RFP NIH-NIAID-DAIDS-01-06

"HIV Vaccine Production, Preclinical Testing, FDA Submissions"

Request for Proposal No.:	NIH-NIAID-DAIDS-01-06
OMB #:	0990-0115
Issue Date:	February 08, 2000
Point of Contract:	Lawrence M. Butler Contracting Officer, NIAID, NIH Contract Management Branch 6700-B Rockledge Drive MSC 7612, Room 2230 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 will 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 01, 2000, 4:00 P.M EST**

Ladies and Gentlemen:

You are invited to submit a proposal in accordance with the requirements of this RFP. The Government anticipates that multiple Indefinite Delivery/Indefinite Quantity contracts will be awarded and requirements for specific services will be issued through the use of task orders, which may be incrementally funded. The period for these contracts will be of a five (5) year duration.

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. The Government reserves the right to hold negotiations, if necessary.

This RFP will utilize the National Institute of Allergy and Infectious Diseases' (NIAID) Contract Review On-line (CRON) system. Offerors must submit their 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. In addition to the electronic submission, Offerors must submit one (1) unbound signed original plus five (5) additional copies (i.e. hardcopies) of both the technical and business proposals to the address listed in Attachment F. An official authorized to bind your organization must sign the hardcopy of your proposal.

Note: If applicable, provide ten (10) paper copies of any SOPs, other pertinent manuals, non-scannable figures or data, letters of collaboration/intent, etc. See Attachment F for details.

Please note and adhere to the page limitations set forth in Attachment F. The narrative portion of the Technical Proposal (which includes the Technical Plan, comprised of the technical Objectives, Approach, Methods, and Schedule) is limited to 50 pages. Pages in excess of this limitation will be deleted and will not be read or evaluated. See Attachment F for complete details on page limitations, 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 documents included with this electronic RFP package are as follows:

Attachments:

A. **BACKGROUND, INTRODUCTION AND STATEMENT OF WORK**, dated February 08, 2000
B. **REPORTING REQUIREMENTS AND DELIVERABLES**, dated February 08, 2000
C. **EVALUATION FACTORS FOR AWARD**, dated February 08, 2000
D. **SPECIFIC RFP INSTRUCTIONS AND PROVISIONS**, dated February 08, 2000
E. **APPLICABLE RFP REFERENCES**, dated February 08, 2000
F. **HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL**, dated February 08, 2000

There are five (5) other referenced documents in Attachment E. above, that must be retrieved, in whole or in part, in order to submit a proposal.

If you are unable to download any of the applicable documents, please contact Lawrence M. Butler, 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. Please 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 and review of proposals.**

IF YOU INTEND TO SUBMIT A PROPOSAL IN RESPONSE TO THIS RFP, IT IS ESSENTIAL THAT YOU SUBMIT THE PROPOSAL INTENT RESPONSE SHEET. 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.

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 Lawrence M. Butler at (301) 402-0192 or at the Internet electronic mail address lb13t@nih.gov or by fax at (301) 402-0972. Collect calls will NOT be accepted.

Sincerely,

Jacqueline C. Holden
Senior Contracting Officer
Contracts Management Branch
National Institute of Allergy and Infectious Diseases, NIH
Attachments: A - F

ATTACHMENT A

RFP NIH-NIAID-DAIDS-01-06
February 08, 2000

BACKGROUND, INTRODUCTION AND STATEMENT OF WORK

BACKGROUND

The development of a vaccine to prevent the spread of HIV infection has been identified by the NIAID as a goal of the highest priority. While advances in immunology and molecular biology continue to offer an ever expanding array of approaches to the development of new candidates, the limited capacity to move promising concepts through the development process presents a substantial barrier to the full achievement of this potential. Limited industry involvement in key areas, especially international (non-clade B) vaccines, calls for a non-traditional, more active and developmentally oriented response by NIH and NIAID to meet the public health threat of the AIDS epidemic. Resources that could rapidly and efficiently close development and production gaps would greatly enhance the capacity to respond to emerging needs identified by NIAID and its advisory groups. The HIV Vaccine Production, Preclinical Testing, and FDA Submissions Contract will support applied research that is not adequately being pursued by industry and will further develop leads derived from investigator-initiated research.

On October 15, 1998, RFP NIH-NIAID-DAIDS-99-21, entitled "HIV Vaccine Production," was issued for the purpose of obtaining vaccine production services, vaccine testing services, and FDA IND submission services. As a result of that solicitation, 14 contracts were awarded in July 1999 to Advanced BioScience Labs. (N01-AI-95366), Chiron Corporation (N01-AI-95367), Immune Response Corporation (N01-AI-95368), Progenics Pharmaceuticals (N01-AI-95369), Protein Sciences Corporation (N01-AI-95370), Therion Biologics Corporation (N01-AI-95371), University of Michigan (N01-AI-95372), VaxGen Incorporated (N01-AI-95373), Vical Incorporated (N01-AI-93574), SRI International (N01-AI-95375), Vical Incorporated (N01-AI-95376), Progenics Pharmaceuticals (N01-AI-95377), Therion Biologics Corporation (N01-AI-95378), and SRI International (N01-AI-95379). Although some good vaccine candidates can be provided through these contracts, there are a number of promising vaccine candidates still available from various companies throughout the world to which the NIAID does not have access. In order to satisfy the initial "need" and to fill this void, the NIAID is resoliciting this effort through NIH-NIAID-DAIDS-01-06. The NIAID reserves the right to resolicit an RFP for these services in future if it is determined necessary to fill the original need."

This Contract will facilitate developmental HIV vaccine research by performing tasks in three areas. Offerors may submit proposals for one or more of the Parts A-C of this solicitation.

INTRODUCTION

The objective of this Contract is to provide the NIAID a full range of developmental resources to bring an HIV vaccine concept from the laboratory to initial human testing. It is envisioned that the ability to encourage and to support the development of multiple approaches will result in a shared knowledge base from which the best vaccine prototypes will emerge.

Part A: Vaccine Production. The first area of work will require a product development team with the expertise to develop candidate vaccines, including scale-up and production of GLP/GMP lots suitable for human use, and to perform the necessary characterization tests required for release of vaccines for clinical use. In some cases, a Task Order may support work on well-developed products that need only final steps in production, formulation and/or filling. Other Task Orders may involve very early and iterative steps in the development process and require several years of effort.

Under Part A, various categories of vaccine concepts will be developed based on: (a) synthetic peptides, (b) recombinant subunits, (c) vector based vaccines, or (d) virus-like particles/replicons. Offerors may submit proposals based on scale-up and production of any one or more of these vaccine categories.

Part B: Safety and Immunogenicity Testing. The second activity area to be supported under this contract is the testing of vaccine preparations as required prior to initial clinical evaluation. This includes testing candidate products for safety and immunogenicity (both cellular and humoral) in small animals and, if appropriate, in non-human primates.

Part C: FDA Submissions. The third area to be supported by this contract is the development for specific vaccines of the Master File, Investigator's Brochure, and compilation of an Investigational New Drug (IND) Application including a vaccine trial protocol (provided by the clinical trials group) appropriate for submission to CBER, FDA for an IND.

