

# SOLICITATION

## SECTION A - SOLICITATION/CONTRACT FORM

1. Requisition or other Purchase Authority: _____		
<b>2. Request for Proposal (RFP) Number:</b>  N01CN25000-26	<b>3. Issue Date:</b>  October 25, 2011	<b>4. Set Aside:</b> <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes See Part IV Section L
5. Title : Preclinical Pharmacology and Toxicology Studies		
<b>6. ISSUED BY:</b> Office of Acquisitions National Cancer Institute National Institutes of Health Executive Plaza South, Room 6012 6120 Executive Boulevard, MSC 7195 Bethesda, MD 20892  _____ _____	<b>7. SUBMIT OFFERS TO:</b>  See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.	
8. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "Packaging and Delivery of the Proposal," until 3:00 PM local time on Friday, December 9, 2011. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043.		
9. This solicitation requires delivery of proposals as stated in ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." If proposals are required to be delivered to two different locations, the OFFICIAL POINT OF RECEIPT for determining TIMELY DELIVERY is the address provided for the OFFICE OF ACQUISITIONS.  IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE OFFICE OF ACQUISITIONS, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH subparagraph (c)(3) of FAR Clause 52.215-1, Instructions to Offerors--Competitive Acquisition," LOCATED IN SECTION L.1. OF THIS SOLICITATION.		
10. Offeror must be registered in the Central Contractor Registry (CCR) prior to award of a contract. <a href="http://www.ccr.gov">http://www.ccr.gov</a>		
11. FOR INFORMATION CALL: Kathleen Sears PHONE: (301) 451-5804 e-MAIL: searsky@mail.nih.gov COLLECT CALLS WILL NOT BE ACCEPTED.		
		Virginia DeSeau Contracting Officer Office of Acquisitions National Cancer Institute

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**PART I - THE SCHEDULE**

THE INFORMATION SET FORTH IN **SECTION A - SOLICITATION/CONTRACT FORM**, HEREIN CONTAINS IMPORTANT INFORMATION FOR ANY OFFEROR INTERESTED IN RESPONDING TO THIS SOLICITATION. ANY CONTRACT RESULTING FROM THIS SOLICITATION WILL INCLUDE IN ITS **SECTION A - SOLICITATION/ CONTRACT FORM**, ACCOUNTING, APPROPRIATION AND GENERAL INFORMATION APPLICABLE TO THE CONTRACT AWARD.

THE CONTRACT SCHEDULE SET FORTH IN **SECTIONS B THROUGH H**, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS NOT AN EXACT REPRESENTATION OF THE CONTRACT DOCUMENT THAT WILL BE AWARDED AS A RESULT OF THIS SOLICITATION. THE CONTRACT COST OR PRICE AND OTHER CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR (i.e., those relating to the organizational structure [e.g., Non-Profit, Commercial] and specific cost authorizations unique to the Offeror's proposal and requiring Contracting Officer Prior Approval) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. THE ENCLOSED CONTRACT SCHEDULE IS INTENDED TO PROVIDE THE OFFEROR WITH THE NECESSARY INFORMATION TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

**SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS**

**ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES**

This contract will support the conduct of toxicological and pharmacological evaluations of potential cancer preventive agents for Investigational New Drug (IND) applications to the Food and Drug Administration (FDA) for phase 0, 1-3 clinical studies, New Drug Applications (NDA) to the FDA, and to select appropriate first-in-human (FIH) doses. This Preclinical Pharmacology and Toxicology Studies contract shall require the Contractor to perform studies in four areas: genotoxicity testing; general toxicology in experimental animals; reproductive toxicology studies in rodents and rabbits; and, specialized studies. The protocols shall fulfill current industry standards and Government regulations for toxicology studies supporting IND/NDA applications and guidelines.

**ARTICLE B.2. ESTIMATED COST AND FIXED FEE**

- a. The estimated cost of this contract is \$\_\_\_\_\_.
- b. The fixed fee for this contract is \$\_\_\_\_\_. The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer, and subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract.
- c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee, is \$\_\_\_\_\_.

**ARTICLE B.3. PRICES**

- a. The Contractor shall be reimbursed by the Government in an amount not less than a total of \$1,000 (minimum) nor more than a total of \$2,200,000 (maximum) for successful performance of this contract.

**FUNDED CONTRACT AMOUNT**

Description	Unit	Funded Quantity	Unit Price (\$)	Period of Performance	Total Funded Amount (\$)

- b. The prices set forth in this ARTICLE B.2. will cover the contract period \_\_\_\_\_ through \_\_\_\_\_.

- c. Upon delivery and acceptance of the item(s) described in SECTION C of this contract and identified in the schedule of charges below, the Government shall pay to the Contractor the unit price(s) set forth below:

**SCHEDULE OF CHARGES FOR THE BASIC AWARD PERIOD**

Description of Item	Quantity (Units)	Price	Unit Price	Total

**ARTICLE B.4. PROVISIONS APPLICABLE TO DIRECT COSTS**

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Acquisition, by purchase or lease, of any interest in real property; 2) Special rearrangement or alteration of facilities; 3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property; and 9) Research Funding.

**ARTICLE B.5. ADVANCE UNDERSTANDINGS**

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

## SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

### ARTICLE C.1. STATEMENT OF WORK

- a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated August 31, 2011, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

### ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. In addition, one hardcopy of each report shall be submitted to the Contracting Officer.

All reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including specific checklists, by application, can be found at: <http://www.hhs.gov/web/508/index.html> under "Helpful Resources."

#### a. Technical Progress Reports

1. In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined prior to contract award. *[Note: Beginning May 25, 2008, the Contractor shall include the applicable PubMed Central or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.]*

For proposal preparation purposes only, it is estimated that in addition to the required electronic version(s) 2 hard copies of these reports will be required as follows:

- Monthly
- Quarterly
- Semi-Annually
- Annually
- Annually (with a requirement for a Draft Annual Report)
- Final - Upon final completion of the contract
- Final - Upon final completion of the contract (with a requirement for a Draft Final Report)

#### 1. Quarterly Progress Reports

The Contractor shall provide quarterly progress reports. These reports shall include: 1) summary of progress on each task order during the past three months , 2) summary of deliverables that have been completed by task order, the completion date, 3) summary of deliverables in progress by task order and whether or not these projects are on schedule, and whether any problems were encountered in the collection, handling or processing of data, including resolution of the problems, and 4) information regarding regulatory submissions such as Investigational New Drug (INDs), Drug Master File (DMF), New Drug Applications (NDA), and other documents required by the FDA. The reporting period is every three (3) month period which will commence upon award of contract.

*The Quarterly Progress Report is not required when the Annual Progress Report is due.*

**2. Draft Final Task Order Reports**

Shall contain all summarized and raw data, and shall be submitted 45 days prior to the end of each task order. Reports shall be formatted and contain information necessary for regulatory FDA submission.

a. Draft Final Task Order Reports shall be organized and formatted into the following specific sections:

- i. Table of Contents
- ii. Summary
- iii. Key Personnel
- iv. Introduction
- v. Purpose and Objectives
- vi. Experimental Design
- vii. Materials and Methods
- viii. Regulatory Compliance
- ix. Results
- x. Discussion and Conclusions
- xi. Quality Assurance Statement
- xii. Tables
- xiii. Figures
- xiv. Appendices

b. The PDF file shall contain bookmarked Table of Contents and also formatted to allow cut and copy.

c. Comments or needed corrections/clarifications will be returned by the COTR or other designee within 30 days of receipt of the Draft Final Task Order Report.

**3. Final Task Order Reports**

Shall contain all summarized and raw data, shall be submitted before the end of the performance period of each task order. Reports shall be formatted and contain information necessary for regulatory FDA submission.

a. Draft Final Task Order Reports shall be organized and formatted into the following specific sections:

- i. Table of Contents
- ii. Summary
- iii. Key Personnel
- iv. Introduction
- v. Purpose and Objectives
- vi. Experimental Design
- vii. Materials and Methods
- viii. Regulatory Compliance
- ix. Results
- x. Discussion and Conclusions
- xi. Quality Assurance Statement
- xii. Tables
- xiii. Figures
- xiv. Appendices

b. The PDF file shall contain bookmarked Table of Contents and also formatted to allow cut and copy.

**4. Annual Progress Reports**

The Contractor shall provide technical annual progress reports. These reports shall include: 1) summary of progress on each task order during the past year , 2) summary of deliverables that

have been completed by task order, the completion date, 3) summary of deliverables in progress by task order and whether or not these projects are on schedule, and whether any problems were encountered in the collection, handling or processing of data, including resolution of the problems, and 4) information regarding regulatory submissions such as Investigational New Drug (INDs), Drug Master File (DMF), New Drug Applications (NDA), and other documents required by the FDA. The reporting period is a 12 month period which will commence upon award of contract.

## 2. Summary of Salient Results

The Contractor will be required to prepare and submit, with the final report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract. This report shall be required on or before the expiration date of the contract.

### b. Other Reports/Deliverables

#### 1. Section 508 Annual Report

The contractor shall submit an annual Section 508 report in accordance with the schedule set forth in the ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY Article in SECTION H of this contract. The Section 508 Report Template and Instructions for completing the report are available at: <http://www.hhs.gov/od> under "Vendor Information and Documents."

## ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, shall be directed to the Division of Extramural Inventions and Technology Resources (DEITR), OPERA, OER, NIH, 6705 Rockledge Drive, Suite 310, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in Section F of this contract. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer  
National Institutes of Health  
National Cancer Institute  
Office of Acquisition  
Executive Plaza South  
6120 Executive Boulevard, MSC 7195, Room 6012  
Bethesda, Maryland 20892- 7195

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating

to the capabilities of the system can be obtained from the Web ( <http://www.iedison.gov>), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

## **SECTION D - PACKAGING, MARKING AND SHIPPING**

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

## SECTION E - INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this SECTION, Contracting Officer's Technical Representative is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at:  
NIH NCI Division of Cancer Prevention  
Chemopreventive Agent Development Research Group  
6130 Executive Boulevard  
Executive Plaza North Suite 2116, MSC 7322  
Bethesda, MD 20892-7322

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

- d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause **52.246-9, Inspection of Research and Development (Short Form)** (April 1984).

