U.S. Department of Health and Human Services, National Institutes of Health

National Institute of Allergy and Infectious Diseases (NIAID)

RFP-NIH-NIAID-DMID-PR2004-02
"Recombinant Type E Botulinum Neurotoxin Vaccine"

1. OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE FOLLOWING WEBSITE FOR ANY SOLICITATION AMENDMENTS. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE. **http://www.niaid.nih.gov/contract/default.htm**		
2. SECTION A – SOLICITATION/CONTRACT FORM -- PURCHASE AUTHORITY: FAR 1.602-1 NOTE: The issuance of this solicitation does not commit the government to an award.		
3. Issue Date: September 21, 2004	4. Due Date: November 5, 2004 **Time:** 3:00 PM, EST	5. Small Bus. Set-Aside: [ ]Yes [X] No 8(a) Set-Aside: [ ]Yes [X] No (See Part IV, Section L.)
6. Just In Time: [X] No [ ] Yes (See Part IV, Section L.)	7. Number of Awards: [X] Only 1 Award [ ] Multiple Awards	8. **Technical Proposal Page Limits**: See Attachment entitled: "Proposal Submission: Number of Copies, Page Limitations and Electronic File Size"
9. Issued By: Olga Acosta-Polston Senior Contracting Officer Research Resources Contract Branch Contract Management Program, DEA NIH, NIAID 6700-B Rockledge Drive Room 3100, MSC 7612 Bethesda, MD 20892-7612	10. [X] We reserve the right to make awards without discussion. 11. Options: [X] No [ ] Yes (See Part IV, Section L.)	12. Period of Performance: 12 months beginning on or about February 22, 2005
13. Primary Point of Contact: Name : **Liem T. Nguyen** Phone: 301-451-3687 Fax: 301-402-0972 E-Mail: ln18x@.nih.gov	14. Secondary Point of Contact: Name: Olga Acosta-Polston Phone: 301-435-4322 Fax: 301-480-4675 **E-Mail:** od3m@.nih.gov	15. Protest Officer: Director, CMP Address (see Block 9.)
16. COLLECT CALLS WILL NOT BE ACCEPTED. FACSIMILE SUBMISSIONS ARE NOT ACCEPTABLE.		
17. 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" (See SECTION J – Attachments)		

18. DELIVERY ADDRESS INFORMATION

Hand Delivery or Overnight Service: Liem T. Nguyen Research Resources Contract Branch Contract Management Program, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	**U.S. Postal Service or an Express Delivery Service** Liem T. Nguyen Research Resources Contract Branch Contract Management Program, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612

19.The Official Point of Receipt for the purpose of determining timely delivery is the address provided in Block 18, above. The paper copy with original signatures is the official copy for recording timely receipt. If the paper copy of 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 HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.

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BACKGROUND

This notice is a combined synopsis/solicitation for other than commercial items. This announcement constitutes the only solicitation; offers are being requested and a written solicitation will not be issued. This procurement is being conducted under the Simplified Acquisition Procedures (SAP) set forth in FAR Part 13. This notice is being issued as a Request for Proposal (RFP) for cGMP production of one lot (approximately 50g) of a recombinant type E botulinum neurotoxin vaccine (starting material to be provided by the Offeror), as well as, preparation of the chemistry, manufacturing and control (CMC) data to support an Investigational New Drug (IND) application submission to the Food and Drug Administration (FDA) for this product.

Statement of Work

NIH-NIAID-DMID-PR2004-02

Recombinant Type E Botulinum Neurotoxin Vaccine

This acquisition is being issued for services to manufacture cGMP bulk drug substance, approximately 50 grams, of a recombinant type E botulinum neurotoxin vaccine (starting material to be provided by the Offeror) with demonstrated potency in a standardized mouse protection bioassay. The vaccine should be suitable for evaluation as a stand alone vaccine or in combination with other recombinant vaccines for types A and B botulinum neurotoxins.