CONTRACT TYPE:

It is anticipated that multiple awards will be made for each part of this Indefinite Quantity Solicitation. The Contract will be in effect for five (5) years. An indefinite quantity contract provides for an indefinite quantity, within stated limits, of supplies or services to be furnished during a fixed period, with deliveries or performance to be scheduled by placing orders with the contractor. Task orders will be issued to the prequalified pool of contractors for parts A, B or C based on the specific requirements of the task order.

In response to this RFP, potential Offerors may submit proposals for one or more of the three Parts described above. **Within Part A, Offerors may submit proposals for any one or more of the vaccine concept Categories**. Proposals will undergo peer review based on the evaluation criteria and awards will be made to the most qualified proposals. Each Offeror awarded a contract under a given Part or Category, will receive a guaranteed minimum dollar award over the term of the Contract. The guaranteed minimum dollar awards for Contractors will be determined by the following scale:

Contract Part	Minimum Award
Part A	$200,000
Part B	$100,000
Part C	$ 50,000

Offerors that receive awards for more than one Part will be eligible for Minimum Awards for each Part. Offerors that receive awards for one or more vaccine Categories under Part A will be eligible for a single Part A minimum award. It is anticipated that the maximum total funding under this Contract will be between $5 – 10 million per year. When a need is established for any of the products or services under this Contract, a Task Order will be submitted to one or more Contractor(s) qualified under that Part or Category. Contractor(s) will submit a detailed proposal with milestones to perform the work stated in the Task Order together with a detailed budget proposal within 35 calendar days. Resulting awards will include specifics on deliverables and reports.

STATEMENT OF WORK

WORK STATEMENT for the HIV Vaccine Production, Preclinical Testing, FDA Submissions Contract.

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract, directly or through subcontractors and/or consultants, as needed to undertake targeted research essential to translating basic research concepts into prototype vaccine products, under the direction of NIAID staff and as recommended by existing and ad hoc NIAID advisory groups.

This Statement of Work is divided into three Parts: A) Vaccine production, B) Safety and immunogenicity testing, and C) FDA submissions. Each Contractor will be responsible for one or more of the three Parts. Contractors for each Part will fully and formally cooperate with the relevant other Part A, B or C Contractors and with the Project Officer.

[GENERAL NOTE: All clinical trials involving these vaccine products will be performed under an IND held by the NIH or the vaccine sponsor and will include IRB approval and informed consent to limit liability of the manufacturer.]

[NOTE #1 TO OFFERORS: Because the Parts A,B,C of this solicitation are not highly related, single institutions may not have the expertise and facilities required to perform all requirements in the Statement of Work. Thus it is acceptable for an Offeror to submit a proposal for Part A, B or C or any combination of the three. See evaluation criteria (Attachment C). Each Part will be independently evaluated so that the Offeror will only be evaluated based on the specific Part(s) for which it applies. Lack of expertise in one Part will not affect the evaluation of other Parts.

Separate review committees will likely be involved in the review of Parts A, B and C. Therefore, responses should be packaged as separate, stand-alone entities for each Part. Offerors for Part A should have a separate section for each category, addressing the evaluation criteria and other requirements (methods, staff, experience, allocated facilities, etc.) separately for each. Each category will be evaluated (scored) individually so that a Part A Offeror will be graded and determined to be Qualified/Not Qualified for each category independently based on the quality of the proposal for each category. The submission format should allow all the information needed to evaluate each category to be dissected free of that which pertains to other categories. If a phase-up period is anticipated, this should be addressed via a timetable for each Part A category, as the time frames could be quite different. There can be core sections which are the same for all categories but which are referenced specifically under the section for each category. An overall summary section may also be included which sums up the total facilities, staff, and resources proposed in order to judge total capacity proposed.

If the Offeror wishes to include in his proposal Parts, Categories or specific tasks for which he does not have direct expertise, then Offeror may propose a subcontract in order to fulfill the requirements of activities in Parts A, B or C. The Contractor shall be directly responsible for all work performed under this contract, including work done by any subcontractor. The Offeror shall describe in the technical proposal, areas of responsibility of any subcontractor as they pertain to the Work Statement in the same detail as their own proposal.

To perform activities in Part A of this RFP, a highly qualified and experienced product development team consisting of Research Scientists and Technicians is required. The Principal Investigator will be responsible for overall management and productivity of the entire conduct of activities in Part A for a given Category. Offerors must be experienced and qualified for GLP/cGMP production.

To perform activities in Part B of this RFP, Offerors should have extensive experience in the preclinical safety and immunogenicity testing of GMP products intended for human use. Offerors must be qualified for GLP level performance.

To perform activities in Part C of this RFP, Offerors should have extensive experience in assembling and filing all documents and records necessary for successful filing of vaccine submissions to FDA.

In responding to this RFP, Offerors should describe in detail the responsibilities and level of effort of all proposed personnel who will be assigned to the contract. In addition, Offerors should describe an administrative framework showing clear lines of authority. Documentation should be provided on the qualifications, experience, education, competence, and availability of the Principal Investigator, Research, Technical and Administrative Support staff; the extent to which outside consultants shall be used as well as assurance of their availability. If a subcontractor is proposed, similar technical information should also be provided as part of the Technical Proposal. Cost details should also be provided by the subcontractor.

Technical proposals must describe specifically how the offeror will fulfill each of the items in the Statement of Work below.

The technical proposal should include:

- **qualifications, experience, and specific assignment of each proposed member of the research team (include resumes/CVs); how they will interact regarding lines of authority (provide an administrative framework in flow chart format); the decision-making authority of the Principal Investigator in relation to the rest of the organization**

- **specific levels of effort proposed for each individual (hours/percentages of time) and availability in relation to other commitments**

- **procedures for initiation of this contract's projects in a timely manner (describe how other projects in general are prioritized within their organization and the level of priority this contract will receive)**

- **all instrumentation, equipment, and laboratory space to be used to fulfill the work requirements (indicate what equipment and resources are under the control of the Principal Investigator and which are to be shared; if shared, indicate who is responsible for controlling access and how determination of priority usage is made)**

- **A production plan with time line.**

For Part A, the technical proposal should be based on the production of a vaccine as proposed in NOTE #A-1 TO OFFEROR.]

Specifically, the Contractor(s) shall:

PART A: VACCINE PRODUCTION

[NOTE #A-1 TO OFFERORS: The number and types of products to be developed under Part A cannot be specified at this time. For the purposes of responding to this RFP, the Offeror should describe in some detail its experience with the development/optimization of a specific vaccine, preferably a biologic product, regardless of the applicability of that particular product to an HIV vaccine.

The intent of this description is to demonstrate to the reviewers of the RFP the capabilities and problem solving experience of the Offeror during early developmental phases. The Offeror should demonstrate understanding of the approach and establish capacity for production and scale-up under cGMP.

Since it is not expected that any one Offerer will have the capacity to produce every category of vaccine, the Offeror may submit a proposal for any one or more of the vaccine categories in Part A. Each Offeror will be evaluated based on the specific category(s) of vaccine for which they apply. Therefore, the Offeror is requested to propose a detailed plan for producing a pilot lot through the final form to be delivered for clinical trials of any one or more of the following four vaccine Categories.