**SECTION F - DELIVERIES OR PERFORMANCE****ARTICLE F.1. DELIVERIES**

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

- a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below [and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract]:

<b>Item</b>	<b>Description</b>	<b>Quantity</b>	<b>Delivery Schedule</b>
(1)	Quarterly Progress Report	1 PDF File each (COTR & CO) & 1 Hardcopy each (COTR & CO)	Due 15 calendar days after end of each reporting period
(2)	Draft Final Task Order Report	1 PDF File each (COTR & CO) & Hardcopy each (COTR & CO)	Due 45 calendar days prior to the task order completion date
(3)	Final Task Order Report	1 PDF File each (COTR & CO) & 1 Hardcopy (COTR & CO)	Due on or before the completion of task order
(4)	Annual Progress Report	1 PDF File each (COTR & CO) & 1 Hardcopy each (COTR & CO)	12 months after contract award and annually thereafter
(5)	Annual Utilization Report	1 PDF File & 1 Hardcopy (CO)	12 months after contract award and annually thereafter
(6)	Final Invention Statement	1 Hardcopy to CO	Due on contract completion date
(7)	Invention Disclosure Report	1 Hardcopy to OPERA	Due on or before contract completion date
(8)	Summary of Salient Results	1 PDF File each (COTR & CO) & 1 Hardcopy each (COTR & CO)	Due on or before contract completion date
(9)	Section 508 Annual Report	1 PDF File each (COTR & CO) & 1 Hardcopy each (COTR & CO)	See Section H
(10)	Section 508 Conformance Certification	Original hardcopy (CO)	See Section H

- b. The above items shall be addressed and delivered to:

<b>Addressee</b>	<b>Deliverable Item No</b>	<b>Quantity</b>
<b>Contracting Officer Technical Representative, (COTR)</b>  <b>[to be named]</b>  NIH NCI Division of Cancer Research  6130 Executive Blvd., EPN Suite 2116, MSC 7322  Bethesda, MD 20892-7322	1 - 4	See quantity
	8 & 9	for each item above

Addressee	Deliverable Item No	Quantity
<b>Contracting Officer (CO) [ to be named]</b>  National Cancer Institute, Office of Acquisitions  6120 Executive Blvd., Room 6002  Bethesda, MD 20892	1 - 6  8 - 10	See quantity  for each item  above
Division of Extramural Inventions and Technology Resources (DEITR) OPERA, OER, NIH 6705 Rockledge Drive, Suite 310, MSC 7980 Bethesda, MD 29892-7980	7	See quantity  for each item  above

**ARTICLE F.2. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)**

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: <http://www.acquisition.gov/comp/far/index.html>

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

**52.242-15, Stop Work Order** (August 1989) with **Alternate I** (April 1984).

## **SECTION G - CONTRACT ADMINISTRATION DATA**

### **ARTICLE G.1. CONTRACTING OFFICER'S TECHNICAL REPRESENTATIVE (COTR)**

The following Contracting Officer's Technical Representative (COTR) will represent the Government for the purpose of this contract:

To be specified prior to award.

The COTR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its COTR designation.

### **ARTICLE G.2. KEY PERSONNEL, HHSAR 352.242-70 (January 2006)**

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

(End of Clause)

The following individual(s) is/are considered to be essential to the work being performed hereunder:

Name	Title

### **ARTICLE G.3. METHOD OF ORDERING**

- a. A Task/Delivery Order Number shall be given to you at the time the order is placed. The Contractor is cautioned not to accept an order unless one of these numbers is issued.
- b. The Consignees/Ordering Officials shall sign all orders (including written confirmation of oral/telephonic orders) involving requests for supplies and/or services under this contract. Each delivery shall be accompanied by a packing slip or other evidence of delivery/performance.

### **PROCEDURES FOR CONSIDERING MULTIPLE AWARDEES FOR TASK ORDERS**

The resultant contract(s) will be awarded in accordance with RFP N01CN25000-26 and FAR Clause 52.216-27, "Single or Multiple Awards" contained in the RFP.

In accordance with FAR 16.505(b)(1), the Contracting Officer must provide each awardee a fair opportunity to be considered for each order exceeding \$3,000 issued under this requirement, except as provided for in the following paragraph. The Contracting Officer may exercise broad discretion in developing appropriate order placement procedures. Normally, each awardee will receive an opportunity to submit a proposal for the requirement. However, the Contracting Officer need not contact each of the multiple awardees before selecting a Task Order awardee if the Contracting Officer has sufficient information available to ensure that each awardee receives a fair opportunity to be considered for each Task Order. This information may include factors such as past performance on earlier tasks under the Basic Contract, quality of deliverables, cost control, price, cost, or other factors that the Contracting Officer believes are relevant to the award of a Task Order under this contract.

In accordance with FAR 16.505(b)(2), awardees need not be given a fair opportunity to be considered for a particular order in excess of \$3,000 if the Contracting Officer determines that:

- (a) The agency need for the supplies or services is so urgent that providing a fair opportunity would result in unacceptable delays;
- (b) Only one awardee is capable of providing the supplies or services required at the level of quality required because the supplies or services ordered are unique or highly specialized;
- (c) The order must be issued on a sole source basis in the interest of economy and efficiency as a logical follow-on to an order already issued under the contract, provided that all awardees were given a fair opportunity to be considered for the original order; or
- (d) It is necessary to place an order to satisfy a minimum guarantee.

Past performance may be used to evaluate the contractor in performance of each Task Order. The Government may use the Contractor's past performance when determining whether sufficient information exists on an awardee prior to considering multiple awardees for award of a Task Order under this contract.

**ORDERING**

When the Government develops a Task Order requirement, it will provide a Statement of Work and enough information for the purpose of soliciting proposals and selecting the most advantageous offer from among the multiple contract awardees.

- (a) The Government shall have the option to issue a Task Order on a cost reimbursement or fixed price basis. If the Statement of Work includes well-defined requirements/specifications and deliverables, a fixed price Task Order will be issued. Performance based statements of work will be used to the maximum extent practicable. The contract type shall be communicated to the contractors at the time a proposal is requested.
- (b) All Task Orders are subject to the terms and conditions of the Basic Contract. In the event of a conflict between a Task Order and the Basic Contract, the Basic Contract shall control.

<b>The authorized designees are:</b>	

**The following Contractor representative(s) is/are authorized to receive and accept orders placed by telephone:**

<b>Name(s):</b>	
<b>Telephone:</b>	

### **TASK ORDER PROCEDURES**

In providing services under this contract, the following procedures shall apply to the award of Task Orders:

All work required under this contract shall be authorized through the execution of a task order signed by the Contractor and the Contracting Officer. Task Orders may be awarded at any time within the contract period.

Subject to the exceptions described under A Procedures for Considering Multiple Awardees for Task Orders above, when the Government elects to fill a requirement that is estimated to exceed \$3,000, the Contracting Officer shall provide a Task Order solicitation to the multiple awardees who were awarded a contract under the RFP referenced above. The Task Order Solicitation shall include, at a minimum, 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 be based on the individual task order requirements. Task Order proposals shall generally be limited to ten (10) pages, excluding CVs and resumes.

Within seven (7) calendar days (or longer if stated in the Task Order solicitation), Contractors shall submit their proposals which shall include, but not necessarily be limited to, the following information:

#### Technical Proposal

- (a) An approach and workplan indicating how each aspect of the statement of work will be accomplished.
- (b) Information about how the project will be organized, staffed and managed, including consultants and subcontractors if appropriate. (A one page CV or resume should be submitted for each individual proposed on the project.)
- (c) A list of names and proposed duties of professional staff (including consultants and subcontract personnel as applicable) assigned to the project. It is not necessary to include resumes unless they were not previously presented as backup for the original award.

#### Business Proposal

- (a) The submission of cost or pricing information in sufficient detail to allow a complete cost analysis.
- (b) A detailed cost breakdown.
- (c) A statement that your proposal is predicated upon all the terms and conditions of your Basic Contract.

The Government will evaluate proposals and conduct negotiations, if necessary. Task Orders will be awarded to the Contractor whose proposal is determined to be the most advantageous to the Government based upon the technical and cost factors specified in the Task Order solicitation. The Government reserves the right to make an award based upon the most favorable initial proposal received without discussions.

The Contracting Officer is the only individual authorized to issue a Task Order solicitation or award a Task Order under the Basic Contract. Unless specifically authorized by the Contracting Officer, the Contractor shall not commence with work on a requirement until a fully executed Task Order has been awarded.

It is anticipated that Task Orders will be awarded within 7-30 days from receipt of Task Order proposals. Each individual Task Order shall be subject to the terms and conditions of the Basic Contract and also will contain terms and conditions specific to that individual Task Order. At a minimum, the individual Task Orders will contain the following information:

Date  
Contract Number

Performance Period, including any options  
Description of Services, quantity, estimated cost and/or unit prices, fixed fee/profit  
Deliverables or performance schedule  
Name and address of sponsoring office  
Name of Task Order Monitor (TOM)  
Place of Performance  
Packaging, packing, and shipping instructions, if any  
Accounting and appropriation data  
Any other pertinent information

No protest under FAR Subpart 33.1 is authorized in connection with the issuance or proposed issuance of a Task Order under the Basic 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 Basic Contract are not subject to the competition requirements of FAR Part 6.

Notwithstanding the procedures above, the Government reserves the right to place Task Orders with each of the Contractors who received a contract as a result of the solicitation sufficient to meet the minimum guarantees specified within Section B. of their Basic Contract, without resorting to the procedures outlined above.

#### **ARTICLE G.4. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT**

- a. Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**

- a. The original invoice shall be submitted to the following **designated billing office**:

National Institutes of Health  
Office of Financial Management  
Commercial Accounts  
2115 East Jefferson Street, Room 4B-432, MSC 8500  
Bethesda, MD 20892-8500

- b. One copy of the invoice shall be submitted to the following **approving official**:

Contracting Officer (to be named)  
Office of Acquisitions  
National Cancer Institute  
Executive Plaza South Room \_\_\_  
6120 Executive Boulevard MSC \_\_\_  
Bethesda, MD 20892- \_\_\_

E-Mail: (electronic submission TBD at time of award)

The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to

the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.

***[Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."]***

2. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:
  - a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is National Cancer Institute .
  - b. Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NCI OA Branch A - ncibranchinvoices@mail.nih.gov .
  - c. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.
  - d. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[ Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.
  - e. Invoice Matching Option. This contract requires a two-way match.
  - f. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.
  
- b. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6452.

## **ARTICLE G.5. INDIRECT COST RATES**

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d)(2), Allowable Cost and Payment incorporated by reference in this contract in PART II, SECTION I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services  
 Office of Acquisition Management and Policy  
 National Institutes of Health  
 6011 EXECUTIVE BLVD, ROOM 549C, MSC-7663  
 BETHESDA MD 20892-7663

These rates are hereby incorporated without further action of the Contracting Officer.

## **ARTICLE G.6. GOVERNMENT PROPERTY**

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real

property), this ARTICLE will include applicable provisions and incorporate the HHS Publication, entitled, "HHS Contracting Guide for Contract of Government Property," which can be found at:

[http://rcb.cancer.gov/rcb-internet/reference/Appendix Q\\_HHS Contracting Guide.pdf](http://rcb.cancer.gov/rcb-internet/reference/Appendix Q_HHS Contracting Guide.pdf).

## **ARTICLE G.7. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE**

### **a. Contractor Performance Evaluations**

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) will be prepared as needed.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

### **b. Electronic Access to Contractor Performance Evaluations**

Contractors may access evaluations through a secure Web site for review and comment at the following address:

<http://www.cpars.csd.disa.mil>

## SECTION H - SPECIAL CONTRACT REQUIREMENTS

### ARTICLE H.1. HUMAN SUBJECTS

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

### ARTICLE H.2. SALARY RATE LIMITATION, HHSAR 352.231-70 (January 2010)

- a. Pursuant to the current and applicable prior HHS appropriations acts, the Contractor shall not use contract funds to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level I in effect on the date an expense is incurred.
- b. For purposes of the salary rate limitation, the terms "direct salary," "salary," and "institutional base salary" have the same meaning and are collectively referred to as "direct salary" in this clause. An individual's direct salary is the annual compensation that the Contractor pays for an individual's direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative [F&A] costs).
 

