shipping conditions appropriate to preserving any specimen, and use containers which will comply with domestic postal regulations and pertinent I.C.C. regulations. Shipments of sera, cells, blood and other tissues from SIV-, SHIV-, or other virus-infected monkeys shall be made in accordance with proper

biocontainment shipping procedures.

d) At the conclusion of this Contract, frozen specimens shall be disposed of or transferred by the Contractor according to directions provided by the Project Officer.

6) **Communicate effectively with the Project Officer**

a) Establish electronic communications with the Project Officer sufficient to support exchange of e-mail and the submission of data files and reports when requested.

b) Provide periodic updates of project status, as requested by the Project Officer, via telephone or e-mail.

c) Submit project plans, project reports, and annual reports in a timely fashion is accordance with the Reporting Requirements and Deliverables section incorporated into this contract.

d) Meet with the Project Officer at an annual site visit.

e) Meet with the Project Officer at least once a year at a meeting in Bethesda or at a scientific meeting to be designated.

[**NOTE 10 TO OFFERORS: For purposes of this proposal, Offerors should estimate the cost of a trip to Bethesda, MD, if on or near the West Coast, or the cost of a trip to the West Coast, if on or near the East Coast.]**

STATEMENT OF WORK
ATTACHMENT 1

CONFIDENTIALITY OF INFORMATION

Certain information and data provided to the Contractor shall require confidential treatment. Information to be treated confidentially may pertain to proprietary information provided by the AIDS vaccine product and reagent developers and vaccine trial investigators. Primate specimens and HIV- or SIV-specific reagents obtained as a result of this contract shall be restricted to contract-related studies, and shall not be released to any other investigators without approval of the Project Officer(s). All information supplied by the Project Officer(s) should be assumed to be proprietary unless specifically identified as non-confidential in writing by the Project Officer(s). Proprietary data confidentiality will be protected by an Advance Understanding to be included in the contract as follows:

(1) The Contractor agrees that the use of materials provided to the Contractor by or through the Government for studies performed under this project shall be restricted to contract-related projects and shall not be released to any other party without approval of the Project Officer. (2) Because the Contractor may be utilizing and evaluating materials provided to the Government by third parties, including AIDS vaccine product and reagent developers and AIDS vaccine trial investigators, it is essential to include provisions that will protect the rights of these third parties. Therefore the Contractor agrees that manuscripts/abstracts based on data/information generated under this contract will not be submitted for publication until written Project Officer(s) clearance has been received. Contract support shall be acknowledged in all such publications. A "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information.

The Project Officer(s) will review all manuscripts/documents in a period of time not to exceed 30 calendar days from receipt, and will either grant clearance for publication/disclosure, recommend changes or, as applicable, refer the document to the Third Party Supplier of materials utilized under this project for their review.

The NIAID will use its best efforts to assist and expedite the review process by the Third Party Suppliers wherever possible.

ATTACHMENT B

RFP-NIH-NIAID-DAIDS-01-04
February 23, 2000

REPORTING REQUIREMENTS AND DELIVERABLES

A. Technical Reports

In addition to those reports required in the Statement of Work and other terms of this contract, the Contractor shall prepare and submit the following written reports in the manner stated below:

1. Single Trial Final Report - Within 6 weeks after the close of a vaccine candidate evaluation, the Contractor shall submit a final report of that study. Four (4) copies of the report shall be submitted to the Project Officer. This report shall include the purpose of the trial, the product tested, the protocol for the study, and a summary of data from the study.

2. Semi-annual Progress Reports - By the fifteenth working day of the month following the end of each quarter, the Contractor shall submit five (5) copies of a quarterly progress report, comprising four (4) copies to the Project Officer and one (1) copy to the Contracting Officer, which consists of the following:

   (a) A title page containing:

   1) Contract number and title

   2) Sequence of report, e.g.- "Year 1, Second Quarterly Report"

   3) Period of performance being reported

   4) Contractor's name and address

   5) Date of submission

   (b) Reports shall include, but are not limited to the following information:

   1) Section A - An introduction covering the purpose and scope of the contract effort, and listing the studies covered in the report.

   2) Section B – This section should be divided into separate reports for each study conducted under the contract. **The report for each study should be a continuous, running report,** starting with the title of the study, names of collaborators, the protocol outline and a description of the study. This shall be followed by the status of the study at each prior reporting period, with an update for the current period. The report shall include information about any immunization or virus challenge, or other treatment that the animals received during the current reporting period, including the date and study week of the treatment. The report shall include the dates of sample collection and list of the assays to be conducted on these samples. If the assays are conducted by the SVEU, the report shall include pertinent data and/or graphs in sufficient detail to follow the progress of individual animals through the phases of a vaccine experiment. If the assays are conducted by the Primate Immunology Laboratory or by another investigator, this shall be indicated, including the dates samples were shipped to the other laboratory, and data that was sent back to the SVEU. The report shall include an overview of information about the health status of the animals, especially CD4 status and virus load status after challenge, and shall report any deaths of animals and the causes of death. The report shall include any other relevant information about the study, including decisions that were reached about future plans for the study.

3) Section C – This section shall list the number of animals in each study and the total number of animals on the contract as of the end of each reporting period.