Submit a plan for each vaccine Category for which you are applying. If Offeror does not have a specific vaccine to propose in one of these Categories, then use the examples below to construct your plan and proposed budget.

a) Synthetic peptide vaccine – 1000 doses of a linear 15-mer, conjugated to tetanus toxoid to be formulated with alum adjuvant, at 200 μg of peptide/dose. Assume that the peptide sequence is established and presents no particular problems in yield, or to subsequent purification.

b) Recombinant subunits – 1000 doses of rGP120, formulated with alum adjuvant at 200 ug/dose. Assume that the HIV strain is a primary NSI strain.

c) Vector based vaccine. Live recombinant vaccinia - 10,000 doses of recombinant vaccinia expressing an HIV env gene from one promoter and an HIV gag gene from another, to be delivered at 10E7 pfu/dose. Assume that The HIV inserts are stable, and the recombinant vector has shown good growth properties in a variety of standard mammalian cell substrates. (Alternatively, propose a bacterial vector based vaccine)

d) Virus-like particle – 1000 doses at 100 ug p24/dose.

For each vaccine concept, the Offeror should propose production, purification and characterization methods and a timeline for obtaining completion of each pilot lot, with sufficient data generated for IND submission. Potential pitfalls and back-up plans should be included. Offeror should include a statement of its maximum capacity for production of each vaccine lot. Include cost estimates in the form of a detailed budget proposal for performing all the activities (Part A, 1-9) listed in the Statement of Work below.

When need arises to issue a task order under this contract, prequalified contractor(s) will be requested to submit a detailed production plan and cost proposal for that specific task.

These vaccines cover a range of complexity and difficulty, which is anticipated to be realistic for HIV vaccines which may be requested under this Contract. Award of this Contract, however, does not commit the Government to approve any of the protocols outlined in the proposal. The Project Officer will determine whether and which pilot lot production projects are actually undertaken.]

1. Produce, scale-up, characterize and formulate specific vaccine products and reagents as requested by the Project Officer via a Task Order issued by the NIAID. Produce pilot lots of candidate vaccines under GLP/cGMP appropriate for Phase I and Phase II human clinical trials, at the direction of the Project Officer in one or more of the following vaccine Categories.

    a) Synthetic peptides

    b) Recombinant subunits

    c) Vector based vaccines [Viral or Bacterial]

    d) Virus-like Particle / Replicon

2. Develop and manufacture specific vaccine products.

[NOTE #A-2 TO OFFEROR: Such products may incorporate multiple components (e.g., geographic variants of HIV, various HIV gene products, immunomodulatory cytokines or the corresponding genes, third party adjuvants, delivery systems, etc.).]

    a) Consult and coordinate with the product inventor throughout the development process. Complete a material transfer agreement, if needed.

    b) Develop detailed production plan and budgets for manufacture of lots of candidate vaccine products prior to undertaking GLP/cGMP production.

c) Prepare, where applicable, master stocks, cell banks, bacterial or viral clones, etc.

d) Purchase, where applicable, products and materials necessary for vaccine production.

e) Optimize expression in systems suitable for vaccine production and scale-up production to required capacity.

[NOTE #A-3 TO OFFEROR: This activity may require direct collaboration with the vaccine inventor.]

f) Formulate (including adjuvant and excipients), vial, label, package, store and ship test lots of candidate products.

g) Produce candidate vaccines in a form suitable for use in clinical trials (including characterization, formulation [including adjuvanting], vialing, labeling, packaging and storage). These products shall be prepared under GLP or cGMP conditions, as appropriate, by methods that meet FDA standards for products for human clinical trials as described in the Code of Federal Regulations, Title 21, Chapter I, Parts 58, 210 & 211, and 600-640 [April 1994] and the Guidelines on Sterile Drug Products Produced by Aseptic Processing [June 1987].

h) Maintain an inventory of test and pilot lots of vaccine candidates that have been produced. Periodically, as required, examine titer or potency of vaccine products.

i) Produce reagents necessary for the testing or evaluation of immune responses to vaccine products.

j) Ship the manufactured, packaged, and labeled dosage forms utilizing shipping procedures and materials to maximize product stability.

[NOTE #A-4 TO OFFEROR: Destination sites and special shipping requirements will be designated by the Project Officer.]

k) Manage and account for intellectual property rights that pre-exist or may develop through the activities of the Contractor, including maintenance of security of confidential and/or proprietary data.

3. Provide facilities, equipment and resources:

a) Receive, store and manipulate biohazardous materials (Biosafety Level 2 or 3 Containment as required) and maintain their viability in facilities which provide aseptic and/or sterile conditions as appropriate.

b) Maintain and operate controlled storage of samples at appropriate temperatures with appropriate monitoring for failure.

[NOTE # A-5 TO OFFEROR: It is anticipated that most products will require storage within the range of room temperature through -90°C. Liquid nitrogen storage may be required for some products.]

c) Provide facilities and equipment suitable for GLP/cGMP production of vaccine products.

d) Provide protective garments, equipment and sufficient monitoring to assure safe handling of potentially hazardous materials, including radioactive materials, for the safety and protection of workers.

e) Conduct work under this contract in accordance with all applicable and current Federal, state, and local laws, codes, ordinances and regulations, as well as all PHS Safety and Health provisions)

4. Perform vaccine lot characterization tests.

At various steps during the manufacture of a vaccine the product must be characterized. Prior to use of a vaccine in clinical studies the manufactured vaccine will need to undergo final lot release testing. As described in the regulations for General Biological Product Standards (21 CFR 610) the following tests shall be performed for each lot of vaccine.

a) Test for Potency. A test for potency shall be performed. (A test for potency [21 CFR 610.10] will evaluate in an in vitro or in vivo test the specific ability of the vaccine to effect a given response, such as an immune response in mice, which should be supportive of the efficacy of the vaccine in humans. In the case of DNA vaccines potency may be evidenced by the production of the pertinent antigen in a transfected cell line.)

b) Test for General Safety. The general safety test [21 CFR 610.11] shall be performed in mice and guinea pigs on each lot of vaccine to detect extraneous toxic contaminants potentially introduced during manufacture.

c) Test for Sterility. A test for sterility [21 CFR 610.12] shall be performed as described in the regulations.

d) Test for Purity. A test for purity [21 CFR 610.13] shall be performed on each lot to ensure that the product is free from extraneous material except for that which is unavoidable due to the manufacturing process. (In addition, the test for purity includes an evaluation of residual moisture and the presence of pyrogenic substances in the product.)

e) Test for Identity. A test for identity shall be performed. (The test for identity [21 CFR 601.14] is generally a physical or chemical test performed to establish the identity of the material in the final container.)

f) Test for Quantity. A test for quantity shall be performed. (A measure of the amount of material present is imperative for calculating the dilution of the bulk material required for the final container fill.)

g) All other tests as may be required for specific vaccine types. Develop and validate procedures as needed.