**Note:** The salary rate limitation does not restrict the salary that an organization may pay an individual working under an HHS contract or order; it merely limits the portion of that salary that may be paid with Federal funds.
- c. The salary rate limitation also applies to individuals under subcontracts. If this is a multiple-year contract or order, it may be subject to unilateral modification by the Contracting Officer to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act in effect when the expense is incurred regardless of the rate initially used to establish contract or order funding.
- d. See the salaries and wages pay tables on the U.S. Office of Personnel Management Web site for Federal Executive Schedule salary levels that apply to the current and prior periods.

(End of clause)

See the following Web site for Executive Schedule rates of pay: <http://www.opm.gov/oca/>.

*(For current year rates, click on Salaries and Wages / Executive Schedule / Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages / select Another Year at the top of the page / Executive Schedule / Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)*

### ARTICLE H.3. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

NIH-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: <http://www.pubmedcentral.nih.gov>.

Additional information is available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html>.

#### **ARTICLE H.4. NEEDLE DISTRIBUTION**

The Contractor shall not use contract funds to distribute any needle or syringe for the purpose of preventing the spread of blood borne pathogens in any location that has been determined by the local public health or local law enforcement authorities to be inappropriate for such distribution.

#### **ARTICLE H.5. PRESS RELEASES**

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

#### **ARTICLE H.6. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH**

The Contractor shall not use contract funds for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

#### **ARTICLE H.7. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING SCIENTIFIC INFORMATION**

The Contractor shall not use contract funds to disseminate scientific information that is deliberately false or misleading.

#### **ARTICLE H.8. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS**

The Contractor shall not use contract funds to employ workers described in section 274A(h)(3) of the Immigration and Nationality Act, which reads as follows:

"(3) Definition of unauthorized alien. - As used in this section, the term 'unauthorized alien' means, with respect to the employment of an alien at a particular time, that the alien is not at that time either (A) an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

#### **ARTICLE H.9. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (October 2009)**

- a. Before undertaking performance of any contract involving animal-related activities where the species is regulated by USDA, the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR sections 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.
- b. The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR Sections 2.1-2.11, or from a source that is exempt from licensing under those sections.
- c. The Contractor agrees that the care, use and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care of Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the

United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR Subchapter A, Parts 1-4). In case of conflict between standards, the more stringent standard shall govern.

- d. If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved Assurances.

**Note:** The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (E-mail: [ace@aphis.usda.gov](mailto:ace@aphis.usda.gov); Web site: ( [http://www.aphis.usda.gov/animal\\_welfare](http://www.aphis.usda.gov/animal_welfare))).

(End of Clause)

## ARTICLE H.10. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy can be accessed at: <http://grants1.nih.gov/grants/olaw/references/phspol.htm>

In addition, the research involving live vertebrate animals shall be conducted in accordance with the description set forth in the Vertebrate Animal Section (VAS) of the contractor's technical proposal, as modified in the Final Proposal Revision (FPR), dated \_\_\_\_\_, which is incorporated by reference.

## ARTICLE H.11. PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

All Contractor personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates shall comply with the procedures set forth in NIH Policy Manual 3044-2, entitled, "Protection of NIH Personnel Who Work with Nonhuman Primates," located at the following URL:

<http://www1.od.nih.gov/oma/manualchapters/intramural/3044-2/>

## ARTICLE H.12. SUBCONTRACTING PROVISIONS

### a. Small Business Subcontracting Plan

1. The Small Business Subcontracting Plan, dated \_\_\_\_\_ is attached hereto and made a part of this contract.
2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

### b. Subcontracting Reports

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at <http://www.esrs.gov>.

1. Individual Subcontract Reports (ISR)

Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:

April 30th  
October 30th  
Expiration Date of Contract

2. Summary Subcontract Report (SSR)

Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

October 30th

For both the Individual and Summary Subcontract Reports, the Contract Specialist shall be included as a contact for notification purposes at the following e-mail address:

searsky@mail.nih.gov  
Contract Specialist

**ARTICLE H.13. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY, HHSAR 352.239-73(b) (January 2010)**

- a. Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 provisions is available at <http://www.section508.gov/>. The complete text of Section 508 Final provisions can be accessed at <http://www.access-board.gov/sec508/provisions.htm>.
- b. The Section 508 standards applicable to this contract/order are identified in the Statement of Work. The contractor must provide a written Section 508 conformance certification due at the end of each contract/order exceeding \$100,000 when the contract/order duration is one year or less. If it is determined by the Government that EIT products and services provided by the Contractor do not conform to the described accessibility standards in the Product Assessment Template, remediation of the products or services to the level of conformance specified in the Contractor's Product Assessment Template will be the responsibility of the Contractor at its own expense.
- c. In the event of a modification(s) to this contract/order, which adds new EIT products or services or revises the type of, or specifications for, products or services the Contractor is to provide, including EIT deliverables such as electronic documents and reports, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template to assist the Government in determining that the EIT products or services support Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS Office on Disability Web site ( <http://www.hhs.gov/od/>).

[(End of HHSAR 352.239-73(b))]

- d. Prior to the Contracting Officer exercising an option for a subsequent performance period/additional quantity or adding funding for a subsequent performance period under this contract, as applicable, the Contractor must provide a Section 508 Annual Report to the Contracting Officer and Project Officer. Unless otherwise directed by the Contracting Officer in writing, the Contractor shall provide the cited report in accordance with the following schedule. Instructions for completing the report are available in the Section 508 policy on the HHS Office on Disability Web site under the heading Vendor Information and Documents. The Contractor's failure to submit a timely and properly completed report may jeopardize the Contracting Officer's exercising an option or adding funding, as applicable.

**Schedule for Contractor Submission of Section 508 Annual Report:**

Annually

[End of HHSAR 352.239-73(c)]

## ARTICLE H.14. INSTITUTIONAL RESPONSIBILITY REGARDING CONFLICTING INTERESTS OF INVESTIGATORS

The Contractor shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that investigators (defined as the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded under NIH contracts) will not be biased by any conflicting financial interest. For the purposes of this part relating to financial interests, "Investigator" includes the Investigator's spouse and dependent children. 45 CFR Part 94 is available at the following Web site:

<http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;sid=cfc3d0caac2d06e14935ada5731b763d;rgn=div5;view=text;node=45%3A1.0.1.1.52;idno=45;cc=ecfr>

As required by 45 CFR Part 94, the Contractor shall, at a minimum:

- a. Maintain a written, enforceable policy on conflict of interest that complies with 45 CFR Part 94 and inform each investigator of the policy, the investigator's reporting responsibilities, and the applicable regulations. The Contractor must take reasonable steps to ensure that investigators working as collaborators or subcontractors comply with the regulations.
- b. Designate an official(s) to solicit and review financial disclosure statements from each investigator participating in NIH-funded research. Based on established guidelines consistent with the regulations, the designated official(s) must determine whether a conflict of interest exists, and if so, determine what actions should be taken to manage, reduce, or eliminate such conflict. A conflict of interest exists when the designated official(s) reasonably determines that a *Significant Financial Interest* could directly and significantly affect the design, conduct, or reporting of the NIH-funded research. The Contractor may require the management of other conflicting financial interests in addition to those described in this paragraph, as it deems appropriate. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests are included in 45 CFR Part 94, under Management of Conflicting Interests.
- c. Require all financial disclosures to be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.
- d. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the Contractor with respect to each conflicting interest 3 years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.
- e. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

If a conflict of interest is identified, the Contractor shall report to the Contracting Officer, the existence of the conflicting interest found. This report shall be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis, within sixty (60) days of that identification.

If the failure of an investigator to comply with the conflict of interest policy has biased the design, conduct, or reporting of the NIH-funded research, the Contractor must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will take appropriate action or refer the matter to the Contractor for further action, which may include directions to the Contractor on how to maintain appropriate objectivity in the funded research.

The Contracting Officer may at any time inquire into the Contractor's procedures and actions regarding conflicts of interests in NIH-funded research, including a review of all records pertinent to compliance with 45 CFR Part 94. The Contracting Officer may require submission of the records or review them on site. On the basis of this review, the Contracting Officer may decide that a particular conflict of interest will bias the objectivity of the NIH-funded research to such an extent that further corrective action is needed or that the Contractor has not managed, reduced,

or eliminated the conflict of interest. The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that NIH-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an investigator with a conflict of interest that was not disclosed or managed, the Contractor must require disclosure of the conflict of interest in each public presentation of the results of the research.

## ARTICLE H.15. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the \_\_\_\_\_, National Institutes of Health, Department of Health and Human Services, under Contract No. \_\_\_\_\_"

## ARTICLE H.16. TASK ORDER/DELIVERY ORDER CONTRACT OMBUDSMAN

In accordance with FAR 16.505(b)(5), the following individual has been designated as the NIH Ombudsman for task order and delivery order contracts.

[The appropriate individual will be included in the resultant contract as follows:]

For R&D Contracts:	For Non R&D Contracts:
Dr. Walter Schaffer	Dr. Richard G. Wyatt
NIH Competition Advocate	NIH Competition Advocate
6705 Rockledge Drive, Room 3537	1 Center Drive, Room 160, MSC 0151
Bethesda, MD 20817	Bethesda, MD 20892-0151
Phone: (301) 435-2687	Phone: (301) 496-4920
FAX: (301) 480-0146	FAX: (301) 402-4273
e-mail: <a href="mailto:schaffew@od.nih.gov">schaffew@od.nih.gov</a> e-mail:	e-mail: <a href="mailto:WyattRG@mail.nih.gov">WyattRG@mail.nih.gov</a>

## ARTICLE H.17. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477)**. All telephone calls will be handled confidentially. The e-mail address is [Htips@os.dhhs.gov](mailto:Htips@os.dhhs.gov) and the mailing address is:

Office of Inspector General  
 Department of Health and Human Services  
 TIPS HOTLINE  
 P.O. Box 23489  
 Washington, D.C. 20026

## ARTICLE H.18. YEAR 2000 COMPLIANCE

In accordance with FAR 39.106, Information Technology acquired under this contract must be Year 2000 compliant as set forth in the following clause(s):

**1. Service Involving the Use of Information Technology**  
**YEAR 2000 COMPLIANCE--SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY**

The Contractor agrees that each item of hardware, software, and firmware used under this contract shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations.

(End of Clause)

**ARTICLE H.19. INTELLECTUAL PROPERTY OPTION TO COLLABORATOR**

NCI may collaborate with an outside investigator who has proprietary rights to compounds which may be assigned under this contract. This collaborator will be identified by the Contracting Officer's Technical Representative (COTR) at the time of assignment and in this case, the following option regarding Intellectual Property Rights will be applicable.

Contractor agrees to promptly notify the NCI and "Collaborator" in writing of any inventions, discoveries or innovations made by the Contractor's principal investigator or any other employees or agents of the Contractor, whether patentable or not, which are conceived and/or first actually reduced to practice in the performance of this study using Collaborator's Study Agent (hereinafter "Contractor Inventions").