The Offeror should propose the following services to complete each of the following milestones:

1. Develop and qualify analytical methods for assessing concentration, identity, integrity, protective efficacy, purity, potency, sterility, stability, and contamination for testing bulk products;
2. Prepare master production records for production of non-GMP pilot lots for approval by the National Institute of Allergy and Infectious Diseases (NIAID), prior to initiation of non-GMP pilot lots;
3. Prepare up to three pilot lots of sterile and endotoxin free non-GMP material using planned cGMP manufacturing process;
4. Prepare and submit batch production records for non-GMP pilot lots;
5. Prepare master production records for cGMP bulk drug substance for NIAID approval, prior to initiation of cGMP bulk drug substance manufacturing;
6. Develop formulation and manufacture and cGMP bulk drug substance, approximately 50g, of a recombinant type E botulinum neurotoxin vaccine (a portion of which, 2000 doses, will be formulated with adjuvant and vialed, the remainder will be retained as Bulk Drug Substance);
7. Demonstrate that the cGMP vaccine protects against lethal challenge from at least 1,000 mouse $IPLD_{50}$ of type E botulinum neurotoxin in at least one standardized mouse protection assay according to protocols approved by NIAID;
8. Conduct assessments of concentration, identity, integrity, protective efficacy, purity, potency, and contamination for of cGMP bulk drug substance and drug product and assessment of product stability 6 months after production.
9. Prepare the chemistry, manufacturing and control (CMC) data to support the submission of an Investigational New Drug (IND) application submitted to the Food and Drug Administration (FDA).
10. Support the preparation of the IND documentation for submission to the FDA.

A. Deliverables:

1. Master production records for production of non-GMP pilot lots prior to initiation of non-GMP pilot lot production.
2. Batch production records for non-GMP material.
3. Master production records for cGMP bulk drug substance prior to initiation of cGMP bulk drug substance manufacturing.
4. One cGMP lot, approximately 50g, of a recombinant type E botulinum neurotoxin vaccine that has passed all bulk drug substance and final drug product characterization and release testing. (, a portion of which, 2000 doses, will be formulated with adjuvant and vialed, the remainder will be retained as Bulk Drug Substance).
5. A certificate of analysis for cGMP bulk drug substance.
6. Data demonstrating that the vaccine protects against lethal challenge from at least 1,000 mouse $IPLD_{50}$ of type E botulinum neurotoxin in a standardized mouse protection bioassay.
7. Data for assessments of concentration, identity, integrity, protective efficacy, purity, potency, and contamination for of cGMP bulk drug substance and drug product and assessment of product stability 6 months after production.
8. Technology transfer of analytical assays to the government or its designee.
9. Prepare and submit to NIAID the chemistry, manufacturing and control (CMC) section for IND application to the FDA.

10. Ship vials of cGMP vaccine and bulk drug substance under cGMP conditions to a facility designated by NIAID.
11. Support for preparation of the IND submission to the FDA.

B. Technical Reports:

For all reports the Contractor shall submit three (3) copies, comprising two (2) copies to the Project Officer and one (1) copy to the Contracting Officer.

1. Monthly Technical Progress Reports

   On the due date specified in the contract the Contractor shall submit a Monthly Technical Report that shall include the following specific information: a) Cover page that lists the contract number and title, the period of performance being reported, the contractor's name and address, the author(s), and the date of submission; b) An introduction covering the purpose and scope of the contract effort; c) Detail, document, and summarize the results of work completed and costs incurred during the period covered wit regard to planned effort and budget. These reports shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project. Also to be included is a summary of the work proposed for the next reporting period.

2. Milestone Reports

   A milestone report will be provided after the completion of each Milestone unless otherwise agreed by the Principal Investigator and the Project Officer. Milestone reports and monthly reports may be combined if agreed by the Contracting Officer and the Project Officer.

3. Final Report

   By the expiration or termination of the contract, the Contractor shall submit a final report that details, documents, and summarizes the results of the entire contract work for the period covered. This report shall be in sufficient detail to explain comprehensively the results achieved.