5. Perform stability testing.

[NOTE #A-6 TO OFFEROR: Stability testing will be required at various points during the production process. There is no single stability-indicating assay or parameter for all biological products. Therefore, manufacturers should propose on a case-by-case basis stability-indicating profiles for their products which provide assurance that changes in identity, purity and potency of the product will be detected.]

6. Provide all data, information and records required for the writing and submission of the Master File, Investigator's Brochure, and all other documents related to IND submission to the Project Officer or to a designated third party (e.g. Part C). Provide information pertaining to the composition, manufacture, and quality control of the vaccine product as appropriate for particular investigations to be covered by an IND.

[NOTE #A-7 TO OFFEROR: This may include information contained in master production and control records, batch production and control records, standard operating procedures (SOP) and laboratory records. This information will be requested when required by the FDA and should be submitted within 3 weeks from the time the Project Officer makes the request.]

7. Participate in discussions with the FDA during pre-IND and IND meetings.

8. Meet with the Project Officer at periodic intervals, to be scheduled after contract award.

9. Retain all records, samples, histopathological slides, etc. as indicated under GLP and cGMP guidelines and be able to make them available to the Project Officer or his designee.

[GENERAL NOTE: In the event that human blood or other specimens need to be obtained for use as assay controls or for the preparation and maintenance of stocks of HIV-1 in the performance of the work specified under this Contract, it is assumed that such material will be purchased from a supplier. If the Contractor elects to collect such samples under the Contract, then the Human Subjects Clause will apply, and collection shall take place with informed consent under an Institutional Review Board approved protocol.]

[**NOTE #A-8 TO OFFERORS: A single Task Order may include any or all of the above requirements. For example, a Task Order may be limited to the vaccine or reagent formulation (including adjuvant and excipients), vialing, labeling, packaging, storage and/or shipment of premanufactured products.]**

PART B: SAFETY AND IMMUNOGENICITY TESTING.

Test candidate products for safety and immunogenicity (both cellular and humoral) in small animals and, if necessary, in non-human primates, and other appropriate tests, including reproductive toxicology. Perform all such tests as are required for approval of a vaccine product for human administration. Testing must be sufficient to meet requirements for IND filing.

[**NOTE #B-1 TO OFFERORS: Documentation of experience in preclinical safety and evaluation of immune response testing should be provided. It is anticipated that the contractor will have the capacity to perform testing for each type of vaccine candidate covered by this contract, including each of the four general vaccine Categories. Offeror should outline in detail the tests and procedures it will use to qualify each type of vaccine product for human administration. Provide an appropriate model for determining the cellular and humoral immunogenicity of an HIV vaccine in small animals and, if necessary, in non-human primates. Offeror(s) may propose subcontracts for any specific testing procedure (e.g., primate studies).**

Documentation of available equipment and access to an AAALAC-accredited (or equivalent) animal facility and the capacity for testing the safety and immunogenicity of products should be included.

For the purposes of providing a cost proposal, Offeror(s) should provide a detailed budget based on the preclinical safety and immunogenicity evaluation of one recombinant protein vaccine product. Assume that tumorigenicity and reproductive toxicity studies are not required. Include documentation for personnel costs and all specific animal, supply, and equipment costs.

1. Specifically, at the request of the Project Officer, contractor shall perform all tests required to qualify a vaccine product for human administration including but not limited to the list below. Such testing must also include all tests required for Investigational New Drug (IND) and Masterfile submission. All studies must be performed in accordance with Good Laboratory Practice (GLP) regulations (21 CFR 58).

    a. Preclinical immunogenicity evaluation.

    The preclinical studies shall be designed to assess the immune response including seroconversion rates, antibody levels, and cell mediated immune responses in vaccinated animals.

    b. Preclinical safety evaluations shall include but are not limited to the following.

        1) Systemic toxicity.

        Preclinical studies shall include dose-ranging and dose escalation studies of systemic toxicity as well as toxicity to potential target organs, including hematopoietic and immune systems.

        2) Local reactogenicity.

        Local site reactivity studies to include detailed clinical observations and histological evaluation of tissue of the injection site or other visible lesions from biopsies or term necropsy samples.

        3) Genetic toxicity.

        In the case of DNA and vector-borne vaccines the pivotal GLP preclinical study shall focus on assessment for the potential of the nucleic acid vaccine to recombine with endogenous host DNA sequences and integrate into cell chromosomes. Studies designed to address the potential for integration shall use the most sensitive methods available.

        4) Tumorigenicity studies.

        Tumorigenicity studies may be appropriate under certain conditions, such as if the preclinical genetic testing demonstrates evidence of integration activity and/or broad tissue distribution. Such studies shall be performed when necessary.

5) Reproductive toxicity studies.

Reproductive toxicity studies must be performed prior to the use of these vaccines in pregnant women. Such studies shall include but are not limited to fertility, general reproductive performance, teratology and developmental toxicity.

6) All other safety tests as may be required for a particular vaccine type.

c. Adjuvant testing.

The use of adjuvants and/or facilitators for the administration of a vaccine will necessitate specific preclinical evaluation procedures to ensure the safety of the candidate formulation to include but not limited to the evaluations listed in b) above.

In addition, the contractor shall:

2. Provide all data, information and records required for the writing and submission of the Masterfile and all other documents related to IND submission to the Project Officer or to a designated third party. This information shall be submitted within 3 weeks from the time the Project Officer makes the request.

3. Provide adequate facilities, equipment and resources necessary to accomplish these studies. Maintain adequate animal facilities.

4. Meet with the Project Officer at periodic intervals (to be scheduled after contract award).

5. Participate as necessary in discussions with the FDA during pre-IND and IND meetings.

6. Retain all records, samples, histopathological slides, etc. and be able to make them available as indicated under GLP guidelines.

[NOTE #B-2 TO OFFERORS. Specific requirements listed in the Statement of Work are not meant to limit the scope or specifics of preclinical vaccine testing. Such testing will include all of the tests required to qualify a vaccine product for human administration.]

[NOTE #B-3 TO OFFERORS. In addition to the CFR, the FDA also provides "Points to Consider" (PTC) Documents. Testing should be conducted consistent with these guidelines. Examples of relevant guidelines include:

a) Points to consider in the Production and Testing of New Drugs and Biologicals Produced by Recombinant DNA Technology(4/10/85). Supplement (4/6/92).

b) Points to Consider in Human Somatic Cell Therapy and Gene Therapy (8/29/91).

c) Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals (7/12/93).

d) Points to Consider for Plasmid DNA Vaccines for Preventive Infectious Disease Indications (10/96)

These documents, as well as additional guidelines relating to testing and manufacture, are available from the Division of Congressional and Public Affairs. To receive copies call 888-223-7329 then dial 999 to get a list of documents and their number. Consumer information number is 301-827-2000. On the internet go to www.cber.fda.gov.]

PART C: FDA SUBMISSIONS

Develop, in consultation with the Project Officer, vaccine sponsors, and other contractors the Master File, Investigator's Brochure, and/or final vaccine trial protocol appropriate for submission to CBER, FDA as part of an Investigational New Drug Application (IND).