Contractor agrees to grant to Collaborator: (1) a paid-up nonexclusive, nontransferable, royalty-free, world-wide license to all Contractor Inventions for research purposes only; and (2) a time-limited first option to negotiate an exclusive world-wide royalty-bearing license for all commercial purposes, including the right to grant sub-licenses, to all Contractor Inventions on terms to be negotiated in good faith by Collaborator and Contractor. Collaborator shall notify Contractor, in writing, of its interest in obtaining an exclusive license to any Contractor Invention within six (6) months of Collaborator's receipt of notice of such Contractor Invention(s). In the event that Collaborator fails to so notify Contractor or elects not to obtain an exclusive license, then Collaborator's option shall expire with respect to that Contractor Invention, and Contractor will be free to dispose of its interests in such Contractor Invention in accordance with its own policies. If Contractor and Collaborator fail to reach agreement within ninety (90) days, (or such additional period as Collaborator and Contractor may agree) on the terms for an exclusive license for a particular Contractor Invention, then for a period of six (6) months thereafter, Contractor shall not offer to license the Contractor Invention to any third party on materially better terms than those last offered to Collaborator without first offering such terms to Collaborator, in which case Collaborator shall have a period of thirty (30) days in which to accept or reject the offer.

Contractor agrees that notwithstanding anything herein to the contrary, any inventions, discoveries or innovations, whether patentable or not, which are not Subject Inventions as defined in 35 U.S.C. 201(e),\* arising out of any unauthorized use of the Collaborator's Study Agent shall be the property of the Collaborator (hereinafter "Collaborator Inventions"). Contractor will promptly notify the Collaborator in writing of any such Collaborator Inventions and, at Collaborator's request and expense, Contractor will cause to be assigned to Collaborator all right, title and interest in an to any such Collaborator Inventions and provide Collaborator with reasonable assistance to obtain patents (including causing the execution of any invention assignment or other documents). Contractor may also be conducting other more basic research using Study Agent under the authority of a separate Material Transfer Agreement (MTA), or other such agreement with the Collaborator. Inventions arising thereunder shall be subject to the terms of the MTA, and not to this clause.

\*35 U.S.C. 201(e): The term "subject invention" means any invention of the Contractor conceived or first actually reduced to practice in the performance of work under a funding agreement: Provided, that in the case of a variety of plant, the date of determination (as defined in section 41(d)(FOOTNOTE 1) of the Plant Variety Protection Act (7 U.S.C. 2401(d)) must also occur during the period of contract performance.

**Protection of Proprietary Data**

Data generated using an investigational agent proprietary to a Collaborator will be kept confidential and shared only with the NCI and the Collaborator. The Contractor retains the right to publish research results subject to the terms of this contract.

## **ARTICLE H.20. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES**

Unique research resources arising from NIH-funded research are to be shared with the scientific research community. NIH provides guidance, entitled, "Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice," (Federal Register Notice, December 23, 1999 [64 FR 72090]), concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at: <http://ott.od.nih.gov/pdfs/64FR72090.pdf> is intended to help contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

Note: For the purposes of this Article, the terms, "research tools", "research materials", and "research resources" are used interchangeably and have the same meaning.

## **ARTICLE H.21. SHARING RESEARCH DATA**

[The data sharing plan submitted by the Contractor is acceptable/The Contractor's data sharing plan, dated \_\_\_\_\_ is hereby incorporated by reference.] The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

The NIH endorses the sharing of final research data to serve health. this contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Privacy Rule at <http://www.hhs.gov/ocr/>). The rights and privacy of people who participate in NIH-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

## **ARTICLE H.22. CONSTITUTION DAY**

Each educational institution that receives Federal funds for a fiscal year shall hold an educational program on the United States Constitution on September 17 of such year for the students serviced by the educational institution in accordance with Public Law 108-447.

## **PART II - CONTRACT CLAUSES**

### **SECTION I - CONTRACT CLAUSES**

THE FOLLOWING ARTICLE I.1. GENERAL CLAUSE LISTING(S) WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP:

The complete listing of these clauses may be accessed at:

<http://rcb.cancer.gov/rcb-internet/appl/general-clauses/clausesDGS.jsp>

#### **ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT CONTRACT WITH EDUCATIONAL INSTITUTIONS**

#### **ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT CONTRACT WITH NON-PROFIT ORGANIZATIONS OTHER THAN EDUCATIONAL INSTITUTIONS**

#### **ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT**

#### **ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED FIXED-PRICE RESEARCH AND DEVELOPMENT CONTRACT**

## ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following substitution(s) will be made part of the resultant contract:

- a. FAR Clauses **52.215-15, Pension Adjustments and Asset Reversions** (October 2010); **52.215-18, Reversion or Adjustment of Plans for Post Retirement Benefits (PRB) Other Than Pensions** (July 2005); and, **52.215-19, Notification of Ownership Changes** (October 1997), are deleted in their entirety.
- b. **Alternate IV** (October 2010) of FAR Clause **52.215-21, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data--Modifications** (October 2010) is added.
- c. **Alternate II** (October 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (January 2011) is added.
- d. FAR Clauses **52.249-6, Termination (Cost-Reimbursement)** (May 2004) and **52.249-14, Excusable Delays** (April 1984), are deleted in their entirety and FAR Clause **52.249-5, Termination for Convenience of the Government (Educational and Other Nonprofit Institutions)** (September 1996), is substituted therefore.
- e. FAR Clause **52.249-9, Default (Fixed-Price Research and Development)** (April 1984) is deleted in its entirety and FAR Clause **52.249-5, Termination for Convenience of the Government (Educational and Other Nonprofit Institutions)** (September 1996), is substituted therefore.

## 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 Clause **52.216-15, Predetermined Indirect Cost Rates** (April 1998).

2. FAR Clause **52.216-18, Ordering** (October 1995).

"(a) ....Such orders may be issued from September 7, 2012 through September 6, 2014 .

3. FAR Clause **52.216-22, Indefinite Quantity** (October 1995).

"(d) ...the Contractor shall not be required to make any deliveries under this contract after the completion of the last Task Order."

4. FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (January 2011).

"(c) Waiver of evaluation preference.....

[ ] Offeror elects to waive the evaluation preference."

5. FAR Clause **52.219-28, Post-Award Small Business Program Rerepresentation** (April 2009).

6. FAR Clause **52.227-14, Rights in Data - General** (December 2007).

7. **Alternate IV** (December 2007), FAR Clause **52.227-14, Rights in Data - General** (December 2007).

8. **Alternate V** (December 2007), FAR Clause **52.227-14, Rights in Data--General** (December 2007).

Specific data items that are not subject to paragraph (j) include:

9. FAR Clause **52.227-16, Additional Data Requirements** (June 1987).

10. FAR Clause **52.227-17, Rights in Data--Special Works** (December 2007).

11. FAR Clause **52.230-2, Cost Accounting Standards** (October 2010).

12. FAR Clause **52.230-3, Disclosure and Consistency of Cost Accounting Practices** (October 2008).

13. FAR Clause **52.230-5, Cost Accounting Standards - Educational Institution** (October 2010).

14. FAR Clause **52.230-6, Administration of Cost Accounting Standards** (June 2010).
  15. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).
  16. FAR Clause **52.243-2, Changes--Cost Reimbursement** (August 1987), **Alternate V** (April 1984).
  17. FAR Clause **52.251-1, Government Supply Sources** (August 2010).
- b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:
1. HHSAR Clause **352.223-70, Safety and Health** (January 2006).

## 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:

a. FAR Clause **52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters** (January 2011)

(a) The Contractor shall update the information in the Federal Awardee Performance and Integrity Information System (FAPIS) on a semi-annual basis, throughout the life of the contract, by posting the required information in the Central Contractor Registration database at <http://www.ccr.gov>.

(b)(1) The Contractor will receive notification when the Government posts new information to the Contractor's record.

(2) The Contractor will have an opportunity to post comments regarding information that has been posted by the Government. The comments will be retained as long as the associated information is retained, i.e., for a total period of 6 years. Contractor comments will remain a part of the record unless the Contractor revises them.

(3) (i) Public requests for system information prior to April 15, 2011, will be handled under Freedom of Information Act procedures, including, where appropriate, procedures promulgated under E.O. 12600.

(ii) As required by section 3010 of Public Law 111-212, all information posted in FAPIS on or after April 15, 2011, except past performance reviews, will be publicly available.

(End of clause)

b. FAR Clause **52.216-19, Order Limitations** (October 1995)

(a) **Minimum Order.** When the Government requires supplies or services covered by this contract in an amount of less than 1,000, the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.

(b) **Maximum Order.** The Contractor is not obligated to honor--

(1) Any order for a single item in excess of 2,200,000.

(2) Any order for a combination of items in excess of 2,200,000; or

(3) A series of orders from the same ordering office within 14 days that together call for quantities exceeding the limitation in subparagraph (1) or (2) above.

(c) If this is a requirements contract (i.e., includes the Requirements clause at subsection 52.216-21 of the Federal Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) above.

(d) Notwithstanding paragraphs (b) and (c) above, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to the ordering office within \_ days after issuance, with written notice stating the Contractor's intent not to ship the item (or

items) called for and the reasons. Upon receiving this notice, the Government may acquire the supplies or services from another source.

## PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

### SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

#### SOLICITATION ATTACHMENTS

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal (R & D)	<a href="#">Attach1-Packaging&amp;Delivery_of_Proposal.pdf</a>
Attachment 2:	Proposal Intent Response Sheet	<a href="http://rcb.cancer.gov/rcb-internet/forms/intent.jsp">http://rcb.cancer.gov/rcb-internet/forms/intent.jsp</a>
Attachment 3:	Statement of Work	<a href="#">Attach3-StatementofWork.pdf</a>

#### TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 4:	Technical Proposal Cost Summary	<a href="http://www.niaid.nih.gov/researchfunding/contract/pages/forms.aspx">http://www.niaid.nih.gov/researchfunding/contract/pages/forms.aspx</a>
Attachment 5:	Summary of Related Activities	<a href="http://www.niaid.nih.gov/researchfunding/contract/pages/forms.aspx">http://www.niaid.nih.gov/researchfunding/contract/pages/forms.aspx</a>
Attachment 6:	Contract Proposal Vertebrate Animal Section (VAS) Worksheet	<a href="http://grants.nih.gov/grants/olaw/VAScontracts.pdf">http://grants.nih.gov/grants/olaw/VAScontracts.pdf</a>
Attachment 7:	HHS Section 508 Product Assessment Template	<a href="http://www.hhs.gov/od/vendors/index.html">http://www.hhs.gov/od/vendors/index.html</a>

#### BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 8:	Proposal Summary and Data Record, NIH-2043	<a href="http://www.niaid.nih.gov/researchfunding/contract/pages/forms.aspx">http://www.niaid.nih.gov/researchfunding/contract/pages/forms.aspx</a>
Attachment 9:	Small Business Subcontracting Plan	<a href="http://www.hhs.gov/about/smallbusiness/subcontractplan.html">http://www.hhs.gov/about/smallbusiness/subcontractplan.html</a>
Attachment 10:	Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet	<a href="http://oamp.od.nih.gov/contracts/BUSCOST.HTM">http://oamp.od.nih.gov/contracts/BUSCOST.HTM</a> <a href="http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls">http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls</a>
Attachment 11:	Offeror's Points of Contact	<a href="http://www.niaid.nih.gov/researchfunding/contract/pages/forms.aspx">http://www.niaid.nih.gov/researchfunding/contract/pages/forms.aspx</a>
Attachment 12:	Disclosure of Lobbying Activities, OMB Form SF-LLL	<a href="http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf">http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf</a>

**INFORMATIONAL ATTACHMENTS**

<b>Attachment No.</b>	<b>Title</b>	<b>Location</b>
Attachment 13:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	<a href="http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf">http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf</a>
Attachment 14:	Safety and Health, HHSAR Clause 352.223-70	<a href="http://rcb.cancer.gov/rcb-internet/forms/safety&amp;health-1-06.pdf">http://rcb.cancer.gov/rcb-internet/forms/safety&amp;health-1-06.pdf</a>
Attachment 15:	References See Attached	<a href="#">Attach15-References.pdf</a>

## **PART IV - REPRESENTATIONS AND INSTRUCTIONS**

### **SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS**

#### **IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :**

1. Go to the **Online Representations and Certifications Application (ORCA)** at: <https://orca.bpn.gov/> and complete the Representations and Certifications; and
2. Complete, and **INCLUDE as part of your BUSINESS PROPOSAL:**  
**SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS**  
which is included as an Attachment in Section J-LIST OF ATTACHMENTS, SOLICITATION ATTACHMENTS of this solicitation.