C. Period of Performance and Budgets

The period of performance for this effort shall be twelve months. Offerors are to base their technical proposal on an estimated maximum total budget of $3M. Cost proposals should provide a breakdown of costs for each milestone described under the Statement of Work section, as well as total cost estimates for the entire project. The proposal must include a detailed Gantt chart that provides timelines delineating each milestone and associated tasks.

SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

A Sample Uniform Contract Format may be found at the following website:

http://rcb.cancer.gov/rcb-internet/wkf/sample-contract.htm

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING PAGES CONTAIN A LISTING(S) OF GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.

ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED FIXED-PRICE RESEARCH AND DEVELOPMENT CONTRACT - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This RFP incorporates the following clauses by reference with the same force and effect as if they were given full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

a. FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

FAR CLAUSE NO.	DATE	TITLE
52.202-1	Jul 2004	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Jul 1995	Restrictions on Subcontractor Sales to the Government (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Jun 2003	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)
52.204-7	Oct 2003	Central Contractor Registration
52.209-6	Jul 1995	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Jan 2004	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other

		than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.219-8	May 2004	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Jan 2002	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-3	Jun 2003	Convict Labor
52.222-26	Apr 2002	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Aug 2003	Toxic Chemical Release Reporting (Over $100,000)
52.225-1	Jun 2003	Buy American Act - Supplies
52.225-13	Dec 2003	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.229-3	Apr 2003	Federal, State and Local Taxes (Over $100,000)
52.232-2	Apr 1984	Payments under Fixed-Price Research and Development Contracts
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over $100,000)
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Oct 2003	Prompt Payment
52.232-33	Oct 2003	Payment by Electronic Funds Transfer--Central Contractor Registration
52.233-1	Jul 2002	Disputes

52.233-3	Aug 1996	Protest After Award
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-1	Aug 1987	Changes - Fixed Price, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings.
52.245-2	May 2004	Government Property (Fixed-Price Contracts)
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-2	Sep 1996	Termination for the Convenience of the Government (Fixed-Price)
52.249-9	Apr 1984	Default (Fixed-Price Research and Development)(Over $100,000)
52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

HHSAR CLAUSE NO.	DATE	TITLE
352.202-1	Jan 2001	Definitions
352.232-9	Apr 1984	Withholding of Contract Payments
352.270-4	Jan 2001	Pricing of Adjustments
352.270-6	Jul 1991	Publications and Publicity
352.270-7	Jan 2001	Paperwork Reduction Act

[End of GENERAL CLAUSES FOR A NEGOTIATED FIXED-PRICE RESEARCH AND DEVELOPMENT CONTRACT - Rev. 07/2004].

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

FAR Clause 52.232-1, PAYMENTS (APRIL 1984) is deleted in its entirety and FAR Clause 52.232-16, PROGRESS PAYMENTS (MARCH 2000) is substituted therefore.

FAR Clause 52.232-20, LIMITATION OF COST, is deleted in its entirety and FAR Clause 52.232-22, LIMITATION OF FUNDS (APRIL 1984) is substituted therefore. [Note: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

(1) FAR 52.215-17, Waiver of Facilities Capital Cost of Money (OCTOBER 1997).

(2) FAR 52.227-14, Rights in Data - General (JUNE 1987).

(3) FAR 52.230-2, Cost Accounting Standards (APRIL 1998).

(4) FAR 52.230-3, Disclosure and Consistency of Cost Accounting Practices (APRIL 1998).

(5) FAR 52.230-6, Administration of Cost Accounting Standards (NOVEMBER 1999).

(6) FAR 52.237-10, Indemnification of Uncompensated Overtime (OCTOBER 1997).

(7) FAR 52.247-64, Preference for Privately Owned U.S. Flag Commercial Vessels (APRIL 2003).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION/PUBLIC HEALTH SERVICE ACQUISITION REGULATION (HHSAR)/(PHSAR) (48 CHAPTER 3) CLAUSES:

HHSAR 352.270-5, Key Personnel (APRIL 1984).