[NOTE #C-1 TO OFFERORS: It is anticipated that the Contractor will not hold the IND for any human trials to be conducted. The IND will be held by either the organization that holds proprietary rights to the product, or by the Division of AIDS, NIAID. However, the Contractor may be requested to work directly with the FDA for Masterfile and IND submission. For this proposal, the Offeror should provide evidence of its previous experience with submissions to CBER.

Offeror should also demonstrate its capacity to obtain, store, collate and arrange data and information and to keep all information secure.]

Specifically, the Contractor shall perform the following tasks:

1. At the request of the Project Officer, provide technical assistance and services in the preparation, assembly, review and delivery and follow-up of original IND submissions, as described in 21 CFR 312.23. This shall involve, but not be limited to, the following activities:

    a. Obtain and review preclinical and clinical information needed for the IND submission through contacting appropriate individuals, other contractors, literature research, and accessing various databases (e.g., MEDLINE, PDQ, or TOXNET).

    b. Prepare or update Investigator's Brochure at the request of the Project Officer as described in 21 CFR 312.23 (e.g., vaccine description and formulation, summary of preclinical and clinical safety, immunogenicity, activity data, risks and side effects).

c. Distribute Investigator's Brochure as directed by the Project Officer.

d. Prepare the Master File.

e. Collect and submit the required documentation for the original IND submission (e.g., chemistry, manufacturing, control, in-process/release testing data, pharmacology, toxicology and previous human experience).

f. Assemble the IND study protocol. The study protocol contains four basic sections:

1) the study protocol or clinical protocol
2) investigator data
3) facilities data
4) IRB data (or Bioethical Committee data if the study is conducted outside the United States).

g. Assemble, edit, and index the original IND submission to be submitted to the Project Officer and DAIDS.

h. Obtain authorization for cross-filing of information when appropriate. Obtain lot release protocols and investigator brochures prepared by the manufacturer.

i. Prepare an environmental assessment, as described in 21 CFR 25.31, if required.

j. Provide additional submissions and amendments as necessary for successful filing of the IND.

2. Coordinate with and provide technical assistance to the vaccine manufacturer, the Contractor performing the safety and immunogenicity testing, and all others involved in the production and preclinical testing of a vaccine product in order to assure that all requirements are met to provide the information required for the FDA submissions.

3. Participate in discussions with the FDA during pre-IND and IND meetings.

4. Meet with Project Officer as needed.

5. Provide adequate facilities, equipment and resources necessary to accomplish this work.

[NOTE # C-2 TO OFFEROR(S): The technical proposal should include a detailed list of required documents and a plan for the production of the Investigator's Brochure, Masterfile, IND proposal and all other documents required by the FDA for a new vaccine. It should contain provisions for cross-filing to other IND's. It should also include a plan for coordinating with vaccine manufacturers and Contractors performing preclinical safety and immunogenicity studies in order to assure that all requirements are met for providing the records and information necessary for filing the FDA submissions. It is anticipated that the protocol for the IND clinical evaluation will be provided by the Vaccine Clinical Trials Group. This proposal should not include provisions for monitoring clinical investigations after the IND has been filed.

For the purpose of preparing the cost proposal, Offeror(s) should assume that 5 vaccine products per year will be submitted to the FDA. The budget should include documentation for personnel costs plus expected direct costs for the preparation of submissions.]

ATTACHMENT to WORK STATEMENT

PROTECTION OF PROPRIETARY DATA

Information and data provided to or generated by the Contractor under this contract shall be treated confidentially and protected by an Advance Understanding to be included in the resulting contract and worded as follows:

"Because there is a likelihood that the Contractor will be utilizing and evaluating materials provided to the Government by a third party Supplier, it is essential to include provisions that will protect the proprietary rights of the Supplier. These materials generally are supplied to the Government under conditions outlined in NIAID's standard Screening Agreement or other appropriate documents. The Contractor shall be bound by the same terms and conditions as the Government in these agreements, with respect to the proprietary and confidential nature of the information provided by the Supplier.

All information provided by the Supplier or Project Officer should be assumed to be confidential unless specifically identified as non-confidential in writing by the Project Officer. Confidential information may not be revealed without written permission. All materials supplied to the Contractor and all test results similarly are to be considered confidential. All materials supplied to the Contractor shall be utilized solely for contract-related research purposes and no unauthorized use or distribution of these materials will be permitted.

Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted for review by the NIAID Project Officer before submission for public presentation or publication. 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 will review all manuscripts/abstracts in a period of time not to exceed 30 calendar days from receipt, and will either agree to the publication/ disclosure, recommend changes and, as applicable, refer the document to the Supplier of the compound for their review. When the Supplier does not consent to publication of the manuscript or abstract, the Project Officer shall notify the Contractor and the NIAID Contracting Officer.

Should patents arise from this contract, they will be subject to federal law governing inventions. Every patent applicant (individual or institutional) is required to provide the Government with a non-exclusive, irrevocable, paid-up license to the invention."

ATTACHMENT B

RFP NIH-NIAID-DAIDS-01-06
February 08, 2000

REPORTING REQUIREMENTS AND DELIVERABLES

In addition to those reports required by the Statement of Work and other terms of this Contract the Contractor shall prepare and submit the following reports in the manner stated below. Reports will be required for Contractors with active Task Orders throughout the period of work.

I. Milestone Reports (each task order will include guidelines for milestone reports).

Upon the completion of each milestone as indicated in the Task Order, the Contractor shall submit three (3) copies of a milestone report as described below. Two (2) copies should be submitted to the Project Officer and one (1) copy to the Contracting Officer. The milestone report should be factual and concise and consist of the following:

1) A title page containing:

   (a) Contract number and title
   (b) Sequence of report; e.g., "Year 1, 2nd Milestone Report"
   (c) Period of performance being reported
   (d) Contractor's name and address
   (e) Date of submission

2) Reports shall include, but are not limited to the following information:
   (a) A report detailing the actions taken to achieve the milestone.
   (b) A report of all products, procedures and outcomes achieved.
   (c) Graphs and tables of data obtained.
   (d) A detailed budget report with invoices and cost justifications related to achieving this milestone.
   (e) Other information as may be required by the Project Officer.

II. Final Report

The contractor shall submit three (3) copies of the final report documents, two (2) copies to the Project Officer and one (1) copy to the Contracting Officer, which will summarize the results of the entire contract work for the complete performance period. This report will be in sufficient detail to explain comprehensively the results achieved and will be submitted no later than the completion date of the Task Order.

The final report shall contain:

1) Title Page as described above in paragraph I.1)a.

2) Introduction covering the purpose and scope of the contract effort.

3) Description of the overall progress, plus a separate description of each protocol and subcontract, protocol or assay employed and its modifications and performance on the contract during the period of performance. Descriptions will include pertinent data in tables or graphs as appropriate to present significant results achieved, conclusions resulting from analysis, and a scientific evaluation of the data accrued under the contract.

4) Copies of any abstracts, manuscripts, and publications.