If you are unable to access this SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

## SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

### 1. GENERAL INFORMATION

#### a. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION [FAR Provision 52.215-1 (January 2006)]

(a) *Definitions.* As used in this provision--

"*Discussions*" are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"*In writing*", "*writing*", or "*written*" means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time*," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations.* If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals.*

(1) Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

(i) The solicitation number;

(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);

(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and

(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals.*

(i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date.* Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

(e) *Restriction on disclosure and use of data.*

(1) The proposal submitted in response to this request may contain data (trade secrets; business data (e.g., commercial information, financial information, cost and pricing data); and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following statements, specifying the particular portions of the proposal which are to be restricted:

"Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services (HHS), data contained in the portions of this proposal which the offeror has specifically identified by page number, paragraph, etc. as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that HHS may not be able to withhold a record (e.g. data, document, etc.) nor deny access to a record requested pursuant to the Act and that the HHS's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if HHS has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages ( *insert page numbers, paragraph designations, etc. or other identification* )."

(2) In addition, the offeror must mark each page of data it wishes to restrict with the following statement:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive statements or statements differing in substance from those cited above may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming statement(s).

(f) *Contract award.*

(1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. 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.

- (5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.
  - (6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.
  - (7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.
  - (8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.
  - (9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.
  - (10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.
  - (11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:
    - (i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.
    - (ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.
    - (iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
    - (iv) A summary of the rationale for award.
    - (v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.
    - (vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.
- (End of Provision)

**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.

**b. 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.

1. The North American Industry Classification System (NAICS) code for this acquisition is 541711.
2. The small business size standard is 500.

**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.**

**c. TYPE OF CONTRACT AND NUMBER OF AWARDS**

1. It is anticipated that 4 award(s) will be made from this solicitation and that the award(s) will be made on/about September 7, 2012.
2. It is anticipated that the award(s) from this solicitation will be an Indefinite Delivery, Indefinite Quantity Type contract with a Period of Performance of 2 years.
3. FAR 16.301-3 limits use of any contract type, other than firm-fixed price, to a contractor whose accounting system is adequate for determining costs applicable to the contract. To be considered for an award under this solicitation, the Offeror is required to certify, in its Business Proposal, the adequacy of its accounting system. See the paragraph entitled, Adequate Accounting System in Section L.2. Business Proposal Instructions in this solicitation for additional information about this certification.

**d. 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.

**e. 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 other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

**f. 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.

**g. PREPARATION COSTS**

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

**h. SERVICE OF PROTEST (SEPTEMBER 2006) - 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 Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Contracting Officer  
Office of Acquisitions  
National Cancer Institute  
Executive Plaza South, Room 6012  
6120 EXECUTIVE BLVD MSC 7195  
BETHESDA MD 20892- 7195

(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)

**i. LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70 (January 2006)**

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors-Competitive Acquisition, the Government may consider a proposal received after the date specified for receipt if it appears to offer the best value to the Government and it was received before proposals were distributed for evaluation, or within 5 calendar days after the exact time specified for receipt, whichever is earlier.

(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 Indefinite Delivery/Indefinite Quantity 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.

### 3. Additional Technical Proposal Instructions

**TOTAL PAGE COUNT DOES INCLUDE:** Principal Investigator's (PI's) resume/Curriculum Vitae (CV), with highlights of any items that are directly related to the subject project, indicated by preceding them with a double asterisk (\*\*).

**TOTAL PAGE COUNT DOES NOT INCLUDE** (some of which may be added as appendices): Title and Back Page; NIH-2043; Table of Contents; Section Dividers that do not contain information other than title of Section; Resumes/CVs of other key personnel (same information and format as used for the PI); certificates and licensures, examples of protocols, Standard Operating Procedures (SOP), Health and Safety Manual, letters of commitment by proposed consultants and subcontractors.

**PAGES THAT ARE 2-SIDED WILL COUNT AS 2 PAGES.**

#### **FORMATTING AND LAYOUT:**

Use your usual word processing and spreadsheet programs to prepare and format the technical and business proposals.

***Documents submitted using Adobe .pdf shall be submitted using a .pdf searchable format.***

- Type size must be 10 to 12 points.
- Type spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
- Print margins must be at least one inch on each edge of the paper.
- Print setup should be single-sided on standard letter size paper (8.5 x 11").
- Offerors shall NOT use 8.5 x 14 legal size paper.
- Proposals shall NOT include links to Internet Web site addresses (URLs) or otherwise direct readers/reviewers to alternate sources of information.
- Additional appendices may be added as needed
- The proposal, including appendices, shall be formatted by sections, cross referenced, and include a detailed Table of Contents

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, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

#### 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 SECTION J, Attachment entitled, TECHNICAL PROPOSAL COST SUMMARY.) 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. Alternate Proposals

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

#### 6. Evaluation of Proposals

The Government will evaluate proposals in accordance with the factors set forth in PART IV, SECTION M of this RFP.

#### 7. 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.

#### 8. 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.

## 9. Privacy Act - Treatment of Proposal Information

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the Government Accountability Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

## 10. Selection of Offerors

- a. The acceptability of the scientific 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 factors 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 NCI's policy to conduct discussions with all offerors in the competitive range, NCI 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 source 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.
- f. The NCI 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 NCI requirements. Synopses of awards exceeding \$25,000 will be published in FedBizOpps.

#### 11. Institutional Responsibility Regarding Conflicting Interests of Investigators

45 CFR Part 94 promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research to be performed under NIH contracts will be biased by any conflicting financial interest of an Investigator. The Institution shall comply with all requirements of 45 CFR Part 94 at <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;sid=9f130b6d2d48bb73803ca91ce943be3a;rgn=div5;view=text;node=45%3A1.0.1.1.53;idno=45;cc=ecfr>

#### 12. ROTC Access and Federal Military Recruiting on Campus

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented ) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

#### 13. Past Performance Information

- a. Offerors shall submit the following information as part of their Business proposal.

A list of the last 3 contracts completed during the past Five years and ALL CONTRACTS currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such

information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as \$500,000.

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. North American Industry Classification System (NAICS) Code

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

- b. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

#### 14. **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.acquisition.gov/far/index.html>.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- a. Facilities Capital Cost of Money, FAR Clause 52.215-16, (June 2003).
- b. Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

#### 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.

**Note to Offerors:** Beginning May 25, 2008, the offeror shall include the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.

#### 1. **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

**a. Statement of Work**

1. Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

2. Approach

The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives. Proposals which merely restate the requirements of the Government's scope of work will not be eligible for award.

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

3. Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

4. Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments of work, as applicable, by contract year as well as for the overall contract. 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.

**b. Personnel**

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.**

### 1. Single 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.

### 2. 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.

### 3. 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.

## 2. 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.

### 3. Technical Evaluation

Proposals will be technically evaluated in accordance with SECTION M - Evaluation Factors for Award of this solicitation.

### 4. Care of Live Vertebrate Animals

The following notice is applicable when contract performance is expected to involve care of live vertebrate animals:

**Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, HHSAR 352.270-5(a) (January 2006)**

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy) establishes a number of requirements for research activities involving animals. Before award may be made to an applicant organization, the organization shall file, with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), a written Animal Welfare Assurance (Assurance) which commits the organization to comply with the provisions of the PHS Policy, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC). In accordance with the PHS Policy, applicant organizations must establish an Institutional Animal Care & Use Committee (IACUC), qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. Applicant organizations are required to provide verification of IACUC approval prior to release of an award involving live vertebrate animals. No award involving the use of animals shall be made unless OLAW approves the Assurance and verification of IACUC approval for the proposed animal activities has been provided to the Contracting Officer. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Assurance and verification of IACUC approval are required. The Contracting Officer will request that OLAW negotiate an acceptable Assurance with those Contractor(s) and request verification of IACUC approval. For further information contact OLAW, at NIH, 6705 Rockledge Drive, RKL1, Suite 360, MSC 7982 Bethesda, Maryland 20892-7982 (E-mail: [olaw@od.nih.gov](mailto:olaw@od.nih.gov); Phone: 301-496-7163).

(End of Provision)

The PHS Policy is available on the internet at: <http://www.grants.nih.gov/grants/olaw/olaw.htm>.

### 5. Research Involving Live Vertebrate Animals

It is intended that live vertebrate animals will be used during performance of this contract. The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (authority derived from the Health Research Extension Act of 1985) specifies that certain information is required from offerors in contract proposals submitted to the NIH that will use live vertebrate animals.

**The following five points must be addressed in a separate section of the Technical Proposal titled "Vertebrate Animal Section" (VAS):**

- a. Detailed description of the proposed use of the animals, including species, strains, ages, sex and number to be used.
- b. Justification for the use of animals, choice of species, and numbers to be used.
- c. Information on the veterinary care of the animals.

- d. Description of procedures for minimizing discomfort, distress, pain and injury.
- e. Method of euthanasia and the reasons for the selection.

A concise (no more than 1-2 pages), complete description addressing these five points must be provided. The description must be cohesive and include sufficient information to allow evaluation by reviewers and NIH staff. For more discussion regarding the five points in the VAS, see NIH Guide Notice NOT-OD-10-049 at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-049.html>.

The Contract Proposal VAS Worksheet is provided as an Attachment in SECTION J of this solicitation to assist in the preparation of the VAS as part of the Technical Proposal. It can be accessed at: <http://grants.nih.gov/grants/olaw/VAScontracts.pdf>.

## 6. Obtaining and Disseminating Biomedical Research Resources

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a condition of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090]) will be included in any contract awarded from this solicitation. It can be found at the following website:

<http://ott.od.nih.gov/pdfs/64FR72090.pdf>

### a. Sharing Research Data

[Note: This policy applies to **all** NIH contracts, regardless of dollar value, that are expected to generate research data.]

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan in its technical proposal for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>

[If the resultant contract is part of a collaborative program involving multiple sites, the data sharing will be governed by a dissemination plan to be developed jointly following award. Offerors must include in their proposals a statement of willingness to work collaboratively after award with the other funded sites to prepare a joint dissemination plan. Coordinating

Center proposals should describe methods to coordinate the dissemination planning and implementation. The Coordinating Center must include a budget and justification for any additional costs of this collaborative effort.]