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

NIH (RC)-7, Procurement of Certain Equipment (APRIL 1984) (OMB Bulletin 81-16).

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

There Are No Applicable Clauses In This Section

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following Attachments are provided in full text with this Solicitation:

PROPOSAL SUBMISSION INSTRUCTIONS – see: http://www.niaid.nih.gov/contract/eproposal.htm

PROPOSAL SUBMISSION: NUMBER OF COPIES AND PAGE LIMITATIONS (Attached to this listing)

PROPOSAL INTENT RESPONSE SHEET (Attached to this listing)

[NOTE: Your attention is directed to the "Proposal Intent Response Sheet". If you intend to submit a proposal, you must complete this form and return it to this office via fax or e-mail on or before the date identified above. The receipt of this form is critical as it contains information essential for CMB's coordination of the electronic submission and review of proposals.]

RFP FORMS AND ATTACHMENTS:

THE RFP FORMS/ATTACHMENTS LISTED BELOW ARE AVAILABLE IN A VARIETY OF FORMATS AND MAY BE VIEWED OR DOWNLOADED DIRECTLY FROM THIS SITE:

http://www.niaid.nih.gov/contract/ref.htm

APPLICABLE TO TECHNICAL PROPOSAL (INCLUDE THESE DOCUMENTS/FORMS WITH YOUR TECHNICAL PROPOSAL):

Technical Proposal Cover Sheet
NIH-1688-1, Project Objectives
Technical Proposal Cost Information
Summary of Related Activities
Government Notice for Handling Proposals

APPLICABLE TO BUSINESS PROPOSAL (INCLUDE WITH YOUR BUSINESS PROPOSAL):

NIH-2043, Proposal Summary and Data Record
Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours
Offeror's Points of Contact

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

Invoice Instructions for NIH Fixed-Price Contracts, NIH(RC)-2, (11/03), 1 page
NIH(RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)

PROPOSAL SUBMISSION: NUMBER OF COPIES, PAGE LIMITATIONS AND ELECTRONIC FILE SIZE

Please refer to http://www.niaid.nih.gov/contract/eproposal.htm for delivery instructions for the submission of PAPER copies.

PAPER SUBMISSION: ***The paper copy is the official copy for recording timely receipt of proposals.***

In addition to the paper submission, you are requested to submit your proposal in PDF Searchable file, not image, on CD. 15 CDs are required. No URLs in the proposal. You must certify that both the original paper and electronic versions of the proposal are identical.

SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE.

NUMBER OF PAPER COPIES:

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

Document	Number of Copies	Page Limits	File Size
Technical Proposal	One (1) unbound signed original. Fifteen (15) unbound copies.	Limited to not-to-exceed 50 pages	Limited to not-to-exceed 4 mega-bytes
Business Proposal	One (1) unbound signed original. Fifteen (15) unbound copies.	included in the Technical Proposal Page Limits	Included in the Technical Proposal File Size
Representations and Certifications	One (1) Original required to be submitted with the Original Business Proposal. (Extra copies are optional.)	N/A	N/A
Proposal Appendices (Optional)	Sixteen (16) unbound copies of all materials not available electronically (i.e. SOPs, Pertinent Manuals, Nonscannable Figures or Data, and Letters of Collaboration/Intent).	Limit to not-to-exceed 50 pages	N/A
Resumes	Sixteen (16) unbound copies	Limited to 2 pages per person	N/A

WARNING: You are advised to read and carefully follow the instructions listed in each RFP. Failure to adhere to these instructions and to the specified limitations for size of paper and electronic proposals may result in the rejection of your proposal.

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DMID-PR2004-02

RFP Title: 'Recombinant Type E Botulinum Neurotoxin Vaccine'

Please review the attached Request for Proposal. Furnish the information requested below and return this page by October 4, 2004. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

Since your proposal will also be submitted electronically, please include the name and e-mail of the individual to whom the electronic proposal instructions, login code, and password should be provided.

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

Company/Institution Name (print): _____
Address (print): _____
_____
_____
_____

Project Director's Name (print): _____
Title (print): _____
Signature/Date: _____
Telephone Number and E-mail Address (print clearly):
_____
_____

*Name of individual to whom electronic proposal instructions should be sent:

Name: _____
Title: _____
E-Mail Address: _____
Telephone Number: _____

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

_____
_____
_____
_____

(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:

CMB, NIAID, NIH
Room 3214, MSC 7612
6700 B Rockledge Drive
Bethesda, Maryland 20892-7612
Attn: Liem T. Nguyen
RFP-NIH-NIAID-DMID-PR2004-02
Phone # 301-451-3687
FAX# 301-480-4675
Email : ln18x@nih.gov

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

Representations, Certifications, and Other Statements of Offerors or Quoters (Negotiated).

REPRESENTATIONS AND CERTIFICATIONS

The Representations and Certifications required by this particular acquisition can be accessed electronically from the INTERNET at the following address:

http://rcb.cancer.gov/rcb-internet/forms/rcneg.pdf

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE AND SUBMIT ONE ORIGINAL OF THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT IT AS PART OF YOUR ORIGINAL BUSINESS PROPOSAL. ADDITIONALLY, A COMPLETED ORIGINAL MUST BE SUBMITTED FOR ANY PROPOSED SUBCONTRACTORS.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

Alternate I (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

a. NAICS CODE AND SIZE STANDARD

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

The North American Industry Classification System (NAICS) code for this acquisition is 541710 .
The small business size standard 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 North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

b. TYPE OF CONTRACT AND NUMBER OF AWARD(S)

It is anticipated that ONE AWARD will be made from this solicitation and that the award will be made on/about February 22, 2005 .

It is anticipated that the award from this solicitation will be a FIXED PRICE type contract with a PERIOD OF PERFORMANCE OF 12 MONTHS, BEGINNING ON/ABOUT FEBRUARY 22, 2005.

c. COMMITMENT OF PUBLIC FUNDS

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

d. COMMUNICATIONS PRIOR TO CONTRACT AWARD

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with the Project Officer or other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

e. RELEASE OF INFORMATION

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

f. COMPARATIVE IMPORTANCE OF PROPOSALS

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

g. PREPARATION COSTS

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

h. SERVICE OF PROTEST (AUGUST 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:

Contracting Officer: [See Block 15 of RFP Cover Page]
Address: [See Block 9 of RFP Cover Page]

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

(End of Provision)

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) Contract Type and General Clauses

It is contemplated that a FIXED PRICE type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J, hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether an original or a copy.

Project Objectives, NIH-1688-1

The Offeror shall insert a completed NIH Form 1688-1, Project Objective, as provided in Section J, Attachments, behind the Title Page of each copy of the proposal, along with the "Government Notice for Handling Proposals." The NIH Form 1688-1 is to be completed as follows:

- For an Institution of Higher Education: The form MUST be completed in its entirety.
- For OTHER than an Institution of Higher Education: The starred items (Department, Service, Laboratory or Equivalent, and Major Subdivision) should be left blank.

The information required under the "Summary of Objectives" portion of the form MUST meet the requirements set forth in the section of the form entitled, "INSTRUCTIONS:"

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

(3) Proposal Summary and Data Record (NIH-2043)

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

(4) Separation of Technical and Business Proposals

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS.) However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any)., and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) Evaluation of Proposal

The Government will evaluate the technical proposal in accordance with the criteria set forth in PART IV, SECTION M of this RFP.

(6) Potential Award Without Discussions

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

(7) Use of the Metric System of Measurement

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(8) Selection of Offeror

(a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

(b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

(c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

(d) If the Government intends to conduct discussions prior to awarding a contract-

1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is this Institute's policy to conduct discussions with all offerors in the competitive range, the Institute reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected sources in accordance with HHSAR 315.370.

(e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

(f) The Institute reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet the Institute's requirements. Synopses of awards exceeding $25,000 will be published in the FedBizOpps.

(9) Salary Rate Limitation in Fiscal Year 2004

Offerors are advised that pursuant to P.L. 108-199, no NIH Fiscal Year 2004 (October 1, 2003 - September 30, 2004) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patent care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I. The salary rate limitation set by P.L. 108-199 applies only to Fiscal Year 2004 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I annual salary rate limit also applies to individuals

proposed under subcontracts, however it does not apply to consultants. P.L. 108-199 states in pertinent part:

"None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of Executive Level I."

LINK TO EXECUTIVE SCHEDULE SALARIES: <http://www.opm.gov/oca/PAYRATES/index.htm> *(click on "Executive Schedule" for the current Fiscal Year's salary rate or scroll down to the "General Schedule Salary Tables from Previous Years" to locate the Executive Level salary rates from previous years).*

(10) Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).

Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

(11) Prohibition on Contractor Involvement with Terrorist Activities

The Offeror/Contractor acknowledges that U. S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under any resultant contract(s).

Office of Health and Safety – Laboratory Registration / Select Agent Transfer Program

The awardee is responsible for ensuring that all work under this grant, cooperative agreement, or contract complies with all Federal requirements related to select agents including CDC's that can be found at http://www.cdc.gov/od/ohs/lrsat.htm and NIH's OBA that can be found at http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-052.html .

b. TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) **Technical Discussions**

The technical discussion included in the technical proposal should be prepared and submitted in the following format to facilitate proposal evaluation. The technical proposal should include a separate section addressing:

(a) **Statement of Work**

1) Access to and characterization of proposed starting material

The technical proposal should contain letter(s) that document access to the proposed starting material, and specific data characterizing the starting material.

2) Methodology, Approach and Schedule

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work Proposals that merely offer to conduct a program in accordance with the requirements of the Government's statement of work will not be eligible for award. The technical proposal should contain an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives. A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. The plan should be in as much detail as considered necessary to fully explain your proposed technical approach or method. The work plan should include a detailed Gant Chart. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

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3) Management Plan and Personnel

The technical proposal must include information on how the project is to be organized, staffed, and managed. This information should demonstrate your understanding of important events or tasks and their management. You must explain how the management and coordination of consultant and/or subcontractor efforts will be accomplished.

The technical proposal must list the names and proposed duties of the professional personnel, consultants, and key subcontractor employees assigned to the project. Their resumes should be included and should contain information on education, background, recent experience, and specific or technical accomplishments. The approximate percentage of time each individual should be allocated against each project task or subtask. The technical proposal should not include names of advisors, consultants, collaborators, or subcontractors that have not been contacted by the offeror and for which there is no letter of agreement to participate included in the offer.

The technical proposal must provide the general background, experience and qualifications of the organization. Similar or related contracts, subcontracts, or grants should be included and contain

the name of the customer, contractor grant number, dollar amount, time of performance, and the names and telephone numbers of the project officer and contracting officer/grants officer. The technical proposal should describe experience with FDA regulated products of a similar nature.

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

5) Facilities

The technical proposal must contain a description of facilities, biosafety considerations for the use of Select Agents, and equipment that will be used to perform the contract. In addition, it should contain letters that document agreement to a pre-award cGMP audit(s) of each performance

site(s) as indicated in a letter attached to their proposal and signed by authorizing officials at each performance site that is proposed.

6) Summary Budget

The technical proposal should include a summary of total costs only. It should not contain reference to detailed costs which are to be addressed in the business proposal.

(2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors and order of relative importance as described in the Technical Evaluation Criteria (SEE SECTION M).

(3) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

(a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

(b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

(c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

(d) Other factors you feel are important and support your proposed research.

(e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

c. BUSINESS PROPOSAL INSTRUCTIONS

1. Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

Cost proposals should provide a breakdown of costs for each milestone as described under Statement of Work section, as well as a monthly and total cost estimate for the entire project.

2. Qualifications of the Offeror

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

(a) General Experience

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

(b) Organizational Experience Related to the RFP

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, but not the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

(c) Performance History

Performance history is defined as meeting contract objectives within delivery and cost schedules on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

(d) Pertinent Contracts

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

(e) Pertinent Grants

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

3. **Other Administrative Data**

(a) Property

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

(b) Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38 (MAY 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

(c) Financial Capacity

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

(d) Incremental Funding

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If

this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

(e) Facilities Capital Cost of Money, FAR 52.215-16, (October 1997)

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

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

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

(End of Provision)

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

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

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

(4) **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).

b) What priority the work will be given and how it will relate to other work.

c) The amount of time and facilities available to this project.

d) Information on their cognizant field audit offices.

e) How rights to publications and patents are to be handled.

f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

http://ocm.od.nih.gov/contracts/rfps/FDP/PDPclausecover.htm

(5) **Proposer's Annual Financial Report**

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

(6) **Representations and Certifications**

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(7) **Travel Costs/Travel Policy**

Travel Policy

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

(8) **Certification of Visa's for Non-U.S. Citizens**

Proposed personnel under research projects are not required to be citizens of the United States. However, if non-U.S. citizens are proposed under a contract to be performed in the United States and its territories, then the offeror must indicate in the proposal that these individuals have the required visas.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of this offeror for contract award will be based on an evaluation of their proposal against three factors. The factors, in order of importance, are: technical, cost/price and Small Disadvantaged Business (SDB) Participation. Past performance is NOT an evaluation factor but will be considered in determining the offeror's responsibility in accordance with FAR 9.104-3(b). (Reference Section L.) All evaluation factors other than cost/price, when combined, are significantly more important than cost/price. In any event, the Government reserves the right to make an award only if it provides the best value to the Government.

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

2. 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 used in determining the relative merits of the offeror's proposal and in considering that the proposal offers the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before final determination of acceptability for award. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. 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.

The offeror will be evaluated on the following sub-factors:

a) Extent of commitment to use SDB concerns
b) Complexity and variety of the work SDB concerns are to perform
c) Extent of participation of SDB concerns in terms of the value of the total acquisition.

3. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance. Because there is no competition, weights have not been assigned for evaluation purposes. The proposal will be determined acceptable or unacceptable.

CRITERA

Mandatory Requirement (Go – No Go)

Documented proof of access to the proposed candidate recombinant type E botulinum neurotoxin vaccine in the form of a letter signed by the authorizing officials is required at the time of response to this solicitation. If it is not received at the time of submission, your proposal will not be evaluated.

Evaluation Criteria

1. Starting material	**30 Points**
Appropriateness and adequacy of the scientific and technical information provided to identify the candidate recombinant type E botulinum neurotoxin vaccine.	
2. Methodology and Technical Approach	**30 Points**
The scientific and technical strength, adequacy, and feasibility of the proposed approach and the schedule of milestones to meet the required statement of work.	
3. Management Personnel	**20 Points**
a. The scientific adequacy of the demonstrated training, availability, experience and ability of the offeror and the key personnel and the availability of these persons to perform the tasks required by the statement of work;	
b. Adequacy and feasibility of the offerors plan for project organization, staffing, and management. Adequacy and demonstrated understanding by the offerors of the importance of specific tasks and the management of those tasks. Adequacy and feasibility of the plan to manage and coordinate consultant and/or subcontractor(s) efforts; and	
c. Strength and adequacy of the documented experience with United States Food and Drug Administration regulated products of a similar nature and the regulatory requirements that govern production of cGMP materials.	
4. Facilities	**20 Points**
Appropriateness and availability of the facilities and the equipment to fulfill the requirements of the statement of work. Documentation of agreement to a pre-award cGMP audit(s) of each performance site(s) as indicated in a letter attached to their proposal and signed by authorizing officials at each performance site that is proposed.	
Total Possible Points	**100 Points**

[END OF SOLICITATION PACKAGE]