III. Other Deliverables.

1) The Contractor, at the request of the Project Officer, shall deliver to the Government or its designee by the completion date of the Task Order, the following items:

PART A:

(a) Test lots of vaccine products, as they are produced.
(b) cGMP quality pilot lots of candidate vaccine products and adjuvants, as they are produced.
(c) All vaccine candidates and adjuvants in various stages of production at termination of the contract with detailed information on them.
(d) A compete listing of accurate and updated information on design, development and production including activities of the Contractor, computerized data files, original data and any necessary information related thereto.
(e) A complete list of accurate and updated information on activities of subcontracts.
(f) Labeled and inventoried paper files.
(g) Government-owned equipment and property.

PART B:

(a) All data obtained from safety and immunogenicity trials.
(b) All vaccine products, adjuvants, etc. remaining from these studies.

PART C:

(a) All files pertaining to this contract at the request of the Project Officer.
(b) Copies of all FDA submissions.

IV. If the Contractor becomes unable to deliver the reports or other deliverables here specified 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 at the address given below in section VII.

V. Copies of the technical reports shall be submitted as follows:

Type of Report	**No. of Copies**	**Addresses:**
Milestone Final	2 2	Project Officer, PRDB, VPRP, NIAID, NIH Room 4106 6700-B Rockledge Drive, MSC 7628 Bethesda, MD 20892-7628
Milestone Final	1 1	Contracting Officer, CMB, DEA, NIAID, NIH Rm. 2108 6700-B Rockledge Drive, MSC 7612 Bethesda, MD 20892-7612

ATTACHMENT C

RFP NIH-NIAID-DAIDS-01-06
February 08, 2000

EVALUATION FACTORS FOR AWARD

Part A, Part B and Part C will be evaluated separately. Evaluation scores for one Part will not affect the evaluation of a separate Part. An Offeror must specify for which Part(s) it wishes to be evaluated.

PROPOSAL EVALUATION CRITERIA FOR PART A – VACCINE PRODUCTION
(This section will be scored independently for each vaccine category.)

I. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against three (3) factors. The factors in order of importance are: (1) technical, (2) cost/price, and (3) 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.

Listed below is a mandatory qualification criterion and technical evaluation criteria. The mandatory qualification criterion establishes conditions that MUST be met by the time of receipt of Final Proposal Revisions in order for your proposal to be considered any further for award.

The technical evaluation criteria are used by the special emphasis panel 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.

II. MANDATORY QUALIFICATION CRITERION

The following mandatory qualification criterion establishes conditions that MUST be met at the time of receipt of Final Proposal Revisions by the Contracting Officer in order for the proposal to be considered for award:

The Offeror must document that they have available biosafety level 2 facilities of sufficient capacity for all laboratory procedures and assays employing live HIV, SIV, or SHIV isolates, at the production levels specified in Note #A-1.

III. TECHNICAL EVALUATION CRITERIA (to be used to evaluate proposed work for each vaccine Category separately).

A. Technical Approach — Weight 40

Overall understanding of the project, and adequacy and feasibility of plans to address all items in the Work Statement. This includes the detailed description of specific tasks to be performed, methods to be used, and discussion of problems likely to occur and plans for addressing them.

1) Vaccine development and production:
Adequacy of the technical approach for preparing experimental vaccines, as requested in the Statement of Work (Note #A-1), including soundness of sample protocol, adequacy of scale-up and production under GLP/cGMP procedures, packaging and formulation, safety, logistics, and coordination.

30 pts

2) Plan for performance of vaccine lot characterization tests (lot release testing):
Technical approach for assessing potency, safety, sterility, purity, identity, quantity and stability including logistics, coordination and preparations for IND submissions.

10 pts

B. Experience and Qualification of Personnel — 35

1) Documented expertise and proficiency of the Principal Investigator in development and pilot lot production of vaccines for use in human clinical trials and in managing a project of comparable size and complexity and documented availability. 15 pts

2) Documented expertise and proficiency of other professional and technical staff in development and production of vaccine products and documented availability.

10 pts

3) Previous institutional expertise and proven track record in vaccine production.

10 pts

C. Facilities and Resources 25

Availability of adequate facilities, equipment and resources necessary to safely and efficiently accomplish the work described in the Statement of Work. Adequacy of detailed floor plan, indicating space to be committed for performance of this project.

1) Availability of facilities and equipment suitable for GLP/cGMP production of vaccine products. 15 pts

2) Dedicated capacity for production of these products in a timely manner. 10 pts

TOTAL POINTS: 100

IV. 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.

PROPOSAL EVALUATION CRITERIA FOR PART B – SAFETY AND IMMUNOGENICITY TESTING

I. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against three (3) factors. The factors in order of importance are: (1) technical, (2) cost/price, and (3) 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.

Listed below are mandatory qualification criteria and technical evaluation criteria. The mandatory qualification criterion establishes conditions that MUST be met by the time of receipt of Final Proposal Revisions in order for your proposal to be considered any further for award.

The technical evaluation criteria are used by the special emphasis panel 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.

II. MANDATORY QUALIFICATION CRITERIA

The following mandatory qualification criteria establish conditions that MUST be met at the time of receipt of Final Proposal Revisions by the Contracting Officer in order for the proposal to be considered any further for award:

A. The Offeror must document that they have available biosafety level 2 facilities of sufficient capacity for all laboratory procedures and assays employing live HIV, SIV, or SHIV isolates.

B. The Offeror must document access to an AAALAC-accredited (or equivalent) animal facility and the capacity needed for testing the safety and immunogenicity of manufactured products as proposed.

III. TECHNICAL EVALUATION CRITERIA

A. Technical Approach — Weight 40

Overall understanding of the project and adequacy and feasibility of plans to address all items in the Work Statement. This includes the detailed description of specific tasks to be performed, methods and resources to be used, and the discussion of problems likely to occur and plans for addressing them. Technical approach for safety and immunogenicity testing of each of the four Categories of vaccine requested in the Statement of Work including logistics, coordination and preparation for IND submission.

B. Experience and Qualification of Personnel — 40

1) Documented expertise and proficiency of the Principal Investigator, in the performance of safety and immunogenicity testing suitable for vaccines destined for human trials and in managing a project of comparable size and complexity and documented availability. 20 pts

2) Documented experience and capabilities of other professional and technical staff in the performance of safety and immunogenicity testing and documented availability. 10 pts

3) Previous institutional expertise and proven track record in the evaluation of vaccines suitable for human trials 10 pts

C) Facilities and Resources — 20

1) Availability of adequate facilities, equipment and resources necessary to safely and efficiently accomplish the work described in the

Statement of Work. Adequacy of detailed floor plan, indicating space to be committed for performance of this project. Adequacy of animal facilities.

15 pts

2) Capacity to perform required testing in a timely and efficient manner (resources dedicated to this project).

5 pts

TOTAL POINTS: 100

IV. 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.

PROPOSAL EVALUATION CRITERIA FOR PART C – FDA SUBMISSIONS

I. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against three (3) factors. The factors in order of importance are: (1) technical, (2) cost/price, and (3) 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.

II. TECHNICAL EVALUATION CRITERIA

The technical evaluation criteria are used by the special emphasis panel 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.