7. **Electronic and Information Technology Accessibility, Section 508 Compliance** is applicable to this solicitation and the following information is provided to assist in proposal preparation.

**IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Technical Proposal, entitled, "Section 508 Compliance."**

**Electronic and Information Technology Accessibility, HHSAR 352.239-73(a)** (January 2010)

- a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that, unless an exception applies, all EIT products and services developed, acquired, maintained, or used by any Federal department or agency permit--
  - i. Federal employees with disabilities to have access to and use information and data that is comparable to the access and use of information and data by Federal employees who are not individuals with disabilities; and
  - ii. Members of the public with disabilities seeking information or services from a Federal agency to have access to and use of information and data that is comparable to the access and use of information and data by members of the public who are not individuals with disabilities.
- b. Accordingly, any vendor submitting a proposal/quotations/bid in response to this solicitation must demonstrate compliance with the established EIT accessibility standards. Information about Section 508 visions is available at <http://www.section508.gov/>. The complete text of Section 508 Final Provisions can be accessed at <http://www.access-board.gov/sec508/provisions.htm>.
- c. The Section 508 accessibility standards applicable to this solicitation are identified in the Statement of Work/Specification/Performance Work Statement. In order to facilitate the Government's evaluation to determine whether EIT products and services proposed meet applicable Section 508 accessibility standards, offerors must prepare an HHS Section 508 Product Assessment Template, in accordance with its completion instructions, and provide a binding statement of conformance. The purpose of the template is to assist HHS acquisition and program officials in determining that EIT products and services proposed support applicable Section 508 accessibility standards. The template allows vendors or developers to self-evaluate their products or services and document in detail how they do or do not conform to a specific Section 508 standard. Instructions for preparing the HHS Section 508 Product Evaluation Template may be found under Section 508 policy on the HHS Office on Disability Web site (<http://www.hhs.gov/od/>).
- d. Respondents to this solicitation must also provide any additional detailed information necessary for determining applicable Section 508 standards conformance, as well as for documenting EIT products or services that are incidental to the project, which would constitute an exception to Section 508 requirements. If a vendor claims its products or services, including EIT deliverables such as electronic documents and reports, meet applicable Section 508 accessibility standards in its completed HHS Section 508 Product Assessment Template, and it is later determined by the Government -- i.e., after award of a contract/order, that products or services delivered do not conform to the described accessibility standards in the Product Assessment Template,

remediation of the products or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor and at its expense.

(End of provision)

The "HHS Section 508 Product Assessment Template" is included in SECTION J - List of Attachments, of this solicitation.

## 8. Additional Technical Proposal Instructions

**It is strongly recommended that Offerors use the following template as the Table of Contents for the Technical Proposal. All information presented in the Technical Proposal should be presented in the order specified below.**

These additional Technical Proposal instructions reflect the requirements of the RFP and provide specific instructions and formatting for the Technical Proposal. While Section L.2.b. of the RFP provides a generic set of Technical Proposal instructions applicable to all NIH R&D solicitations, these additional Technical Proposal instructions are tailored to the specific requirements of the RFP. The information requested in these instructions should be used, along with Section L. to format and prepare the Technical Proposal, and should be used as a Table of Contents for your Technical Proposal. Offerors should follow the instructions requested here.

Offerors are advised to give careful consideration to the Statement of Work (SOW) and attachments, the Technical Evaluation Criteria in Section M, and the RFP as a whole in the development of their Technical Proposals.

Offerors should submit a proposal that addresses all four (4) task areas in the Statement of Work. If the proposed approach will involve a subcontracting arrangement, then the offeror shall include a letter of commitment from the subcontractor, plus documentation of subcontractor's expertise, qualifications and prior performance, as well as a narrative describing how the contractor will manage the subcontractor.

A detailed work plan should be submitted indicating how each aspect of the Statement of Work is to be accomplished. Your technical proposal should be in as much detail as you consider necessary to explain fully your proposed methods and rationale for their selection and should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must also include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding of management of timeframes for planning and accomplishing the work to be performed.

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include: Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

**The Government encourages offerors to be complete but succinct in their presentation and to limit the number of pages to 150. See content below:**

**TOTAL PAGE COUNT DOES INCLUDE:** Principal Investigator's (PI's) resume /*Curriculum Vitae* (CV), with highlights of any items that are directly related to the subject project, indicated by preceding them with a double asterisk (\*\*).

**TOTAL PAGE COUNT DOES NOT INCLUDE:** (some of which may be added as appendices): Title and Back Page; NIH-2043; Table of Contents; Section Dividers that do not contain information other than title of Section; Resumes/CVs of other key personnel (same information and format as used for

the PI); certificates and licensures, examples of protocols, Standard Operating Procedures (SOP), Safety and Health Manual, letters of commitment by proposed consultants and subcontractors.

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- Additional appendices may be added as needed.
- The proposal, including appendices, shall be formatted by sections, cross referenced, and include a detailed Table of Contents

**TECHNICAL PROPOSAL - TABLE OF CONTENTS**

**General Instructions:**

**SECTION 1**

- A. PROPOSAL TITLE PAGE.** Include RFP title and number, name of organization, DUNS number, proposal part, and identify if the proposal is an original or a copy.
- B. PROJECT OBJECTIVES (NIH FORM 1688-1)**
- C. GOVERNMENT NOTICE OFR HANDLING PROPOSALS**
- D. PROPOSAL SUMMARY AND DATA RECORD (NIH-2043)**
- E. TABLE OF CONTENTS**

Section L of the RFP specifies the minimum documentation requirements for cost data and all cost related support. All related documentation should be included in the proposal in a clearly marked section. Cost and Pricing support should be provided for all proposed subcontractors.

**SECTION 2: MANDATORY QUALIFICATION CRITERIA**

The offeror should include all information which documents and/or support the mandatory qualification criteria in one clearly marked section of its technical proposal.

**SECTION 3: TECHNICAL DISCUSSIONS**

**A. Personnel and Experience**

The Technical Proposal should include all information relevant to document individual training, education, experience, qualifications and expertise necessary for the successful completion of all contract requirements. Clearly identify who is to be assigned as Key Personnel. Limit CVs to 2-3 pages and provide selected references for publications relevant to the scope of the RFP, and include experience with projects of similar scope, size and complexity carried out by the Offerer and any proposed subcontractors over the past five (5) years.

Provide a list of study reports that have been submitted to the FDA as part of an Investigational New Drug (IND) application. This listing should not include any proprietary information, but should list type of agent, study, route and species. Offerors should limit this information to the past five (5) years.

1. Principal Investigator: Describe the education, training, experience, expertise, qualifications, and percentage of effort of the proposed Principal Investigator to lead and direct the activities to be carried out under this contract, including: managing an interdisciplinary team in the conduct of toxicology and pharmacology assessments to qualify potential cancer preventative or other pharmacological, hormonal, or nutritional agents for further testing and clinical development according to Food and Drug Administration (FDA) requirements; managing projects similar in size and scope to the Statement of Work in this RFP; and adherence to FDA and International Conference on Harmonization (ICH) guidelines for toxicity and safety studies of compounds. The Principal Investigator should have a Ph.D., D.V.M. or M.D. degree or equivalent experience. Offerors should, as appropriate, discuss the proposed management of collaborations with subcontractors. Discuss how the technical and scientific planning and implementation of Task Orders will be managed by the Principal Investigator.

2. Other Scientific and Technical Personnel: Describe the education, training, experience, expertise, qualifications, and percentage of effort for all proposed key scientific and technical personnel of the offeror and all proposed subcontractors. Document relevant qualifications for: pathology (specifically necropsy of animals and microscopic evaluation of blood and tissues), clinical pathology, statistics, veterinary medicine, laboratory animal care, analytical chemistry, pharmacokinetics and quality assurances.

### 3. Additional Personnel

- Offerors staff should include an experienced DVM pathologist with certified as an American College of Veterinary Pathology (ACVP) diplomate to oversee necropsy and conduct histopathological evaluations. If the offeror does not have a DVM pathologist with the above credentials, the offeror may propose a subcontractor.
- Offerors should include on their staff a DVM who is Board Certified in Laboratory Animal Medicine (ACLAM). Alternatively, the ACLAM-certified veterinarian may have an established relationship as a contracted on-call consultant. Continuous veterinary care must be assured.
- Offerors should include on their staff a Toxicologist who should have documented experience and background in animal toxicity testing and who is certified by the American Board of Toxicology.

## **B. TECHNICAL APPROACH**

Offerors shall submit a proposal that addresses all four (4) task areas in the Statement of Work. Only proposals from offerors who demonstrate the capability to perform all aspects of the Statement of Work, either at their institution or through their subcontractors, will be considered for award. If the proposed approach will involve a subcontracting arrangement, then the offeror shall include a letter(s) of commitment from the subcontractor(s), plus documentation of subcontractor's expertise, qualifications and prior performance, as well as a narrative describing how the contractor will manage the subcontractor. (see below)

1. Describe the procedures to be used for carrying out the types of preclinical toxicology studies indicated in the Statement of Work, including criteria for moribund sacrifice, method and equipment to be used for euthanasia, collection, handling and storage of blood samples for clinical pathology and plasma drug analysis, necropsy and histopathology procedures, and analytical chemistry procedures.

**Please provide a response to each of the sample task orders for the following types of assays, as described in the Statement of Work:**

a) Sample Task Order - Genotoxicity battery.

- b) Sample Task Order - 14-day dose range finding and 28-day subchronic rat study with recovery.
- c) Sample Task Order - Segment II teratogenicity study in rabbits and rats.
- d) Sample Task Order - Pharmacokinetics and bioavailability in dogs.

**See also the Additional Business Proposal Instructions regarding development of budgets for each sample task order response.**

2. Describe the approach to the development of analytical procedures for the assay of a drug in plasma, urine, and tissues.
3. Describe the features and capabilities of data management, including software programs currently in use.
4. Describe proposed plans for oversight of data management functions, including protection of intellectual property and confidentiality of compound data.
5. Describe the operation of the Quality Assurance Unit within your organization concerning auditing of critical study events, raw data and study reports. Indicate when these audits take place in relation to the generation of data and reports.
6. Provide a copy of Standard Operating Procedures (SOPs) relating to the conduct of the type of tasks found in the Statement of Work, including laboratory SOPs.

### **C. FACILITIES AND EQUIPMENT**

1. Facilities - The offeror shall have an operating laboratory which is suitable for cell culture and laboratory animal studies using hazardous and/or carcinogenic test materials. The laboratory shall be capable of handling hazardous chemicals safely and must be able to provide appropriate facilities for housing animals required in the study. The laboratory and animal care must be sanitary and properly maintained in accordance with the criteria set forth by the animal accreditation organizations (see Mandatory Qualifications Criteria).