4) Section D – This section shall include a description of any technical or performance problems encountered and corrective actions planned or taken. An explanation of any differences between planned and actual progress shall be included.

5) A semi-annual report will not be required when an annual report is due.

3. Annual Report - On or before the last day of the Contract year, the Contractor shall submit five (5) copies of an annual report. Four (4) copies shall be submitted to the Project Officer and one (1) copy shall be submitted to the Contracting Officer. The annual report shall summarize progress for the entire Contract year, using the same format described for Quarterly Progress Reports.

4. Final Contract Report - The Contractor shall submit five (5) copies of the final report; four (4) copies shall be submitted to the Project Officer and one (1) copy shall be submitted to the Contracting Officer. The final report shall summarize the results of the entire contract work for the period of performance covered, using the format described above for the Quarterly Progress Reports. This report shall be in sufficient detail to explain comprehensively the results achieved, and shall be submitted on completion date of the Contract.

The final report shall contain:

a. Title Page as described above in paragraph a.2.a.

b. Introduction covering the purpose and scope of the contract effort.

c. Description of the overall progress, plus a separate description of each task on which effort was expended during the period of performance. Descriptions will include pertinent data to present significant results achieved and a scientific evaluation of the data accrued under the contract.

5. If the Contractor becomes unable to deliver the specified reports within the period of performance because of unforeseen difficulties, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer immediate written notice of anticipated delays with reasons therefore.

B. Technical Report Distribution

Copies of the technical reports shall be submitted as follows:

Type of Report	No. of Copies	Addressee	Due Dates
Single Trial	4	Project Officer PRDB, VPRP, DAIDS NIAID 6700-B Rockledge Drive Bethesda. MD 20897-7628	
Semi-annual	4	Project Officer PRDB, VPRP, DAIDS NIAID 6700-B Rockledge Drive Bethesda. MD 20897-7628	
Semi-annual	1	Contracting Officer CMB, NIAID 6700-B Rockledge Drive	

		Bethesda. MD 20892-7612	
Annual	4	Same as P.O. above	
Annual	1	Same as C.O. above	
Final	4	Same as P.O. above	
Final	1	Same as C.O. above	

ATTACHMENT C

RFP-NIH-NIAID-DAIDS-01-04
February 23, 2000

EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: technical, cost/price and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, cost/price and SDB participation are also important to the overall contract award decision. Technical factors are significantly more important than cost/price or other factors when combined. However, cost/price and SDB participation may become a critical factor in source selection in the event that two or more offerors are determined to be essentially equal following the evaluation of all technical evaluation factors.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. Proposals will be judged solely on the written material provided by the offeror. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

CRITERIA (POINTS)

A. PERSONNEL: **(50 points)**

Documented experience, expertise, and availability of scientific, technical, and veterinary staff, with emphasis on the experience and expertise of the proposed staff in the conduct of SIV and/or HIV vaccine studies in non-human primate models, and experience in handling SIV-infected, SHIV-infected, or HIV-infected non-human primates.

1) Experience and expertise of the Principal Investigator in the conduct and management/direction of SIV or HIV vaccine studies, particularly in the management of multiple simultaneous studies. **15 points**

2) Experience, expertise, and availability of veterinary, animal tech, and animal care staff. **10 points**

3) Experience, expertise, and availability of scientific and technical laboratory staff proposed to conduct immunological, virological, and other laboratory tasks outlined in the Statement of Work. **15 points**

4) Experience and availability of a study coordinator who will be responsible for day-to-day management of the components of the protocol, receipt and shipping and storage of samples related to the studies conducted under this contract, and reporting of the status of studies to the Project Officer on an ongoing basis. **10 points**

B. TECHNICAL APPROACH/METHODOLOGY: **(30 points)**

Appropriateness and thoroughness of description of proposed methodology and technical approach to be used to conduct the elements of the Statement of Work:

1) Proposed procedures for animal husbandry, immunization, blood sample collection, virus inoculation, and other tasks related to conducting studies using non-human primates, as outlined in the Statement of Work. Description of procedures and precautions used in dealing with virus-infected animals. **10 points**

2) Proposed methodology, including biocontainment precautions, to be used to process samples and to conduct immunological assays to assess the animals' responses to immunization and infection. **10 points**

3) Proposed methodology, including biocontainment precautions, to be used to process samples from virus-inoculated animals and to conduct virus isolation and other assays for virus detection or quantitation. **10 points**

C. RESOURCES AND FACILITIES: **(20 points)**

1) Documented availability to this contract of appropriate biocontainment facilities for housing and conducting studies with SIV-infected, SHIV-infected, or HIV-infected non-human primates; documented availability to this contract of appropriate biosafety laboratory facilities for handling virus as well as blood and other tissues from virus-infected animals, for conducting immunological assays, for culturing and handling virus, and for conducting virological assays. **10 points**

2) Documented availability of access to non-human primates for the studies to be conducted under this contract. **10 points**

TOTAL POINTS: 100

3. EVALUATION OF TARGETS FOR EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the Offeror's SDB Participation targets will be highly influential in determining the relative merits of the Offeror's proposal and in selecting the Offeror whose proposal is considered to offer the best value to the Government.