A. Technical Approach — Weight 50

Overall understanding of the project, and adequacy and feasibility of plans to address all items in the Work Statement. This includes the detailed description of specific tasks to be performed, methods to be used, and discussion of problems likely to occur and plans for addressing them.

1) Technical approach for obtaining all required data and documentation and for producing all documents required by the FDA for a new vaccine (see NOTE #C-2). — 25 pts

2) Technical approach for coordinating with vaccine manufacturers and with Contractors performing preclinical safety and immunogenicity studies and with NIAID staff in order to assure that all requirements are met for producing and providing records and information necessary for filing the FDA submissions.

25 pts

B) Experience and Qualification of Personnel 40

1) Documented expertise and proficiency of the professional and technical staff in the preparation of final protocols to be submitted to the CBER, FDA for Investigational New Drug review and documented availability. 20 pts

2) Institutional expertise and track record in the successful completion, submission and approval of new drug applications.

20 pts

C) Facilities and Resources 10

Documented availability of adequate facilities, equipment and resources necessary to accomplish the work described in the Statement of Work with an appropriate plan for management of privileged, proprietary, and confidential information.

TOTAL POINTS: 100

III. 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-01-06
February 08, 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 multiple awards will be made from this solicitation and that the awards will be made on/about December 1, 2000. It is anticipated that the awards from this solicitation will be Indefinite Quantity type contracts with a 5 year performance period, and that Task Order Procedures will be used.

2. **DEFINITIONS**

Indefinite-Quantity Contract - FAR 16.504 defines an indefinite-quantity contract as a contract that provides for an indefinite quantity, within stated limits, of supplies or services to be furnished during a fixed period, with deliveries or performance to be scheduled by placing orders with the contractor.

Under an indefinite-quantity contract, the Government's agreement to order the minimum quantity provides the consideration necessary to bind the contractor to furnish additional quantities, which the Government may, but is not required to, order.

Task and delivery order contracting is authorized for use with indefinite-quantity contracts as described in FAR 16.504.

Task Order Contract - FAR 16.501-1 defines a task order contract as a contract for services that does not procure or specify a firm quantity of services (other than a minimum or maximum quantity) and that provides for the issuance of orders for the performance of tasks during the period of the contract.

3. **FAIR OPPORTUNITY TO BE CONSIDERED PROCESS**

When the government develops a task order requirement, it will prepare a "Task Order Request" (TOR) for the purpose of soliciting proposals and selecting the most advantageous offer from among the multiple contract awardees.

Normally, each awardee will receive an opportunity to submit a proposal for those task order requests solicited under parts A, B, or C, for which they received a contract. However, the Contracting Officer need not contact each of the multiple awardees before selecting a task order source if the Contracting Officer has sufficient information available to ensure that each awardee receives a fair opportunity to be considered for the task order. For example, if the Government issues a task order request for a specific vaccine under Part A, Vaccine Production, for which one of the contract holders under that part is the supplier of the vaccine being requested for production under the task order request, then only that contract holder would be eligible to submit a proposal in response to that particular task order request.

Further, awardees need not be given an opportunity to be considered for a particular order in excess of $2,500 if the Contracting Officer determines that:

(i) The agency need for the supplies or services is of such urgency that the normal solicitation and evaluation process would result in unacceptable delays;

(ii) Only one such contractor is capable of providing such supplies or services at the level of quality required because the supplies or services ordered are unique or highly specialized;

(iii) The task order needs to be issued on a sole-source basis in the interest of economy and efficiency as a logical follow-on to a task order already issued under the contract, provided that all awardees which were qualified under the specific Part A, B, or C for which the task order request covers were given a fair opportunity to be considered for the original task order request solicited under that part; or

(iv) It is necessary to award the task order to a specific contractor to satisfy the minimum guarantee provision in its contract.

4. **TASK ORDER PROCEDURES**

In providing services under the contract, the following procedures shall apply to the award of task orders.

All work required under the contract shall be authorized through the execution of a bilateral task order. Each task order will obligate the necessary funds to complete the required task and will include the work statement of the task order as an attachment. Task orders may be issued at any time within the contract period. Subject to the exceptions described under "Fair Opportunity To Be Considered Process" above, when the Government elects to fill a requirement that is estimated to exceed $2,500, the Contracting Officer shall provide a TOR to the awardees that received contracts for the particular Part for which responses are being solicited. A TOR shall, at a minimum, include a Statement of Work, evaluation factors, specific reporting requirements, deliverables and delivery schedule, the relevant importance of technical and cost factors, and any special instructions.

Business proposals shall include direct and indirect costs necessary for performing the proposed task. Task order proposals shall generally be limited to a total of 20 pages, including attachments.

Within the time allowed for proposal preparation (time allowed for proposal preparation and submission will vary depending on the task), which will be designated in the task order request, Contractors shall submit their proposals in response to a task order request, which shall include, but not necessarily be limited to the following information:

(i) A statement of the contractor’s clear understanding of the task requirements;

(ii) A statement of technical and managerial resources and expertise the contractor can provide to satisfy the requirement;

(iii) An approach to perform the work;

(iv) The labor category necessary, and the numbers of hours for each labor category necessary, and an explanation of the rationale for determining hours;

(v) Resumes with identification of the actual personnel proposed for the work;

(vi) A schedule of performance identifying major milestones, deliverables and delivery date, and task completion; and

(vii) an itemization of all costs, both direct and indirect, (i.e. personnel, fringe benefits, equipment, travel, supplies, other direct costs, overhead, etc.) necessary to complete the work.

The Government will evaluate proposals and conduct negotiations as necessary. Task orders will be awarded to the contractor whose proposal is determined to be the most advantageous to the Government based on the technical and price factors specified in the TOR. The Government reserves the right to make an award on the most favorable initial proposal without discussion.

The Contracting Officer is the only individual authorized to issue a TOR or award a task order under the contract. Unless specifically authorized by the Contracting Officer, the contractor shall not commence work on a requirement until a task order has been fully executed. It is anticipated that task orders will be awarded within 30 calendar days from receipt of task order proposals. Each task order shall, at a minimum, contain the following information:

- Date of order
- Contract number and task order number sequentially; e.g., N01-AI-12345 (Task order No. 01, 02, 03, etc).
- Description of services, and estimated cost.
- Performance period.
- Name and address of sponsoring office.
- Name of Contracting Officer's technical representative.
- Place of performance.
- Packaging, packing, and shipping instructions, if any.
- Accounting and appropriation data.
- Pricing Arrangements
  FAR 16.501-2(c) states that indefinite delivery contracts may provide for any appropriate cost or pricing arrangement under Part 16. Therefore, firm fixed price, cost reimbursement, time and materials, and labor-hour arrangements may be used.
- Any other pertinent information.

No protest under FAR Subpart 323.1 is authorized in connection with the issuance or proposed issuance of a task order under the contract except for a protest on the grounds that the order increases the scope, period, or maximum value of the contract. Task orders awarded under the contract are not subject to the competition requirements of FAR Part 6.