Discuss operation, procedures, and administration of the cell culture and animal facility and provide floor plan (including a scale factor). Discussion shall include, as appropriate, but not be limited to:

- available room capacities
- temperature controlled CO2 incubators, sterile laminar flow hoods
- sterile tissue culture materials and techniques
- cryopreservation capability, microscopy capability
- climate controls and alarm systems
- caging and exercise
- diet and compound storage and preparation areas
- water systems
- cage washing areas
- data collection and computer systems
- animal treatment laboratories (cardiology, ophthalmology, phlebotomy, necropsy)
- clinical and anatomic pathology laboratories and established quality control practices
- electrical and environmental back up provisions for critical components e.g. animal rooms, chemical test article and biological samples, etc.
- data back-up systems

2. Equipment - The offeror shall have all the equipment necessary to accomplish the studies including but not limited to, incubators, microscopes, centrifuges, animal racks and caging, hazardous chemical storage cabinets and refrigerators, pathology equipment such microtomes, laboratory and analytical chemistry equipment. The laboratory shall have or have access to appropriate terminal and computer facilities and equipment for data collection and storage.

### **D. ORGANIZATIONAL BACKGROUND AND EXPERIENCE**

Offeror should include an organizational chart that describes reporting structure of the organization.

Discuss prior experience with similar tasks and provide documentation of completed studies. Provide documentation of abilities to interact with industrial collaborators and academic researchers. Discuss FDA inspections and provide Form FDA 483 reports with corrective actions. At a minimum, a copy of the two (2) most recent Food and Drug (FDA) Good Laboratory Practice (GLP) inspection reports shall be included in the proposal.

1. Quality Assurance - The offeror shall discuss the organization, operation, and responsibilities of the Quality Assurance Unit in similar studies. FDA inspections, data audits, and outcomes should be presented. Validation studies undertaken to assure the accuracy of transmitted data for the version(s) of software shall be described.

2. Statistics - Methods of statistical analysis (parametric versus nonparametric) shall be described by the offeror for data and underlying distributions being compared. Specifications of the in-house historical database for each species shall be described. In the dog study the statistical analyses shall include change with treatment over time, i.e. differences or percent changes for an analyte between testing intervals for each dog, which are then averaged within the group and compared across groups.

3. Subcontracts - In the event that the offeror does not have facilities, equipment, or personnel for performing any component of the described task, then the offeror shall be prepared to implement the work through a suitable subcontractor. Letters of commitment from and qualifications of all proposed subcontractors shall be included in the proposal. The offeror shall describe any previous working relationship with proposed subcontractors. Furthermore, the offeror shall address how they will handle privity of contract issues, i.e., the offeror should explain how information will flow between the NCI, the prime contractor (offeror), and any subcontractors since the prime contractor's presence is required for any discussions.

4. Agents - to be investigated by this project are potentially hazardous. Discuss laboratory practices that will be employed which shall keep any element of risk to personnel at an absolute minimum.

5. Safety and Health for Personnel - Provide a Safety and Health Plan. Offerors' Safety and Health Plan shall include recent and ongoing organizational background and experience in each task area in the Statement of Work (SOW), especially where data has been utilized for Investigational New Drug/ New Drug Application (IND/NDA) submissions and/or publications in peer-reviewed journals. Offerors shall also submit their Safety Manual on a CD.

Offerors should describe procedures and controls to be employed during tests included in the SOW to insure that the work is conducted in a safe and healthful manner. All pertinent chemical and or biological hazards shall be addressed in the Plan, from receipt of test agents to ultimate disposal of contaminated waste. Details of appropriate administrative and emergency controls, personnel, protective equipment and work practices should be addressed. All work shall comply with applicable local, state and federal statutes relating to occupational safety and health, transportation and handling, and environmental protection. Discuss equipment and unusual operating procedures established to protect personnel from hazards associated with this project and other factors you feel are important and support your proposed approach.

## 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.

## 2. Proposal Cover Sheet

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and
9. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when certified cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not required to be certified in accordance with FAR 15.406-2.

## 3. Data Other than Certified Cost or Pricing Data

- a. Data submitted shall be sufficient to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., data to support an analysis of material costs (when sufficient data on labor and overhead rates is already available), or data on prices and quantities at which the offeror has previously sold the same or similar items.

Data submitted must support the price proposed. The offeror shall include sufficient detail or cross references to clearly establish the relationship of the data provided to the price proposed. The offeror shall support any data provided with explanations or supporting rationale, as needed, to permit the Contracting Officer and authorized representative to evaluate the documentation.

[Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.]

- b. The data submitted shall be at the level of detail described below.

### a. Direct Labor

Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

### b. Materials

Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

**c. Subcontracted Items**

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over \$650,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

**d. Raw Materials**

Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

**e. Purchased Parts**

Includes material items not covered above. Provide priced quantities of items required for the proposal.

**f. Fringe Benefits**

Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

**g. Indirect Costs**

Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

**h. Special Equipment**

If direct charge, list any equipment in accordance with Item (13) Other Administrative Data, subparagraph (2) Government Property of this Section L.2.c of this solicitation.

**i. Travel**

Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

**j. Other Costs**

List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

**4. Salary Rate Limitation in Fiscal Year 2011**

Offerors are advised that pursuant to P.L. 112-10, no NIH Fiscal Year 2011 (October 1, 2010 - September 30, 2011) 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, patient 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. 112-10 applies only to Fiscal Year 2011 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 limitation also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 112-10 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 other extramural mechanism at a rate in excess of Executive Level I\*."

**LINK TO EXECUTIVE SCHEDULE SALARIES:** <http://www.opm.gov/oca/11tables/indexSES.asp>

**\*Note to Offerors:** The current Fiscal Year Executive Level I Salary Rate shall be adhered to in the preparation of your proposal. All costs associated with any resultant contract award shall be in compliance with the current Fiscal Year Executive Level I Salary rates.

## 5. Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of \$650,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, See SECTION J - LIST OF ATTACHMENTS, BUSINESS PROPOSAL ATTACHMENTS of this RFP for an example of such a plan.

- a. THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.
- b. The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.
- c. The offeror understands that:
  1. No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.
  2. An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.
  3. If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

4. Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.
  5. It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HUBZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.
  6. The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.
- d. Each plan must contain the following:
1. Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.
  2. A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
  3. A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.
  4. A description of the method used to develop the subcontracting goals.
  5. A description of the method used to identify potential sources for solicitation purposes.
  6. A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
  7. The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.
  8. A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.
  9. Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of \$650,000 adopt a plan similar to the plan agreed upon by the offeror.
  10. Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (Individual Subcontract Reports (ISRs) and Summary Subcontract Reports (SSRs) to the Government.
  11. List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small

Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained in the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

HHS expects each procuring activity to establish minimum subcontracting goals for all procurements. The anticipated minimum goals for this RFP are as follows:

28% for Small Business; 5% for Small Disadvantaged Business; 5% for Women-Owned Small Business; 3% for HUBZone Small Business; and 3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

#### **6. Mentor-Protégé Program, HHSAR 352.219-70 (January 2010)**

- a. Large business prime contractors serving as mentors in the HHS Mentor-Protégé program are eligible for HHS subcontracting plan credit, and shall submit a copy of their HHS Office of Small and Disadvantaged Business Utilization (OSDBU)-approved mentor protégé agreements as part of their offers. The amount of credit provided by the Contracting Officer to a mentor firm for protégé firm developmental assistance costs shall be calculated on a dollar for dollar basis and reported by the mentor firm in the Summary Subcontract Report via the Electronic Subcontracting Reporting System (eSRS) at <http://www.esrs.gov>. The mentor firm and protégé firm shall submit to the Contracting Officer a signed joint statement agreeing on the dollar value of the developmental assistance the mentor firm provided. (For example, a mentor firm would report a \$10,000 subcontract awarded to a protégé firm and provision of \$5,000 of developmental assistance as \$15,000 of developmental assistance.) The mentor firm may use this additional credit towards attaining its subcontracting plan participation goal under this contract.
- b. The program consists of--
  - i. Mentor firms--large businesses that: (i) demonstrate the interest, commitment, and capability to provide developmental assistance to small business protégé firms; and (ii) have a Mentor-Protégé agreement approved by HHS' OSDBU;
  - ii. Protégé firms--firms that: (i) seek developmental assistance; (ii) qualify as small businesses, veteran-owned small businesses, service-disabled veteran-owned small businesses, HUBZone small businesses, small disadvantaged businesses, or woman-owned businesses; and (iii) have a Mentor-Protégé agreement approved by HHS' OSDBU; and
  - iii. Mentor-Protégé agreements--joint agreements, approved by HHS' OSDBU, which detail the specific terms, conditions, and responsibilities of the mentor-protégé relationship.

(End of provision)

#### **7. HUBZone Small Business Concerns**

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at <http://www.sba.gov/hubzone>.

#### **8. Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed \$650,000 (\$1.5 million for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b)). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled "Extent of Small Disadvantaged Business Participation" as set forth in Section M - Evaluation Factors for Award shall be used for evaluation purposes.

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: <http://www.sba.gov/size>

The Department of Commerce website for the annual determination for NAICS codes\* is: <http://www.acquisition.gov/References/sdbadjustments.htm>.

\* *Note: Public Law 103-355 which authorized the SDB Price Evaluation Adjustment (PEA) and associated percentages/factors expired on December 9, 2004, therefore, the percentages shown at this website are no longer applicable.*

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the Prime Contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An *example* of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

#### EXAMPLE

#### Targets for SDB Participation - NAICS Industry Subsector 223

	<b>SDB Percentage of Total Contract Value</b>	<b>SDB Dollars</b>
Total Contract Value- \$1,000,000	25%	\$250,000
SDB Participation by Prime  (Includes joint venture partners and team arrangements)*	10%	\$100,000
SDB Participation by subcontractors	15%	\$150,000

\*Note: FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential Prime Contractor, or a potential Prime Contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

## 9. Total Compensation Plan

### a. Instructions

1. Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors as a part of their Business Proposal will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.
2. The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).
3. Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

### b. Evaluation

#### 1. Total Compensation Plan (Professional Employees)

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

#### 2. Cost (Professional Compensation)

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract.

The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

**3. Other (Labor Relations)**

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

**4. Federal Acquisition Regulation Clauses incorporated by Reference**

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

**10. Other Administrative Data**

**a. Property**

1. It is HHS policy that Contractors will provide all property necessary for contract performance. Exception may be granted to provide Government property (Government-furnished or Contractor-acquired), but only when approved by the Contracting Officer. If the offeror requests that Government property be provided, other than that specified under "Government Furnished Property," below, the proposal must include a comprehensive justification addressing the following items:

- a. State why the property is essential to contract performance and whether the property will be used exclusively for this contract.
- b. Describe other alternatives (e.g., purchase, lease, etc.) pursued and why they were not viable options.

**2. Government Property**

The offeror shall identify Government property in its possession which it proposes to use in the performance of the prospective contract as follows:

- a. A list or description of all Government property that the offeror or its subcontractors propose to use on a rent-free basis. The list shall identify the accountable contract under which the property is held and the authorization for its use (from the Contracting Officer having cognizance of the property);
- b. The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to support prorating the rent;
- c. The amount of rent that would otherwise be charged in accordance with FAR 52.245-9, Use and Charges; and
- d. The voluntary consensus standard or industry leading practices and standards to be used in the management of Government property, or existing property management plans, methods, practices, or procedures for accounting for property.