The extent of the Offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. The evaluation will be based on information provided by the offeror in their technical proposal. Evaluation of SDB participation will be a subjective assessment based on consideration of all relevant facts and circumstances. The Government is seeking to determine whether the Offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform as the prime contractor.

Offers will be evaluated on the following sub-factors:

1) The extent of an Offeror's commitment to use SDB concerns.

2) The complexity and variety of the work SDB concerns are to perform. Greater emphasis will be given for arrangements where the SDB shall be performing work appropriate to the scientific objectives expressed in the statement of work.

3) Fairness, reasonableness, and realism of costs proposed by SDBs for the work they will perform.

ATTACHMENT D

RFP-NIH-NIAID-DAIDS-01-04
February 23, 2000

SPECIFIC RFP INSTRUCTIONS AND PROVISIONS

NOTICE TO OFFERORS: This attachment contains proposal instructions and information that are specifically related to this acquisition. The information provided below is only a portion of the instructions and notices required for the submission of a proposal. References to additional, more general information, and forms regarding proposal preparation are contained in Attachment E, "*APPLICABLE RFP REFERENCES*". *If there is any conflict between the instructions given in this Attachment D and any of the "Applicable RFP References" in Attachment E, the instructions contained in this Attachment D take precedence.*

1. NUMBER AND TYPE OF AWARD(S)

It is anticipated that up to seven (7) awards will be made from this solicitation and that the awards will be made on/about January 5, 2001.

It is anticipated that awards from this solicitation will be cost reimbursement completion type contracts with a 5-year performance period, and that incremental funding will be used.

2. ESTIMATE OF EFFORT

It is estimated by the Government that the total labor effort may fall within the ranges listed below. However, this information is furnished for the Offerors information only and is not to be considered restrictive for proposal purposes.

Labor Category	Annual Estimated Effort	5-Year Total
Principal Investigator	10%	50%
Other Professional	105%	525%
Laboratory Technicians	300%	1,500%
Animal Caretakers	300%	1,500%
Total	715%	3,575%

3. SIC CODE AND SIZE STANDARD

Note: The following information is to be used by the Offeror in preparing its Representations and Certifications, specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATIONS (FEB 1998), FAR 52.219-1:

a. The standard industrial classification (SIC) code for this acquisition is 8731.

b. (1) The small business size standard is 500 employees.

c. This requirement is NOT Set-Aside for Small Business. However, the Federal Acquisition Regulation (FAR) requires in every solicitation (except for foreign acquisitions) the inclusion of the Standard Industrial Classification (SIC) Code and corresponding size standard that best describes the nature of the requirement in the solicitation.

4. Targets for Extent of Small Disadvantaged Business Participation

In accordance with FAR part 15.304(c)4, the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized SIC Major Groups shall be evaluated in unrestricted acquisitions expected to exceed a total estimated cost of $500,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.201 and 19.1202). The factor entitled "Evaluation of Targets for Extent of Small Disadvantaged Business Participation" in the Technical Evaluation Criteria shall be used for this purpose and will be evaluated by Government staff prior to determination of the competitive range. SDBs will not be evaluated under this factor unless the SDB concern waives the Price Evaluation Adjustment (PEA) at Subpart 19.11. **Waiver of the price evaluation adjustment shall be clearly stated in the proposal.** If the SDB so waives the PEA, it shall be evaluated under this factor, and participation in performance of the contract shall include the work expected to be performed by SDB concerns at the prime contract level. **Any targets will be incorporated into and become part of any resulting contract.**

Offerors shall seek out and include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized SIC Major Groups, and a total target for SDB participation by the contractor. This can include joint ventures, teaming arrangements, subcontracts and participation in performance of the contract expected to be performed by SDB concerns at the prime contract level. **This information shall be provided in one clearly marked section of the technical proposal which shall describe the extent of participation of SDB concerns in the performance of the contract.** Offerors must include information that addresses the evaluation factor entitled "Evaluation of Targets for Extent of Small Disadvantaged Business Participation" in the Technical Evaluation Criteria.

SDB Participation information will be used as an evaluation factor against which offerors' relative rankings will be compared to assure the best value to the Government.

If the offeror does not include targets for SDB participation, a specific rationale for this exclusion must be provided. The rationale will be evaluated for its appropriateness during the technical evaluation by the government.

5. SERVICE OF PROTEST (AUG 1996) - FAR 52.233-2

a. Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Hand-Carried Address:	Mailing address (U.S.) Postal Service
Brenda J. Velez Chief, Contract Management Branch DEA, NIAID, NIH Room 2230, 6700-B Rockledge Drive Bethesda, MD 20817-7612	Brenda J. Velez Chief, Contract Management Branch DEA, NIAID, NIH Room 2230, MSC 7612 6700-B Rockledge Drive Bethesda, MD 20892-7612

NOTE: All material sent to this office by Federal Express should be sent to the Hand Carried Address.

b. The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

6. GOVERNMENT NOTICE FOR HANDLING PROPOSALS

AN OFFEROR SHALL PLACE THIS NOTICE ON TOP OF EACH COPY OF ITS TECHNICAL PROPOSAL.

> "This proposal shall be used and disclosed for evaluation purposes only, and a copy of this Government notice shall be applied to any reproduction or abstract thereof. Any authorized restrictive notices that the submitter places on this proposal shall also be strictly complied with. Disclosure of this proposal outside the Government for evaluation purposes shall be made only to the extent authorized by, and in accordance with, the procedures in HHSAR paragraph 315.608-72."

(For information regarding authorized restrictive notices, offerors should refer to the "Confidentiality of Proposals" section, Item F.6, of the STANDARD RFP INSTRUCTIONS AND PROVISIONS, General Instructions.)

7 SAFETY AND HEALTH DEVIATION PHS 352.223-70 (AUG 1997)

(a) To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State, and local laws and regulations applicable to the work being performed under the contract. These laws are implemented and/or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration, and other agencies at the Federal, State, and local levels (Federal, State and local regulatory/enforcement agencies.)

(b) Further, the Contractor shall take or cause to be taken such additional safety measures as the Contracting Officer, in conjunction with the project or other appropriate officers, determines to be reasonably necessary. If compliance with such additional safety measures results in an increase or decrease in the cost or time required of performance of any part of work under this contract, an equitable adjustment will be made in accordance with the applicable "Changes" Clause as set forth in the contract.

(c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; and/or damage to property incidental to work performed under the contact and all violations for which the Contractor has been cited by any Federal, State, or local regulatory/enforcement agency. The report shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State, or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

(d) If the Contractor fails or refuses to comply promptly with the Federal, State, or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State, or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any such stop work order shall be subject to a claim for extension of time or costs or damages by the Contractor.

(e) The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or hazardous operations. Compliance with the provisions of this clause by subcontractors will be the responsibility of the Contractor.

8. PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DAIDS-01-04

RFP Title: *"Simian Vaccine Evaluation Units"*

Please review the attached Request for Proposals. Furnish the information requested below and return this page by **April 3, 2000**. Your expression of intent is not binding; however, the information requested below is required by the NIAID in order to coordinate the electronic submission of proposals and will greatly assist us in planning for proposal evaluation.

[ ] DO INTEND TO SUBMIT A PROPOSAL

[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

Company/Institution Name (print): _____

Address (print): _____
_____
_____
_____

Project Director's Name (print): _____

Title (print): _____

Signature/Date: _____

Telephone Number and E-mail Address (print clearly):
_____
_____

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):

_____
_____
_____
_____

(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:

CMB, NIAID, NIH
Room 2230
6700 Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: Grace Bruce
RFP-NIH-NIAID-DAIDS-01-05
FAX# (301) 480-5253

Email: gb15w@nih.gov

ATTACHMENT E

APPLICABLE RFP REFERENCES

This section identifies the items found in the RFP Web directory entitled RFP REFERENCES that are applicable to this RFP.

1. The entire file entitled "STANDARD RFP INSTRUCTIONS AND PROVISIONS" is applicable to this RFP, except as otherwise may be modified by the inclusion of an item from the "OPTIONAL RFP INSTRUCTIONS AND PROVISIONS".

2. The following items are applicable from the file entitled "OPTIONAL RFP INSTRUCTIONS AND PROVISIONS:"

    - LATE PROPOSALS, MODIFICATIONS OF PROPOSAL, AND WITHDRAWALS OF PROPOSALS, PHS 352.215-10

    - SMALL, SMALL DISADVANTAGED AND WOMEN OWNED SMALL BUSINESS SUBCONTRACTING PLAN (does not apply to small business or to work performed in foreign countries) *Note: A subcontracting Plan is not due with the initial proposal. The Contracting Officer will notify offerors if a Plan becomes due.*

3. The following items/files are applicable from the subdirectory entitled "FORMS, FORMATS, AND ATTACHMENTS":

Applicable to Technical Proposal

- Technical Proposal Cover Sheet
- Technical Proposal Cost Information
- Summary of Current and Proposed Activities

Applicable to Business Proposal

- Proposal Summary and Data Record, NIH-2043
- Business Proposal Cost Information
- Disclosure of Lobbying Activities, OMB Form SF-LLL
- Excel cost spreadsheet (Template provided)

To Become Contract Attachments

- Invoice/Financing Requests Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1, May 1997
- Procurement of Certain Equipment, NIH(RC)-7 (OMB Bulletin 81-16), Apr. 1984
- Form NIH 2706 (Financial Report) and Instructions for Completing Form NIH 2706 *Note: Financial reports are not always required. This will be discussed during negotiations.*

Other-to be submitted as directed by Contracting Officer

- Certificate of Current Cost or Pricing Data, NIH-1397

- Small, Small Disadvantaged, HUBZone and Women-Owned Small Business Model Subcontracting Plan Outline

4. The "Representations and Certifications" are applicable.

5. The "Sample Contract Format-General" is applicable.

ATTACHMENT F

RFP-NIH-NIAID-DAIDS-01-04
February 23, 2000

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

1. ELECTRONIC SUBMISSION INSTRUCTIONS

GENERAL --- To submit a proposal electronically under this RFP, Offerors will need to prepare the proposal on a word processor or spreadsheet program (for the cost portions) and convert them to Adobe Acrobat Portable Document Format (PDF). THE TECHNICAL PROPOSAL AND BUSINESS PROPOSAL MUST BE CONTAINED ON SEPARATE FILES. Further, to expedite the file transferring process, the two files must be named using the following DOS naming convention:

- Technical Proposal: c:\rfp____\techprop.pdf
- Business Proposal: c:\rfp____\busiprop.pdf

If your organization does not have the capability to submit electronically, or unforeseen difficulties occur during transmission, you may submit the electronic copy of your proposal with the original proposal on a diskette, CD-Rom or ZipDisk, in lieu of the internet. The Contract Specialist/Contracting Officer must be notified in advance of using these optional methods.

OFFERORS SHALL INCLUDE THE FOLLOWING STATEMENT IN THEIR BUSINESS PROPOSAL:

I HEREBY CERTIFY THAT ALL ELECTRONIC AND PAPER COPIES OF PROPOSALS SUBMITTED IN RESPONSE TO RFP NO. NIH-NIAID-DAIDS-01-04 ARE IDENTICAL.

Approximately TWO weeks prior to the due date of proposals, all offerors will be provided with specific electronic access information and electronic proposal transmission instructions. For this reason, it is imperative that all offerors who are intending to submit a proposal in response to this RFP contact the Contracting Officer identified in this RFP and **complete and submit the attached Proposal Intent Form by April 3, 2000**.

NOTE: There is no limit to the size (MB) of the two electronic PDF files to be submitted. Technical proposals will be viewed using the print function of the Adobe Acrobat Reader, Version 3.0.

ADDITIONAL SUGGESTIONS --- Do not embed sound or video (e.g., MPEG) files into the proposal documents. The evaluation system will not incorporate a capability to read these files. Graphics which are embedded into documents should be kept as simple as possible. Complex graphics require longer periods for the computers used in the evaluation system to draw, and redraw these figures and scrolling through the document is slowed significantly. Suggestions include:

- Limit colors to 256 colors at 1024 x 768 resolution; avoid color gradients.
- Simplify the color palette used in creating figures.
- Be aware of how large these graphics files become. Large files are discouraged.
- Limit scanned images as much as possible.

There are no page limits for this RFP. However, Offerors are encouraged to limit the overall size of the

Technical Proposal, inclusive of appendices, attachments, etc. Note that although no page limits have been placed on the Business Proposal, Offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.

Type density and size must be 10 to 12 points. If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be set to 1 inch around.

Technical Proposal and Business Proposal preparation instructions along with proposal table of contents are detailed below.

2. TECHNICAL PROPOSAL INSTRUCTIONS

a. **GENERAL** ---In addition to the paper copies required under paragraph 4. below, one copy of the technical proposal, except as noted below in the "Technical Proposal Table of Contents", is to be submitted electronically. The STANDARD RFP INSTRUCTIONS AND PROVISIONS provide more detail on the TECHNICAL PROPOSAL requirements.

b. **TECHNICAL PROPOSAL TABLE OF CONTENTS/FORMAT**

(NOTE: Instructions to offerors are indicated in parentheses or as footnotes.)

1) TECHNICAL PROPOSAL COVER SHEET ..... Page 1

2) TECHNICAL PROPOSAL TABLE OF CONTENTS ..... Page 2

3) SUMMARY OF OBJECTIVES AND METHODS (Abstract)*... Page 3

4) TECHNICAL PLAN (Refer to Technical Proposal Instructions located in the Standard RFP Instructions and Provisions.)

STATEMENT OF WORK

a) Objectives ..... Page 4
b) Approach ..... _____
c) Methods ..... _____
d) Schedule ..... _____

PERSONNEL (List by name, title, department and organization, and detail each person's qualifications and role in the Project.)

Provide narrative for:

e) Principal Investigator/Project Director
f) Other Investigators
g) Additional Personnel, (e.g., technical support, subcontractors,consultants)

(Note: For key personnel, include 2 page biosketch/resume and the form entitled "Summary of Current and Proposed Activities.") -- Page ____

5) FACILITIES/RESOURCES AND DIRECT COSTS (List/describe all equipment, facilities and other resources available for this project; attach "Technical Proposal Cost Information" form, and marked laboratory/clinical space floor plan in Item 6.)-- Page ____

6) OTHER CONSIDERATIONS (Provide brief narrative of any unique arrangements, safety procedures in place, animal welfare issues, human subject and minority and gender issues, etc.)-- Page ____

7) HUMAN SUBJECTS, PARTICIPATION OF CHILDREN AND MINORITY AND GENDER ISSUES NOT OTHERWISE ADDRESSED (IF APPLICABLE) -- Page ____

8) VERTEBRATE ANIMALS (IF APPLICABLE) – Page _____.

9) "TECHNICAL PROPOSAL COST INFORMATION" summary spreadsheet -- Page ____

10) LITERATURE CITED -- Page ____

11) APPENDICES** (Protocols, policy manuals, etc. for above Technical Plan; list each Appendix; Appendices must be clear and legible, and easily located.)

** State the proposal's broad, long-term objectives and specific aims. Describe concisely the research design and methods for achieving these goals. DO NOT EXCEED ONE PAGE in providing the abstract. Identify the RFP number, institution, and Principal Investigator on the abstract.*

*** HARDCOPY SUBMISSION OF APPENDICES: The following items are excluded from our electronic submission requirement and will not be subject to page limitations. Offerors may provide appendices electronically or may instead submit ten (10) paper copies of the information.*

- *Complete SOPs; any other pertinent policy manuals; any letters of collaboration from other investigators; non-scannable figures or data.*

3. BUSINESS PROPOSAL INSTRUCTIONS

a. **GENERAL** --- In addition to the paper copies required in paragraph 4. below, one copy of the business proposal is to be submitted electronically. There are no page limits with the business proposal. The STANDARD RFP INSTRUCTIONS AND PROVISIONS provide more detail on the BUSINESS PROPOSAL requirements.

Following proposal submission and review, additional information will be requested by the Contracting Officer from all offerors that comprise the competitive range. The format of your BUSINESS PROPOSAL is detailed in the "Business Proposal Table of Contents", below.

With the Business Proposal, please submit Form NIH-2043, "Proposal Summary and Data Record." Note that in addition to telephone and fax numbers, the INTERNET addresses of both the Principal Investigator and the responsible business representative are to be included on the form.

b. **ESCALATION**. Due to the National Institute of Allergy and Infectious Diseases' current budget restrictions, it is recommended that any proposed annual increase in costs for inflation be limited to no more than 3% of total costs per year. Final inflation increases will be subject to the negotiation process taking into consideration the most current consumer price index (cpi).

c. BUSINESS PROPOSAL TABLE OF CONTENTS

Please use the following format to organize and present your Business Proposal:

SECTIONS/FORMAT

1. Proposal Summary and Data Record, NIH-2043

2. Business Proposal Cost Information and cost spreadsheets which include an itemized cost element breakdown, for each year of the contract. Cost elements on these spreadsheets include (as applicable): Direct Labor, Fringe Benefits, Materials, Subcontracts, Travel, Equipment, ODC, Raw Materials, Purchased Parts, Indirect Costs, Fee.

[Note: We have included a template cost spreadsheet in Microsoft Excel. Offerors are requested

to complete this spreadsheet and include it with their business proposal. This spreadsheet can replace the cost sheets that you ordinarily provide. It is our hope that this spreadsheet will provide you with a useful tool, allow us to more easily understand your cost proposal, and eliminate our need to recreate your spreadsheets. This spreadsheet template is a new approach, and we would appreciate any feedback you could give us about it.]

3. Business Plan - the business plan has the following components:

    - A narrative of the BASIS of costs proposed; do not provide documentation with initial proposal
    - Qualification of the Offeror - This includes: General Experience, Organizational Experience Related to the RFP, Performance History, Pertinent Contracts and Grants
    - Property, Equipment, Facilities to be dedicated to this work
    - Royalties, Financial Capacity, Subcontractors

4. Representations and Certifications

5. Other Forms/Information:

    - Disclosure of Lobbying Activities, OMB Form SF-LLL

4. PACKAGING AND DELIVERY OF THE PROPOSAL

[Note to Offeror: Listed below are delivery instructions for the submission of the PAPER copies of your proposal. Instructions for your electronic submission are described above in Electronic Submission Instructions.]

Shipment and marking shall be as indicated below:

A. EXTERNAL PACKAGE MARKING:

In addition to the address cited below, mark each package as follows:

"RFP NO. NIH-NIAID-DAIDS-01-04
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. NUMBER OF COPIES:

The number of copies required of each part of your proposal are as specified below.

Technical Proposal: One (1) unbound signed original and 25 copies.

Business Proposal: One (1) unbound signed original and 5 copies.

C. PAPER COPIES TO:

If hand delivered or delivery service:

Grace Bruce
Contract Management Branch
NIAID, NIH
Room 2230
6700-B Rockledge Drive
Bethesda, Maryland 20817

If using U.S. Postal Service:

Grace Bruce
Contract Management Branch
NIAID, NIH
Room 2230
6700-B Rockledge Drive, MSC 7612
Bethesda, Maryland 20892-7612

NOTE: All material sent to this office by a delivery service should be sent to the Hand Carried Address.

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with PHSAR 352.215-10, Late Proposals, Modifications of Proposals and Withdrawals of Proposals (NOV 1986).

Top | RFP References

NIH RFP Directory | NIAID/CMB Home | NIH Home

NIH Request for Proposals (RFP) Directory

STREAMLINED RFP REFERENCES
OPTIONAL RFP INSTRUCTIONS AND PROVISIONS

Updated through FAC 97-14
Last updated on 10/15/99

If any items contained in this section are applicable to a specific RFP, they will be identified in the "Applicable RFP REFERENCES" section of that RFP.

A. NOTICE: THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS

However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the Standard Industrial Classification (SIC) Code and corresponding size standard which best describes the nature of the requirement in the solicitation. The SIC Code and corresponding size standard will be set forth in the specific RFP.

B. NOTICE OF SMALL BUSINESS SET-ASIDE

1. General. Bids or proposals under this procurement are solicited only from small business concerns. The procurement is to be awarded only to one or more such concerns, organizations, or individuals. This action is based on a determination by the Contracting Officer, alone or in conjunction with a representative of the Small Business Administration, that it is in the interest of maintaining or mobilizing the Nation's full productive capacity, or in the interest of war or national defense programs, or in the interest of assuring that a fair proportion of Government procurement is placed with small business concerns. Bids or proposals received from others will be considered non-responsive.

2. Definitions. The term "small business concern" means a concern, including its affiliates, which is independently owned and operated, is not dominant in the field of operation in which it is bidding on Government contracts, and can further qualify under the criteria set forth in the regulations of the Small Business Administration (13 CFR 121.3-8). In addition to meeting these criteria, a manufacturer or a regular dealer submitting bids or proposals in his own name must agree to furnish in the performance of the contract end items manufactured or produced in the United States, its territories and possessions, Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the District of Columbia, by small business concerns. Provided, that this additional requirement does not apply in connection with construction or service contracts.

C. NOTICE OF 8(a) COMPETITIVE SET-ASIDE

Offers are solicited only from small business concerns expressly certified by the Small Business Administration (SBA) for participation in the SBA's 8(a) Program. Bids or proposals received from others will be considered non-responsive.

D. CONCEPT REVIEW

This project has not been given concept review. Such review will occur prior to technical evaluation. Thus potential offerors are cautioned that cancellation of this RFP due to disapproval by the Board of Scientific Counselors/IC Advisory Council, or equivalent, is a possibility.

E. LATE PROPOSALS, MODIFICATIONS OF PROPOSAL, AND WITHDRAWALS OF PROPOSALS, PHS 352.215-10

Notwithstanding the procedures contained in the provision of this solicitation entitled Late Submissions, Modifications, and Withdrawals of Proposals, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government, and it was received before proposals were distributed for evaluation, or within five working days after the exact time specified for receipt, whichever is earlier.

F. HUMAN SUBJECTS

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (SEPTEMBER 1985)

1. Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Protection from Research Risks (OPRR), National Institutes of Health, Bethesda, Maryland 20892. The

regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

2. The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information. The regulations extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR, Part 46.

3. Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.

4. Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The Public Health Service will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consultation with OPRR, (telephone: 301-496-7041), is recommended.

5. In accordance with 45 CFR, Part 46, prospective Contractors being considered for award shall be required to file with OPRR an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. Prospective Contractors proposing research that involves human subjects shall be contacted by OPRR and given detailed instructions for establishing an institutional review board and filing an Assurance of Compliance.

6. It is recommended that OPRR be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

G. CARE OF LIVE VERTEBRATE ANIMALS

Notice to Offerors of requirement for adequate assurance of protection of vertebrate animal subjects - (SEPTEMBER 1985)

The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals by Awardee Institutions establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH), PHS, a written Animal

Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No PHS award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OPRR. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OPRR negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OPRR may be contacted at 6100 Executive Boulevard, Suite 3B01, MSC 7507, Rockville, Maryland 20892-7507 (301-496-7163, ext. 234). Copies of the PHS Policy are available on the Internet at http://www.nih.gov:80/grants/oprr.htm.

H. SMALL BUSINESS SUBCONTRACTING PLAN

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan ," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation.

1. THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

2. The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

3. The offeror understands that:

a. No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

b. An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for small business concerns and small business concerns owned and controlled by socially and economically disadvantaged persons to participate in the performance of the contract.

c. If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

d. Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

e. It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to

small business concerns, small business concerns owned and controlled by socially and economically disadvantaged individuals, and women-owned small business concerns and that each such aspect of the offeror's plan will be judged independent of the other.

f. The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

4. Each plan must contain the following:

a. Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, small disadvantaged, and women-owned small business concerns as subcontractors.

b. A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, and Women-Owned Small Businesses.

c. A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to small, small disadvantaged, and/or women-owned small business concerns.

d. A description of the method used to develop the subcontracting goals.

e. A description of the method used to identify potential sources for solicitation purposes.

f. A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with small, small disadvantaged and women-owned small business concerns.

g. The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

h. A description of the efforts the offeror will make to assure that small, small disadvantaged and women-owned small business concerns have an equitable chance to compete for subcontracts.

i. Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns" Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.

j. Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

k. List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate small, small disadvantaged, and women-owned small business concerns and award subcontracts to them.

For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9 (JAN 1999), Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is included in the FORMS, FORMATS AND ATTACHMENTS.

I. ALTERNATE II (JAN 1999) of FAR Clause 52.219-9, Small Business Subcontracting Plan (OCT

1999) applies to this RFP.

J. INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations) which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research" which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513), [(this was reprinted to correct typesetting errors from Federal Register dated March 9, 1994 (FR 59 11146-11151)], and reprinted in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11. A copy of this document is available in the FORMS, FORMATS AND ATTACHMENTS directory. Unless otherwise specified in the specific RFP,the Government has determined that the work set forth herein does not involve a gender specific study or a single or limited number of minority population groups. Therefore, the Government believes that the inclusion of women and minority populations is appropriate for this project. (See the Technical Evaluation Criteria of the specific RFP for more information about evaluation factors for award.) The format for the Annual Technical Progress Report also found in the FORMS directory shall be used in proposal preparation.

K. TOTAL COMPENSATION PLAN - INSTRUCTIONS

1. Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. As a part of their business proposals, offerors will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

2. The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).

3. Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

L. TOTAL COMPENSATION PLAN - EVALUATION

1. Total Compensation Plan (Professional Employees)

   In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.
2. Cost (Professional Compensation)

   Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.
3. Other (Labor Relations)

   An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.
4. Federal Acquisition Regulation Clauses incorporated by Reference 52.222-46, Evaluation of Compensation for Professional Employees (February 1993)

M. PAST PERFORMANCE INFORMATION

1. Offerors shall submit the following information as part of their business proposals (for both the offeror and proposed major subcontractors): A list of the contracts completed during the past three years and all contracts currently in progress for products or services similar to the solicitation workscope. Contracts listed may include those entered into with the Federal

Government, agencies of state and local governments and commercial customers. Offerors that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel. Include the following information for each contract or subcontract:

a. Name of Contracting Organization
b. Contract Number (for subcontracts, provide the prime contract number and subcontract number)
c. Contract Type
d. Total Contract Value
e. Description of Requirement
f. Contracting Officer's Name and Telephone Number
g. Project Officer's Name and Telephone Number

2. Each offeror will be evaluated on their performance under existing and prior contracts for similar products or services. Performance information will be used for both responsibility determinations and as an evaluation factor against which offerors' relative rankings will be compared to assure the greatest value to the Government. The Government will focus on information that demonstrates quality of performance relative to the size and complexity of the acquisition under consideration. The Government is not required to contact all references provided by the offeror, References other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of an offeror's past performance.

N. FAR 32.215-16, FACILITIES CAPITAL COST OF MONEY (October 1997)

(This is applicable if you are a commercial organization.)

a. Facilities capital cost of money [see FAR 15.408(h)] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulations are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

b. If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

___ The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

___ The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

O. "JUST IN TIME"

This RFP contains special procedures for the submission of business management proposals. These special procedures are designed to reduce the administrative burden on offerors without compromising the information needed during the initial evaluation of proposals. Certain documents will not be required to be submitted with initial proposals, but will be requested at a later stage in the competitive process. Specifically, the travel policy, the annual financial statement, the total compensation plan, the subcontracting plan, and certain types of cost/pricing information will only be required to be submitted from those offerors included in the competitive range, or the apparent successful offeror. The special procedures for submission of this documentation are set forth in detail below. Applicable items, if any, are identified in the appropriate section of each specific RFP.

Travel Policy. The offeror's (and any proposed subcontractor's) written travel policy shall not be submitted with the initial business proposal. All offerors included in the competitive range will be required to submit a travel policy as a part of their best and final offer.

Annual Report. The offeror's most recent annual report shall not be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a copy of their most recent annual report as a part of their best and final offer.

Total Compensation Plan. The offeror's total compensation plan shall not be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a total compensation plan as a part of their best and final offer.

Subcontracting Plan. The offeror's Small, Small Disadvantaged, and Women-Owned Small Business Subcontracting Plan shall not be submitted with the initial business proposal. Only those offerors included in the competitive range will be required to submit an acceptable subcontracting plan.

OR

Subcontracting Plan. The offeror's Small, Small Disadvantaged, and Women-Owned Small Business Subcontracting Plan shall not be submitted with the initial business proposal. Only the apparent successful offeror will be required to submit an acceptable subcontracting plan.

Cost/Pricing Information. The offeror's business proposal shall include the basic cost/pricing information specified in this RFP. In addition, the Government may require offerors included in the competitive range to submit additional information substantiating their proposed costs or prices. This additional cost/pricing information will be requested after establishment of the competitive range, and potentially includes payroll documentation, vendor quotes, invoice prices, and/or any other information deemed necessary by the Contracting Officer to evaluate the reasonableness of the price or to determine cost realism. The information may also include submission and certification of cost or pricing data.

P. ALTERNATE II (OCTOBER 1997) of FAR Clause 52.215-1, Instructions to Offerors--Competitive Acquisition (OCTOBER 1997) applies to this RFP.

As perscribed in 15.209(a)(2), the following paragraph, (c)(9), is added to the basic FAR Clause

52.215-1:

(C)(9) Offerors may submit proposals that depart from stated requirements. Such proposals shall clearly identify why the acceptance of the proposal would be advantageous to the Government. Any deviations from the terms and conditions of the solicitation, as well as the comparative advantage to the Government, shall be clearly identified and explicitly defined. The Government reserves the right to amend the solicitation to allow all offerors an opportunity to submit revised proposals based on the revised requirements.

Q. IT SYSTEMS SECURITY

If this project involves IT, the proposal must present a detailed outline of its proposed IT systems security program which complies with the requirements of the Statement of Work, the Computer Security Act of 1987 Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems," and the DHHS Automated Information Systems Security Program Handbook (Release 2.0, dated May, 1994). The proposal will also need to include similar information for any subcontract proposed.

NOTE: OMB A-130 is accessible via web site:
http://www.whitehouse.gov/WH/EOP/OMB/html/circular.html

R. INCLUSION OF CHILDREN IN RESEARCH INVOLVING HUMAN SUBJECTS

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are scientific or ethical reasons not to include them. For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 21 years.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempt from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. In the technical proposal, the offeror should create a section titled "Participation of Children." This section should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. The RFP will contain a review criterion addressing the adequacy of plans for including children as appropriate for the scientific goals of the research, or justification of exclusion.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998 and is available at the following URL address:

http://www.nih.gov/grants/guide/notice-files/not98-024.html

Offerors may also obtain copies from the contact person listed in the RFP.

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