5. **SMALL BUSINESS SUBCONTRACTING PLAN**

For those concerns other than small business concerns, subcontracting plans will be required when the cumulative dollar amount for tasks issued against the contract exceed $500,000 in accordance with P.L. 95-507. The small, small disadvantaged, and women owned business subcontracting plans will have to reflect goals that allow the maximum practicable subcontracting opportunities retroactive to day one of the effective date of the contract. As subsequent tasks may be issued against the contract once small, small disadvantaged, and women owned business subcontracting goals have been established, the subcontracting goals will be subject to modification with each subsequent task.

6. **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.

7. **MINIMUM AND MAXIMUM QUANTITY OR DOLLAR VALUE**

In response to this RFP, potential Offerors may submit proposals for one or more of the three Parts described in the Statement of Work (SOW). Within Part A, Offerors may submit proposals for any one or more of the vaccine concept Categories. Proposals will undergo peer review based on the evaluation criteria and awards will be made to the most qualified proposals. Each Offeror awarded a contract under a given Part or Category, will receive a guaranteed minimum dollar award over the term of the Contract (offerors that qualify for more than one part will receive only one contract). The guaranteed minimum dollar awards for Contractors will be determined by the following scale:

Contract Part - Minimum Award

Part A - $200,000
Part B - $100,000
Part C - $ 50,000

Offerors that receive awards for more than one Part will be eligible for Minimum Awards for each Part. Offerors that receive awards for one or more vaccine Categories under Part A will be eligible for a single Part A minimum award. It is anticipated that the maximum total funding under the Contract for all parts will be between $5 – 10 million per year. The minimum guarantee may be obligated incrementally, on an annual basis, in order to minimize the funding required for each contract year.

8. **LIMITATION ON PERIOD OF PERFORMANCE OF ORDERS**

The clause at FAR 52.216-22, Indefinite Quantity, permits orders issued during the effective period of the contract, and not completed within that period, to be completed within the time specified in the order. The time specified in such orders, however, will not extend unreasonably beyond the contract expiration date.

9. **TASK ORDER CONTRACT AND DELIVERY ORDER CONTRACT OMBUDSMEN**

a. FAR 16.505(b)(4) requires that each agency designate a task order contract and delivery order contract ombudsman who will be responsible for reviewing complaints from contractors and ensuring that all contractors are afforded a fair opportunity to be considered for orders.

b. The Ombudsman for R&D task and delivery order contracts is Anthony Demsey, Ph.D. Correspondence from awardees on multiple award R&D task and delivery order contracts may be forwarded to the following address:

Dr. Anthony Demsey
Ombudsman for R&D Task and Delivery Order Contracts
c/o Ms. Zaiga Tums, Director, Division of Acquisition Policy and Evaluation, OCM
Building 6100, Room 6C01
Bethesda, Maryland 20892-7540

10. **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.

(1) The small business size standard is 500 Employees.

(2) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 Employees.

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.

11. **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:

Brenda J. Velez, Chief
Contract Management Branch
DEA, NIAID, NIH
6700-B Rockledge Drive
Room 2230
Bethesda, MD 20817

Mailing address (U.S.) Postal Service

Brenda J. Velez, Chief
Contract Management Branch
DEA, NIAID, NIH
6700-B Rockledge Drive MSC 7612
Room 2230
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.

12. **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.)

13. **PRIVACY ACT SYSTEM OF RECORDS**

The Privacy Act will not apply to this contract. No data that can be personally identified with individuals will be collected to accomplish a Department function as part of the requirements of the contract. Records will be filed by organization and not by individuals, and therefore, the Privacy Act does not apply.

14. **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 the 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.

15. **PROPOSAL INTENT RESPONSE SHEET**

RFP No.: NIH-NIAID-DAIDS-01-06

RFP Title: "HIV VACCINE PRODUCTION"

Please review the attached Request for Proposals. Furnish the information requested below and return this page by April 03, 2000. Your expression of intent is not binding; however, the below information is required by the NIAID in order to coordinate the electronic submission and review of proposals.

[ ] DO INTEND TO SUBMIT A PROPOSAL

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

_____
_____
_____
_____

Company/Institution Name: _____
Address: _____
_____
_____
_____
Project Director's Name: _____
Title: _____
Signature/Date: _____
Telephone Number and E-mail Address: _____
Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants):
_____
_____
_____
_____

(Continue list on a separate page if necessary)

RETURN TO:
CMB, NIAID, NIH
6700-B Rockledge Drive MSC 7612
Room 2230
Bethesda, MD 20892-7612
Attn: Lawrence M. Butler
RFP-NIH-NIAID-DAIDS-01-06
FAX# (301) 402-0972
Email lb13t@nih.gov

ATTACHMENT E
RFP-NIH-NIAID-DAIDS-01-06
February 08, 2000

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
   - FACILITIES CAPITAL COST OF MONEY
   - CARE OF LIVE VERTEBRATE ANIMALS
   - 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

- Small, Small Disadvantaged, HUBZone and Women-Owned Small Business Model Subcontracting Plan Outline
- Certificate of Current Cost or Pricing Data, NIH-1397

4. The "Representations and Certifications" are applicable.

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

ATTACHMENT F

RFP-NIH-NIAID-DAIDS-01-06
February 08, 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 this method.

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 **MONDAY, APRIL 03, 2000.**

NOTE: There is no limit to the size (MB) of the two electronic PDF files to be submitted; however, the size of the technical proposal is limited to the page limitation language outlined below. For purposes of assessing compliance with the page count, 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.

PAGE LIMITS -- The narrative portion of the Technical Proposal, (see item 3.b.4. (Technical Plan) below, items a through d)is limited to fifty (50) pages. Pages in excess of this will be deleted and will not be read or evaluated. Each page of the Technical Proposal must be numbered sequentially. Offerors are encouraged to limit the overall size of the Technical Proposal, inclusive of appendices, attachments, etc. Note that although no page limit has 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 (characters per inch), 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 --- The entire 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.)

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

   Provide narrative for:

   a. Principal Investigator/Project Director
   b. Other Investigators
   c. 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 _____

6. 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 _____

7. "Technical Proposal Cost Information" summary spreadsheet --.....Page _____

8. 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 _____

9. HUMAN SUBJECTS, PARTICIPATION OF CHILDREN AND MINORITY AND GENDER ISSUES NOT OTHERWISE ADDRESSED (IF APPLICABLE) -- Page _____

10. VERTEBRATE ANIMALS (IF APPLICABLE) --
    .....Page _____

11. LITERATURE CITED -- Page _____

12. 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 --- THE ENTIRE 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-01-06
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 Five (5) unbound copies, with ten (10) copies of items excluded from electronic submission requirements that you choose to provide in paper format (SOPs, pertinent manuals, nonscannable figures or data, and letter of collaboration/intent.)

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

C. PAPER/HARD COPIES TO:

If hand delivered or delivery service:

Lawrence M. Butler, Contracting Officer
Contract Management Branch
NIAID, NIH
Room 2230
6700-B Rockledge Drive
Bethesda, Maryland 20817

If using U.S. Postal Service:

Lawrence M. Butler, Contracting Officer
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 Federal Express 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).

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