**NOTE: The Contracting Officer will consider any potentially unfair competitive advantage that may result from the Contractor possessing Government property, and for evaluation purposes only, adjust the offers using a rental equivalent evaluation factor, as appropriate.**

3. Government-Furnished Property

No Government Furnished Property is offered for this acquisition

4. The management and control of any Government property shall be in accordance with the HHS Publication entitled, "HHS Contracting Guide for Contract of Government Property," which can be found at: [http://rcb.cancer.gov/rcb-internet/reference/Appendix Q HHS Contracting Guide.pdf](http://rcb.cancer.gov/rcb-internet/reference/Appendix_Q_HHS_Contracting_Guide.pdf)

**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.*

*(End of Provision)*

**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. Adequate Accounting System**

FAR Part 16 sets forth the requirements and limitations for consideration of contract type. As stated in Section L.1., General Instructions of this solicitation, the resultant contract will not be Firm-Fixed Price. Therefore, the offeror's/contractor's accounting system and practices must be adequate and suitable for accumulating costs under government contracts.

To be considered for an award under this solicitation, the offeror shall include, in the Business Proposal, the following Certification:

"By submission of its signed offer, the Offeror certifies that its accounting system:

- Complies with generally accepted accounting principles (GAAP).
- Provides for:
  - Proper segregation of direct costs from indirect costs.
  - Identification and accumulation of direct costs by contract.
  - A logical and consistent method for the allocation of indirect costs to intermediate and final cost objectives.
  - Accumulation of costs under general ledger control.
  - A timekeeping system that identifies employees' labor by intermediate or final cost objectives.
  - A labor distribution system that charges direct and indirect labor to the appropriate cost objectives.
  - Interim (at least monthly) determination of costs charged to a contract through routine posting of books of account.
  - Exclusion from costs charged to government contracts of amounts that are not allowable in terms of FAR 31, "Contract Cost Principles and Procedures," or other contract provisions.
  - Identification of costs by contract line item and by units (as if each unit or line item were a separate contract) if required by the proposed contract.
  - Segregation of preproduction costs from production costs (applies primarily to manufacturing contracts).
  - Provides financial information required by contract clauses concerning limitation of cost (FAR 52.232-20 and 21) or limitation on payments (FAR 52.216-16).
  - Provides financial information required to support requests for progress payments.
  - Ability to develop adequate reliable data for use in pricing follow-on acquisitions.
  - Accounting system is in full operation."

**e. Facilities Capital Cost of Money, FAR 52.215-16, (June 2003)**

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

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

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

(End of Provision)

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

**Fac Cap Cost of Money (Has)** 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).

**Fac Cap Cost of Money (Has Not)** **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.

## 11. 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.

**12. 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/FDPclausecover.htm>

**13. Proposer's Annual Financial Report**

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

**14. Travel Costs/Travel Policy****a. Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

**b. 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.

**15. Additional Business Proposal Instructions****1. Sample Protocol Budgets:**

Please provide budgets for each of the following sample protocols/task orders.

- a) Sample Task Order - Genotoxicity battery.
- b) Sample Task Order - 14-day dose range finding and 28-day subchronic rat study with recovery.
- c) Sample Task Order - Segment II teratogenicity study in rabbits and rats.

d) Sample Task Order - Pharmacokinetics and bioavailability in dogs.

**Note: Actual task order budgets will be negotiated at the time of issuance.**

**The following uniform cost assumptions shall be used by all offerors in preparation of their cost proposal.**

2. Assume the following:

**A. Travel**

- Assume one (1) staff member will be required to meet with the Contracting Officer's Technical Representative (COTR) one (1) time each year. The meeting will last one day. The meeting will be held in Rockville, Maryland.

- Assume two (2) staff members will be allowed to travel to a scientific meeting one (1) time each year. Assume costs for (2) travelers, three (3) night stay and travel must be within the United States.

**B. Animals**

- Assume the following number of animals in your budget

- o 560 Mice
- o 2,000 Rats
- o 208 Dogs

## SECTION M - EVALUATION FACTORS FOR AWARD

### 1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost. The Government intends to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

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 factors listed below.

### 2. COST/PRICE EVALUATION

Offeror(s) cost/price proposal will be evaluated for reasonableness. For a price to be reasonable, it must represent a price to the government that a prudent person would pay when consideration is given to prices in the market. Normally, price reasonableness is established through adequate price competition, but may also be determined through cost and price analysis techniques as described in FAR 15.404.

[Cost Realism: The specific elements of each offeror(s) proposed costs are realistic when the proposed cost elements are evaluated and found to: 1) be realistic for the work to be performed; 2) reflect a clear understanding of the requirements; and 3) be consistent with the unique methods of performance and materials described in the offeror(s) technical proposal.

Realism will be evaluated only on the offeror(s) inputs which the Government will use to determine the most probable cost to perform the contract in a manner consistent with the offeror's proposal. Cost realism analysis will be conducted in accordance with FAR 15.404-1(d). The result of the cost realism analysis will be considered in the making the best value tradeoff decision.]

### 3. LIVE VERTEBRATE ANIMALS EVALUATION

The offerors proposal must include, as a separate section of the Technical Proposal titled "Vertebrate Animal Section," (VAS) a complete, concise (no more than 1-2 pages) description addressing the following five points. (See NIH Guide Notice NOT-OD-10-049 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-049.html>):

- a. Detailed description of the proposed use of the animals, including species, strains, ages, sex and number to be used.
- b. Justification for the use of animals, choice of species, and numbers to be used.
- c. Information on the veterinary care of the animals.
- d. Description of procedures for minimizing discomfort, distress, pain and injury.
- e. Method of euthanasia and the reasons for the selection.

As part of the overall technical evaluation of proposals, the reviewers will consider the acceptability of the offeror's description in the VAS of the technical proposal. The discussion of all five points will be addressed and evaluated. Based on the evaluation of this Section, the VAS may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the description addressing each of the five points, or no discussion can be

found regarding the VAS), or "acceptable." If the reviewers find that this Section of the technical proposal is "unacceptable" they will provide a narrative supporting their findings.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed description under the VAS is still found to be unacceptable, then your proposal may not be considered further for award.

#### 4. MANDATORY QUALIFICATION CRITERIA

Listed below are mandatory qualification criteria. THE OFFEROR SHALL [INCLUDE ALL INFORMATION WHICH DOCUMENTS AND/OR SUPPORTS THE QUALIFICATION CRITERIA IN ONE CLEARLY MARKED SECTION OF ITS TECHNICAL PROPOSAL. / PROVIDE AN INDEX WITHIN ITS TECHNICAL PROPOSAL WHICH DIRECTS THE REVIEWER(S) TO THE SPECIFIC AREA(S) OF THE TECHNICAL PROPOSAL THAT ADDRESS A PARTICULAR MANDATORY QUALIFICATION.]

The qualification criteria establishes conditions that must be met at the time of receipt of Technical Proposals by the Contracting Officer in order for your proposal to be considered any further for award.

- 1) Demonstration of compliance to perform studies in accordance with the Food and Drug Administration (FDA) Good Laboratory Practice Regulations (GLP) as published in the CFR Title 21, Part 58 and as updated. Compliance shall be documented with the two most recent FDA inspection reports.
- 2) Current Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) (or equivalent) accreditation.
- 3) National Regulatory Commission licensure for use of radioactive materials and presence of organizational unit monitoring safe use and disposal.
- 4) Documented participation of an American College of Laboratory Animal Medicine (ACLAM) certified veterinarian

#### 5. EVALUATION OF DATA SHARING PLAN

The offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy.

If your proposal does not include a plan or if the plan in your proposal is considered "unacceptable," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your data sharing plan during discussions and in your Final Proposal Revision (FPR). If your data sharing plan is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

#### 6. 1. GENERAL

Selection of an offeror for award will be based on an evaluation of proposals against four factors. The factors, in order of importance are: technical, cost, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price and SDB participation are also important to the overall contract award decision. All

evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The Government intends to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

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 factors listed below.

## **2. TECHNICAL EVALUATION FACTORS**

The evaluation criteria are used by the technical evaluation panel to evaluate the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

### **a. Personnel**

#### **WEIGHT 30 Points**

- Availability and qualifications of a Principal Investigator (PI) with experience in managing interdisciplinary team in the conduct of Good Laboratory Practice (GLP) toxicology and pharmacology studies to qualify potential cancer preventive or other pharmacological, hormonal, or nutritional agents for further testing and for clinical development.
- Suitability and adequacy of Principal Investigator's scientific accomplishments for leading this project as evidenced by bibliography and resume, including study reports, peer-reviewed publications, and unpublished manuscripts relevant to the Statement of Work.
- Suitability of training, experience, and qualifications of other staff in technical aspects of the Statement of Work.
- Adequacy of potential subcontractor, including training, experience, qualifications, availability, and specific area of expertise to be contributed to the projects (s).
- Adequacy of how the technical and scientific planning and implementation of Task Orders will be managed by the Principal Investigator (PI).
- Adequacy of how the PI will manage the proposed team(s) within the prime's institution and across subcontracting institutions, as applicable.
- Organizational chart for this project

### **b. Technical Approach**

#### **WEIGHT 30 points**

- Demonstrated knowledge and familiarity with the regulatory requirements and general study design, conduct, data-gathering, and evaluations required to undertake the tasks and to produce a final report that integrates all the observations. Documented utilization and adherence to quality assurance and control procedures in areas such as animal health and husbandry, compound formulation and administration, analytical chemistry, and clinical and anatomic pathology.
- Demonstrated adequacy of data gathering systems, validated computer systems, and Quality Assurance Unit.
- Adequacy of sample protocols/task orders completed.
- Demonstrated adequacy of proposed staffing plan and work schedule to complete the task within the period of award.
- Demonstrated adequacy of potential subcontractors, anticipated contribution to their technical approach to the project(s), and management of projects.

### **c. Facilities and Equipment**

#### **WEIGHT 20 points**

- Suitability of facilities and floor plan (including a scaling factor) to accomplish each task.
- Documented compliance with federal, state, and local regulations and statutes and appropriate accreditations and licensures.
- Evidence of availability of appropriate equipment to accomplish each task, including but not limited to:
  - o Cell culture facilities and associated equipment & techniques
  - o Animal caging, cleaning, and husbandry
  - o Compound formulation and administration
  - o Analytical and clinical chemistry laboratories

- o Necropsy and histopathology laboratories
- o Data collection and computerization
- o Data/sample archive

- Adequacy of facility design and maintenance to meet chemical and biological control of potential teratogens, carcinogens, and radioactive material, in compliance with applicable safety and health standards and laws.

#### **d. Organizational Background and Experience**

**WEIGHT 20 points**

- Adequacy of offeror's Safety and Health Plan
- Documented data collection and processing capabilities (computer systems), including statistical analysis, and an effective Quality Assurance Unit.
- Documented ability to collaborate with other individuals and organizations.
- Reasonableness of reliance on off-site subcontracts in areas that could jeopardize performance of work.
- Adequacy of how the infrastructures composed of one or more collaborating institutions will be managed.
- Staff reporting organizational chart

### **7. PAST PERFORMANCE FACTOR**

Offerors' past performance information will be evaluated prior to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal is determined to be technically unacceptable.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

### **8. 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 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. 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.

Offers will be evaluated on the following sub-factors:

- a. Extent to which SDB concerns are specifically identified
- b. Extent of commitment to use SDB concerns
- c. Realism of the proposal
- d. Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation